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 REPLY BRIEF

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INTRODUCTION

This case presents a single overarching issue: whether the Court should unwind a life-saving Transaction that will accelerate the adoption of a groundbreaking cancer-screening test called Galleri, based on speculation that Illumina might disadvantage hypothetical rival tests many years in the future if and when they are introduced. Complaint Counsel bore the burden to prove that the Transaction will *substantially* lessen competition. Complaint Counsel came nowhere close to meeting that burden. Instead, it grounded its case on "legal" propositions that are unsupported by the law, cherry-picked anecdotes that are contradicted by the overwhelming weight of the evidence, and a series of double standards unrecognized in the law. Complaint Counsel's challenge of the Transaction should be rejected.

To begin, Illumina's reunion with GRAIL is a purely vertical merger. Unlike in a horizontal transaction, where there can be a presumption of harm to competition based on structural market evidence, no such presumption operates here. Complaint Counsel was required to show that the Transaction will *substantially* lessen competition by specific record evidence, not by presumption, assumption or speculation. But presumption, assumption and speculation are all that Complaint Counsel mustered here. Complaint Counsel advocates a legal standard that (1) presumes a vertical merger is unlawful where self-interested, purported rivals say that the acquiring company has market power over an input; (2) avoids meaningfully defining or proving the relevant market or the related product market; (3) ignores the benefit of the elimination of double marginalization; (4) fails to address commercial realities including the Open Offer, upstream competition and declining costs; and (5) renders unrefuted, life-saving efficiencies irrelevant. In its attempt to usher in a new era of antitrust enforcement, the FTC might want such a standard to be the law, but it is not. No court has ever adopted the collection of legal propositions on which Complaint Counsel pins its case.

In addition to a faulty legal standard, Complaint Counsel's case depends mostly on truisms (*e.g.*, that Illumina sees opportunity for profit in acquiring GRAIL) and isolated anecdotes from non-credible sources (*e.g.*, that Illumina allegedly was slow, nearly a decade ago, to respond to a Natera concern). Complaint Counsel has no answer for dispositive facts including that: (1) Galleri is the only MCED test on the market today, and there is no basis to predict (and ample evidence to doubt) that a close substitute for Galleri will launch at any point in the near future; (2) Complaint Counsel failed to offer a reliable model demonstrating a post-merger incentive to harm rivals, or that the alleged harm from the Transaction offsets its benefits; (3) harming GRAIL's putative rivals would reduce Illumina's NGS sales and hurt its reputation, while making it more vulnerable to increasing NGS competitors; (4) more than a dozen fact witnesses, experts and Illumina board members concluded—based on decades of expertise—that the Transaction will save lives, and Complaint Counsel undermined none of that testimony on cross-examination; and (5) Illumina's Open Offer changed the economic realities for its customers in ways Complaint Counsel failed even to consider and protects against the very harms imagined by Complaint Counsel. Each one of these facts is sufficient on its own to debunk Complaint Counsel's case.

By misstating the law and cherry-picking the record, Complaint Counsel built its case on a series of double standards. For example, Complaint Counsel:

- Argues that the relevant market must *include* MCED tests in early-stage development, but that the related product market must *exclude* NGS platforms in development, though they are more advanced and more poised to launch than any putative MCED test in development.

- Urges the Court to ignore *actual and imminent entry* in the upstream market by well-funded NGS competitors with actual products, but to assume that, downstream, Galleri will face immediate competition from tests whose features are unknown and untested and whose launches are far more uncertain and distant.

- Claims that the relevant market must include *any* NGS-based test in development that aims to screen for more than one cancer, but the related market can include *only* Illumina NGS systems (and really only NovaSeq) and nothing more, despite the uncontested evidence that non-NGS technology is currently used for tests that screen for multiple cancers and [redacted]

- Contends that the number of early-stage cancers *Galleri* can screen for must be based on prospective clinical trial data from asymptomatic individuals, while [redacted]

- Asserts that *Complaint Counsel* need not provide robust proof of the harm from foreclosed competition in the future, as the future is unknown, but *Respondents* must quantify any future efficiencies from the Transaction with precision.

- Argues that the Open Offer is insufficient on the ground that contracts are incapable of constraining Illumina's conduct, but that every efficiency of the Transaction could be fully realized through contracts with GRAIL.

- Seeks to force Illumina not only to divest GRAIL but also to disgorge any profits made from a divestiture sale as punishment for closing the Transaction, though Complaint Counsel *dismissed its own action* for a preliminary injunction and thus removed any impediment to closing the Transaction under U.S. law.

A case built on double standards cannot prevail.

As explained in Respondents' Post-Trial Brief, Complaint Counsel's challenge to the Transaction founders for multiple reasons (summarized briefly below). While Complaint Counsel's Post-Trial Brief attempts to address some (but not all) of these failings—any one of which is sufficient to defeat its case—Complaint Counsel offers nothing to overcome any of them. On the contrary, its papers highlight the following fatal flaws in Complaint Counsel's case:

Unsupported by Controlling Law. Complaint Counsel contends the Transaction violates Section 7 of the Clayton Act. As stated, however, its arguments misstate and misapply the controlling law. Contrary to Complaint Counsel's contention, vertical mergers are usually procompetitive and cannot be presumed unlawful, even when the government perceives the

upstream firm as dominant and theoretically capable of foreclosure at some future time. Section 7 requires Complaint Counsel to establish more than a theoretical concern—it must prove harm that is *probable*, substantial and imminent, and that can be established only with facts, not mere theory or assumption. Complaint Counsel came nowhere close to meeting its burden, and its claims of harm are readily refuted and easily offset by unparalleled, concrete efficiencies, which it wrongly dismisses as legally irrelevant. (*See* Section I below.)

Failure to Prove Relevant/Related Markets. Complaint Counsel alleges a relevant product market consisting of all "MCED tests", purportedly based on the *Brown Shoe* practical indicia and the hypothetical monopolist test. But Complaint Counsel's proposed market (1) runs counter to the *Brown Shoe* factors; (2) fails to satisfy the hypothetical monopolist test; (3) disregards interchangeability and cross-elasticity of demand; (4) is impermissibly speculative and both over- and under-inclusive; and (5) depends on subjective policy assessments, rather than established law and objective evidence. While Complaint Counsel describes the related product market as consisting of NGS products and services, it made no effort to prove the contours of any such market, and its claim that there are no viable alternatives to Illumina is contrary to the record evidence. Notably, Complaint Counsel failed to call any expert to testify about MCED test development or NGS. Complaint Counsel's failure to prove either a relevant product market or a related product market dooms its case. (*See* Section II 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 (which it has not), it failed to prove the Transaction is likely to *substantially* lessen competition, the touchstone of any claim under Section 7 of the Clayton Act. Complaint Counsel's claim that

Illumina has a post-merger ability and incentive to harm putative GRAIL rivals is refuted by (1) the record evidence, including the Open Offer, which disables each of the purported foreclosure "tools" Complaint Counsel hypothesizes and reinforces Illumina's incentives to treat customers fairly with its comprehensive terms and binding arbitration; (2) intensifying upstream competition, which is far more concrete and certain than Complaint Counsel's claims of entry in the alleged MCED market; (3) the shrinking costs and margins on Illumina's NGS inputs, which represent powerful constraints on Illumina that Complaint Counsel ignores; and (4) the fact that Illumina would lose far more than it would gain if it attempted Complaint Counsel's hypothesized foreclosure tactics. Importantly, Illumina has always owned a material portion of GRAIL (without causing any of the claimed harms), and Complaint Counsel failed to show that the Transaction will change Illumina's behavior or incentives. (*See* Section III below.)

Overwhelming Evidence of Efficiencies. Even if Complaint Counsel met its *prima facie* burden, any alleged harm arising from the Transaction is easily outweighed by merger-specific efficiencies, including, in particular, that it will save tens of thousands of lives in the U.S. and many more throughout the world. To that end, the Transaction will (1) accelerate market access to a life-saving test; (2) lead to new innovations from synergistic R&D; (3) eliminate double margins and a royalty GRAIL was otherwise required to pay; and (4) lead to supply chain, operational and international efficiencies, resulting in lower prices and faster testing for patients. While Complaint Counsel discounts these efficiencies, it ignores the unrefuted testimony of numerous fact witnesses substantiating them, and it failed to present any credible evidence to the contrary. (*See* Section IV 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 prospect that the Transaction could harm any putative GRAIL rival. Complaint Counsel's criticisms of the Open Offer fall considerably short. They underestimate contractual remedies, disregard the record, and substitute rank speculation for reasonable probabilities. The Open Offer alone, and in combination with Illumina's proposed consent order, is more than sufficient to prevent the hypothesized future foreclosure of still non-existent products. (*See* Section V below.)

Unjustified and Unjustifiable Remedy. As a remedy, Complaint Counsel seeks to require Illumina to divest GRAIL and abide by a web of punitive implementing obligations. However, there is no basis for a divestiture remedy because Complaint Counsel's case lacks merit for all the reasons discussed above. There is also no reason for an extreme remedy when an order adopting the terms of Illumina's Open Offer will be more than sufficient to protect competition and preclude any alleged harm and has the benefit of preserving the substantial efficiencies from the Transaction. Furthermore, the requested remedy runs afoul of several provisions of the U.S. Constitution. (*See* Section VI below.)

In sum, Complaint Counsel's challenge to the full reunion of Illumina and GRAIL should be rejected, and judgment should be entered in favor of Respondents. In asking this Court to undo the Transaction (despite the fatal flaws in its case), Complaint Counsel asks the Court to do what no court ever has (or ever should). It asks the Court to unwind a vertical merger where:

- The alleged relevant market is unspecified and comprises products that, save one (Galleri), are pre-commercial, may never launch and are likely to be dissimilar to the Galleri test;
- Complaint Counsel does not even profess to have defined a related product market, despite hinging its case on the claim that Illumina is an upstream monopolist;
- Complaint Counsel did not offer an economic model showing that the alleged anticompetitive effects of the Transaction outweigh its benefits;

- No empirical evidence supports Complaint Counsel's claim that Illumina would have the incentive and ability to harm downstream rivals;
- The alleged foreclosure strategy could not benefit Illumina for years, if it ever could, but would cause serious damage to Illumina's upstream business;
- There is ongoing investment and entry in the upstream market, whereas there will not be meaningful entry in the downstream market for years;
- The only other vertical transaction involving the upstream firm (Illumina) was followed by a period of increased (not decreased) competition;
- The Transaction will result in substantial, merger-specific efficiencies that will save lives and billions of dollars; and
- The upstream firm made a binding, long-term commitment making it impossible (absent severe penalties) to raise downstream rivals' costs.

Complaint Counsel's attempt to scuttle a life-saving transaction should therefore be denied.

ARGUMENT

I. COMPLAINT COUNSEL'S CASE IS BASED ON FLAWED LEGAL PROPOSITIONS AND SPECULATION INCAPABLE OF ESTABLISHING A VIOLATION OF THE CLAYTON ACT.

Unable to satisfy its burden under governing precedent, Complaint Counsel seeks to move the goal posts. It seeks to unwind a life-saving transaction based on a wish list of legal propositions rather than established law. Contrary to Complaint Counsel's claims, (1) the vast majority of vertical mergers are procompetitive; (2) unlike in horizontal cases, no presumptions of harm apply; (3) Complaint Counsel came nowhere close to meeting the burden of proof imposed on it by controlling precedent; and (4) Complaint Counsel's claims of harm are readily refuted and easily offset by tangible, merger-specific efficiencies.

A. Complaint Counsel Ignores the Fact that Vertical Mergers Are Typically Procompetitive.

Complaint Counsel begins its argument with the assertion that a vertical merger "*may* substantially lessen competition under Section 7". (CC Post-Trial Br. at 38 (emphasis

added).) In fact, however, vertical mergers are *procompetitive* in the vast majority of cases. Complaint Counsel attempts to obscure this fact in a quest to impose an extremely low threshold burden on the government for future challenges to vertical mergers. But whatever the Commission's current policy views on the supposed harms of vertical integration, they cannot supplant the widespread recognition by courts, scholars and economists that vertical mergers typically generate efficiencies that promote competition and consumer welfare and overcome the potential harms.[1]

Citing a handful of vertical cases, many from decades past, Complaint Counsel asserts that vertical merger challenges are common and suggests the government often prevails in them.[2] In reality, such challenges are rare, and *neither agency* has successfully challenged a vertical merger in more than 40 years.[3] In most instances where the agencies have identified competitive concerns with a vertical merger, they settled upon behavioral commitments that

[1] Complaint Counsel's proposed legal standard would upend the consensus understanding that "the overwhelming majority of vertical mergers increase efficiency." Roundtable on Vertical Mergers, Note by the Delegation of the United States to the Organization for Economic Co-operation and Development, Competition Committee ("OECD Note") at 7, ¶ 26 (Feb. 15, 2007); Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles & Their Application* ("*Antitrust Law*") (3rd and 4th Editions, 2018 Cum. Supp. 2010-2017), ¶ 1000; James C. Cooper et al., *Vertical Antitrust Policy as a Problem of Inference*, 23 Int. J. of Indus. Org. 639, 648 (2005); Francine Lafontaine & Margaret Slade, *Vertical Integration and Firm Boundaries: The Evidence*, 45 J. of Econ. Literature 629, 680 (2007).

[2] A number of commentators (including a sitting Commissioner) have questioned the reasoning of the decades-old vertical merger cases cited in Complaint Counsel's Post-Trial Brief. *See* Roger D. Blair, Christine S. Wilson, et al., *Analyzing Vertical Mergers: Accounting for the Unilateral Effects Tradeoff and Thinking Holistically About Efficiencies*, 27 Geo. Mason L. Rev. 761, 788 (2020) (hereinafter "Blair & Wilson"). But the Court need not do so here to reject Complaint Counsel's challenge, as none of those cases endorse Complaint Counsel's proposed lesser standard for vertical merger challenges (*see* Section III below).

[3] As the court in *AT&T* observed, an "analysis of vertical mergers" is "made more difficult still by the lack of modern judicial precedent involving vertical merger challenges—a dearth of authority that is unsurprising, considering that the Antitrust Division apparently has not tried a vertical merger case to decision in four decades". *See United States v. AT&T Inc.* (*AT&T I*), 310 F. Supp. 3d 161, 193–94 (D.D.C. 2018), *aff'd*, 916 F.3d 1029 (D.C. Cir. 2019) (*AT&T II*).

preserved the efficiencies of the merger. *See AT&T II*, 916 F.3d at 1041 (noting in past cases the Government "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" (internal citations and quotations omitted)).[4]

The Commission's current antipathy to vertical mergers is unsupported by precedent and out of step with modern antitrust law, which recognizes that vertical integration is good for competition and consumers in most instances.[5] Until now, both the FTC and the DOJ were unanimous in recognizing that vertical mergers bring substantial benefits. As the agencies recognized in the Vertical Merger Guidelines, "[v]ertical mergers combine complementary economic functions and eliminate contracting frictions, and therefore have the capacity to create a range of potentially cognizable efficiencies that benefit competition and consumers", including the creation of "innovative products in ways that would not likely be achieved through arm's-length contracts". U.S. Dep't of Justice & Fed. Trade Comm'n, Vertical Merger Guidelines 2020 (withdrawn 2021) § 6 [hereinafter *Vertical Merger Guidelines*]. The withdrawal of these guidelines on a party-line basis by a split Commission does not change the reality that most vertical mergers benefit consumers. As two Commissioners noted in dissenting from the

[4]As one sitting Commissioner observed, "among the enforcement actions that the Commission brings [against vertical mergers], many are settled with behavioral remedies rather than divestitures, and few of our enforcement actions challenge vertical mergers outright." Statement of Commissioner Rebecca Kelly Slaughter, In the Matter of Sycamore Partners, Staples, and Essendant, Commission File No. 181-0180 (Jan. 28, 2019).

[5] *See, e.g.*, *National Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 840 (D.C. Cir. 2006) ("[V]ertical integration creates efficiencies for consumers."); *Alberta Gas Chems. Ltd. v. E.I. du Pont de Nemours & Co.*, 826 F.2d 1235, 1244 (3d Cir. 1987) (noting that "respected scholars question the anticompetitive effects of vertical mergers in general."); *It's My Party, Inc. v. Live Nation, Inc.*, 811 F.3d 676, 689 (4th Cir. 2016) (observing that "vertical integration has generally been permitted"); *see also Leegin Creative Leather Prod., Inc. v. PSKS, Inc.*, 551 U.S. 877, 888 (2007) (observing that courts should "formulate antitrust principles in accordance with the appreciated differences in economic effect between vertical and horizontal agreements").

withdrawal, "the fact remains that vertical mergers are different animals from mergers of competitors, changing incentives in ways that are, on the whole, more likely to improve efficiency, bolster competition, and benefit consumers", and "[a]s such, they require an approach that fully accounts for their good as well as their bad effects" because "[a]nything less will hurt consumers, not help them". Fed. Trade Comm'n, Dissenting Statement of Commissioners Phillips and Wilson, at 3–4. Complaint Counsel's opposition to vertical integration here will hurt consumers by depriving them of swifter, cheaper access to a life-saving test. It must be rejected.

B. Complaint Counsel Understates Its Burden.

Although the *Baker Hughes* burden-shifting framework may apply to a vertical merger challenge, Complaint Counsel's contention that it applies precisely as it would in a horizontal case misstates the law. Complaint Counsel asserts that its "burden of production" for its *prima facie* case is extremely low, relying on the Court's observation in *Otto Bock* that the burden shifts to Respondents once the FTC provides evidence "sufficient to raise an inference of anticompetitive effect". (CC Post-Trial Br. at 43.) But *Otto Bock* involved a horizontal merger, as to which "proof of market structure and direct competition between Ottobock and Freedom [was] sufficient to raise an inference of likely anticompetitive effects". *In re Otto Bock HealthCare N. Am., Inc.*, Dkt. No. 9378, 2019 WL 2118886, *27 n.25 (F.T.C. May 6, 2019). Those presumptions do not apply here, in the vertical context.

"A vertical merger, unlike a horizontal one, does not eliminate a competing buyer or seller from the market". *Fruehauf Corp. v. FTC*, 603 F.2d 345, 351 (2d Cir. 1979); *AT&T I*,

310 F. Supp. 3d at 192.[6] Thus, "the familiar horizontal merger playbook is of little use", "there is no short-cut way to establish anticompetitive effects, as there is with horizontal mergers", and there is no "theoretical basis for dealing with vertical mergers" that is "comparable" to the "well-founded and rather generally accepted" "economic reason for limiting horizontal mergers". *AT&T I*, 310 F. Supp. 3d at 192 (internal citations and quotation marks omitted). Therefore, contrary to Complaint Counsel's assertion, in a vertical case, there is no "short cut to establish a presumption of anticompetitive effect". *AT&T II*, 916 F.3d at 1032. Rather, the law demands robust proof of probable anticompetitive effects "on the basis of the record evidence relating to the market and its probable future". *AT&T I*, 310 F. Supp. 3d at 190; *Fruehauf*, 603 F.2d at 352–53 (rejecting "that a significant level of foreclosure is itself the proscribed effect [of the Clayton Act]. . . . A showing of some probable anticompetitive impact is still essential") Complaint Counsel failed to adduce such evidence here.

C. Complaint Counsel Relies on Cherry-Picked Anecdotes, Not Credible Evidence.

While Complaint Counsel contends it has easily met its burden, in fact it came nowhere close to doing so. As discussed in Respondents' Post-Trial Brief and further below, Complaint Counsel relies on assertions that mischaracterize and omit essential facts, and are dependent on unsubstantiated claims by third parties that are not credible and are contradicted by the evidence. (*See* Sections II–III.) Complaint Counsel's case also relies heavily on truisms,

[6] As an authoritative treatise explains, "[m]ost instances of vertical integration, including those that result from mergers, are economically beneficial. As a result, the presumptions in favor of vertical mergers should be stronger than the presumptions favoring horizontal mergers." Areeda & Hovenkamp, *Antitrust Law*, ¶ 1020. "[I]t is widely conceded that as a general matter, vertical mergers are inherently more likely to create substantial efficiencies than horizontal mergers," David T. Scheffman & Richard S. Higgins, *Vertical Mergers: Theory and Policy*, 12 Geo. Mason L. Rev. 967 (2004), and that "vertical mergers generally raise fewer competitive concerns than do horizontal mergers." OECD Note at 10, ¶ 37; *id.* at ¶ 24 ("Vertical mergers have a stronger claim to being efficient than do horizontal mergers, given the fundamentally different effects of improved coordination between complements versus substitutes.").

such as the proposition that Illumina has a duty to shareholders and is a profit-maximizing firm.[7] The government tried to rely on such truisms in *AT&T*, and both the district court and court of appeals rightly rejected them. *See AT&T II*, 916 F.3d at 1044 ("Nor is the conclusion that the merged firm would not be able to maximize its profits by raising prices during negotiations inconsistent with the principle of corporate-wide profit maximization . . . [since] it is still in the best interests of the merged entity as a profit maximizer to license programming broadly to other distributors".).

Complaint Counsel's predictions of future harm lack support in credible, empirical evidence. Complaint Counsel offered no model, did no diversion analysis, and failed altogether to provide any robust proof to support its predictions of the supposedly anticompetitive effects of the Transaction. Moreover, its theory is refuted by the "real world facts" of the Open Offer, intensifying upstream competition and dramatically declining sequencing costs and shrinking upstream margins. (*See* Section III.) In the face of such shortcomings, Complaint Counsel has not come close to satisfying its burden. *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)). Accordingly, Complaint Counsel failed to make out a *prima facie* case, and is therefore not entitled to any burden shifting.

[7] Complaint Counsel's cherry-picking of the record came early and often. In the opening paragraph of its brief, Complaint Counsel writes that Illumina executives pursued the goal of profit maximization with the following mantra in mind: "May God have mercy on my enemies, because I will not!" (CC Post-Trial Br. at 1 (citing CCFF ¶ 3080).) There is no mention that the quote was buried near the end of a document written in 2015 by a former executive, and was never shown to any witness during discovery or trial, and is a quote from General George Patton. (RRFF ¶ 3080.)

D. Complaint Counsel Assumes Away the Transaction's Efficiencies in Derogation of Long-Standing Precedent.

Assuming, *arguendo*, Complaint Counsel *had* made out a *prima facie* case, its allegations of harm are readily rebutted and easily offset by the tangible merger-specific efficiencies here. Complaint Counsel predicts harm occurring far into the future, but it has not quantified the harm in any way, nor described its effects with any specificity. Its case reduces to the claim that there is innovation occurring in the development of putative MCED tests today, and at some point, in some way, to some extent, some of that innovation may be lessened because of the Transaction, even as innovation has accelerated since the time Illumina first announced its agreement to re-acquire GRAIL. Even if that were sufficient to establish a *prima facie* case (and it is not), such vague allegations of distant harm pale in comparison to the outsized efficiencies the Transaction will create in the immediate future and beyond.

Just as it incorrectly attempts to minimize its own burden, Complaint Counsel artificially inflates Respondents' burden. Complaint Counsel claims that no set of efficiencies, no matter how impressive, can overcome a *prima facie* showing of anticompetitive effect, no matter how vague and speculative. (CC Post-Trial Br. at 46.) According to Complaint Counsel, "[t]he Supreme Court has never recognized the efficiencies defense and—to the contrary—has suggested efficiencies are no defense to a Clayton Action violation". (*Id.* at 46 n.40.) Complaint Counsel misstates the law. Although efficiencies may not be "a defense" to an illegal merger, it is simply untrue that efficiencies are *irrelevant* to a merger challenge under Section 7. The Supreme Court has previously stated that "[p]ossible economies cannot be used as a defense to illegality". *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 207 (S.D.N.Y. 2020) (citations omitted). But "lower courts have since considered whether possible economies might serve not as justification for an illegal merger *but as evidence that a merger would not actually*

be illegal." *Id.* (collecting cases recognizing that efficiencies must play a role in a Section 7 case) (emphasis added). Courts "recognize or at least assume that evidence of efficiencies may rebut the presumption that a merger's effects will be anticompetitive, even if such evidence could not be used as a defense to an actually anticompetitive merger." *Id.*; *see also AT&T I,* 310 F. Supp. 3d at 161 ("One way defendants may [contest the government's case] is to offer evidence that post-merger efficiencies will outweigh the merger's anticompetitive effects.") (internal quotations omitted).

Until now, the FTC and DOJ has long recognized that efficiencies matter and can offset competitive concerns, especially in a vertical case. As stated, there is widespread recognition that vertical mergers can generate enormous efficiencies that create large, tangible benefits for competition and consumers. So it is here, where the unrefuted evidence shows that the Transaction will give rise to unparalleled benefits to competition and consumers. (*See* Section IV.) Yet, Complaint Counsel contends such large efficiencies should play no role in the evaluation of the competitive effects of a vertical merger. This is a radical re-making of law that the Court should reject as contrary to precedent and logic.

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

Complaint Counsel's challenge to the Transaction must be rejected because Complaint Counsel also failed to prove either its relevant product market allegations or its related product market allegations. Those defects are fatal to its case without further inquiry. *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285 (2018) ("Without a definition of the market there

is no way to measure the defendant's ability to lessen or destroy competition.") (citations and alterations omitted).

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

Complaint Counsel does not dispute that defining the relevant market is a "necessary predicate" to finding a Clayton Act violation. *United States v. E. I. du Pont de Nemours & Co.* ("*du Pont II*"), 353 U.S. 586, 593 (1957); *see also United States v. SunGard Data Sys., Inc.*, 172 F. Supp. 2d 172, 181 (D.D.C. 2001). Nor does it dispute that it "bears the burden of proof and persuasion in defining the relevant market", *Arch Coal*, 329 F. Supp. 2d at 119 (citations omitted), and that 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).

Instead, Complaint Counsel argues that all "MCED tests", no matter their stage of development, constitute the relevant product market based on the *Brown Shoe* practical indicia and the hypothetical monopolist test. To show this, however, Complaint Counsel relies solely on a "negative" market definition—what MCED tests are not. According to Complaint Counsel, they are *not* oncology tests for patients already diagnosed with cancer (therapy selection tests or minimal residual disease ("MRD") tests), and they are *not* single cancer screening tests (including the current standard of care ("SOC") screening tests such as colonoscopies and mammograms). (CC Post-Trial Br. at 51–53.) But Complaint Counsel fails to answer the more fundamental question: what attributes determine whether a cancer screening test is an "MCED test" that is reasonably substitutable for Galleri in the "arena within which significant substitution in consumption or production" will occur? *See Am. Express Co.*, 138 S. Ct. at 2285

(quoting Areeda & Hovenkamp § 5.02). For example, is a two-cancer test a substitute for a test for 50 cancer types? What about a four-cancer test that focuses exclusively on cancers with existing standard-of-care screening? An eight-cancer test that cannot detect cancer signal of origin? Or a blood test that also requires, for every positive case, a whole-body PET-CT scan?

Rather than answer these questions, Complaint Counsel suggests that it need not explain what attributes will determine whether a cancer screening test is an "MCED test" that will compete with Galleri in the foreseeable future because "[i]n an innovative market . . . differentiation and new approaches are attributes of competition, not indicia of its absence". (CC Post-Trial Br. at 59–60.) But whether the relevant market is labeled as a commercial market or an innovation one, Complaint Counsel cannot ignore the attributes of the tests at issue, because the essential attributes of a market "provide[] the context against which to measure [] competitive effects". *Geneva Pharms. Tech. Corp. v. Barr Lab'ys Inc.*, 386 F.3d 485, 496 (2d Cir. 2004). As discussed below, Complaint Counsel's alleged market (1) is out of step with the *Brown Shoe* factors; (2) is unsupported by the Hypothetical Monopolist Test; (3) disregards reasonable interchangeability and cross-elasticity of demand; (4) is impermissibly speculative and simultaneously over- and under-inclusive; and (5) is not salvaged by labeling the market an innovation one.

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

Complaint Counsel purports to base its proposed market on the *Brown Shoe* practical indicia. (CC Post-Trial Br. at 50–51). In fact, it ignores three of the seven factors in *Brown Shoe* altogether, and its arguments as to the remainder fail to address the key disputed issue. No one contests that Galleri is not in the same market as single-cancer screening tests, therapy selection tests or MRD tests. (CCFF ¶¶ 611–87; RRFF ¶ 826.) The disputed issue is

whether Galleri is in the same market as putative MCED tests in development that have not yet been launched and may never be commercialized. On the disputed market definition, Complaint Counsel's argument amounts to a few sentences and is contrary to the clear weight of the evidence.

a. Complaint Counsel makes no argument as to three of the seven *Brown Shoe* factors.

As set out in Respondents' Post-Trial Brief, all seven of the *Brown Shoe* factors point to a relevant market consisting only of Galleri. They do not support an "MCED market" comprising Galleri *and* unfinished potential tests in development that lack, and cannot plausibly develop in the foreseeable future, the distinctive features of Galleri. (Resps.' Post-Trial Br. at 41–64.) In addition, Complaint Counsel does not even address three of the seven factors, including "unique production facilities", "sensitivity to price changes" and "specialized vendors". (CC Post-Trial Br. at 50–57.) Thus, Complaint Counsel cannot argue (in its reply or otherwise) that factors not raised in its Post-Trial Brief support its proposed market definition.[8] That is especially true for a party that bears the burden of proof as to market definition.

b. Complaint Counsel focuses its argument on issues not in dispute.

While Complaint Counsel does argue that four *Brown Shoe* factors support its alleged market, its argument is almost entirely devoted to a nonissue. In arguing that the

[8] It is well settled that new arguments cannot be raised for the first time in reply. *See, e.g.*, *Hess v. Reg-Ellen Mach. Tool Corp.*, 423 F.3d 653, 665 (7th Cir. 2005) (declining to reach plaintiffs' argument "because its appearance for the first time in [their] reply brief means that it is waived"); *Redhawk Holdings v. Daniel J. Schreiber Tr.*, 836 F. App'x 232, 235 (5th Cir. 2020) ("[g]enerally, neither this court nor the district courts of this circuit will review arguments raised for the first time in [a] reply brief.") (internal citation omitted); *Al-Amin v. Smith*, 511 F.3d 1317, 1336 n.38 (11th Cir. 2008) ("defendants neglected to make these arguments in their initial brief on appeal, and our precedent unambiguously provides that issues that are not clearly outlined in an appellant's initial brief are deemed abandoned.") (internal citation omitted); *United States v. Levy*, 416 F.3d 1273, 1276 n. 3 (11th Cir. 2005) (collecting cases and observing this Court "declines to consider issues raised for the first time in an appellant's reply brief").

"peculiar characteristics and uses" and "distinct customers" factors support its market definition, Complaint Counsel argues only that MCED tests are different from tests for patients already diagnosed with cancer (therapy selection and MRD tests) and single cancer screening test (including SOC tests). (CC Post-Trial Br. at 51–54.) There is not now, and has never been, an issue in this case as to whether Galleri is in the same market as such tests. (RRFF ¶ 826.) The only relevant product market issue in the case is whether Galleri is in the same market as the putative tests in development that were raised by Complaint Counsel (which it is not). Thus, Complaint Counsel's argument as to the "peculiar characteristics and uses" and "distinct customers" factors does nothing to substantiate its proposed market.

Complaint Counsel's failure to address these issues is no surprise in view of the trial record. The undisputable trial evidence showed that the peculiar characteristics and use of Galleri vis-à-vis other putative MCED tests in development place Galleri in a relevant market of its own. Most of the putative tests are too early in development to permit a meaningful comparison of their features, and regardless are being developed as single-cancer tests (not MCED tests). And for the two tests (other than Galleri) where some data has been developed, the existing information shows that Galleri is highly differentiated from the others:

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.) These differences are significant (PFF ¶¶ 725–726), and provide no basis to predict that the CancerSEEK and PanSeer tests will be close substitutes for Galleri. Not only do CancerSEEK and PanSeer detect many fewer cancer types, but, unlike Galleri, they are also unable to identify the cancer signal of origin (also known as tumor of origin) of a detected cancer from a blood test alone, [redacted][9]

Similarly, the dramatically different specificities of the tests (comparing the single blood tests, which are the most relevant comparisons) also show that CancerSEEK and PanSeer will not be substitutable for Galleri. [redacted]—as shown by the CancerSEEK [redacted] The PanSeer test's specificity is equally unacceptable at 96%. (PFF ¶ 736.) [redacted] Further, Complaint Counsel has not shown why CancerSEEK and PanSeer will be used similarly to Galleri despite those tests' inability to detect the cancer signal of origin. (PFF ¶¶ 735, 737.) [redacted]

[9] [redacted]

[redacted] Further, Singlera is "at least seven to ten years" from launching PanSeer, which it does not plan on marketing in the US until it has received FDA approval. (PFF ¶¶ 706–706.3.)

With respect to the remaining tests raised by Complaint Counsel, they are single-cancer tests that the developer claims to be using as a starting point for a test that includes some additional cancers in the future. (PFF ¶ 728.1.) There is no evidence that these would be used similarly to Galleri. [redacted]

Certain of these putative tests are designed to be used as replacements for standard of care screening tests, which both sides agree are excluded from any relevant product market in which Galleri competes. (RRFF ¶¶ 659, 661.)

At bottom, that Galleri is highly differentiated from other putative MCED tests in development cannot seriously be disputed. As the party with the burden on market definition, Complaint Counsel was required to prove that differentiated attributes such as the number of cancers detected, the level of sensitivity and specificity of the test, the ability to detect cancer signal of origin, and others, will not matter to future substitution. Not only did it fail to make

that showing, but the evidence showed the opposite. Furthermore, having failed to argue these factors ("peculiar characteristics and uses" and "distinct customers") support inclusion of all putative MCEDs in the same market, Complaint Counsel cannot be heard to make any such argument in its reply brief, to which Respondents have no opportunity to respond. *See, e.g.*, *Hess*, 423 F.3d at 665.

c. Complaint Counsel misplaces reliance on the "distinct prices" and "industry recognition" factors.

While its argument concerning the "distinct prices" and "industry recognition" factors is also focused on the differences between putative MCED tests and tests no one says are in the relevant market (*e.g.*, single-cancer tests), Complaint Counsel does argue that these two factors support the inclusion of all putative MCED tests in the same market. (CC Post-Trial Br. at 54–57.) However, Complaint Counsel devotes no more than a few sentences to the subject (*id.*), and, as discussed below, its contentions combust under pressure.

Distinct Prices. Complaint Counsel argues that "many MCED test developers expect their tests to compete with Galleri on price", that [redacted] and that "Grail regularly monitors the pricing of its MCED Test rivals". (CC Post-Trial Br. at 55.) But, these assertions are either based on mischaracterizations of the record or grounded in no more than superficial support,[10] and crumble under the weight of a simple fact: the only NGS-based MCED test on the

[10] The fact that [redacted] (PFF ¶¶ 750.1–750.4.) The distinct prices inquiry is quantitative, *see Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 n.4 (D.C. Cir. 1986), and cannot be based on ephemeral "expectations". The assertion that [redacted] The document in which Grail allegedly "monitors the pricing of its MCED Test rivals" [redacted]

planet with a price is Galleri. No other putative test is commercialized—there are no prices, only conjecture about the future.[11] (PFF ¶ 750.) Thus, Complaint Counsel failed to show that any of the putative MCED tests will have a similar price to Galleri.

Industry Recognition. Complaint Counsel's industry-recognition argument is similarly wanting. Complaint Counsel argues that GRAIL "considers other MCED test developers as its '[key] competitors' and they view GRAIL as the same"; that "GRAIL listed as one of its 2020 corporate goals to 'define the MCED category and introduce GRAIL as the leader in the space'"; that "Illumina executives have recognized that acquiring GRAIL would mean potentially competing with some of our customers"; and that "test developers [have] referred to their tests as MCED tests". (CC Post-Trial Br. at 56.) None of these assertions substantiates Complaint Counsel's alleged market. To be sure, there is some evidence that some of the putative MCED test developers have described one another as competitors. But this, standing alone, does not "provide a sound economic basis for assessing the market . . . the way that a proper interchangeability test would." *Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 919 (6th Cir. 2009). That is especially true here, where there is such a "high degree of uncertainty" as to what these tests will eventually look like. (RRFF ¶ 775 (RX6004 (Katz Trial Dep. at 21–22)).) Thus, "it may well be they think of these firms as their competitor or prospectively so, but that's not really enough . . . to reliably tell us what the market

[redacted]

[11] For example, Singlera, has said that it "couldn't know right now" at what price Singlera plans to market PanSeer (PFF ¶ 750.1); [redacted] and there is no evidence Helio, [redacted] has made any determination on the price of any putative test that detects multiple cancer types. (PFF ¶ 750.4.)

boundaries are going to be." (RRFF ¶ 775 (RX6004 (Katz Trial Dep. at 21–22)).) This is reflected by the testimony of the putative MCED test developers called by Complaint Counsel: virtually none of them agreed as to who the supposed competitors would be (though they all, conveniently, would purportedly compete with GRAIL).[12]

Neither the industry nor the public recognizes an MCED market *as defined by Complaint Counsel*. Complaint Counsel has not cited, and we are not aware of, a single case in which a court found the "industry recognition" factor cut in favor of a market comprising a single marketed product and a collection of possible future products, much less one in which the future products, based on everything known about them, have very different attributes from the marketed product. On the contrary, 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); *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"); *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).

[12] [redacted]

To the extent analysts and academics talk about MCED tests and markets, they do not take Complaint Counsel's expansive view. For example, an industry report from Cowen 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; RRFF ¶ 820.) Cowen does not recognize [redacted] as pursuing early cancer detection at all: it describes [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.[13] (PFF ¶ 717.1.3; RRFF ¶ 820.)

2. The Alleged Market Fails the Hypothetical Monopolist Test.

Complaint Counsel's supposed application of the hypothetical monopolist test also fails to support the proposed market. In fact, it fails for the same reason Complaint Counsel's *Brown Shoe* analysis fails. To show the hypothetical monopolist test is met here, Complaint Counsel relies exclusively on the testimony of Dr. Fiona Scott Morton. (PFF ¶ 764.)

[redacted]

[13] 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.) Likewise, peer-reviewed publications have not recognized an "MCED" market as Complaint Counsel wishes to define it. 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.) Among 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), and the data from those trials shows that the tests are very different from Galleri. (PFF ¶ 721.)

[redacted]

For these reasons alone, Dr. Scott Morton's analysis fails. *See 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 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"); *Grason Elec. Co. v. Sacramento Mun. Util. Dist.*, 571 F. Supp. 1504, 1521 (E.D. Cal. 1983) (holding that market definition 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") (quoting *Morton Bldgs. of Neb. Inc. v. Morton Bldgs., Inc.*, 531 F.2d 910, 919 (8th Cir. 1976)).

[redacted] However, Complaint Counsel cites no case accepting an application of the hypothetical monopolist test based entirely upon a *qualitative* assessment of the market, without any supporting *quantitative* economic analysis, and courts typically reject purely qualitative assessments. *In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d 966, 985–86 (C.D. Cal. 2012); *see also Se. Mo. Hosp.*, 642 F.3d at 616; *Reifert v. S. Cent. Wisconsin MLS Corp.*, 450 F.3d 312, 320 (7th Cir. 2006) ("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[.]").[14]

Even if a purely qualitative SSNIP test could be used here (which it cannot), Dr. Scott Morton's approach was legally insufficient, as she did not "gather[] and analyz[e] evidence pertinent to customer substitution". U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines (2010) § 4.1.3 [hereinafter *Horizontal Merger Guidelines*]. Nor did she consider any evidence about how "consumers weigh the different characteristics [of putative MCED tests] against each other . . . or what do they do if maybe one test looks better than the other in certain technical respects". (RRFF ¶ 828.) Instead, Dr. Scott Morton's analysis

[14] Complaint Counsel asserts that a [redacted] (CC Post-Trial Br. at 58 n.47.) What Complaint Counsel fails to say is that Dr. Katz testified that Dr. Scott Morton's qualitative approach here was insufficient. (RRFF ¶ 828; PFF ¶ 683.1.)

consisted of a thought exercise in which she weighed the subset of the record evidence provided to her by Complaint Counsel and her staff, and pronounced that the hypothetical monopolist test is satisfied.[15] [redacted]

For these reasons and more, Dr. Scott Morton's market definition opinions should be given no weight and disregarded. "Expert testimony that is speculative is not competent proof and contributes nothing to a legally sufficient evidentiary basis." *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2000) (internal quotations omitted); s*ee 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]."). Yet, Dr. Scott Morton's qualitative test is fundamentally speculative with none of the rigor required by *Brown Shoe*. She lacks expertise concerning MCED tests. (*See* Resps.' Post-Trial

[15] As Dr. Katz explained, "because we don't have the actual switching behavior to study . . . there's an information gap" and Dr. Scott Morton did not attempt to fill the information gaps—using surveys or other qualitative evidence—"to understand what [clinicians and payors] would think about . . . 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". (RRFF ¶ 828; PFF ¶ 683.1.) Her failure to analyze likely substitution from the perspective of payors is an especially glaring omission, given that she acknowledged that payor choices will drive adoption of different screening tests. (PFF ¶ 683.2.)

Br. at 260–66; PFF ¶¶ 2057–2136.) She did not do the required analysis. And by her own admission, real world evidence played little part in her thinking. [redacted] To paraphrase Tolstoy, she "borrowed an idea, stripped it of all that gave it its force and want[s] to make believe it is something new". LEO TOLSTOY, ANNA KARENINA Pt. 3, Ch. 32 at 152 (1878) That is not a basis on which to scuttle a life-saving transaction.

3. The Alleged Market Disregards Reasonable Interchangeability and Cross-Elasticity of Demand.

Complaint Counsel does not dispute that 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.* ("*du Pont I*"), 351 U.S. 377, 404 (1956). Nor does it dispute that Galleri and the MCED tests in development are differentiated (CC Post-Trial Br. at 59–62), as Respondents have described at length (Resps.' Post-Trial Br. at 100–08; PFF ¶¶ 832–45).

Instead, Complaint Counsel argues that differentiation does not undermine its alleged "MCED test" market because "all MCED test developers are pursuing the same goal of creating the best MCED test" and "[e]very MCED test is designed for the same purpose – detecting multiple cancers simultaneously in asymptomatic people". (CC Post-Trial Br. at 59–60.) None of this, however, satisfies the test for determining the relevant antitrust market. Market definition turns *not* on whether producers share the same general goal but on the reasonable interchangeability of use or the cross-elasticity of demand between the product and the substitutes for it. *Brown Shoe*, 370 U.S. at 325; *du Pont I*, 351 U.S. at 395. Simply stating that products "need not be identical" (CC Post-Trial Br. at 59), to occupy the same relevant product market does not discharge Complaint Counsel of its burden to identify the attributes that would make a test part of the market it alleges—that is, to specify and prove the boundaries of

the "arena within which significant substitution in consumption or production" will occur.[16] *See Am. Express Co.*, 138 S. Ct. at 2286. Under Complaint Counsel's theory, every motor vehicle would comprise the same market because all manufacturers are pursing the same goal of cost effective transportation, every food item would be in the same market because all suppliers are pursuing the same goal of cost effective nutrition, all clothing would be in the same market because every fashion brand is pursing the same goal of clothing people. No court has adopted such a broad approach to market definition. *See, e.g., In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d at 987 (excluding expert's market definition opinions in part because he "never meaningfully considered any *narrower* definition of the market").

In the same vein, Complaint Counsel contends "the evidence shows that MCED tests will *ultimately* be quite similar". (CC Post-Trial Br. at 59 (emphasis added).) According to Complaint Counsel, "[w]hile some MCED test developers plan to start with one or a few cancers, and add other cancers later, they all share the same *ultimate* goal to detect a wide range of cancers simultaneously in a single test". (*Id.* (emphasis added).) Here again, Complaint Counsel applies the wrong standard. 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) (emphasis added); *see*

[16] Close inspection of the cases Complaint Counsel cites shows they are of no help to it. In *United States v. Energy Sols., Inc*, the court held that "[t]he strongest indicator that [the merging parties] offer[ed] reasonably interchangeable products" was cross-elasticity of demand. 265 F. Supp. 3d 415, 437 (D. Del. 2017). The "claim[] of increased effectiveness" that the court in *Hicks v. PGA Tour, Inc.* found unavailing was the purported increased effectiveness of advertisements during live golf tournaments compared to advertising in other forms of golf media (print and television commercials). 897 F.3d 1109, 1122 (9th Cir. 2018).

also Rothery, 792 F.2d at 218 (citation omitted) (only substitutes that can enter the market "promptly" should be considered).

At present, there is no product in existence that is reasonably interchangeable with Galleri; nor is one expected to enter in the foreseeable future. (PFF ¶ 697.) Galleri is the only multi-cancer early detection test on the market supported by prospective clinical data, with relevant regulatory authorizations, testing for anywhere near 50 cancer types, with a high degree of specificity and an ability to detect cancer signal origin. (PFF ¶ 724.) The putative MCED test developers identified by Complaint Counsel do not expect (and none can reasonably be expected) to launch a screening test with attributes that are comparable to Galleri at any point in the foreseeable future. (PFF ¶¶ 750.1–750.4, 701–706.) This is because developing a cancer screening test that can detect even just a few cancers simultaneously is challenging and requires many years of research, development and clinical validation; developing a test like Galleri is all the more difficult. (PFF ¶¶ 294–95, 310–11.) In fact, there are many barriers to market entry that could cause any putative MCED test developer to fail: generating sufficient feasibility data, locking a test classifier, generating robust prospective clinical data in an interventional study, and obtaining necessary regulatory authorizations. (*See* PFF ¶¶ 233–329.) Accounting for all of these steps in the development process, Dr. Cote opined that most of the putative MCED test developers identified by Complaint Counsel were at least five to seven years away from launching any kind of MCED test, much less one that could be expected to compete closely with Galleri. (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. (*See* Resps.' Post-Trial Brief at 30-37; PFF ¶¶ 700-707.3.)[17] As the hypothetical products at issue will take five to seven—or possibly 10—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).

All agree that the purchasers of any MCED test will be patients, health care providers and/or insurers. (PFF ¶ 708.1.) Yet, 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, or to say what attributes they would need to see in a test to make it a close substitute for Galleri. (PFF ¶ 708.2.) Nor did Complaint Counsel conduct any surveys of such groups. (PFF ¶ 708.3.) On the contrary, numerous witnesses testified Galleri is not, and will not be, reasonably interchangeable with the putative MCED tests in development, including Messrs. deSouza and Bishop, Drs. Aravanis, Ofman, Cote and Abrams, and [redacted][18]

[17] 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.)

[18] For example, Dr. 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); Dr. Ofman 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]

Complaint Counsel seeks to bridge the gap between Galleri and the tests in development by claiming (really for the first time) that Galleri detects only seven cancer types at early stages. But that argument ignores the trial evidence of numerous witnesses who testified that Galleri has demonstrated, with clinical data, the ability to detect 50 cancer types, including Dr. William Cance of the American Cancer Society—the only fact witness who is avowedly neutral about this case's outcome (PFF ¶¶ 1918, 1920)—as well as several witnesses involved in developing Galleri, including Alex Aravanis (PFF ¶ 1296), Hans Bishop (PFF ¶ 698) and Josh Ofman (PFF ¶ 698). The draft legislation regarding coverage of MCED tests—which Complaint Counsel relies upon—notes that Galleri is able to screen for more than 50 cancer types. (RRFF ¶ 817.) Not a single witness testified that Galleri detects only seven cancer types.

Complaint Counsel bases this new argument on the fact that GRAIL's only prospective interventional clinical trial, PATHFINDER, has detected seven types of stage I–III cancers to date. What Complaint Counsel fails to say is that PATHFINDER was not designed to detect 50 cancer types. The study has only 6,667 participants and is still ongoing. (PFF ¶ 398.1.) Given the low background incidence of cancer in the population (*see* PFF ¶ 321), it would not be expected that 50 types of cancer would even develop in a group of 6,000 or so participants. (RRFF ¶ 6265.) PATHFINDER was not "designed or powered to replicate the sensitivity of Galleri or to try to find . . . all the cancers that Galleri can find, because that would require hundreds of thousands of people." (PFF ¶ 398.3.) The point of PATHFINDER was to replicate the specificity and positive predictive value Galleri demonstrated in the robust

[redacted]

Circulating Cell-free Genome Atlas (CCGA) study, and it has done so. (PFF ¶¶ 398.2, 398.4, 400.) Thus, Complaint Counsel's argument—which is not supported by any expert testimony in this case—that the number of cancers an MCED test can detect is limited to those detected at early stages in prospective trials reflects a profound misunderstanding of clinical development and the regulatory framework under which Galleri is offered. It is also emblematic of the double standard Complaint Counsel applies to the evidence: Galleri must demonstrate how many Stage I–III cancer types it can detect via prospective trials in asymptomatic patients, but all the other putative developers can do so via the *ipse dixit* of their executives.

Unlike those other putative developers, Galleri's ability to detect 50 cancer types has been demonstrated with published data and has been analytically and clinically validated under stringent regulatory guidelines.[19] (RRFF ¶ 6272 (Ofman (GRAIL) Tr. 3294).) GRAIL's prospective, multi-center, case control, observational CCGA study is believed to be the largest case-control study ever conducted for the early detection of cancer. (RRFF ¶ 6270 (Ofman (GRAIL) Tr. 3291).). It involved 15,254 participants from 142 trial sites in the U.S. and Canada. (PFF ¶ 371.) And unlike many case-control studies, CCGA was unique because the samples were prospectively collected along with relevant clinical data about the participants (in contrast to other companies' studies that rely on biobanked samples). (RRFF ¶ 6239 (Cote Tr. 3794–95);

[19] Galleri's data has been reviewed by multiple regulatory health authorities. In particular, New York State Department of Health has reviewed the validation data supporting Galleri and has approved Galleri as an LDT to be offered to New York state residents; Galleri is the only MCED test with approval from New York State Department of Health, which is considered the highest state regulatory bar for a laboratory developed test. (RRFF ¶ 6288 (Ofman (GRAIL) Tr. at 3440; Qadan (Illumina) Tr. at 4279; [redacted]).) In addition, Galleri was reviewed by the FDA as part of two investigational device exemption applications for the conduct of PATHFINDER and PATHFINDER 2, and in both cases, FDA allowed GRAIL to report out all cancer type information generated by Galleri. (RRFF ¶ 6288 (Ofman (GRAIL) Tr. at 3306, 3318.) Further, Galleri is analytically validated under CLIA, and clinically validated under CAP. (RRFF ¶ 6272.) CLIA-certified laboratories undergo routine audits in which the clinical data supporting their tests and the claims that they put on their reports are reviewed; laboratories put their CLIA license at risk if they don't have sufficient data supporting their tests. (PFF ¶ 1375.)

PFF ¶ 371.2).) As Dr. Cote explained, this meant that CCGA would be a better predictor of how Galleri would perform in a prospective interventional trial with a large enough patient population than an ordinary case control study would, because the samples were collected "under circumstances that would be similar to an actual clinical collection of samples." (RRFF ¶ 6270 (Cote Tr. 3794–95).) Further, while Galleri has a long way to go before it can be widely accessible, it is being used, today, by (mostly affluent) customers for the purpose of screening for 50 cancer types. There is no marketing gimmick here—it is science, with regulatory oversight. Complaint Counsel offers no evidence that any regulator has challenged the fact that Galleri has been shown to detect 50 cancer types. Complaint Counsel merely parrots the talking points of executives from Exact and Thrive, who are unqualified to make this challenge and have their own agenda.[20]

Even if (contrary to fact) prospective clinical trials were the only way to determine the number of cancers a putative MCED test can detect, Galleri would still be in a class of its own. Besides GRAIL, Exact/Thrive is the only company that has conducted a prospective interventional clinical trial, and the Exact/Thrive trial (DETECT-A) studied tests that *Exact/Thrive is not planning to commercialize*.[21] (PFF ¶¶ 726.6–726.8.) Otherwise, no other putative MCED developer Complaint Counsel identified has performed (or even started) any

[20] [redacted] (*See* CCFF ¶ 6209 (Conroy (Exact) Tr. 1577 [redacted] (CCFF ¶ 6270.) The CCGA study was prospective case-control study in that all blood samples were collected prospectively by consented participants for the purpose of the CCGA study. (RRFF ¶ 6270.)

[21] Even if Exact/Thrive's trial had reflected the current version of CancerSEEK, it nevertheless proved its test to be very different from GRAIL. (*See* Section II.A.1.)

prospective, interventional trial for more than one cancer type. (*See* RRFF ¶¶ 3534–44 (RX3869 (Cote Expert Report) Appendix D).) Under Complaint Counsel's rubric then, these developers can detect, at best, either one or zero cancer types. (RRFF ¶ 6270.) Critically, none of these other putative MCED test developers has sufficient validation data to obtain the necessary regulatory permissions, including in New York State, to launch a test *today* that claims to test for 11 or more cancer types, let alone the 50 cancer types detected by the Galleri test.

Finally, Complaint Counsel argues that there are "benefits of having multiple approaches to the development of MCED tests". (CC Post-Trial Br. at 62.) Even if true, that does nothing to substantiate Complaint Counsel's proposed market, which 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.").)

4. <u>The Alleged Relevant Market Is Impermissibly Speculative and Simultaneously Over- and Under-Inclusive.</u>

In addition to the fact that Complaint Counsel's proposed market runs counter to *Brown Shoe*, cannot meet the hypothetical monopolist test and disregards product differentiation, the proposed market fails because it is impermissibly speculative. Again, [redacted] (PFF ¶ 680.1.) [redacted]

[redacted] (PFF ¶ 680.2.) [redacted] (PFF ¶ 680.3.) [redacted] (PFF ¶ 680.4.) Since aspiration is no 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, including [redacted] Dr. William Cance of the American Cancer Society, and [redacted][22]

Moreover, Complaint Counsel's proposed market is simultaneously over- and under-inclusive. The proposed market is over-inclusive because it includes any test that purports to detect more than one cancer type, including tests that are capable of detecting only two or

[22] 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. v. Xerox Corp.*, 645 F.2d 1195, 1211 (2d. Cir. 1981) (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.*, 559 F. Supp. 3d 898, 987 (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.").

three cancer types and that would plainly be no substitute for Galleri, which has been shown to detect more than 50 cancer types. [redacted] As Complaint Counsel defines the relevant market, it includes as substitutes a test that screens only for breast and ovarian cancer and a test that screens only for prostate and testicular cancer. This despite the indisputable fact that the two tests would be for very different customers. That makes no sense, as Dr. Katz explained without any meaningful cross-examination by Complaint Counsel or any counteracting evidence. (PFF ¶ 690.)

At the same time, Complaint Counsel's proposed market is under-inclusive, because it excludes putative MCED tests that are not based on NGS technology. (PFF ¶ 690.) Complaint Counsel is silent about the fact that there are at least two MCED tests *currently on the market* that are not based on NGS technology, including StageZero's Aristotle test, and Genesys Biolabs' OneTest. (PFF ¶¶ 692.1–692.2.) And, 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 ¶¶ 693–94.) There is no evidence, and Complaint Counsel has not provided any 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.) Complaint Counsel even appears to concede that what customers care about is *whether* a test works and *which* cancer types it detects, not *how* exactly it works. (PFF ¶ 692 (RX3852 (Scott Morton Dep. at 51) ("[U]ltimately the patient and the doctor are going to care about the ability of the test to prevent the disease and save lives.").)

5. Complaint Counsel Alleges, But Does Not Prove, a "Research and Development" Market.

Lacking proof of its proposed commercial market, Complaint Counsel suggests there is some kind of innovation market that renders all of the flaws identified above irrelevant.

See Hicks, 897 F.3d at 1121 (rejecting plaintiffs' proposed market as "not natural," "artificial," and "contorted to meet their litigation needs."). But Complaint Counsel failed to prove an appropriate innovation market either. While it is true that Galleri is a nascent commercial product, that other putative MCED tests in development do not yet even exist and that there is limited economic evidence, none of this relieves Complaint Counsel of its burden to prove the relevant market and the attributes that define the boundaries of the alleged market. The law does not set a different standard for establishing a nascent market or an innovation one. *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").[23] Complaint Counsel's lax approach would effectively relieve it of the burden of proof and substitute the FTC's subjective policy assessments for established law and objective evidence.

What's more, Complaint Counsel failed altogether to prove a relevant innovation market. Complaint Counsel did not apply the *Brown Shoe* test to the putative MCED products at

[23] *See also, 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*, 559 F. Supp. 3d at 987 (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 consume[r]s will or do consider these products reasonably interchangeable").

the research and development stage. Nor did Dr. Scott Morton perform any analysis to determine whether the hypothetical monopolist test would be met in a research and development market. As Dr. Katz explained, in analyzing an innovation market, the relevant 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.

Complaint Counsel's reliance on innovation principles (to compensate for the infirmity of its case) seeks to substitute abstract notions of competition for examination of the ability of the merged entity to exercise market power. This approach is flawed. "[T]he research and development that is described as being of concern is not happening in a market . . . There are no arm's length transactions between suppliers and customers. There are no prices, there are no readily recognized indicia of market power." Federal Trade Commission Hearings on Global and Innovation-Based Competition (1995) (testimony of Lawrence White, former Director of the DOJ Antitrust Division's Economic Policy Office).

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

Complaint Counsel's failure to prove its alleged product market (for which it unquestionably bears the burden of proof) is fatal to its case, obviating the need for further inquiry. But Complaint Counsel's case should also be rejected because it failed to prove an appropriate related product market.

As explained in Respondents' Opening Brief, Complaint Counsel was required to prove a related product market, but did not do so. (Resps.' Post-Trial Br. at 72–85.) Complaint Counsel does not dispute that it failed to prove that its alleged related product market constitutes a relevant antitrust market, instead arguing that it was not required to do so. (CC Post-Trial Br. at 66–67.) That is incorrect. Complaint Counsel requests that the Court simply find that (1) MCED test developers require highly accurate, high-throughput NGS platforms (without identifying any objective criteria for determining the levels of accuracy or throughput developers need), (2) Illumina has the only NGS platform that meets the (undefined) requirements of the putative MCED tests; and (3) non-NGS technologies are not suitable for putative MCED tests. But this is insufficient: such findings (even if justified) could not substitute for ascertaining an appropriate related product market based on the market definition principles set forth in precedent. (CC Post-Trial Br. at Br. at 68).

1. Complaint Counsel Bore the Burden to Prove a Related Product Market.

Complaint Counsel's burden to prove a related product market follows naturally from its burden to prove the Transaction will *substantially* lessen competition. *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."). Defining a cognizable related product market is a necessary element of making this showing because "[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." *Am. Express Co.*, 138 S. Ct. at 2285, n.7; *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 Corp.*, 603 F.2d at 353.

While the case law expressly addressing this issue is sparse, the requirement to prove a related product market can also be inferred from prior decisions on vertical mergers, including *Fruehauf*. The *Fruehauf* Court held that in assessing the anticompetitive effect of a vertical merger, it is necessary to 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.* (emphasis added). Similarly, commentary on the Vertical Merger Guidelines states it is necessary to (1) "understand what inputs are included in the 'related product' category," (2) determine "whether price increases by the merging firm that produces the 'related product' will lead to accommodating price increases by its competitors" and (3) "measure the share of output accounted for by the related product." 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.[24]

[24] As support for its claim that it need not prove a related product market, Complaint Counsel cites *Brown Shoe*, *du Pont II* and *AT&T I*. (CC Post-Trial Br. at 66–67.) However, the burden to prove a related product market was not at issue in those cases, 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. 370 U.S. at 326. The Court 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. 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 retail stores market, Brown could 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. In *du Pont II*, the issue was that du Pont's stake in General Motors enabled du Pont to foreclose its competitors in the upstream market for automobile finishes and fabrics by preventing them from selling to General Motors. 353 U.S. at 595. Critical to such a finding was that General Motors was a "colossus of the giant automobile industry" that accounted for upwards of two fifths of the total sales of cars in the country. *Id.* Finally, in *AT&T I*, while defendants had not "meaningfully challenged the Government's proposed product market", 310 F. Supp. 3d at 195, the court observed that "accepting the Government's proposed product market does not mean that Turner's position in the upstream programming market is irrelevant to evaluating the Government's theories of harm in this case". *Id.* at 196. Instead, the court found that "examining the importance of Turner's content to distributors in the upstream programming market is a necessary (but not sufficient) step in evaluating the Government's increased-leverage theory". *Id.*

2. Complaint Counsel Provided No Credible Evidence to Justify the Related Product Market Findings It Seeks.

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), is yet another manifestation of the double standard Complaint Counsel seeks to employ; it proposes a related product market that could not be more narrow (it includes only products from only a single supplier—Illumina), and a relevant product market that could not be more broad (it includes MCED tests that are little more than a glimmer in the developers' eye).

In asking this Court to find that putative MCED test developers require NGS platforms that only Illumina can provide and for which there are no substitutes, Complaint Counsel effectively asks the Court to define a related product market without any real analysis. Complaint Counsel has not offered the evidence necessary to define the related product market as Illumina NGS instruments and consumables (or anything else). Complaint Counsel makes no mention of the *Brown Shoe* factors—none—and did not conduct any hypothetical monopolist test (quantitative, qualitative or otherwise). Complaint Counsel simply declares that Illumina occupies 100% of what Complaint Counsel calls the related market. That is not analysis; it is unsupported assertion. But even if unsupported assertions were credited in the law (and they are not), they are no basis for blocking a life-saving transaction.

3. Complaint Counsel's Claim About Illumina's Platform Is Insufficient to Support Its Foreclosure Theory

Complaint Counsel's contention that Illumina's platform is the best NGS system is insufficient to support Complaint Counsel's foreclosure theory. The issue is not whether Illumina is the best alternative for MCED test developers that use Illumina today. The question

is whether there will be viable alternatives to Illumina if and when it could foreclose a GRAIL rival, if and when one were to launch a substitute MCED test.

Contrary to Complaint Counsel's unproven assertions, there are other NGS platforms on the market that can support MCED tests in development. Complaint Counsel claims that putative MCED tests require "high-throughput" NGS platforms and that Illumina's NovaSeq is the only cost-effective option. (CC Post-Trial Br. at 70–72.) Yet, Complaint Counsel acknowledges that Singlera runs its PanSeer test on the lower-throughput NextSeq, (CC Post-Trial Br. at 22), and [redacted] The other viable platforms include those offered by BGI, Thermo Fisher and ONT. 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.) [redacted]

But for the soon-to-expire injunction[25] against BGI, BGI's technology would be available to test developers in the US, [redacted]

BGI's DNBSEQ sequencer's reported accuracy is comparable to Illumina's sequencers (about 99.9% accurate (>87% of bases >Q30), PFF ¶ 576), and BGI guarantees more than 80% of bases with quality score greater than Q30 (over 99.9% accurate). (PFF ¶ 777.4.) [redacted]

[25] After the expiry of certain Illumina patents which BGI was found to infringe, BGI will 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).) Certain later-expiring patents had been the subject of a separate lawsuit between Illumina and a BGI entity, but a federal jury recently found those Illumina patents to be invalid. (RRFF ¶¶ 341, 1293 (Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022).)

[redacted] In particular, Singlera's PanSeer test in development is capable of using Thermo Fisher's Ion Torrent platform. (PFF ¶¶ 668.)

Similarly, Oxford Nanopore's NGS platforms are also available in the United States and its recent improvements, such as adaptations to its sequencers and library preparation, have made its platform more suitable for multi-cancer screening. (PFF ¶ 779.1.) Oxford Nanopore's NGS platforms reportedly will compete with Illumina's on throughput, accuracy and cost. Oxford Nanopore's highest throughput instrument, the PromethION, reportedly has a higher throughput (up to 10 Tb/run) than Illumina's NovaSeq 6000 with the S4 flow cell (up to 6 Tb/run). (PFF ¶ 779.2.) New approaches enable Oxford Nanopore's instruments' accuracy to

[26] [redacted]

"trend[] towards 99.9% (Q30)" and even up to more than 99.999% (Q50). (PFF ¶ 779.3.) In addition, Oxford Nanopore has stated that it will offer per Gb sequencing costs that are lower than what Illumina offers. (PFF ¶ 779.3.) New approaches also enable short fragments of DNA to be conjoined into very, very long strands of DNA to take advantage of the high throughput of Oxford Nanopore's NGS platforms for liquid biopsy applications. (RRFF ¶ 904 (Cote Tr. 3754–56).)

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 is planning for a flood of upstream competition in the near future, as is reflected in Illumina's ordinary course strategy documents. [redacted] Future entrants include Singular Genomics (PFF ¶ 783), [redacted] Element (PFF ¶ 786), and Omniome (PFF ¶ 787). [redacted]

In downplaying the evidence of the emerging NGS platforms (not to mention those already on the market), 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 II.A

above), while simultaneously discarding evidence of actual competition and imminent 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 (RX6000 (Carlton Trial Dep. at 37–38 ("[A]ll I can do is point out the asymmetry in [Complaint Counsel's] analysis . . . in which [it] assumes that the MCED products are going to come into existence, but the NGS alternatives to Illumina are not.")).)

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

Even if Complaint Counsel had proven its relevant and related market allegations, its case should be rejected because it failed to show that the Transaction is likely to *substantially* lessen competition. Complaint Counsel has no answer for the shortcomings described in Respondents' Post-Trial Brief. It relies instead on arguments that misstate the law, ignore the facts and strain common sense. Complaint Counsel failed to meet its burden, and its case should be rejected.

A. Complaint Counsel Rests Its Case on a Mistaken Legal Framework.

To prove a violation of the Clayton Act, Complaint Counsel was required to 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. Rather than do that, Complaint Counsel grounded its case on a mistaken legal framework, one that seeks to import into vertical merger cases the same types of shortcut presumptions that may be used in horizontal cases. As discussed below, Complaint Counsel seeks refuge in a watered-down standard, but precedent demands much more.

Ability alone is not enough. Unable to show that balance of competitive effects disfavors the Transaction, Complaint Counsel asks this Court simply to presume it is unlawful. Complaint Counsel attributes this presumption to what it calls the "*Brown Shoe* Vertical Merger Framework". However, as discussed below (Section III.D), neither the Supreme Court's decision in *Brown Shoe* nor any other case imposes a *per se* prohibition of vertical mergers whenever the FTC alleges the upstream firm is dominant and theoretically capable of foreclosure at some future time. There is no empirical evidence to support such a presumption (based on structure or any other grounds). Complaint Counsel's approach is entirely inconsistent with its burden to prove (by evidence, not presumption) that the Transaction is unlawful. *AT&T I*, 310 F. Supp. 3d at 194; *RAG-Stiftung*, 436 F. Supp. at 311.

Real world facts must be considered. If Complaint Counsel's standard were the law (it is not), the government would only need to show that the merged firm has a high share of the related product market (here, an undefined one), and then the burden would shift to the merging parties to prove that real world facts, such as contractual, reputational and competitive constraints, impose real world constraints on the merged firm's ability and incentive to harm rivals. (*E.g.*, CC Post-Trial Br. at 133, 159 (asserting incorrectly that upstream entry and the Open Offer are defenses to an unlawful merger, not real world facts that bear on whether the merger is unlawful at all).) But no case supports such presumptions in a vertical merger challenge. Rather, as discussed below (Section III.B), Complaint Counsel was required to prove that its theory "fit" the facts in the real world, taking into account real world constraints that have "real world effects" on Illumina's post-merger conduct, such as the Open Offer and intensifying upstream competition. *AT&T II*, 916 F.3d at 1039.

Unproven assumptions are inadequate. As the FTC has recognized, Section 7 "requires [Complaint Counsel] to establish more than a theoretical concern—it must be *probable . . . and substantial*", and it must be established with facts, not theory and assumption. Statement of Chairman Simons, Commissioner Phillips, and Commissioner Wilson Concerning the Proposed Acquisition of Essendant, Inc. by Staples, Inc. FTC File No. 181-0180, at 6 (emphasis added). Thus, Complaint Counsel was required to provide empirical evidence of its claims, not mere assumptions. But assumptions are the foundation of Complaint Counsel's case. It offered no diversion ratios, no reliable analysis of upstream losses that Illumina would incur from foreclosure, and no vertical arithmetic at all to back up its theory that the Transaction will give rise to competitive harm. Its assumptions of harm (*e.g.*, 100% diversion, no upstream losses) are implausible and refuted by the record facts. (*See* Section III.C.3.)

The alleged harm must be shown to be substantial and imminent. Complaint Counsel asserts that it can win the day without quantifying the likely magnitude of the purported harm it alleges or that such harm is imminent. That is wrong. As the cases make clear, Complaint Counsel was required to demonstrate that the harm it claims will result from the Transaction is of "substantial" magnitude and "imminent". *See United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1109 (N.D. Cal. 2004) (holding that the government must show that the transaction "will *likely* lead to a *substantial* lessening of competition" (emphasis added)); *Arch Coal*, 329 F. Supp. 2d at 115 (holding that the government must show the harm from the transaction is "sufficiently *probable and imminent* to warrant relief") (citing *United States v. Marine Bancorp.*, 418 U.S. 602, 623 n.22 (1974) (emphasis added)); *see also In re Altria Grp., Inc.*, FTC No. 9393, at 110 ("The competitive conditions of a market five years in the future cannot reliably be predicted.") (citing *Mercantile Tex. Corp. v. Bd. Of Governors of Fed. Rsrv.*

Sys., 638 F.2d 1255, 1272 (5th Cir. 1981)). Complaint Counsel's failure to establish the magnitude or imminency of the alleged harms is yet additional reason to reject its case (*see* Section III).

Any harm and efficiencies must be balanced. Although Complaint Counsel bears the burden to demonstrate that the Transaction is anticompetitive when any resulting harm is balanced against any resulting efficiencies, *AT&T I*, 310 F. Supp. 3d 161, it failed to do so.[27] Complaint Counsel did no balancing at all. It simply relied on an expert who expressed the opinion that the merger would harm competition but ignored the efficiencies—which were proven by testimony and documents that the expert *never even considered*. (PFF ¶¶ 808–811.) As Dr. Carlton testified, "[i]f you don't take account of the efficiencies or, more broadly, the incentive to lower price, you risk preventing a merger that would bring large benefits to society because you've failed to balance the benefits against the possible harms." (PFF ¶ 803.1.) Thus, even if Complaint Counsel had shown that the Transaction gives Illumina an ability and incentive to raise rivals' costs (and it has not), its case fails for the independent reason that it did no balancing of those supposed harms against the substantial efficiencies that the Transaction will generate—and given the speculative nature of the harm and the substantialness of the efficiencies, the balancing Complaint Counsel failed to do weighs decisively in favor of allowing the Transaction to stand. (*See* Sections III-IV.)

[27] In arguing that it need not take efficiencies into account, Complaint Counsel quotes the district court in *AT&T*, claiming that the court there "'rejected 'as a matter of law and logic,' defendants' assertion that the Section 7 burden-shifting framework is inapplicable to vertical merger cases such that the Government 'has the burden to account for all of defendants' proffered efficiencies as part of making its prima facie case'. (CC Post-Trial Br. at 42 (quoting *AT&T*, 310 F. Supp. 3d at 191 n.17.) But Complaint Counsel elides the rest of the district court's discussion of efficiencies, omitting that the court immediately went on to explain that "given that the ultimate burden of proving a Section 7 violation rests with the plaintiff, any debate over burden shifting may be somewhat academic". *AT&T*, 310 F. Supp. 3d at 191 n. 17 (internal quotations and citations omitted).

B. Complaint Counsel Failed to Make Out a Prima Facie Case of Reduced Competition

As discussed above (Section III.A) and below (Section III.D), the mere ability of a vertically integrated company to harm competitors is insufficient alone to establish a claim under Section 7. But there is no dispute that it is a necessary but not sufficient element of Complaint Counsel's claim and, even if it were sufficient in theory, Complaint Counsel's "ability" theory is refuted by real world facts in the record.[28]

1. The Open Offer Refutes Complaint Counsel's "Ability" Theory.

Complaint Counsel identifies a number of purported levers that it contends Illumina could pull to harm GRAIL's putative rivals. (CC Post-Trial Br. at 88–99.) But it ignores the real world constraints on Illumina's ability to pull those levers, such as the Open Offer. As the court in *AT&T* explained, 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 AT&T II*, 916 F.3d at 1046–47.

While it may be theoretically possible for a supplier to pull the purported levers identified by Complaint Counsel, Illumina has no incentive to do so and would be contractually unable to do so here. As illustrated in the below table, the Open Offer precludes Illumina from using each of the alleged foreclosure "tools" identified in Complaint Counsel's Post-Trial Brief:

[28] Complaint Counsel's claims as to Illumina's alleged ability to target and harm GRAIL's putative rivals is also riddled with mischaracterizations of fact. Respondents address those mischaracterizations in more detail in their Reply to Complaint Counsel's Proposed Findings of Fact. (*See* RRFF ¶¶ 2607–2701.)

Alleged Lever	Open Offer Constraint
"*Illumina Can Completely Foreclose Grail's Rivals*" (CC Post-Trial Br. at § II.E.1.a)	Illumina *must* supply any and all sequencing instruments and core consumables ordered by the customer in a timely manner. (PFF ¶¶ 1000, 1037; RRFF ¶¶ 2832, 2839, 2841, 2843, 2852, 2854, 2858.)
"*Illumina can increase prices*" (CC Post-Trial Br. at § II.E.1.b)[29]	Illumina cannot increase prices beyond inflation for the entire 12-year term of the Open Offer, until August 18, 2033. (PFF ¶¶ 1021–22; RRFF ¶¶ 2705, 4363.) Illumina *must* lower sequencing prices by at least 43% by 2025. (PX0064 (Illumina) at 5; PFF ¶ 1023; RRFF ¶¶ 4363, 4658.) And if Illumina offers GRAIL or any other oncology customer lower prices, it *must* offer those same lower prices to the customer. (PFF ¶¶ 1017–18 RRFF ¶¶ 2750, 4361–63.)
"*Illumina can impact supply*" (CC Post-Trial Br. at II.E.1.c)	Illumina *must* supply any and all sequencing instruments and core consumables as ordered by the customer in a timely manner. (PFF ¶¶ 1000, 1037; RRFF ¶¶ 2832, 2839, 2841, 2843, 2852, 2854, 2858.)
"*Illumina can diminish service and support*" (CC Post-Trial Br. at II.E.1.d)	Illumina *must* supply the same levels of service and support to the customer as it provided pre-merger and as it makes available to GRAIL. (PFF ¶ 1004; RRFF ¶¶ 2855–57, 2868, 2871–73, 2878–93.)
"*Illumina can delay or deny access to new technology*" (CC Post-Trial Br. at II.E.1.e)	Illumina *must* provide the customer access to new technology at the same time—within five days—as it provides that technology to GRAIL. (PFF ¶¶ 1005, 1008; RRFF ¶¶ 2810–25.)
"*Illumina can develop products specifically for GRAIL*" (CC Post-Trial Br. at II.E.1.f)[30]	Upon customer request, Illumina must enter into a development agreement on commercially reasonable terms relating to the design or modification of sequencing products to optimize interoperability with the customer's tests. (*See* PFF ¶¶ 1005, 1008, 1010; RRFF ¶¶ 2825, 2830, 2986–97.)

[29] In its Post-Trial Brief, Complaint Counsel, for the first time, asserts that Illumina will raise the *relative* prices of the NGS products it sells to GRAIL's putative rivals, and, it claims, thereby squeeze rivals' profits. (CC Post-Trial Br. at 91.) Complaint Counsel does not explain what it means by "relative price", but presumably it means that Illumina will raise prices "relative" to GRAIL, in that GRAIL, through EDM, will be able to internalize the cost of Illumina's upstream inputs, enabling it to lower the price of Galleri for consumers. But contrary to Complaint Counsel's suggestion, EDM is a procompetitive benefit of a vertical merger, not a basis to unwind it. (*See* Section I.) There is no support in the record for the suggestion that, through EDM and attendant lower prices, putative rivals would have their profits squeezed, and it is contradicted by Complaint Counsel's contention, elsewhere, that MCED tests will command substantial profit margins. (*E.g.*, CC Post-Trial Br. at 105–06.)

[30] As demonstrated in Respondents' Reply Post-Trial Findings, Complaint Counsel's claim that Illumina "commonly customizes its library preparation products for its customers" (CC Post-Trial Br. at 99), is at

Alleged Lever	Open Offer Constraint
"*Illumina can deny access to critical information and agreements for FDA approval*" (CC Post-Trial Brief at II.E.1.g)	Illumina must provide the same level of support during the FDA approval process that it did pre-merger and enter into IVD agreements on pre-merger terms with any customer who desires one. (PFF ¶ 1026–27; RRFF ¶¶ 2963–85.)

Complaint Counsel's assertion that it need not account for the Open Offer because it is merely a remedy is contrary to law. *AT&T II,* 916 F. 3d 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); *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).

2. Complaint Counsel Failed to Take Into Account Intensifying Upstream Competition.

Complaint Counsel argues that it need not account for any new entry in the (undefined) related product market, because it contends that it is Respondents' burden to prove such entry will be "timely, likely and sufficient" to counteract the alleged harm from the Transaction. (CC Post-Trial Br. at 159.) As shown in Respondents' Post-Trial Brief, however, the "timely, likely, sufficient" defense applies only in horizontal cases, where the government can meet its burden by demonstrating that the combination of two competitors into one results in

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best misleading. While Illumina has done some limited customization of library preparation products in the past, that customization is irrelevant to this case as purported MCED test developers do not buy such products from Illumina, nor does GRAIL—rather, they can and do procure library preparation products through self-supply or third parties. (*See, e.g.*, RRFF ¶¶ 2613–14.) The products that GRAIL's putative rivals claim they need from Illumina are NGS instruments and core consumables, not library preparation; and as to NGS instruments and core consumables, Illumina does not engage in any customization (nor did it ever for GRAIL). These are, and always have been, off the shelf products. (*See, e.g.*, RRFF ¶ 2988.) As noted above, even if it were true that Illumina could "customize[] products for Grail in a way that it does not do for 'external' customers", such collaboration plainly would be a benefit of vertical integration, not a harm. *See, e.g.*, *Vertical Merger Guidelines* at 11 (describing as a procompetitive benefit of vertical mergers that the merged firm "may also be able to create innovative products in ways that would not likely be achieved through arm's-length contracts").

impermissibly high levels of concentration in the relevant market. (*See* Resps.' Post-Trial Br. at 130-131.) The framework in which competitive entry is a rebuttal point rather than a part of Complaint Counsel's case has no application in a vertical challenge such as this one. Moreover, it is particularly inappropriate here, given that, by its own admission, Complaint Counsel's claim that Illumina has the ability to harm GRAIL's putative rivals depends on the proposition that those rivals will have "no viable alternative" to Illumina, and Complaint Counsel's case is about supposed rival products that will exist (if ever) in the future. (*E.g.*, CC Post-Trial Br. at 89.)

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 Post-Trial Br. at 130 (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. Complaint Counsel failed to meet that burden, because, among other things, its theory does not, and could not, account for the surge of impending entry and attendant investment in NGS.

Complaint Counsel claims that none of the existing or developing alternative NGS systems should be credited as viable substitutes to Illumina, now or in the near future. But its supposed support is riddled with errors, as shown in Respondents' Reply Proposed Findings of Fact. (RRFF ¶¶ 886–1901.) Complaint Counsel further asserts that, even if there are or will be viable upstream platforms, "switching to these platforms due to any foreclosure by Illumina would still cause harm, delaying commercialization, increasing the cost, and reducing quality of MCED tests". (CC Post-Trial Br. at 134.) But as the Vertical Merger Guidelines reflect, the

ability "element [cannot] be satisfied" if "rivals [can] readily switch purchases to alternatives to the related product" without a "meaningful effect on the price, quality, or availability of products or services in the relevant market". *Vertical Merger Guidelines* at 4–5. That is the case here, as the time required to switch platforms would be insignificant because putative MCED test developers are many years from commercializing a substitutable test. (RRFF ¶ 656.) Nor is the cost of switching prohibitive, especially in view of the profit margins that Complaint Counsel claims will be enjoyed by a successful MCED test developer. (*See* CC Post-Trial Br. at 108; RRFF ¶¶ 1768–1901.) Thus, the time and cost of switching is unlikely to have a meaningful effect on the price, quality or availability of any MCED tests, and Complaint Counsel has not shown otherwise.

C. Complaint Counsel's Incentive Theory is Baseless

Even if Complaint Counsel had established that Illumina has the ability to foreclose GRAIL's putative rivals, it failed to show that the Transaction gives Illumina any incentive to do so. Complaint Counsel's incentive theory (1) ignores the Open Offer; (2) misreads the evidence concerning future MCED revenues and profits; and (3) relies on contrived assumptions divorced from reality. Complaint Counsel's contention regarding Illumina's prior behavior is likewise wanting; it proves exactly the opposite of what Complaint Counsel seeks to show, refuting Complaint Counsel's case.

1. Complaint Counsel's Incentive Theory Ignores the Open Offer.

Just as it was required to take account of real world facts constraining Illumina's purported ability to harm putative GRAIL rivals, so too was Complaint Counsel required to take account of such constraints on Illumina's incentives. Complaint Counsel failed to do so. The Open Offer plays no role in Complaint Counsel's narrative of Illumina's supposed post-merger incentives, as if it could have no impact at all. That is a striking proposition given the Open

Offer's guarantee of baseball style arbitration for any dispute arising under it, and that, in any such arbitration, the arbitrator is expressly empowered to order "*any relief necessary to restore the status quo prior to Illumina's breach*, including monetary and/or injunctive relief. The Open Offer even requires that the arbitrator decide any dispute based on the principle that the purpose of the Open Offer is to prevent the Transaction from disadvantaging any GRAIL putative rival. (PFF ¶¶ 1055–56.)

Complaint Counsel appears to contend that the threat of being caught by an audit (which occurs *at least* bi-annually, but also occurs upon customer request), and being subjected to an arbitrator's award of injunctive and monetary relief that can go as far as necessary to restore the pre-merger status quo, has no appreciable effect on Illumina's incentives. That cannot be. The Open Offer plainly "will have real world effects"; it puts Illumina's "'money where [its] mouth is' in showing that the [Transaction], far from being aimed at 'doing any of the things that the government alleges,' is instead a 'vision deal' being pursued to achieve 'lower prices, improved quality, enhanced service, and new products.'" *AT&T I*, 310 F. Supp. at 241 n.51. Complaint Counsel's failure to account for the Open Offer in attempting to establish Illumina's post-merger incentives is a fatal defect in its case.

As noted, Complaint Counsel was required to demonstrate a *merger-specific* change in Illumina's purported incentives. *See, e.g.*, *Vertical Merger Guidelines* at 2 ("[T]he Agencies focus on competitive outcomes caused by conduct that would be compatible with firms' abilities and incentives following a vertical merger, but would not be in the absence of the merger."). It failed to do so. If Illumina had not consummated the Transaction, it would have had a sizeable stake in GRAIL's profits and revenues (through its minority equity position and its right to 7% of GRAIL's revenues), but would not be bound by any of the Open Offer

commitments. It is simply implausible, and Complaint Counsel has not established, that a world with the Transaction and the Open Offer is one in which GRAIL's purported rivals are *less* protected than the world that would have existed, where Illumina would have had a substantial stake in GRAIL *without* the robust protections of the Open Offer.

2. Illumina's Projections of Future MCED Revenues and Profits Do Not Support Complaint Counsel's Incentive Theory.

Complaint Counsel asks this Court to place significant weight on the fact that Illumina, and others, project that, over time, the market for clinical testing (which includes but is not limited to MCED testing) will be huge, and that revenues and profit pools will shift from sequencing to clinical testing over time. (CC Post-Trial Br. at 105–09.) The very evidence cited by Complaint Counsel undercuts its theory.

First, the evidence Complaint Counsel relies on shows that clinical testing services will not reach the projected estimate of $56 billion before *2035*. (*See* CC Post-Trial Br. at 36.) The same evidence shows that the [redacted] As Illumina's CEO 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".[31] (PFF ¶¶ 869–871.) Thus, Illumina's NGS business will remain its core business and will account for most of its profits for "many, many years". (PFF ¶ 872.) Plainly, any harm that Complaint Counsel hypothesizes will

[31] Contrary to Complaint Counsel's suggestion (CC Post-Trial Br. at 105), there is no tension between Mr. deSouza's statement that "Illumina's core business is to sell sequencers and consumables" and the projections in Illumina's documents. [redacted] (PFF ¶¶ 868–72.)

occur as a result of changes projected to occur in *2035* is in no way "probable and *imminent*". *Arch Coal*, 329 F. Supp. 2d at 115 (citing *Marine Bancorp.*, 418 U.S. at 623 n. 22) (emphasis added).

Second, as Dr. Carlton explained, [redacted] (PFF ¶ 910.) Complaint Counsel denies that these forces exist, yet simultaneously seeks to rely on the evidence of their existence for its incentive theory. (CC Post-Trial Br. at 104–15.) Complaint Counsel cannot have it both ways. If the projections of dramatically declining costs and margins are accurate, then plainly there are forces at work that constrain Illumina's ability to raise price and capture more of the profits from clinical testing. Complaint Counsel offers no coherent theory as to how the Transaction would remove those constraints, while the evidence shows that they will remain, post-merger, to continue to drive Illumina's incentives to lower NGS costs and grow demand for its NGS products.[32]

[32] Complaint Counsel seeks to prove Illumina's incentives through the assertions of certain putative GRAIL rivals, who speculate that because clinical testing may eventually be lucrative, Illumina will have an incentive to disadvantage them. (CC Post-Trial Br. at 107–109.) In so doing, Complaint Counsel again relies on a double standard, under which the speculation of a small number of ***complaining*** executives regarding Illumina's supposed intent is credited, whereas the testimony of Illumina's ***own executive leaders*** as to their intent is given no weight.

3. Complaint Counsel's Incentive Theory Relies on Contrived Assumptions, Not on Empirical Evidence.

Complaint Counsel was required to establish its allegations as to Illumina's post-merger foreclosure incentives with empirical evidence. *See, e.g.*, *AT&T I*, 310 F. Supp. 3d at 237. To do so required, at a minimum, proof that the purported gains from foreclosure would outweigh the losses that Illumina would incur from any foreclosure strategy. But Complaint Counsel adduced no such evidence, relying instead on assumptions about the future of the upstream and downstream segments that have no basis in reality. It claims, for example, that "a better quality test could allow a competitor to leapfrog [GRAIL]" (CC Post-Trial Br. at 112), but does not identify the supposed competitor, the timeframe, or how it would be done—only naked speculation. As such, Complaint Counsel failed to show that Illumina would have any post-merger incentive to foreclose putative GRAIL rivals, and, therefore, failed to establish an essential element of its case.

a. *Complaint Counsel failed to show material diversion.*

It is undisputed that Illumina could have no incentive to foreclose putative GRAIL rivals unless such foreclosure would result in a material volume of rivals' MCED test revenues diverting to GRAIL. (PFF ¶¶ 825–27.) Yet, Complaint Counsel offered no empirical evidence of diversion, just the blithe assertion of its expert that since Galleri is the only commercially available test, foreclosure of any second MCED test entrant will necessarily result in 100% of that test's lost sales diverting to GRAIL. (CC Post-Trial Br. at 110; CCFF ¶ 3099.) That is not analysis; it is raw assumption, contradicted by the facts and blind to commercial reality.

The notion that if Illumina were able to, and did, foreclose an MCED test, 100% of its sales would divert to Galleri, is unproven and implausible. It naively assumes that the only

customers of a new MCED test will be those that use, or would otherwise use, Galleri, rather than one of the many other complementary methods of cancer detection available today or in development. In reality, however, any MCED test that may launch in the foreseeable future will be a complement to Galleri, not a substitute, and certainly far from a perfect substitute. Complaint Counsel acknowledges that tests in development are differentiated, and even notes that new MCED tests may benefit consumers by "focus[ing] on cancers that Galleri does not". (CC Post-Trial Br. at 29.) By definition, such a test would act as a complement to Galleri, reaching individuals and physicians who are particularly concerned about those cancers, and resulting in far greater NGS sales for Illumina than if Galleri were the only screening test on Illumina's platform. It would be economically irrational for Illumina to attempt to foreclose such a test and miss the opportunity to sell more NGS products.

Even assuming, *arguendo*, that such a test eventually took some sales from Galleri (which Complaint Counsel has not shown), there is no question that it would also expand demand in ways Galleri would not, resulting in a larger downstream pie into which Illumina can sell its profitable NGS products. (PFF ¶¶ 826–28.) Foreclosure of such a test would risk diverting sales to current and future NGS rivals, as well as to the screening modalities that the new test would have otherwise displaced, such as PCR, imaging, proteomics or standard-of-care protocols. The upstream losses to Illumina would be large, while the downstream gains would be minimal at best, and likely non-existent.[33] (PFF ¶¶ 825–29, 837.) [redacted]

[33] 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 (RX6000 (Carlton Trial Dep. at 40–41).)

[redacted]

To understand the costs and benefits (if any) of attempted foreclosure, and therefore reliably assess Illumina's incentives to attempt it, requires an analysis of these real world dynamics. But Complaint Counsel glosses over them entirely. Its simplistic analysis is plainly inadequate to carry its burden. Complaint Counsel compounds its error by relying entirely on the self-serving testimony of test developers who claim they are in a "race" with GRAIL but adduced no proof that they are developing tests comparable to Galleri, much less substitutable tests that will soon launch. If those claims had a basis in reality, there would be documentation substantiating them in the record, such as approvals of the substantial budgets needed for clinical trials comparable to what GRAIL has accomplished to create Galleri. No such documentary evidence exists, which alone is reason to reject Complaint Counsel's claim that these developers are in a race with GRAIL. And the evidence, in fact, shows that none are likely to have a test that would be likely to compete with Galleri at any point in the foreseeable future. (RRFF ¶¶ 3189–3607.) The public filings of both Exact and Natera make clear their development efforts are fraught with risk and uncertainty. (*See* RRFF ¶ 2013; PFF ¶ 1878.)

Having failed to prove that foreclosure of any putative GRAIL rival would likely result in material diversion of rival sales to Galleri, Complaint Counsel 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").

b. *Complaint Counsel downplays the upstream losses that a foreclosure strategy would generate.*

Further undermining Complaint Counsel's incentive theory is the fact that it does not account for the likely 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 foreclosure theory because foreclosure would result in significant lost profits for the merged firm); *Fruehauf Corp.*, 603 F.2d at 354 (rejecting the Commission's assumptions of vertical foreclosure because the upstream firm "would risk [customers'] retaliating by shifting to competing suppliers not only their purchases of [Heavy Duty Wheels] but of other products presently bought from [the upstream firm], which could cause it greater economic harm"); *HTI Health Servs. Inc.*, 960 F. Supp. at 1137 (rejecting the plaintiff's 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[s]").[34]

[34] As the Commission has acknowledged, a "merged firm's incentive to raise its rivals' costs or foreclose rivals from access to the related product depends on the profitability of the strategy", and the profitability of such a strategy, in turn, depends on the "significance of the merged firm's potential gains in the relevant market and any potential losses from reduced sales of the related product" resulting from the strategy. Fed. Trade Comm'n, *Commentary on Vertical Merger Enforcement* § 3(A)(ii) (2020), https://www.ftc.gov/system/files/documents/reports/federal-trade-commissionscommentary-vertical-merger-enforcement/p180101verticalmergercommentary_1.pdf

In addition to not showing that Illumina would gain materially from any attempted foreclosure, Complaint Counsel has not established that Illumina's losses would be so insignificant that Illumina would have no issue incurring them. The evidence showed that the losses to Illumina from any attempted foreclosure strategy would be enormous. In its Post-Trial Brief, Complaint Counsel makes no mention of the evidence that an attempted foreclosure strategy would have an adverse impact on Illumina's reputation. In fact, the evidence was unrefuted that if Illumina attempted to foreclose cancer screening test developers, its reputation would suffer in ways that would cause serious damage to Illumina's NGS business, and harm its opportunity for future profits from the expansion of NGS-based clinical testing, when NGS has only just begun to scratch the surface of its potential. (PFF ¶¶ 853–67.)

The only purported quantification of upstream losses offered by Complaint Counsel is relegated to a footnote, and amounts to a sleight of hand. In particular, Complaint Counsel claims that "Illumina told investors that its MCED test developer customers 'represent roughly 2% of our revenue'", and that such a loss "would have little impact on Illumina's overall business." (CC Post-Trial Br. at 89 n.65.) However, the "2%" figure is a reflection of Illumina's *historical* business with those test developers, and Illumina's NGS profits from clinical testing lie largely in the future. (PFF ¶ 857.) Thus, the historical perspective Complaint Counsel cites says nothing about the future significance of these customers to Illumina's upstream business, or the magnitude of future lost profits that Illumina would incur if it attempted to foreclose them. The *future* profits Illumina expects from clinical customers who Complaint Counsel claims would be foreclosed, and from other test developers who would be dissuaded from investing on Illumina's platform in response to a foreclosure strategy, is substantial. (*See, e.g.*, PFF ¶ 857.1 (Dr. Aravanis explaining that NGS is still in the "early days" as a "tool for clinical diagnostics",

and Mr. deSouza explaining that "we have so much undiscovered in front of us" and that there is "no doubt we will see a lot more clinical applications emerge in the future.")). Dr. Scott Morton admitted that Illumina does not [redacted] (PFF ¶ 857.8.)

At bottom, Complaint Counsel failed to show that the upstream losses 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 supposedly would pick up from GRAIL's putative rivals. And it 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. Hence, Complaint Counsel failed to meet its burden, which cannot be satisfied with speculation. *Rag-Stiftung*, 436 F. Supp. 3d at 311 ("[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)).

4. Illumina's Prior Behavior Undercuts Complaint Counsel's Incentive Theory.

Complaint Counsel contends that "Illumina's past behavior when vertically integrated" "illustrates its post-acquisition incentives". (CC Post-Trial Br. at 116–19.) But the evidence from Illumina's past vertical integrations undercuts, rather than supports, Complaint Counsel's theory of harm.

First, while it is true that Illumina gave GRAIL special pricing and certain other benefits shortly after it was formed and when it was wholly owned by Illumina, Complaint Counsel mischaracterizes the type of customization and support that Illumina provided to GRAIL at this time. (RRFF ¶¶ 3669–3708.) More importantly, there was (and is) nothing wrong with Illumina helping GRAIL at that time. Doing so was the only way Illumina could get GRAIL off the ground, and it is likely the only way GRAIL could have made the strides that have resulted in Galleri's launch years before any MCED test would have otherwise reached the market. Illumina's prior ownership of GRAIL has little relevance to the very different circumstances that prevail today, when (unlike then) GRAIL has developed and brought its MCED test to market, Illumina has continued to grow and strengthen its own clinical testing capabilities, the costs of sequencing have come down dramatically, and Illumina has bound itself by the Open Offer to treat any GRAIL rival fairly. In seeking to use Illumina's early support of GRAIL against the Transaction, Complaint Counsel attacks the very thing that sparked MCED development in the first place and ignores that Illumina has always owned part of GRAIL and had a stake in its future revenues.

Tellingly, Complaint Counsel has not pointed to a single instance over the last four years when Illumina has disadvantaged any GRAIL rival, despite Illumina's partial ownership of GRAIL. Nor is there any such evidence since Illumina closed the Transaction.[35] Thus, this case is unlike those that Complaint Counsel relies upon, where the evidence of

[35] If Complaint Counsel's theory were correct, Illumina would have the incentive to foreclose right now. According to Complaint Counsel, "Illumina has the incentive to harm Grail's rivals *as soon as they pose a threat to Grail's market position*" (CC Post-Trial Br. at 109), which, says Complaint Counsel, is "imminent" (CC Post-Trial Br. at 129).

foreclosure materialized after the mergers at issue were consummated.[36] Here, there is no such evidence, because Illumina has no incentive (nor ability) to harm the companies who claim to be competing with GRAIL.

Second, Complaint Counsel's contention that Illumina declined to grant Roche IVD rights in 2017, and, in 2018, evaluated internally whether it made sense for Illumina to partner with Roche, is likewise unhelpful to Complaint Counsel's challenge. Besides cherry-picking portions of dated events, Complaint Counsel did not actually examine the therapy selection market or the impact of Illumina's vertical integration in it. Nor it did it 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 merely points to the fees that Illumina has charged for IVD rights and labels them "excessive", with no analysis of their reasonableness, no comparison to the fees charged by other platforms for IVD rights, no analysis

[36] *See United States v. Kennecott Copper Corp.*, 231 F. Supp. 95, 104 (S.D.N.Y. 1964) ("Kennecott's acquisition of Okonite has in fact operated to foreclose Okonite as a customer to other copper suppliers. . . . Okonite is now obtaining virtually all of its copper requirements from Kennecott."); *United States v. Kimberly-Clark Corp.*, 264 F. Supp. 439, 446 (N.D. Ca. 1967) (noting that in the four years after Kimberley-Clark's acquisition of BMT, BMT's purchases from K-C increased by 258%, while BMT's purchases from K-C's competitors declined); *U.S. Steel Corp. v. FTC*, 426 F.2d 592, 600 (6th Cir. 1970) ("The Commission found that the acquisition brought about the largest single foreclosure which could have been obtained in the relevant geographic markets of the cement-concrete industries."); *Mississippi River Corp. v. FTC*, 454 F.2d 1083, 1091 (8th Cir. 1972) ("By these acquisitions Mississippi was able to foreclose a substantial portion of the portland cement market in the area of each acquisition."); *Ford Motor Co. v. United States*, 405 U.S. 562, 568, 581 (1972) (finding that evidence following Ford's consummated acquisition of Autolite showed that the merger actually raised barriers to entry in the spark plug market); *Heatransfer Corp. v. Volkswagenwerk, A.G*, 553 F.2d 964, 982 (5th Cir. 1977) ("After the acquisition of Intercontinental Motors, sales of the VPC unit increased markedly . . . to the detriment of other suppliers", supporting the jury's finding of a Section 7 violation); *In re Scott Paper*, 57 FTC 1415, 1424 (1960) ("The record conclusively establishes that the challenged acquisitions have been the direct cause of the respondent's progressively increasing market power and dominance in the relevant markets."); *United States v. Md. & Va. Milk Producers Ass'n*, 167 F. Supp 799 (D.D.C. 1958), *aff'd in rel. part by* 362 U.S. 458 (1960) (finding that evidence of the effects of the Association's acquisition of Embassy Dairy showed that it actually lessened competition in the Washington milk market in numerous ways).

of the effect of those fees on downstream investment and innovation, and no analysis of downstream prices or output. As noted in Respondents' Post-Trial Brief, by charging fees for IVD rights, Illumina was following market practice, [redacted] IVD rights have value, and there is nothing anticompetitive about charging fees for things of value. Complaint Counsel offered no analysis whatsoever of the competitive effects of Illumina's vertical integration in therapy selection.

If Complaint Counsel had examined the competitive effects of Illumina's vertical integration in therapy selection, it would have discovered that the parade of horribles and innovation harms Complaint Counsel speculates will occur in the alleged MCED market as a result of the Transaction never materialized. (PFF ¶¶ 966–973.) Today, Illumina has collaboration agreements in place with Roche, PGDx and numerous other test developers in therapy selection pursuant to which these formidable competitors are developing IVD tests that will compete with Illumina's own therapy selection test. (PFF ¶ 966.) Illumina provides customer support to its therapy selection rivals, and investment and innovation has increased in in recent years. (PFF ¶ 967.) In fact, the therapy selection market is thriving. Despite all of Complaint Counsel's allegations about Roche, no Roche witness testified about any foreclosure concern in therapy selection. And it is telling that even Guardant, Complaint Counsel's own witness who has a therapy selection test, did not mention any foreclosure concern in that market either.[37] (*See* PFF ¶ 1810.)

[37] Thus, it is of no moment that, in the early days of its IVD technology and its therapy selection strategy, Illumina evaluated the impact of IVD partnerships on its profits. Illumina had invested substantial amounts in its IVD technology, there were few IVD kitted tests even commercially available, and Illumina had not yet even received FDA authority to market a higher-throughput IVD system. The evaluation Illumina undertook of different potential approaches to this new technology and mode of distribution is what any profit maximizing firm would do when considering a major strategic decision

What matters to understanding Illumina's incentives are the choices Illumina made, not the strategies some within Illumina evaluated along the way. [redacted] (PFF ¶ 971.3.) Therefore, the evidence from Illumina's vertical integration in therapy selection shows the opposite of what Complaint Counsel claims: Illumina determined that having others in the space who would be willing to invest resources and effort toward developing NGS-based IVD tests, and growing demand for them, was the best outcome for Illumina's reputation and bottom line. In short, Illumina's conduct in therapy selection does not support Complaint Counsel's speculative claims of future harm in the alleged MCED market.

Third, Complaint Counsel suggests Illumina disadvantaged rivals in NIPT after it acquired Verinata, citing only the testimony of Natera's Chairman. But the market data refutes those unsupported claims. As the data shows, Illumina's acquisition of Verinata brought increased competition, lower prices, increased output and enormous benefits to patients.[38] Since the acquisition, between 2015 and 2019, the number of NIPT tests conducted by Verinata's rivals

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such as the one Illumina faced when it first considered how and to what extent to enable third party kits on its new IVD systems. (PFF ¶¶ 971–72.)

[38] While purporting to give a full account of Illumina's prior vertical integrations, Complaint Counsel's Post-Trial Brief makes no mention of Illumina's spinout of Helix, a population genomics company that competes with providers such as Ancestry.com. (PFF ¶ 974.) It is undisputed that Illumina's conduct in connection with the formation and spinout of Helix was recognized, even by Helix's competitors, as "fantastic". (PFF ¶ 975.) [redacted]

on Illumina's platforms in the U.S. more than doubled, output expanded, and, critically, Verinata's share of NIPT sales *decreased* while rival sales *increased*. (PFF ¶ 956 & Figure 7.) While Natera claims it was the victim of foreclosure, the evidence showed that Natera became the market leader around the time Illumina acquired Verinata, and has maintained its position with a consistently high share. (PFF ¶ 958.) There has also been a steady stream of new entry and substantial investment into NIPT testing in the U.S. since the Verinata acquisition. (PFF ¶ 962.) A number of fact witnesses confirmed what the economic evidence alone starkly demonstrates: Illumina's entry into NIPT via a vertical transaction was decidedly procompetitive.[39] (PFF ¶ 963.)

D. *Brown Shoe* Does Not Support Complaint Counsel's Allegations of Competitive Harm.

Unable to demonstrate that the Transaction will give Illumina *both* the ability *and* the incentive to disadvantage putative GRAIL rivals in the foreseeable future, Complaint Counsel seeks—again—to move the goal posts. Under the guise of following what it calls "The *Brown Shoe* Vertical Merger Framework", Complaint Counsel argues that Illumina's purported "dominance as an NGS platform provider" is, by itself, sufficient to establish that the Transaction is unlawful. (CC Post-Trial Br. at 119, 121.) And, if the Court is not buying that, Complaint Counsel argues that the Transaction should be found unlawful based on two additional factors: "the very nature and purpose of the arrangement" and "barriers to entry". (*Id.* at 122–25.) Complaint Counsel is wrong on all counts.

First, while the Court in *Brown Shoe* noted that Section 7 may be violated where the "share of the market foreclosed is so large that it approaches monopoly proportions",

[39] In addition, Illumina has played a major role in expanding payor coverage for NIPT, resulting in much broader market access. (PFF ¶¶ 1131.12, 1225.)

370 U.S. at 327, it *did not say* that foreclosure can be shown by high shares alone. To the contrary, it required actual evidence of a probable foreclosure effect: one that, for example, could simultaneously "run afoul of the Sherman Act". *See id.* at 328, 332 (holding that it was "apparent both from past behavior of Brown and from the testimony of Brown's President, that Brown would use its ownership of Kinney to force Brown shoes into Kinney stores. Thus, in operation this vertical arrangement would be quite analogous to one involving a tying clause."). The other vertical cases Complaint Counsel cites likewise required actual evidence of likely foreclosure effects. *See United States v. Am. Cyanamid Co.*, 719 F.2d 558, 566 (2d. Cir. 1983) (noting that courts in vertical cases require evidence as to "the *likelihood and size* of any market foreclosure"); *Fruehauf*, 603 F.2d at 352 ("The Supreme Court's insistence that each merger challenged under [Section] 7 be viewed . . . in the context of its particular industry, and that the Clayton Act protects Competition, not Competitors, contravenes the notion that a significant level of foreclosure is itself the proscribed effect" of Section 7) (internal citations and quotation marks omitted); *In re Zinc Antitrust Litig.*, No. 14-cv-3728, 2016 WL 3167192, at *23 (S.D.N.Y. 2016) ("[T]he allegations in the [Complaint] do not even attempt to raise an inference that Glencore Ltd.'s acquisition of Pacorini foreclosed [competitors]" and "[t]here is no plausible allegation that competition was lessened or likely to be lessened in the relevant sense.").[40] No modern court has ever held that the government can so easily condemn a vertical merger.

[40] Complaint Counsel misplaces reliance on *In re Union Carbide Corp.*, 59 F.T.C. 614, 1961 WL 65409, (1961), for the proposition that it need not prove Illumina would likely engage in conduct causing market foreclosure, so long as it shows that Illumina has the "power" to do so. (CC Post-Trial Br. at 81, 104). However, as a 61-year-old Commission decision, and a splintered one at that, *Union Carbide* does not control the standard to be applied here. Further, the Commissioners who voted to affirm the ALJ's ruling in that case were concerned that the merger there would compel other market participants to vertically integrate, and that such market-wide vertical integration would harm competition, and that such effects had already occurred as a result of the merger. Thus, contrary to Complaint Counsel's suggestion, the Commissioners in *Union Carbide* did not uphold the ALJ decision on the basis that the merged firm had a theoretical power to foreclose rivals but no incentive to do so.

Second, as to the "nature and purpose" of the Transaction, that factor cuts decisively against Complaint Counsel's case, not in favor of it. While Illumina obviously acquired the shares of GRAIL that it did not already own to improve Illumina's overall business and profitability in the long term, part and parcel of that was Illumina's determination that it can do for GRAIL what needs to be done to accelerate the widespread adoption of Galleri, save lives and accelerate the growth of a nascent use case for its NGS technology. That is not a reason to block the Transaction; it is a reason to endorse it. And, the fact that Illumina believed that acquiring GRAIL will create value for shareholders is a far cry from showing that Illumina did so with an intent to foreclose its clinical customers.

While Complaint Counsel stresses the importance of intent, it points to no evidence that Illumina acquired GRAIL with the intent to foreclose any putative GRAIL rival. Rather, all internal documents and testimony from Illumina relating to its strategic rationale for the merger show that Illumina's intent was to accelerate consumer access to Galleri, help expand GRAIL's technology to other disease states, and, of course, profit from that acceleration and growth. (RRFF ¶ 208.) There is nothing anticompetitive about Illumina's acquisition intent. *See United States v. Hammermill Paper Co.*, 429 F. Supp. 1271, 1288-89 (W.D. Pa. 1977) (rejecting the government's vertical theory, *inter alia*, because there was no evidence that the defendant's intent in consummating the acquisition was "to foreclose competing suppliers from access to the acquired paper merchant outlets", and "[t]he lack of evidence of intent to foreclose in the instant case is material.").

Third, there is no evidence the Transaction will erect any barriers to entry. Complaint Counsel's claim to the contrary is remarkably devoid of evidentiary support. Complaint Counsel contends that the Transaction "has caused MCED test developers to

reevaluate their appetites", but the only "evidence" Complaint Counsel cites is the bald assertion by [redacted]

There is also abundant evidence that the Transaction has *spurred* investment in early cancer detection, and in liquid biopsy more broadly, indicating that the Transaction has *lowered* entry barriers, not raised them. 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][41] The timing of this investment activity is inconsistent with Complaint Counsel's speculative theory that the Transaction has dampened, or will dampen, incentives to

[41] Thus, the facts here present a striking contrast with the facts in the cases on which Complaint Counsel relies, where the mergers were consummated and there was concrete evidence showing the predicted harm had already started to materialize. (*See supra* n. 36.) Here, the market has become *more* vibrant since the deal was announced, and all Complaint Counsel can do is speculate, without evidence, that perhaps that massive surge in investment would have been even more substantial absent the deal.

invest in NGS-based cancer testing and cause innovation harms.[42] (PFF ¶ 933.) Complaint Counsel's theory is further undermined by its own representation that "innovation is vibrant in this 'rapidly evolving market landscape'". (CC Post-Trial Br. at 3.)

E. Complaint Counsel Failed to Prove that the Transaction Will Harm (Much Less Substantially Harm) Innovation or Commercial Competition.

Complaint Counsel's inability to establish that the Transaction gives Illumina a likely ability and incentive to harm putative GRAIL rivals is reason enough to reject its claim that the Transaction "will harm the vibrant innovation competition happening today and the head-to-head commercial competition poised to commence in the near future." (CC Post-Trial Br. at 125.) The unrefuted evidence shows that Illumina benefits from any vibrant innovation that may catalyze development and expansion of sequencing into new applications, increasing demand for sequencing and growing Illumina's opportunity to sell more of its sequencing products. And, as discussed above, Illumina's past entry into clinical markets provides a real world demonstration of Illumina's strong incentives to support the development and commercialization work of all customers willing to invest on Illumina's platform, including downstream rivals. That track record of support, and of downstream rivals flourishing alongside Illumina's own clinical tests in NIPT and therapy selection, stands in stark contrast to Complaint Counsel's unsupported speculation about what Illumina might do in the future.

[42] 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.) 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. (PFF ¶ 938.2.) Similarly, the price that Illumina paid for GRAIL—approximately $8.3 billion for the voting shares it did not already own—further undercuts Complaint Counsel's case. It would not make any sense for [redacted] (PFF ¶ 945.)

The overwhelming weight of the evidence shows that Illumina is incentivized, and is now contractually bound, to support any development and commercialization on its platform by any downstream rivals. Thus, even if Complaint Counsel's characterization of supposed MCED competition reflected reality (and it does not), there would be no basis to conclude that the Transaction is likely to harm innovation or commercial competition in the alleged MCED market. The fact also remains that there are no close rivals to Galleri—neither at the innovation stage, nor the commercial stage. Complaint Counsel's contentions to the contrary, which make up the balance of its claim that it has met its burden to show a substantial lessening of competition, are divorced from reality.

1. Complaint Counsel Has Not Proven Any Likely Harm to Innovation in the Alleged MCED Test Market.

Complaint Counsel's various assertions about the benefits of innovation competition (CC Post-Trial Br. at 125–29) are red herrings. There is no dispute that innovation benefits consumers and should be allowed to flourish. But as shown below (*see* Section IV), the Transaction, in fact, will spur greater innovation through the substantial efficiencies it will generate, and it has already catalyzed excitement and investment in the liquid biopsy field. Thus, it is not the Transaction that threatens innovation in MCED testing, but rather Complaint Counsel's misguided effort to unwind it.

Attempting to show otherwise, Complaint Counsel theorizes about the development work of supposed GRAIL rivals and about the Galleri test. As stated, however, Complaint Counsel failed altogether to define an appropriate innovation market, such that its allegations are left to waft about, incapable of being weighed or balanced as the law requires. Moreover, Complaint Counsel's claim that "[i]t is undisputed that MCED test developers have already invested hundreds of millions of dollars and years of development on their MCED tests"

(CC Post-Trial Br. at 126) is incorrect in two ways: it is disputed, and the facts refute it. As shown above (*see* Section II.A), the evidence makes clear that there is no test in development with features comparable to Galleri, and none is likely to launch at any point in the near future. Finally, Complaint Counsel contends that Galleri has not actually demonstrated an ability to detect 50 cancer types, that its claim to 50 cancers is a marketing ploy, and that it may be "leapfrogged" at any point by tests that are close behind it. (CC Post-Trial Br. at 128.) These too are falsehoods, contradicted by an abundance of record evidence (*see* Section II.A.3).

2. Complaint Counsel Has Not Proven Any Likely Harm to Commercial Competition in the Alleged MCED Test Market.

Complaint Counsel's allegation that the Transaction will harm commercial competition between MCED tests similarly relies on unproven allegations about the state of MCED test development. Complaint Counsel argues that commercial competition between Galleri and other MCED tests is "imminent" and that tests comparable to Galleri will be commercially launched "in the next few years". (CC Post-Trial Br. at 129.) As shown above (*see* Section II.A), these claims are speculative at best.

Complaint Counsel points only to unsubstantiated and implausible statements by test developers [redacted] But merely spending money and even doing development work does not a make viable test. If Complaint Counsel's claims had any basis in reality, there would be data (such as reports from clinical studies) [redacted] There would be documentation as to how many cancers the developer's test can detect, with what specificity and sensitivity, and with what tumor of origin accuracy. None of that is in the record, [redacted]

[redacted] (*See* PFF ¶¶ 703.8–703.13; RRFF ¶¶ 2185–2256.) Complaint Counsel hangs its entire case on the say-so of non-credible testimony of test developers whose own internal documents refute their claims.

In sum, Complaint Counsel's allegations that the Transaction harms innovation and commercial competition each fail on multiple grounds. They depend on claims as to Illumina's incentives that have no support in the record and are contradicted by Illumina's track record of vertical integration. They depend on claims about putative GRAIL rivals that are divorced from reality. And they depend on claims about the Galleri test that are easily refuted. Complaint Counsel thus has failed to show that the Transaction will cause any harm to competition at all, much less an imminent, substantial lessening of competition.

IV. THE TRANSACTION WILL GENERATE ENORMOUS BENEFITS THAT EASILY 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 any realistic risk of harm, the benefits of the deal easily outweigh the alleged harm. Complaint Counsel argues that the claimed benefits of the Transaction are not legally cognizable, lack support in the record, and are too speculative to matter. That is false. The Transaction will result in merger-specific benefits, far exceeding the benefits of any vertical merger ever litigated.

A. Efficiencies Matter, Legally and Practically.

As an initial matter, Complaint Counsel contends that the efficiencies associated with the Transaction are of no consequence. It goes so far as to suggest that efficiencies may not be cognizable under the Clayton Act. As discussed in Section I, however, Complaint Counsel is

mistaken. None of its cited cases says any such thing. While it may be that efficiencies cannot save an unlawful merger, they necessarily bear upon whether a transaction will substantially lessen competition.

Courts have repeatedly held that a Transaction is lawful under Section 7 unless any anticompetitive effects outweigh any procompetitive effects. *See, e.g.*, *Deutsche Telekom AG*, 439 F. Supp. 3d at 207; *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1054–55 (8th Cir. 1999) (courts should consider "evidence of enhanced efficiency in the context of the competitive effects of the merger" since "the merged entity may well enhance competition"); *Saint Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775, 790 (9th Cir. 2015) ("[A] defendant can rebut a prima facie case with evidence that the proposed merger will create a more efficient combined entity and thus increase competition."); *FTC v. Univ. Health, Inc.*, 938 F.2d 1206, 1222 (11th Cir. 1991) ("[A] defendant may rebut the government's prima facie case with evidence showing that the intended merger would create significant efficiencies in the relevant market."); *AT&T I*, 310 F. Supp. 3d at 190 ("One way defendants may [contest the Government's case] is to offer evidence that post-merger efficiencies outweigh the merger's anticompetitive effects."). Cases cited by Complaint Counsel are not to the contrary. *See FTC v. H.J. Heinz Co.*, 246 F.3d 708, 720–21 (D.C. Cir. 2001); *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 89 (D.D.C. 2011); *FTC v. Wilh. Wilhelmsen Holding ASA*, 341 F. Supp. 3d 27, 72 (D.D.C. 2018); *FTC v. CCC Holdings, Inc.*, 605 F. Supp. 2d 26, 72–73 (D.D.C. 2009).

B. The Benefits of the Transaction Are Supported by Overwhelming Evidence.

Like its suggestion that efficiencies do not matter under the Clayton Act, Complaint Counsel's claim that the efficiencies resulting from the Transaction are speculative, unverified and not merger-specific is, to be frank, nonsense. It is also the product of another double standard, as Complaint artificially inflates the threshold for proving efficiencies, while

artificially deflating its own burden to show anticompetitive effect (for which, according to Complaint Counsel, speculation and mere assertions suffice).

As set out in Respondents' Post-Trial Brief, the overwhelming and unrefuted evidence showed that the Transaction will result in numerous, merger-specific benefits, including that it will save thousands of lives (in the U.S. alone, and many more throughout the world) and billions of dollars. To that end, the reunion of Illumina and GRAIL will accelerate market access to a life-saving test; lead to new innovations from synergistic R&D; reduce costs through the elimination of a royalty that GRAIL was otherwise contractually required to pay to Illumina and elimination of double marginalization ("EDM"), the savings from which will be passed on to consumers; and lead to supply chain, operational and international efficiencies, resulting in lower prices and faster testing for patients. These efficiencies are described in Respondents' Post-Trial Brief (pages 181-231) and Proposed Findings of Fact (¶¶ 1106–79).

Far from being unsubstantiated, these efficiencies are supported by every Illumina and GRAIL witness to address them, including: Francis deSouza, Dr. Alex Aravanis, Dr. Phil Febbo, Ammar Qadan, Jay Flatley, Hans Bishop, Dr. Joshua Ofman, Aaron Freidin and Dr. Arash Jamshidi. (PFF ¶ 1108.) They are supported by "analogous past experience" (Mergers Guidelines § 10), including most notably Illumina's vertical acquisition of Verinata resulting in expanded access to NIPT testing and the discovery of GRAIL. And they are supported by the testimony of highly qualified experts and reluctant admissions by Complaint Counsel's own experts. The following table is illustrative of the proof offered at trial as to each efficiency:

No.	Efficiency	Witness	PFF
1	**Saves Lives**	Aravanis, deSouza, Febbo, Flatley, Bishop, Freidin, Jamshidi, Ofman, Conroy, Chahine, Fiedler, Nolan, Rabinowitz, Carlton, Deverka	¶¶ 1117, 1119–26
2	**Accelerates Market Access**	Aravanis, deSouza, Febbo, Flatley, Qadan, Bishop, Della Porta, Freidin, Ofman, Conroy, Gao, Nolan, Rabinowitz, Deverka	¶¶ 1127–35
3	**R&D Innovations**	Aravanis, deSouza, Febbo, Flatley, Bishop, Jamshidi, Klausner, Carlton	¶¶1136–45
4	**Reduced Royalty Burden**	Aravanis, deSouza, Freidin, Strom, Carlton	¶¶1146–51
5	**Eliminated Double Margin**	Aravanis, deSouza, Carlton	¶¶ 1152–55
6	**Supply Chain and Operational Efficiencies**	Aravanis, deSouza, Flatley, Bishop, Carlton	¶¶ 1156–67
7	**Accelerated Fruits of International Expansion**	Aravanis, deSouza, Febbo, Flatley, Bishop, Freidin	¶¶ 1168–73

What's 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 these efficiencies. (PFF ¶ 1110.) At the time it 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 these directors 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.) Also, Complaint Counsel either conducted no cross examination of these witnesses on the Transaction's benefits or its questioning readily affirmed the efficiencies. (PFF ¶ 1109.) The proof of efficiencies is conclusive and uncontroverted. (PFF ¶ 1116.)

C. Complaint Counsel's Specific Criticisms of the Transaction's Efficiencies Are Specious (At Best).

To the extent Complaint Counsel asserts any specific criticisms of the Transaction's efficiencies, those criticisms are misplaced. They bear no relationship to the evidence presented at trial.

1. The Full Reunion of Illumina and GRAIL Will Save Lives.

Despite its claim that the Transaction will not generate any efficiencies, Complaint Counsel effectively concedes the Transaction's most important efficiency: that it will save lives. Complaint Counsel admits that cancer screening saves lives. (PFF ¶¶ 1117–19.) And Complaint Counsel admits that accelerating the adoption of a multi-cancer screening test will save even more lives. (PFF ¶ 1122.) Complaint Counsel appears to dispute only that reuniting Illumina and GRAIL will accelerate the adoption of the Galleri test.

If evidence matters more than rhetoric, then there can be no doubt that reuniting Illumina and GRAIL will accelerate the adoption of Galleri. How could it not? Illumina is the world's foremost expert in NGS technology. Its brand is synonymous with innovative and low-cost sequencing. (PFF ¶ 855.) It has single-handedly driven down the cost of sequencing from $300,000 per gigabase to less than $8 per gigabase today. (PFF ¶ 855.1.) These reductions in costs have allowed for the development of entire industries that now exist, but would not without Illumina's sequencing and innovation. (PFF ¶ 855.2.) Notably, these cost reductions, and the development that they have enabled, were made possible by Illumina's first major acquisition, of Solexa in 2006, which gave Illumina promising NGS intellectual property to which Illumina added its own manufacturing resources, commercial acumen, technical expertise and an unprecedented commitment to innovation and improving human health. (PFF ¶¶ 574–77.) Thus, starting from its very beginning as an NGS company, Illumina has established a track record of

successful acquisitions that have resulted in technology innovation and acceleration, new products and lower costs for consumers. One of Illumina's oncology customers, who is also a downstream rival to Illumina in NIPT (Invitae), in a sworn declaration to the FTC, praised Illumina's role "as an innovator in NGS" that "has moved the field forward tremendously". (PFF ¶ 856.1.) Illumina founded GRAIL. It has been repeatedly recognized as an innovator, earning recognition as one of the hundred most influential companies by TIME and by MIT as a "World's Smartest Company". (PFF ¶ 1139.3.)

Illumina's ability to accelerate the Galleri test, advance innovation and access to NGS testing, and thus save lives, is not just wishful thinking. It was sworn to and explained by multiple leaders in the field including Francis deSouza (PFF ¶ 1121.2), Dr. Alex Aravanis (PFF ¶ 1121.3), Dr. Phil Febbo (PFF ¶ 1121.4), Jay Flatley (PFF ¶ 1121.5), [redacted], Aaron Freidin (PFF ¶ 1121.8) and {[redacted] And it is borne out by experience. The evidence substantiating this efficiency has been described at length. (*See* Resps.' Post-Trial Br. at 182–189; PFF ¶¶ 1117–26.)

Illumina has conservatively estimated that a fully reunited Illumina and GRAIL will accelerate Galleri's scaled adoption by at least one year. (PFF ¶ 1122.1.) Dr. Carlton, a former DOJ chief economist, testified that accelerating the adoption of Galleri by one year would lead to an additional 10 million tests performed in the U.S. over a nine-year period (2022-2030), preserving "7,429 to 10,441" lives, which can be valued in the many billions of dollars. (PFF ¶ 1123.) [redacted]

[redacted].[43] (PFF ¶ 1122.2.)

None of Complaint Counsel's alleged experts offered any basis to dispute that the Transaction will save lives. They conceded cancer screening saves lives and its acceleration will save more. (PFF ¶ 2128.) Complaint Counsel's "experts" lack the expertise to opine on Illumina's ability to accelerate the adoption of Galleri (PFF ¶ 2127), and their criticisms are debunked in Respondents' Post-Trial Brief and Proposed Findings of Fact. (*E.g.*, PFF ¶ 1126; RRFF ¶ 5721–36.) The idea that reuniting Illumina and GRAIL would not accelerate the adoption of Galleri makes no sense. Illumina unquestionably has what GRAIL lacks but needs to maximize the benefits of its ground breaking technology.

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

All agree that to achieve widespread adoption, GRAIL will need to achieve regulatory approval and payor coverage for Galleri (PFF ¶ 1127.1), and Respondents showed that the full reunion of Illumina and GRAIL will substantially accelerate regulatory approval and payor coverage for Galleri at pages 189-200 of Respondents' Post-Trial Brief and paragraphs 1127–35 of Respondents' Proposed Findings of Fact. In response, Complaint Counsel says Respondents have not proven the Transaction will accelerate regulatory approval or payor coverage or that any acceleration will be merger specific. But neither claim withstands scrutiny.

[43] Dr. Carlton's estimate is necessarily conservative. (PFF ¶ 1124.) 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.)

Despite Complaint Counsel's conclusory criticisms, Respondents demonstrated the Transaction will accelerate FDA approval and market access through numerous Illumina and GRAIL fact witnesses, including Mr. deSouza, Dr. Aravanis, Dr. Febbo, Mr. Qadan, Mr. Flatley, Mr. Bishop, Dr. Freiden, and Mr. Della Porta. (PFF ¶¶ 1130–33.) Complaint Counsel did not present any contrary fact witness testimony, and none of its experts is qualified to address the subject. (PFF ¶ 1133.22.) Echoing this unrefuted fact testimony, Dr. Deverka, an expert in the field of health economics and outcomes research, testified that the full 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.) Dr. Deverka presented a detailed table (*see* Resps.' Post-Trial Br. at 196–97), comparing GRAIL's and Illumina's capabilities in relevant respects and summarizing how the Transaction will accelerate FDA, CMS and private payor coverage.[44]

[44] Complaint Counsel 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.) But neither Dr. Rothman nor Dr. Navathe has sufficient 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).) Neither Dr. Navathe nor Dr. Rothman attempts to undermine the undisputed testimony described above. (PFF ¶ 1134.6.)

Ignoring the overwhelming weight of the evidence, Complaint Counsel takes pot shots at Dr. Carlton, Illumina's "ordinary course" documents and Illumina's regulatory track record. (CC Post-Trial Br. at 144-48.) But the criticisms are misplaced:

First, Complaint Counsel nitpicks Dr. Carlton's quantification and faults him for not offering expert testimony on the FDA regulatory process or fact testimony on Illumina's and GRAIL's capabilities. However, Dr. Carlton is not an FDA expert and does not purport to be. (*See* PFF ¶¶ 1934-37.) He is a professor of economics and former Deputy Assistant Attorney General for Economic Analysis at the DOJ. (PFF ¶¶ 1934, 1936.) Relying on undisputed facts and the opinions of other experts, and the Illumina deal model that is the basis for Illumina's valuation of GRAIL, Dr. Carlton employed his expertise as an economist to set out the relevant economic principles and quantify the magnitude of this efficiency. He did so conservatively, and none of Complaint Counsel's criticisms survives scrutiny. There is a reason Complaint Counsel failed to conduct any meaningful examination of Dr. Carlton on this (or any other) issue.

Second, Complaint Counsel reliance on Illumina's internal documents amounts to obfuscation. Complaint Counsel contends that the acceleration efficiencies are not verifiable because "Illumina did not estimate the probability that it would be successful in accelerating FDA approval of Galleri", which, according to Complaint Counsel, means Illumina did not "model" the efficiency. (CC Br. at 146.) But Illumina does not need to estimate the probability of acceleration in order to model it, and Illumina did in fact model a one-year acceleration as a conservative estimate of what Illumina could likely achieve for Galleri. (RRFF ¶ 5043 (Dr. Febbo explaining that Illumina "did model acceleration, for example, of regulatory approval by a year and saw the impact that could have on testing and on the value of GRAIL".)) That Illumina did not model the "probability" of achieving this conservative estimate of a one-year acceleration

is of no moment, since all involved in the approval of the transaction—from the Illumina executive team to its independent directors—concluded with full confidence that Illumina could meet, and likely exceed, this goal. (PFF ¶ 1122.) Complaint Counsel also points to Illumina documents stating that [redacted]. (CC Post-Trial Br. at 146.) But those documents, which include an Employee FAQ, refer to "cost synergies" of the type that "typically happen in acquisition when you're laying people off or eliminating roles". (RRFF ¶ 215.) That Complaint Counsel must resort to mischaracterizing statements in documents intended to assure employees that there will not be layoffs underscores the lack of merit to Complaint Counsel's attacks on the Transaction's acceleration benefits.[45]

Third, Complaint Counsel claims that the acceleration efficiency lacks sufficient detail as to how it will be achieved. (CC Post-Trial Br. at 144.) The claim ignores the record evidence, which provides ample detail as to how Illumina can and will accelerate Galleri's FDA approval and payer coverage. Illumina's internal experts on these points explained how Illumina will leverage its relationships and credibility with payers to gain early coverage for Galleri; how Illumina will use its experience and reputation as a trusted expert and educator to the FDA on NGS issues to help GRAIL overcome FDA concerns with an NGS-based MCED test; how Illumina is committed to spending upwards of $1 billion to generate the clinical evidence necessary to secure broad payor coverage; how Illumina can put GRAIL on its quality management system ("QMS"), short-cutting the long and arduous task GRAIL would otherwise have to develop such a system itself; and how large payors have already approached Illumina about forming partnerships to expand access to Galleri for their insured customers at lower costs.

[45] Complaint Counsel's mischaracterization of these statements is striking in light of the FTC's stated goal of protecting competition in labor markets.

(PFF ¶¶ 1131, 1386, 1389.) These are far from "surface-level" claims, and there is far more "precision" in the record about Illumina's ability to accelerate GRAIL's FDA and market access efforts than there is as to Complaint Counsel's alleged harms.

Fourth, relatedly, there is no merit to Complaint Counsel's claim that FDA acceleration is not verifiable because Illumina will need to work with GRAIL through integration planning to identify all of the specific steps Respondents will take to achieve acceleration, which it has not yet done. (CC Post-Trial Br. at 146.) While Illumina has not completed its integration planning, that is only because it is not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).) But that is irrelevant to the question of verifiability. As noted, the law does not require Illumina to identify all the "specific steps" (CC Post-Trial Br. at 146) it will take to achieve an efficiency for that efficiency to be verifiable. There is ample detail substantiating the acceleration efficiency, which is more than sufficient to verify it.

Fifth, Complaint Counsel's attacks on Illumina's regulatory record are unfounded. While it is true that Illumina has faced regulatory challenges over the years (*e.g.*, with its NIPT submissions), that is neither surprising nor inconsistent with the Transaction accelerating FDA approval and market access for Galleri. Complaint Counsel blithely glosses over the reality that NGS is a novel technology for the FDA that presents unique, unprecedented challenges for anyone seeking FDA approval of an NGS-based clinical diagnostic test. Illumina, the world's foremost expert in NGS technology, has been at the vanguard of these efforts, guiding the FDA through educational sessions and as it seeks to achieve the most challenging of approvals for kitted IVD NGS-based tests. (RRFF ¶ 5145; PFF ¶ 1131.7.) The evidence showed that the supposed "mistakes" and setbacks that Complaint Counsel points to were not mistakes or

setbacks at all. Rather, as the unrefuted testimony showed, they were a reflection of Illumina setting aggressive and demanding goals for itself, while pushing the FDA to shift from its "traditional methods of IVD validation" to one that is suitable and scalable for NGS diagnostic tests. (RRFF ¶¶ 5236–40.)[46] Accelerating Galleri does not require a perfect past record, nor is such a record possible. It requires the experience and expertise Illumina has accumulated through years of interacting with the FDA on challenging and novel issues fundamental to the use of NGS technology to solve critical health questions—which GRAIL does not have. (PFF ¶ 1131.5–31.7; RRFF ¶¶ 5065–66.) Complaint Counsel's economic experts can attack from their ivory tower Illumina's work in the trenches to educate and change the mindset of the FDA in ways that are necessary for NGS approvals, but those baseless attacks can have no bearing on the verifiability of the acceleration efficiency.

Sixth, Complaint Counsel's attacks on the Transaction's acceleration efficiencies overlook that these efficiencies are further verified by experience. For example, since entering the NIPT space through a vertical merger, Illumina has vastly expanded payer coverage of NIPT testing, entering ground-breaking partnerships with payers, and advancing the first-ever application for FDA approval of an NIPT kitted test. (*See, e.g.*, PFF ¶ 1131 (Mr. Qadan describing how Illumina spearheaded a risk-sharing agreement with a payor to develop the evidence needed to expand coverage of NIPT tests for all pregnancies, and the publication of that work has led to a significant increase in coverage for NIPT—a model that Illumina can use to accelerate Galleri).) Such "analogous past experience" on its own is sufficient to verify the

[46] As Dr. Febbo explained, Illumina's NIPT application presents "the first use of next-generation sequencing in NIPT for a distributed test", so "this is new ground, and it's not uncommon in new ground that you have to work with the agency to find a path to success that moves away from their traditional expectations." (RRFF ¶ 5145.)

Transaction's acceleration efficiencies. *See Deutsche Telekom AG*, 439 F. Supp. 3d at 216-217 ("[T]he Merger Guidelines state that efficiency claims may be verifiable if substantiated by analogous past experience" and "Defendants' claimed efficiencies are verifiable in significant part because of T-Mobile's successful acquisition of MetroPCS in 2013", given trial testimony that the parties "could follow the same basic organizational structure and strategy [to achieve similar efficiencies for the challenged merger]") (citing *Horizontal Merger Guidelines* § 10).

Complaint Counsel's claim that Illumina's ability to accelerate market access is not merger-specific is baseless. Complaint Counsel points to a number of GRAIL's achievements in developing Galleri, such as receiving a "breakthrough device" designation. (CC Post-Trial Br. at 148–50.) While important, those achievements do not give GRAIL all that it needs to accelerate FDA and payor approval (in fact, breakthrough designation is granted by FDA early in a product development process, before a company conducts pivotal studies necessary for FDA approval). Numerous witnesses testified that GRAIL needs what Illumina has to accelerate the approval of Galleri. (PFF ¶¶ 1133–33.26.) For example, Francis DeSouza, CEO of Illumina, testified that 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 the right innovation focus to come up with new models to accelerate the evidence generation needed to get payers on board." (PFF ¶ 1132.2.) [redacted]

Recognizing that GRAIL cannot accelerate market access on its own, Complaint Counsel contends that it could simply hire consultants and get the same result. But GRAIL has hired consultants and, as every fact witness to address this issue has said, consultants have not and would not be able to do for GRAIL what Illumina can. (PFF ¶¶ 1175.2–75.2.4.) For example, Dr. Febbo testified that from his experience with consultants into "regulatory, into market access", "there's just not a deep, rich bench of experience . . . that just doesn't work as effectively as having internal employees." (PFF ¶ 1175.2.1.) In addition, [redacted] (PFF ¶ 1175.2.4.) [redacted] (PFF ¶ 1175.2.4.)

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

Complaint Counsel contends that Respondents "provide almost no evidence whatsoever to verify" the Transaction will result in R&D efficiencies and that any efficiencies could not be merger-specific, because, says Complaint Counsel, "the claimed breakthroughs have already been discovered by GRAIL." (CC Post-Trial Br. at 151.)

Illumina and GRAIL witnesses testified—without contradiction—that Galleri-specific efficiencies will arise from the reunion of Illumina and GRAIL. (PFF ¶ 1141.) For example:

- 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.)

- 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.)

- Mr. 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.)

- [redacted]

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

Similarly, the Court heard undisputed testimony that the Transaction will generate a number of non-Galleri-related R&D efficiencies. (PFF ¶ 1142.)

- Mr. 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." (PFF ¶ 1142.1.)

- Dr. Aravanis testified that: "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. . . . 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.)

- Mr. Flatley testified that the Illumina Board 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.) By contrast, Respondents' experts corroborated the undisputed fact testimony that R&D efficiencies will arise from the full reunion of Illumina and GRAIL. (PFF ¶ 1143.)

Courts have rejected merger challenges based on R&D efficiencies less developed than those here. *See, e.g.*, *Deutsche Telekom AG*, 439 F. Supp. 3d at 209; *AT&T I*, 310 F. Supp. 3d at 182–83, 191 n.17; *Great Lakes Chem. Corp.*, 528 F. Supp. at 94, 98. Moreover, there is a better case for R&D efficiencies here because Illumina has a history of creating synergies through vertical integration. (PFF ¶¶ 975–81.) It is undisputed that Illumina's acquisition of

Verinata not only led to more competition in NIPT, but also brought about the formation of GRAIL and thus ushered in the era of cancer screening in asymptomatic patients (as further described in Section III above). *See Deutsche Telekom AG*, 439 F. Supp. 3d at 216–217.

4. The Reunion of Illumina and GRAIL Has Already Reduced GRAIL's Royalty Burden, Which Will Benefit Consumers.

Complaint Counsel makes the astonishing claim that the elimination of GRAIL's royalty burden is neither verifiable nor merger-specific. (CC Post-Trial Br. at 158–59.) It is hard to imagine how any efficiency could be more verifiable or merger-specific. The Transaction has already reduced GRAIL's royalty burden. {[redacted]

Complaint Counsel says this efficiency is not verifiable because (1) "the royalty payments that GRAIL previously paid to Illumina were (at least partly) offset by the Contingent Value Rights ("CVRs") that Illumina issued" when the royalty was eliminated, and (2) Respondents' experts "did not analyze the tax treatment of CVRs compared to the royalty". (CC Post-Trial Br. at 158.) But this ignores that Dr. Carlton did in fact [redacted] (PFF

¶ 1150, Table 13; RRFF ¶¶ 5780–85.) Complaint Counsel provides no explanation for why a partial offset would render this efficiency unverifiable. Further, while [redacted] (PFF ¶¶ 1151.3–1151.5.)

Complaint Counsel did nothing to rebut the evidence that this reduction of royalties 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.) And Dr. Carlton testified [redacted] (PFF ¶ 1149.5.) Complaint Counsel did 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.)

Lastly, Complaint Counsel argues the reduction in royalties is not merger-specific because [redacted]

[redacted]

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

As stated above (*see* Section III), Complaint Counsel ignored EDM as part of its competitive-effects analysis. But even if EDM were merely an efficiency as to which Respondents bear the burden of proof, Respondents tendered considerable evidence that the EDM resulting from the Transaction will generate considerable consumer benefits, as shown in Respondents' Post-Trial Brief at pages 211–15 and Proposed Findings of Fact ¶¶ 1152–55. Complaint Counsel does not appear to dispute that the Transaction will eliminate double marginalization, but argues, incorrectly, that the resulting EDM cannot be reliably quantified, is not merger-specific, and will not be passed on to consumers.

In truth, Respondents reliably quantified a lower bound of the EDM savings from the Transaction, as illustrated in the below table:

[redacted]

[redacted] Complaint Counsel does not present any factual testimony or other evidence showing that there were not two margins prior to the Transaction or that the elimination of double marginalization will not be achieved. (PFF ¶ 1155.1.)

Complaint Counsel's claim that EDM is not merger-specific is likewise deficient. The government argues that EDM was not merger-specific because it supposedly could have been achieved through contract. But that argument is at odds with both Complaint Counsel's claim about contracts in dismissing the Open Offer and with the trial record. If it were feasible to achieve EDM through contract, Illumina and GRAIL would have done so pre-merger. (PFF ¶ 1177.3.) The fact that they did not do so (and Illumina has not done so with any other customer) undermines Complaint Counsel's speculation that EDM could be achieved by contract absent the Transaction. (PFF ¶ 1177.4.) If Complaint Counsel's argument about EDM were correct, then there would be no reason for any vertical merger, as all transaction benefits (including EDM) could be achieved by contract alone. (PFF ¶ 1155.4.) Complaint Counsel's argument 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).

Also meritless is Complaint Counsel's contention that the resulting EDM will not be passed to consumers. The cost savings and consumer surplus arising from EDM is a well-

accepted benefit of vertical integrations, as numerous courts have recognized. *See, e.g.*, *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 465 (7th Cir. 2020); *Alberta Gas*, 826 F.2d at 1247; *AT&T I*, 310 F. Supp. 3d at 197. Both Drs. Carlton and Scott Morton acknowledge that EDM is a benefit that can often arise from vertical mergers. (PFF ¶¶ 1152.1–52.2.) The evidence is clear that the savings from EDM will be passed onto consumers, and Dr. Carlton conservatively estimated the resulting consumer surplus for the period from 2022 to 2030 to be over $600 million. (PFF ¶ 1154.)

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

Fully reuniting Illumina and GRAIL will allow them to achieve significant supply chain and operational efficiencies, which are described in Respondents' Post-Trial Brief (pp. 215–220) and Proposed Findings of Fact (¶¶ 1156–67). The evidence of this is entirely one-sided, fully favoring Respondents. (PFF ¶ 1158.)

Complaint Counsel argues that "Respondents have not offered any reliable evidence sufficient to substantiate" any supply chain and operational efficiencies. However, Complaint Counsel's argument simply ignores the *uncontested* testimony of Messrs. deSouza, Flatley, and Bishop, and Drs. Aravanis and Febbo. (PFF ¶¶ 1162, 1165.) Complaint Counsel did not conduct any meaningful cross-examination of these witnesses on this issue. Nor did it present any fact witness or other evidence rebutting the testimony of Respondents' fact witnesses on these efficiencies, which are estimated at no less than $140 million over a 10-year period. (PFF ¶¶ 1157, 1166.)

Parroting their Pre-Trial Brief, Complaint Counsel argues that Dr. Carlton did not verify this efficiency or determine it to be merger-specific and that one of the numbers in one of the documents he cites cannot be verified. (CC Post-Trial Br. at 152.) Complaint Counsel once

against makes the mistake of assuming only economic experts can substantiate facts. While Complaint Counsel relies on Dr. Scott Morton's unsupported speculation well outside her area of expertise for its case, Respondents did not do the same. Instead, Respondents relied upon fact witnesses who have deep knowledge, based on experience, of the efficiencies to which they testified. Those fact witnesses include Dr. Aravanis (PFF ¶¶ 1157, 1160, 1162–65), Mr. deSouza (PFF ¶¶ 1157, 1162–65), Mr. Flatley (PFF ¶¶ 1157, 1159, 1162, 1165), and Mr. Bishop (PFF ¶¶ 1157, 1161–62, 1164–65). They explained in detail how the combined company can achieve operational and supply chain efficiencies, as described in detail in Respondents' proposed findings. Complaint Counsel identifies no basis to question that testimony. Nor does Complaint Counsel address the cases recognizing supply chain and operational efficiencies can be sufficient to justify mergers. *See, e.g., United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121, 147 (E.D.N.Y. 1997); *FTC v. Lab'y Corp. of Am.*, No. SACV 10-1873 AG MLGX, 2011 WL 3100372, at *10–11 (C.D. Cal. 2011); *FTC v. Butterworth*, 946 F. Supp. 1285, 1301 (W.D. Mich. 1996); *Deutsche Telekom AG*, 439 F. Supp. 3d at 209.

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

Finally, the Transaction will accelerate the international expansion of Galleri resulting in lives saved outside the U.S. and data that will improve Galleri and accelerate its clinical validation in the U.S. (PFF ¶ 1168.) This efficiency is described in Respondents' Post-Trial Brief at pages 220–24 and its Proposed Findings of Fact ¶¶ 1156, 1168–73.

Complaint Counsel contends this efficiency is not cognizable because Dr. Carlton did not quantify it (or estimate the associated costs) and that the benefits are allegedly "outside the United States". (CC Post-Trial Br. at 153.) Here again, Dr. Carlton's testimony is only a small fraction of the evidence demonstrating the Transaction's international expansion benefits.

Respondents properly relied on the testimony of experienced fact witnesses with deep knowledge of the challenges facing GRAIL's international adoption, the ways in which Illumina can accelerate it, and the ways in which that acceleration can benefit U.S. consumers. That testimony, from witnesses such as Messrs. deSouza, Flatley, Febbo, Qadan, Bishop, Frieden and Dr. Aravanis (PFF ¶¶ 1168–73), amply substantiates the international acceleration effects anticipated from the Transaction. As Mr. Friedin, GRAIL's CFO, testified, GRAIL lacks the presence and capabilities to expand internationally any time in the foreseeable future, so much so that its long range plan for the next 10 years ignores international testing. (PFF ¶ 1169.) On the other hand, Illumina has a strong international presence with platforms and/or tests registered in over 140 countries around the world and significant experience working with foreign regulators and payors. (PFF ¶ 1168.) All of these fact witnesses concluded, based on their real world experience, that Illumina will be able to utilize these vast competencies to accelerate Galleri's international adoption by many years.

Complaint Counsel did not present any fact witnesses or other evidence rebutting the testimony of Respondents' fact witnesses on this efficiency. (PFF ¶ 1168.1.) That Respondents did not quantify the benefits of international expansion is no impediment to the Court counting them. The trial testimony makes clear that the benefits are real and substantial: they bear directly on saving lives. Courts have recognized unquantified efficiencies under Section 7 of the Clayton Act. *See, e.g.*, *Tenet Health Care Corp.*, 186 F.3d at 1054–55 (courts should consider "evidence of enhanced efficiency in the context of the competitive effects of the merger" such as better medical care and more highly qualified physicians); (*see also* PFF ¶¶ 2190–90.7.) Complaint Counsel's quantitative criticism is yet another example of it applying a double standard, as Complaint Counsel makes no effort to quantify the alleged anti-competitive

effect of the Transaction and relies on far more speculative grounds for its qualitative predictions of the future than the evidence substantiating the efficiencies described herein.

Lastly, Complaint Counsel's contention that this particular efficiency is not cognizable because accelerated international expansion occurs "outside the United States" (CC Br. at 153) misunderstands the efficiency. While the Transaction will have large benefits outside the United States, the unrefuted evidence shows those benefits redound to U.S. consumers and are plainly cognizable. Specifically, international expansion will generate more data from Galleri being used in diverse populations across the globe sooner than it would absent the Transaction, and that data will allow GRAIL 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.) Dr. Aravanis testified, for example, that "[w]ith 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.) Other fact witnesses testified similarly. (*See, e.g.*, PFF ¶ 1395.) International acceleration will also help improve the Galleri test. (PFF ¶ 1172.) As Mr. deSouza testified:

> [B]y 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.) Tellingly, Complaint Counsel did not call any fact witness who undermined the testimony from Illumina and GRAIL witnesses. (PFF ¶ 1173.1.)[47]

D. Complaint Counsel's Experts Failed to Undermine Any Efficiency.

Unable to find a single fact witness to substantiate its contention that the Transaction will not generate any significant efficiencies, Complaint Counsel falls back on the unqualified and misguided opinions of three alleged experts: Amol Navathe, Dov Rothman, and Fiona Scott Morton. Those opinions do not undermine any of the efficiencies of the Transaction. None took full account of the actual trial testimony, which by itself renders their opinions unreliable, and all lacked the expertise to rebut the substantial evidence of efficiencies presented by Respondents. (*See* PX7139 (Navathe Trial Dep.); PFF ¶ 1144.5; (PX7138 (Scott Morton Trial Dep. At 19, [redacted]).))

Dr. Navathe. Dr. Navathe focuses on only two (of the many) efficiencies established by Respondents; as to the remainder, he is silent in the face of overwhelming proof. Dr. Navathe challenges Respondents' claim that the Transaction will save lives and accelerate FDA approval and market access for the Galleri test. But he is not qualified to express these opinions, as described at ¶¶ 2140–49 of our Proposed Findings of Fact and ¶ 97 of our Proposed Conclusions of Law. 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

[47] [redacted] Thus, there is no actual dispute that the Transaction will accelerate international adoption of Galleri. (PFF ¶ 1173.3.) Like the Court in *FTC v. Great Lakes Chem. Corp.*, this Court should rely on the Transaction's effects on international expansion as another reason to reject Complaint Counsel's challenge. 528 F. Supp. 84, 98 (N.D. Ill. 1981)

process that may be influenced by the novel nature of the Galleri test. (PFF ¶¶ 2140, 2142–43.)

[redacted] (PFF ¶¶ 2141, 2144–49.)

Dr. Navathe gets wrong even the basic facts on which he bases his opinions. That was demonstrated, without rebuttal, by the fact witnesses called by Respondents who have deep experience in NGS-based FDA and market access issues and who know the Galleri test and the challenges facing it far better than Dr. Navathe. For example, at trial, Dr. Ofman, GRAIL's Chief Medical Officer, was shown various factual assertions in Dr. Navathe's report asserting that there would be pressure on payers to extend coverage to Galleri even without Illumina's support or the real world evidence that Illumina will help GRAIL generate; and Dr. Ofman testified that those assertions were factually inaccurate, "not at all" consistent with GRAIL's experience with and feedback from payers. (RRFF ¶ 5469.) Similarly, Dr. Febbo, Illumina's Chief Medical Officer, was shown statements from Dr. Navathe's report about FDA issues and testified that the statements are "inaccurate" and reflect fundamental confusion about NGS-based FDA approvals. (RRFF ¶ 5163.)

As to Dr. Navathe's criticisms of Dr. Carlton's analysis of the value of lives saved, Dr. Navathe mostly quibbles with Dr. Carlton's valuation but misses the mark for the reasons stated in our opening brief. (Resps.' Post-Trial Brief at 266–68.) Dr. Navathe did not reach independent conclusions about whether the Transaction will accelerate approval of Galleri. (PFF ¶¶ 2170–76.) [redacted]

[redacted] (PFF ¶ 2185; (PX7139 (Navathe Trial Dep.) at 138.)) As Dr. Carlton testified, while one can quibble with whether the value of an older person's life is the same as a younger person's, for example, in all events, "no matter how you do this, it's billions of dollars that are benefitting U.S. society." (RRFF ¶ ¶ 5376–78.) For all these reasons and those explained in Respondents' opening submission, Dr. Navathe's testimony regarding acceleration deserves no weight and falls woefully short of countering the massive, proven benefits generated by Galleri's merger-specific 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").

Dr. Rothman. None of Dr. Rothman's opinions are any more supportive of Complaint Counsel's position. Like Dr. Navathe, Dr. Rothman expressed no opinion as to a number of the Transactions' efficiencies—four to be specific: that it reduced GRAIL's royalty burden and that it will save lives, eliminate double marginalization, and generate benefits through international expansion—leaving them unrefuted. He sought to cast doubt on whether the Transaction will accelerate market access, generate greater R&D innovation, and lead to supply chain and operation efficiencies. However, he is unqualified to render these opinions, as described at ¶¶ 2194.1-2194.7 of Respondents' Proposed Findings of Fact and ¶ 97 of Respondents' Proposed Conclusions of Law. 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.[48] (PFF ¶¶ 2194–94.7.)

Dr. Rothman's opinions consisted of his interpretation of what agency guidelines require to substantiate merger efficiencies and his critique as to whether Respondents' experts substantiated certain efficiencies by those standards as he understands them. 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. The Rothman Report does not cite a single economic treatise, study, or authority. Dr. Rothman instead relied 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, which the FTC has now repudiated; 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

[48] This is not the first time Dr. Rothman has offered opinions for which he lacks the requisite expertise, which has led other courts, including this Court, to find his economic analysis to be flawed. *See, e.g.*, *In re Altria*, No. 9393, at 91 (F.T.C. Feb. 15, 2022) ("Dr. Rothman's post-Transaction HHI calculations are not economically sound"); *Aya Healthcare Servs., Inc. v. AMN Healthcare, Inc.*, No. 17-cv-205, 2020 WL 3414662, at *4 (S.D. Cal. June 22, 2020) ("Dr. Rothman's study allegedly showing supracompetitive prices is seriously flawed," based on a "bare assertion," and devoid of any "economic analysis"); *Aya Healthcare Sers., Inc. v. AMN Healthcare, Inc.*, No. 17-cv-205, 2020 WL 2553181, at *18 (S.D. Cal. May 20, 2020) (his analysis is "unreliable under the *Daubert* standard and of marginal relevance"), *aff'd* 9 F.4th 1102 (9th Cir. 2021); *RAG-Stiftung*, 436 F. Supp. 3d at 319 & n.33 (Dr. Rothman's product and geographic markets are "ill-conceived" and his calculation of a GUPPI is "unreliable" and inapplicable to the industry at issue).

personal method for efficiency substantiation. His "I know it when I see it" test has no place in sound merger analysis.

Dr. Rothman also critiqued Respondents' expert evidence regarding medical breakthroughs and cost savings from combining supply chain and laboratory resources. But [redacted] (PFF ¶ 2203.) That by itself renders Dr. Rothman's opinions unworthy of weight, especially when they are contradicted by the sworn testimony of numerous fact witnesses whose testimony Dr. Rothman did not consider.

Dr. Scott Morton. Dr. Scott Morton purports to address most of the Transaction's efficiencies, except for its ability to accelerate international expansion. But she is not qualified to opine on the likelihood or magnitude of those benefits, as described at ¶¶ 2058–63, 2127 of Respondents' Proposed Findings of Fact and ¶ 135 of Respondents' Proposed Conclusions of Law. [redacted]

[redacted][49] [redacted]

Moreover, Dr. Scott Morton's conclusions defy record evidence, economic logic and widely acknowledged views regarding the treatment of efficiencies in a vertical transaction. *First*, Dr. Scott Morton calls into question whether certain of the efficiencies are cognizable. But she effectively ignored unrefuted witness testimony presented at trial that establishes how the Transaction will lead to numerous efficiencies. (PFF ¶¶ 2065, 2068, 2131). She demands a high level of specificity as to efficiencies while she speculates about the Transaction's supposed harms based on nothing but conjecture. *Second*, Dr. Scott Morton argues—contrary to witness testimony, long established precedent and economic logic—that the efficiencies are not merger-specific because she theorizes they could be achieved by contract. But the fact is that these efficiencies were not being realized by contract before the Transaction. Dr. Scott Morton has not refuted fact witness testimony that the merger will allow them to be realized. She did not study the barriers to achieving the Transaction's efficiencies through contract, whereas those with actual real world experience cogently explained why contractual solutions are no substitute for common ownership. (*E.g.*, PFF ¶ 1400 (Dr. Febbo explaining from experience that "[y]ou just don't see the layer of engagement that's necessary to get to the full realization of those benefits through partnerships").) For example, Dr. Scott Morton testified that she has [redacted]

[redacted]

[49] In addition, Dr. Scott Morton 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; did not consider any normal course business documents describing how any MCED test customer would respond to a price increase; and did not attempt to fill the information gaps using surveys or other means, including information about the preferences and behavior of clinicians, patients, and payors. (PFF ¶ 708.3; PFF ¶ 2067.2.)

[redacted] (PX7138 (Scott Morton Trial Dep. At 309).) [redacted] (PFF ¶ 2065; PX7138 (Scott Morton Trial Dep. At 334).) [redacted] PX7138 (Scott Morton Trial Dep. At 338–339).)

Finally, Dr. Scott Morton argues that any efficiencies are outweighed by the harm she alleges. But aside from arguing that the efficiencies are likely small, she has not engaged in the work necessary to quantify the efficiencies, nor the supposed harms. Stating the obvious, one cannot balance a scale when one does not have any idea how much weight is on each side of it. Dr. Scott Morton's failure to reliably balance efficiencies against supposed harms is reason enough to reject her bald proclamations of anticompetitive effects. Yet while she did not do the work, the record unequivocally shows that the alleged harms are distant, speculative and unsubstantiated, whereas the efficiencies are enormous, concrete, and substantiated by a wealth of evidence. The outcome of that balancing is clear—the Transaction is decidedly procompetitive, and should be allowed to stand.

E. Complaint Counsel Failed Fairly to Address, Let Alone Weigh, the Efficiencies.

Even if the Court were to dismiss or discount some the efficiencies that will be created by the reunion of Illumina and GRAIL, there can be no serious question that the Transaction will create a number of substantial efficiencies. Some, like reduced royalty burden, have already been realized as matter of indisputable fact, and no one has offered any evidence to

substantiate Complaint Counsel's speculation that combining GRAIL with the company that founded it will not accelerate the adoption of Galleri. How could it not?

In seeking to commercialize a 50-cancer early detection test at scale, GRAIL seeks to accomplish an unprecedent feat, requiring enormous global resources, as well as deep expertise in NGS technology to navigate the complexities that NGS creates for regulatory approvals, payor reimbursement and scaled laboratory operations. It is farcical to posit that Illumina—the world's foremost NGS expert, the creator of GRAIL, and a company with extensive global operations, unprecedented regulatory experience, relationships with key payors, and years of experience operating clinical NGS laboratories—is not optimally positioned to help GRAIL overcome these obstacles and navigate this unprecedented terrain.

Yet, in its haste to condemn the Transaction, Complaint Counsel made no effort to weigh efficiencies against alleged harm. While Respondents actually quantified a number of verified efficiencies, even some that should require no quantification (*e.g.*, the value of a life saved), Complaint Counsel neither quantified nor weighed any element of alleged harm or any efficiency. It simply declared that there can be no good rationale for the Transaction and therefore the Transaction should be unwound—evidence be damned. The Clayton Act requires more.

V. THE OPEN OFFER REMOVES ANY REALISTIC RISK OF HARM.

Even if the Transaction might otherwise have given Illumina an incentive and ability to foreclose GRAIL's putative rivals (which it would not), the Open Offer prevents any possible anticompetitive harms.

As explained in Respondents' Post-Trial Brief, Illumina made an Open Offer to its oncology customers, which a number of them have now accepted, addressing point-by-point the concerns Complaint Counsel has raised about the Transaction. The Open Offer extends

protections far beyond what is necessary to address Complaint Counsel's most speculative concerns, even though there is no credible evidence of a need for a "fix" of any kind. Yet, Complaint Counsel dismisses the Open Offer as a mere conduct remedy, which it says could never address the kinds of alleged harm at issue. That is not true.

A. The Open Offer Is Not a Litigation Tactic; It Is a Binding, Enforceable Contract Designed to Preserve a Life-Saving Transaction.

Complaint Counsel disparages Illumina's Open Offer as a mere "behavioral remedy" that was "made for litigation", a set of "surface-level assurances" that were "pushed on its customers" merely "to quell customer opposition to the Acquisition". (CC Post-Trial Br. at 161–66.) There is nothing behind Complaint Counsel's curtain of rhetoric. The Open Offer was *not* made for litigation. It was made to avoid litigation. Pushing a new brand of political antitrust theory, and seeking to fashion a new set of legal standards, rather than simply following the law and facts, Complaint Counsel seeks to block the Transaction even though it will save lives and billions of dollars. Because Illumina and GRAIL are firmly convinced (indeed, morally certain) that the Transaction is good for patients, good for consumers and good for competition, and because Illumina has no interest in or rational business bases to disadvantage any of its customers, Illumina made a comprehensive set of commitments to avoid any realistic prospect of the harms hypothesized by Complaint Counsel. Ironically, it is Complaint Counsel's response to the Open Offer that was made for litigation. Respondents tried repeatedly to engage with Complaint Counsel to resolve its purported concerns but it declined any meaningful engagement, even when the Court directed the parties to discuss the prospect of settlement. (PFF ¶ 1072; Resps.' Post-Trial Br. at 178–79.)

Nor is there any merit to Complaint Counsel's claim that the Open Offer is just a collection of hollow promises made without regard to customer needs. The Open Offer and the

resulting agreements set out a series of all-encompassing protections that prevent any foreclosure by Illumina. 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 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. Illumina developed customer protections that extend beyond those requested by individual customers because its primary goal was to guarantee that ***all*** of its oncology customers, including any potential GRAIL competitors, were secure in their supply relationships with Illumina after the Transaction. (PFF ¶ 1000.2.)

Any claim that Illumina "pushed" the Open Offer on any customer is misleading. To be sure, Illumina hoped that the customers that Complaint Counsel was courting as "complaining witnesses" would accept the Open Offer in the spirit in which it was intended and choose to support the Transaction from the outset. But no one was pressured into anything. Quite the opposite. Customers can continue to sign the Open Offer at any time until six years after the close of the Transaction. (PFF ¶ 995.) And if any customer who signs the Offer decides it no longer likes its terms, that customer can unilaterally terminate its supply agreement at any time and for any reason. (PFF ¶ 1001.) Thus, Complaint Counsel's suggestion that

Illumina tried to pressure customers into a supply agreement they'd be stuck with for the long-term is false. The Open Offer is pure upside for Illumina's oncology customers.[50]

Contrary to Complaint Counsel's suggestion, courts adjudicating merger challenges have found remedies like the Open Offer sufficient to address the alleged anticompetitive harms. *See, e.g., AT&T II*, 916 F.3d at 1042–43 (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); *Butterworth*, 946 F. Supp. at 1298 (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 Deutsche Telekom AG*, 439 F. Supp. 3d at 223, 225, 233 (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").

B. The Open Offer Eliminates Any Incentive Illumina Could Have Had to Favor GRAIL.

In addition to dismissing the Open Offer as a litigation tactic, Complaint Counsel argues that it "does not change Illumina's strong incentives to favor GRAIL." That too is incorrect. The Open Offer and analogous supply agreements not only ensure Illumina has no

[50] As noted below, [redacted]

incentive to harm GRAIL's rivals, but also they ensure it has no ability to do so. (CC Post-Trial Br. at 166–69.) They thus put another nail in the coffin of Complaint Counsel's case.

The crux of Complaint Counsel's case is that the Transaction will enable and incentivize Illumina to harm GRAIL's rivals. Complaint Counsel imagines that Illumina will discriminate against GRAIL's rivals by giving GRAIL better NGS products, better service and better prices. While the Transaction will not make Illumina any more likely to do any of that (as discussed above), the Open Offer legally obligates Illumina to refrain from disadvantaging GRAIL rivals in these ways. Were Illumina to try, it would not only lose NGS sales (to the disadvantaged GRAIL rivals) and inflict injury to its own reputation, but it would be in breach of its legal obligations and subject to whatever remedies a third-party arbitrator believed necessary to ensure GRAIL's rivals were treated fairly. Under these circumstances, no rational actor would harm its own customers, even if they were GRAIL's rivals.

Complaint Counsel argues that the Open Offer and the resulting supply agreements could not possibly provide all the protection that is required because there are too many contingencies, too much that cannot be foreseen. (CC Post-Trial Br. at 167.) But this argument gives far too little credit to the efficacy of contracts, which have played a vital role in ordering and controlling markets for centuries. It ignores the fact that the Open Offer expressly provides that it must be broadly construed to ensure no GRAIL rival is disfavored, requires Illumina to arbitrate (baseball style) any claim of discrimination, and empowers the arbitrator with extensive remedial powers. It ignores (with no hint of irony) Complaint Counsel's argument that contracts can be so effective that they will achieve all the efficiencies of the Transaction. And it disregards the fact that Illumina has repeatedly stated—and again here

reaffirms—that it consents to entry of the terms of the Open Offer in the form of an Order so that there can be no doubt as to its efficacy.[51]

Complaint Counsel misplaces reliance in DOJ's 2020 Merger Remedies Manual, *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36 (D.D.C. 2011), and a speech by former FTC Bureau of Competition Director Bruce Hoffman. (CC Post-Trial Br. at 166–67.) The DOJ Manual speaks in generalities that do not begin to take account of the extensive terms of the Open Offer. *H&R Block* concerns a narrow remedy that lacked the detail and breadth of the Open Offer and did not mandate baseball style arbitration with an arbitrator empowered to restore the status quo. 833 F. Supp. 2d at 82. And the quoted comment from Mr. Hoffman concerns "conduct remedies that only address the ability to engage in anticompetitive behavior", whereas the Open Offer addresses both ability and incentive. Thus, the authorities on which Complaint Counsel relies are inapposite. Neither the case law nor common sense indicates that contracts combined with court orders cannot be effective in limiting abilities and incentives. Yet, as supposed proof of an incentive to harm, Complaint Counsel argues that "Illumina has already violated its own commitments to favor GRAIL", pointing to the fact that the GRAIL board was dissolved and an Illumina executive, Bob Ragusa, replaced GRAIL's CEO when he stepped down. (CC Post-Trial Br. at 166.) Any suggestion that dissolving GRAIL's board was improper or a violation of a commitment to hold GRAIL separate is entirely baseless. The merger agreement (signed in September 2020) contemplated that GRAIL's board would dissolve

[51] While it is true that no contract can anticipate every contingency, this criticism misses the point. Parties can and do 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 II*, 916 F.3d at 1041 (affirming the district court's approval of merger given defendant's offer of arbitration and no-blackout agreements).

immediately upon closing. (RRFF ¶¶ 3040–41.) Dissolving GRAIL's board did not violate any commitment to run GRAIL as a separate entity or to only engage with GRAIL on an arm's-length basis. Complaint Counsel did not develop any evidence to show how the dissolution of GRAIL's board would enable Illumina to disadvantage putative GRAIL rivals, and it could not do so. The existence of GRAIL's board is entirely immaterial to the terms on which Illumina deals with its customers.[52] As further discussed in Section V.D. below, Complaint Counsel's arguments about the appointment of Mr. Ragusa are also misplaced.[53]

C. Complaint Counsel's Criticisms of the Access and Pricing Provisions Are Baseless.

Despite the breadth of its rhetoric about the supposed shortcomings of the Open Offer, Complaint Counsel focuses its critique on (1) Illumina's pricing guarantees and (2) Illumina's guarantee that a customer shall have "access to the same product services and support services for purchase as GRAIL". (CC Post-Trial Br. at 169–74.) Complaint Counsel's general criticism is that the provisions are "a poor substitute for the free market". (*Id*.) But free market principles do not support Complaint Counsel's case; its case is designed to alter, not honor, free market principles by killing a transaction that is the product of the free market. The record does not support the conclusion that customers would be better off without the Transaction and the resulting Open Offer.

[52] Complaint Counsel insinuates that Illumina sued Guardant in Delaware federal court for putting forward two witnesses to testify at trial on Complaint Counsel's behalf. (CC Post-Trial Br. at 169 n.112.) That suit is not in the record, as Complaint Counsel knows, but the Court may take judicial notice of the fact it has nothing to do with Illumina's current supply agreement with Guardant, and there is not a shred of evidence it was filed to retaliate against Guardant for making witnesses available to Complaint Counsel. Any such suggestion is baseless.

[53] For instance, Complaint Counsel alleges that Ragusa held $1 million in Illumina stock (CC Post-Trial Br. at 166, n.108), but acknowledges in its findings that that was only the case as of September 2020. (CCFF ¶ 3036.) Mr. Ragusa no longer holds Illumina stock. (RRFF ¶ 3036.)

Complaint Counsel faults Illumina's commitment that customers shall have "access to the same product services and support services for purchase" as GRAIL on the grounds that the Open Offer "does not define 'product services' or 'support services' or "explain how such services could be measured to ensure consistency in treatment between Grail and its rivals". (CC Post-Trial Br. at 170.) However, 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). And Complaint Counsel's argument 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 for different prices. (PFF ¶ 1004.3.) Thus, what counts as a service can be easily defined and tracked.

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 no reason an auditor or arbitrator could not determine whether Illumina was providing degraded services to a GRAIL rival, given the wealth of detailed information available on Illumina's normal course service and support levels. As [redacted]

[redacted][54] (PFF ¶ 989.18.)

Complaint Counsel also faults Illumina's access commitment on the ground that it "does not prevent Grail from having knowledge of Illumina's new technology before its competitors" or "prevent Illumina from making improvements to its technology specifically tailored to Grail". (CC Post-Trial Br. at 170–71.) But 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.) 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.) 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.)

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.) Nor can Illumina 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*

[54] Contrary to the unfounded claims of one Illumina customer, [redacted] (PFF ¶¶ 1092–1092.1.)

from when they are made available to GRAIL[55] (PFF ¶¶ 1005.1, 1007.1.) Far from disadvantaging GRAIL's putative rivals, the Open Offer requires Illumina to affirmatively support them in a way that it otherwise would not (particularly in the pre-merger world where it also had a substantial stake in GRAIL), 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.)

In addition to criticizing the access provisions, Complaint Counsel faults the Open Offer's pricing provisions. It acknowledges that "the Open Offer provides that Illumina will not increase prices, and that, by 2025, the volume-based price 'per gigabase of sequencing using the highest throughput Illumina instrument then available . . . will be at least 43% lower' than the current price per gigabase of sequencing using the NovaSeq instrument", *but* it claims that "absent the Acquisition, a free market would likely lead to even lower sequencing prices for MCED test developers". (CC Post-Trial Br. at 171-72.) That critique is not only pure speculation, but also it is contrary to Illumina's deal model (on the basis of which it spent billions of dollars to buy GRAIL) and contrary to Illumina's normal course projections. Complaint Counsel's own expert conceded that, without the merger sequencing, prices could decrease by *less than* 43% by 2025 (PFF ¶ 1023.13), whereas under the Open Offer, Illumina is contractually committed to a 43% price reduction, so if Illumina failed to meet its goal of

[55] 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.

reducing pricing by 43%, a customer could obtain relief from Illumina's breach. (PFF ¶ 1055.) The Open Offer's price reduction term represents a significant improvement for customers over the pre-Transaction status quo. (PFF ¶ 1023.12.)

Complaint Counsel also claims that "given that Grail is under Illumina's ownership, Grail's pricing is a fiction that can be easily manipulated by Illumina". (CC Post-Trial Br. at 172.) Complaint Counsel speculates that Illumina could "manufacture whatever price it want[ed] for Grail and peg the prices for other MCED developers to that artificial transfer price". (CC Post-Trial Br. at 172.) However, under the Open Offer, Illumina is prohibited from raising the prices of its current products and would face serious reputational and commercial risks by setting unreasonable prices for its materially improved products. (PFF ¶¶ 1015, 1021.1, 1022.2, 1023.) For Illumina's current products, Illumina is bound to either the prices customers paid before the Transaction or the prices under the Universal Pricing grid that "shall not increase" and must be lowered by 43% for the highest throughput product by 2025. (PFF ¶¶ 1015, 1021.1, 1023.) For materially improved products, the Open Offer requires prices to be "commercially reasonable" and allows Illumina's customers to challenge those prices in arbitration. (PFF ¶ 1022.2.) In such an arbitration, the arbitrator can lower Illumina's price for all customers to a price lower than what Illumina would have set had it not increased its prices. (PFF ¶ 1022.2.) And if Illumina increased prices for its non-MCED oncology customers, Illumina would only be harming those customers without the benefit of diverting their sales to GRAIL, thus needlessly discouraging development of non-MCED tests on its platform.

Finally, Complaint Counsel contends that "the Open Offer's pricing terms exclude the additional discretionary discounts that Illumina has commonly offered to customers prior to the Acquisition". (CC Post-Trial Br. at 173.) The Open Offer expressly addresses this

and resolves Complaint Counsel's purported concerns. Under the most-favored nations 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. (PFF ¶¶ 1020–20.3.)

D. Complaint Counsel's Criticism of the Firewall Is Misplaced.

Illumina responded to Complaint Counsel's claim that the Transaction might allow Illumina to misuse the competitively sensitive information of GRAIL's alleged rivals by committing to erect a firewall, which Complaint Counsel dismisses on the grounds that firewalls are hard to implement and Illumina would have an incentive to breach it to favor GRAIL. (CC Post-Trial Br. 164–76.) But firewalls are used successfully to protect information all the time and have been implemented by the FTC (and other agencies) in vertical transactions. (PFF ¶ 1041.1); *see also Broadcom Inc.*, FTC Dkt. No. C-4622 at 5–7 (Aug. 17, 2017); *Evanston Nw. Healthcare Corp.*, FTC Dkt. No. 9315 at 6 (Apr. 24, 2008); *Northrop Grumman Corp.*, FTC Dkt. No. C-4652, at 9–13 (June 5, 2018); *PepsiCo, Inc.*, FTC Dkt. No. C-4301, at 6–9 (Sept. 27, 2010); *Sycamore Partners II*, FTC Dkt. No. C-4667, at 7 (Jan. 25, 2019). That a person might have an incentive to breach a firewall does not render the firewall ineffectual; people also have incentives to adhere to firewalls, such as to avoid liability, keep customers happy and honor commitments. By Complaint Counsel's reasoning, Illumina had an incentive to harm GRAIL's

putative rivals for years before the Transaction (as it owned a meaningful chunk of GRAIL); yet even without a firewall, there is not any evidence Illumina shared the confidential information of any putative GRAIL rival with GRAIL.

Complaint Counsel also argues that a firewall "may not be practical", claiming that (1) the collaborations Illumina is planning with GRAIL "are in direct conflict with the supposed ability of the firewall to segregate access to confidential information"; and (2) "as people switch between Illumina and GRAIL" "a firewall will be hard to maintain". (CC Post-Trial Br. at 175.) None of the R&D and other collaborations Illumina has planned with GRAIL require any information from or relating to GRAIL's rivals, and not a single witness said otherwise, debunking Complaint Counsel's strawman argument. Nor is there any evidence to support Complaint Counsel's speculation that the possibility that a person might move between Illumina and GRAIL exposes confidential information to misuse. There is movement of individuals between and among companies in this industry entirely independent of the Transaction. Erecting an effective firewall, which Illumina does all the time (PFF 1041.3), is easier—by orders of magnitude—than what Illumina and GRAIL do every day in sequencing the human genome in their quest to revolutionize cancer care.

Finally, Complaint Counsel insinuates that Illumina has already violated confidentiality obligations to GRAIL rivals, pointing again to the dissolution of the GRAIL board, the appointment of Mr. Ragusa as GRAIL's CEO, and the fact that the Illumina account manager in charge of GRAIL's account reports to senior sales leaders who have access to confidential pricing information of GRAIL's putative rivals. (CC Post-Trial Br. at 176.) However, there is not a shred of evidence in the record that Illumina has violated any confidentiality obligation to any GRAIL rival or anyone else. Complaint Counsel fails even to

point to an allegation of a breach. Complaint Counsel cites no evidence to suggest that confidential pricing information would make its way up the reporting chain to senior sales leadership. With respect to Mr. Ragusa, Complaint Counsel offers no explanation for how Mr. Ragusa's [redacted] (CC Post-Trial Br. at 166 n.108) could possibly result in a breach of the firewall. Complaint Counsel cites no evidence that shows that [redacted] would permit Mr. Ragusa to use confidential information to advantage GRAIL. That Complaint Counsel continues to reach beyond the record for evidence to support its claims is telling.

E. Complaint Counsel's Criticisms of the Monitoring and Enforcement Provisions Lack Merit.

Complaint Counsel's attack on the monitoring and enforcement provisions of the Open Offer is similarly without merit. According to Complaint Counsel, "it would be difficult–if not impossible—to monitor Illumina's compliance unless violations of the contract could be detected and enforced quickly", which it suggests could not be done. (CC Post-Trial Br. at 177.) It is difficult to take Complaint Counsel's position seriously, given that it apparently sees no issue with monitoring provisions or compliance reporting when it comes to its own proposed divestiture order. (*See* CC Proposed Order §§ V.A, VIII.A.) That aside, Complaint Counsel offers no proof of this assertion, and it is belied by common sense. GRAIL's rivals have every incentive to discover any favoritism of GRAIL, as it would result in more favorable treatment for them. Illumina has agreed to a rigorous audit provision to ensure third-party review will unearth any non-compliance, and to give comfort to customers. 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); requires Illumina to engage an auditor to assess any good-faith

allegation of a breach (separate from the biannual audits) (PFF ¶ 1047.2); and mandates that Illumina provide customers with a written report of the audits and to ensure that customers are notified of any potential noncompliance within 10 days. (PFF ¶ 1048.)

Complaint Counsel dismisses the audit provision on the grounds that "it is unclear how an auditor could gauge accurately compliance with certain non-quantitative terms of the Open Offer". (CC Post-Trial Br. at 177.) However, the audit provision works in conjunction with a provision requiring binding arbitration in the event of a breach. Under this provision, the arbitrator 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.'" *AT&T I*, 310 F. Supp. 3d at 241 n.51.

[redacted]

[redacted]

In other words, the Proposed Consent Order would entirely remedy any concerns that Illumina could evade the terms of the Open Offer with a belt-and-suspenders approach of private enforcement by individual customers (through the audit and arbitration provisions) and public enforcement by the FTC. 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), and 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 Dkt. No. C-4622 (Aug. 17, 2017); *Evanston Nw. Healthcare Corp.*, FTC Dkt. No. 9315 (Apr. 24, 2008); *Northrop Grumman Corp.*, FTC Dkt. No. C-4652 (June 5, 2018); *PepsiCo, Inc.*, FTC Dkt. No. C-4301 (Sept. 27, 2010); *Sycamore Partners II*, FTC Dkt. No. C-4667 (Jan. 25, 2019). Complaint Counsel has not shown that 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.[56]

[56] 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"); *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).

Thus, Complaint Counsel is left to argue that arbitration "takes time, costs money, and put customers in a difficult antagonistic position with a supplier" and "ties up company resources". (CC Post-Trial Br. at 179.) However, there is no reason the kind of arbitration at issue could not proceed quickly, effectively and cost effectively, without significant disruption; it happens all the time. 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). Even before any binding arbitration, the Open Offer allows for an immediate dispute resolution process. (PFF ¶ 1054.3.)

F. Complaint Counsel Misplaces Reliance on Customer Criticisms.

Finally, Complaint Counsel urges the Court to disregard the Open Offer because it "fails to resolve customer concerns", pointing specifically to statements by Guardant, Freenome, Natera and FMI. (CC Post-Trial Br. at 179.) What Complaint Counsel neglects to say is that Illumina has more than 6,600 customers (*see* CCFF ¶ 3472), yet it only managed to find six of them to criticize this Transaction. Moreover, a number of the companies focused on oncology testing have expressed support for the Transaction.[57] Still others—including some customers Complaint Counsel called in its case—have shown interest in the Open Offer:

[57] [redacted] Invitae's CEO said in a sworn declaration that Invitae does not oppose the Transaction and believes Illumina would "continue to be a tremendous partner to Invitae". (RRFF ¶ 4506 (RX1100 (George (Invitae) Decl. ¶¶ 16–17).) Tempus Labs expressed its support for the Transaction in a letter to the Commission. (RRFF ¶ 4476 (PX9207 (Tempus) at 1).)

[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—until August 18, 2027. (PFF ¶ 995.)

The complaining customers (courted by Complaint Counsel) are not credible witnesses regarding the terms of the Open Offer, and their complaints should be weighed accordingly. Most are barely familiar with its terms. For example, the CEO of Exact, Mr. Kevin Conroy, 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), and [redacted] Many of the complaints about the Open Offer come not from customers with genuine concerns about its efficacy, but rather from customers seeking to use Complaint Counsel's investigation to pressure Illumina into accepting unreasonable demands. [redacted] The aim of Section 7 is to preserve competition, not advantage individual actors. *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 338 (1990) ("The antitrust laws were

enacted for 'the protection of *competition*, not *competitors*.'") (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)) (emphasis in original).

VI. COMPLAINT COUNSEL'S PROPOSED REMEDY IS UNJUSTIFIED AND SHOULD NOT BE ALLOWED.

Complaint Counsel's request that Illumina be required to divest GRAIL through a web of burdensome and punitive divestiture obligations should be rejected. That is true because among other things: (1) Complaint Counsel failed to meet its burden to show the Transaction is unlawful, obviating the need for any remedy; (2) even if a remedy were required, there are far less extreme remedies than the proposed divestiture; (3) the proposed divestiture would be needlessly punitive and impractical; (4) Complaint Counsel's effort to impose a remedy runs afoul of the U.S. Constitution; and (5) the requested relief should not be granted absent a further hearing.

A. No Remedy is Justified, Because There Is No Violation.

It is well-established that there is no basis for a remedy under the law where there is no violation. *See Bacon v. City of Richmond*, 475 F.3d 633, 638 (4th Cir. 2007) ("Remedies . . . are the consequence of some wrong. At its most basic, this principle limits the reach of judicial decrees to parties found liable for a legal violation"); *Breaux Bros. Farms v. Teche Sugar Co.*, 21 F.3d 83, 89 (5th Cir. 1994) ("[C]ompetition has not been injured and [thus] the antitrust laws offer them no relief."). Complaint Counsel effectively concedes this. (CC Post-Trial Br. at 180–81, 191) (noting that remedy is only appropriate where there has been a violation of Section 7). For all the reasons discussed above, and in Respondents' Post-Trial Brief and Proposed Findings of Fact and Conclusions of Law, Complaint Counsel cannot show that the Transaction violates Section 7 of the Clayton Act. Thus, the proposed divestiture bears

no "reasonable relation to [any] unlawful practices". *Jacob Siegel v. FTC*, 327 U.S. 608, 611–13 (1946).

B. Divestiture Would Be an Extreme and Unnecessary Remedy.

Even if a remedy were required here, there are less extreme remedies than the proposed divestiture, including an order embodying the terms of the Open Offer, which would be more than sufficient to address the alleged harm.

The purpose of an antitrust remedy is to "restore competition". *United States* v. *E. I. du Pont de Nemours & Co.* ("*du Pont III*"), 366 U.S. 316, 326 (1961). 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." *Deutsche Telekom AG*, 439 F. Supp. 3d at 230 n.23 (quoting *United States v. Microsoft Corp.*, 253 F.3d at 80). "[R]emedies should be proportional to the strength of the proof that [defendant's] illegal actions actually reduced competition . . . [W]here you have that relatively weak evidence of likely anticompetitive effect, then you need more evidence to support more [d]raconian remedies." Sherman Act Section 2 Joint Hr'g: Remedies Hr'g Tr. 60 (Mar. 29, 2007) (Remarks of William H. Page).

Here, a divestiture order would be disproportionate to any legitimate need as it would eliminate the life-saving benefits of the Transaction in order to address concerns that are unproven and, in any case, eliminated by the Open Offer. As explained in detail in Section V, 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. An order requiring Illumina to abide by the terms of the Open Offer would be a more appropriate

and effective remedy than divestiture. *See AT&T II*, 916 F.3d at 1041 (noting that the government has recognized that "especially in vertical mergers, . . . conduct remedies . . . can be a very useful tool to address the competitive problems while preserving competition and allowing efficiencies that may result from the transaction"); *Butterworth*, 946 F. Supp. at 1298 (holding that respondents successfully rebutted FTC's prima facie case with their proposed "Community Commitment" that served as an "additional assurance" that the merged entity could not engage in any anticompetitive behavior); *see also Jacob Siegel*, 327 U.S. at 611–13 (remedy must bear "reasonable relation to the unlawful practices found to exist.")

A divestiture order would not only be disproportionate to any genuine need to restore competition but would also harm "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. *See* U.S. Dep't of Justice, Merger Remedies Manual § III.B.2 ("[A] stand-alone conduct remedy may be appropriate to consider" when "requiring a structural divestiture might remedy the competitive concerns only at the cost of unnecessarily sacrificing significant efficiencies"); *In re Retail Credit Co.*, Dkt. No. 8920, 1978 WL 206499, at *89 ("In cases where several equally effective remedies are available short of a complete divestiture, a due regard should be given to the preservation of substantial efficiencies or important benefits to the consumer in the choice of an appropriate remedy."); *Evanston*, 2007 WL 2286195, at *4 (reversing divestiture order and entering an injunctive remedy where "divestiture may reduce or eliminate the resulting benefits for a material period of time"). As explained above, if the Transaction is allowed to proceed, it will result in significant efficiencies, including the saving of thousands of lives and billions of dollars. A divestiture would eliminate all of these efficiencies at great loss to the public.

C. The Proposed Divestiture Would Be Needlessly Punitive.

In addition to being unnecessary, the proposed divestiture order would be impermissibly punitive. Divestiture is an equitable remedy. *du Pont III*, 366 U.S. at 326. "Equitable relief in an antitrust case should not embody harsh measures when less severe ones will do". *New York v. Microsoft Corp.*, 224 F. Supp. 2d 76, 100 (D.D.C. 2002) (internal quotations omitted); *see also Jacob Siegel*, 327 U.S. at 612–13 (rejecting overbroad remedies when "less drastic means will accomplish the same result"); *Reynolds Metals Co. v. FTC*, 309 F.2d 223, 231 (D.C. Cir. 1962) (describing divestiture as an "extremely harsh remedy"). "Courts are not authorized in civil proceedings to punish . . . and relief must not be punitive." *du Pont III*, 366 U.S. at 326.

Respondents object to each and every one of the provisions in the proposed order for the reasons set out above. Some of the more objectionable provisions of the proposed order are illustrated in our mark-up of Complaint Counsel's proposed order, which appears in Appendix A, would be unduly punitive. By its proposed divestiture order, Complaint Counsel seeks to:

- implement a divestiture plan within 90 days of the Order (CC Proposed Order § II.A), even though this would compel a fire sale, force Illumina to incur a substantial loss on its investment, and give less time than has been allowed in previous FTC orders. *See In re Chi. Bridge & Iron Co.*, Dkt. No. 9300, 2004 WL 3142892, at *5, *9 (F.T.C. Dec. 21, 2004) (final order) (Section VI) (180 days, followed by a 12-month period for the divestiture trustee); *In re ProMedica Health Sys., Inc.*, Dkt. No. 9346, 2012 WL 2450574, at *6, *9 (F.T.C. June 25, 2012) (final order) (Section II) (same); *In re Bos. Sci. Corp.*, No. C-4164, 2006 WL 2330115, at *14-21 (F.T.C. July 21, 2006) (consent order) (30 months for one respondent and 18 months for the other to divest a minority interest, followed by up to three-year period for the divestiture trustee).

- extend Respondents' obligations regarding confidentiality and use of Respondents' information for five years after the Divestiture Date (CC Proposed Order § II.K), even though such an extension would only serve as an impractical and unworkable impediment to GRAIL's progress that is unwarranted by any evidence in this case.

- require Illumina to disgorge any profits earned naturally through the Transaction (CC Proposed Order § II.D), even though this requirement would not "restore competition", *Ford Motor Co.*, 405 U.S. at 573; would harm competition by depriving Illumina of profits it would have invested into other procompetitive pursuits; would discourage other companies from entering into procompetitive transactions; would deprive Respondents of due process as it is "outside the scope of the violations alleged in the Complaint and the scope of the notice of contemplated relief"; and is improper under Section 5(b) of the FTC Act and Section 11(b) of the Clayton Act, which limit Complaint Counsel to injunctive relief in "cease and desist" proceedings. *In re N.C. Bd. of Dental Exam'rs ("NCBDE")*, 2011 WL 11798452, at *97 (F.T.C. July 14, 2011); *see AMG Cap. Mgmt. LLC v. FTC*, 141 S.Ct. 1341 (2021); 15 U.S.C. §§ 45(b), 21(b); *compare* Notice ¶¶ 1-5, *with* Proposed Order § II.D.

- require Respondents to seek Commission approval before acquiring any interest in any business that, in the previous 12 months, engaged in, or had plans to engage in, the business of developing, marketing, or selling MCED tests (CC Proposed Order § VII), even though this provision is not necessary to restore competition; would harm competition by delaying acquisitions where the acquired business's plans regarding MCED tests are long-term, highly speculative, or have been abandoned; and would deprive Respondents of due process as it is outside the scope of the Notice and exceeds both FTC and court precedents. *Compare* Notice ¶ 3 (including a "prior notice" provision), *with* Proposed Order § VII (requiring prior approval); *see also In re Am. Brake Shoe Co.*, Dkt. No. 8622, 1970 WL 117382, at *1 (F.T.C. Nov. 27, 1970) (requiring prior approval for acquisitions of only corporations engaged in commerce and in the production of sintered metal friction material, not corporations with mere plans to engage in such commerce).

- mandate annual compliance reports from Respondents for nine years (CC Proposed Order § VIII.A.2), even though a nine-year period is far longer than necessary to effectuate the divestiture remedy that is supposedly "simple" and "relatively easy to administer"; is not warranted by any evidence in the case; would harm competition by disrupting business operations and wasting scarce business resources; and would be inconsistent with precedent. *See In re Otto Bock HealthCare N. Am. Inc.*, Dkt. No. 9378, ¶ VIII (Nov. 1, 2019) (defining the acquired assets to exclude any pending applications for or renewals of governmental authorizations); *In re Am. Sec. Partners VII*, No. 211-0131, 2022 WL 1261917, at *10 (F.T.C. Apr. 20, 2022) (same).

- burden Respondents under its Proposed Order for 10 years (CC Proposed Order § XI), even though this length of time is not warranted by any evidence in this case.

For these reasons, among others, the proposed order is impractical, unnecessarily punitive and it seeks to impose on Illumina obligations that go far beyond addressing the alleged anticompetitive effects.

D. Complaint Counsel's Proposed Remedy Would Violate the U.S. Constitution.

As explained in Respondents' Post-Trial Brief, Complaint Counsel's challenge to the Transaction, including its required remedy, should be rejected because it violates Article II and the Due Process and Equal Protection Clauses of the Fifth Amendment to the U.S. Constitution. Complaint Counsel's proposed remedy would violate the Constitution for the same reasons. It would violate Article II, because FTC ALJs are afforded dual-layer protection from presidential review. It would violate the Due Process Clause, because the FTC is acting simultaneously as prosecutor, judge and jury. And it would violate the Equal Protection Clause, because it would irrationally deprive Respondents of the structural and procedural protections they would possess in a challenge brought by the DOJ.

In addition, Complaint Counsel's proposed remedy would violate Article I of the Constitution. Article I of the Constitution provides that "[*a]ll* legislative Powers herein granted shall be vested in a Congress of the United States", U.S. Const. art. I, § 1 (emphasis added), "to ensure that the lines of accountability [between the people and their elected representatives] would be clear", *Gundy v. United States*, 139 S. Ct. 2116, 2134 (2019) (Gorsuch, J., dissenting). In keeping with founding principles of separations of powers, Congress can delegate that power to another entity only if it provides an "intelligible principle" by which that entity can exercise it. *Mistretta v. United States*, 488 U.S. 361, 372 (1989). Congress gave the FTC the power to bring antitrust actions within the agency instead of in an Article III court whenever the FTC in its unfettered discretion decides to do so. *See* 15 U.S.C. § 45(b). That was a delegation of legislative power, as "the mode of determining" which cases are assigned to administrative tribunals "is completely within congressional control". *Crowell v. Benson*, 285 U.S. 22, 50 (1932) (quoting *Ex parte Bakelite Corp.*, 279 U.S. 438, 451 (1929)). Congress gave the FTC no guidance, much less an intelligible principle, with which to exercise that power. *See* 15 U.S.C.

§§ 45(b), 53(b). Thus, Complaint Counsel's remedy is unconstitutional as a product of FTC's improperly delegated legislative power.

Complaint Counsel's proposed remedy would also violate the Seventh Amendment of the Constitution because it would deny Respondents the right to a jury trial on the issue of disgorgement. The Seventh Amendment protects the right to a civil jury trial, a "fundamental" component of our legal system that "remains one of our most vital barriers to governmental arbitrariness". *Reid v. Covert*, 354 U.S. 1, 9–10 (1957). It provides that "[i]n Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved". U.S. Const. amend. VII. The Supreme Court has interpreted the Seventh Amendment to apply whenever an action's claims arise "at common law", *see Tull v. United States*, 481 U.S. 412, 417 (1987), and do not center on "public rights", *see Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 54 (1989). Respondents are entitled to a jury trial on any request for disgorgement because the request for disgorgement was available at common law: it is akin to "actions in debt from early in our nation's history which were distinctly legal claims". *Tull*, 481 U.S. at 418–19; *see also Retractable Techs., Inc. v. Becton Dickinson & Co.*, 919 F.3d 869, 883–84 (5th Cir. 2019) (affirming district court's holding that disgorgement was not an equitable remedy against the larger backdrop of a "meritless antitrust claim"). The request for disgorgement does not center on "public rights" because reserving that question for a jury would not "dismantle the statutory scheme" or "impede swift resolution" of the statutory claims. *Granfinanciera*, 492 U.S. at 54. Thus, the Seventh Amendment precludes Complaint Counsel's request for disgorgement.

The U.S. Court of Appeals from the Fifth Circuit recently entered a decision regarding an SEC proceeding that confirms the unconstitutionality of both Complaint Counsel's

entire challenge and its proposed remedy. *Jarkesy v. SEC*, No. 20-61007, 2022 U.S. App. LEXIS 13460, *2–3 (5th Cir. 2022). In *Jarkesy*, petitioners raised five constitutional challenges to an SEC enforcement proceeding, all of which are relevant here. *See id.* at *5–6, *38 n.21. The Fifth Circuit concluded that the proceeding violated the Seventh Amendment, Article I, and Article II; it did not reach the due process and equal protection issues. *Id.* at *38 n.21. While *Jarkesy* concerned SEC ALJs, there is no constitutional difference between that case and this one, and if it is followed here (as it should be), Complaint Counsel's challenge to the Transaction and its requested remedy fall short for yet more reasons. The Fifth Circuit held that Congress unconstitutionally delegated legislative power to the SEC because the SEC, like the FTC, has unfettered discretion with respect to whether to bring a suit in an administrative or federal district court. *See id.* at *24–32. The court held that the statutory removal restrictions for SEC ALJs, the same restrictions that protect FTC ALJs from the Merits Systems Protection Board (MSPB) and the MSPB from the President, are unconstitutional because SEC ALJs, like FTC ALJs, perform executive functions as "inferior officers" of the United States. *See id.* at *32–37. And the court held the SEC's administrative adjudication of the petitioners' case violated their Seventh Amendment right to a jury trial, because, like the FTC in this case, the SEC made a claim arising at common law, seeking a civil penalty. *See id.* at *6–24. This Court should do the same thing here for the same reasons, as well as the reasons not reached by the Fifth Circuit (due process and equal protection). While these constitutional arguments come at the end of this brief (as they follow an issue raised at the end of Complaint Counsel's brief), they are by their nature of the upmost importance. Complaint Counsel's challenge to the Transaction is not only legally and factually misguided, but also it is constitutionally deficient.

E. The Court Should Hold a Hearing If It Intends to Grant Complaint Counsel Relief.

In the event that this Court were to decide a remedy of some form, Respondents respectfully request a further hearing. *See* 16 C.F.R. § 3.51(e)(1) (allowing the Court to reopen the proceeding to receive "further evidence for good cause shown" prior to entry of an Initial Decision). Absent such a hearing, Respondents should not be subject to *any* of the relief sought by Complaint Counsel.

CONCLUSION

For all the foregoing reasons, Complaint Counsel's challenge to the full reunification of Illumina and GRAIL should be rejected, and they should be permitted get about the business of revolutionizing cancer care.

Dated: May 25, 2022

Respectfully submitted,

/s David R. Marriott

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ATTACHMENT A

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CERTIFICATE OF SERVICE

I hereby certify that on June 2, 2022, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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I also certify that I caused the foregoing document to be served via email to:

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