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

MOTION OF NON-PARTY ANTITRUST, PATENT, AND LAW-AND-ECONOMICS SCHOLARS AND JURISTS FOR LEAVE TO FILE BRIEF AS AMICI CURIAE SUPPORTING RESPONDENTS

Professors Richard Epstein, Adam Mossoff, and other signatories listed in the addendum to this motion (hereinafter "Amici") respectfully ask leave to file the accompanying brief as amici curiae. Amici are scholars and other jurists specializing in antitrust, patent law, and law and economics. While having no personal stake in the outcome of the proceeding, they have an interest in promoting antitrust enforcement that is informed by modern economics and that protects the public's access to new technologies. Although Amici are not privy to the confidential evidence in this case, they hope to serve the Court by elaborating the complex legal and economic principles at the case's center.

The Commission's rules specify that "[d]uring the time a proceeding is before an Administrative Law Judge, all other motions [besides those expressly designated for Commission decision or referral] shall be addressed to and decided by the Administrative Law

Judge, if within his or her authority."[1] 16 C.F.R. § 3.22(a). The Commission's rules do not expressly contemplate an amicus brief filed at this stage, but nor do they prohibit it. Many federal district courts have no express rules allowing amici to file briefs, yet motions for leave to file such briefs are within a district court's inherent authority to consider and are routinely granted.[2] Indeed, the FTC regularly files amicus briefs in district court.[3] Because the instant motion does not "fail[] to comply with the Commission's rules," *id*. § 4.2(g), and because an Administrative Law Judge has authority to decide whether an amicus brief would aid an Initial Decision, the motion should be ruled on by the Court.

Amicus briefs in FTC adjudications are appropriate when they will serve the public interest. *See, e.g.*, *Evanston Nw. Healthcare Corp.*, 2006 WL 367352 *2 (Jan. 24, 2006). The ultimate decision in this case will have repercussions beyond the market for multi-cancer early detection tests, potentially affecting the ability of companies in many different sectors to commercialize new and existing technologies more efficiently. For this reason, the public would benefit from the Court's consideration of Amici's views, which are informed by decades of collective research and experience in relevant fields. This benefit would be enhanced by considering Amici's brief at the post-hearing stage, rather than waiting until the case is before the full Commission on appeal. Granting the motion at this stage would allow the Court to consider Amici's insights and any counterarguments of Complaint Counsel, and the Commission

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[1] All other motions outside of the Judge's authority to decide shall be certified—by the Judge—to the Commission. 16 C.F.R. § 3.22(a).

[2] *See, e.g.*, *NGV Gaming, Ltd. v. Upstream Point Molate, LLC*, 355 F. Supp. 2d 1061, 1067 (N.D. Cal. 2005) ("District courts frequently welcome amicus briefs from non-parties concerning legal issues that have potential ramifications beyond the parties directly involved . . . .").

[3] *See, e.g.*, https://www.ftc.gov/policy/advocacy/amicus-briefs?combine=&field_federal_court_tid=85&date_filter%5Bmin%5D%5Bdate%5D=&date_filter%5Bmax%5D%5Bdate%5D=.

would ultimately benefit if the Initial Decision addresses these issues. The Commission's rules do not prohibit such consideration, and Amici therefore ask that the instant motion be considered and granted.

Dated: October 22, 2021

Respectfully submitted,

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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

[PROPOSED] ORDER GRANTING MOTION OF NON-PARTY ANTITRUST, PATENT, AND LAW-AND-ECONOMICS SCHOLARS AND JURISTS FOR LEAVE TO FILE BRIEF AS AMICI CURIAE SUPPORTING RESPONDENTS

IT IS ORDERED THAT the motion of Antitrust, Patent, and Law-and-Economics Scholars and Jurists for leave to file a brief as amici curiae supporting Respondents be, and hereby is, **GRANTED**.

ORDERED: ______________________________

D. Michael Chappell
Chief Administrative Law Judge

Date:

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

In the Matter of	
Illumina, Inc., a corporation	**PUBLIC** Docket No. 9401
and	
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BRIEF OF AMICI CURIAE ANTITRUST, PATENT, AND LAW-AND-ECONOMICS SCHOLARS

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INTEREST OF AMICI CURIAE

Amici curiae are twenty-three law professors, economists, and former government officials with expertise in antitrust, patent law, and law and economics. They have an interest in promoting the coherence and development of legal doctrines consonant with sound economic principles, and in ensuring that consumers and the general public benefit from new inventions and technologies. They have no stake in any party or in the outcome of this proceeding. Although amici are not privy to the confidential evidence in this case, amici hope to serve the Commission by emphasizing the legal and economic principles that frame this dispute. The amici and their affiliations are listed in the Appendix.[1]

INTRODUCTION

This case presents a complex set of transactions whereby Illumina, Inc. ("Illumina") created GRAIL, Inc. ("GRAIL"), spun it off while retaining a minority interest, and now has reacquired it. Complaint Counsel seeks to unwind this recent reacquisition. This enforcement effort is not based on a sound understanding of this transaction, which reflects similar, longstanding practices of the past several decades that have promoted the efficient development and commercialization of new innovations in health care, to the ultimate benefit of patients. In particular, Complaint Counsel does not appear to have analyzed the efficiency justifications of this transaction and weighed them properly against the putative harms. An imprudent attempt to unwind the transaction, based on an inapt economic theory, could easily deter innovative

[1] No party's counsel authored the brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting the brief; and no person—other than the amici curiae or their counsel—contributed money that was intended to fund preparing or submitting the brief.

companies like Illumina from creating early-stage spinoffs or acquiring startups similar to GRAIL, solely to escape the punitive antitrust sanctions.

Absent any reliable evidence of probable anticompetitive effect, Complaint Counsel's approach is premised on a false and dangerous presumption: that vertical mergers are inherently anticompetitive if the merged firm may possibly have the ability, but not necessarily the economic incentive, to disadvantage potential future rivals. *See* Complaint ¶ 11 ("As the only supplier of a critical input, Illumina already possesses the ability to foreclose or disadvantage GRAIL's MCED rivals."); Complaint Counsel Pre-Trial Br. ("CC Br.") at 65-92. This overbroad presumption flies in the face of both economic theory and a well-established body of empirical evidence that has developed in recent decades, and is particularly inappropriate in the complicated institutional landscape of biopharmaceutical markets. It is also out of step with the approach taken by courts, which do not enjoin vertical mergers without compelling, concrete evidence that a vertical merger is likely to harm competition to a substantial degree. *See, e.g.*, *United States v. AT&T, Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019). In sum, scholars and courts have recognized that the efficiency gains from vertical mergers make it impossible to treat this class of transactions as presumptively anticompetitive. Yet, Complaint Counsel effectively urges such a presumption in this case.

The conclusion that there is market foreclosure resulting from the vertical merger is particularly inappropriate here because Complaint Counsel applies it to a rapidly evolving innovation market still in its nascent stages. It appears from the public pre-trial briefing that Complaint Counsel makes errors at every turn. Complaint Counsel postulates a future Multi-Cancer Early Detection Test ("MCED") product market before rival products are even created, and thus before product substitutability can be shown. Complaint Counsel cannot establish *any*, much less a decisive, foreclosure incentive if it cannot make this showing.

Complaint Counsel's arguments regarding other barriers to entry are threadbare. The Commission should be skeptical of the dubious claim that, notwithstanding the expiration of Illumina's patents and the large profit opportunity presented by serving the MCED market, the technology is too complex for a viable next-generation sequencing ("NGS") competitor to emerge. Breakthrough advances in medical technology by single firms are common in the health-care industry, particularly when the long-term profit opportunity is high. Complaint Counsel's switching costs argument is largely beside the point (as well as based on self-serving testimony of potential MCED rivals); it simply does not analyze the relevant question of the comparative switching costs of moving to Illumina's next generation of NGS products vis-à-vis competitive offerings.

Aside from those shortcomings, Complaint Counsel fails to conduct the necessary theoretical and econometric analyses to demonstrate that foreclosure would be in the merged Illumina-GRAIL entity's interest. Complaint Counsel asserts that the merged Illumina-GRAIL firm will profit by foreclosing GRAIL's future competitors. But the Commission should consider the equally plausible alternative that Illumina-GRAIL might be better off selling its next-generation NGS products to GRAIL's competitors. Even if the Commission were to find any merit in Complaint Counsel's showing of anticompetitive harms, it must also take into account the efficiencies achieved by the merger in terms of enabling innovation, lowering prices, improving quality, or speeding up commercialization. These efficiencies are regular occurrences in the life sciences and technology industries when larger firms acquire startups—indeed, they are usually the core motivation behind the mergers. Illumina's acquisition of GRAIL mirrors this efficient commercial practice.

Vertical mergers should never be subject to an antitrust regime of strong presumptions that create de facto per se rules of illegality, which is what Complaint Counsel effectively employs in this case. Instead, courts have consistently required a rigorous economic analysis of market conditions and other economic factors. The Commission should follow this same approach in this case.

The potential costs of preventing such a merger, and the negative effects it would have on similar mergers, are particularly high, as experience in emerging-technology markets amply demonstrates. Given the ultimate benefits to consumers, the Commission should tread warily before upsetting this model, absent compelling evidence that a particular acquisition would harm consumers.

ARGUMENT

I. Vertical Mergers Are Not Presumptively Anti-Competitive

A. Vertical Mergers Differ Fundamentally from Horizontal Mergers

Vertical mergers differ from horizontal mergers in their nature and economic effects. Horizontal mergers pose a substantial inherent risk of reducing competition absent entry or any offsetting efficiency advantages. Higher market concentrations, as measured by the Herfindahl-Hirschman Index, have the potential to weaken competition through higher prices or lower quality for consumers. *See* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 901a (5th ed. 2020). Antitrust law, therefore, justifiably scrutinizes most horizontal mergers to see if their efficiency gains outweigh their restrictive effects.

As a leading antitrust treatise has noted, vertical mergers do not carry these inherent risks: "In contrast to horizontal mergers, which have certain inherent anticompetitive consequences, vertical mergers generally have no inherent anticompetitive characteristics." 4 Earl W. Kintner et al., *Federal Antitrust Law* § 35.3 (2020); *see also* Oliver E. Williamson, *Economics As an Antitrust*

Defense: The Welfare Tradeoffs, 58 Am. Econ. Rev. 18 (1968) (advancing a basic model to weigh the efficiency gains versus the restrictive effects of these mergers). The key difference between vertical and horizontal mergers is that the latter eliminate substitute firms, whereas vertical mergers bring complementary firms together, thereby reducing the coordination problems in bringing new products to market. *See* ABA Section of Antitrust Law, *Mergers and Acquisitions* 439 (3d ed. 2008).

To be sure, at one time many scholars worried that vertical mergers would harm competition by raising barriers to entry. If a manufacturer were allowed to buy one of its retailers, for example, then competing manufacturers would lose access to that retailer, leading to the dubious inference that this change in supply practices actually harmed competition. *See* Ralitza A. Grigorova-Minchev & Thomas W. Hazlett, *Policy-Induced Competition: The Case of Cable TV Set-Top Boxes*, 12 Minn. J. L. Sci. & Tech. 279, 284 (2011) (first describing and then refuting this historical concern). Commentators and legal authorities also used to express concerns that a manufacturer with a monopoly on a particular good might stop selling that good to competitive retailers. Judge Richard Posner long ago explained why this concern, which evidently animates Complaint Counsel's theory in this case, does not hold up:

> Suppose, for example, that kryptonite is an indispensable input in the manufacture of widgets. *A* owns all the kryptonite in the universe and also manufactures widgets. He could, of course, refuse to sell kryptonite to *B*, a prospective entrant into widget production. The cost to *A* of this refusal is the price *B* would have been willing to pay. Stated differently, by his control of kryptonite *A* can extract any monopoly rents available in the widget industry without denying a place in widget manufacture to others [sic] firms. If there is a proper antitrust objection, it is to the kryptonite monopoly rather than to vertical integration.

Richard A. Posner, *The Chicago School of Antitrust Analysis*, 127 U. Pa. L. Rev. 925, 936-37 (1979). In other words, since some monopoly rent is assured whether or not the monopolist licenses its product to others, if licensing to others is more efficient, then firms will engage in that practice

without any antitrust compulsion. Here, Complaint Counsel has not established that Illumina has monopoly power; but even if it did, that would not be a basis for enjoining the GRAIL merger.

Today, Judge Posner's conclusion—that a company cannot double its monopoly profits just by vertically merging with another firm—is well accepted in both economic theory and in law. The leading antitrust treatise notes that,

> [a]s a general proposition, the profit-maximizing price is determined by the willingness to pay of end-use consumers, and a firm monopolizing a single stage of the production process can obtain all the monopoly profits that are available for that product. Adding another stage cannot simply "leverage" additional profits or lead to higher prices.

Areeda & Hovenkamp, *supra*, ¶ 1003a (footnote omitted). Indeed, even if Illumina were the sole supplier of NGS platforms, as Complaint Counsel asserts, it could not increase its profits by converting its downstream acquisition, GRAIL, into a monopolist. The lost opportunities are often worth more than the exclusive control over the downstream market.

Complaint Counsel emphasizes that the upstream patents owned by Illumina necessarily would grant Illumina downstream market power. But like past mistaken assumptions about the market effects of vertical mergers, any presumption that patents confer such market power has also been rightly discarded by scholars and courts. *See, e.g.*, *Illinois Tool Works Inc. v. Independent Ink, Inc.*, 547 U.S. 28, 44-45 (2006) (abrogating the "patent equals market power" presumption in favor of rule-of-reason analysis).

B. Most Vertical Mergers Are Pro-Competitive

Vertical mergers usually benefit consumers by achieving efficiencies. Indeed, Areeda and Hovenkamp take the view "that most vertical mergers are procompetitive," since "most instances of vertical integration, even by a monopolist, are competitive." *Antitrust Law* at subchapter 10A-1 introduction. In this context, efficiencies outweigh the restrictive effects because vertical mergers are generally motivated by legitimate business considerations—such as reducing costs—that

increase, rather than stifle, competition. *See* 4 Kintner et al., *supra*, § 35.6 ("The same factors that make a vertical merger advantageous from a business viewpoint also may make the merger procompetitive."); ABA Section of Antitrust Law, *supra*, at 440 (noting economists' view that, because vertical mergers involve complements rather than substitutes, such mergers are "more likely to be motivated by a desire to reduce, rather than increase, the prices of the parties' products").

These efficiencies include the reduction of various transaction costs, including various breakdown and hold-up problems that can plague distribution chains when separate firms engage in sequential activities, each of which is necessary to produce the finished product. Vertical mergers can also facilitate intra-firm coordination that improves products or service. *See* 2 Julian von Kalinowski et al., *Antitrust Laws and Trade Regulation* §§ 30.03-.04 (2d ed. 2021). An acquired firm may also be made a stronger competitor through infusions of capital, new management, or reduced overhead costs, all of which can lead to more competitive pricing or expanded production. *See* 4 Kintner et al., *supra*, § 35.6. The downstream firm can also reduce uncertainty in the demand for the upstream supplier's products, which can further reduce costs and consumer prices. *See* 2 Kalinowski et al., *supra*, § 30.03.

Notably, vertical mergers eliminate the double-marginalization problem, since the upstream firm would no longer need to charge a markup to the downstream firm. *See* 2 Kalinowski et al., *supra*, § 30.04. The downstream firm is thus able to acquire the upstream firm's products at marginal cost, allowing the downstream firm to increase its output and lower its prices. *See* Areeda & Hovenkamp, *supra*, ¶ 1022. This benefit is likely to materialize whenever one or both firms has some market power (as a result of patent protections, for example). "[T]he only occasions when no gains can be anticipated from the elimination of double marginalization is when at least one of

the two merger levels is very nearly perfectly competitive." *Id*. Complaint Counsel does not allege that to be the case here.

C. A Presumption Against Vertical Mergers Is Unwarranted

Economists and antitrust scholars have cautioned against presuming the illegality of vertical mergers, given their likely benefits and reduced risks. In 2008, Daniel P. O'Brien, then an economic-policy advisor at the Commission, endorsed this conclusion after a lengthy review of economic theory and the empirical evidence:

> The theoretical literature . . . implies a largely benign view of the effects of vertical restraints/integration, consistent with what I have called the fundamental theorem of antitrust ("combining substitutes is bad and combining complements is good, unless demonstrated otherwise"). The empirical literature over the last 25 years largely supports this theorem, at least with respect to the statement about complements. . . . Given the state of the literature, a scientific approach to policy regarding vertical restraints/integration would challenge these practices under two circumstances: (1) direct evidence of likely harm in a specific case, e.g., a natural experiment that suggests that the practice will be harmful; or (2) a belief that the loss associated with committing type II error (failing to condemn an anticompetitive practice) would be very large relative to the cost of committing type I error (wrongly condemning a pro-competitive practice). There is no empirical basis for such a belief. Thus, my own view, based largely on a Hippocratic philosophy of non-intervention absent good evidence that intervention will have benefits, is that direct evidence of likely harm should be required before condemning a vertical practice. If there were a Hippocratic Oath among antitrust practitioners, this is where a scientific approach would lead.

Daniel P. O'Brien, *The Antitrust Treatment of Vertical Restraints: Beyond the Possibility Theorems*, *in* The Pros and Cons of Vertical Restraints 40, 81-82 (2008).

The courts have reached similar conclusions, requiring case-specific evidence of likely and substantial harms to competition before interfering with a vertical merger or other vertical restraint. Three recent cases warrant discussion.

In *United States v. AT&T, Inc.*, the government challenged the merger of AT&T's satellite- and cable-television divisions with Time Warner's television networks. 916 F.3d 1029, 1035 (D.C. Cir. 2019). The government alleged that, "by combining Time Warner's programming and

DirecTV's distribution, the merger would give Time Warner increased bargaining leverage in negotiations with rival distributors, leading to higher, supracompetitive prices for millions of consumers." *Id*. (internal quotation marks and citation omitted). The D.C. Circuit affirmed the district court's decision in favor of AT&T, noting that the district court properly discounted the government's theories of harm because they were based on "speculative, future predictions [that] lacked adequate factual support." *Id*. at 1045. At the same time, the district court credited AT&T's evidence, which included "real-world data from prior instances of vertical integration." *Id*. at 1037. The district court also properly "credited the efficacy of Turner Broadcasting's 'irrevocable' offer of arbitration agreements," which reduced possible anticompetitive effects during a seven-year period following the merger.[2] *Id*. at 1041. The court of appeals emphasized the government's burden to establish that harm to competition is both substantial and likely—not just possible—in light of the case-specific facts. *See id*. at 1032 ("[T]he government must show that the proposed merger is likely to *substantially* lessen competition . . . .").

In *Ohio v. American Express*, the Supreme Court considered whether provisions in a credit-card company's merchant contracts—which prohibited merchants from steering customers toward competing credit cards—were anticompetitive under section 1 of the Sherman Act. 138 S. Ct. 2274, 2279-80 (2018). The Court held that the plaintiffs had not met their burden. *Id*. at 2287. The plaintiffs were required to adduce evidence comparing the actual price (resulting from the alleged

[2] Illumina has similarly made an enforceable Open Offer to its customers, guaranteeing, among other things, the same level of service that GRAIL receives, and that any disputes over supply terms can be resolved through arbitration. *See* Respondents' Pretrial Br. at 80-82. Complaint Counsel characterizes the Open Offer as a remedy, CC Br. at 5, but that is not how the D.C. Circuit treated AT&T's similar offers. Rather, the court treated the offers as going directly to the government's *prima facie* case, asking whether, in light of the offers, the government had established that the merger was likely to substantially harm competition. *AT&T*, 916 F.3d at 1038.

restraint) against the counterfactual price (what a competitive price would otherwise have been): "This Court will 'not infer competitive injury from price and output data absent some evidence that tends to prove that output was restricted or prices were above a competitive level.'" *Id*. at 2288 (quoting *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 237 (1993)).

And in *FTC v. Qualcomm Inc.*, the issue was whether Qualcomm violated section 1 of the Sherman Act by requiring downstream device manufacturers to license Qualcomm's patents in order to procure crucial modem chips. 969 F.3d 974, 986-87 (9th Cir. 2020). The district court had enjoined the practice, in part on the ground that Qualcomm had an antitrust duty to license its patents to its competitors. *See FTC v. Qualcomm Inc.,* 411 F. Supp. 3d 658, 758-760 (N.D. Cal. 2019). The district court ordered Qualcomm to do so on "fair, reasonable, and non-discriminatory" royalty and other terms that would be subject to judicial or arbitral determination upon challenge by customers (including its rivals). *Id.* at 821.

The Ninth Circuit reversed, finding that the Commission had failed to establish that Qualcomm's policy was anticompetitive. *See Qualcomm*, 969 F.3d at 1005. The court adopted a rule-of-reason approach, which requires case-specific analysis of a restraint's "'actual effect' on competition." *Id*. at 989 (citation omitted). The court explained that a bare allegation of reduced choice or increased price is not enough to make out an antitrust claim. *Id*. at 990. And "novel business practices—*especially* in technology markets—should not be 'conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use.'" *Id*. at 990-91 (citation omitted).

Moreover, compared to *American Express* and *Qualcomm*, which addressed post-hoc challenges under section 1 of the Sherman Act, the test for finding a vertical merger illegal is "much more stringent," since it involves "the difficult task of assessing probabilities in the

commercial marketplace." *AT&T*, 916 F.3d at 1032 (citation omitted). Complaint Counsel's request to unwind the transaction cannot be reconciled with these precedents.

II. Complaint Counsel Faces a High Hurdle To Prove Anticompetitive Effects in Speculative Future Markets

The courts' recent treatment of vertical mergers and vertical restraints makes three things clear. *First*, Complaint Counsel must prove—based on empirically evidenced probabilities, not just speculative possibilities—that the Illumina-GRAIL merger would substantially lessen competition. *See AT&T*, 916 F.3d at 1038 (holding that speculative evidence, evidence not based in fact, and evidence premised on unproven assumptions cannot make out a violation of Section 7 of the Clayton Act).

Second, and following directly from the first point, the likelihood of anticompetitive behavior *must* be supported by both sound economic theory and empirical evidence. *See United States v. AT & T Inc.*, 310 F. Supp. 3d 161, 229 (D.D.C. 2018) ("[T]he lack of empirical support is reason enough to disregard the slide deck's analysis of the set top box data . . . ."), *aff'd sub nom. United States v. AT&T, Inc.*, 916 F.3d 1029 (D.C. Cir. 2019). Government claims not backed by hard evidence should be viewed skeptically, keeping in mind the natural tendency to view novel business practices in new markets as anticompetitive. *See Qualcomm*, 969 F.3d at 986.

Third, a complete analysis must account for the procompetitive efficiencies likely to be achieved by the merger. *See AT & T*, 310 F. Supp. 3d at 198 (noting the "important principle" that "to understand whether the proposed merger will harm consumers, . . . it is necessary to 'balance' whether the Government's asserted harms outweigh the merger's conceded consumer benefits") (citations omitted). By acknowledging the fact-specific costs and benefits of vertical mergers, the courts refuse to embrace a presumption of illegality. Complaint Counsel should be held to a similarly rigorous burden—to prove that the proposed merger is *likely* (not just possible) to cause

substantial (not theoretical) harm to consumers by injuring competition in the market. When there is evidence of significant efficiencies to be realized from a vertical merger—as is the case here, *see* Respondents' Pretrial Brief at 84-111—then Complaint Counsel's burden is that much higher.

This is true especially for markets that are still mostly pre-commercial, where the full effects of a merger on other market participants are particularly difficult to predict. Unwinding the merger may even have the negative effect of delaying the downstream product market from developing to commercial viability. The current case law imposes sensible evidentiary hurdles that Complaint Counsel should be required to overcome. *Cf. United States v. Baker Hughes Inc.*, 908 F.2d 981, 991 (D.C. Cir. 1990) ("By focusing on the future, section 7 gives a court the uncertain task of assessing probabilities. In this setting, allocation of the burdens of proof assumes particular importance. . . . If the burden of production imposed on a defendant is unduly onerous, the distinction between that burden and the [government's] ultimate burden of persuasion—always an elusive distinction in practice—disintegrates completely.").

A. Essential Considerations

In considering Complaint Counsel's request, the Commission should be mindful of four specific considerations: (1) Illumina's comparative incentives, (2) the likely responses of Illumina's upstream competitors, (3) the contractual landscape, and (4) the risks that a premature and overbroad injunction would pose to consumers.

1. Comparative Incentives

It should not be presumed that any supplier who has merged with a downstream customer has an inflexible economic incentive to shut out downstream rivals. As an initial matter, no potential rival has developed an MCED product that is a substitute for, and thus competes with, GRAIL's product; if Complaint Counsel cannot establish a competitive substitute product, the merged entity necessarily would have no incentive to foreclose access to the NGS market. But

even if this Court were to find a relevant market with downstream rivals, the more profitable post-merger course is often that the supplier will continue selling to downstream customers—especially if, as is very possible in GRAIL's market, a significant number of entrants develop superior or alternative technology that does not directly compete with GRAIL's product. Foreclosure will never take place with the false expectation that the same monopoly profits can be collected twice. *See supra* at 8-9. If downstream companies are as dependent on Illumina's NGS platform as Complaint Counsel claims, then Illumina is already in a position to charge monopoly prices to GRAIL's competitors, with or without the merger. And, indeed, if a rival emerged with a directly competitive MCED product superior to GRAIL's, a foreclosure strategy might cut Illumina out of a substantial part of the anticipated market. That risk must factor into an assessment of the likelihood that Illumina would pursue a foreclosure strategy.

To overcome these likely possibilities, Complaint Counsel must present a rigorous econometric analysis of these two alternatives—either to foreclose or to supply GRAIL's rivals—based on reliable evidence and empirically supported assumptions about how the new market is likely to unfold. *See AT & T*, 310 F. Supp. 3d at 215 (crediting defendant's econometric analysis based upon "significant, real-world evidence" while discounting the government's presumption as speculation). Complaint Counsel cannot rely on a presumption that the incentive to foreclose downstream competitors always dominates.

Complaint Counsel must also prove, by reliable evidence, that the alleged anticompetitive effects of the merger will outweigh the benefits of the merger's efficiencies. *See Qualcomm*, 969 F.3d at 990-91 (cautioning against presuming anticompetitive effects where none exist, especially in new technology markets). This inquiry entails rigorous comparative analysis of the likely benefits from the Illumina-GRAIL merger.

2. Upstream Competitive Response

Complaint Counsel cannot prove its case based on the current configuration of the upstream market or the current market dominance of the merging supplier, assuming a static model with a fixed and invulnerable monopolist. A proper analysis must meaningfully account for the likely competitive responses of present and future upstream rivals.

Thus, if a large downstream market emerges for MCED tests, in all probability it will attract new entrants at each stage of the production cycle. Complaint Counsel must show a durable monopoly for the entire period that can be effectively defended by exclusionary conduct against rivals, which may well be self-defeating. The case can only be made by modeling the likely responses of multiple competitors who have every incentive to occupy niches that may be created by some as-yet-unknown emerging alternatives to Illumina's sequencing technologies. That dynamic analysis must also recognize the strong incentive for upstream competitors to design around Illumina's patents and to exploit their technologies once those patents have expired. The Commission should be especially skeptical of speculative claims that the technology will prove too complex for NGS competitors to enter the upstream market, or that rely on anecdotal and self-serving testimony of potential GRAIL rivals that the costs of switching to a competitive platform is too high. *See* CC Br. at 95-105.

3. Contractual Landscape

Complaint Counsel must also account for Illumina's long-term contracts with GRAIL's downstream rivals. These contracts offer strong evidence that the company will not opt to terminate these beneficial—and enforceable—arrangements after the Illumina-GRAIL merger is complete. *Cf. United States v. General Dynamics Corp.*, 415 U.S. 486, 503-04 (1974) (noting that a merging company's long-term contracts, among other factors, effectively rebutted the government's *prima facie* case). Complaint Counsel must offer persuasive evidence to explain

why a total reversal in direction by the merged firm should be expected. Again, assertions of speculative possibilities are legally insufficient under well-established antitrust law.

Complaint Counsel speculates that Illumina would degrade its performance of its preexisting contracts with GRAIL's rivals, including information sharing and product support. *See* CC Br. at 75-95. But Complaint Counsel must prove that this is likely, particularly in light of the costs to Illumina of alienating its present and potential customers. Even if Illumina had a sufficient incentive to degrade its contract performance, Complaint Counsel must prove that this degradation is likely to affect competition in a substantial way.

In addition, whether Complaint Counsel has met its burden must be assessed in light of Illumina's enforceable commitments, through its Open Offer, not to foreclose GRAIL's competitors. These public commitments were made presumably because Illumina has determined that such foreclosure would be self-defeating. By making these binding commitments, Illumina not only dramatically reduces the risk of anticompetitive acts but increases the willingness of its trading partners to make greater investments in Illumina-specific products. Contrary to Complaint Counsel's claim, the Open Offer is not a proposed alternative remedy, but an existing contractual commitment that has to be evaluated in assessing the probability of anticompetitive harm. *See, e.g.*, *AT&T*, 916 F.3d at 1031 (faulting the government for not taking into account a merging company's "irrevocable offers of no-blackout arbitration agreements"). When companies know that foreclosure is a losing option, they lose nothing—but gain much—by guaranteeing that their trading partners will not be subject to holdout problems down the road. These guarantees can be enforced through a number of mechanisms, including the baseball-style arbitration provided in Illumina's Open Offer, that avoid the potential harms to consumers of enjoining the merger altogether. And Complaint Counsel cannot discount these contractual commitments because of the

risk that Illumina might theoretically provide lesser service to GRAIL's competitors than to GRAIL short of breaching the contract; it must show that any such acts would probably substantially diminish competition when GRAIL's competitors would still have access to the same NGS technology as GRAIL.

4. Risks to Consumer Welfare of Unwinding the Merger

The risk to consumers of an imprudent judgment is particularly high where, as in this case, the merger concerns a prospective market for technology that is developing quickly but is not yet commercially mature. The question is not simply whether the Illumina-GRAIL merger would help or hamper competition if MCED technology becomes commercially viable. The Commission must weigh the risk that enjoining the merger would delay patients' access to MCED tests, as well as the development of superior or alternative MCED technology. Complaint Counsel has rightly noted that the public benefits of successful MCED technology are potentially massive. *See* CC Br. at 1-2. Complaint Counsel should therefore be held to an especially high burden, given the potential for an imprudent injunction to delay the very benefits that Complaint Counsel seeks to protect.

B. The FTC Should Tread Carefully in Blocking Collaborative Arrangements Vital to Innovation in Complex Emerging Technologies

In the modern biopharmaceutical industry, Illumina is following a business model that has generated massive innovation over the past several decades. The small start-up hands off new products to experienced firms that are better able to bring them to market. At the initial stage, small start-ups rely on entrepreneurial risk-taking and rewards, specialization, and structural diversity and versatility to speed up early-stage technological innovation. In contrast, the larger firms have complementary advantages in assembling the capital, labor, and management expertise required for the next two stages in the process: funding and delivering later-stage development of

therapeutic or diagnostic technologies, including navigating regulatory hurdles, especially before the FDA, followed by ramping up the manufacture and successful commercialization of the products.

This model has only been able to facilitate innovation, through efficiencies in research and development, because of the flexibility to set up firms and to staff them with the necessary talent. There is no single blueprint for success, and quick strategic adjustments in plans and personnel may look chaotic from the outside, but in reality are the necessity for success. Switches, even reversals, of ownership arrangements are part of the overall package, for myriad reasons. Often, product development requires the close scientific or engineering collaboration within an integrated firm, or cooperation agreements among multiple firms. Management synergies are often key in this phase of development. Frequently, substantial and unexpected cost-sharing opportunities may emerge as the process goes forward. For example, one of the most prominent recent successes arose out of the research-and-development collaboration agreement between BioNTech and Pfizer to develop mRNA vaccines for influenza. This collaboration allowed the two companies to pivot quickly from the development, to the FDA approval process, to the manufacture and distribution of the COVID-19 vaccine in ways that no single firm could have accomplished. *See* Roland Lindner, *Biontech's Friend in New York*, Deutschland.de (Jan. 27, 2021), https://www.deutschland.de/en/topic/knowledge/katrin-jansen-and-the-collaboration-between-pfizer-and-biontech.

Illumina's divestment of GRAIL may have made perfect sense at time X but not time Y. Regulators typically lack the knowledge to second-guess the parties on these timing and planning

issues.[3] That knowledge is embodied in business plans, as well as rapidly depreciating IP assets subject to competition by design-around therapeutics or generic entry. *See* Geoffrey A. Manne, Kristian Stout & Eric Fruits, *The Fatal Economic Flaws of the Contemporary Campaign Against Vertical Integration*, 68 U. Kan. L. Rev. 923, 964 (2020) (the presumption that vertical mergers are procompetitive relates to "recognition that the boundaries of firms are somewhat arbitrary from an outside perspective" and "efficient outcomes" depend on "transaction costs, corporate governance, asset specificity issues, and other intangible qualities of firms").

The biotech industry and its consumers would be harmed by a ruling that blocks Illumina from reacquiring GRAIL, having now concluded based on new information that the original ownership structure, or some variant thereof, is now superior to the preexisting arrangement. Innovation in the biotechnology industry increasingly depends on firms' freedom to tailor collaborative arrangements.[4] The Commission should be wary of imposing steep costs on the current business model, not only in this case, but in all settings where today big and small firms are free to optimize between licensing arrangements and outright acquisition, finding the most efficient level of vertical integration.

There has recently been extensive merger-and-acquisition activity in the biopharmaceutical and medical-device sector, predominantly involving smaller companies joining forces with larger

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[3] This is certainly a lesson of the AT&T-Time Warner merger that the DOJ sought unsuccessfully to block in 2018. *See AT&T*, 916 F.3d at 1031-32. Far from the merged entity becoming a monopolistic behemoth, its market remained in such flux that AT&T chose to spin off the acquired assets three years later to adapt to the fast-changing media ecosystem. *See* Lauren Feiner, *AT&T Battled the DOJ to Buy Time Warner, Only to Spin It Out Again Three Years Later*, CNBC (updated May 17, 2021, 1:30 PM), https://www.cnbc.com/2021/05/17/att-fought-doj-for-time-warner-only-to-spin-out-three-years-later.html.

[4] *See, e.g.*, Deloitte, *How biopharmaceutical collaborations are fueling biomedical innovation* (2017), available for download at https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/how-biopharma-collaborations-are-fueling-biomedical-innovation.html.

companies. More than 200 deals, collectively worth over $123 billion, were concluded just in the first half of 2021, but uncertainty over antitrust regulation is clouding the future of this trend. *See* Arlene Weintraub, *Biopharma M&A set for a strong H2 despite political noise—and Biogen and Gilead look like buyers: analysts*, Fierce Pharma (June 28, 2021), https://www.fiercepharma.com/pharma/biopharma-m-a-track-for-a-strong-second-half-despite-political-noise-analysts; Jacob Bell, *5 Trends in Biotech Dealmaking To Watch in 2021*, Biopharma Dive (Jan. 13, 2021), https://www.biopharmadive.com/news/biotech-pharma-deal-trends-2021/593267.

Excessive and legally unwarranted wariness could easily inhibit many sensible corporate reorganizations that are essential to success in an ever-evolving biotech sector. Those hidden efficiency losses will reverberate throughout this dense and informed market. Firms generally have better information than any agency or the courts on which path for developing is best, both in research and development and in commercial and institutional organization. Higher costs and uncertainty will hurt in all cases.

Any regulatory system that effectively locks firms into initial organizational decisions, thereby deterring them from acquiring former collaborative partners, would eliminate a key option offered by vertical mergers: namely, "entrepreneurial exit," whereby startups and venture-capital investors specialize in developing new methods and technologies in the hope of being acquired by an established company with the resources to effectively and efficiently commercialize their products. *See* D. Daniel Sokol, *Vertical Mergers and Entrepreneurial Exit*, 70 Fla. L. Rev. 1357, 1362-63 (2018); *see also* Manne, Stout & Fruits, *supra*, at 925 (contract is not always a "simple" substitute for merger "in highly dynamic industries in which effective competition often demands both process and product innovation" and where "the management of intangible information assets . . . may not be as readily (or at all) accomplished by contract as by internal coordination"). But if

such vertical mergers can be blocked on inherently speculative and unprovable foreclosure grounds, that exit strategy could be blunted, thereby reducing the rate of firm formation at the beginning of the entrepreneurial cycle.

Suppose that Illumina and GRAIL had remained integrated; is there any reason to think that Illumina would not sell its products to GRAIL's rivals if it could gain more from those revenues than it lost from its own sales? If licensing to many rivals expands the pie, even a perfect monopolist would pursue that course rather than be the exclusive user of the invention. The dollars are fungible, and the outside players can supply more capital investment into the MCED industry, leaving all parties better off. The same would be true if the two companies reunite. *See* Roger D. Blair et al., *Analyzing Vertical Mergers: Accounting for the Unilateral Effects Tradeoff and Thinking Holistically about Efficiencies*, 27 Geo. Mason L. Rev. 761, 788 (2020) ("Profit-maximizing firms, regardless of whether they are vertically integrated, will sell to unintegrated rivals if the price paid by those rivals exceeds marginal cost and will purchase inputs from unintegrated rivals if the cost is lower than that of alternatives, including self-supply."); Michael A. Salinger, *Vertical Mergers and Market Foreclosure*, 103 Q.J. Econ. 345, 355 (1988) (explaining that vertical mergers "do[] not [] necessarily result in market foreclosure of unintegrated producers"). Indeed, Illumina has already bound itself to its anti-foreclosure commitments. Incentives to exclude rivals cannot be presumed; they must be proven, with due accounting of the comparative profitability of non-exclusion.

CONCLUSION

Success in delivering on the promise of a commercially viable MCED technology, and the enormous gains to consumer welfare it would bring, is by no means certain. Illumina and GRAIL are best positioned to understand how to bring this critical technology to fruition quickly and

efficiently, and the Commission should not intervene except on compelling evidence that the merger is likely to substantially lessen competition, notwithstanding the procompetitive benefits of the merger. The Commission should decline to import from horizontal-merger law a presumption of competitive harm, especially given the risks to consumers of an imprudent decision to unwind this merger.

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Respectfully submitted,

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