PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Lina M. Khan, Chair**
Rebecca Kelly Slaughter
Alvaro M. Bedoya

In the Matter of **Illumina, Inc.** **a corporation,** **and** **GRAIL, Inc.,** **a corporation.**	**DOCKET NO. 9401**

RESPONDENTS' APPLICATION FOR A STAY PENDING REVIEW BY A UNITED STATES COURT OF APPEALS

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GLOSSARY OF TERMS

ABBREVIATION	MEANING
ALJ	Administrative Law Judge, Chief Judge Chappell
CC	Complaint Counsel of the Federal Trade Commission
FTC or Commission	Federal Trade Commission
Galleri	MCED Test developed by GRAIL
Grail	GRAIL, Inc. (now known as GRAIL, LLC)
Illumina	Illumina, Inc.
MCED Test	Multicancer Early Detection Test
Open Offer	Illumina's offer to oncology customers dated March 30, 2021
Transaction	Illumina's Acquisition of the shares of Grail that it did not already own by a Merger Agreement dated August 18, 2021

Pursuant to 15 U.S.C. § 45(g)(2) and 16 C.F.R. § 3.56, Respondents Illumina, Inc. and GRAIL, Inc. respectfully apply to the Federal Trade Commission (the "Commission") for an expedited stay of the effective date of the Commission's Final Order dated March 31, 2023 (the "Order").

INTRODUCTION

This is a case about a vertical merger that reunited a next-generation sequencing ("NGS") company, Illumina, with the company it founded, Grail, in an effort to revolutionize cancer care. Complaint Counsel ("CC") challenged the Transaction on the theory that it could harm competition for screening tests that did not exist at the time of challenge, do not exist even today (years later) and may yet never come to market. Chief Judge Chappell (the "ALJ") rejected the challenge after a lengthy trial, but the Commission overruled the ALJ and entered the Order, requiring Illumina to unwind the Transaction, and imposing on Illumina onerous hold separate and other obligations. The Order misstates the law and misrepresents the record, and Respondents intend to seek reversal of the Order on appeal. While the Order's divestiture provisions are automatically stayed pending appeal, the non-divestiture provisions are not. These include hold separate and monitoring requirements that prevent Illumina and Grail from working together. The Order could even require Grail to terminate its current CEO (without due process) because of his prior connection to Illumina before this appeal is decided. If those provisions are allowed to take effect—as they would in 60 days—they will further delay Illumina's ability to realize the Transaction's efficiencies and save lives by accelerating Galleri's accessibility. The removal of Grail's CEO—who has primary responsibility over Grail's decision-making and has been determined independent and acting in Grail's best interest for the past 18 months by the appointed monitoring trustee (Mazars) in Europe—would seriously harm Grail's ability to operate. Thus, Respondents respectfully request that the Commission stay

those provisions pending an appellate decision. The stay requirements are satisfied: Respondents are likely to succeed on appeal and will suffer irreparable harm absent a stay, whereas no other parties will be injured by a stay. Because lives will be saved through wider access to the Galleri test, a stay is in the public interest. And, because this matter raises legal questions related to a complex record, a stay is necessary to give an appellate court sufficient time to consider them. Given the time-sensitivity of this issue, Respondents seek expedited consideration of this motion.

BACKGROUND

The relevant facts are detailed in Respondents' post-trial and appeal papers, which are incorporated here by reference, and which we do not repeat, except as follows:

In 2021, Illumina sought to reunite with Grail in a purely-vertical merger to accelerate Galleri's adoption and generate significant efficiencies. If allowed, the Transaction will save tens of thousands of lives in the U.S. alone and many more worldwide.

Although it is widely recognized that vertical mergers rarely harm competition and are typically procompetitive, the FTC commenced litigation seeking to unwind the Transaction. It did so, even though Illumina founded Grail and has always owned part of it, and—as CC has conceded—there is no evidence Illumina's ownership of Grail has ever had any anticompetitive effect.

Following extensive discovery, the ALJ conducted a five-week trial. The ALJ heard from 66 witnesses and received more than 4,500 exhibits into evidence. Finding Illumina's witnesses credible and a number of CC's witnesses to be unreliable, the ALJ concluded CC failed to meet its *prima facie* burden.

Despite the ALJ's 20 years of experience adjudicating merger challenges, the Commission overruled the ALJ. In so doing, the Commission ignored the facts, disregarded the law and defied common sense.

LEGAL STANDARD

In assessing an application for a stay of a cease and desist order under 16 C.F.R. § 3.56(b), the Commission analyzes four factors: (1) the applicant's likelihood of success on appeal; (2) whether the applicant will suffer irreparable harm absent a stay if it succeeds on appeal; (3) the degree of injury to other parties if a stay is granted; and (4) whether the stay is in the public interest. *In re Novartis Corp.*, 128 F.T.C. 233, 233 (1999).

ARGUMENT

Each factor supports a stay.

A. Respondents Are Likely To Succeed On Appeal.

Respondents are likely to succeed on the merits of their appeal because the Commission committed five sets of legal and other errors that warrant reversal of the Order. Specifically: the Order (1) errs in finding that the Transaction is likely to substantially lessen competition; (2) fails adequately to account for the Open Offer; (3) incorrectly defines the relevant product market and rejects the need to define the related product market; (4) disregards merger-specific efficiencies that easily outweigh the alleged harm and thus foreclose CC's contention that the Transaction will substantially lessen competition; and (5) is unconstitutional.

No Substantial Lessening of Competition. After a five-week trial, the ALJ found that the Transaction did not give Illumina an incentive to foreclose any purported Grail rival. The ALJ was uniquely qualified to reach this conclusion. He received testimony from 56 fact and 10 expert witnesses (including three former DOJ chief economists) and an extensive documentary record. In rejecting the ALJ's conclusions, the Commission: (i) applied the wrong test for a

vertical merger; (ii) resorted to speculation about future competition; (iii) grounded its decision on unproven theory and assumption; (iv) cherry-picked the record, ignoring critical real-world facts (not the least of which is that, after two and a half years, the potential competition the Commission sought to protect has never materialized as alleged); (v) failed to perform the requisite balancing of competing interests; and (vi) misplaced reliance on untested theories concerning nascent competition.

The Open Offer Addresses the Alleged Concern. Even if Illumina had an incentive to attempt to foreclose purported rivals (*e.g.*, by raising rivals' costs or foreclosing supply or services)—which it does not—the Open Offer ***effectively constrains*** Illumina from acting on that supposed incentive, both in the short term and the long term. This is borne out by the facts: four of Grail's purported rivals have signed the Open Offer, and ten companies overall have done so. CC admitted during closing argument that it had no evidence of foreclosure attempts by Illumina while the Open Offer was in place. (Closing Tr. 4613:18-20.) As the ALJ found, "[t]he Open Offer constrains Illumina from using virtually any of the tools that CC asserts will raise rivals' costs or otherwise foreclose Grail's alleged rivals", as shown by "well qualified" and "persuasive" experts. (ALJ Decision at 179.) In coming to a different conclusion, the Commission wrongly rejected the Open Offer as a behavioral remedy and dismissed the Open Offer based on speculation about supposed imperfections.

Legally Erroneous Relevant Markets. The Commission's Order is also legally flawed and should be reversed because it depends on mistaken definitions of the relevant product market and related product market. While the ALJ found that each of Grail's purported rivals is years away from launching any kind of MCED test and that CC failed to prove that any putative test is "reasonably interchangeable" with Galleri, the Commission nevertheless found—erroneously—

that there is a relevant market for the research, development and commercialization of MCED tests. In fact, such a market: (i) runs counter to the *Brown Shoe* factors; (ii) fails to satisfy the hypothetical monopolist test; (iii) disregards product interchangeability; (iv) is impermissibly speculative and both over- and under-inclusive; and (v) depends on subjective policy assessments, rather than established law and objective evidence.

Overwhelming Evidence of Efficiencies. The Commission's Order errs and is likely to be reversed because any alleged harm arising from the Transaction is outweighed by merger-specific efficiencies, including that the reunification of Illumina and Grail will save tens of thousands of lives in the U.S. and many more throughout the world. The unrefuted evidence showed that the Transaction will: (i) accelerate market access to a life-saving test; (ii) lead to new R&D innovations; (iii) eliminate double margins and a royalty Grail was otherwise required to pay; and (iv) lead to supply chain, operational and international efficiencies, resulting in lower prices and faster testing for patients. In dismissing these efficiencies, the Commission misunderstood the law and disregarded the evidence.

Unconstitutionality/Impropriety of the Order. The Order violates Article I of the U.S. Constitution because it is the product of improperly delegated legislative power. It violates Article II because FTC Commissioners exercise vast enforcement, investigative and prosecutorial authority while insulated from removal. It violates the Due Process Clause because the same people who voted out and/or prosecuted the complaint against Respondents adjudicated it. It violates the Equal Protection Clause because Respondents were subject to different treatment, and afforded fewer protections, than they would have had in a DOJ challenge. Moreover, the Commission's divestiture remedy and web of implementing obligations are

extreme and unnecessary, especially when an order adopting the terms of Illumina's Open Offer would be more than sufficient to protect competition.

That the Commission does not believe it made these errors is not a reason to deny Respondents' request for a stay. The likelihood of success factor can be met even when "[t]he Commission harbors no doubts about its . . . decision", *In re N.C. Bd. of Dental Exam'rs*, 2012 WL 588756, at *2 (F.T.C. Feb. 10, 2012) where, as here, the case involves "a difficult legal question", *id.* at *2, or is "based on a complex factual record." *In re Rambus, Inc.*, 2007 WL 901600, at *3 (F.T.C. Mar. 16, 2007).

B. Respondents Would Suffer Irreparable Harm Absent A Stay.

Enforcing the Order against Respondents before the Court of Appeals is able to review and reverse it would result in irreparable harm to Respondents. The further unification of Illumina and Grail will generate enormous efficiencies, including saving thousands of lives worldwide. These efficiencies require the Illumina and GRAIL teams collaborating together to enable GRAIL to take advantage of Illumina's deep expertise and resources in market access, lab operations, regulatory approvals and more. While Illumina is presently subject to hold separate requirements in Europe, those will fall away if Illumina prevails in its appeal of the European Commission's assertion of jurisdiction over the transaction—a decision that is expected as soon as the end of this year. Absent a stay, the Order threatens to extend Respondents' inability to realize the transaction's life-saving efficiencies if the U.S. appeal is not concluded before the European Union jurisdiction case. Every day that integration is delayed, lives are put at risk. An appellate order reversing the Commission's decision will not bring back the time lost or the lives that would have been saved but for the hold separate provisions. That is classic irreparable harm.

The non-divestiture provisions will also interfere with Grail's ability to operate as a standalone entity while the appeal is pending. As an example of critical importance for the

viability and competitiveness of GRAIL, under Order Section III.F, Grail may not "employ any person as a GRAIL Executive who has served as an Illumina Restricted Executive [defined to include Illumina's CEO, CFO and COO] during the preceding 5 years." (Order at 4, 9.) Crucially, this provision appears to require Grail to terminate its current CEO, Bob Ragusa, who previously served as Illumina's Chief Operations Officer (though not Illumina's "Chief Operating Officer"), within 60 days of the Order's issuance. Mr. Ragusa has served as CEO of Grail since October 2021, acting in the best interests of Grail at all times, and has proven his knowledge of Grail's business, independence, and command of the support of Grail's entire executive team (including the deputy Hold Separate Managers—Grail's President and CFO—and Grail's General Counsel) and employees. He is a highly experienced leader with deep operational experience in the NGS space and, after a rigorous and extensive evaluation into his independence and suitability by the European Commission ("EC") (supported by the monitoring trustee), was approved by the EC as the primary hold separate manager for Grail after being observed weekly by the monitoring trustee for the past 18 months. Requiring his termination, and forcing Grail to attempt to find a new CEO who has the depth of Mr. Ragusa's experience and capabilities—and forcing Grail and the EC to go through the approval process from scratch—during the pendency of the appeal would be wholly arbitrary, and would be highly disruptive and destabilizing—both internally and externally—to Grail, creating a substantial and unnecessary risk of damaging Grail's viability and competitiveness. Such damage cannot be undone if Illumina prevails on appeal (even if Illumina does not prevail, Mr. Ragusa's termination would risk harm to Grail's prospects as an independent entity).

Even setting these harms aside, it is well-established that a violation of constitutional rights—as is occurring here—is irreparable harm. *See Elrod v. Burns*, 427 U.S. 347, 373 (1976).

C. No One Will Be Harmed If The Commission Grants A Stay.

While enforcing the Order would result in irreparable harm to Respondents, deferring enforcement of the Order would not result in harm to anyone else. The FTC declined to move for a preliminary injunction when it had the opportunity, thereby effectively conceding that a stay of injunctive relief pending resolution of an appeal will not harm anyone. Further, as the ALJ found, the Transaction did not give Illumina an incentive to foreclose any purported Grail rival, and even if it had, the Open Offer precludes any realistic risk of Illumina acting on any such incentive, even if it had one.

On the contrary, staying the hold separate and monitoring provisions will enable Illumina to realize all of the benefits of the Transaction if Respondents prevail in the EU jurisdictional case.

D. A Stay Is In The Public Interest.

In addition to avoiding irreparable harm to Respondents, staying enforcement of the Order is overwhelmingly in the public interest. There is no public interest against the reunification of Illumina and Grail. This is not a horizontal merger where the proverbial eggs cannot be feasibly unscrambled after the parties come together. All public interest considerations weigh decisively in favor of a stay. Again, the Transaction will generate enormous efficiencies—in particular, making Grail's Galleri test available to more patients at lower prices—which will save thousands of lives. Because it interferes with the realization of those efficiencies, the Order is contrary to the public interest and should be stayed pending appellate review. *Cf. Alleghany Corp. v. Breswick & Co.*, 353 U.S. 151, 167 (1957) (citation omitted) ("The public interest is served by economy and efficiency in operation.").

An agency's compliance with its organic statute, the Administrative Procedure Act (the "APA"), and the federal Constitution is always in the public interest. *See Odebrecht Constr. v.*

Sec'y, Fla. DOT, 715 F.3d 1268, 1290 (11th Cir. 2013). Here, the Commission's Order does not comply with the APA or the Constitution insofar as it seeks to unwind a vertical merger where no court ever has.

CONCLUSION

For the foregoing reasons, Respondents respectfully request that the Commission stay the Order pending resolution of the Respondents' appeal.

Dated: April 4, 2023

Respectfully submitted,

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[PROPOSED] ORDER GRANTING RESPONDENTS' APPLICATION FOR A STAY PENDING REVIEW BY A UNITED STATES COURT OF APPEALS

The Commission entered its Opinion and Final Order in the matter dated March 31, 2023 (the "Order"), and issued and served the Order on Illumina and Grail (collectively, "Respondents") on April 3, 2023. Respondents applied to the Commission on April 4, 2023, pursuant to 15 U.S.C. § 45(g)(2) and 16 C.F.R. § 3.56, for a stay of the Order pending appellate review.

Having considered Respondents' Application and all supporting and opposition papers,

IT IS ORDERED that the effective date and enforcement of the Order be stayed upon the filing of a timely petition for review of the Order in an appropriate United States court of appeals pursuant to 15 U.S.C. § 45(c). This stay shall remain effective until the expiration of all periods for petitions for rehearing, rehearing en banc, or certiorari to the United States Supreme Court, or until final disposition of all such petitions and any proceedings initiated by a grant of such a petition.

By the Commission.

_____
April Tabor
Secretary

ISSUED:

CERTIFICATE OF SERVICE

I hereby certify that on April 4, 2023, 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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