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**

COMPLAINT COUNSEL'S OPPOSITION TO RESPONDENTS' APPLICATION FOR A STAY PENDING REVIEW BY A UNITED STATES COURT OF APPEALS

Respondents move for an expedited stay of the effective date of the Commission's Final Order (the "Order"). Complaint Counsel does not oppose Respondents' request to stay Sections II, VI, IX, and Paragraphs IV.B, VIII.A.2 of the Order in their entirety nor a limited stay of Paragraphs III.E and III.F. The remainder of the Order, however, is necessary to preserve the status quo, protect competition during the pendency of the Respondents' appeal, and preserve potential post-appellate relief.

INTRODUCTION

On March 31, 2023, the Commission found that Illumina Inc.'s ("Illumina"), acquisition of GRAIL LLC ("Grail") (the "Acquisition") violated Section 7 of the Clayton Act, 15 U.S.C § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45, because it "may substantially lessen competition" for the research, development and commercialization of life-saving multi cancer early detection ("MCED" tests. Opinion of the Commission, at 93 ("Opinion"). The Commission

also held that Respondents failed to show *any* cognizable efficiencies—much less efficiencies sufficient to offset the likely anticompetitive harm arising from the Acquisition. Opinion at 74-87. Specifically, the Commission found that "evidence shows that standalone Grail had the incentive and ability to achieve acceleration through means short of this anticompetitive Acquisition" and that Respondents "have failed to show that the Acquisition, as opposed to [Grail's] Galleri test, would save any lives." Opinion at 78. The Commission also rejected Respondents' proposed behavioral remedy (the "Open Offer"), finding that it would not "restore the pre-Acquisition level of competition" because it "does not eliminate Illumina's ability to favor Grail and harm Grail's rivals, and it does not fundamentally alter Illumina's incentives to do so." Opinion at 73.

Respondents now ask the Commission to ignore its own factual findings and stay the Order in its entirety. Specifically, Respondents argue that fully merging is necessary to bring Grail to market and "save lives." Respondents' Application for a Stay Pending Review by a United States Court of Appeals at 1 ("Resp. Appl."). Respondents have failed to meet their burden for four reasons.

First, Respondents cannot show a likelihood of success on appeal. Respondents raise no new arguments in their Application to Stay and simply repeat the same factual and legal arguments that were raised to and rejected by the Commission. Mere repetition – however loudly and frequently – is insufficient to show a likelihood of success on appeal. *In re Toys "R" Us, Inc.*, 126 F.T.C. 695, 697 (Dec. 1, 1998).

Second, Respondents' argument that they will suffer irreparable harm ignores that Illumina is currently required to hold Grail separate pursuant to an order by the European Commission

("EC"). Presuming that Illumina will abide by this order (as it assured its shareholders),[1] the Commission's Order, with the minimal stays Complaint Counsel proposes, imposes nominal additional burden on Respondents while still protecting the public interest in an effective remedy if the Commission's Opinion is upheld.

Third, Respondents ignore the Commission's findings of vibrant current competition in the market for the research, development, and commercialization of MCED tests. Opinion at 40-42. Staying the hold separate provisions (and thus, allowing further integration between Illumina and Grail) would allow Respondents to exercise their ability to disadvantage Grail's rivals, threatening MCED test developers' ability to fairly compete to bring these life-saving tests to U.S. patients. A separate order enforceable in the U.S. courts is necessary to protect this current competition during the pendency of a U.S. appeal in the event of either a lapse in the EC hold separate or decision by Respondents to no longer abide by the EC hold separate.

Finally, Respondents cannot show that a stay is in the public interest. Respondents assert that granting a stay would "save lives" by giving them the benefit of the Acquisition during the appeal process. However, the Commission found that Respondents failed to show that the Acquisition would save lives and instead found that the Acquisition may substantially lessening competition. Opinion at 87. More importantly, there is a strong public interest in the effective enforcement of the antitrust laws. *FTC v. Tronox, Ltd.*, 332 F.Supp.3d 187, 198 (D.D.C. 2018). If a complete stay is granted, the FTC will face "an especially daunting and potentially impossible task of 'unscrambling' the eggs" after the appellate court proceedings, thus reducing the

[1] As Respondents acknowledge in their Application to Stay, they are "presently subject to hold separate requirements in Europe." Resp. Appl. at 6. However, Respondents have previously disregarded their legal obligations to hold separate.

Commission's ability to effectively enforce the antitrust laws and preserve competition. *FTC v. Sysco Corp.*, 113 F.Supp.3d 1, *87 (D.D.C. 2015).

BACKGROUND

On September 20, 2020, Illumina entered into an Agreement and Plan of Merger to acquire Grail for $8 billion. Opinion, at 11. On March 30, 2021, the Commission voted 4-0 to issue an administrative Complaint. The ALJ conducted an administrative hearing and found that Complaint Counsel had failed to prove a substantial lessening of competition is probable or imminent. Complaint Counsel appealed the ALJ's Initial Decision.

Pursuant to its *de novo* review of the facts and the law, the Commission unanimously declined to adopt certain portions the ALJ's Initial Decision, concluding that the Acquisition may substantially lessen competition in the relevant U.S. market for the research, development, and commercialization of MCED tests. Opinion at 2. Concurrent with its Opinion, the Commission issued an Order requiring Illumina to divest Grail, as well as to hold Grail separate pending the divestiture.

During the FTC's litigation, the EC also investigated the Acquisition and publicly stated in April 2021 that Illumina and Grail could not "implement the transaction before notifying and obtaining clearance from the Commission." *Mergers: Commission to assess proposed acquisition of GRAIL by Illumina*, European Commission (April 20, 2021), https://ec.europa.eu/commission /presscorner/detail/en/mex_21_1846. While the EC review was pending, Illumina and Grail consummated the Acquisition but volunteered to hold separate during the pendency of the EC's investigation. Opinion at 11. Upon completion of its investigation, the EC issued a decision prohibiting Illumina's acquisition of Grail because "the merger would have stifled innovation, and reduced choice in the emerging market for blood-based early cancer detection tests" and extended

its interim measures holding the two companies separate. *Mergers: Commission prohibits acquisition of GRAIL by Illumina* (September 6, 2022), https://ec.europa.eu/commission/presscorner/detail/en/ip_22_5364. These measures remain "applicable until the Commission notifies any possible decision under Article 8(4) of the EU Merger Regulation, ordering the unwinding of the transaction." *Mergers: Commission renews interim measures to ensure Illumina and GRAIL continue to be kept separate following the prohibition decision* (October 28, 2022), https://ec.europa.eu/commission/presscorner/detail /en/MEX_22_6467. Illumina has appealed the EC's decision to prohibit the merger with a decision not expected for several years. Separately, Illumina's appeal of the EC's exercise of jurisdiction over the merger is pending with the European Court of Justice after the European General Court ruled in the EC's favor. Under any scenario, it appears that the EC's hold separate measures will be in place for an extended period.

ARGUMENT

To determine if a stay is appropriate under Commission Rule 3.56, the Commission considers the following four factors: (1) "the likelihood of the applicant's success on appeal; (2) whether the applicant will suffer irreparable harm if a stay is not granted; (3) the degree of injury to other parties if a stay is granted; and (4) the public interest." *In re LabMD, Inc.,* 2016 WL 5815256, at *2 (F.T.C. Sept. 20, 2016) (internal quotations omitted). It is Respondents' burden to establish each factor. *Id.* Respondents have failed to meet their burden here.

A. Applicants Have Failed to Show Likelihood of Success on the Merits

To support its claim of a likelihood of success on the merits, Respondents repeat multiple arguments previously raised before the Commission. *See e.g.*, Respondents Answering Brief to Complaint Counsel's Appeal Brief at 15-17; 25-27; 33-37; and 38-40. Merely revisiting such arguments is insufficient to justify a stay. *Toys "R" Us, Inc.*, 126 F.T.C. at 697. Instead,

Respondents must show that, at minimum, "serious questions" as to the merits of the case exist—such questions arise when the case presents [the] application of difficult legal questions to a complex factual record" and the equities weigh in favor of maintaining the status quo. *In re Ecm BioFilms*, 2015 WL 7843258, at *1 (F.T.C Nov. 18, 2015) (internal citations omitted). Respondents fail to raise any such serious question.

First, Respondents contend that the mere fact that the Commission's outcome differed from the ALJ's Initial Decision demonstrates a likelihood of success on the merits. Resp. Appl. at 3 (arguing the "ALJ was uniquely qualified to" assess whether there was a substantial lessening of competition); 4 (arguing "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'"). However, the Commission reviews the ALJ's findings of fact and conclusions of law *de novo*, considering "such parts of the record as are cited or as may be necessary to resolve the issues presented," 16 C.F.R. § 3.54(a), and exercising "all the powers which it could have exercised if it had made the initial decision." *Id*.; *see also* 5 U.S.C. § 557(b) (2022). The *de novo* standard of review applies to both findings of fact and inferences drawn from those facts. *See In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 5957363, at *10, 335 (F.T.C. Nov. 1, 2019). On appeal, the Circuit Court will "review the Commission's ruling, not the ALJ's." *Impax v. FTC*, 994 F.3d 484, 491 (5th Cir. 2021) and "[t]he 'findings of the Commission as to the facts, if supported by evidence, shall be conclusive.'" *Id.* As such, differences between the decisions of the ALJ and the Commission do not "suggest a likelihood of reversal." *In re 1-800 Contacts, Inc.*, 2019 WL 696993, at *2-3 (F.T.C. Feb. 12, 2019).

Second, Respondents argue that the Commission applied the wrong legal tests to assess vertical mergers, define the relevant market, and assess efficiencies. Turning first to the

Commission's application of the vertical merger framework, the Commission applied two separate tests to determine that this Acquisition was illegal: an application of long-standing Supreme Court precedent, *United States v. Brown Shoe*, and the ability and incentive framework applied by the D.C. Circuit. Opinion at 41. While it is unclear which test Respondents believe the Commission or ALJ should have applied, both the *Brown Shoe* and ability and incentive frameworks are well grounded in case law. *See, e.g., Brown Shoe*, 370 U.S. 294, 317 (1962); *United States v. AT&T*, 310 F.Supp. 3d 161, 243-45 (D.D.C. 2018).

Respondents' critiques of the Commission's market definition analysis ring similarly hollow. In contrast to Respondents' contentions, the Commission applied the *Brown Shoe* practical indicia and assessed product interchangeability. Opinion at 25-30. These tests are well-founded in law, regularly applied by federal courts, and appropriately applied to the facts in this case. Finally, Respondents argue that the Commission "misunderstood the law" but fail to identify a particular case or law that the Commission supposedly misunderstood. As such, Respondents again fail to raise a serious question of fact or law sufficient to meet their burden.

Third, Respondents appear in large part to simply disagree with the Commission's factual analysis repeating arguments made, and rejected, by the Commission. *See, e.g.*, Resp. Appl. at 3-4 (arguing that the Commission "cherry-picked the record"); 5-6 (repeating the same constitutional arguments made in previous briefing); and 6 (arguing this merger would generate efficiencies). Again, Respondents must do more than repeat previously rejected arguments to meet their burden of showing a serious question on the merits. *See, e.g.*, *Toys "R" Us, Inc.*, 126 F.T.C. at 697.).

B. Applicant Will not Suffer Irreparable Harm if a Stay is Granted

Respondents admit that the EC hold separate will remain in place (and apparently that they will abide by it) until at least the end of the year. Resp. Appl. at 6. Thus, any additional time that

the hold separate provisions of this Order remain in place—if any—are likely minimal and, as the Commission found, will have no impact on Grail's ability to benefit American patients. Rather, the Order's hold separate provisions would preserve current life-saving competition between Grail and its MCED rivals to research, develop, and commercialize MCED tests to the benefit of U.S. patients, and allow Complaint Counsel to obtain an effective remedy if the Commission's decision is upheld.[2]

C. This Order is Necessary to Protect American Patients and Save Lives

Respondents claim that "deferring enforcement of the Order would not result in harm to anyone else," Resp. Appl. at 8, and instead, that the "further unification of Illumina and Grail will generate enormous efficiencies, including saving thousands of lives worldwide." *Id.* at 6. Leaving aside the fact that "further unification" would violate Respondents' legal obligations in Europe, *see supra* n. 1, the Commission has already found that Respondents failed to show that this merger will save lives. Opinion at 78-79. Thus, absent a stay, U.S. patients would be harmed as they would be deprived the benefits of this life-saving competition between Grail and its MCED rivals.

D. A Stay is in the Public Interest

Respondents incorrectly argue that "staying enforcement of the Order is overwhelmingly in the public interest," primarily arguing that "this is not a horizontal merger where the proverbial eggs cannot be feasibly unscrambled after the parties come together." Resp. Appl. at 8. First, as noted *infra*, holding Grail separate is necessary to prevent Illumina from acting on its incentive to disadvantage Grail's MCED rivals, thus reducing life-saving competition. Second, the hold separate requirements are necessary to ensure that Illumina takes all actions necessary to maintain

[2] Respondents' contention that Mr. Ragusa's termination will be necessary has been rendered moot by Complaint Counsel's agreement to stay certain provisions of the Order that could potentially affect Mr. Ragusa's employment. *See also*, Exhibit A.

and preserve the full economic viability, competitiveness, independence, and marketability of the Grail business and assets until the divestiture is completed. Hold separate and asset maintenance obligations are common in Commission orders. *See, e.g.*, *In re Otto Bock HealthCare N. Am., Inc.*, 2019 FTC LEXIS 78, at *25-27 (F.T.C. Nov. 1, 2019). The alternative would require American consumers to bear the considerable risk that separating an already integrated Illumina and Grail could fully restore competition for these critical tests. Risk of a failed remedy should fall on Respondents, not the patients who will ultimately rely on these life-saving tests. *See Otto Bock*, 2019 WL 5957363, at *47 (explaining that "we aim to avoid placing the risk of a failed remedy on consumers").

CONCLUSION

For the foregoing reasons, Complaint Counsel respectfully asks the Commission to deny Respondents' request for a full stay and instead to enter the limited stay in Complaint Counsel's Proposed Order.

Dated: April 11, 2023

Respectfully submitted,

s/ Susan A. Musser
Susan A. Musser

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Counsel Supporting Complaint

EXHIBIT A

PUBLIC

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April 11, 2023

By Electronic Mail

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RE: Commission Order *In the Matter of Illumina Inc. et al.*, Docket No. 9401

Dear Mr. Marriott:

As you know, the Commission issued its Final Order ("Order") on March 31, 2023, in the above-referenced matter. We wanted to reach out to engage regarding certain provisions of the Order, which will become effective in early June absent a stay. In the first instance, the European Commission ("EC") has imposed Interim Measures requiring Illumina, Inc. ("Illumina") and GRAIL, LLC ("Grail") (collectively, "Respondents") to operate independently during the pendency of the EC proceedings. To date, Illumina and Grail have not provided Complaint Counsel with these Interim Measures nor have they authorized the EC to share these Interim Measures. If Respondents provide the FTC with the Interim Measures and related documents, we will evaluate the requirements of the Order in light of the Interim Measures and work with Respondents, the Monitor, and any Hold Separate Manager to facilitate compliance with the Order in a manner that is not unnecessarily disruptive to the existing status quo and to the operation of GRAIL.

Further, Paragraph IV.A of the Order authorizes Commission staff to select the Hold Separate Manager from qualified candidates nominated by Respondents. So long as the current deputy Hold Separate Managers continue in their respective roles in GRAIL and continue to perform their roles in a manner consistent with the EC's Interim Measures, Commission staff intends to select the current Hold Separate Manager under the Interim Measures as the Hold Separate Manager under the Order if he is nominated by the Respondents.

Further, given that the Commission has not yet ruled on Respondents' Motion seeking a complete stay of the hold separate and related provisions imposed by the Order, we expect Respondents will take into account all portions of the Order related to hold separate requirements

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when contemplating any new agreements or activities under the Interim Measures, as this will avoid creating any unnecessary conflicts or inconsistencies between implementation of the Order and the Interim Measures going forward.

Sincerely,

MARIBETH PETRIZZI Digitally signed by MARIBETH PETRIZZI Date: 2023.04.11 13:38:00 -04'00'

Maribeth Petrizzi

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**

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

Upon consideration of Respondents' Application for a Stay Pending Review by a United States Court of Appeals and all supporting and opposing papers, IT IS ORDERED:

1. As required under FTC Act, 15 USC sec. 45(g)(4), Sections II and VI are stayed in their entirety until the stay is lifted by operation of the statute;

2. Section IX and Paragraphs IV.B, and VIII.A.2 of the Final Order are stayed in their entirety until the United States Circuit Court of Appeals issues a ruling disposing of the petition for review filed by Respondents;

3. Paragraph III.E is stayed except as to (a) GRAIL Employees who were employed by GRAIL on March 31, 2023; and (b) GRAIL Employees hired after March 31, 2023, until the United States Circuit Court of Appeals issues a ruling disposing of the petition for review filed by Respondents;

4. Paragraph III.F is stayed as applied to Illumina Restricted Executives who were employed by GRAIL on March 31, 2023, which is the date the Final Order was issued, until the United States Circuit Court of Appeals issues a ruling disposing of the petition for review filed by Respondents; and

5. References to the "date this Order is issued" in Sections II, VI, and IX and Paragraphs III.E, III.F, IV.B, and VIII.A of the Final Order shall refer to the date the stay is lifted.

IT IS FURTHER ORDERED THAT Respondents' Application for a Stay Pending Review by a United States Court of Appeals is DENIED in all other respects, and that all other references in the Final Order to the "date this Order is issued" shall refer to the 60th day after service of the Final Order on Respondents.

By the Commission.

April Tabor
Secretary

SEAL:
ISSUED:

CERTIFICATE OF SERVICE

I hereby certify that on April 11, 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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The Honorable D. Michael Chappell
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I also certify that I caused the foregoing document to be served via email to:

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