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

In the Matter of Illumina, Inc., a corporation and GRAIL, Inc., a corporation, Respondents.	Docket No. 9401

RESPONDENTS' UNOPPOSED MOTION FOR LEAVE TO AMEND ANSWER TO ADD AFFIRMATIVE DEFENSES

Respondents Illumina, Inc. and GRAIL, LLC (collectively, "Respondents"), through undersigned counsel respectfully bring this unopposed motion for leave to amend their answer, pursuant to Commission Rule 3.15(a), to plead the following additional affirmative defenses: (1) violation of the Appointments Clause in Article II, Section 2 of the United States Constitution, (2) violation of the President's removal powers, as vested in Article II of the United States Constitution and as outlined in *Myers v. United States*, 272 U.S. 52, 117 (1926), and (3) violation of the Due Process and Equal Protection Clauses of the Fifth Amendment of the United States Constitution.

Because these defenses challenge the constitutional sufficiency of this tribunal and its jurisdiction, they "can never be forfeited or waived," *U.S. v. Cotton*, 535 U.S. 625, 630 (2002). Nevertheless, out of an abundance of caution, Respondents bring this motion now under Commission Rule 3.15. As explained below, Respondents' motion should be granted because it will not prejudice Complaint Counsel, the defenses are not futile and (putting aside that these

defenses cannot be waived) Respondents have proceeded without undue delay. Complaint Counsel has indicated that it will not oppose this motion.

I. BACKGROUND

A. The Transaction and the FTC's Investigation

On September 20, 2020, Illumina and GRAIL reached an agreement to reunite.[1] On October 9, 2020, Illumina and GRAIL submitted a filing pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. § 18A, and the Rules promulgated thereunder, to the Department of Justice ("DOJ") and the Federal Trade Commission (the "FTC") notifying them of the transaction. Based on an agreement between the DOJ and the FTC (the details of which are a complete black box), the FTC took jurisdiction over the action.[2] From that point on, Respondents were faced with the possibility of litigating the merits of their transaction in a proceeding where the FTC is the prosecutor, judge and jury. Had the DOJ taken jurisdiction over the transaction, the merits of the transaction would have been litigated in a federal district court, before a neutral trier of fact.

On November 9, 2020, the FTC issued a second request, initiating a prolonged six month investigation of the transaction. As part of that investigation, in response to the FTC's demands, Respondents produced millions of documents, provided narrative responses to the FTC's inquiries and cooperated fully by making Respondents' employees available for investigational hearings. During that investigational period, Respondents made numerous offers

[1] The merger agreement provides for termination rights if the transaction has not been consummated by September 20, 2021 (subject to an extension of three months under certain circumstances).

[2] *See* https://www.ftc.gov/news-events/media-resources/mergers-and-competition/merger-review ("Because the FTC and the Department of Justice share jurisdiction over merger review, transactions requiring further review are assigned to one agency on a case-by-case basis depending on which agency has more expertise with the industry involved.")

to resolve the investigation. *See* Exhibit F to Declaration in Support of Respondents' Motion for Conference to Facilitate Settlement (summarizing offers to Staff made during investigation period). However, armed with the knowledge that they would be able to bring any action in the FTC's own administrative tribunal, the FTC refused to negotiate or even provide a single counter offer to Respondents. *See id.* at 3-4.

B. The Litigation and the FTC's Gamesmanship

In mid-March of 2021, the FTC notified Respondents that it intended to file an administrative action as well as a motion for temporary restraining order ("TRO") and preliminary injunction in federal district court seeking to enjoin the transaction. While Respondents disagreed with the FTC's claims that the transaction is unlawful, they consented to a TRO that would expire on September 20, 2021 on an express understanding that the district court action would afford Respondents an opportunity to adjudicate its dispute in an Article III court before the September 20 deadline upon which this transaction will expire (subject to extension under certain limited circumstances). *See* Opposition to FTC's Motion to Dismiss, *FTC v. Illumina, Inc.*, Case No. 3:21-cv-00800-CAB-BGS, Doc. 124, at 7 (S.D. Cal. May 26, 2021).

On March 31, 2021, the FTC filed a lawsuit in the District Court for the District of Columbia seeking a preliminary injunction against the proposed transaction, Complaint, *FTC v. Illumina*, Doc. 4, as well as a Part 3 administrative complaint against Respondents, Dkt. No. 9401, Complaint (Mar. 30, 2021). Respondents timely filed their respective answers to the FTC's federal court and administrative complaints on April 5th and 13th. Answer, *FTC v. Illumina*, Doc. 49; Dkt. No. 9401, Answer (Apr. 13, 2021). On April 20, 2021, the District Court Action was transferred to the Southern District of California. On the same day, the parties wrote

a joint letter to the Chief Judge for the District Court of the Southern District of California, notifying the Court that "the parties have tentatively agreed to propose an expedited schedule, with a preliminary injunction hearing to begin on July 26, 2021 and to last at least two weeks" and requesting that they be assigned to a judge who had availability to accommodate that schedule. April 20, 2021 Letter to Judge Sabraw. On April 26, 2021, the parties jointly moved for a case management and scheduling order ("CMSO"). *FTC v. Illumina*, Doc. 87. That same day, the District Court for the Southern District of California entered a CMSO, which scheduled a preliminary injunction hearing to commence on August 9, 2021. *Id.*, Doc. 88.

Despite the parties' express understanding that they would work expeditiously to allow a federal court to consider and decide the FTC's preliminary injunction motion by the expiration of the TRO on September 20, 2021, on May 28, 2021, the FTC moved to dismiss its district court complaint without prejudice, which was subsequently granted. Judgment, *FTC v. Illumina*, Doc. 127. The FTC justified seeking this dismissal by arguing that the European Commission's ("EC") ongoing investigation of the proposed transaction rendered the FTC's request for a preliminary injunction unnecessary, because the parties could not close until the EC cleared the transaction. Memorandum in Support of Plaintiff's Ex Parte Application to Dismiss the Complaint Without Prejudice, *FTC v. Illumina*, Doc. 120-1., at 5.

But the FTC's justification was contradicted by the facts. The FTC was in regular contact with the EC throughout the month of March, and would have been aware of the pendency of the EC's investigation before even filing its Complaint, and certainly before agreeing to the TRO. Opposition to FTC's Motion to Dismiss, *FTC v. Illumina*, Doc. 124, at 10. So, in the face of a weak case, knowing that the EC was going to open an investigation, the

FTC's motion to dismiss was plainly designed to defer the decision regarding this transaction to the EC and to deny the Respondents an opportunity for review in a federal district court.

The FTC's subsequent refusal to even engage in negotiations for a settlement confirms that it has full confidence that the administrative process will favor the FTC, regardless of the strength of its case. On July 2, 2021, Respondents moved this administrative tribunal to convene a settlement conference to facilitate a negotiated resolution to the dispute. *See* Dkt. No. 9401, Respondents' Motion for Conference to Facilitate Settlement, dated July 2, 2021, at 3-4. Complaint counsel opposed that motion, first asking for an additional week to respond and then telling this tribunal that any settlement conference would be a waste of time. *See* Dkt. No. 9401, Complaint Counsel's Memorandum in Opposition to Respondents' Request for Expedited Consideration, dated July 6, 2021; Dkt. No. 9401, Complaint Counsel's Memorandum in Opposition to Respondents' Request for Expedited Consideration, dated July 15, 2021 at 1 ("Complaint Counsel opposes Respondents . . . request for a conference to facilitate settlement as a waste of this Court's time"). This tribunal denied Respondents' request for a settlement conference on July 21, 2021. Dkt. No. 9401, Order Denying Respondents' Motion for Conference to Facilitate Settlement, dated July 21, 2021.

II. RESPONDENTS' MOTION FOR LEAVE TO AMEND SHOULD BE GRANTED

Rule 3.15 provides that this administrative tribunal may grant leave to amend a pleading where doing so would "facilitate" the "determination of a controversy on the merits . . . upon such conditions as are necessary to avoid prejudicing the public interest and the rights of the parties." 16 C.F.R. § 3.15(a). This tribunal has not defined the circumstances under which "a determination on the merits will be facilitated", *In the Matter of Daniel Chapter One*, FTC No. 082-3085, 2009 WL 871702, at *2 (Mar. 9, 2009), but has noted that when considering

whether to grant leave to amend under Rule 3.15, it looks to the factors outlined in *Foman v. Davis,* 371 U.S. 178, 182 (1962). Under *Foman*, federal courts ***deny*** motions for leave to amend only where "(1) there has been "undue delay, bad faith or dilatory motive on the part of the movant;" (2) there would be "undue prejudice to the opposing party by virtue of allowance of the amendment" or (3) the amendment is "futil[e]." *Id*. (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)). None of these three factors is met here, and therefore, Respondents' motion for leave should be granted.

A. Respondents' Affirmative Defenses Are Not Waivable.

As an initial matter, because Respondents seek to raise affirmative challenges to the constitutionality of this tribunal and its jurisdiction, such affirmative defenses "involve[] [this] court's power to hear a case," and such defenses "can never be forfeited or waived." *U.S. v. Cotton*, 535 U.S. 625, 630 (2002).[3] Consequently, Respondents do not need to seek leave to add these affirmative defenses, but do so in an exercise of caution. Regardless, as discussed below, Respondents meet the requirements of Rule 3.15, and thus the amendment they seek is appropriate under the Rule.

B. Respondents' Amendment Will Not Prejudice Complaint Counsel Nor the Public Interest.

Neither Complaint Counsel nor the public interest will be prejudiced by the proposed amendment. In determining whether an amendment imposes undue prejudice, this tribunal has considered whether the defense "require[s] additional discovery" and whether the defense "is purely legal in nature." *In the Matter of LabMD, Inc.*, FTC No. 9357, 2015 WL

[3] Indeed, the Ninth Circuit in *Axon* appeared to acknowledge that these constitutional questions may be raised *after* the FTC enters a final order. *Axon Enter., Inc. v. Fed. Trade Commn.*, 986 F.3d 1173, 1183 (9th Cir. 2021) ("Axon can present its constitutional claims to this court after the conclusion of the FTC enforcement proceedings".)

4651650, at *2 (July 27, 2015). The constitutional defenses Respondents seek to add are purely legal and will not require any additional discovery as they rest entirely on the constitutionality of the structure of the FTC.

Furthermore, the public interest will be served by granting Respondents leave to amend their answer to raise the constitutional issues outlined above. The constitutional sufficiency of this proceeding is a matter of significant public concern, and the resolution and review of such "weighty constitutional" questions, which "call[] on courts to test the bounds of the Constitution's defined structural limitations" *Axon Enterprise, Inc. v. Federal Trade Commission*, 986 F.3d 1173 (9th Cir. 2021) (Bumatay, C.J., concurring-in-part and dissenting-in-part), is certainly to the benefit, rather than the detriment, of the public.

C. Respondents' Constitutional Defenses Are Not Futile.

Respondents' amendment is not futile. The defenses Respondents seek to add plainly raise colorable arguments as to the constitutionality of this proceeding. Indeed, these same defenses were raised in the *Axon* case, where Axon Enterprises ("Axon") filed suit in federal district court against the unconstitutional structure and processes employed by the FTC and sought to enjoin an impending administrative trial while its constitutional challenge was pending. Axon's complaint was dismissed on jurisdictional grounds, but on appeal, the Ninth Circuit entered an emergency stay of the FTC administrative trial, pending Axon's appeal. Order, *Axon Enterprise, Inc. v. Federal Trade Commission*, Case: 20-15662 ("*Axon II*"), Dkt. No. 40 (9th Cir. Oct. 2, 2020). Although the Ninth Circuit declined to hear Axon's claims on jurisdictional grounds, it observed that Axon raised: (1) "serious concerns about how the FTC operates," (2) "substantial questions about whether the FTC's dual-layered for-cause protection for ALJs violates the President's removal powers under Article II" and (3) "legitimate questions

about whether the FTC has stacked the deck in its favor in its administrative proceedings." *See Axon Enterprise, Inc. v. Federal Trade Commission*, 986 F.3d 1173, 1187 (9th Cir. 2021). Further underscoring the substantial and serious nature of these defenses, the Ninth Circuit recently granted Axon's motion to stay the administrative proceeding in that case so that Axon could seek Supreme Court review of the Ninth Circuit's decision on jurisdictional grounds. Order, *Axon II*, Doc. No. 58 (Apr. 21, 2021); Petition for Writ of Certiorari, *Axon* (July 20, 2021).

D. Respondents Have Proceeded Without Undue Delay, Bad Faith or Dilatory Motive.

Respondents' defenses are timely. This motion is filed in the context of a series of events, many orchestrated and executed by Complaint Counsel, which highlight the timely nature of Respondents' motion to amend. As described above, contrary to the parties' expectations at the time that Respondents' filed their answer, the FTC succeeded in dismissing its own federal court complaint without prejudice. The FTC's dismissal with prejudice set the stage for an administrative proceeding in its home court. The FTC's dismissal was a clear attempt to avoid having the transaction adjudicated on the merits in an impartial forum. *See* Plaintiff's Ex Parte Application To Dismiss the Complaint Without Prejudice, *FTC v. Illumina, Inc*, Doc. No. 120 (S.D. Cal. May 21, 2021).[4] And, because it is sure that the administrative process—and the ultimate outcome—will favor the FTC, Complaint Counsel has also exercised the power it has in Part 3 proceedings to oppose any settlement discussions. This tactic would not have been available to the FTC had it still been litigating in federal court—where "[r]equests for a conference from a party indicating willingness to talk settlement normally should be

[4] The district court granted the FTC's motion on June 1, 2021. Judgment in a Civil Case, *FTC v. Illumina, Inc. and Grail, Inc.*, No. 3:21-cv-00800 (S.D. Cal. May 21, 2021).

honored" (Fed. R. Civ. P. 16(a)(5), Notes of Advisory Committee, 1983). In fact, the local rules for the District Court for the Southern District of California provide for mandatory settlement conferences in civil cases. S.D. Cal. Local Rule 16.3.

Simply put, the FTC's decision to seek dismissal of its complaint in federal court—where the FTC is the accuser but *not* the adjudicator—while continuing its administrative challenge—where the FTC is both the accuser *and* the adjudicator—illustrates the validity and timeliness of Respondents' request to amend.[5]

III. CONCLUSION

For the reasons stated above, Respondents respectfully request that the tribunal grant their Unopposed Motion for Leave to Amend Answer to Add Affirmative Defenses.

[5] Notably, Complaint Counsel will be hard pressed to argue that there is undue delay here, given its position in the *Axon* case that these defenses cannot be adjudicated until a final order is entered in the administrative proceedings. *See* Answering Brief for the Federal Defendants, *Axon II*, Doc. No. 24, at 19-27, 30-34 (June 1, 2020) (arguing that "the FTC Act provides for judicial review of Axon's claims . . . *if* the FTC renders a final adverse decision.") (emphasis added). Moreover, under the FTC's theory in the *Axon* matter, Respondents are merely ensuring these defenses are preserved for review by the Commission and the federal courts.

Dated: August 23, 2021

Respectfully submitted,

/s/ Sharonmoyee Goswami

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CERTIFICATE OF SERVICE

I hereby certify that on August 23, 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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August 23, 2021

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CERTIFICATE FOR ELECTRONIC FILING

I certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

August 23, 2021

By: */s/ Sharonmoyee Goswami*
Sharonmoyee Goswami

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, Respondents.	Docket No. 9401

STATEMENT IN SUPPORT OF RESPONDENTS' UNOPPOSED MOTION FOR LEAVE TO AMEND ANSWER TO ADD AFFIRMATIVE DEFENSES

Pursuant to Paragraph 4 of the Scheduling Order entered on April 26, 2021, Respondents hereby represent that counsel for the moving parties has conferred with Complaint Counsel by email in an effort in good faith to resolve by agreement issues raised by the motion. Complaint Counsel has informed Respondents that Complaint Counsel "will not oppose [Respondents'] Amended Answer so long as Respondents do not intend to seek additional discovery".

August 23, 2021

Respectfully submitted,

/s/ Sharonmoyee Goswami
Sharonmoyee Goswami

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
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In the Matter of Illumina, Inc., a corporation, and GRAIL, Inc., a corporation, Respondents.	Docket No. 9401

DECLARATION OF SHARONMOYEE GOSWAMI

I, Sharonmoyee Goswami, declare and state:

1. I am a partner at Cravath, Swaine & Moore LLP and counsel for Respondent Illumina, Inc ("Illumina") in this matter.

2. I make this declaration pursuant to 28 U.S.C. § 1746 in support of the Respondents' Unopposed Motion For Leave to Amend Answer to Add Affirmative Defenses.

3. Attached hereto as Exhibit A is a true and correct copy of the Proposed Amended Answer and Defenses of Respondents Illumina, Inc. and GRAIL, Inc.

4. Attached hereto as Exhibit B is a true and correct copy of a redline of the Proposed Amended Answer and Defenses of Respondents Illumina, Inc. and GRAIL, Inc. against the original Answer and Defenses of Respondents Illumina, Inc. and GRAIL, Inc.

5. Attached hereto as Exhibit C is a true and correct copy of the Order granting Defendants' Motion to Transfer Case to the Southern District of California in *FTC v. Illumina*, Case No. 1:21-cv-00873-RC, Doc. 57 (D.D.C.) on April 20, 2021.

6. Attached hereto as Exhibit D is a true and correct copy of the April 20, 2021 Letter from the parties to Chief Judge Sabraw.

7. Attached hereto as Exhibit E is a true and correct copy of the proposed case management and scheduling order filed in *FTC v. Illumina, Inc.*, Case No. 3:21-cv-00800-CAB-BGS, Doc. 87 (S.D. Cal.) on April 26, 2021.

8. Attached hereto as Exhibit F is a true and correct copy of the case management and scheduling order entered in *FTC v. Illumina, Inc.*, Case No. 3:21-cv-00800-CAB-BGS, Doc. 88 (S.D. Cal.) on April 26, 2021.

9. Attached hereto as Exhibit G is a true and correct copy of the FTC's Memorandum in Support of Plaintiff's Ex Parte Application to Dismiss the Complaint Without Prejudice filed in *FTC v. Illumina, Inc.*, Case No. 3:21-cv-00800-CAB-BGS, Doc. 120-1 (S.D. Cal.) on May 21, 2021.

10. Attached hereto as Exhibit H is a true and correct copy of Illumina and GRAIL's Opposition to FTC's Motion to Dismiss filed in *FTC v. Illumina, Inc.*, Case No. 3:21-cv-00800-CAB-BGS, Doc. 124 (S.D. Cal.) on May 26, 2021.

11. Attached hereto as Exhibit I is a true and correct copy of the Order granting the FTC's Ex Parte Application to Dismiss the Complaint Without Prejudice in *FTC v. Illumina, Inc.*, Case No. 3:21-cv-00800-CAB-BGS, Doc. 127 (S.D. Cal.) on June 1, 2021.

Dated: August 23, 2021

Respectfully submitted,

/s/ Sharonmoyee Goswami
Sharonmoyee Goswami

Exhibit A

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 **PUBLIC VERSION**

ANSWER AND DEFENSES OF RESPONDENTS ILLUMINA, INC. AND GRAIL, INC.

Pursuant to Rule 3.12 of the Federal Trade Commission's ("FTC") Rules of Practice for Adjudicative Proceedings, Respondents Illumina, Inc. ("Illumina") and GRAIL, Inc. ("GRAIL") (together, "Respondents") answer the Complaint (the "Complaint") filed by the FTC in relation to Illumina's proposed acquisition of GRAIL (the "Transaction") as follows:

PRELIMINARY STATEMENT

This case involves a transaction that, if consummated, will save tens of thousands of lives. In the United States alone, cancer kills more than 500,000 people annually. The Transaction will accelerate the development, approval and adoption of a revolutionary blood test that can simultaneously detect more than 50 cancers, over 45 of which have no approved screening test today. The test does so across all stages, including earlier stages when cancers are more likely to be cured. The FTC's challenge to the Transaction, which would deprive patients of this acceleration, is speculative and baseless. The FTC and DOJ have not successfully enjoined a vertical merger in over forty years. There is a reason for that track record. Longstanding legal precedent, agency guidelines and economic literature recognize that vertical

mergers of this kind lead to efficiencies that promote consumer welfare and generally do not raise competitive concerns. The FTC's request for relief should be denied.

Illumina is a leading provider of sequencing products for genetic and genomic analyses. Its mission is to improve human health by unlocking the power of the genome. Illumina founded GRAIL five years ago with the goal of developing an early screening test for multiple cancers. In 2017, GRAIL was spun out as a standalone company to invest in the extensive, population-scale clinical trials needed to create an "atlas" of cancer signals in the blood, and the attendant state-of-the art machine learning platform to interpret those signals, enabling asymptomatic early cancer screening tests. Since the spinoff, GRAIL has developed an early screening test, Galleri, that can simultaneously screen for more than 50 cancers in asymptomatic patients who have no signs of cancer. GRAIL is also continuing to develop other tests for different patient populations. GRAIL has launched its Galleri test as a laboratory developed test in the United States in April 2021, but GRAIL is still many years from being able to commercialize Galleri at a wide scale. In short, GRAIL is a discovery and development company that has accomplished the very discovery and development goal contemplated by Illumina when it created GRAIL. Illumina stands poised to help GRAIL bring those benefits to the public as quickly and efficiently as possible.

Illumina maintains approximately a 14.5% equity stake in GRAIL and, under its existing supply agreement with GRAIL, is entitled to a percentage of GRAIL's net revenues, once GRAIL has such revenues. The transaction seeks to fully reunite Illumina and GRAIL at a critical juncture. While GRAIL has made significant progress in developing Galleri, it still faces significant hurdles, including obtaining regulatory approval, payor reimbursement and production and distribution of its test at scale. As the Complaint acknowledges, there are no

early cancer screening tests on the market today that simultaneously screen for more than one cancer. No other company has publicly disclosed a test in development that can identify such a broad range of cancers in asymptomatic patients. And Illumina is uniquely situated to use its experience and resources to accelerate the widespread adoption of GRAIL's early cancer screening test, Galleri, and reach more patients faster. The combined company will launch a new era of cancer screening, accelerating commercialization and adoption of GRAIL's transformative multi-cancer screening test. Galleri has the potential to reduce the cancer burden in the U.S. and worldwide—this Transaction thus means saving thousands of lives by reducing that burden sooner and at lower costs.

The FTC's challenge to this purely vertical transaction is hopelessly speculative. No NGS-based cancer screening tests have been launched on the market anywhere in the world. There are no "rivals" to GRAIL. The FTC's case is based entirely on speculation about what, theoretically, Illumina might be able to do to a hypothetical rival to GRAIL in the future. Even if such speculation were permitted, it would have no place here: before the FTC filed its Complaint, Illumina offered binding, irrevocable contractual commitments to all of its U.S. oncology customers, which address every one of the FTC's stated concerns. Specifically, such commitments include guarantees that:

- Under a 12-year supply agreement, customers will have uninterrupted supply of the sequencing instruments and consumables that they use;
- During that 12-year term, Illumina will not increase the price of any of the supplied sequencing instruments or consumables;
- Far from increasing the price, by 2025, Illumina will decrease the cost of sequencing on Illumina's highest throughput sequencing instrument, using the highest throughput consumable, by at least 43%, for all customers, regardless of application or use case;
- All customers shall receive "universal pricing" for any new sequencing product, and customers shall receive access to the same sequencing products at the same pricing as GRAIL under a "most-favored nations" clause;

- Illumina will not discontinue any sequencing product supplied for a 12-year term as long as the customer continues to purchase that product;

- To the extent Illumina receives confidential information from any customer, Illumina will not share that information with GRAIL;

- Illumina will provide any documentation or information reasonably required to seek FDA approval or FDA marketing authorization to sell a clinical test using the sequencing products supplied under the agreement;

- Any customer who wants to develop an *in vitro* diagnostic ("IVD") distributable kitted test using Illumina's FDA-approved instruments may enter into a separate agreement with Illumina under the standard terms in Illumina's commitments;

- An annual audit will be conducted by an independent third-party auditor confirming compliance with the terms of the supply commitments; and

- Disputes on supply terms will be adjudicated through baseball-style arbitration, and Illumina must continue to supply products to the customer during the pendency of any dispute.

These binding, irrevocable commitments are publicly available on Illumina's website[1] and open for a period of six years. Some of Illumina's largest oncology customers have signed agreements on similar terms and stated that these binding commitments address any concerns they may have had regarding the merger. The FTC received these contractual commitments prior to filing its Complaint and does not address any of the specific terms in those agreements, despite the fact that the most analogous legal authority (and the only decision involving a challenge to a vertical merger in the last 40 years) relied on similar commitments in rejecting a vertical merger challenge. *United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 241 n.51 (D.D.C. 2018) (finding that arbitration commitment "will have real world-effects" and puts the merging parties' "'money where [their] mouth is' in showing that the proposed merger, far from being aimed at

[1] https://www.illumina.com/areas-of-interest/cancer/test-terms.html?SCID=2021-270ECL5522.

'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'").

In order to prove a violation of the Clayton Act, the FTC must show that, "notwithstanding the merger's [] procompetitive effects, [it] has met its burden of proof of establishing" that the merger of Illumina and GRAIL, "at this time and in this remarkably dynamic industry, [] is likely to substantially lessen competition in the manner it predicts." *U.S. v. AT&T*, 310 F.Supp.3d 161, 194 (D.D.C. 2018). That burden is significant, especially in a case like this where the FTC's theory is speculative and the benefits of this transaction are concrete and profound: accelerating access to life-saving technology, and at lower prices. In addition, because the FTC does not contest that the proposed merger is a purely vertical transaction, the FTC "cannot use a short cut to establish a presumption of anticompetitive effect"; it must make a "fact-specific" showing that the proposed merger is anticompetitive. *United States v. AT&T, Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019). The FTC has not met its heavy burden here.

The FTC Improperly Defines the Relevant Product Markets. "Defining the relevant market is a necessary predicate to finding a Clayton Act violation." *RAG-Stiftung*, 436 F. Supp. 3d at 291. The FTC cannot meet this predicate.

First, as the Complaint acknowledges, the downstream market in which Galleri will compete is non-existent and many years from reaching commercial scale. At this early stage of its development, it is impossible to know what technologies will be deemed substitutes for non-invasive early cancer screening. Today, some tests are based on polymerase chain reaction ("PCR") technology, which amplifies DNA to detect the presence of genomic mutations and methylation changes. GRAIL's Galleri test is based on next-generation sequencing ("NGS") technology, which uses sequencing to identify changes in methylation profiles in cell-free DNA

in the blood. A variety of different technologies are expected to be used for cancer screening tests in the future, including proteomics, which identifies cancer antigens or other pathologically significant proteins in blood samples, microarray, which identifies genomic mutations and methylation changes using an orderly and specific arrangement of probes attached to solid support, and PCR. The FTC offers no factual basis to exclude these innovative technologies from the relevant market in which, years from now, multi-cancer screening tests may compete. Only five years ago, GRAIL was a newly formed subsidiary of Illumina with a moonshot goal of finding a way to detect multiple cancers early from a blood draw. The FTC has no grounds to predict that, *five-plus years from now*, other technologies, some already used today, others being developed, for cancer screening will not compete in the relevant downstream market with NGS-based multi-cancer screening tests.

Second, the FTC fails to define a relevant upstream market. It is the FTC's burden to define a relevant upstream market, and it has not even alleged one. Indeed, other clinical diagnostics platforms compete with Illumina's NGS systems as a platform for cancer screening tests, and, just as the downstream market is dynamic and evolving, so too is the upstream market—as the FTC itself alleged over a year ago in its challenge to Illumina's proposed acquisition of Pacific Biosciences of California, Inc. The FTC improperly ignores this intensifying competitive landscape.

No Vertical Foreclosure. The merger will not lead to any form of foreclosure or higher prices of any potential rival to GRAIL who is, or may become, an Illumina customer. As the FTC has recognized, the profitability of a foreclosure strategy 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.[2] Here, a foreclosure strategy would cause significant losses from reduced sales of Illumina's upstream sequencing products, and there is no basis to predict that those losses would be offset by diversion of sales of unknown future rivals to Galleri. Thus, it is implausible that Illumina would attempt any such strategy, even if it were not contractually prohibited from doing so (which it is).

Illumina's long-standing and core strategy is to catalyze development and expansion of sequencing into new applications, particularly in clinical markets. By increasing demand for sequencing tests, Illumina grows its opportunity to sell more sequencing products. Illumina's reacquisition of GRAIL is transformational for both companies. However, it does not change this strategic imperative to supply test developers with low-cost NGS products that facilitate the expansion of sequencing into emerging clinical applications such as cancer screening. Following the transaction, Illumina will continue to have powerful strategic and economic incentives to reduce the cost of sequencing and provide innovative products to all customers, regardless of whether they may compete with GRAIL in the future.

Illumina currently faces competition from rival platforms and will face increased competition in the near future. Illumina recognizes that its customers have options, and that the platform landscape is only growing more competitive. That is why Illumina has put its money where its mouth is by extending long-term contracts that prevent price increases and ensure customers receive the benefits of Illumina's upstream innovations—which Illumina would do in all events given its strategic goal to accelerate adoption of NGS testing. The hypothetical future conduct that the FTC alleges—which is impossible given those commitments—would also be

[2] 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.

incredibly damaging to Illumina's core strategy and financial incentives. Such tactics would cause significant harm to Illumina's reputation and discourage future development of tests on Illumina's platform. Further, because the cost of Illumina's sequencing products are a small—and shrinking—portion of the likely costs of future cancer screening tests, any attempt by Illumina to divert sales to GRAIL by raising any future rivals' costs would be ineffective, while still inflicting substantial reputational and financial damage on Illumina's core business.

Additionally, in evaluating vertical mergers, the FTC must show that "the merged firm will benefit significantly from responsive changes in rivals' behavior or from their lost sales" as a result of a foreclosure strategy.[3] The FTC cannot show that such "diversion" of sales in the future market in which Galleri will compete is likely. [redacted] In reality, it is impossible to know what such future tests might actually turn out to be, which cancers they might be able to screen, what patient populations they might serve, or for what uses they might be approved. What is known today is that Galleri is the only test that has demonstrated the ability to screen at least 50 cancers, and also the only test to demonstrate the capability to detect the "cancer signal of origin" to help identify the location of the cancer.

The tests alleged in the FTC's Complaint are in such early stages of development that most have not even been publicly disclosed. For example, the FTC asserts, without any supporting evidence, that [redacted]. (Compl. ¶ 49.) Yet, there is no indication [redacted]

[3] 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.

[redacted] that is remotely similar to Galleri, much less tha[redacted] According to its public disclosures, [redacted] is nothing like a generalized 50+ cancer test for population-scale screening of asymptomatic individuals who are not known to have had cancer and certainly have never been treated for cancer. The Complaint also asserts that [redacted]. (*Id.* ¶ 48.) [redacted] In developing Galleri, GRAIL has conducted multiple multi-year large-scale clinical studies, costing several hundred million dollars, and has initiated more, aimed at demonstrating the clinical value and safety of a 50+ cancer screening test that has cancer signal of origin capabilities; and GRAIL is still years from achieving scaled adoption. Given the low prevalence of cancer in asymptomatic average-risk individuals, such multi-year studies are essential to safely launch such a test. The FTC's baseless speculation that the test developers identified in the Complaint (or others) will develop close substitutes to Galleri—when none have disclosed an intent to develop a test for nearly as many cancers as Galleri much less given any public indication that they have started similar studies themselves—does not come close to satisfying the FTC's burden.

In fact, other tests, whenever they are developed, are likely to be differentiated from Galleri in several ways, including the number and types of cancers detected, the level of

sensitivity and specificity for different cancers, the ability or inability to detect cancer signal of origin, the indications approved by the FDA and the clinical uses for which Medicare and other coverage is available. The FTC's assertion that these tests, with very different characteristics based on what is known today, will be close substitutes to Galleri in a future market that does not yet exist is pure speculation. And, given the degree of differentiation among tests in development, there is no basis to predict that Illumina would recoup the value of its lost sales of sequencing products by selling more Galleri tests. It would make no economic sense for Illumina to sacrifice profits upstream—and cause substantial and irreversible injury to its reputation as a trusted supplier of NGS platforms—by pursuing a foreclosure strategy when it could have no confidence that the strategy would create enough incremental profits from diverted downstream sales to offset such damage to its core business. And, in any event, Illumina has contractually disabled itself from pursuing such a strategy.

Illumina's Long-Term Contracts. Illumina has addressed every one of the FTC's alleged harms by making binding contractual commitments to all of its U.S. oncology customers. The Complaint alleges three ways in which Illumina purportedly could harm future downstream rivals: raising their prices for NGS products, impeding their research and development efforts, and refusing or delaying the execution of an IVD agreement. Compl. ¶ 11. Illumina's long-term commitments, summarized above, address all of these concerns. In the Complaint, the FTC merely asserts that supply agreements "cannot account for each and every current and future" foreclosure method (Complaint ¶ 70), ignoring that the commitments Illumina has made in fact address ***each and every*** method alleged in the Complaint, and provide even more protections to current or future oncology customers.

The Complaint also ignores that [redacted]

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

The few customers that appear to have voiced objections to the transaction are not credible; [redacted] Such baseless objections offer no support to the FTC's speculative claims and must be disregarded.

The Merger Will Produce Enormous Procompetitive Effects. While the FTC's allegations of harm are speculative and improbable, the procompetitive benefits arising from the reunion of Illumina and GRAIL are certain to be realized and substantial. Most critically, the transaction will enable GRAIL to get its life-saving test to more patients, in the U.S. and globally, more quickly, and at lower prices than GRAIL could achieve absent the transaction. The impact of such acceleration and price reductions cannot be overstated—tens of thousands of additional lives will be saved, and there will be substantial cost savings for consumers and healthcare systems, because of the merger. This acceleration will also pave the way for other test developers to obtain regulatory approvals, reimbursement and adoption of NGS-based multi-cancer screening tests. The merger will thus save lives and encourage innovation in cancer screening.

These important benefits arise from a number of merger-specific efficiencies, including:

- Accelerating FDA Approval and Medicare Reimbursement. Despite GRAIL's progress in developing Galleri, it still faces the challenge of obtaining FDA approval. Indeed, FDA approval will be an enormous undertaking, and GRAIL on its own could readily hit speedbumps that result in delays of several months or even years. Illumina brings significant regulatory and quality resources with deep experience in obtaining FDA approval for clinical diagnostic products. Illumina will be able to leverage these resources to accelerate GRAIL's submission activities, minimize the chance of error, and speed up FDA review time to result in earlier approval for Galleri. Moreover, because it is unlikely that Galleri will be able to obtain Medicare coverage without FDA approval, accelerating FDA approval will accelerate Medicare coverage, which is critical for Galleri to achieve widespread adoption in the U.S.

- Accelerating Private Insurance Reimbursement. Illumina has extensive experience obtaining reimbursement for NGS-based products, and has set the standard in value-based healthcare through partnerships with insurers for clinical tests. GRAIL has no such experience. Illumina will leverage its capabilities to accelerate obtaining reimbursement for GRAIL's tests from private insurers. [redacted] This will *vastly* accelerate access to Galleri for U.S. consumers.

- Speed to Scale. Illumina has the global operational infrastructure and experience operating regulated manufacturing and laboratory facilities to assist GRAIL in commercializing its tests at scale, in compliance with the quality and safety standards required by regulators. Illumina's operational and commercial infrastructure will allow GRAIL to make its test more widely available at a faster rate and at lower costs.

- Elimination of Double Marginalization ("EDM"). Absent the transaction, Illumina and GRAIL would each separately charge a mark-up over their costs, resulting in two margins (Illumina's on NGS products; GRAIL's on its tests) reflected in the price for GRAIL's tests. The merger will eliminate this double margin. Moreover, Illumina will have strong incentives to pass the resulting savings through to consumers in the form of lower prices for GRAIL's tests, which will increase output and save lives. As the FTC itself acknowledged in its Vertical Merger Guidelines, "vertical mergers often benefit consumers through the elimination of double marginalization, which tends to lessen the risks of competitive harm."[4] In addition to these standard EDM benefits, the merger will uniquely eliminate a significant royalty that GRAIL would otherwise owe Illumina on its future revenues. In combination with EDM, the savings from these efficiencies will be in excess of $2 billion over the next 10 years, which will be passed through to consumers. Thus, the merger will create an enormous opportunity to lower

[4] Federal Trade Commission *Vertical Merger Guidelines*, at 34 (June 30, 2020).

the price of Galleri far more than GRAIL would be able to absent the merger, and expand its reach to underserved communities.

- Accelerating International Expansion. GRAIL has virtually no international presence and no international expansion plans, while Illumina has boots on the ground across the globe, has platforms or tests registered in over 45 countries globally, and has substantial experience commercializing clinical tests internationally. Illumina's global footprint will significantly accelerate the availability of GRAIL's products outside the U.S. by years. Importantly, international acceleration will benefit not just the patients in those foreign jurisdictions, but also U.S. patients and the U.S. healthcare system. The diverse datasets generated from testing patients in different regions of the globe can be used as evidence of additional clinical validation as part of GRAIL's FDA submission, and to demonstrate the economic benefits of Galleri to U.S. insurers, which cover patient populations with diverse ethnic backgrounds. Thus, international acceleration will further accelerate U.S. adoption of GRAIL's tests.

- R&D Efficiencies. The combination of Illumina's expertise in sequencing-based solutions and molecular biology with GRAIL's machine learning capabilities and repository of clinical data will help accelerate new breakthroughs in oncology and other fields. These efficiencies are important and far from speculative, as history demonstrates. When Illumina acquired Verinata Health, Inc.—through which it vertically integrated into the downstream market for NIPT—over 100,000 expectant mothers had taken Verinata's NIPT test. In a handful of cases, a signal was detected in the mother's blood that was initially believed to be a false signal indicating a genetic abnormality in the fetus. After the acquisition, scientists at Illumina gained access to and analyzed that data, discovering that the NIPT test had detected circulating tumor DNA fragments present in the mother's bloodstream. Verinata's NIPT test had, incidentally, detected cancer in the blood, albeit at a late stage. From there, Illumina set out to achieve one of the most critical goals of cancer care—detecting cancer in the blood at its earliest stages. It is from that discovery, arising from R&D efficiencies created as a result of the vertical acquisition of Verinata, that Illumina formed GRAIL.

Importantly, these critical benefits are merger-specific. GRAIL does not have the capabilities that Illumina can bring to bear to accelerate the scaled launch of GRAIL's tests. The institutional expertise, experiences and competencies that Illumina will use to aid GRAIL in its regulatory and commercialization efforts will minimize the chances of delays, and maximize the chances of accelerating wide-scale access to Galleri by U.S. consumers. Even if it were assumed that, absent the merger, GRAIL eventually could build the competencies that Illumina has developed from years of investment and experience, there is significant timing and execution risk. Illumina has those competencies already and, with the merger, GRAIL will have access to

them swiftly, which will minimize the risks of missteps and delay—and here, delay will cost lives.

Further, there is no possibility that the parties would achieve these benefits absent the merger. Illumina does not provide such services to any third party, and has no history of providing such extensive development and go-to-market services as a third-party consultant. Illumina is not involved in the development or regulatory efforts of its clinical customers in any material way. And Illumina's clinical customers, including GRAIL, do not and would not share proprietary data relating to the development or use of their tests with Illumina. Without access to such data, Illumina cannot materially assist GRAIL in its regulatory, payor and commercialization efforts. The merger is necessary to eliminate these barriers to collaboration between Illumina and GRAIL in order to unlock the enormous, life-saving efficiencies that this procompetitive reunion will create.

RESPONSE TO THE SPECIFIC ALLEGATIONS OF THE COMPLAINT

Except to the extent specifically stated herein, Respondents deny each and every allegation contained in the Complaint, including all allegations contained in headings or otherwise not contained in one of the Complaint's 81 numbered paragraphs.

The preamble to the Complaint characterizes this action and asserts legal conclusions to which no response is required; to the extent that a response is deemed necessary, Respondents state that the FTC has issued a Complaint regarding the Transaction and in all other respects denies the allegations in the first paragraph of the preamble to the Complaint.

Respondents respond to the numbered paragraphs of the Complaint as follows:

NATURE OF THE CASE

1. Respondents deny the allegations in Paragraph 1.

2. Respondents deny the allegations in Paragraph 2, and state that GRAIL's Galleri test for early-cancer screening for asymptomatic patients is poised to revolutionize how cancer is detected and treated, and has the potential to save millions of lives in the United States and around the world; cancer is the second leading cause of death in the United States, and healthcare providers currently are able to screen for only a small number of cancer types; doctors currently lack the option to broadly screen for multiple types of cancer simultaneously using a single test and certain cancers are only detected after patients exhibit symptoms, when it is often too late to treat the cancer effectively.

3. Respondents deny the allegations in Paragraph 3, and state that GRAIL's Galleri test for early-cancer screening for asymptomatic patients uses a "liquid biopsy" process to examine fragments of DNA in the bloodstream; as part of certain testing workflows, a phlebotomist may collect a blood sample from a patient and that blood sample may be tested in a laboratory, which, for the current version of the Galleri test, would analyze the sample using an NGS platform; an NGS platform may include the NGS instruments and designated consumables used for sequencing, such as flow cells; an NGS platform can identify the order of the component blocks—called nucleotides—in the DNA sample and Galleri uses NGS to identify the methylation patterns in the DNA fragments in the bloodstream to identify whether a cancer signal is present in the body and potentially the "cancer signal of origin" to help identify the location of the cancer. Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 as they relate to any other person or entity.

4. Respondents deny the allegations in Paragraph 4, and state that GRAIL is working to develop and commercialize its Galleri test for early-cancer screening for asymptomatic patients; GRAIL has launched its Galleri test as a laboratory developed test in the

United States in April 2021 in limited commercial channels; Galleri is a test that seeks to shift the cancer paradigm by simultaneously screening for multiple cancers, including those not screened for today, using blood samples; Illumina recognizes the life-saving benefits of GRAIL's tests and estimates that it will save thousands of lives each year; GRAIL views Galleri as a major advancement in the war against cancer. Respondents further state that the FTC purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents. Respondents further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 as they relate to any other person or entity.

5. Respondents deny the allegations in Paragraph 5, and state that GRAIL is an Illumina NGS customer; that some other companies that have publicly stated that they are developing oncology tests are also Illumina NGS customers and that GRAIL's Galleri test for early cancer screening for asymptomatic patients uses Illumina's NGS platform to sequence DNA found in the bloodstream, known as cell-free DNA or "cfDNA", to determine whether a cancer signal is present in the body and potentially the "cancer signal of origin" for the identified cancer. Respondents further state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

6. Respondents deny the allegations in Paragraph 6, and state that Illumina is a provider of NGS platforms, which are used for a wide array of applications. Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

7. Respondents deny the allegations in Paragraph 7, and state that Illumina formed GRAIL in 2015 with the purpose of enabling the early screening of cancer in asymptomatic individuals; in 2015 Illumina identified cancer screening as [redacted] and [redacted], which is memorialized in certain agreements, and Respondents refer to the underlying agreements for their contents. Respondents further state that the FTC purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents.

8. Respondents deny the allegations in Paragraph 8, and state that two years after forming GRAIL, Illumina reduced its ownership interest to below 20% of the voting rights in the company and that today Illumina owns approximately 14.5% of GRAIL's voting shares; other investors, including Johnson & Johnson and entities affiliated with Bill Gates, Jeff Bezos and Amazon hold voting shares in GRAIL; since reducing its stake in GRAIL, [redacted], and Respondents refer to the underlying agreements for their contents.

9. Respondents deny the allegations in Paragraph 9, and state that GRAIL is developing a revolutionary blood test that can simultaneously detect more than 50 cancers, over 45 of which have no approved screening test today, in asymptomatic individuals; [redacted]; GRAIL has launched its Galleri test as a laboratory developed test in the United States in April 2021 in limited commercial channels and GRAIL anticipates submitting an application for single-site premarket approval with the U.S. Food and Drug Administration ("FDA") for Galleri.

10. Respondents deny the allegations in Paragraph 10, and state that Illumina has recognized that cancer screening is [redacted] with a

projected market size of tens of billions of dollars by 2035 and that [redacted]. Respondents further state that the FTC purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents. Respondents further state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

11. Respondents deny the allegations in Paragraph 11, and state that the FTC purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents. Respondents further state that, following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its sequencing products low and to provide innovative products to all customers.

12. Respondents deny the allegations in Paragraph 12, and state that Illumina benefits from selling NGS platforms and consumables to all testing companies that use such products, and may profit, in the future, from sales of GRAIL's tests, including its early cancer screening test, Galleri. Respondents state that the FTC purports to reference unidentified written materials and refer to the referenced unidentified written materials for their contents. Respondents further state that, following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its sequencing products low and to provide innovative products to all customers.

13. Respondents deny the allegations in Paragraph 13.

14. Respondents deny the allegations in Paragraph 14, and state that the FTC purports to quote from unidentified written materials and refer to the referenced unidentified written material for their contents.

15. Respondents deny the allegations in Paragraph 15.

16. Respondents deny the allegations in Paragraph 16, and state that the merger will result in substantial merger-specific efficiencies and other procompetitive effects that will directly benefit consumers and that these benefits greatly outweigh any and all alleged anticompetitive effects.

JURISDICTION

17. Respondents state that because Paragraph 17 states conclusions or characterizations of law, no response is required. To the extent a response is required, Respondents deny the allegations in Paragraph 17, except refer to Section 4 of the FTC Act, and Section 1 of the Clayton Act, 15 U.S.C. § 12, for their contents.

18. Respondents state that because Paragraph 18 states conclusions or characterizations of law, no response is required. To the extent a response is required, Respondents deny the allegations in Paragraph 18, except refer to Section 7 of the Clayton Act, 15 U.S.C. § 18 for their contents.

THE PARTIES AND THE PROPOSED ACQUISITION

19. Respondents deny the allegations in Paragraph 19 and state that the Federal Trade Commission is an agency of the United States government and refer to the FTC Act, 15 U.S.C. § 41, Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45 for their contents.

20. Respondents deny the allegations in Paragraph 20, and state that Illumina is a publicly-traded Delaware corporation, headquartered in San Diego, California; Illumina develops, manufactures, and markets life sciences tools and integrated systems for the large-scale analysis of genetic variation and function; founded in 1998, Illumina's main product offerings are NGS systems and the associated consumables; Illumina's NGS platforms are used for DNA

sequencing; in the United States, Illumina sells NGS platforms used for DNA sequencing; Illumina's platforms are used by GRAIL and are used by other companies that may be developing tests using NGS products sold by Illumina and in 2020, Illumina earned $3.24 billion in revenue worldwide, 49 percent of which was from U.S. sales.

21. Respondents deny the allegations in Paragraph 21, and state that Defendant, GRAIL, is a private diagnostics company, headquartered in Menlo Park, California; GRAIL develops oncology tests, with a focus on early cancer screening; GRAIL's development pipeline includes three NGS-based oncology tests: Galleri, a test that screens for early signs of cancer in asymptomatic patients; a diagnostic aid to cancer ("DAC") test, which helps confirm cancer diagnoses in patients suspected to have cancer or other symptoms; and a minimal residual disease ("MRD") test, designed to assess cancer recurrence after a patient has already undergone treatment; today, GRAIL has no revenue and has raised approximately $2 billion in private funding since 2016.

22. Respondents deny the allegations in Paragraph 22, and state that GRAIL is developing a revolutionary blood test that can simultaneously detect more than 50 cancers, over 45 of which have no approved screening test today, in asymptomatic individuals. Respondents further state that [redacted] GRAIL has launched its Galleri test as a laboratory developed test in the United States in April 2021 in limited commercial channels; GRAIL anticipates submitting an application for single-site premarket approval with the FDA for Galleri and [redacted]

23. Respondents deny the allegations in Paragraph 23, and state that GRAIL was originally formed by Illumina in 2015; starting in 2017, Illumina reduced its ownership of

GRAIL to below 20 percent of the company's voting interest; currently, Illumina retains approximately 14.5 percent ownership of GRAIL's voting shares and on September 20, 2020, Illumina entered into an Agreement and Plan of Merger to acquire the approximately 85.5 percent of GRAIL voting shares outstanding that it does not already own for cash and stock consideration valued on March 4, 2021 at approximately $7 billion and, at the election of GRAIL stockholders and holders of GRAIL equity awards, either contingent rights to receive revenue share payments or additional stock consideration.

INDUSTRY BACKGROUND

24. Respondents deny the allegations in Paragraph 24 and state that cancer is the second leading cause of death in the world; in 2020, nearly two million new cases of cancer were diagnosed in the United States and over six hundred thousand Americans died from the disease; certain cancers are detected only after a patient exhibits symptoms, when the tumor has grown and the cancer has often metastasized, or spread, to other parts of the body and at an advanced stage, after the cancer has progressed to stages 3 or 4, it is frequently too late for effective treatment and, unfortunately, the patient often dies from the disease.

25. Respondents deny the allegations in Paragraph 25 and state that the U.S. Preventive Services Task Force ("USPSTF") provides recommendations for more cancers than are listed in this paragraph, that cancers without screening tests may go undetected, and in some cases, this may lead to worse treatment options and prognoses.

26. Respondents deny the allegations in Paragraph 26, and state that GRAIL is researching, designing and working to commercialize products that seek to shift the cancer screening paradigm; if successful, Galleri is designed to simultaneously screen for multiple cancers, including cancers that are not screened for at all today in asymptomatic patients, using blood samples; Galleri compares the methylation patterns in the DNA fragments in the patients'

blood samples with a database of known methylation patterns that suggest the presence of cancer; for Galleri, additional clinical data can help improve test performance. Respondents further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations that relate to any other person or entity in Paragraph 26.

27. Respondents deny the allegations in Paragraph 27.

28. Respondents deny the allegations in Paragraph 28 and state that test developers may seek to market IVD tests either as laboratory-developed tests, which do not require FDA approval, or after obtaining premarket approval from the FDA, either as a single-site PMA or a PMA for a distributed, kitted test; laboratory-developed tests and single-site PMA tests are performed in a test supplier's own laboratory. Respondents further state that the FTC purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents.

29. Respondents deny the allegations in Paragraph 29, and state that GRAIL's Galleri test for early cancer screening for asymptomatic patients uses NGS platforms and consumables to identify methylation patterns in DNA consistent with the presence of cancer and Galleri uses Illumina's NGS platform and sequencing reagents. Respondents further state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity in Paragraph 29.

30. Respondents deny the allegations in Paragraph 30, and state that GRAIL is an Illumina NGS customer and that some other companies that have publicly stated that they are developing oncology tests are also Illumina's NGS customers. Respondents further state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 30.

THE ALLEGED RELEVANT ANTITRUST MARKET IS MCED TESTS

31. Respondents state that because Paragraph 31 states conclusions or characterizations of law, no response is required. To the extent a response is required, Respondents deny the allegations in Paragraph 31.

32. Respondents deny the allegations in Paragraph 32 and state that GRAIL's Galleri test for early cancer screening for asymptomatic patients is being designed to detect multiple types of early stage cancer in asymptomatic individuals; cfDNA that comes from cancerous cells is referred to as circulating tumor DNA or "ctDNA" and Galleri, involves the analysis of ctDNA using an NGS platform, and is designed to screen for cancer before a patient manifests any symptoms. Respondents further state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 32.

33. Respondents deny the allegations in Paragraph 33, and state that certain cancers, including pancreatic, liver and stomach cancer, are typically only detected after patients have more advanced cancer (after exhibiting symptoms), which is often too late to treat the cancer effectively; that GRAIL's Galleri test for early-cancer screening for asymptomatic patients can screen for multiple types of cancer by looking at methylation patterns consistent with a cancer signal. When a cancer signal is detected, the test can determine the cancer signal of origin for the identified cancer. Respondents further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 33.

34. Respondents deny the allegations in Paragraph 34, and state that polymerase chain reaction ("PCR") technology can be used to look for changes in a gene or chromosome.

35. Respondents deny the allegations in Paragraph 35, and state that GRAIL's Galleri test for early-cancer screening for asymptomatic patients can improve patient compliance. Respondents further state that the FTC purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents.

36. Respondents deny the allegations in Paragraph 36, and state that a tissue biopsy requires the removal of a tissue sample from a patient to analyze and that some tumors are inaccessible for biopsy and others do not provide sufficient tissue to elicit conclusive results.

37. Respondents state that because Paragraph 37 states conclusions or characterizations of law, no response is required. To the extent a response is required, Respondents deny the allegations in Paragraph 37.

38. Respondents deny the allegations in Paragraph 38.

39. Respondents deny the allegations in Paragraph 39. Respondents further state that the FTC purports to quote from GRAIL's amended Form S-1 Registration Statement and refer to that document for its contents.

40. Respondents deny the allegations in Paragraph 40, and state that Illumina has recognized that cancer screening is [redacted] with a projected market size of tens of billions of dollars by 2035 and that GRAIL projects Galleri could earn [redacted]. Respondents further state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity and that the FTC purports to quote from unidentified written materials and Respondents refer to the referenced unidentified written materials for their contents.

41. Respondents deny the allegations in Paragraph 41, and state that GRAIL uses data collected from clinical trials measuring the performance of Galleri to improve the quality of the Galleri test; GRAIL also uses Illumina's NGS platform to perform its test and certain other companies that have stated that they are developing tests are also Illumina NGS customers. Respondents further state that the FTC purports to quote from [redacted] and refer to the referenced document for its contents. Respondents further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

42. Respondents deny the allegations in Paragraph 42, and state that GRAIL is developing a revolutionary blood test that can simultaneously detect more than 50 cancers, over 45 of which have no approved screening test today; GRAIL has launched its Galleri test as a laboratory developed test in the United States in April 2021 in limited commercial channels and [redacted].

43. Respondents deny the allegations in Paragraph 43, and state that [redacted] and state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

44. Respondents deny the allegations in Paragraph 44, and state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

45. Respondents deny the allegations in Paragraph 45, and state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

46. Respondents deny the allegations in Paragraph 46, and state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

47. Respondents deny the allegations in Paragraph 47, and state that Illumina's internal projections reflect that no other multi-cancer screening test for use in asymptomatic patients will launch this year. Respondents further state that GRAIL is developing a revolutionary blood test that can simultaneously detect more than 50 cancers, over 45 of which have no approved screening test today, and that GRAIL has launched its Galleri test as a laboratory developed test in the United States in April 2021 in limited commercial channels.

ALLEGED ANTICOMPETITIVE EFFECTS

48. Respondents state that because Paragraph 48 states conclusions or characterizations of law, no response is required. To the extent a response is required, Respondents deny the allegations in Paragraph 48, except refer to the Vertical Merger Guidelines for their contents.

49. Respondents deny the allegations in Paragraph 49, and state that GRAIL uses Illumina's NGS platform to research and develop its tests and certain other companies that have stated that they are developing tests are also Illumina NGS customers. Respondents further state that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers. Illumina's commitments guarantee that, *inter alia*, (i) during the 12-year term of the supply agreement, Illumina will not increase the price of any of the sequencing instruments and consumables used by an oncology customer; (ii) any customer who wants to develop an *in vitro* diagnostic ("IVD") kitted test using Illumina's FDA-approved instrument may enter into an

agreement under the standard terms and (iii) Illumina will provide any documentation or information reasonably required for a customer to seek FDA marketing authorization to sell a clinical test using Illumina's sequencing instruments and consumables.

50. Respondents deny the allegations in Paragraph 50, and state that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers. Illumina's commitments guarantee that, *inter alia*, (i) during the 12-year term of the supply agreement, Illumina will not increase the price of any of the sequencing instruments and consumables used by an oncology customer; and (ii) customers will have uninterrupted supply of the sequencing instruments and consumables that they use.

51. Respondents deny the allegations in Paragraph 51, and state that GRAIL uses a sequencing platform to analyze methylation patterns in DNA fragments.

52. Respondents deny the allegations in Paragraph 52.

53. Respondents deny the allegations in Paragraph 53, and state that certain NGS platforms can be used for de novo whole-genome sequencing or detecting large structural rearrangements.

54. Respondents deny the allegations in Paragraph 54.

55. Respondents deny the allegations in Paragraph 55 and state that Illumina provides NGS platforms in the United States; Illumina offers a suite of NGS platforms and Illumina's NGS platform portfolio offers high throughput, competitive costs and high accuracy rates.

56. Respondents deny the allegations in Paragraph 56, and state that Thermo Fisher is an NGS platform manufacturer in the United States. Respondents are without knowledge or

information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity. Respondents state that the FTC purports to quote and/or reference unidentified written materials and refer to the referenced unidentified written materials for their contents.

57. Respondents deny the allegations in Paragraph 57, and state that BGI is an NGS platform provider. Respondents further state that the FTC purports to refer to separate, ongoing litigation and refer to the court records in *Illumina, Inc. v. BGI Genomics Co., Ltd.*, 19-CV-03770-WHO and *Illumina Inc. v. BGI Genomics Co., Ltd.*, 20-CV-01465-WHO for their contents.

58. Respondents deny the allegations in Paragraph 58, and state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 58.

59. Respondents deny the allegations in Paragraph 59.

60. Respondents deny the allegations in Paragraph 60, and state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 60.

61. Respondents deny the allegations in Paragraph 61, and state that the FTC purports to refer to separate litigation and refer to the court records in *Illumina, Inc. v. Qiagen, N.V.*, 3:16-cv-02788-WHA, *Illumina, Inc. v. BGI Genomics Co., Ltd.*, 19-CV-03770-WHO and *Illumina Inc. v. BGI Genomics Co., Ltd.*, 20-CV-01465-WHO for their contents. Respondents further state that Qiagen has purported to design around Illumina's valid patents and relaunched its NGS platform in the United States and are otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 61.

62. Respondents deny the allegations in Paragraph 62, and state that some firms are attempting to develop NGS platforms and that test developers can and have switched platforms which may require re-validation. Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 62.

63. Respondents deny the allegations in Paragraph 63, and state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers and that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers. Illumina's commitments guarantee that, *inter alia*, during the 12-year term of the supply agreement, Illumina will not increase the price of any of the sequencing instruments and consumables used by an oncology customer.

64. Respondents deny the allegations in Paragraph 64, and state that when Illumina releases new updates to its NGS platforms, its latest technology is typically cheaper, more accurate and has a higher throughput than past versions of Illumina's NGS platforms, and Illumina's NovaSeq platform's scalable output generates up to tens of billions of reads and up to multiple terabases of sequences in dual flow cell mode. Respondents further state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers and that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers.

65. Respondents deny the allegations in Paragraph 65, and state that a test developer may submit an application seeking pre-market approval from the FDA to market a distributed version of an IVD test. Respondents further state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers and that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers. Illumina's commitments guarantee that, *inter alia*, any customer who wants to develop an IVD kitted test using Illumina's FDA-approved instrument may enter into an agreement under the standard terms.

66. Respondents deny the allegations in Paragraph 66, and state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers.

67. Respondents deny the allegations in Paragraph 67, and state that GRAIL uses Illumina's NGS platforms; that Illumina negotiates and interacts with those test developers and that a customer may seek advice from an Illumina customer sales representative as to which reagents it should purchase. Respondents further state that the FTC's quotation from unidentified written material is taken out of context and is misleading. Respondents further state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers.

68. Respondents deny the allegations in Paragraph 68. Respondents further state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers.

Respondents further state that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers.

69. Respondents deny the allegations in Paragraph 69, and state that the FTC's quotation from unidentified written material is taken out of context and is misleading. Respondents further state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers. Respondents further state that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers.

70. Respondents deny the allegations in Paragraph 70, and state that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers.

71. Respondents deny the allegations in Paragraph 71, and state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers. Respondents further state that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers.

72. Respondents deny the allegations in Paragraph 72, and state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 72.

73. Respondents deny the allegations in Paragraph 73, and state that GRAIL has launched its Galleri test as a laboratory developed test in the United States in April 2021.

74. Respondents deny the allegations in Paragraph 74.

75. Respondents deny the allegations in Paragraph 75.

76. Respondents deny the allegations in Paragraph 76, and state that Illumina has recognized that cancer screening is [redacted] with a projected market size of tens of billions of dollars by 2035 and that GRAIL projects [redacted]. Respondents further state that the FTC purports to quote and/or reference unidentified written materials and refer to the referenced unidentified written materials for their contents. Respondents further state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers.

ALLEGED ABSENCE OF COUNTERVAILING FACTORS

77. Respondents deny the allegations in Paragraph 77, and state that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers and that the merger will result in substantial merger-specific efficiencies, synergies and other procompetitive effects that will directly benefit consumers and that these benefits greatly outweigh any and all alleged anticompetitive effects.

78. Respondents deny the allegations in Paragraph 78, and state that the FTC's quotation from unidentified written material is taken out of context and is misleading. Respondents further state that the merger will result in substantial merger-specific efficiencies, synergies and other procompetitive effects that will directly benefit consumers and that these benefits greatly outweigh any and all alleged anticompetitive effects.

ALLEGED VIOLATION

COUNT I – ALLEGED ILLEGAL ACQUISITION

79. Respondents state that a separate response to paragraphs 1 through 79 is not required. To the extent that a separate response is required, Respondents incorporate their responses to paragraphs 1 through 79 as though fully stated herein.

80. Respondents deny the allegations in Paragraph 80 and further state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers. Illumina's proposed offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers. The merger will result in substantial merger-specific efficiencies, synergies and other procompetitive effects that will directly benefit consumers and will greatly outweigh any and all alleged anticompetitive effects.

81. Respondents state that because Paragraph 81 states conclusions or characterizations of law, no response is required. To the extent a response is required, Respondents deny the allegations in Paragraph 81.

DEFENSES

Respondents assert the following defenses, without assuming the burden of proof on such defenses that would otherwise rest with the FTC.

1. The Complaint fails to state a claim on which relief can be granted.

2. The combination of Respondents' businesses will be procompetitive. The merger will result in substantial merger-specific efficiencies, cost synergies and other procompetitive effects that will directly benefit consumers. These benefits greatly outweigh any and all alleged anticompetitive effects.

3. The FTC's claims are too speculative to support any claim on which relief can be granted.

4. Illumina's offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers.

5. The FTC has failed to define any appropriate relevant market or markets.

6. The FTC has failed to establish that Respondents exercise market power with respect to any relevant market.

7. The FTC's claim reflects improper selective enforcement of the antitrust laws.

8. The FTC's claim is barred in whole or in part by failure to show any plausible harm to consumers or consumer welfare or any plausible anticompetitive effect.

9. The customers at issue in the Complaint have a variety of tools to ensure that they receive competitive pricing and terms.

10. The FTC fails to allege a time frame for the alleged anticompetitive effects.

11. The relief that the FTC seeks is inconsistent with the public interest. The public interest favors consummation of the Transaction and alternative remedies are available to the Commission.

12. These proceedings are invalid because the constraints on removal of the Commissioners violate Article II of the Constitution and the separation of powers.

13. These proceedings are invalid because the constraints on removal of the Administrative Law Judge violate Article II of the Constitution and the separation of powers.

14. These proceedings are invalid because adjudication of the Complaint by the Administrative Law Judge and the Commission in turn violates Article III of the Constitution and the separation of powers.

15. These proceedings are invalid because adjudication of the Complaint by the Administrative Law Judge and the Commission in turn violates the right to due process of law under the Fifth Amendment to the Constitution, which requires a neutral decision-maker.

16. These proceedings violate the right to due process under the Fifth Amendment to the Constitution, which requires equal protection of the laws, because the federal government seeks to enforce antitrust laws against other parties by bringing civil actions in federal district courts.

Respondents reserve the right to assert any other available defenses.

NOTICE

Respondents state that the Notice of the Complaint is a restatement of the rules of the FTC to which no response is required. To the extent a response is required, Respondents deny the allegations in the Notice of the Complaint except state that the FTC has provided notice of a hearing date on August 24, 2021.

NOTICE OF CONTEMPLATED RELIEF

Respondents state that the Notice of Contemplated Relief is a restatement of the rules of the FTC to which no response is required. To the extent a response is required, Respondents deny the allegations in the Notice of Contemplated Relief.

Respondents respectfully request that the Court: (i) deny the FTC's requested relief; (ii) dismiss the Complaint in its entirety with prejudice; (iii) award to Respondents their costs of suit, including expert fees and reasonable attorneys' fees, as may be allowed by law; and (iv) award to Respondents such other and further relief as the Court deems just and appropriate.

Dated: August 23, 2021

Respectfully submitted,

/*s*/ Christine A. Varney

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Exhibit B

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 **NON-PUBLIC VERSION**

ANSWER AND DEFENSES OF RESPONDENTS ILLUMINA, INC. AND GRAIL, INC.

Pursuant to Rule 3.12 of the Federal Trade Commission's ("FTC") Rules of Practice for Adjudicative Proceedings, Respondents Illumina, Inc. ("Illumina") and GRAIL, Inc. ("GRAIL") (together, "Respondents") answer the Complaint (the "Complaint") filed by the FTC in relation to Illumina's proposed acquisition of GRAIL (the "Transaction") as follows:

PRELIMINARY STATEMENT

This case involves a transaction that, if consummated, will save tens of thousands of lives. In the United States alone, cancer kills more than 500,000 people annually. The Transaction will accelerate the development, approval and adoption of a revolutionary blood test that can simultaneously detect more than 50 cancers, over 45 of which have no approved screening test today. The test does so across all stages, including earlier stages when cancers are more likely to be cured. The FTC's challenge to the Transaction, which would deprive patients of this acceleration, is speculative and baseless. The FTC and DOJ have not successfully enjoined a vertical merger in over forty years. There is a reason for that track record.

Longstanding legal precedent, agency guidelines and economic literature recognize that vertical mergers of this kind lead to efficiencies that promote consumer welfare and generally do not raise competitive concerns. The FTC's request for relief should be denied.

Illumina is a leading provider of sequencing products for genetic and genomic analyses. Its mission is to improve human health by unlocking the power of the genome. Illumina founded GRAIL five years ago with the goal of developing an early screening test for multiple cancers. In 2017, GRAIL was spun out as a standalone company to invest in the extensive, population-scale clinical trials needed to create an "atlas" of cancer signals in the blood, and the attendant state-of-the art machine learning platform to interpret those signals, enabling asymptomatic early cancer screening tests. Since the spinoff, GRAIL has developed an early screening test, Galleri, that can simultaneously screen for more than 50 cancers in asymptomatic patients who have no signs of cancer. GRAIL is also continuing to develop other tests for different patient populations. GRAIL has launched its Galleri test as a laboratory developed test in the United States in April 2021, but GRAIL is still many years from being able to commercialize Galleri at a wide scale. In short, GRAIL is a discovery and development company that has accomplished the very discovery and development goal contemplated by Illumina when it created GRAIL. Illumina stands poised to help GRAIL bring those benefits to the public as quickly and efficiently as possible.

Illumina maintains approximately a 14.5% equity stake in GRAIL and, under its existing supply agreement with GRAIL, is entitled to a percentage of GRAIL's net revenues, once GRAIL has such revenues. The transaction seeks to fully reunite Illumina and GRAIL at a critical juncture. While GRAIL has made significant progress in developing Galleri, it still faces significant hurdles, including obtaining regulatory approval, payor reimbursement and

production and distribution of its test at scale. As the Complaint acknowledges, there are no early cancer screening tests on the market today that simultaneously screen for more than one cancer. No other company has publicly disclosed a test in development that can identify such a broad range of cancers in asymptomatic patients. And Illumina is uniquely situated to use its experience and resources to accelerate the widespread adoption of GRAIL's early cancer screening test, Galleri, and reach more patients faster. The combined company will launch a new era of cancer screening, accelerating commercialization and adoption of GRAIL's transformative multi-cancer screening test. Galleri has the potential to reduce the cancer burden in the U.S. and worldwide—this Transaction thus means saving thousands of lives by reducing that burden sooner and at lower costs.

The FTC's challenge to this purely vertical transaction is hopelessly speculative. No NGS-based cancer screening tests have been launched on the market anywhere in the world. There are no "rivals" to GRAIL. The FTC's case is based entirely on speculation about what, theoretically, Illumina might be able to do to a hypothetical rival to GRAIL in the future. Even if such speculation were permitted, it would have no place here: before the FTC filed its Complaint, Illumina offered binding, irrevocable contractual commitments to all of its U.S. oncology customers, which address every one of the FTC's stated concerns. Specifically, such commitments include guarantees that:

- **Under a 12-year supply agreement, customers will have uninterrupted supply of the sequencing instruments and consumables that they use;**

- **During that 12-year term, Illumina will not increase the price of any of the supplied sequencing instruments or consumables;**

- **Far from increasing the price, by 2025, Illumina will decrease the cost of sequencing on Illumina's highest throughput sequencing instrument, using the highest throughput consumable, by at least 43%, for all customers, regardless of application or use case;**

- **All customers shall receive "universal pricing" for any new sequencing product, and customers shall receive access to the same sequencing products at the same pricing as GRAIL under a "most-favored nations" clause;**

- **Illumina will not discontinue any sequencing product supplied for a 12-year term as long as the customer continues to purchase that product;**

- **To the extent Illumina receives confidential information from any customer, Illumina will not share that information with GRAIL;**

- **Illumina will provide any documentation or information reasonably required to seek FDA approval or FDA marketing authorization to sell a clinical test using the sequencing products supplied under the agreement;**

- **Any customer who wants to develop an *in vitro* diagnostic ("IVD") distributable kitted test using Illumina's FDA-approved instruments may enter into a separate agreement with Illumina under the standard terms in Illumina's commitments;**

- **An annual audit will be conducted by an independent third-party auditor confirming compliance with the terms of the supply commitments; and**

- **Disputes on supply terms will be adjudicated through baseball-style arbitration, and Illumina must continue to supply products to the customer during the pendency of any dispute.**

These binding, irrevocable commitments are publicly available on Illumina's website[1] and open for a period of six years. Some of Illumina's largest oncology customers have signed agreements on similar terms and stated that these binding commitments address any concerns they may have had regarding the merger. The FTC received these contractual commitments prior to filing its Complaint and does not address any of the specific terms in those agreements, despite the fact that the most analogous legal authority (and the only decision involving a challenge to a vertical merger in the last 40 years) relied on similar commitments in rejecting a vertical merger challenge. *United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 241 n.51 (D.D.C. 2018) (finding that arbitration commitment "will have real world-effects" and puts the merging

[1] https://www.illumina.com/areas-of-interest/cancer/test-terms.html?SCID=2021-270ECL5522.

parties' "'money where [their] 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'").

In order to prove a violation of the Clayton Act, the FTC must show that, "notwithstanding the merger's [] procompetitive effects, [it] has met its burden of proof of establishing" that the merger of Illumina and GRAIL, "at this time and in this remarkably dynamic industry, [] is likely to substantially lessen competition in the manner it predicts." *U.S. v. AT&T*, 310 F.Supp.3d 161, 194 (D.D.C. 2018). That burden is significant, especially in a case like this where the FTC's theory is speculative and the benefits of this transaction are concrete and profound: accelerating access to life-saving technology, and at lower prices. In addition, because the FTC does not contest that the proposed merger is a purely vertical transaction, the FTC "cannot use a short cut to establish a presumption of anticompetitive effect"; it must make a "fact-specific" showing that the proposed merger is anticompetitive. *United States v. AT&T, Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019). The FTC has not met its heavy burden here.

The FTC Improperly Defines the Relevant Product Markets. "Defining the relevant market is a necessary predicate to finding a Clayton Act violation." *RAG-Stiftung*, 436 F. Supp. 3d at 291. The FTC cannot meet this predicate.

First, as the Complaint acknowledges, the downstream market in which Galleri will compete is non-existent and many years from reaching commercial scale. At this early stage of its development, it is impossible to know what technologies will be deemed substitutes for non-invasive early cancer screening. Today, some tests are based on polymerase chain reaction ("PCR") technology, which amplifies DNA to detect the presence of genomic mutations and methylation changes. GRAIL's Galleri test is based on next-generation sequencing ("NGS")

technology, which uses sequencing to identify changes in methylation profiles in cell-free DNA in the blood. A variety of different technologies are expected to be used for cancer screening tests in the future, including proteomics, which identifies cancer antigens or other pathologically significant proteins in blood samples, microarray, which identifies genomic mutations and methylation changes using an orderly and specific arrangement of probes attached to solid support, and PCR. The FTC offers no factual basis to exclude these innovative technologies from the relevant market in which, years from now, multi-cancer screening tests may compete. Only five years ago, GRAIL was a newly formed subsidiary of Illumina with a moonshot goal of finding a way to detect multiple cancers early from a blood draw. The FTC has no grounds to predict that, *five-plus years from now*, other technologies, some already used today, others being developed, for cancer screening will not compete in the relevant downstream market with NGS-based multi-cancer screening tests.

Second, the FTC fails to define a relevant upstream market. It is the FTC's burden to define a relevant upstream market, and it has not even alleged one. Indeed, other clinical diagnostics platforms compete with Illumina's NGS systems as a platform for cancer screening tests, and, just as the downstream market is dynamic and evolving, so too is the upstream market—as the FTC itself alleged over a year ago in its challenge to Illumina's proposed acquisition of Pacific Biosciences of California, Inc. The FTC improperly ignores this intensifying competitive landscape.

No Vertical Foreclosure. The merger will not lead to any form of foreclosure or higher prices of any potential rival to GRAIL who is, or may become, an Illumina customer. As the FTC has recognized, the profitability of a foreclosure strategy 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.[2] Here, a foreclosure strategy would cause significant losses from reduced sales of Illumina's upstream sequencing products, and there is no basis to predict that those losses would be offset by diversion of sales of unknown future rivals to Galleri. Thus, it is implausible that Illumina would attempt any such strategy, even if it were not contractually prohibited from doing so (which it is).

Illumina's long-standing and core strategy is to catalyze development and expansion of sequencing into new applications, particularly in clinical markets. By increasing demand for sequencing tests, Illumina grows its opportunity to sell more sequencing products. Illumina's reacquisition of GRAIL is transformational for both companies. However, it does not change this strategic imperative to supply test developers with low-cost NGS products that facilitate the expansion of sequencing into emerging clinical applications such as cancer screening. Following the transaction, Illumina will continue to have powerful strategic and economic incentives to reduce the cost of sequencing and provide innovative products to all customers, regardless of whether they may compete with GRAIL in the future.

Illumina currently faces competition from rival platforms and will face increased competition in the near future. Illumina recognizes that its customers have options, and that the platform landscape is only growing more competitive. That is why Illumina has put its money where its mouth is by extending long-term contracts that prevent price increases and ensure customers receive the benefits of Illumina's upstream innovations—which Illumina would do in all events given its strategic goal to accelerate adoption of NGS testing. The hypothetical future conduct that the FTC alleges—which is impossible given those commitments—would also be

[2] 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.

incredibly damaging to Illumina's core strategy and financial incentives. Such tactics would cause significant harm to Illumina's reputation and discourage future development of tests on Illumina's platform. Further, because the cost of Illumina's sequencing products are a small—and shrinking—portion of the likely costs of future cancer screening tests, any attempt by Illumina to divert sales to GRAIL by raising any future rivals' costs would be ineffective, while still inflicting substantial reputational and financial damage on Illumina's core business.

Additionally, in evaluating vertical mergers, the FTC must show that "the merged firm will benefit significantly from responsive changes in rivals' behavior or from their lost sales" as a result of a foreclosure strategy.[3] The FTC cannot show that such "diversion" of sales in the future market in which Galleri will compete is likely. [redacted] In reality, it is impossible to know what such future tests might actually turn out to be, which cancers they might be able to screen, what patient populations they might serve, or for what uses they might be approved. What is known today is that Galleri is the only test that has demonstrated the ability to screen at least 50 cancers, and also the only test to demonstrate the capability to detect the "cancer signal of origin" to help identify the location of the cancer.

The tests alleged in the FTC's Complaint are in such early stages of development that most have not even been publicly disclosed. For example, the FTC asserts, without any supporting evidence, that [redacted] (Compl. ¶ 49.) Yet, there is no indication [redacted]

[3] 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.

[redacted] that is remotely similar to Galleri, much less that [redacted] According to its public disclosures, [redacted] is nothing like a generalized 50+ cancer test for population-scale screening of asymptomatic individuals who are not known to have had cancer and certainly have never been treated for cancer. The Complaint also asserts that [redacted] (*Id.* ¶ 48.) [redacted] In developing Galleri, GRAIL has conducted multiple multi-year large-scale clinical studies, costing several hundred million dollars, and has initiated more, aimed at demonstrating the clinical value and safety of a 50+ cancer screening test that has cancer signal of origin capabilities; and GRAIL is still years from achieving scaled adoption. Given the low prevalence of cancer in asymptomatic average-risk individuals, such multi-year studies are essential to safely launch such a test. The FTC's baseless speculation that the test developers identified in the Complaint (or others) will develop close substitutes to Galleri—when none have disclosed an intent to develop a test for nearly as many cancers as Galleri much less given any public indication that they have started similar studies themselves—does not come close to satisfying the FTC's burden.

In fact, other tests, whenever they are developed, are likely to be differentiated from Galleri in several ways, including the number and types of cancers detected, the level of sensitivity and specificity for different cancers, the ability or inability to detect cancer signal of origin, the indications approved by the FDA and the clinical uses for which Medicare and other coverage is available. The FTC's assertion that these tests, with very different characteristics based on what is known today, will be close substitutes to Galleri in a future market that does not yet exist is pure speculation. And, given the degree of differentiation among tests in development, there is no basis to predict that Illumina would recoup the value of its lost sales of sequencing products by selling more Galleri tests. It would make no economic sense for Illumina to sacrifice profits upstream—and cause substantial and irreversible injury to its reputation as a trusted supplier of NGS platforms—by pursuing a foreclosure strategy when it could have no confidence that the strategy would create enough incremental profits from diverted downstream sales to offset such damage to its core business. And, in any event, Illumina has contractually disabled itself from pursuing such a strategy.

Illumina's Long-Term Contracts. Illumina has addressed every one of the FTC's alleged harms by making binding contractual commitments to all of its U.S. oncology customers. The Complaint alleges three ways in which Illumina purportedly could harm future downstream rivals: raising their prices for NGS products, impeding their research and development efforts, and refusing or delaying the execution of an IVD agreement. Compl. ¶ 11. Illumina's long-term commitments, summarized above, address all of these concerns. In the Complaint, the FTC merely asserts that supply agreements "cannot account for each and every current and future" foreclosure method (Complaint ¶ 70), ignoring that the commitments Illumina has made in fact

address ***each and every*** method alleged in the Complaint, and provide even more protections to current or future oncology customers.

The Complaint also ignores that [redacted]

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

The few customers that appear to have voiced objections to the transaction are not credible; [redacted] Such baseless objections offer no support to the FTC's speculative claims and must be disregarded.

The Merger Will Produce Enormous Procompetitive Effects. While the FTC's allegations of harm are speculative and improbable, the procompetitive benefits arising from the reunion of Illumina and GRAIL are certain to be realized and substantial. Most critically, the transaction will enable GRAIL to get its life-saving test to more patients, in the U.S. and globally, more quickly, and at lower prices than GRAIL could achieve absent the transaction. The impact of such acceleration and price reductions cannot be overstated—tens of thousands of additional lives will be saved, and there will be substantial cost savings for consumers and

healthcare systems, because of the merger. This acceleration will also pave the way for other test developers to obtain regulatory approvals, reimbursement and adoption of NGS-based multi-cancer screening tests. The merger will thus save lives and encourage innovation in cancer screening.

These important benefits arise from a number of merger-specific efficiencies, including:

- **Accelerating FDA Approval and Medicare Reimbursement. Despite GRAIL's progress in developing Galleri, it still faces the challenge of obtaining FDA approval. Indeed, FDA approval will be an enormous undertaking, and GRAIL on its own could readily hit speedbumps that result in delays of several months or even years. Illumina brings significant regulatory and quality resources with deep experience in obtaining FDA approval for clinical diagnostic products. Illumina will be able to leverage these resources to accelerate GRAIL's submission activities, minimize the chance of error, and speed up FDA review time to result in earlier approval for Galleri. Moreover, because it is unlikely that Galleri will be able to obtain Medicare coverage without FDA approval, accelerating FDA approval will accelerate Medicare coverage, which is critical for Galleri to achieve widespread adoption in the U.S.**

- **Accelerating Private Insurance Reimbursement. Illumina has extensive experience obtaining reimbursement for NGS-based products, and has set the standard in value-based healthcare through partnerships with insurers for clinical tests. GRAIL has no such experience. Illumina will leverage its capabilities to accelerate obtaining reimbursement for GRAIL's tests from private insurers. [redacted] This will *vastly* accelerate access to Galleri for U.S. consumers.**

- **Speed to Scale. Illumina has the global operational infrastructure and experience operating regulated manufacturing and laboratory facilities to assist GRAIL in commercializing its tests at scale, in compliance with the quality and safety standards required by regulators. Illumina's operational and commercial infrastructure will allow GRAIL to make its test more widely available at a faster rate and at lower costs.**

- **Elimination of Double Marginalization ("EDM"). Absent the transaction, Illumina and GRAIL would each separately charge a mark-up over their costs, resulting in two margins (Illumina's on NGS products; GRAIL's on its tests) reflected in the price for GRAIL's tests. The merger will eliminate this double margin. Moreover, Illumina will have strong incentives to pass the resulting savings through to consumers in the form of lower prices for GRAIL's tests, which will increase output and save lives. As the FTC itself acknowledged in its Vertical Merger Guidelines, "vertical mergers often benefit consumers**

through the elimination of double marginalization, which tends to lessen the risks of competitive harm."[4] In addition to these standard EDM benefits, the merger will uniquely eliminate a significant royalty that GRAIL would otherwise owe Illumina on its future revenues. In combination with EDM, the savings from these efficiencies will be in excess of $2 billion over the next 10 years, which will be passed through to consumers. Thus, the merger will create an enormous opportunity to lower the price of Galleri far more than GRAIL would be able to absent the merger, and expand its reach to underserved communities.

- **Accelerating International Expansion. GRAIL has virtually no international presence and no international expansion plans, while Illumina has boots on the ground across the globe, has platforms or tests registered in over 45 countries globally, and has substantial experience commercializing clinical tests internationally. Illumina's global footprint will significantly accelerate the availability of GRAIL's products outside the U.S. by years. Importantly, international acceleration will benefit not just the patients in those foreign jurisdictions, but also U.S. patients and the U.S. healthcare system. The diverse datasets generated from testing patients in different regions of the globe can be used as evidence of additional clinical validation as part of GRAIL's FDA submission, and to demonstrate the economic benefits of Galleri to U.S. insurers, which cover patient populations with diverse ethnic backgrounds. Thus, international acceleration will further accelerate U.S. adoption of GRAIL's tests.**

- **R&D Efficiencies. The combination of Illumina's expertise in sequencing-based solutions and molecular biology with GRAIL's machine learning capabilities and repository of clinical data will help accelerate new breakthroughs in oncology and other fields. These efficiencies are important and far from speculative, as history demonstrates. When Illumina acquired Verinata Health, Inc.—through which it vertically integrated into the downstream market for NIPT—over 100,000 expectant mothers had taken Verinata's NIPT test. In a handful of cases, a signal was detected in the mother's blood that was initially believed to be a false signal indicating a genetic abnormality in the fetus. After the acquisition, scientists at Illumina gained access to and analyzed that data, discovering that the NIPT test had detected circulating tumor DNA fragments present in the mother's bloodstream. Verinata's NIPT test had, incidentally, detected cancer in the blood, albeit at a late stage. From there, Illumina set out to achieve one of the most critical goals of cancer care—detecting cancer in the blood at its earliest stages. It is from that discovery, arising from R&D efficiencies created as a result of the vertical acquisition of Verinata, that Illumina formed GRAIL.**

Importantly, these critical benefits are merger-specific. GRAIL does not have the capabilities that Illumina can bring to bear to accelerate the scaled launch of GRAIL's tests. The institutional expertise, experiences and competencies that Illumina will use to aid GRAIL in its

[4] Federal Trade Commission *Vertical Merger Guidelines*, at 34 (June 30, 2020).

regulatory and commercialization efforts will minimize the chances of delays, and maximize the chances of accelerating wide-scale access to Galleri by U.S. consumers. Even if it were assumed that, absent the merger, GRAIL eventually could build the competencies that Illumina has developed from years of investment and experience, there is significant timing and execution risk. Illumina has those competencies already and, with the merger, GRAIL will have access to them swiftly, which will minimize the risks of missteps and delay—and here, delay will cost lives.

Further, there is no possibility that the parties would achieve these benefits absent the merger. Illumina does not provide such services to any third party, and has no history of providing such extensive development and go-to-market services as a third-party consultant. Illumina is not involved in the development or regulatory efforts of its clinical customers in any material way. And Illumina's clinical customers, including GRAIL, do not and would not share proprietary data relating to the development or use of their tests with Illumina. Without access to such data, Illumina cannot materially assist GRAIL in its regulatory, payor and commercialization efforts. The merger is necessary to eliminate these barriers to collaboration between Illumina and GRAIL in order to unlock the enormous, life-saving efficiencies that this procompetitive reunion will create.

RESPONSE TO THE SPECIFIC ALLEGATIONS OF THE COMPLAINT

Except to the extent specifically stated herein, Respondents deny each and every allegation contained in the Complaint, including all allegations contained in headings or otherwise not contained in one of the Complaint's 81 numbered paragraphs.

The preamble to the Complaint characterizes this action and asserts legal conclusions to which no response is required; to the extent that a response is deemed necessary,

Respondents state that the FTC has issued a Complaint regarding the Transaction and in all other respects denies the allegations in the first paragraph of the preamble to the Complaint.

Respondents respond to the numbered paragraphs of the Complaint as follows:

NATURE OF THE CASE

1. Respondents deny the allegations in Paragraph 1.

2. Respondents deny the allegations in Paragraph 2, and state that GRAIL's Galleri test for early-cancer screening for asymptomatic patients is poised to revolutionize how cancer is detected and treated, and has the potential to save millions of lives in the United States and around the world; cancer is the second leading cause of death in the United States, and healthcare providers currently are able to screen for only a small number of cancer types; doctors currently lack the option to broadly screen for multiple types of cancer simultaneously using a single test and certain cancers are only detected after patients exhibit symptoms, when it is often too late to treat the cancer effectively.

3. Respondents deny the allegations in Paragraph 3, and state that GRAIL's Galleri test for early-cancer screening for asymptomatic patients uses a "liquid biopsy" process to examine fragments of DNA in the bloodstream; as part of certain testing workflows, a phlebotomist may collect a blood sample from a patient and that blood sample may be tested in a laboratory, which, for the current version of the Galleri test, would analyze the sample using an NGS platform; an NGS platform may include the NGS instruments and designated consumables used for sequencing, such as flow cells; an NGS platform can identify the order of the component blocks—called nucleotides—in the DNA sample and Galleri uses NGS to identify the methylation patterns in the DNA fragments in the bloodstream to identify whether a cancer signal is present in the body and potentially the "cancer signal of origin" to help identify the

location of the cancer. Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 as they relate to any other person or entity.

4. Respondents deny the allegations in Paragraph 4, and state that GRAIL is working to develop and commercialize its Galleri test for early-cancer screening for asymptomatic patients; GRAIL has launched its Galleri test as a laboratory developed test in the United States in April 2021 in limited commercial channels; Galleri is a test that seeks to shift the cancer paradigm by simultaneously screening for multiple cancers, including those not screened for today, using blood samples; Illumina recognizes the life-saving benefits of GRAIL's tests and estimates that it will save thousands of lives each year; GRAIL views Galleri as a major advancement in the war against cancer. Respondents further state that the FTC purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents. Respondents further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 as they relate to any other person or entity.

5. Respondents deny the allegations in Paragraph 5, and state that GRAIL is an Illumina NGS customer; that some other companies that have publicly stated that they are developing oncology tests are also Illumina NGS customers and that GRAIL's Galleri test for early cancer screening for asymptomatic patients uses Illumina's NGS platform to sequence DNA found in the bloodstream, known as cell-free DNA or "cfDNA", to determine whether a cancer signal is present in the body and potentially the "cancer signal of origin" for the identified cancer. Respondents further state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

6. Respondents deny the allegations in Paragraph 6, and state that Illumina is a provider of NGS platforms, which are used for a wide array of applications. Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

7. Respondents deny the allegations in Paragraph 7, and state that Illumina formed GRAIL in 2015 with the purpose of enabling the early screening of cancer in asymptomatic individuals; in 2015 Illumina identified cancer screening as [redacted] and [redacted] which is memorialized in certain agreements, and Respondents refer to the underlying agreements for their contents. Respondents further state that the FTC purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents.

8. Respondents deny the allegations in Paragraph 8, and state that two years after forming GRAIL, Illumina reduced its ownership interest to below 20% of the voting rights in the company and that today Illumina owns approximately 14.5% of GRAIL's voting shares; other investors, including Johnson & Johnson and entities affiliated with Bill Gates, Jeff Bezos and Amazon hold voting shares in GRAIL; since reducing its stake in GRAIL, [redacted] and Respondents refer to the underlying agreements for their contents.

9. Respondents deny the allegations in Paragraph 9, and state that GRAIL is developing a revolutionary blood test that can simultaneously detect more than 50 cancers, over 45 of which have no approved screening test today, in asymptomatic individuals; [redacted] GRAIL has launched its Galleri test as a laboratory

developed test in the United States in April 2021 in limited commercial channels and GRAIL anticipates submitting an application for single-site premarket approval with the U.S. Food and Drug Administration ("FDA") for Galleri.

10. Respondents deny the allegations in Paragraph 10, and state that Illumina has recognized that cancer screening is [redacted] with a projected market size of tens of billions of dollars by 2035 and that [redacted] Respondents further state that the FTC purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents. Respondents further state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

11. Respondents deny the allegations in Paragraph 11, and state that the FTC purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents. Respondents further state that, following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its sequencing products low and to provide innovative products to all customers.

12. Respondents deny the allegations in Paragraph 12, and state that Illumina benefits from selling NGS platforms and consumables to all testing companies that use such products, and may profit, in the future, from sales of GRAIL's tests, including its early cancer screening test, Galleri. Respondents state that the FTC purports to reference unidentified written materials and refer to the referenced unidentified written materials for their contents. Respondents further state that, following the transaction, Illumina will continue to have strategic and economic

incentives to keep the costs of its sequencing products low and to provide innovative products to all customers.

13. Respondents deny the allegations in Paragraph 13.

14. Respondents deny the allegations in Paragraph 14, and state that the FTC purports to quote from unidentified written materials and refer to the referenced unidentified written material for their contents.

15. Respondents deny the allegations in Paragraph 15.

16. Respondents deny the allegations in Paragraph 16, and state that the merger will result in substantial merger-specific efficiencies and other procompetitive effects that will directly benefit consumers and that these benefits greatly outweigh any and all alleged anticompetitive effects.

JURISDICTION

17. Respondents state that because Paragraph 17 states conclusions or characterizations of law, no response is required. To the extent a response is required, Respondents deny the allegations in Paragraph 17, except refer to Section 4 of the FTC Act, and Section 1 of the Clayton Act, 15 U.S.C. § 12, for their contents.

18. Respondents state that because Paragraph 18 states conclusions or characterizations of law, no response is required. To the extent a response is required, Respondents deny the allegations in Paragraph 18, except refer to Section 7 of the Clayton Act, 15 U.S.C. § 18 for their contents.

THE PARTIES AND THE PROPOSED ACQUISITION

19. Respondents deny the allegations in Paragraph 19 and state that the Federal Trade Commission is an agency of the United States government and refer to the FTC Act, 15 U.S.C. §

41, Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45 for their contents.

20. Respondents deny the allegations in Paragraph 20, and state that Illumina is a publicly-traded Delaware corporation, headquartered in San Diego, California; Illumina develops, manufactures, and markets life sciences tools and integrated systems for the large-scale analysis of genetic variation and function; founded in 1998, Illumina's main product offerings are NGS systems and the associated consumables; Illumina's NGS platforms are used for DNA sequencing; in the United States, Illumina sells NGS platforms used for DNA sequencing; Illumina's platforms are used by GRAIL and are used by other companies that may be developing tests using NGS products sold by Illumina and in 2020, Illumina earned $3.24 billion in revenue worldwide, 49 percent of which was from U.S. sales.

21. Respondents deny the allegations in Paragraph 21, and state that Defendant, GRAIL, is a private diagnostics company, headquartered in Menlo Park, California; GRAIL develops oncology tests, with a focus on early cancer screening; GRAIL's development pipeline includes three NGS-based oncology tests: Galleri, a test that screens for early signs of cancer in asymptomatic patients; a diagnostic aid to cancer ("DAC") test, which helps confirm cancer diagnoses in patients suspected to have cancer or other symptoms; and a minimal residual disease ("MRD") test, designed to assess cancer recurrence after a patient has already undergone treatment; today, GRAIL has no revenue and has raised approximately $2 billion in private funding since 2016.

22. Respondents deny the allegations in Paragraph 22, and state that GRAIL is developing a revolutionary blood test that can simultaneously detect more than 50 cancers, over 45 of which have no approved screening test today, in asymptomatic individuals. Respondents

further state that [redacted] GRAIL has launched its Galleri test as a laboratory developed test in the United States in April 2021 in limited commercial channels; GRAIL anticipates submitting an application for single-site premarket approval with the FDA for Galleri and [redacted]

23. Respondents deny the allegations in Paragraph 23, and state that GRAIL was originally formed by Illumina in 2015; starting in 2017, Illumina reduced its ownership of GRAIL to below 20 percent of the company's voting interest; currently, Illumina retains approximately 14.5 percent ownership of GRAIL's voting shares and on September 20, 2020, Illumina entered into an Agreement and Plan of Merger to acquire the approximately 85.5 percent of GRAIL voting shares outstanding that it does not already own for cash and stock consideration valued on March 4, 2021 at approximately $7 billion and, at the election of GRAIL stockholders and holders of GRAIL equity awards, either contingent rights to receive revenue share payments or additional stock consideration.

INDUSTRY BACKGROUND

24. Respondents deny the allegations in Paragraph 24 and state that cancer is the second leading cause of death in the world; in 2020, nearly two million new cases of cancer were diagnosed in the United States and over six hundred thousand Americans died from the disease; certain cancers are detected only after a patient exhibits symptoms, when the tumor has grown and the cancer has often metastasized, or spread, to other parts of the body and at an advanced stage, after the cancer has progressed to stages 3 or 4, it is frequently too late for effective treatment and, unfortunately, the patient often dies from the disease.

25. Respondents deny the allegations in Paragraph 25 and state that the U.S. Preventive Services Task Force ("USPSTF") provides recommendations for more cancers than are listed in this paragraph, that cancers without screening tests may go undetected, and in some cases, this may lead to worse treatment options and prognoses.

26. Respondents deny the allegations in Paragraph 26, and state that GRAIL is researching, designing and working to commercialize products that seek to shift the cancer screening paradigm; if successful, Galleri is designed to simultaneously screen for multiple cancers, including cancers that are not screened for at all today in asymptomatic patients, using blood samples; Galleri compares the methylation patterns in the DNA fragments in the patients' blood samples with a database of known methylation patterns that suggest the presence of cancer; for Galleri, additional clinical data can help improve test performance. Respondents further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations that relate to any other person or entity in Paragraph 26.

27. Respondents deny the allegations in Paragraph 27.

28. Respondents deny the allegations in Paragraph 28 and state that test developers may seek to market IVD tests either as laboratory-developed tests, which do not require FDA approval, or after obtaining premarket approval from the FDA, either as a single-site PMA or a PMA for a distributed, kitted test; laboratory-developed tests and single-site PMA tests are performed in a test supplier's own laboratory. Respondents further state that the FTC purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents.

29. Respondents deny the allegations in Paragraph 29, and state that GRAIL's Galleri test for early cancer screening for asymptomatic patients uses NGS platforms and consumables

to identify methylation patterns in DNA consistent with the presence of cancer and Galleri uses Illumina's NGS platform and sequencing reagents. Respondents further state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity in Paragraph 29.

30. Respondents deny the allegations in Paragraph 30, and state that GRAIL is an Illumina NGS customer and that some other companies that have publicly stated that they are developing oncology tests are also Illumina's NGS customers. Respondents further state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 30.

THE ALLEGED RELEVANT ANTITRUST MARKET IS MCED TESTS

31. Respondents state that because Paragraph 31 states conclusions or characterizations of law, no response is required. To the extent a response is required, Respondents deny the allegations in Paragraph 31.

32. Respondents deny the allegations in Paragraph 32 and state that GRAIL's Galleri test for early cancer screening for asymptomatic patients is being designed to detect multiple types of early stage cancer in asymptomatic individuals; cfDNA that comes from cancerous cells is referred to as circulating tumor DNA or "ctDNA" and Galleri, involves the analysis of ctDNA using an NGS platform, and is designed to screen for cancer before a patient manifests any symptoms. Respondents further state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 32.

33. Respondents deny the allegations in Paragraph 33, and state that certain cancers, including pancreatic, liver and stomach cancer, are typically only detected after patients have

more advanced cancer (after exhibiting symptoms), which is often too late to treat the cancer effectively; that GRAIL's Galleri test for early-cancer screening for asymptomatic patients can screen for multiple types of cancer by looking at methylation patterns consistent with a cancer signal. When a cancer signal is detected, the test can determine the cancer signal of origin for the identified cancer. Respondents further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 33.

34. Respondents deny the allegations in Paragraph 34, and state that polymerase chain reaction ("PCR") technology can be used to look for changes in a gene or chromosome.

35. Respondents deny the allegations in Paragraph 35, and state that GRAIL's Galleri test for early-cancer screening for asymptomatic patients can improve patient compliance. Respondents further state that the FTC purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents.

36. Respondents deny the allegations in Paragraph 36, and state that a tissue biopsy requires the removal of a tissue sample from a patient to analyze and that some tumors are inaccessible for biopsy and others do not provide sufficient tissue to elicit conclusive results.

37. Respondents state that because Paragraph 37 states conclusions or characterizations of law, no response is required. To the extent a response is required, Respondents deny the allegations in Paragraph 37.

38. Respondents deny the allegations in Paragraph 38.

39. Respondents deny the allegations in Paragraph 39. Respondents further state that the FTC purports to quote from GRAIL's amended Form S-1 Registration Statement and refer to that document for its contents.

40. Respondents deny the allegations in Paragraph 40, and state that Illumina has recognized that cancer screening is [redacted] with a projected market size of tens of billions of dollars by 2035 and that GRAIL projects Galleri could earn [redacted] Respondents further state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity and that the FTC purports to quote from unidentified written materials and Respondents refer to the referenced unidentified written materials for their contents.

41. Respondents deny the allegations in Paragraph 41, and state that GRAIL uses data collected from clinical trials measuring the performance of Galleri to improve the quality of the Galleri test; GRAIL also uses Illumina's NGS platform to perform its test and certain other companies that have stated that they are developing tests are also Illumina NGS customers. Respondents further state that the FTC purports to quote from [redacted] and refer to the referenced document for its contents. Respondents further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

42. Respondents deny the allegations in Paragraph 42, and state that GRAIL is developing a revolutionary blood test that can simultaneously detect more than 50 cancers, over 45 of which have no approved screening test today; GRAIL has launched its Galleri test as a laboratory developed test in the United States in April 2021 in limited commercial channels and [redacted]

43. Respondents deny the allegations in Paragraph 43, and state that [redacted]

[redacted] and state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

44. Respondents deny the allegations in Paragraph 44, and state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

45. Respondents deny the allegations in Paragraph 45, and state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

46. Respondents deny the allegations in Paragraph 46, and state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity.

47. Respondents deny the allegations in Paragraph 47, and state that Illumina's internal projections reflect that no other multi-cancer screening test for use in asymptomatic patients will launch this year. Respondents further state that GRAIL is developing a revolutionary blood test that can simultaneously detect more than 50 cancers, over 45 of which have no approved screening test today, and that GRAIL has launched its Galleri test as a laboratory developed test in the United States in April 2021 in limited commercial channels.

ALLEGED ANTICOMPETITIVE EFFECTS

48. Respondents state that because Paragraph 48 states conclusions or characterizations of law, no response is required. To the extent a response is required, Respondents deny the allegations in Paragraph 48, except refer to the Vertical Merger Guidelines for their contents.

49. Respondents deny the allegations in Paragraph 49, and state that GRAIL uses Illumina's NGS platform to research and develop its tests and certain other companies that have stated that they are developing tests are also Illumina NGS customers. Respondents further state that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers. Illumina's commitments guarantee that, *inter alia*, (i) during the 12-year term of the supply agreement, Illumina will not increase the price of any of the sequencing instruments and consumables used by an oncology customer; (ii) any customer who wants to develop an *in vitro* diagnostic ("IVD") kitted test using Illumina's FDA-approved instrument may enter into an agreement under the standard terms and (iii) Illumina will provide any documentation or information reasonably required for a customer to seek FDA marketing authorization to sell a clinical test using Illumina's sequencing instruments and consumables.

50. Respondents deny the allegations in Paragraph 50, and state that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers. Illumina's commitments guarantee that, *inter alia*, (i) during the 12-year term of the supply agreement, Illumina will not increase the price of any of the sequencing instruments and consumables used by an oncology customer; and (ii) customers will have uninterrupted supply of the sequencing instruments and consumables that they use.

51. Respondents deny the allegations in Paragraph 51, and state that GRAIL uses a sequencing platform to analyze methylation patterns in DNA fragments.

52. Respondents deny the allegations in Paragraph 52.

53. Respondents deny the allegations in Paragraph 53, and state that certain NGS platforms can be used for de novo whole-genome sequencing or detecting large structural rearrangements.

54. Respondents deny the allegations in Paragraph 54.

55. Respondents deny the allegations in Paragraph 55 and state that Illumina provides NGS platforms in the United States; Illumina offers a suite of NGS platforms and Illumina's NGS platform portfolio offers high throughput, competitive costs and high accuracy rates.

56. Respondents deny the allegations in Paragraph 56, and state that Thermo Fisher is an NGS platform manufacturer in the United States. Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations as they relate to any other person or entity. Respondents state that the FTC purports to quote and/or reference unidentified written materials and refer to the referenced unidentified written materials for their contents.

57. Respondents deny the allegations in Paragraph 57, and state that BGI is an NGS platform provider. Respondents further state that the FTC purports to refer to separate, ongoing litigation and refer to the court records in *Illumina, Inc. v. BGI Genomics Co., Ltd.*, 19-CV-03770-WHO and *Illumina Inc. v. BGI Genomics Co., Ltd.*, 20-CV-01465-WHO for their contents.

58. Respondents deny the allegations in Paragraph 58, and state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 58.

59. Respondents deny the allegations in Paragraph 59.

60. Respondents deny the allegations in Paragraph 60, and state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 60.

61. Respondents deny the allegations in Paragraph 61, and state that the FTC purports to refer to separate litigation and refer to the court records in *Illumina, Inc. v. Qiagen, N.V.*, 3:16-cv-02788-WHA, *Illumina, Inc. v. BGI Genomics Co., Ltd.*, 19-CV-03770-WHO and *Illumina Inc. v. BGI Genomics Co., Ltd.*, 20-CV-01465-WHO for their contents. Respondents further state that Qiagen has purported to design around Illumina's valid patents and relaunched its NGS platform in the United States and are otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 61.

62. Respondents deny the allegations in Paragraph 62, and state that some firms are attempting to develop NGS platforms and that test developers can and have switched platforms which may require re-validation. Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 62.

63. Respondents deny the allegations in Paragraph 63, and state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers and that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers. Illumina's commitments guarantee that, *inter alia*, during the 12-year term of the

supply agreement, Illumina will not increase the price of any of the sequencing instruments and consumables used by an oncology customer.

64. Respondents deny the allegations in Paragraph 64, and state that when Illumina releases new updates to its NGS platforms, its latest technology is typically cheaper, more accurate and has a higher throughput than past versions of Illumina's NGS platforms, and Illumina's NovaSeq platform's scalable output generates up to tens of billions of reads and up to multiple terabases of sequences in dual flow cell mode. Respondents further state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers and that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers.

65. Respondents deny the allegations in Paragraph 65, and state that a test developer may submit an application seeking pre-market approval from the FDA to market a distributed version of an IVD test. Respondents further state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers and that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers. Illumina's commitments guarantee that, *inter alia*, any customer who wants to develop an IVD kitted test using Illumina's FDA-approved instrument may enter into an agreement under the standard terms.

66. Respondents deny the allegations in Paragraph 66, and state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers.

67. Respondents deny the allegations in Paragraph 67, and state that GRAIL uses Illumina's NGS platforms; that Illumina negotiates and interacts with those test developers and that a customer may seek advice from an Illumina customer sales representative as to which reagents it should purchase. Respondents further state that the FTC's quotation from unidentified written material is taken out of context and is misleading. Respondents further state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers.

68. Respondents deny the allegations in Paragraph 68. Respondents further state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers. Respondents further state that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers.

69. Respondents deny the allegations in Paragraph 69, and state that the FTC's quotation from unidentified written material is taken out of context and is misleading. Respondents further state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers. Respondents further state that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged

anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers.

70. Respondents deny the allegations in Paragraph 70, and state that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers.

71. Respondents deny the allegations in Paragraph 71, and state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers. Respondents further state that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers.

72. Respondents deny the allegations in Paragraph 72, and state that Respondents are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 72.

73. Respondents deny the allegations in Paragraph 73, and state that GRAIL has launched its Galleri test as a laboratory developed test in the United States in April 2021.

74. Respondents deny the allegations in Paragraph 74.

75. Respondents deny the allegations in Paragraph 75.

76. Respondents deny the allegations in Paragraph 76, and state that Illumina has recognized that cancer screening is [redacted] with a

projected market size of tens of billions of dollars by 2035 and that GRAIL projects [redacted] [redacted] Respondents further state that the FTC purports to quote and/or reference unidentified written materials and refer to the referenced unidentified written materials for their contents. Respondents further state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers.

ALLEGED ABSENCE OF COUNTERVAILING FACTORS

77. Respondents deny the allegations in Paragraph 77, and state that Illumina's irrevocable offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers and that the merger will result in substantial merger-specific efficiencies, synergies and other procompetitive effects that will directly benefit consumers and that these benefits greatly outweigh any and all alleged anticompetitive effects.

78. Respondents deny the allegations in Paragraph 78, and state that the FTC's quotation from unidentified written material is taken out of context and is misleading. Respondents further state that the merger will result in substantial merger-specific efficiencies, synergies and other procompetitive effects that will directly benefit consumers and that these benefits greatly outweigh any and all alleged anticompetitive effects.

ALLEGED VIOLATION

COUNT I – ALLEGED ILLEGAL ACQUISITION

79. Respondents state that a separate response to paragraphs 1 through 79 is not required. To the extent that a separate response is required, Respondents incorporate their responses to paragraphs 1 through 79 as though fully stated herein.

80. Respondents deny the allegations in Paragraph 80 and further state that following the transaction, Illumina will continue to have strategic and economic incentives to keep the costs of its products low and to provide innovative products to all customers. Illumina's proposed offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers. The merger will result in substantial merger-specific efficiencies, synergies and other procompetitive effects that will directly benefit consumers and will greatly outweigh any and all alleged anticompetitive effects.

81. Respondents state that because Paragraph 81 states conclusions or characterizations of law, no response is required. To the extent a response is required, Respondents deny the allegations in Paragraph 81.

DEFENSES

Respondents assert the following defenses, without assuming the burden of proof on such defenses that would otherwise rest with the FTC.

1. The Complaint fails to state a claim on which relief can be granted.

2. The combination of Respondents' businesses will be procompetitive. The merger will result in substantial merger-specific efficiencies, cost synergies and other procompetitive effects that will directly benefit

consumers. These benefits greatly outweigh any and all alleged anticompetitive effects.

3. The FTC's claims are too speculative to support any claim on which relief can be granted.

4. Illumina's offers of binding contractual commitments to all of its U.S. oncology customers address all of the alleged anticompetitive effects in the alleged downstream market for NGS-based cancer screening tests and ensure that there will be no harm to competition or consumers.

5. The FTC has failed to define any appropriate relevant market or markets.

6. The FTC has failed to establish that Respondents exercise market power with respect to any relevant market.

7. The FTC's claim reflects improper selective enforcement of the antitrust laws.

8. The FTC's claim is barred in whole or in part by failure to show any plausible harm to consumers or consumer welfare or any plausible anticompetitive effect.

9. The customers at issue in the Complaint have a variety of tools to ensure that they receive competitive pricing and terms.

10. The FTC fails to allege a time frame for the alleged anticompetitive effects.

11. The relief that the FTC seeks is inconsistent with the public interest. The public interest favors consummation of the Transaction and alternative remedies are available to the Commission.

12. These proceedings are invalid because the constraints on removal of the Commissioners violate Article II of the Constitution and the separation of powers.

13. These proceedings are invalid because the constraints on removal of the Administrative Law Judge violate Article II of the Constitution and the separation of powers.

14. These proceedings are invalid because adjudication of the Complaint by the Administrative Law Judge and the Commission in turn violates Article III of the Constitution and the separation of powers.

15. These proceedings are invalid because adjudication of the Complaint by the Administrative Law Judge and the Commission in turn violates

the right to due process of law under the Fifth Amendment to the Constitution, which requires a neutral decision-maker.

16. These proceedings violate the right to due process under the Fifth Amendment to the Constitution, which requires equal protection of the laws, because the federal government seeks to enforce antitrust laws against other parties by bringing civil actions in federal district courts.

Respondents reserve the right to assert any other available defenses.

NOTICE

Respondents state that the Notice of the Complaint is a restatement of the rules of the FTC to which no response is required. To the extent a response is required, Respondents deny the allegations in the Notice of the Complaint except state that the FTC has provided notice of a hearing date on August 24, 2021.

NOTICE OF CONTEMPLATED RELIEF

Respondents state that the Notice of Contemplated Relief is a restatement of the rules of the FTC to which no response is required. To the extent a response is required, Respondents deny the allegations in the Notice of Contemplated Relief.

Respondents respectfully request that the Court: (i) deny the FTC's requested relief; (ii) dismiss the Complaint in its entirety with prejudice; (iii) award to Respondents their costs of suit, including expert fees and reasonable attorneys' fees, as may be allowed by law; and (iv) award to Respondents such other and further relief as the Court deems just and appropriate.

Dated: ~~April 13~~**August 23**, 2021

Respectfully submitted,

/*s*/ Christine A. Varney

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Exhibit C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION,	:		
	:		
Plaintiff,	:	Civil Action No.:	21-873 (RC)
	:		
v.	:	Re Document No.:	41
	:		
ILLUMINA, INC., *et al.*,	:		
	:		
Defendants.	:		

ORDER

GRANTING DEFENDANT'S MOTION TO TRANSFER VENUE

For the reasons stated in the Court's Memorandum Opinion separately and contemporaneously issued, Defendants' Motion to Transfer (ECF No. 41) is **GRANTED**. The Clerk of the Court is directed to transfer this case to the Southern District of California.

Dated: April 20, 2021

RUDOLPH CONTRERAS
United States District Judge

Exhibit D

Honorable Dana M. Sabraw
John P. Morrill, Clerk of Court
United States District Court for the Southern District of California
James M. Carter and Judith N. Keep U.S. Courthouse
333 West Broadway
San Diego, CA 92101

BY HAND
Encl.

April 20, 2021

Re: *F.T.C. v. Illumina Inc. et al.*, No. 1:21-cv-00873-RC

Dear Chief Judge Sabraw and Mr. Morrill:

We write on behalf of Defendants Illumina, Inc. ("Illumina") and GRAIL, Inc, ("GRAIL") (the "Defendants") and Plaintiff the Federal Trade Commission ("Plaintiff" or "FTC"), to bring to the Court's attention the above-captioned matter, which was transferred from the District Court for the District of Columbia ("D.D.C.") to the District Court for the Southern District of California ("S.D. Cal.") earlier today. (*See* D.D.C. Dkt. 57.)

On March 30, the FTC filed a complaint in the D.D.C. seeking a preliminary injunction to prevent Illumina and GRAIL from consummating their proposed merger. To allow the relevant district court time to determine whether a preliminary injunction is warranted, the parties stipulated to a temporary restraining order providing that Defendants may not close until the earliest of (a) 12:01 AM Eastern Time on September 20, 2021; (b) 11:59 PM Eastern Time on the second (2nd) business day after the Court rules on Plaintiff's motion for a preliminary injunction or (c) immediately upon dismissal of this action by the FTC. Today, Judge Contreras, the presiding judge in the D.D.C. action, entered the attached order and opinion transferring this action to S.D. Cal. (D.D.C. Dkt. Nos. 57–58.)

Subject to approval of the assigned judge, the parties have tentatively agreed to propose an expedited schedule, with a preliminary injunction hearing to begin on July 26, 2021 and to last at least two weeks.

Accordingly, the parties respectfully request that, to the extent possible, this case be assigned to a judge who will have the availability to accommodate the expedited schedule in this case.

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION,	:	
	:	
Plaintiff,	:	Civil Action No.: 21-873 (RC)
	:	
v.	:	Re Document No.: 41
	:	
ILLUMINA, INC., *et al.*,	:	
	:	
Defendants.	:	

ORDER

GRANTING DEFENDANT'S MOTION TO TRANSFER VENUE

For the reasons stated in the Court's Memorandum Opinion separately and contemporaneously issued, Defendants' Motion to Transfer (ECF No. 41) is **GRANTED**. The Clerk of the Court is directed to transfer this case to the Southern District of California.

Dated: April 20, 2021

RUDOLPH CONTRERAS
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION,	:	
	:	
Plaintiff,	:	Civil Action No.: 21-873 (RC)
	:	
v.	:	Re Document No.: 41
	:	
ILLUMINA, INC., *et al.*,	:	
	:	
Defendants.	:	

MEMORANDUM OPINION

GRANTING DEFENDANT'S MOTION TO TRANSFER VENUE

I. INTRODUCTION

Two biotechnology firms agreed that one would acquire the other. The federal government then filed suit to stop the merger, arguing that the deal would stifle innovation and harm consumers. But before any court can decide whether the merger can go forward, this Court must determine where the litigation should take place. Between this district and a district that would be easier for the most witnesses to get to, the latter is more appropriate.

II. BACKGROUND

Illumina, Inc. is a market leader in genetic sequencing products. Redacted Compl. ¶¶ 5–6, ECF No. 14. Its sequencing platforms are a key component in multi-cancer early detection tests, which promise to revolutionize cancer treatment. *Id.* ¶¶ 2, 6. These tests will allow healthcare providers to screen for a wide variety of cancers and detect cancer early on in a tumor's development. *Id.* ¶¶ 2–3. Several biotechnology firms are racing to develop the technology and bring it to market. *Id.* ¶ 4.

In 2015, Illumina formed GRAIL, Inc. to compete in that race. *Id.* ¶ 7. Two years later, however, Illumina reduced its share in GRAIL to below 20%. *Id.* ¶ 8. It currently owns just 14.5% of GRAIL's voting shares, with well-known investors like Jeff Bezos, Bill Gates, and Johnson & Johnson owning the rest. *Id.* GRAIL has now developed a multi-cancer early detection test called "Galleri." *Id.* ¶¶ 4, 9. It plans to seek approval to commercialize Galleri from the U.S. Food and Drug Administration ("FDA"). *Id.* ¶ 9. Last year, Illumina and GRAIL (collectively, "Defendants") entered into a merger agreement whereby Illumina would acquire the remaining 85.5% of GRAIL's shares it does not already own. *Id.* ¶ 26.

Concerned that the merger would have serious anticompetitive effects on the U.S. multi-cancer early detection test market, *see id.* ¶¶ 1, 11–14, the Federal Trade Commission decided to conduct an administrative adjudication to determine if the deal would violate federal antitrust laws, *id.* ¶ 27. That adjudication is scheduled to begin in the District of Columbia on August 24, 2021. *See id.*; Pl.'s Mem. Opp'n Defs.' Mot. Transfer Venue ("Pl.'s Opp'n") at 11, ECF No. 55. To prevent Defendants from executing the merger while the adjudication is pending, the Commission filed this action. *See* Pl.'s Mot. TRO, ECF No. 4. The parties have stipulated to a temporary restraining order that prevents the merger until the earliest of (1) September 20, 2021; (2) the end of the second business day after a court rules on the Commission's motion for a preliminary injunction; or (3) the Commission's dismissal of the action. TRO at 2, ECF No. 8.

The dispute at issue now is which court should decide the Commission's preliminary injunction motion. Defendants ask that the case be transferred to the Southern District of California. *See* Mem. P & A Supp. Defs.' Mot. Transfer Venue ("Defs.' Mot."), ECF No. 41-1. Both companies are headquartered in California—Illumina in the Southern District, Schwillinksi Decl. ¶ 4, ECF No. 41-3, and GRAIL in the Northern District, Song Decl. ¶ 3, ECF No. 41-2.

California was also the site of the merger negotiations. Schwillinksi Decl. ¶ 5; Song Decl. ¶ 6. And Defendants say that, if an in-person hearing on the motion is possible, more witnesses would have an easier time getting to the Southern District than this one. Defs.' Mot. at 1–2. The Commission opposes transfer. *See* Pl.'s Opp'n. It stresses that its choice of forum deserves considerable deference. *Id.* at 1. And it disputes Defendants' claim that the Southern District would be more convenient. *Id.* at 2. Ultimately, Defendants have the better argument.

III. LEGAL STANDARD

Even when venue is already proper, "[f]or the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought." 28 U.S.C. § 1404(a). Assessing a transfer request requires an "individualized, case-by-case consideration of convenience and fairness." *Van Dusen v. Barrack*, 376 U.S. 612, 622 (1964). The party who asks for a transfer bears the burden of showing it is warranted. *Chauhan v. Napolitano*, 746 F. Supp. 2d 99, 102 (D.D.C. 2010). First, the movant must demonstrate that venue would be proper in the proposed transferee district. *Wolfram Alpha LLC v. Cuccinelli*, 490 F. Supp. 3d 324, 330 (D.D.C. 2020). Second, the movant must show that the balance of private and public interests weighs in favor of transfer. *Id.*

IV. ANALYSIS

The Commission does not disagree that venue would be proper in the Southern District of California. Nor could it, seeing as Illumina is headquartered there and GRAIL is headquartered elsewhere in California. *See* 28 U.S.C. § 1391(b)(1) (stating that venue is proper in "a judicial district in which any defendant resides, if all defendants are residents of the State in which the district is located"); *see also* 15 U.S.C. § 53(b) (permitting the Commission to bring suit, *inter*

alia, wherever venue is proper under section 1391). As a result, this dispute centers on whether private and public interests warrant transfer.

Almost all those factors are neutral or favor transfer. But the one factor weighing in favor of keeping the case is ordinarily entitled to a great deal of deference. Although the question is a close call, the Court agrees with Defendants that transfer is appropriate.

A. The Effect of the COVID-19 Pandemic

Before delving into an assessment of the private and public interest factors, the Court addresses how the ongoing COVID-19 pandemic affects its analysis. For over a year, courts across the country—including this one and the District Court for the Southern District of California—have held limited in-person hearings to slow the spread of the COVID-19 virus. *See, e.g.*, Standing Order 20-9 (D.D.C. Mar. 16, 2020); Standing Order 18-A (S.D. Cal. Mar. 23, 2020). In the meantime, courts have mostly resorted to holding hearings over the telephone and videoconferencing software. But the proliferation of vaccines raises the possibility of returning to regular in-person proceedings soon. *See COVID-19 Vaccinations in the United States*, Ctr. for Disease Control & Prevention, https://covid.cdc.gov/covid-data-tracker/#vaccinations (showing that, as of April 18, 2021, 25.4% of the U.S. population was fully vaccinated).

The parties spar over how the possibility of an in-person preliminary injunction hearing impacts the appropriateness of transfer. Defendants want the hearing—which they say "will function as a trial on the merits"—to be in person. Defs.' Mot. at 1. And if the hearing is in person, they say, then it would be much easier for witnesses and parties who largely reside in California and the Western United States to travel to the Southern District than it would be for them to travel to the District of Columbia. *Id.* at 1, 7. Defendants assert that the risk of contracting COVID-19 may dissuade West Coast witnesses' attendance at a hearing on the other

side of the country, and they point out that local D.C. travel restrictions (such as testing and isolation requirements) would raise logistical hurdles. *See id.* at 7–8; *see also, e.g.*, D.C. Health, *Coronavirus 2019 (COVID-19): Guidance for Travel* (Mar. 3, 2021), https://coronavirus.dc.gov/sites/default/files/dc/sites/coronavirus/page_content/attachments/Travel_Guidance_DCHealth_COVID-19_Updated%203.3.21.pdf. According to Defendants, relocating the case to the Southern District would minimize these burdens.

The Commission responds that an in-person proceeding is unnecessary, so none of Defendants' claimed burdens should hold weight. *See* Pl.'s Opp'n at 6–8. It points to cases where other district courts found that videoconference platforms permitted adequate assessment of remote witnesses' credibility. *Id.* at 6 (citing *Flores v. Town of Islip*, No. 18-cv-3549, 2020 WL 5211052, at *2 (E.D.N.Y. Sept. 1, 2020); *Raffel Sys., LLC v. Man Wah Holdings Ltd., Inc.*, No. 18-cv-1765, 2020 WL 8771481, at *3 (E.D. Wis. Nov. 13, 2020)). Given the effectiveness of remote proceedings, the Commission argues, there is no point in risking participants' health with an in-person hearing—especially in light of concerns that a fourth surge in COVID-19 cases may be coming or that variants of the virus may stall recent progress. *See* Pl.'s Opp'n at 7–8.[1] If the hearing will be remote anyway, the Commission concludes, then transferring the case would do little for the convenience of the parties or witnesses. *See id.* at 7.

Yet significantly, "[l]ive testimony is . . . markedly preferable" to remote testimony. *Beall v. Edwards Lifesciences LLC*, 310 F. Supp. 3d 97, 106 (D.D.C. 2018) (quoting *Pyrocap Int'l Corp. v. Ford Motor Co.*, 259 F. Supp. 2d 92, 98 (D.D.C. 2003)); *see also United States v.*

[1] *See also* Reis Thebault, *Are We Entering a 'Fourth Wave' of the Pandemic? Experts Disagree.*, Wash. Post (Apr. 4, 2021), https://www.washingtonpost.com/health/2021/04/04/covid-fourth-wave/; Apoorva Mandavilli & Benjamin Mueller, *Virus Variants Threaten to Draw Out the Pandemic, Scientists Say*, N.Y. Times (Apr. 5, 2021), https://www.nytimes.com/2021/04/03/health/coronavirus-variants-vaccines.html.

Lattimore, No. 20-cv-123, 2021 WL 860234, at *7 (D.D.C. Mar. 8, 2021) ("The Court would greatly prefer to hold all pre-trial hearings in person. . . . Unfortunately, the COVID-19 pandemic simply prevents the Court from holding in-person hearings safely at this time."). The utility of live proceedings is not limited to aiding in the evaluation of witness credibility—though that is one important benefit, *see Beall*, 310 F. Supp. 3d at 106; *Pyrocap*, 259 F. Supp. 2d at 98. Among other advantages, live proceedings permit more natural dialogue among hearing participants, allow participants to handle any physical evidence, and avoid the technical difficulties that can sometimes trip up virtual proceedings. The Court will therefore seek to maximize the chances that the preliminary injunction hearing can occur in person or, in the event of a hybrid proceeding, that as many people as possible can safely provide live testimony.

Due to the continued rollout of vaccines, an in-person or hybrid proceeding may be possible by July or August, which is when the parties anticipate the hearing taking place. *See* Sheryl Gay Stolberg, *Biden Moves Up Vaccine Eligibility Deadline for All Adults to April 19*, N.Y. Times (Apr. 6, 2021), https://www.nytimes.com/2021/04/06/us/politics/biden-vaccine-all-adults-eligible.html. But between the spread of virus variants, the possibility of another surge, and regional differences in vaccination rates, there is no way to predict whether a live hearing is more likely in one district versus the other. As a result, the relative likelihood of an in-person hearing between the two districts will not factor into the Court's analysis.

Nevertheless, the Court will assume in its assessment that the hearing will occur, at least in part, in person. *Cf. Montgomery v. Barr*, No. 20-cv-03214, 2020 WL 6939808, at *9 (D.D.C. Nov. 25, 2020) ("[T]his factor, as well as some others geared towards convenience, seems less relevant today because of the frequency of telephone and video conferences due to the COVID-19 pandemic. Even so, the Court must apply the legal framework, which envisions in-person

hearings and trials, as it exists. To do otherwise would eviscerate the idea that local courts should hear local matters." (citation omitted)). If that assumption turns out to be wrong, then—as the Commission points out—it matters little for convenience's sake which court hears the case. Either way, witnesses, lawyers, and the parties will be able to join the videoconference proceedings from the safety of their homes and offices. But if the hearing will be in person, then pandemic-related risks and restrictions could significantly impact participants' ability and willingness to attend. It is safer to plan for an in-person hearing so that, in case one does occur, as many participants as possible can safely appear.

B. The Private Interest Factors Support Transfer

When weighing a motion to transfer, a court takes into account the following private interest considerations: (1) the plaintiff's choice of forum; (2) the defendant's preferred forum; (3) the location where the claim arose; (4) the convenience of the parties; (5) the convenience of the witnesses; and (6) ease of access to sources of proof. *Vasser v. McDonald*, 72 F. Supp. 3d 269, 282 (D.D.C. 2014). Only one private interest factor—the plaintiff's choice of forum—favors this Court retaining the case. The remaining factors range from having a neutral effect on the venue analysis to strongly favoring transfer. Those factors win out.

Because the last four factors help assess the weight the first two are entitled to, the Court begins with them. For starters, the location where the claim arose benefits Defendants. A claim originates "in the location where the corporate decisions underlying those claims were made or where most of the significant events giving rise to the claims occurred." *Beall*, 310 F. Supp. 3d at 104 (citation omitted). Defendants emphasize that their officers negotiated the acquisition agreement in California. Song Decl. ¶ 6; Schwillinski Decl. ¶ 5. Although they do not specify that the negotiations took place in the Southern District, they are adamant that the negotiations

did not touch the District of Columbia at all. Song Decl. ¶ 6; Schwillinksi Decl. ¶ 5. At a minimum, then, the location where the claim arose is a neutral factor. *Cf. United States v. Energy Sols., Inc.*, No. 16-cv-1056, 2016 WL 7387069, at *4 (D. Del. Dec. 21, 2016) (explaining that the factor was "largely neutral" when the record was unclear and did not "definitively indicate" that merger negotiations took place in the proposed transferee district). But even if the negotiations occurred, say, in the Northern District of California, that district is much closer to the Southern District than this one. So to the extent that the factor is "a proxy for where the witnesses, parties, and evidence are likely to be located," *United States v. H & R Block, Inc.*, 789 F. Supp. 2d 74, 80 (D.D.C. 2011), the Southern District would likely provide a more convenient forum for this dispute than one across the country. *Cf. FTC v. Graco Inc.*, No. 11-cv-2239, 2012 WL 3584683, at *5 (D.D.C. Jan. 26, 2012) (determining that the factor favored transfer when the merger agreement "was negotiated, drafted, and executed" in the proposed transferee district). Indeed, the Court's analysis of the other factors bears that hypothesis out.

The convenience-of-the-parties factor is neutral. For a "burden suffered by a party from litigating in a particular forum to weigh in favor of transfer, litigating in the transferee district must not merely shift inconvenience to the non-moving party; instead, it should lead to increased convenience overall." *Mazzarino v. Prudential Ins. Co. of Am.*, 955 F. Supp. 2d 24, 31 (D.D.C. 2013). Defendants' potential benefit from transfer is obvious. Illumina is headquartered in the Southern District. *See* Schwillinski Decl. ¶ 4; *see also Virts v. Prudential Life Ins. Co. of Am.*, 950 F. Supp. 2d 101, 107 (D.D.C. 2013) (explaining that a company's headquarters in a district made that forum a more convenient one). And GRAIL is headquartered in the Northern District of California, which is much closer to the Southern District than the District of Columbia. *See* Song Decl. ¶ 3. But because transfer would take the case away from where the Commission is

headquartered, it would merely shift inconvenience to the Commission. As a result, the factor favors neither party. *See Graco*, 2012 WL 3584683, at *6 (finding that convenience of the parties did "not weigh in favor of either party" because "Minnesota is more convenient for the defendants and the District of Columbia is more convenient for the FTC").[2]

Weighing heavily toward transfer is the convenience of witnesses. This factor is the most important one. *Beall*, 310 F. Supp. 3d at 105 ("The most critical factor to examine under 28 U.S.C. § 1404(a) is the convenience of the witnesses." (citation omitted)). Significantly, the inquiry is "not whether certain witnesses may be located outside the chosen forum, but instead whether those witnesses would be unwilling to testify in the District of Columbia." *FTC v. Cephalon, Inc.*, 551 F. Supp. 2d 21, 28 (D.D.C. 2008) (internal quotation marks and citation omitted). And because parties can typically compel their employees to appear regardless of the forum, the convenience of nonparty witnesses matters more than the convenience of party witnesses. *See H & R Block*, 789 F. Supp. 2d at 82; *see also Cephalon*, 551 F. Supp. 2d at 28 ("The employee witnesses located at Cephalon's headquarters are under the control of Cephalon and could most likely be compelled to testify here.").

Defendants' argument on this factor is strong. By their count, eleven of the nineteen third-party witnesses that the Commission has deposed or examined via investigational hearings "appear to be based in California." Mot. Hr'g Tr. at 13:14–15. And of the fourteen Illumina and GRAIL employees the Commission examined, thirteen live in California. *Id.* at 13:11–12. In addition, Defendants' competitors—which, both parties agree, will supply some witnesses—are

[2] The Commission mentions that the Southern District would require more lawyers to travel. *See, e.g.*, Pl.'s Opp'n at 7–8. But "[t]he location of counsel 'carries little, if any, weight in an analysis under § 1404(a).'" *Reiffin v. Microsoft Corp.*, 104 F. Supp. 2d 48, 52 n.7 (D.D.C. 2000) (citation omitted).

largely based in California and the Western United States. Of the competitors the Commission lists in its sealed complaint, more are headquartered in California than any other state or the East Coast as a whole, others have offices in California, and another has offices in nearby Arizona. *See* Sealed Compl. ¶ 46, ECF No. 3; *see also* Pl's. Opp'n at 18; Mot. Hr'g Tr. at 26:4–6 (Commission attorney stating that "potential witnesses" live in California, Arizona, Maryland, Massachusetts, and the District of Columbia). The Commission points out that the third-party witnesses' geographic distribution remains to be seen because the parties have not yet identified them for the hearing. Pl.'s Opp'n at 18. It also suggests that, while some potential witnesses' employers are in California, the witnesses live elsewhere. Mot. Hr'g Tr. at 25:23–25. Ultimately, however, the Commission does not offer any hard figures to dispute the general point that likely witnesses would have an easier time getting to the Southern District than this district.

Travel that would ordinarily pose a mere inconvenience may well, under the current circumstances, deter witnesses from attending proceedings in the case. "[T]he pandemic has highlighted that there can be risks associated with travel," so "[s]ome people who would not have been worried about travel before the pandemic are now reluctant to travel." *Express Mobile, Inc. v. Web.com Grp., Inc.*, No. 19-cv-1936, 2020 WL 3971776, at *4 (D. Del. July 14, 2020). Furthermore, witnesses may be less willing to attend proceedings if it means elongating their stay to account for local COVID-19 travel protocols such as testing and quarantining.

Given that more potential witnesses appear to be located in or near California than anywhere else, transferring proceedings in the Southern District would minimize the burdens and risks of travel for the greatest number of witnesses. *Cf. id.* at *3 (finding that the convenience of the witnesses "favor[ed] transfer" in part because "the bulk of non-expert witnesses are more likely to reside in the Middle District of Florida than anywhere else"). Even if many of the

witnesses live in other districts in the Western United States, holding proceedings in the Southern District would still reduce the need for potentially hazardous long-haul airplane trips. *See Safer Travel Ideas*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-risk.html (warning travelers to avoid long flights with layovers). Indeed, "[c]ourts have consistently transferred actions when the majority of witnesses live *near* the transferee forum." *Beall*, 310 F. Supp. 3d at 105 (alteration in original) (emphasis added) (quoting *Mathis v. Geo Grp., Inc.*, 535 F. Supp. 2d 83, 87 (D.D.C. 2008)). In sum, the critical convenience-of-the-witnesses factor strongly favors transfer.

The Southern District also provides easier access to some sources of proof, though the factor carries limited weight. Between housing Illumina's headquarters and its relatively close proximity to GRAIL's headquarters in the Bay Area, the Southern District has a geographic advantage over this district when it comes to obtaining corporate records about the merger. That said, modern technology permitting the instantaneous transfer of those kinds of records nearly eliminates that advantage. *See H & R Block*, 789 F. Supp. 2d at 83. *But see Beall*, 310 F. Supp. 3d at 106 ("While the records may be in electronic form, this factor weighs nonetheless in favor of transfer because 'all of the . . . documents' are located in the transferee forum." (citation omitted)). More important is the Southern District's proximity to physical exhibits such as company equipment and products, which Defendants remarked in oral argument would help a court decide the case. *See* Mot. Hr'g Tr. at 20:3–9. Because Defendants failed to raise that argument in their brief, *see* Defs.' Mot. at 11, the Court is hesitant to put too much stock in it, *see Walker v. Pharm. Rsch. & Mfrs. of Am.*, 461 F. Supp. 2d 52, 58 n.9 (D.D.C. 2006) (explaining that a party forfeits an argument not raised in its opening brief). Nevertheless, the Southern District appears marginally better poised to access relevant evidence than this Court.

What remains to be considered are the parties' preferences. Usually, a plaintiff's choice of forum is "a 'paramount consideration' that is entitled to 'great deference' in the transfer inquiry." *Cephalon*, 551 F. Supp. 2d at 26 (quoting *Thayer/Patricof Educ. Funding, L.L.C. v. Pryor Res., Inc.*, 196 F. Supp. 2d 21, 31 (D.D.C. 2002)). Indeed, "some courts have found that the government's choice of venue in an antitrust case is 'entitled to heightened respect.'" *Id.* (quoting *United States v. Brown Univ.*, 772 F. Supp. 241, 242 (E.D. Pa. 1991)); *see also United States v. Microsemi Corp.*, No. 08-cv-1311, 2009 WL 577491, at *7 (E.D. Va. Mar. 4, 2009) ("Where venue is proper, a plaintiffs [sic] choice of forum is entitled to substantial weight, particularly where the plaintiff's choice of forum is authorized by the more liberal antitrust venue provision."). But the deference owed to a plaintiff diminishes if "there is an insubstantial factual nexus between the case and the plaintiff's chosen forum." *Fed. Hous. Fin. Agency v. First Tenn. Bank Nat. Ass'n*, 856 F. Supp. 2d 186, 192 (D.D.C. 2012) (quoting *New Hope Power Co. v. U.S. Army Corps of Eng'rs*, 724 F. Supp. 2d 90, 95 (D.D.C. 2010)). And "when the weight of the plaintiff's choice is comparatively weak," the defendant's choice deserves greater consideration. *Mazzarino*, 955 F. Supp. 2d at 31 (quoting *Virts*, 950 F. Supp. 2d at 106).

This case has little connection to the District of Columbia. After all, it originated out of a merger that two California-based companies negotiated in California. *Cf. Cephalon, Inc.*, 551 F. Supp. 2d at 26 ("None of the negotiations that led to the settlement agreements at the heart of this controversy took place in, or were in any other way related to, the District."); *cf. also Bergmann v. U.S. Dep't of Transp.*, 710 F. Supp. 2d 65, 72 (D.D.C. 2010) ("Plaintiff's choice of forum is also entitled to less deference where, as here, the majority of operative facts took place outside the District of Columbia."). The Commission nevertheless insists that this case is tied to the District in several ways. It first asserts that the merger will cause nationwide harm that will

affect consumers in the District of Columbia. Pl.'s Opp'n at 10. It then infers that, because Defendants claim in their answer that the merger will help GRAIL obtain FDA approval for Galleri, that GRAIL's small, D.C.-based government-relations office will play a "notably outsized role . . . in a review of this merger." *Id.* at 10–11; *see also, e.g.*, Redacted Answer at 12, ECF No. 49. And finally, it says that the parallel administrative adjudication pending in the District of Columbia warrants keeping the cases in the same locale. Pl.'s Opp'n at 11.

Each of those attempts to demonstrate a meaningful connection to this forum falls flat. While D.C. residents may feel the anticompetitive effects of the merger, the nationwide impact makes this forum no different than any other. *Cf. FTC v. Acquinity Interactive, LLC*, No. 13-cv-5380, 2014 WL 37808, at *2 (N.D. Ill. Jan. 6, 2014) (concluding that the Commission's choice of forum was entitled to "less weight" than usual because "the only real connection between the lawsuit and this district is that some of the alleged consumer injury occurred here," but that "d[id] not differentiate this district from any other district in the country"); *cf. also Graco*, 2012 WL 3584683, at *5 (similar); *Cephalon*, 551 F. Supp. 2d at 27–28 (similar). Likewise, GRAIL's D.C. office is not as relevant as the Commission claims it is. The office has fewer than ten employees, Song Decl. ¶ 5, and it is focused on lobbying rather than securing regulatory approvals (which is handled out of the company's California headquarters), Mot. Hr'g Tr. at 7:14–22. *Cf. Cephalon*, 551 F. Supp. 2d at 26 (finding that a corporation's "very small public affairs office in the District of Columbia" did not create a meaningful connection to the District). The yet-to-begin administrative adjudication does not help the Commission either. Its claim that the proceeding connects this case to the District was unsupported by any legal authority. *See* Pl.'s Opp'n at 11; *cf. Graco*, 2012 WL 3584683, at *5 ("The FTC argues that because this case is [a] preliminary injunction proceeding in aid of an administrative proceeding currently pending in

the District of Columbia, this case, in a procedural sense, arises out of that administrative action. There is, however, no legal support provided for the plaintiff's proposition."). And "this Court has long recognized that mere involvement on the part of federal agencies, or some federal officials who are located in Washington, D.C. is not determinative of whether the plaintiffs' choice of forum in the District of Columbia receives deference." *First Tenn. Bank*, 856 F. Supp. 2d at 192 (cleaned up) (quoting *New Hope Power*, 724 F. Supp. 2d at 95–96).

To the extent the Commission suggests that the FDA approval process ties this case to this district because the agency is headquartered nearby in Maryland, it is wrong. *See* Mot. Hr'g Tr. at 27:18 to 28:1. Of course, one of the many reasons Defendants agreed to the merger is that they believe it will allow Illumina to help secure FDA approval for GRAIL's Galleri product. *See* Redacted Answer at 12. But a federal agency's general oversight of an industry does not link its home forum to every controversy that somehow relates to its regulatory processes. *See Bergmann*, 710 F. Supp. 2d at 73 ("While plaintiff argues that his claims 'arose principally at the headquarters offices of the Defendants in Washington, D.C.,' defendants persuasively counter that 'the only real connection [the] lawsuit has to the District of Columbia is that a federal agency headquartered here . . . is charged with generally regulating and overseeing the [administrative] process.'" (alterations and omissions in original) (citations omitted)). The FDA has not taken any specific action toward Defendants. Its regulatory regime was merely part of the backdrop that motivated the deal.

The *H & R Block* case that the Commission relies on dealt with an agency that played a much more direct role in prompting the challenged merger. There, the government alleged that a do-it-yourself tax preparation company negotiated the acquisition of a competitor to stop it from disrupting the industry. *See* 789 F. Supp. 2d at 77. One of the competitor's prominent moves

involved a public-private partnership between tax preparation companies and the D.C.-based Internal Revenue Service that let qualified taxpayers prepare and file their taxes for free. *Id.* The competitor introduced an offer through the partnership that was free to all U.S. taxpayers, forcing major players in the industry to follow suit. *Id.* The industry then lobbied for restricting the type and number of taxpayers that could receive the partnership's free services, which the IRS eventually did. *Id.* Because "facts underlying the complaint took place" in the District and IRS employees would likely be witnesses, the government asserted that its choice of forum was entitled to deference. *Id.* at 79. The court agreed. *Id.* at 79–80. But the factors that drove that decision are not present here. In *H & R Block*, the IRS had a direct hand in the events that led to the challenged transaction. It partnered with tax preparation companies and, in response to lobbying, reduced industry participants' ability to compete through that partnership. By contrast, the FDA's sole involvement in this case is that GRAIL will one day ask it to approve Galleri for sale. The agency plays just the passive, background role of industry regulator. Indeed, it is telling that no party has indicated that FDA employees will serve as witnesses. The FDA's approval process thus does not connect the case with this forum.

Having determined that this case lacks a meaningful connection to the District other than the fact that the Commission is located here, the Court will not defer to the Commission's choice of forum. *See First Tenn. Bank*, 856 F. Supp. 2d at 192. That means the Defendants' choice deserves greater weight. *See Mazzarino*, 955 F. Supp. 2d at 31. And because the only contrary factor is diminished, the private interest factors collectively weigh toward transfer.

C. The Public Interest Factors Are Essentially Neutral

There are three public interest factors that courts typically consider when deciding a motion to transfer: (1) whether there is a local interest in making a local decision about a local

controversy; (2) the proposed transferee court's familiarity with the applicable law; and (3) the relative congestion of the transferor and transferee courts. *H & R Block*, 789 F. Supp. 2d at 83. Because these factors are basically neutral with only the local interest factor possibly favoring transfer, the Court will keep its discussion brief.

First, if there is any local interest in this lawsuit, it would support transferring the case to the Southern District. The Court has already explained how the case's origins in California favor transfer. *Cf. Graco*, 2012 WL 3584683, at *6 (finding that the local interest factor favored transfer because the challenged transaction was negotiated in the proposed district and one of the defendants was headquartered there). In addition, Illumina is headquartered in the Southern District, and a decision blocking or permitting the merger could affect the company's employees who live there. *Cf. Bader v. Air Line Pilots Ass'n, Int'l*, 63 F. Supp. 3d 29, 36 (D.D.C. 2014) (noting that there was "some local interest" in the proposed transferee district because a related organization was headquartered there and the case "could have some impact on its employees"); That said, no district has a peculiarly local interest in hosting a suit that alleges nationwide anticompetitive effects. *See H & R Block*, 789 F. Supp. 2d at 83 ("The local interest in making decisions regarding local controversies is a neutral factor here because, as defendants concede, this case has national economic significance and does not present an essentially local matter."); *Cephalon*, 551 F. Supp. 2d at 31 (explaining that the public interest factor had "little application" because the "use of reverse-payment settlements" was "not a local issue at all" but instead "a question that has nationwide significance"). Consequently, this factor gives little reason to transfer the case beyond those already discussed—if any.

Second, because "all federal courts are presumed to be equally familiar with the law governing federal statutory claims," neither district court enjoys an expertise-based advantage

over the other. *See Mazzarino*, 955 F. Supp. 2d at 32 (quoting *Intrepid Potash–N.M., LLC v. U.S. Dep't of Interior*, 669 F. Supp. 2d 88, 98 (D.D.C. 2009)). This factor is therefore neutral.

Third, caseload statistics do not indicate that one forum would be able to dispose of the case more efficiently than the other. While district judges in the Southern District have more cases (503 cases per judge) than those in the District of Columbia (373 cases per judge), the median time between the filing of a civil case and the case's disposition is nearly equal across the two districts (6.0 months in the Southern District versus 5.8 months in the District of Columbia). Admin. Off. of U.S. Courts, *United States District Courts—National Judicial Caseload Profile* 2, 69 (Sept. 30, 2020), https://www.uscourts.gov/sites/default/files/data_tables/fcms_na_distprofile0930.2020.pdf. None of the parties try to tell a different story from those statistics. *See* Defs.' Mot. at 11–12; Pl.'s Opp'n at 21. Instead, the Commission suggests that, if the case is transferred, there could be delays as the new court gets up to speed. Pl.'s Opp'n at 21. But seeing no evidence that the Southern District courts are more backlogged than courts in this district, the Court doubts that any delay will be material. Moreover, accepting the Commission's argument would give the initial court an automatic advantage in any transfer dispute. As Defendants point out, a transferee court will always have to play catch-up when it receives a new case. Mot. Hr'g Tr. at 18:17–22. This factor is neutral too.

* * *

In the final calculation, only one factor favors this Court retaining the case: the Commission's choice of forum. But because the case lacks a meaningful connection to the District of Columbia, that ordinarily important factor carries little weight. The remaining factors are either neutral or support transfer. Most significantly, transferring the case to the Southern District of California would be much more convenient for the bulk of the witnesses. That

already substantial factor holds even greater force during the ongoing COVID-19 pandemic. The Court will therefore transfer the case.

V. CONCLUSION

For the foregoing reasons, Defendants' Motion to Transfer (ECF No. 41) is **GRANTED**. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: April 20, 2021

RUDOLPH CONTRERAS
United States District Judge

Exhibit E

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UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION, Plaintiff, v. ILLUMINA, INC, and GRAIL, INC., Defendants.	Case No. 3:21-cv-00800-CAB-BGS **PLAINTIFF AND DEFENDANTS' JOINT MOTION AND STIPULATION FOR ENTRY OF A STIPULATED CASE MANAGEMENT AND SCHEDULING ORDER** Complaint Filed: March 30, 2021 Judge: Hon. Cathy Ann Bencivengo Magistrate: Hon. Bernard G. Skomal Trial Date: Not Set

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Pursuant to Rule 7.2 of the Local Rules of the U.S. District Court for the Southern District of California ("S.D. Cal."), and subject to the Court's approval, Plaintiff Federal Trade Commission (the "FTC" or "Plaintiff") and Defendants Illumina, Inc. ("Illumina") and GRAIL, Inc. ("GRAIL") (collectively, the "Defendants"), through their undersigned counsel, stipulate and jointly agree as follows:

WHEREAS, on March 30, 2021, the FTC filed a complaint in the Federal District Court for the District of Columbia ("D.D.C.") seeking a preliminary injunction to prevent Illumina and GRAIL from consummating their proposed merger.

WHEREAS, to allow the relevant district court time to determine whether a preliminary injunction is warranted, the parties stipulated to a temporary restraining order ("TRO") providing that Defendants may not close until the earliest of (a) 12:01 AM Eastern Time on September 20, 2021; (b) 11:59 PM Eastern Time on the second (2nd) business day after the Court rules on Plaintiff's motion for a preliminary injunction; or (c) immediately upon dismissal of this action by the FTC.

WHEREAS, on April 20, 2021 Judge Contreras, the presiding judge in the D.D.C. action, entered an order and opinion transferring this action to S.D. Cal. (D.D.C. Dkt. Nos. 57–58.)

WHEREAS, on April 23, 2021, the action was formally transferred and assigned to this Court.

WHEREAS, the parties have agreed to an expedited schedule with a preliminary injunction hearing proposed to begin on July 26, 2021, and to last at least two weeks.

WHEREAS, the parties' proposed schedule is memorialized in the attached Exhibit A.

NOW, THEREFORE, the parties stipulate and move the Court to adopt the accompanying CMSO.

DATED: April 26, 2021

FEDERAL TRADE COMMISSION

/s/ Susan Musser
Susan Musser
Attorney for Plaintiff
FEDERAL TRADE COMMISSION

DATED: April 26, 2021

CRAVATH, SWAINE & MOORE LLP

/s/ David R. Marriott
David R. Marriott
Attorney for Defendant
ILLUMINA, INC.

DATED: April 26, 2021

JONES DAY

/s/ Karen P. Hewitt
Karen P. Hewitt
Attorney for Defendant
ILLUMINA, INC.

DATED: April 26, 2021

LATHAM & WATKINS, LLP

/s/ Marguerite M. Sullivan
Marguerite M. Sullivan
Attorney for Defendant
GRAIL, INC.

SIGNATURE CERTIFICATION

Pursuant to Section 2(f)(4) of the Electronic Case Filing Administrative Policies and Procedures Manual, I hereby certify that the content of this document is acceptable to the above signatories, and that I have obtained their authorization to affix their electronic signatures to this document.

DATED: April 26, 2021

JONES DAY

/s/ Karen P. Hewitt
Karen P. Hewitt

UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ILLUMINA, INC, and GRAIL, INC.,

Defendants.

Case No. 3:21-cv-00800-CAB-BGS

EXHIBIT A TO JOINT MOTION AND STIPULATION FOR ENTRY OF A STIPULATED CASE MANAGEMENT AND SCHEDULING ORDER

Complaint Filed: March 30, 2021

Judge: Hon. Cathy Ann Bencivengo
Magistrate: Hon. Bernard G. Skomal

Trial Date: Not Set

As described in the parties' joint motion, the parties have agreed to the following proposed schedule:

A. TEMPORARY RESTRAINING ORDER. Defendants consented to the entry of a Temporary Restraining Order, which the District Court for the District of Columbia entered on March 31, 2021. Under that Temporary Restraining Order, the Defendants have agreed not to close their transaction until the earlier of 12:01 AM Eastern Time on September 20, 2021 or after 11:59 PM Eastern Time on the second (2nd) business day after this Court rules on the Plaintiff's motion for preliminary injunction.

B. ANSWER. Defendants answered Plaintiff's Complaint on April 5, 2021.

C. DISCOVERY.

1. Fact Discovery. Fact discovery commenced on April 1, 2021 and shall be completed by June 4, 2021. To the extent a third-party deposition is properly noticed in accordance with the Court's CMSO and the third party's schedule cannot accommodate a deposition before the end of fact discovery, a later deposition may occur with the agreement of both sides. No party may unreasonably withhold agreement. All discovery in this case, including discovery initiated prior to the entry of the CMSO, shall be subject to the CMSO as entered by any Court.

2. Initial Disclosures. The parties agree to forego the requirement to exchange initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1).

3. Pre-Trial Discovery Conference. The Court's entry of a CMSO pursuant to the parties' proposed schedule relieves the parties of their duty under Federal Rule of Civil Procedure 26(f) to confer about scheduling and a discovery plan.

4. Third-Party Discovery. No party issuing a third-party subpoena for the production of documents or electronically stored information shall request a

return date sooner than seven (7) calendar days after service. Each party shall produce all materials received pursuant to a third-party subpoena or other formal or informal request, including any declarations or affidavits obtained from a third party, to the other party in the format in which those materials were received within two (2) business days of receiving those materials. In the event a non-party produces documents or electronic information that are non-Bates-stamped—in addition to producing the materials in the format in which they were received within two (2) business days of receiving them—the party receiving the documents shall promptly Bates-stamp the documents or electronic information and produce them in a reasonable timeframe. The parties shall serve document subpoenas to third parties by May 7, 2021.

5. Limitations on Party and Third-Party Declarations or Affidavits. No party may submit as evidence a declaration or affidavit from a party or third-party witness if such declaration or affidavit was executed or served less than one week prior to his or her agreed-to deposition date. In any event, no party or third-party declaration or affidavit may be submitted as evidence if it was executed or served less than fourteen (14) calendar days before the close of fact discovery unless it is a supplemental third-party declaration or affidavit related to a previously given third-party declaration or affidavit, in which case the parties agree to not oppose any efforts to depose, or re-depose, such a declarant or affiant irrespective of any other provisions of the Court's CMSO.

6. Document Requests and Production. There shall be no limit on the number of requests for production of documents that the parties may serve. The parties shall serve any objections to requests for the production of documents no later than ten (10) calendar days after the date of service of the document requests to which they assert objections. Within two (2) business days of service of any such objections, the parties shall meet and confer in a good faith attempt to resolve the objections. Responsive productions (subject to any objections or custodian

issues that have not been resolved) must be made on a rolling basis and must begin as soon as reasonably practicable after the date of service. All productions must be completed within 30 calendar days of the document request. In response to any document requests, the parties need not produce to each other in discovery in this case any documents previously produced by Defendants to the FTC in the course of the investigation of the acquisition of GRAIL by Illumina, FTC File No. 201-0144.

Document Productions shall be sent to the attention of:

To the FTC: William Cooke
Sadie Goering
Matthew Joseph
Stephen Mohr
Susan Musser
Sarah Wohl
Nicholas Widnell
David Gonen
Lauren Gaskin
Dylan Naegele
Eric Edmondson
Hana Verwilt

For Illumina: Sharonmoyee Goswami
Jesse Weiss
Michael Zaken
Illumina Trial Team (list serv)
Cravath, Swaine & Moore LLP
825 Eighth Avenue
New York, NY 10019

For GRAIL: Marguerite Sullivan
Anna Rathbun
Latham Antitrust Team (list serv)
Latham & Watkins LLP
555 Eleventh Street, NW
Suite 1000
Washington, D.C. 20004

7. Interrogatories. The parties shall serve no more than twenty-five (25) interrogatories per side. The parties may serve up to five (5) contention

interrogatories per side. The parties shall serve objections and responses to interrogatories no later than ten (10) calendar days after the date of service. Within two (2) business days of any objections, the parties must meet and confer to attempt to resolve the objections. The parties must make good-faith efforts to provide complete answers to interrogatories no later than twenty (20) calendar days after service of the interrogatories.

8. Deadline to Issue Written Discovery to Parties. The parties shall serve document requests and interrogatories to parties by April 28, 2021.

9. Expert Reports. Plaintiff shall serve its expert report(s) on June 8, 2021. Defendants shall serve their expert report(s) on June 29, 2021. Plaintiff shall serve its rebuttal expert report(s) on July 9, 2021.

10. Expert Materials Not Subject to Discovery. Expert disclosures, including each side's expert report(s), shall comply with the requirements of Federal Rule of Civil Procedure 26(a)(2), except as modified herein:

a) Neither side must preserve or disclose, including in expert deposition testimony, the following documents or materials:

i. any form of communication or work product shared between any of the parties' counsel and their expert(s) or consultants, or between any of the experts themselves;

ii. any form of communication or work product shared between an expert and persons assisting the expert;

iii. expert's notes, unless they constitute the only record of a fact or an assumption relied upon by the expert in formulating an opinion in this case;

iv. drafts of expert reports, analyses, or other work product; or

v. data formulations, data runs, data analyses, or any database-related operations not relied upon by the expert in the opinions contained

in his or her final report, except as set forth in 13(b).

b) The parties agree that they will disclose the following materials with all expert reports:

i. a list by Bates number of all documents relied upon by the testifying expert(s);

ii. copies of any materials relied upon by the expert not previously produced that are not readily available publicly; and

iii. for any calculations appearing in the report, all data and programs underlying the calculation, including any processed data files relied upon by the expert in forming his or her opinion and all programs and codes necessary to recreate the calculation from the initial ("raw") data files.

11. Exchange of Lists of Witnesses to Appear at Hearing.

a) *Preliminary Witness Lists:* The parties shall exchange preliminary witness lists no later than 11:59 PM Eastern Time two business days after the CMSO is entered. Defendants shall jointly submit one list. Preliminary witness lists shall include for each witness (including both fact and expert witnesses): (a) the witness's name and employer; (b) the name, address, telephone number, and email address of the witness's counsel (or, if not represented by counsel, the witness's address, telephone number, and email address); (c) an indication of whether the witness will offer expert testimony; and (d) a summary of the general topics of each witness's anticipated testimony. The number of fact witnesses who may be included on any side's preliminary witness list shall not exceed twenty five (25). The preliminary witness lists shall include only witnesses that a side believes in good faith it will present at the evidentiary hearing live (including remotely if necessary to satisfy COVID-19 protocols). Defendants reserve all rights to object to Plaintiff's use, in its proposed findings of fact or conclusions of law, of deposition designation testimony (including investigational hearing testimony) of witnesses who were not disclosed on Plaintiff's preliminary

or final witness lists. Plaintiff similarly reserves all rights to admit investigational hearing transcripts and deposition designations regardless of whether those witnesses were included on the Plaintiff's preliminary, supplemental, or final witness lists.

b) *Supplemental Witness Lists:* Each party shall supplement their witness list to include all expert witnesses that will be or may be submitting an expert report and/or testifying at trial. With this supplemental witness list, each side shall provide a summary of the general topics of each witness's anticipated testimony on or before 11:59 PM Eastern Time on May 14, 2021.

c) *Final Witness Lists:* Final party and third-party witness lists shall be exchanged on or before 11:59 PM Eastern Time on July 19, 2021. Only a witness who appears on either party's preliminary witness list, supplemental witness list, or were otherwise deposed during fact discovery may be included on a party's final witness list. Final witness lists shall include for each witness (including both fact and expert witnesses): (a) an indication of whether the witness will offer expert testimony; and (b) a summary of the general topics of each witness's anticipated testimony. No witness shall be permitted at trial unless the opposing side had an opportunity to depose the witness before trial. Defendants reserve all rights to object to Plaintiff's use, in its proposed findings of fact or conclusions of law, of deposition designation testimony (including investigational hearing testimony) of witnesses who were not disclosed on Plaintiff's preliminary or final witness lists. Defendants' position is that final witness lists shall also include an indication of whether the witness will testify live (including remotely if necessary to satisfy COVID-19 protocols) or through reading or playing of a deposition at the preliminary injunction evidentiary hearing. Plaintiff similarly reserves all rights to admit investigational hearing transcripts and deposition designations regardless of whether those witnesses were included on the Plaintiff's preliminary, supplemental, or final witness lists and to rely on those transcripts in

the Findings of Fact and Conclusions of Law.

12. Depositions.

a) *Number of Fact Depositions:*

i. Each side is entitled to depose any individual who is listed on either side's preliminary, supplemental or final witness lists. In addition, each side is entitled to depose (1) any individual who signed a declaration or letter of support or any third party that is developing or commercializing oncology tests and has signed with Illumina, since September 21, 2020, a (i) supply agreement, amended supply agreement, letter of intent, or open offer containing terms relating to the proposed transaction, or (ii) "standard contract for U.S. oncology customers" on Illumina's website; and (2) any third-party witness who appeared for an investigational hearing taken in the investigation conducted by the FTC. Each witness may only be deposed once in this litigation in their individual capacity unless that witness or third party signs a (1) new declaration or letter of support, or (2) supply agreement, amended supply agreement, letter of intent, or open offer containing terms relating to the proposed transaction, or (3) "standard contract for U.S. oncology customers" on Illumina's website, after they were deposed in this litigation. In that case, the witness may be re-deposed in a deposition of limited duration for the limited purpose of inquiry into that modified agreement or declaration, notwithstanding any other provisions in the CMSO.

ii. In addition to those individuals listed under (C.12(a)(i)), each side may take a maximum of fifteen (15) fact depositions of party and third-party witnesses. Plaintiffs may take the deposition of any party witness listed on either side's preliminary witness list as well as no more than five (5) additional depositions of party witnesses.

iii. A Rule 30(b)(6) notice counts as no more than one (1) deposition, in the event a party or third party designates multiple individuals in response to a notice. Additional depositions of fact witnesses shall be permitted

only by agreement of the parties or by leave of the Court for good cause shown. The parties shall consult with each other prior to confirming any deposition to coordinate the time and place of the deposition. The parties shall use reasonable efforts to reduce the burden on witnesses noticed for depositions and to accommodate the witness's schedule.

b) *Allocation of time:* All depositions, including depositions of fact (including 30(b)(6) witnesses) and expert witnesses, shall last no more than seven (7) hours on the record. For the avoidance of doubt, a single 30(b)(6) notice entitles the serving side a maximum of seven (7) hours of testimony on the record on the topics in the notice, regardless of whether multiple witnesses are designated to respond to those topics. If both Plaintiff and Defendants notice any third-party deposition, they shall allocate the time evenly between them. If both Plaintiff and Defendants notice any third-party fact deposition, the deposition shall count against each side's respective deposition totals. Unused time in any side's allocation of deposition time shall not transfer to the other party. The parties anticipate reaching a separate protocol governing remote depositions. For party witnesses or third-party witnesses retained by any party (*e.g.*, as a consultant, agent, contractor, or representative) in connection with the proposed transaction, or any former employees of any party, the other side will have the opportunity to use up to seven (7) hours for the deposition, consistent with the restrictions on 30(b)(6) depositions described in this section.

c) *Notice:* The parties may not serve a deposition notice with fewer than seven (7) calendar days' notice. The parties shall consult with each other prior to confirming any deposition to coordinate the time and place of the deposition. The parties shall use reasonable efforts to reduce the burden on witnesses noticed for depositions and to accommodate the witness's schedule. If a party serves a non-party with a subpoena for the production of documents or electronically stored information and a subpoena commanding attendance at a

deposition, the deposition date must be at least seven (7) calendar days after the original return date for the document subpoena. No notice for a deposition of a fact witness shall issue after May 7, 2021, except that deposition notices of witnesses who sign, after May 7, 2021, (1) a declaration or letter of support, (2) a new supply agreement, amended supply agreement, letter of intent, or open offer containing terms relating to the proposed transaction, or (3) a "standard contract for U.S. oncology customers" on Illumina's website, may be served anytime within five (5) calendar days of the declaration, letter of support, supply agreement, amendment, letter of intent or contract being provided to the opposing party. The parties agree to make good-faith efforts to schedule all third-party depositions by the close of fact discovery. If a third-party deposition is properly noticed pursuant to the above but the third party's schedule cannot accommodate a deposition before the end of fact discovery, a later deposition may occur at the agreement of both sides. No party may unreasonably withhold agreement.

13. Expert Depositions. A single seven (7) hour (on the record) deposition of each expert shall be allowed. Expert depositions must be conducted between July 12 and July 16, 2021.

14. Discovery Uses. All discovery taken in the above-captioned litigation can be used in connection with the Part 3 administrative proceeding (FTC Docket No. 9401). Only discovery obtained by a party in the Part 3 administrative proceeding before the close of fact discovery in this proceeding may be used as part of this litigation, except by agreement of the parties or by leave of the Court for good cause shown.

D. MOTIONS AND BRIEFING SCHEDULE.

15. Plaintiff will file its memorandum in support of its motion for a preliminary injunction by June 18, 2021. This brief shall not exceed forty-five (45) pages.

16. Defendants will file their opposition to Plaintiff's motion for a

preliminary injunction by July 12, 2021. This brief shall not exceed forty-five (45) pages.

17. Plaintiff will file its reply memorandum in further support of its motion for a preliminary injunction by July 20, 2021. This brief shall not exceed twenty-five (25) pages.

18. Any motions *in limine*, including any *Daubert* motions, shall be filed by July 21, 2021. Responses to motions *in limine* shall be filed by July 23, 2021.

19. The parties' proposed findings of fact and conclusions of law shall be filed within ten (10) calendar days after the close of the evidentiary hearing.

E. PRELIMINARY INJUNCTION EVIDENTIARY HEARING.

20. The Parties propose that the evidentiary hearing on Plaintiff's motion for a preliminary injunction begin on July 26, 2021. Given disagreement between the Plaintiff and Defendants regarding the scope of evidence to be admitted in this preliminary injunction proceeding, the parties will meet and confer after the close of fact discovery and will make a joint proposal to the Court on June 21, 2021 regarding (1) whether all witnesses for whom either party will move to admit deposition transcripts or investigational hearing transcripts need to be included on the preliminary, supplemental and/or the final witness list; (2) the number of witnesses that shall be included on the final witness list; and (3) whether deposition or investigational hearing testimony can be admitted for someone on the final witness list if that person testifies live at the preliminary injunction hearing; and (4) how much time each side will have to present its case, including opening statements and closing statements. Examination time will count against the side conducting the examination of the witness. Plaintiff may reserve a portion of its time for rebuttal.

F. OTHER MATTERS.

21. Service. Service of any documents not filed via ECF, including discovery requests, notice of Rule 45 subpoenas for testimony or documents, expert disclosure, and delivery of all correspondence, whether under seal or otherwise, shall be served by electronic mail to the following individuals designated by each party:

22. For Plaintiff:

To the FTC: William Cooke
Sadie Goering
Matthew Joseph
Stephen Mohr
Susan Musser
Sarah Wohl
Nicholas Widnell
Hana Verwilt

For Defendants:

For Illumina: Sharonmoyee Goswami
Jesse Weiss
Michael Zaken
Illumina Trial Team (list serv)
Cravath, Swaine & Moore LLP
825 Eighth Avenue
New York, NY 10019

For GRAIL: Marguerite Sullivan
Anna Rathbun
Latham Antitrust Team (list serv)
Latham & Watkins LLP
555 Eleventh Street, NW
Suite 1000
Washington, D.C. 20004

In the event that any documents are too voluminous for electronic mail, the parties may serve an electronic version of the papers on opposing counsel via an electronic file transfer platform. The serving party will

telephone or email the other side's principal designee when the materials are sent to alert them that the materials are being served. Service of court filings by 11:59 PM Eastern Time shall be considered to have been filed on that day. For purposes of this provision, service of all other correspondence, discovery requests, witness lists, exhibit lists, objections, expert reports, and productions from parties and third parties by 11:59 PM Eastern Time shall be considered served on that day.

23. Nationwide Service of Process. Good cause having been shown in view of the geographic dispersion of potential witnesses in this action, the parties will be allowed nationwide service of process of discovery and trial subpoenas pursuant to Federal Rule of Civil Procedure 45 and 15 U.S.C. § 23, to issue from this Court. The availability of nationwide service of process, however, does not make a witness who is otherwise "unavailable" for purposes of Federal Rule of Civil Procedure 32 and Federal Rule of Evidence 804 available under these rules regarding the use at trial of a deposition taken in this action.

24. Third-Party Confidential Information. The Protective Order entered by the Court on April 1, 2021 shall govern discovery and production of Confidential Information. Any party serving discovery requests, notices, or subpoenas sent to a non-party shall provide the non-party with a copy of the Protective Order.

25. Privilege Logs. The parties agree to suspend the obligations of Federal Rule of Civil Procedure 26(b)(5)(A) to produce a log of privileged materials withheld from discovery taken in this action (excluding Defendants' productions made during the course of the FTC's pre-complaint investigation). Notwithstanding the foregoing, the parties shall log withheld materials that are: (1) authored by, addressed to, or received from any non-party; (2) internal to a party that are not authored by, sent to, or received from the party's attorneys; (3) authored by, addressed to, or received from any party executive who serves both in-house business and legal roles; and (4) authored by, addressed to, or received from any

executive who has a law degree, even if the executive is not a practicing attorney. For purposes of this Paragraph, a "non-party" excludes a party's retained expert and employees of such expert within the meaning of Federal Rule of Civil Procedure 26(b) and/or Federal Rule of Evidence 702. The parties shall maintain all documents responsive to a discovery request that they withhold pursuant to a claim of privilege or protection. The FTC agrees to log any external communication withheld due to deliberative process privilege. This Paragraph shall not alter either Party's right to challenge any privilege claims made by either Party, including, but not limited to, any deliberative process privilege claim.

26. Electronically Stored Information. The parties agree as follows regarding the preservation and production of electronically stored information ("ESI"):

a) All parties have established litigation holds to preserve ESI that may be relevant to the expected claims and defenses in this case. In addition, the parties have taken steps to ensure that automatic deletion systems will not destroy any potentially relevant information.

b) All parties will request ESI in the form or forms that facilitate efficient review of ESI. In general, the parties will produce ESI according to the same ESI technical specifications used by Defendants in the FTC's pre-complaint investigation.

27. Evidentiary Presumptions.

a) Documents produced by non-parties from the non-parties' files shall be presumed to be authentic. Any good-faith objection to a document's admissibility must be provided with the exchange of other objections to trial exhibits. If a party serves a specific good-faith written objection to the document's authenticity, the presumption of authenticity will no longer apply to that document and the parties will promptly meet and confer to attempt to resolve any objection. The Court will resolve any objections that are not resolved through this means or

through the discovery process.

b) All documents produced by a Defendant either in response to document requests in this litigation or in the course of the FTC's pre-complaint investigation of the proposed acquisition, FTC File No. 2021-0063, or any prior FTC investigation, are presumed to be authentic. If a party serves a specific good-faith written objection to any such document's authenticity, the parties will promptly meet and confer to attempt to resolve any objection. The Court will resolve any objections that are not resolved through this means or through the discovery process.

28. Modification of Case Management and Scheduling Order. Any party may seek to modify the Court's CMSO for good cause.

29. Statements Regarding Local Rules 16.1 and 16.3. The parties do not consent to assignment of this case to a magistrate judge for all purposes, including trial. The parties are amenable to settling this case but, despite their pre-Complaint efforts, have not been able to resolve their different views on the likely effects of the proposed merger. Presently, the parties do not believe that the case would benefit from the Court's alternative dispute resolution procedures.

30. Exhibit Lists. The parties shall exchange exhibit lists on or before July 16, 2021. Objections shall be filed on or before July 21, 2021. The parties will file their final exhibit lists with the Court on or before July 23, 2021.

31. Fact Witness Deposition/Investigational Hearing Designations. The parties shall exchange affirmative fact witness deposition or investigational hearing designations on or before July 12, 2021. Fact witness deposition or investigational hearing counter-designations and objections to affirmative fact witness deposition designations shall be exchanged on or before July 16, 2021. Objections to fact witness deposition or investigational hearing counter-designations shall be exchanged on or before July 21, 2021. Defendants reserve all rights to object to designations that are in contravention of the Federal Rules of

Evidence. Defendants reserve all rights to object to Plaintiff's use, in its proposed findings of fact or conclusions of law, of deposition designation testimony (including investigational hearing testimony) of witnesses who were not disclosed on Plaintiff's preliminary or final witness lists. Plaintiff similarly reserves all rights to admit investigational hearing transcripts and deposition designations regardless of whether those witnesses were included on the Plaintiff's preliminary, supplemental, or final witness lists and to rely on those transcripts in the Findings of Fact and Conclusions of Law. Plaintiff also reserves all right to argue for designations consistent with the 16 C.F.R. § 3 and federal case law.

32. Federal Rule of Civil Procedure 6(a)(1)(C) is to be applied when computing the deadlines in the Court's CMSO.

OVERVIEW OF SCHEDULE

Event	Date(s)
Exchange of Preliminary Witness Lists, including Expert Witnesses	Two days post-entry of CMSO by Court
Deadline to serve Written Discovery to Parties	April 28, 2021
Deadline to serve Written Discovery to Third Parties	May 7, 2021
Deadline to serve Deposition Notices for Fact Witnesses	May 7, 2021
Exchange of Supplemental Witness Lists	May 14, 2021
Close of Fact Discovery	June 4, 2021
Plaintiff's Expert Report(s) due	June 8, 2021
Plaintiff's Memorandum of Law in Support of Preliminary Injunction Motion	June 18, 2021
Joint Proposal Regarding Designation of Fact Witness Testimony and Final Witness Lists	June 21, 2021
Defendants' Expert Report(s) due	June 29, 2021
Plaintiffs' Rebuttal Expert Report(s) due	July 9, 2021
Exchange of Affirmative Fact Witness Designations	July 12, 2021
Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction	July 12, 2021
Close of Expert Discovery	July 16, 2021
Exchange of Exhibit Lists	July 16, 2021
Exchange of Fact Witness Counter-Designations and Objections to Affirmative Fact Witness Designations	July 16, 2021
Exchange of Final Witness Lists, including Expert Witnesses	July 19, 2021
Plaintiff's Reply Brief in Further Support of Motion for Preliminary Injunction	July 20, 2021
Last day for Motions In Limine to be filed	July 21, 2021
Exchange of Objections to Fact Witness Counter-Designations	July 21, 2021
Objections to Exhibit Lists	July 21, 2021
Final Exhibit Lists due	July 23, 2021
Last day for Responses to Motions In Limine to be filed	July 23, 2021
Pre-Hearing Conference	TBD
Evidentiary Hearing begins	July 26, 2021
Proposed Findings of Fact and Conclusions of Law	10 days after the close of the Hearing

Exhibit F

UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION, Plaintiff, v. ILLUMINA, INC, and GRAIL, INC., Defendants.	Case No. 3:21-cv-00800-CAB-BGS **CASE MANAGEMENT AND SCHEDULING ORDER** Complaint Filed: March 30, 2021 Judge: Hon. Cathy Ann Bencivengo Magistrate: Hon. Bernard G. Skomal Trial Date: Not Set

It is hereby ordered as follows:

A. TEMPORARY RESTRAINING ORDER. Defendants consented to the entry of a Temporary Restraining Order, which the District Court for the District of Columbia entered on March 31, 2021. Under that Temporary Restraining Order, the Defendants have agreed not to close their transaction until the earlier of 12:01 AM Eastern Time on September 20, 2021 or after 11:59 PM Eastern Time on the second (2nd) business day after this Court rules on the Plaintiff's motion for preliminary injunction.

B. ANSWER. Defendants answered Plaintiff's Complaint on April 5, 2021.

C. DISCOVERY.

1. Fact Discovery. Fact discovery commenced on April 1, 2021 and shall be completed by **June 4, 2021**. To the extent a third-party deposition is properly noticed in accordance with this Order and the third party's schedule cannot accommodate a deposition before the end of fact discovery, a later deposition may occur with the agreement of both sides. No party may unreasonably withhold agreement. All discovery in this case, including discovery initiated prior to the entry of the CMSO, shall be subject to the CMSO as entered by any Court.

2. Initial Disclosures. The parties agree to forego the requirement to exchange initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1).

3. Pre-Trial Discovery Conference. This Order relieves the parties of their duty under Federal Rule of Civil Procedure 26(f) to confer about scheduling and a discovery plan.

4. Third-Party Discovery. No party issuing a third-party subpoena for the production of documents or electronically stored information shall request a return date sooner than seven (7) calendar days after service. Each party shall produce all materials received pursuant to a third-party subpoena or other formal or informal request, including any declarations or affidavits obtained from a third

party, to the other party in the format in which those materials were received within two (2) business days of receiving those materials. In the event a non-party produces documents or electronic information that are non-Bates-stamped—in addition to producing the materials in the format in which they were received within two (2) business days of receiving them—the party receiving the documents shall promptly Bates-stamp the documents or electronic information and produce them in a reasonable timeframe. The parties shall serve document subpoenas to third parties by **May 7, 2021**.

5. Limitations on Party and Third-Party Declarations or Affidavits. No party may submit as evidence a declaration or affidavit from a party or third-party witness if such declaration or affidavit was executed or served less than one week prior to his or her agreed-to deposition date. In any event, no party or third-party declaration or affidavit may be submitted as evidence if it was executed or served less than fourteen (14) calendar days before the close of fact discovery unless it is a supplemental third-party declaration or affidavit related to a previously given third-party declaration or affidavit, in which case the parties agree to not oppose any efforts to depose, or re-depose, such a declarant or affiant irrespective of any other provisions of this order.

6. Document Requests and Production. There shall be no limit on the number of requests for production of documents that the parties may serve. The parties shall serve any objections to requests for the production of documents no later than ten (10) calendar days after the date of service of the document requests to which they assert objections. Within two (2) business days of service of any such objections, the parties shall meet and confer in a good faith attempt to resolve the objections. Responsive productions (subject to any objections or custodian issues that have not been resolved) must be made on a rolling basis and must begin as soon as reasonably practicable after the date of service. All productions must be completed within 30 calendar days of the document request. In response to any

document requests, the parties need not produce to each other in discovery in this case any documents previously produced by Defendants to the FTC in the course of the investigation of the acquisition of GRAIL by Illumina, FTC File No. 201-0144.

Document Productions shall be sent to the attention of:

To the FTC:
William Cooke
Sadie Goering
Matthew Joseph
Stephen Mohr
Susan Musser
Sarah Wohl
Nicholas Widnell
David Gonen
Lauren Gaskin
Dylan Naegele
Eric Edmondson
Hana Verwilt

For Illumina:
Sharonmoyee Goswami
Jesse Weiss
Michael Zaken
Illumina Trial Team (list serv)
Cravath, Swaine & Moore LLP
825 Eighth Avenue
New York, NY 10019

For GRAIL:
Marguerite Sullivan
Anna Rathbun
Latham Antitrust Team (list serv)
Latham & Watkins LLP
555 Eleventh Street, NW
Suite 1000
Washington, D.C. 20004

7. Interrogatories. The parties shall serve no more than twenty-five (25) interrogatories per side. The parties may serve up to five (5) contention interrogatories per side. The parties shall serve objections and responses to interrogatories no later than ten (10) calendar days after the date of service. Within two (2) business days of any objections, the parties must meet and confer to attempt

to resolve the objections. The parties must make good-faith efforts to provide complete answers to interrogatories no later than twenty (20) calendar days after service of the interrogatories.

8. Deadline to Issue Written Discovery to Parties. The parties shall serve document requests and interrogatories to parties by **April 28, 2021**.

9. Expert Reports. Plaintiff shall serve its expert report(s) on **June 8, 2021**. Defendants shall serve their expert report(s) on **June 29, 2021**. Plaintiff shall serve its rebuttal expert report(s) on **July 9, 2021**.

10. Expert Materials Not Subject to Discovery. Expert disclosures, including each side's expert report(s), shall comply with the requirements of Federal Rule of Civil Procedure 26(a)(2), except as modified herein:

a) Neither side must preserve or disclose, including in expert deposition testimony, the following documents or materials:

i. any form of communication or work product shared between any of the parties' counsel and their expert(s) or consultants, or between any of the experts themselves;

ii. any form of communication or work product shared between an expert and persons assisting the expert;

iii. expert's notes, unless they constitute the only record of a fact or an assumption relied upon by the expert in formulating an opinion in this case;

iv. drafts of expert reports, analyses, or other work product; or

v. data formulations, data runs, data analyses, or any database-related operations not relied upon by the expert in the opinions contained in his or her final report, except as set forth in 13(b).

b) The parties agree that they will disclose the following materials with all expert reports:

i. a list by Bates number of all documents relied upon by the testifying expert(s);

ii. copies of any materials relied upon by the expert not previously produced that are not readily available publicly; and

iii. for any calculations appearing in the report, all data and programs underlying the calculation, including any processed data files relied upon by the expert in forming his or her opinion and all programs and codes necessary to recreate the calculation from the initial ("raw") data files.

11. Exchange of Lists of Witnesses to Appear at Hearing.

a) *Preliminary Witness Lists:* The parties shall exchange preliminary witness lists no later than 11:59 PM Eastern Time two business days after the CMSO is entered. Defendants shall jointly submit one list. Preliminary witness lists shall include for each witness (including both fact and expert witnesses): (a) the witness's name and employer; (b) the name, address, telephone number, and email address of the witness's counsel (or, if not represented by counsel, the witness's address, telephone number, and email address); (c) an indication of whether the witness will offer expert testimony; and (d) a summary of the general topics of each witness's anticipated testimony. The number of fact witnesses who may be included on any side's preliminary witness list shall not exceed twenty five (25). The preliminary witness lists shall include only witnesses that a side believes in good faith it will present at the evidentiary hearing live (including remotely if necessary to satisfy COVID-19 protocols). Defendants reserve all rights to object to Plaintiff's use, in its proposed findings of fact or conclusions of law, of deposition designation testimony (including investigational hearing testimony) of witnesses who were not disclosed on Plaintiff's preliminary or final witness lists. Plaintiff similarly reserves all rights to admit investigational hearing transcripts and deposition designations regardless of whether those witnesses were included on the Plaintiff's preliminary, supplemental, or final

witness lists.

b) *Supplemental Witness Lists:* Each party shall supplement their witness list to include all expert witnesses that will be or may be submitting an expert report and/or testifying at trial. With this supplemental witness list, each side shall provide a summary of the general topics of each witness's anticipated testimony on or before 11:59 PM Eastern Time on **May 14, 2021**.

c) *Final Witness Lists:* Final party and third-party witness lists shall be exchanged on or before 11:59 PM Eastern Time on **July 19, 2021**. Only a witness who appears on either party's preliminary witness list, supplemental witness list, or were otherwise deposed during fact discovery may be included on a party's final witness list. Final witness lists shall include for each witness (including both fact and expert witnesses): (a) an indication of whether the witness will offer expert testimony; and (b) a summary of the general topics of each witness's anticipated testimony. No witness shall be permitted at trial unless the opposing side had an opportunity to depose the witness before trial. Defendants reserve all rights to object to Plaintiff's use, in its proposed findings of fact or conclusions of law, of deposition designation testimony (including investigational hearing testimony) of witnesses who were not disclosed on Plaintiff's preliminary or final witness lists. Defendants' position is that final witness lists shall also include an indication of whether the witness will testify live (including remotely if necessary to satisfy COVID-19 protocols) or through reading or playing of a deposition at the preliminary injunction evidentiary hearing. Plaintiff similarly reserves all rights to admit investigational hearing transcripts and deposition designations regardless of whether those witnesses were included on the Plaintiff's preliminary, supplemental, or final witness lists and to rely on those transcripts in the Findings of Fact and Conclusions of Law.

12. Depositions.

a) *Number of Fact Depositions:*

i. Each side is entitled to depose any individual who is listed on either side's preliminary, supplemental or final witness lists. In addition, each side is entitled to depose (1) any individual who signed a declaration or letter of support or any third party that is developing or commercializing oncology tests and has signed with Illumina, since September 21, 2020, a (i) supply agreement, amended supply agreement, letter of intent, or open offer containing terms relating to the proposed transaction, or (ii) "standard contract for U.S. oncology customers" on Illumina's website; and (2) any third-party witness who appeared for an investigational hearing taken in the investigation conducted by the FTC. Each witness may only be deposed once in this litigation in their individual capacity unless that witness or third party signs a (1) new declaration or letter of support, or (2) supply agreement, amended supply agreement, letter of intent, or open offer containing terms relating to the proposed transaction, or (3) "standard contract for U.S. oncology customers" on Illumina's website, after they were deposed in this litigation. In that case, the witness may be re-deposed in a deposition of limited duration for the limited purpose of inquiry into that modified agreement or declaration, notwithstanding any other provisions in the CMSO.

ii. In addition to those individuals listed under (C.12(a)(i)), each side may take a maximum of fifteen (15) fact depositions of party and third-party witnesses. Plaintiffs may take the deposition of any party witness listed on either side's preliminary witness list as well as no more than five (5) additional depositions of party witnesses.

iii. A Rule 30(b)(6) notice counts as no more than one (1) deposition, in the event a party or third party designates multiple individuals in response to a notice. Additional depositions of fact witnesses shall be permitted only by agreement of the parties or by leave of the Court for good cause shown.

The parties shall consult with each other prior to confirming any deposition to coordinate the time and place of the deposition. The parties shall use reasonable efforts to reduce the burden on witnesses noticed for depositions and to accommodate the witness's schedule.

b) *Allocation of time:* All depositions, including depositions of fact (including 30(b)(6) witnesses) and expert witnesses, shall last no more than seven (7) hours on the record. For the avoidance of doubt, a single 30(b)(6) notice entitles the serving side a maximum of seven (7) hours of testimony on the record on the topics in the notice, regardless of whether multiple witnesses are designated to respond to those topics. If both Plaintiff and Defendants notice any third-party deposition, they shall allocate the time evenly between them. If both Plaintiff and Defendants notice any third-party fact deposition, the deposition shall count against each side's respective deposition totals. Unused time in any side's allocation of deposition time shall not transfer to the other party. The parties anticipate reaching a separate protocol governing remote depositions. For party witnesses or third-party witnesses retained by any party (*e.g.*, as a consultant, agent, contractor, or representative) in connection with the proposed transaction, or any former employees of any party, the other side will have the opportunity to use up to seven (7) hours for the deposition, consistent with the restrictions on 30(b)(6) depositions described in this section.

c) *Notice:* The parties may not serve a deposition notice with fewer than seven (7) calendar days' notice. The parties shall consult with each other prior to confirming any deposition to coordinate the time and place of the deposition. The parties shall use reasonable efforts to reduce the burden on witnesses noticed for depositions and to accommodate the witness's schedule. If a party serves a non-party with a subpoena for the production of documents or electronically stored information and a subpoena commanding attendance at a deposition, the deposition date must be at least seven (7) calendar days after the

original return date for the document subpoena. No notice for a deposition of a fact witness shall issue after **May 7, 2021**, except that deposition notices of witnesses who sign, after May 7, 2021, (1) a declaration or letter of support, (2) a new supply agreement, amended supply agreement, letter of intent, or open offer containing terms relating to the proposed transaction, or (3) a "standard contract for U.S. oncology customers" on Illumina's website, may be served anytime within five (5) calendar days of the declaration, letter of support, supply agreement, amendment, letter of intent or contract being provided to the opposing party. The parties agree to make good-faith efforts to schedule all third-party depositions by the close of fact discovery. If a third-party deposition is properly noticed pursuant to the above but the third party's schedule cannot accommodate a deposition before the end of fact discovery, a later deposition may occur at the agreement of both sides. No party may unreasonably withhold agreement.

13. Expert Depositions. A single seven (7) hour (on the record) deposition of each expert shall be allowed. Expert depositions must be conducted between **July 12** and **July 16, 2021**.

14. Discovery Uses. All discovery taken in the above-captioned litigation can be used in connection with the Part 3 administrative proceeding (FTC Docket No. 9401). Only discovery obtained by a party in the Part 3 administrative proceeding before the close of fact discovery in this proceeding may be used as part of this litigation, except by agreement of the parties or by leave of the Court for good cause shown.

D. MOTIONS AND BRIEFING SCHEDULE.

15. Plaintiff will file its memorandum in support of its motion for a preliminary injunction by **June 18, 2021**. This brief shall not exceed forty-five (45) pages.

16. Defendants will file their opposition to Plaintiff's motion for a preliminary injunction by **July 12, 2021**. This brief shall not exceed forty-five (45)

pages.

17. Plaintiff will file its reply memorandum in further support of its motion for a preliminary injunction by **July 20, 2021**. This brief shall not exceed twenty-five (25) pages.

18. Any motions *in limine*, including any *Daubert* motions, shall be filed by **July 21, 2021**. Responses to motions *in limine* shall be filed by **July 23, 2021**.

19. The parties' proposed findings of fact and conclusions of law shall be filed within ten (10) calendar days after the close of the evidentiary hearing.

E. PRELIMINARY INJUNCTION EVIDENTIARY HEARING.

20. The evidentiary hearing on Plaintiff's motion for a preliminary injunction will begin on **August 9, 2021**. Given disagreement between the Plaintiff and Defendants regarding the scope of evidence to be admitted in this preliminary injunction proceeding, the parties will meet and confer after the close of fact discovery and will make a joint proposal to the Court on **June 21, 2021** regarding (1) whether all witnesses for whom either party will move to admit deposition transcripts or investigational hearing transcripts need to be included on the preliminary, supplemental and/or the final witness list; (2) the number of witnesses that shall be included on the final witness list; and (3) whether deposition or investigational hearing testimony can be admitted for someone on the final witness list if that person testifies live at the preliminary injunction hearing; and (4) how much time each side will have to present its case, including opening statements and closing statements. Examination time will count against the side conducting the examination of the witness. Plaintiff may reserve a portion of its time for rebuttal.

F. OTHER MATTERS.

21. Service. Service of any documents not filed via ECF, including discovery requests, notice of Rule 45 subpoenas for testimony or documents, expert

disclosure, and delivery of all correspondence, whether under seal or otherwise, shall be served by electronic mail to the following individuals designated by each party:

22. For Plaintiff:

To the FTC: William Cooke
Sadie Goering
Matthew Joseph
Stephen Mohr
Susan Musser
Sarah Wohl
Nicholas Widnell
Hana Verwilt

For Defendants:

For Illumina: Sharonmoyee Goswami
Jesse Weiss
Michael Zaken
Illumina Trial Team (list serv)
Cravath, Swaine & Moore LLP
825 Eighth Avenue
New York, NY 10019

For GRAIL: Marguerite Sullivan
Anna Rathbun
Latham Antitrust Team (list serv)
Latham & Watkins LLP
555 Eleventh Street, NW
Suite 1000
Washington, D.C. 20004

In the event that any documents are too voluminous for electronic mail, the parties may serve an electronic version of the papers on opposing counsel via an electronic file transfer platform. The serving party will telephone or email the other side's principal designee when the materials are sent to alert them that the materials are being served. Service of court filings by 11:59 PM Eastern Time shall be considered to have been filed on that day. For purposes of

this provision, service of all other correspondence, discovery requests, witness lists, exhibit lists, objections, expert reports, and productions from parties and third parties by 11:59 PM Eastern Time shall be considered served on that day.

23. Nationwide Service of Process. Good cause having been shown in view of the geographic dispersion of potential witnesses in this action, the parties will be allowed nationwide service of process of discovery and trial subpoenas pursuant to Federal Rule of Civil Procedure 45 and 15 U.S.C. § 23, to issue from this Court. The availability of nationwide service of process, however, does not make a witness who is otherwise "unavailable" for purposes of Federal Rule of Civil Procedure 32 and Federal Rule of Evidence 804 available under these rules regarding the use at trial of a deposition taken in this action.

24. Third-Party Confidential Information. The Protective Order entered by the Court on April 1, 2021 shall govern discovery and production of Confidential Information. Any party serving discovery requests, notices, or subpoenas sent to a non-party shall provide the non-party with a copy of the Protective Order.

25. Privilege Logs. The parties agree to suspend the obligations of Federal Rule of Civil Procedure 26(b)(5)(A) to produce a log of privileged materials withheld from discovery taken in this action (excluding Defendants' productions made during the course of the FTC's pre-complaint investigation). Notwithstanding the foregoing, the parties shall log withheld materials that are: (1) authored by, addressed to, or received from any non-party; (2) internal to a party that are not authored by, sent to, or received from the party's attorneys; (3) authored by, addressed to, or received from any party executive who serves both in-house business and legal roles; and (4) authored by, addressed to, or received from any executive who has a law degree, even if the executive is not a practicing attorney. For purposes of this Paragraph, a "non-party" excludes a party's retained expert and employees of such expert within the meaning of Federal Rule of Civil Procedure

26(b) and/or Federal Rule of Evidence 702. The parties shall maintain all documents responsive to a discovery request that they withhold pursuant to a claim of privilege or protection. The FTC agrees to log any external communication withheld due to deliberative process privilege. This Paragraph shall not alter either Party's right to challenge any privilege claims made by either Party, including, but not limited to, any deliberative process privilege claim.

26. Electronically Stored Information. The parties agree as follows regarding the preservation and production of electronically stored information ("ESI"):

a) All parties have established litigation holds to preserve ESI that may be relevant to the expected claims and defenses in this case. In addition, the parties have taken steps to ensure that automatic deletion systems will not destroy any potentially relevant information.

b) All parties will request ESI in the form or forms that facilitate efficient review of ESI. In general, the parties will produce ESI according to the same ESI technical specifications used by Defendants in the FTC's pre-complaint investigation.

27. Evidentiary Presumptions.

a) Documents produced by non-parties from the non-parties' files shall be presumed to be authentic. Any good-faith objection to a document's admissibility must be provided with the exchange of other objections to trial exhibits. If a party serves a specific good-faith written objection to the document's authenticity, the presumption of authenticity will no longer apply to that document and the parties will promptly meet and confer to attempt to resolve any objection. The Court will resolve any objections that are not resolved through this means or through the discovery process.

b) All documents produced by a Defendant either in response to document requests in this litigation or in the course of the FTC's pre-

complaint investigation of the proposed acquisition, FTC File No. 2021-0063, or any prior FTC investigation, are presumed to be authentic. If a party serves a specific good-faith written objection to any such document's authenticity, the parties will promptly meet and confer to attempt to resolve any objection. The Court will resolve any objections that are not resolved through this means or through the discovery process.

28. Modification of Case Management and Scheduling Order. Any party may seek modification of this Order for good cause.

29. Statements Regarding Local Rules 16.1 and 16.3. The parties do not consent to assignment of this case to a magistrate judge for all purposes, including trial. The parties are amenable to settling this case but, despite their pre-Complaint efforts, have not been able to resolve their different views on the likely effects of the proposed merger. Presently, the parties do not believe that the case would benefit from the Court's alternative dispute resolution procedures.

30. Exhibit Lists. The parties shall exchange exhibit lists on or before **July 16, 2021**. Objections shall be filed on or before **July 21, 2021**. The parties will file their final exhibit lists with the Court on or before **July 23, 2021**.

31. Fact Witness Deposition/Investigational Hearing Designations. The parties shall exchange affirmative fact witness deposition or investigational hearing designations on or before **July 12, 2021**. Fact witness deposition or investigational hearing counter-designations and objections to affirmative fact witness deposition designations shall be exchanged on or before **July 16, 2021**. Objections to fact witness deposition or investigational hearing counter-designations shall be exchanged on or before **July 21, 2021**. Defendants reserve all rights to object to designations that are in contravention of the Federal Rules of Evidence. Defendants reserve all rights to object to Plaintiff's use, in its proposed findings of fact or conclusions of law, of deposition designation testimony (including investigational hearing testimony) of witnesses who were not disclosed

on Plaintiff's preliminary or final witness lists. Plaintiff similarly reserves all rights to admit investigational hearing transcripts and deposition designations regardless of whether those witnesses were included on the Plaintiff's preliminary, supplemental, or final witness lists and to rely on those transcripts in the Findings of Fact and Conclusions of Law. Plaintiff also reserves all right to argue for designations consistent with the 16 C.F.R. § 3 and federal case law.

32. Federal Rule of Civil Procedure 6(a)(1)(C) is to be applied when computing the deadlines in this Order.

It is **SO ORDERED.**

Dated: April 26, 2021

Hon. Cathy Ann Bencivengo
United States District Judge

OVERVIEW OF SCHEDULE

Event	Date(s)
Exchange of Preliminary Witness Lists, including Expert Witnesses	Two days post-entry of CMSO by Court
Deadline to serve Written Discovery to Parties	April 28, 2021
Deadline to serve Written Discovery to Third Parties	May 7, 2021
Deadline to serve Deposition Notices for Fact Witnesses	May 7, 2021
Exchange of Supplemental Witness Lists	May 14, 2021
Close of Fact Discovery	June 4, 2021
Plaintiff's Expert Report(s) due	June 8, 2021
Plaintiff's Memorandum of Law in Support of Preliminary Injunction Motion	June 18, 2021
Joint Proposal Regarding Designation of Fact Witness Testimony and Final Witness Lists	June 21, 2021
Defendants' Expert Report(s) due	June 29, 2021
Plaintiffs' Rebuttal Expert Report(s) due	July 9, 2021
Exchange of Affirmative Fact Witness Designations	July 12, 2021
Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction	July 12, 2021
Close of Expert Discovery	July 16, 2021
Exchange of Exhibit Lists	July 16, 2021
Exchange of Fact Witness Counter-Designations and Objections to Affirmative Fact Witness Designations	July 16, 2021
Exchange of Final Witness Lists, including Expert Witnesses	July 19, 2021
Plaintiff's Reply Brief in Further Support of Motion for Preliminary Injunction	July 20, 2021
Last day for Motions In Limine to be filed	July 21, 2021
Exchange of Objections to Fact Witness Counter-Designations	July 21, 2021
Objections to Exhibit Lists	July 21, 2021
Final Exhibit Lists due	July 23, 2021
Last day for Responses to Motions In Limine to be filed	July 23, 2021
Pre-Hearing Conference	TBD
Evidentiary Hearing begins	August 9, 2021
Proposed Findings of Fact and Conclusions of Law	10 days after the close of the Hearing

Exhibit G

Susan A. Musser (D.C. Bar No. 1531486)
Daniel K. Zach (N.Y. Bar No. 4332698)
Stephen Mohr (D.C. Bar 982570)
Sarah Wohl (D.C. Bar No. 1016357)
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Counsel for Plaintiff Federal Trade Commission

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ILLUMINA, INC. and GRAIL, INC.,

Defendants.

Case No.: 3:21-cv-00800-CAB-BGS

MEMORANDUM IN SUPPORT OF PLAINTIFF'S *EX PARTE* APPLICATION TO DISMISS THE COMPLAINT WITHOUT PREJUDICE

Judge: Hon. Cathy Ann Bencivengo
Magistrate: Hon. Bernard G. Skomal
Courtroom: 15A
Hearing Date:

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MEMORANDUM IN SUPPORT OF PLAINTIFF'S *EX PARTE APPLICATION* TO DISMISS UNDER FEDERAL RULE OF CIVIL PROCEDURE 41(A)(2)

The Federal Trade Commission ("FTC" or "Commission") moves to voluntarily dismiss its Complaint for Preliminary Injunction and Temporary Restraining Order ("PI Complaint") under Federal Rule of Civil Procedure 41(A)(2). Fed. R. Civ. P. 41(A)(2). The FTC filed its PI Complaint on March 31, 2021 to maintain the *status quo* and prevent Illumina, Inc. and GRAIL, Inc. (collectively, "Defendants") from consummating their proposed transaction before the administrative trial on the merits could be conducted.[1] (PI Complaint, p. 1). Since the FTC filed the PI Complaint, the European Commission ("EC") announced that it has accepted requests from member states to assess Defendants' proposed transaction and publicly stated that Illumina and GRAIL cannot "implement the transaction before notifying and obtaining clearance from the Commission."[2] Although Defendants appear to be appealing the EC's exercise of jurisdiction,[3] unless either the EC completes its investigation and allows the proposed transaction to proceed, or the European General Court determines that the EC lacks jurisdiction to investigate, Defendants are prohibited from closing.[4] Currently, the EC has not accepted Defendants'

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[1] The Administrative Complaint was issued by the Commission on March 30, 2021. The administrative trial is scheduled to begin on August 24, 2021.

[2] *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.

[3] *Illumina Files Action for Annulment of European Commission's Decision Asserting Jurisdiction to Review GRAIL Acquisition*, Illumina.com (April 29, 2021, 9:05 AM), https://investor.illumina.com/news/press-release-details/2021/Illumina-Files-Action-for-Annulment-of-European-Commissions-Decision-Asserting-Jurisdiction-to-Review-GRAIL-Acquisition/default.aspx.

[4] European Commission Communication, Commission Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases (March 26, 2021), at 7; 2004 O.J. (L 24), art. 7; 2004 O.J. (L 24), art. 14(2)(b).

Form CO filing[5]—nor is there a notice of briefing schedule for the Defendants' appeal to the European General Court.[6] The FTC is authorized to seek a preliminary injunction or temporary restraining order only if necessary to preserve the *status quo*. The EC's prohibition on closing now moots the FTC's PI Complaint as no temporary restraining order or preliminary injunction is currently needed to maintain the *status quo* pending the administrative trial. Therefore, the FTC moves to dismiss its Complaint without prejudice because relief is not necessary at this time.

BACKGROUND

Illumina, Inc., the dominant provider of next-generation genome sequencers, announced that it entered into a definitive agreement to acquire GRAIL, Inc., a healthcare company racing to develop multi-cancer early detection tests, for cash and stock consideration of $8 billion (hereinafter, "Proposed Transaction").[7] After an investigation, the Commission found reason to believe that, if consummated, Defendants' merger would be anticompetitive and violate Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45, and voted 4-0 to issue an Administrative Complaint to permanently enjoin Defendants from consummating the Proposed Transaction and set an administrative hearing for August 24, 2021 to decide the merits of this case. (Complaint, *In the Matter of Illumina, Inc. v. GRAIL, Inc.*, FTC Docket No. 9401, p. 1. (hereinafter "Administrative Complaint").

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[5] At the time of filing this application, the EC's database shows that the EC has not accepted a Form CO. The Form CO filing initiates the EC's merger review process. Exhibit 1 (showing no entry for the Form CO Filing).

[6] The docket entry for Illumina's appeal shows that a briefing and hearing schedule has not even been set for that proceeding. Exhibit 2 (listing no hearing or briefing schedule).

[7] *Illumina to Acquire GRAIL to Launch New Era of Cancer Detection*, Illumina.com (September 21, 2020, 7:00 AM), https://investor.illumina.com/news/press-release-details/2020/Illumina-to-Acquire-GRAIL-to-Launch-New-Era-of-Cancer-Detection/default.aspx.

At the time the Commission voted to issue the Administrative Complaint, the EC had not yet announced that Defendants had to notify the EC and obtain clearance prior to closing. As such, the FTC understood that Defendants would be able to close the transaction after March 30, 2021 absent preliminary injunctive relief.[8] Twenty days later, however, the EC announced that it "has accepted the requests submitted by Belgium, France, Greece, Iceland, the Netherlands, and Norway to assess the proposed acquisition of GRAIL by Illumina under the EU Merger Regulation."[9] The EC's investigation was initiated pursuant to an Article 22(1) referral request to the Commission.[10] "[Article 22(1)] allows Member States to request the Commission to examine a merger that does not have an EU dimension but affects trade within the single market and threatens to significantly affect competition within the territory of the Member States making the request."[11]

The EC has clearly and publicly stated that it has an open investigation and the parties must obtain clearance prior to closing.[12] As Latham and Watkins—attorneys for GRAIL, Inc.—have explained in other contexts, after the EC accepts referral (as it has done here) the "EUMR applies and the parties can no longer close their deal . . .if they want to avoid fines of up to a maximum of 10% of their worldwide turnover."[13] Based

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[8] During the FTC's investigation, Defendants refused to waive the confidentiality provisions of the Hart Scott Rodino Act and the FTC Act to allow the FTC to discuss its investigation with other foreign regulators. 15 U.S.C. § 18a; 15 U.S.C. § 41.

[9] *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.

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] *Article 22 EU Merger Referrals: Analysis of Commissioner Vestager's announcement to accept referrals from NCAs for non-reportable concentrations*, Latham Watkins (September 18, 2020), https://www.lw.com/thoughtLeadership/article-22-eu-merger-referrals; European Commission Communication, Commission Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to

on this new, post-Complaint information from the EC—and our assumption that Defendants will abide by the laws of all jurisdictions in which they operate—the FTC's understanding is that Defendants cannot currently close this transaction.[14] As such, at this time a preliminary injunction in no longer needed to maintain the *status quo* pending the completion of the administrative trial on the merits.

STANDARD OF REVIEW

The FTC asks this Court to dismiss this case under Federal Rule of Civil Procedure 41(A)(2) without prejudice or condition. Fed. R. Civ. P. 41(A)(2). Rule 41(A)(2) states that "an action may be dismissed at the plaintiff's request only by court order, on terms that the court considers proper." Fed. R. Civ. P. 41(A)(2). Plaintiff's request to dismiss an action should be granted unless Defendants can show they will suffer plain legal prejudice as a result of the dismissal. *Hamilton v. Firestone Tire & Rubber Co.*, 679 F.2d 143, 145 (9th Cir. 1982) ("In ruling on a motion for voluntary dismissal, the District Court must consider whether the defendant will suffer some plain legal prejudice as a result of the dismissal."). Dismissal is favored when it secures the "just, speedy, and inexpensive determination of every action and proceeding." *HANGINOUT, Inc. v. Google, Inc.*, 2015 WL 11254688, at *2 (S.D. Cal. Apr. 22, 2015); *see also*, Fed R. Civ. P. 1 ("These rules govern the procedure in all civil actions and proceedings in the United States district courts, except as stated in Rule 81. They should be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding.").

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certain categories of cases (March 26, 2021), at 7; 2004 O.J. (L 24), art. 7; 2004 O.J. (L 24) art. 14(2)(b).

[14] The FTC has invited Defendants to provide additional detail regarding the EC's process and its impact on the investigation. Defendants have steadfastly refused to provide meaningful detail. Moreover, Defendants have failed to correct any misunderstanding of fact or law. (Exhibit 3; Exhibit 4; Musser Decl.)

ARGUMENT

I. Dismissal of the PI Complaint is Appropriate Under Rule 41(A)(2)

The FTC requests that this Court dismiss the PI Complaint because (a) the relief sought in the PI Complaint is no longer necessary; (b) dismissing the PI Complaint is in the public interest; and (c) Defendants will not suffer legal prejudice from dismissal. This dismissal should be without prejudice and with no conditions.

(a) A Preliminary Injunction is no Longer Necessary to Preserve the Status Quo

Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), permits the FTC to seek interim, injunctive relief to preserve the *status quo pendente lite* and protect the Commission's ability to conduct its administrative adjudicatory proceeding on the ultimate merits of whether the Defendants violated the antitrust laws. *See, e.g.*, *FTC v. Warner Communications, Inc.*, 742 F.2d 1156, 1159 (9th Cir. 1984) ("The Federal Trade Commission brought an action seeking a preliminary injunction under section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b) to block the proposed merger until the completion of administrative proceedings."); *FTC v. Whole Foods Market, Inc.*, 548 F.3d 1028, 1034 (D.C. Cir. 2008) ("Section 53(b), codifying the ability of the FTC to obtain preliminary relief, preserves the 'flexibility' of traditional 'equity practice.'") (quoting *FTC v. Weyerhaeuser Co.*, 665 F.2d 1072, 1082, 1084 (D.C. Cir. 1981)).[15] "The district court is not authorized to determine whether the antitrust laws have been or are about to be violated. That adjudicatory function is vested in the FTC in the first

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[15] The administrative trial is scheduled to begin on August 24, 2021, during which the parties collectively, can present up to 210 hours of testimony, present opening statements and closing statements (each can be up to two hours long), and introduce evidence into the record. 16 C.F.R. § 3.41. The administrative law judge will then issue a proposed opinion which the Commission may review and adopt. 16 C.F.R. § 3.51 *et seq*. If the Commission finds that the proposed merger violates the antitrust laws, it may order such relief as is necessary and appropriate, including a prohibition against the consummation of the proposed merger. 15 U.S.C. §§ 21, 45. Either party may appeal that ruling to a federal, appellate court. 15 U.S.C. § 45(c).

instance.'" *FTC v. H. J. Heinz Co.*, 246 F.3d 708 (D.C. Cir. 2001), 714 (quoting *FTC v. Food Town Stores, Inc.*, 539 F.2d 1339, 1342 (4th Cir. 1976)). "The *only* purpose of a proceeding under § 13 is to preserve the status quo until [the] FTC can perform its function." *Food Town*, 539 F.2d at 1342 (emphasis added).

Since filing the PI Complaint, the FTC has learned that the EC has opened an investigation and as a result Defendants are currently prohibited from closing the Proposed Transaction.[16] Given this recent development, a preliminary injunction pursuant to Section 13(b) is rendered moot as the EC's current investigation preserves the *status quo* and accomplishes the same relief sought in the PI Complaint. *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 352 (3d Cir. 2016) ("The purpose of Section 13(b) is to preserve the status quo and allow the FTC to adjudicate the anticompetitive effects of the proposed merger in the first instance.").

In an analogous context, courts have found applications for preliminary injunction similarly unnecessary when another authority or case has obviated the need for judicial relief.[17] As in this case, the courts found plaintiffs' claims moot because there was no pending harm and, therefore, no further relief which could be granted. *See, Ocean*

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[16] *Article 22 EU Merger Referrals: Analysis of Commissioner Vestager's announcement to accept referrals from NCAs for non-reportable concentrations*, Latham Watkins (September 18, 2020), https://www.lw.com/thoughtLeadership/article-22-eu-merger-referrals.

[17] While the requirements for obtaining a preliminary injunction under Section 13(b) are different than the requirements under the traditional four-part equity standard, important analogies can be drawn from these cases. Section 13(b), "allows a district court to grant preliminary relief "[u]pon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest." *FTC v. Whole Foods Market, Inc.*, 548 F.3d at 1034. "Congress recognized the traditional four-part equity standard for obtaining an injunction was not appropriate for the implementation of a Federal statute by an independent regulatory agency. Therefore, to obtain a § 53(b) preliminary injunction, the FTC need not show any irreparable harm, and the 'private equities' alone cannot override the FTC's showing of likelihood of success. *Id*. (internal citations omitted).

Conservancy, Inc. v. National Marine Fisheries Services, 90 Fed. Appx. 499, 501 (9th Cir. 2003) (holding that the appeal of the district court's preliminary injunction denial is moot because "under no circumstances may [Defendant] engage in the conduct Plaintiffs seek to enjoin."); *Lee v. Van Boening*, 81 F.3d 168, 1996 WL 145303 , at *1 (9th Cir. 1996) (affirming the district court's denial for preliminary injunction "as moot on the basis that in another case, the district court had permanently enjoined the [same conduct]"). The same principles apply here: now that the EC has opened an investigation there is no additional relief that this Court can provide, accordingly there is no live case or controversy and this case is moot.

Proceeding straight to an administrative hearing and bypassing the federal proceeding when the EC has an open investigation into the same merger is consistent with the Commission's practices in past cases. For example, *In the Matter of Tronox Limited/Cristal USA* the Commission declined to file a complaint seeking a preliminary injunction and instead proceeded straight to the administrative hearing. (Complaint, *In the Matter of Tronox Limited/Cristal USA*, Dkt. 9377 (December 5, 2017)); *see also* Complaint, *In the Matter of Illumina Inc./Pacific Biosciences of California, Inc.*, Dkt. 9387 (December 17, 2019)). The Commission's reasoning in those cases was consistent with our reasoning here, namely, that a TRO or a PI is only necessary to "protect [the administrative] proceeding, which we consider to be the merits proceedings and the proceeding where we actually determine the legality of the merger." (Exhibit 5 at 6:18, Transcript, Complaint, *In the Matter of Tronox Limited/Cristal USA*, Dkt. 9377 (December 5, 2017)). In *Tronox*, foreign regulators later cleared the transaction at issue, allowing the parties to close. At that time – after the conclusion of the administrative trial but before the ruling on the merits – the FTC moved the District Court of D.C. to seek a preliminary injunction. *Federal Trade Commission v. Tronox, Ltd.*, 332 F.Supp.3d 187, 194 (D.D.C. 2018). The court in that case explained that the FTC was correct in seeking a preliminary injunction only after the foreign regulators had cleared the merger and noted that "[u]ntil foreign regulators approved the proposed merger, there was no

imminent threat to competition, so a request for injunctive relief would have likely been unripe." *Id.* at 218-19. Given that Defendants here are likewise blocked from closing by the EC, the current case should also be dismissed as unripe and be filed only if and when the *status quo* changes.

(b) ***Continuing to Litigate an Unnecessary PI Complaint is Inefficient and a Waste of Resources***

Continuing to litigate an unnecessary PI Complaint in federal court is against the public interest and would waste the resources of the court, third-parties, and taxpayers. First, calendaring this case, of course, is not cost neutral and necessarily comes at the expense of other litigants' cases that have been pushed back to accommodate this case's schedule. Beyond the substantial time this court would be asked to devote to conducting the PI hearing and reaching a decision on the (now unnecessary) PI Complaint, to the extent that disputes arise—as they often do in complex, civil litigation—the Magistrate Court and this Court will be asked to set aside time to address those disputes. Second, Plaintiffs and Defendants anticipate that the PI hearing would last at least two weeks and involve testimony from numerous third-party and party witnesses. (Exhibit 6). This PI hearing will unnecessarily burden both witnesses who will need to devote time and resources to travel and testify at this hearing as well as this Court that will need to dedicate finite resources to conduct a hearing and render a decision that will have no impact on the *status quo*.

Finally, continuing to litigate the PI Complaint while simultaneously preparing for the administrative trial also imposes substantial unnecessary expenses on the parties and taxpayers. While fact discovery conducted in the federal court proceeding can be used in the administrative proceeding (and thus, federal discovery completed to date is by no means wasted), the two proceedings have fundamentally different purposes and are on different timelines. To obtain a preliminary injunction pursuant to section 13(b), the FTC merely must raise "questions going to the merits so serious, substantial, difficult and doubtful as to make them fair ground for thorough investigation, study, deliberation and

determination by the FTC in the first instance and ultimately by the Court of Appeals." *FTC v. Warner Communications, Inc.*, 742 F.2d at 1162. In contrast, at the administrative trial, the FTC must show by a preponderance of the evidence that "the effect of the merger 'may be to substantially lessen competition.'" *United States v. Philadelphia Nat.* Bank, 374 U.S. 321, 362 (1963). The different standards across the two proceedings can create differences across, among other things, expert reports, pre-trial briefing, and post-trial conclusions of law and findings of fact. Requiring the FTC to pay for and submit different briefing and reports is inefficient and expensive to the government and ultimately taxpayers.

(c) Dismissal of the Complaint will not Legally Prejudice Defendants

A Court should exercise its discretion to dismiss a case under Fed. R. Civ. P. 41(A)(2) as long as the dismissal will not result in legal prejudice to the defendants. To show legal prejudice, the defendant must show "prejudice to some legal interest, some legal claim, some legal argument." *Bader v. Elecs. For Imaging, Inc.*, 195 F.R.D. 659, 661–62 (N.D. Cal. 2000); *Westlands Water Dist. v. United States*, 100 F.3d 94, 97 (9th Cir. 1996) ("We conclude that legal prejudice is just that—prejudice to some legal interest, some legal claim, some legal argument."). Defendants will suffer no such legal prejudice.

"The only purpose of a proceeding under § 13 is to preserve the status quo until [the] FTC can perform its function." *Food Town*, 539 F.2d at 1342. That function is the administrative trial on the merits which will determine whether the Proposed Transaction is permanently enjoined. The PI complaint merely seeks to preserve the FTC's ability to obtain meaningful relief if Complaint Counsel proves the Proposed Transaction violates Section 7 of the Clayton Act or Section 5 of the FTC Act. Since preserving the *status quo* is the only purpose of this proceeding, Defendants have no separate legal interest or claim that can be prejudiced by dismissing the PI Complaint. Nor does dismissing the PI Complaint prejudice Defendants from raising any legal argument in the administrative trial.

II. This Case Should be Dismissed Without Prejudice and Without the Imposition of Any Conditions

To determine whether a case should be dismissed with or without prejudice the Court should consider whether it would be "inequitable or prejudicial to defendant to allow plaintiff to refile the action." *Burnette v. Godshall*, 828 F. Supp. 1439, 1443 (N.D. Cal. 1993). To make that determination, courts consider "(1) the defendant's effort and expense involved in preparing for trial, (2) excessive delay and lack of diligence on the part of the plaintiff in prosecuting the action, [and] (3) insufficient explanation of the need to take a dismissal." *Id.*

Plaintiff has acted quickly and the explanation for dismissing the PI Complaint is clear. At the time of filing its PI Complaint, FTC had a good faith basis to believe that a preliminary injunction was needed. That changed when twenty days after the FTC filed the PI Complaint, the EC announced that it opened an investigation that prohibits Defendants from consummating the Proposed Transaction.

Shortly after learning of the EC announcement, the FTC emailed Defendants asking whether the EC's investigation prevented them from closing and when Defendants intended to initiate EC's proceedings by filing a Form CO. (Exhibit 3). Defendants refused to provide a clear answer regarding the impact of the EC's proceedings and provided no answer as to when they were filing their Form CO or whether they would be fined in the event they were to close. (Exhibit 3). The FTC then sent an interrogatory asking Defendants to identify all "events, conditions, investigations, proceedings or barriers" to closing the transaction and RFPs asking for communications and documents sent to regulators. (Musser Decl., ¶ 2). In Defendants' May 3, 2021 responses and objections to the FTC's interrogatory and subsequent conversations regarding the same, Defendants again refused to answer directly whether the EC investigation prohibited it from closing and refused to produce responsive documents. (Musser Decl., ¶ 3). The FTC notified Defendants that it may seek to dismiss this case on May 18, 2021. (Musser

Decl., ¶ 4). Clearly there has been no excessive delay and the FTC has been diligent in prosecuting this action.

The efforts Defendants have made to date to prepare for the PI hearing are useful for the administrative trial on the merits. Federal court fact discovery may be used in the administrative proceeding. (Exhibit 7, ¶ 7). Thus, Defendants have incurred minimal expense that they would have otherwise not incurred in the administrative process.[18] If the Court dismisses the PI Complaint, the Parties will continue to conduct fact and expert discovery for the more-expansive administrative proceeding. While the FTC does not anticipate needing to re-file a Complaint for Preliminary Injunction or Temporary Restraining Order, if it does, Defendants would not suffer any prejudice or inequity.[19] If the EC clears the Proposed Transaction during the pendency of the administrative trial, or if the Defendants attempt to close in violation of EC law, both Parties would be able to use the evidence gathered to date in this proceeding as well as evidence gathered in the administrative proceeding in any future proceeding for a preliminary injunction.[20]

III. The Compressed Case Schedule Necessitates Expedited Relief

The FTC contacted Defendants on May 18, 2021, telling them that the FTC intended to file this application and asked them to meet and confer that day. (Musser

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[18] The FTC has also offered to honor all negotiations and agreements reached with either parties or third parties regarding discovery sent in this case to corresponding discovery requests sent in the administrative process. (Exhibit 4, p 4-5).

[19] The FTC also stipulates that, while not anticipated, in the event that it later needs to file a temporary restraining order or preliminary injunction it will file its complaint in the Southern District of California.

[20] The Case Management and Scheduling Order ("CMSO") (Dkt. 88) notes that "[o]nly discovery obtained by a party in the Part 3 administrative proceeding before the close of fact discovery in this proceeding may be used as part of this litigation, except by agreement of the parties or by leave of the Court for good cause shown," (CMSO, ¶ 10). In the event that this case is dismissed, the FTC is willing to stipulate to the use of evidence gather post-dismissal in a subsequent filing for a temporary restraining order of preliminary injunction.

Decl. at ¶ 4). The FTC and Defendants met and conferred the next day. (Musser Decl. at ¶ 5). In a follow-up email, the FTC proposed an expedited briefing schedule and again offered to meet and confer on the proposed schedule. (Musser Decl. at ¶ 5). Defendants responded the next day that they opposed the application but agreed to meet and confer on a briefing schedule. (Musser Decl. at ¶ 6-7). Pursuant to this Courts' "Civil Case Procedures" the FTC has served on Defendants a copy of this application with return receipt requested. ("Honorable Cathy Ann Bencivengo U.S. District Judge Civil Case Procedures", "IV. Ex Parte Motions.").

The FTC respectfully requests expedited relief in this application and for all deadlines under the CMSO to be stayed while a decision is pending. As this Court is aware, fact discovery closes on June 4, 2021 and numerous other deadlines are due shortly thereafter. (CMSO, Dkt. 88, p. 17). In the event that the Court dismisses this action, both parties would have incurred unnecessary expense proceeding under extremely compressed deadlines while a decision is pending.

CONCLUSION

Under Rule 13(b) preliminary injunctive relief in federal court should only be sought if and when it is necessary to preserve the *status quo* during the pendency of the administrative adjudicative proceedings, not as a prophylactic measure. Forcing the FTC to litigate a case when there is no live case or controversy to address the mere hypothetical that preliminary relief may later be necessary is inconsistent with case law and a waste of judicial resources. As such, the FTC moves this court to dismiss the PI Complaint without prejudice.

Dated: May 21, 2021

Respectfully submitted,

/s/ Susan A. Musser
Susan Musser
Counsel for Federal Trade Commission

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 21, 2021, I served the foregoing on the following counsel via electronic mail and the Court's CM/ECF system:

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UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ILLUMINA, INC, and GRAIL, INC.,

Defendants.

Case No. 3:21-cv-00800-CAB-BGS

OPPOSITION TO FTC'S MOTION TO DISMISS THE COMPLAINT WITHOUT PREJUDICE

Complaint Filed: March 30, 2021
Judge: Hon. Cathy Ann Bencivengo
Magistrate: Hon. Bernard G. Skomal
Trial Date: August 9, 2021

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Defendants Illumina, Inc. ("Illumina") and GRAIL, Inc. ("GRAIL") respectfully submit this memorandum in opposition to the Federal Trade Commission's (the "FTC's") motion to dismiss this case *without prejudice*.

PRELIMINARY STATEMENT

Defendants Illumina and GRAIL do not oppose the dismissal of this case ***with*** *prejudice*, because it should never have been brought in the first place. The FTC's motion to dismiss *without prejudice* is a different matter. The FTC purports to seek a routine dismissal *without prejudice* for the sake of efficiency. However, there is nothing routine or efficient about the FTC's request. In the guise of a non-substantive motion, the FTC seeks to scuttle a pro-competitive transaction that will save thousands of lives. The FTC seeks to achieve by procedural gamesmanship what it cannot achieve on the merits. The FTC's motion should be denied.

The FTC chose to invoke the jurisdiction of this Court in an attempt to enjoin Illumina's reacquisition of GRAIL, in a purely-vertical combination that, if consummated, will save thousands of lives. While Illumina and GRAIL dispute the FTC's allegations, they consented to a temporary restraining order (the "TRO") to afford this Court a full and fair opportunity to consider the merits of the FTC's claims before the transaction is set to expire on its terms on September 20, 2021 (absent extension). The FTC received the benefits of that deal, with the TRO preventing closing for two months now. Defendants have been working diligently to prepare the case for a hearing beginning on August 9. Defendants have produced more than 34 million pages of documents; made more than 20 witnesses available for investigatory hearings or deposition; obtained discovery from at least 25 third parties; retained more than 15 experts; and gathered considerable evidence that we believe debunks the FTC's case.

Now, having gotten the benefit of the stipulated TRO, just as fact discovery is about to close, and with the evidence mounting that the FTC could never prove what is necessary to obtain a preliminary injunction to preclude Illumina and GRAIL from reuniting, the FTC seeks to renege on its deal and dismiss its case *without prejudice*, insisting on the right to file a new case seeking exactly the same relief in a few months—when there will be insufficient time for a full hearing on the merits before the transaction expires.

While voluntary dismissal is frequently allowed, it is not justified, and should not be permitted, where, as here, (1) the plaintiff fails to provide a sufficient explanation of the need for a dismissal, (2) dismissal *without prejudice* would be inequitable and result in legal prejudice to the defendants, or (3) dismissal *without prejudice* would be wasteful, inefficient and impractical.

First, the FTC's rationale for dismissing its case *without prejudice* is baseless. The FTC contends that it learned from an April 20, 2021, press release that the European Commission ("EC") is investigating the transaction and that the EC investigation bars Defendants from closing, making a preliminary injunction unnecessary. That, of course, was a full month before it filed this motion, during which time the FTC took full advantage of this proceeding. In any event the FTC knew about the EC investigation long before April 20; it knew about the investigation by, if not before, March 9, 2021, which was three weeks ***before*** the FTC filed its Complaint in this action. Thus, its suggestion that a *recent* development in the EU necessitates its motion is without merit.

Moreover, the EC investigation does not necessarily bar closing the transaction. Illumina has challenged the EC's decision to review Illumina's merger in the European courts, because the transaction (i) does not qualify for review by any member state, (ii) the EC's decision to investigate is time-barred and (iii) the process by which the investigation was initiated is unlawful. Even assuming the

EC's investigation could be an obstacle to closing at this time, Illumina and GRAIL are working diligently to resolve any EC concerns, such that the EC could approve the transaction at or about the time the TRO is set to expire on September 20. Furthermore, as a legal matter, the existence of a foreign investigation does not moot an action for a preliminary injunction. (*See* Section I below.)

Second, dismissal *without prejudice* would be inequitable and result in legal prejudice to the Defendants and the public interest. The FTC seeks to dismiss the case *without prejudice*, so that it can file a new case seeking exactly the same relief whenever the FTC unilaterally concludes the EC is closer to clearing the transaction. That gambit is disrespectful to the Court and to the Defendants. The parties agreed to, and the Court entered, a case management order permitting the FTC's request for a preliminary injunction to be tried, and the Court to rule, on or before September 20, when the consented-to-TRO expires. The parties recognized that the agreed-upon schedule was the only practical way to put the Court in a position to make an informed judgment about the merits of the transaction before it expires by its terms. Nothing has changed.

Allowing the FTC to remake the parties' agreement would have real, prejudicial consequences. Any material deviation from the schedule to which the parties agreed would make it nearly impossible for any court to make an informed decision regarding the fate of what Defendants believe is a pro-competitive life-saving transaction. Permitting the FTC to withdraw its case now and refile later would thus make it impossible (as a practical matter) for a court to properly address the merits of a subject matter that is not uncomplicated. Indeed, dismissal *without prejudice* would put the FTC in a position to effectively block a pro-competitive, life-saving combination irrespective of its merits, simply by running out the clock. That tactic has no place in an equitable proceeding. (*See* Section II below.)

Third, even if the agreed TRO and CMSO did not exist, dismissal of this case *without prejudice* would be wasteful and inefficient, so long as the FTC seeks to enjoin the closing of the transaction. Contrary to the FTC's contention, dismissing this case would not conserve any resources. The vast majority of fact discovery, which closes on June 4, is done. The first wave of expert reports is due on June 8 and trial is just 11 weeks away. Illumina and GRAIL (and probably also the FTC) have made substantial progress in preparing for trial. Moreover, all of the discovery taken (and to be taken) in this matter will be available to the parties in the separate administrative proceeding before the FTC, that is scheduled to commence on August 24, 2021, which the FTC has said it will pursue irrespective of whether the Court dismisses the present case (with or without prejudice). So, nothing done here will be wasted no matter the outcome of the present motion.

By contrast, dismissing this case *without prejudice* would require duplicative efforts when the FTC seeks to restart the case in a few months. Defendants would have to answer anew; the parties would have to negotiate and the Court would have to enter a new CMSO; discovery would have to be completed on any new allegations; experts would have to restart work on their reports, submit the reports and undergo depositions; and pretrial disclosures would have to be made—all on a much shorter schedule than the already-aggressive schedule to which all parties agreed. In fact, it would be a practical impossibility for the parties to have a trial on the merits of the FTC's preliminary injunction request and for the Court to issue a decision on the merits following that trial, unless the trial happens on August 9, as planned. (*See* Section III below.)

If the FTC wanted to dismiss this case *with prejudice*, then Defendants would join the motion. But as the FTC seeks a dismissal *without prejudice* that would allow it to bring a new case several months from now seeking exactly the same relief but on a schedule that would preclude review by an Article III court

before the deal expires on its own terms, the motion should be denied. Dismissal *without prejudice* would increase the likelihood of chaos on a decision on a matter of enormous importance to the parties and the public.

STATEMENT OF FACTS

Defendant Illumina is a leading provider of sequencing products for genetic and genomic analyses. (Answer of Defendants Illumina, Inc. and GRAIL, Inc. (Dkt. 49) (the "Answer") at 2.) Illumina was founded in 1998 in San Diego. (*Id.* at ¶ 23.) Its mission is to improve human health by unlocking the power of the genome. (*Id.* at 2.)

Defendant GRAIL is a developer of a multi-cancer screening test, Galleri. (*Id.*) Illumina founded GRAIL in 2016 with the goal of developing an early screening test for multiple cancers to detect cancer at an early stage, when they can be more easily cured. (*Id.*) In 2017, GRAIL was spun out as a standalone company to invest in the extensive, population-scale clinical trials needed to develop Galleri. (*Id.*) Illumina retained a 14.5% equity interest, and the right to receive a percentage royalty from GRAIL's future revenues. (*Id.*) GRAIL is also continuing to develop other tests for different patient populations. (*Id.*)

On September 20, 2020, Illumina and GRAIL announced that they had reached an agreement to reunite. (*Id.* at ¶ 26.) This reunification will produce numerous pro-competitive efficiencies that will help GRAIL bring its cancer screening test to more patients, sooner, including: (1) accelerating FDA approval and Medicare reimbursement; (2) accelerating private insurance reimbursement; (3) accelerating the commercialization of GRAIL's test at scale; (4) elimination of double marginalization; (5) accelerating international expansion of GRAIL's test; and (6) R&D efficiencies. (*Id.* at 11-13.)

In fact, the merging parties believe the reunification of Illumina and GRAIL will revolutionize cancer care, saving tens of thousands of lives. (*Id.* at 1.)

It will do that by accelerating the commercialization of GRAIL's Galleri test and leading to the development of new innovative products in the future. (*Id.*) Illumina is uniquely situated to use its experience and substantial resources to accelerate the widespread adoption of Galleri and reach more patients faster. (*Id.* at 3.) GRAIL projects that, if it can get the help this transaction will provide, the test can save many thousands of lives annually. Acceleration by one year will avert between 18,037 and 25,349 deaths over a 10-year period.

Despite these benefits, the FTC has alleged that the transaction could have anticompetitive effects in what the FTC calls the "multi cancer early detection" or "MCED" test market, which does not exist. (Complaint (Dkt. 14) at ¶ 1.) The FTC contends, for example, that a reunited Illumina and GRAIL would be able to raise prices and otherwise disadvantage GRAIL's *potential* rivals. (*Id.* at ¶¶ 11, 54.)

The FTC's claim that the transaction will harm competition in a future MCED testing market would be purely speculative at best. (Answer at 3.) GRAIL's Galleri test, which was provided one month ago to a limited number of concierge medicine practices, is currently the only multi-cancer screening test close to commercial launch. (*Id.* at 3); Press Release, *GRAIL Announces First Health System to Offer Galleri, Novel Multi-Cancer Early Detection Blood Test* (Mar. 2, 2021), https://grail.com/press-releases/grail-announces-first-health-system-to-offer-galleri-novel-multi-cancer-early-detection-blood-test/. Neither GRAIL nor its potential rivals will obtain FDA approval and reimbursement, a prerequisite to wide-scale adoption and access of multi-cancer screening tests, before 2025 at the earliest. In any case, the reunification of Illumina and GRAIL will not harm competition; it will bring down prices, foster efficiency, facilitate competition on the merits, and stimulate further innovation in an expanded marketplace. (Answer at 11-13.)

Although Illumina disputes the FTC's allegation that the transaction will have an anticompetitive effect in any actual market, Illumina offered current and prospective oncology customers contract terms (an "open offer") to resolve any concern the FTC might have.[1] (*Id.* at 3.) Specifically, Illumina made a binding 12-year commitment to enter into a supply agreement that guarantees oncology customers the same access to Illumina's sequencing products that they enjoy today, at the same prices. (*Id.* at 3-4.) Under that commitment, Illumina has committed not only *not* to raise prices, but also to lower them by at least 43% by 2025, to provide uninterrupted supply to all oncology test developers, and not to withhold any technical or regulatory assistance requested by GRAIL's potential rivals. (*Id.* at 3-4.) Illumina's compliance with the open offer will be subject to regular audits by an independent, third-party auditor and a binding arbitration provision. (*Id.* at 4.)

The FTC has refused to seriously engage with the open offer and, instead, on March 30, 2021, filed this lawsuit seeking a preliminary injunction against the transaction. (*Id.* at 4, ¶ 27.) The merger agreement provides for termination rights if the transaction has not been consummated by September 20, 2021 (subject to an extension of three months under certain circumstances). (*Id.* at 14.) Accordingly, the parties agreed to a TRO that would expire on September 20, 2021 on the express understanding that the parties would work together to allow a federal court to consider and decide the FTC's preliminary injunction motion by September 20, 2021. (Temporary Restraining Order (Dkt. 8) ("TRO") at 1.)

Since entry of the TRO, the parties have been engaged in expedited fact discovery, which is set to close on June 4. Illumina and GRAIL have produced

[1] These terms are available on Illumina's website: *Oncology Contract Terms*, Illumina, https://www.illumina.com/areas-of-interest/cancer/test-terms.html?SCID=2021-270ECL5522 (last visited May 26, 2021).

over 34 million pages from over 250 custodians and provided responses to 49 investigative inquiries and 21 interrogatories in this litigation and the preceding investigation. Illumina and GRAIL have also engaged more than 15 experts to address the flaws in the FTC's challenge to the transaction.

In the face of mounting evidence against it, on May 20 the FTC issued a press release announcing that it was dismissing this case, even before any motion had been filed and before the FTC had completed the meet and confer process with Defendants.[2]

As is further discussed below, the case should not be dismissed *without prejudice*.

STANDARD OF DECISION

The FTC's motion to dismiss *without prejudice* is governed by Federal Rule of Civil Procedure 41. The decision whether to grant a motion to dismiss *without prejudice* under Rule 41, or order that any dismissal be *with prejudice*, is "discretionary with the court." *Burnette v. Godshall*, 828 F. Supp. 1439, 1443 (N.D. Cal. 1993), *aff'd sub nom. Burnette v. Lockheed Missiles & Space Co.*, 72 F.3d 766 (9th Cir. 1995); *Neville v. Dill*, 19CV321-CAB-MDD, 2019 WL 4242502, at *2 (S.D. Cal. Sept. 6, 2019) (Bencivengo, J.) ("[A]n action may be dismissed at the plaintiff's request only by court order, on terms that the court considers proper." (internal citation and quotation marks omitted)).

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[2] Press Release, FTC, *Statement of FTC Acting Bureau of Competition Director Maribeth Petrizzi on Bureau's Motion to Dismiss Request for Preliminary Relief in Illumina/GRAIL Case* (May 20, 2021), https://www.ftc.gov/news-events/press-releases/2021/05/statement-ftc-acting-bureau-competition-director-maribeth; *FTC v. Illumina*, Plaintiff's *Ex Parte* Application to Dismiss the Complaint Without Prejudice, No. 3:21-cv-00800-CAB-BGS, Dkt. No 120 (May 21, 2021); *FTC v. Illumina*, Ex. 4 to Declaration of Susan A. Musser in Support of Plaintiff's *Ex Parte* Application to Dismiss the Complaint Without Prejudice, No. 3:21-cv-00800-CAB-BGS, Dkt. No 120-3, at 10 (May 21, 2021).

Courts have found that dismissal *with prejudice* is appropriate where (1) the plaintiff provides insufficient explanation of the need to take a dismissal; (2) where it would be inequitable or prejudicial to defendant to allow plaintiff to refile the action; and (3) where it would result in waste, great delay and duplication. *Burnette*, 828 F.Supp. at 1443-44 (citing "defendant's effort and expense involved in preparing for trial", "delay and lack of diligence on the part of plaintiff" and "insufficient explanation of the need to take a dismissal" as factors favoring dismissal with prejudice); *Blue Spike, LLC v. Adobe Sys., Inc.*, No. 14-CV-01647-YGR, 2015 WL 13655824, at *3 (N.D. Cal. May 4, 2015) (citing fact that plaintiff "failed to provide a sufficient explanation for the basis for its request" and that "it would be inequitable or prejudicial to defendant to allow plaintiff to refile the action" as relevant factors favoring dismissal with prejudice).

ARGUMENT

Defendants do not oppose the dismissal of this case ***with*** *prejudice*. But the FTC seeks to dismiss this case *without prejudice*, so that it can refile its action in a few months. As explained below, the FTC's request for dismissal *without prejudice* should be denied because (1) the FTC fails to provide a sufficient explanation of the need to take a dismissal, (2) dismissal *without prejudice* would be inequitable and result in legal prejudice to the Defendants and the public interest, and (3) dismissal *without prejudice* would be wasteful, inefficient and impractical.

I. The FTC's Request for Dismissal Without Prejudice is Unjustified.

Dismissal *without prejudice* is only appropriate when the plaintiff has provided a sufficient explanation of the need to take a dismissal. *See Thompson v. Janssen Pharms., Inc.*, No. CV162628PSGAGRX, 2017 WL 5135548, at *6 (C.D. Cal. Oct. 23, 2017); *Blue Spike*, No. 14-CV-01647-YGR, 2015 WL 13655824, at *3; *White v. Donley*, No. CV05-7728ABCFMOX, 2008 WL 4184651, at *3 (C.D. Cal. Sept. 4, 2008). The FTC seeks to justify its motion to dismiss based on a

supposed "recent development": that the EC is investigating the transaction and that the merging parties cannot close the transaction while that investigation is pending. This claim is baseless and therefore insufficient to justify dismissal with prejudice.

No recent development. To begin, there is no recent development, and the FTC did not *just* learn about the EC investigation or the alleged standstill. By its own telling, the FTC knew about the investigation no later than April 20, 2021, and yet did not bring the present motion until a month later. In fact, the FTC knew about the investigation much earlier. The fact of the investigation was a matter of public record no later than March 9, 2021.[3] Thus, at a minimum, the FTC was on notice of the investigation at least three weeks before the FTC filed its Complaint in this action on March 30 and over six weeks before it moved this Court to enter the CMSO on April 26.

In truth, the FTC knew about the specifics of the EC investigation before all of the details were public. The privilege log produced by the FTC shows that the FTC was in frequent contact with the EC throughout the month of March ***prior*** to filing the Complaint and TRO.[4] Specifically, the privilege log shows

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[3] The EC's purported stay pending review of the merger has been in place since March 11, 2021, when the EC accepted France's referral under Article 22. That referral was public since March 9, 2021. *Referral: The French Competition Authority Refers to the European Commission the Acquisition of a US Biotechnology Company by a Company Specialised in Integrated Systems for the Analysis of Genetic Variation and Biological Function (Illumina/GRAIL),* Concurrences: Antitrust Publications & Events (Mar. 9, 2021), https://www.concurrences.com/en/review/issues/no-2-2021/alerts/referral-the-french-competition-authority-refers-to-the-european-commission-the. The FTC is of course aware of the relevant rules and penalties related to the EC (MTD 5 n.4, 7 n.13); its motion touts "past cases" in which it deferred to the investigations of foreign regulators, including the EC (MTD 11).

[4] The FTC marked its privilege log confidential under the protective order entered in this action. While Defendants do not believe the information in the log is

communications between the FTC and the EC in early to mid-March.[5] That privilege log also shows communications with Member States as early as mid-November. In a recent European court filing challenging Illumina's motion to expedite its appeal, the EC indicated that it is actively speaking to the FTC about the timing of the FTC's actions.[6] Thus, the FTC's contention that a *recent* development in the EU necessitates its motion is untenable.

No legal bar. Irrespective of when the FTC learned of the EC investigation, it is not a legitimate bar to closing the transaction.[7] The EC initiated its investigation of the transaction under an untested interpretation of Article 22 of the EU Merger Regulations prior to issuing any guidelines on the use of that

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confidential they have not filed it with this brief. However, upon request, Defendants will provide the brief to this Court under seal or in person at the hearing for this motion.

[5] While Defendants cannot say for sure, there is reason to believe that the FTC engineered the EC investigation they now claim moots the need for a preliminary injunction. In mid-March, the FTC sent the EC contact information for a third party complainant with whom they met on numerous occasions. When Defendants sought full information regarding these communications, the FTC refused on the basis of a claimed privilege under the Agreement Between United States and European Communities On The Application of Positive Comity Principles In The Enforcement Of Antitrust Laws, which governs requests from one antitrust enforcement authority to another to investigate conduct.

[6] Observations on the Application for Expedited Procedure, Case T-227/21 (May 21, 2021). The EC's brief is not public and Defendants cannot file it on the public docket at this time. However, upon request, Defendants will provide the brief to this Court under seal or in person at the hearing.

[7] The question of the legal effect of the EC proceedings is a question of EU law, and one not implicated by the FTC's complaint in this Court. To the extent that the FTC's motion seeks an advisory opinion from this Court about such legal effects, Defendants respectfully object.

process.[8] Moreover, the EC's initiation of an investigation was made outside the proper time period and is procedurally flawed. Illumina has challenged the EC's decision to review Illumina's merger under Article 22 in the European courts on an expedited basis and believes that the European courts will find that the investigation was unlawful and that the EC lacks jurisdiction.

Even if the EC's investigation were legitimate, Illumina and GRAIL believe that it will not bar them from closing should this Court issue a decision denying the FTC's request for a preliminary injunction. While Defendants are challenging the EC's investigation, they are also cooperating with EC authorities and believe that the EC will ultimately clear the transaction on the merits. The EC process runs in parallel to these proceedings and Illumina and GRAIL are optimistic it can be completed at or about the time the TRO is set to expire on September 20.

No investigatory mootness/unripeness. Contrary to the FTC's suggestion (MTD 10), the existence of a foreign investigation does not simultaneously moot and make unripe the action for a preliminary injunction under Section 13(b) of the FTC Act. Section 13(b) of the FTC Act authorizes the FTC to seek a preliminary injunction "[w]henever [it] has reason to believe" that defendants are "about to violate" the laws that it enforces. 15 U.S.C. § 53(b).

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[8] The EC's action is unprecedented and highly controversial because under the EC's own rules and those of every one of its Member States, the transaction did not trigger jurisdiction for review at the EC or any Member State, and the EC used Article 22 to invite Member States who did not have jurisdiction in the first place to request referral of the transaction for centralized review by the EC in Brussels. Natalie McNelis & Nicholas Hirst, *Comment: Illumina-Grail Case Exposes Controversy Behind EU Grab for Non-notifiable Mergers*, MLex Market Insight (April 7, 2021), https://mlexmarketinsight.com/news-hub/editors-picks/area-of-expertise/mergers-and-acquisitions/illumina-grail-case-exposes-controversy-behind-eu-grab-for-non-notifiable-mergers.

Courts have approved the FTC's use of that authority to enjoin allegedly illegal conduct even where the conduct at issue has been deferred because of potential legal penalties, as the FTC has alleged with regard to the EC investigation. *See FTC v. Agora Financial, LLC*, 447 F. Supp. 3d 350, 358-59, 369-70 (D. Md. 2020) (rejecting a mootness challenge to the FTC's ability to enjoin an allegedly misleading promotion that was stopped in light of "an inquiry . . . about consumer confusion"); *see also FTC v. Affordable Media*, 179 F.3d 1228, 1238 (9th Cir. 1999) (explaining that the party asserting mootness must make it "absolutely clear" that the "allegedly wrongful behavior cannot reasonably be expected to recur"). In fact, courts in this Circuit have specifically held that the FTC can enjoin conduct that would happen *but for* governmental investigation, regardless of the conduct's likelihood while the investigation is ongoing. *See FTC v. Triangle Media Corp.*, No. 18CV1388-LAB (LL), 2018 WL 6305675, at *1 (S.D. Cal. Dec. 3, 2018) ("Absent the [government's] enforcement action, there would be little doubt [defendant] would still be 'violating' or 'about to violate' the law . . . ."); *FTC v. Sage Seminars, Inc.*, No. C 95-2854 SBA, 1995 WL 798938, at *6 (N.D. Cal. 1995) (rejecting the argument that the FTC's claim to enjoin conduct was mooted, including because the conduct was only stopped "*after* defendants learned that the [government] had commenced an investigation into [defendant's] practices").

The FTC's claim that its Complaint is moot and unripe ignores its own pleading and its prior practice. In its complaint, the FTC alleges that a preliminary injunction is required to prevent the transaction from closing "while the Commission adjudicates whether the Acquisition is unlawful". (Complaint at 2.) The EC investigation does nothing to change that because Defendants expect any EC concerns will be resolved before or about the time the TRO will expire and the administrative proceeding will not run its course until early 2022. In addition, the FTC has brought challenges to transactions while an EC investigation is pending.

For example in connection with the Staples/Office Depot merger, the FTC brought an action for a preliminary injunction after the EC had initiated an investigation of the transaction.[9]

The FTC contends that "proceeding straight to an administrative hearing and bypassing the federal proceeding when the EC has an open investigation into the same merger is consistent with the Commission's practices in past cases". (MTD 11.) However, that is not the process the FTC took here. It chose to bring an action in this Court. The FTC's reliance on *FTC v. Tronox Limited* (MTD 11-12) is misplaced. In that case, the FTC waited to bring a request for a preliminary injunction against a merger until after the conclusion of a European investigation and an administrative trial. 332 F. Supp. 3d 187, 218 (D.D.C. 2018). The Court assessed whether the FTC's delay in bringing a request for a preliminary injunction tipped the equities in favor of the defendants. It did not assess the question presented here – whether it would be proper for the FTC to withdraw a request for a preliminary injunction that was already pending, having obtained an agreement to a TRO in exchange for an accelerated CMSO. The Court's passing reference to ripeness was *dicta* and has no bearing on actual

[9] *See FTC v. Staples, Inc.*, Pls.' Mot. and Statement of Points and Authorities in Support of Request for Preliminary Inj., No. 15CV02115, 2015 WL 10682935 (D.D.C. Dec. 7, 2015); Press Release, European Commission, Mergers: Commission Opens In-Depth Investigation into Staples' Proposed Takeover of Office Depot (Sept. 25, 2015), *available at* https://ec.europa.eu/commission/presscorner/detail/en/ IP_16_278; Case M.7555—Staples/Office Depot, Merger Procedure Regulation (EC) 139/2004, at 3 (2016) ("On 25 November 2015 . . . the Phase II proceedings were extended . . . . On 10 December 2015 the Parties submitted revised commitments."), https://ec.europa.eu/competition/mergers/cases/decisions/m7555_5720_3.pdf.

ripeness in applying Section 13(b) here.[10] Nothing in *Tronox* justifies the FTC's seeking to abdicate to the EU its responsibility to decide a transaction between two U.S. companies or to use that policy decision to short-circuit a federal court's ability to review the FTC's effort to bar the closing of the transaction by procedural gamesmanship.[11]

Because its rationale for dismissal *without prejudice* lacks merit, the FTC's motion to dismiss *without prejudice* should be denied. *See, e.g.*, *Stone v. Fisher*, No. 20-CV-1818 (JMF) (BCM), 2020 WL 2765107, at *3 (S.D.N.Y. May 28, 2020) ("The Court further concludes that plaintiff's 'explanation for the need to dismiss' is inadequate, particularly given his announced intention to resume the litigation of his federal claims at such time as he can do so unburdened by the TRO."); *Thompson*, 2017 WL 5135548, at * 6 (denying motion for voluntary dismissal where plaintiff "g[a]ve no explanation as to why they waited until this relatively late date" to seek dismissal); *Blue Spike*, 2015 WL 13655824, at *3 (dismissing *with prejudice* where plaintiff "failed to provide a sufficient

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[10] The FTC also cites two cases (MTD 10-11) in which district courts refused to grant injunctions duplicating their prior orders in suits brought by private plaintiffs under statutes other than Section 13(b). *See Ocean Conservancy, Inc. v. Nat'l Marine Fisheries Servs.*, 90 F. App'x 499, 500-01 (9th Cir. 2003) (refusing to enjoin an office from conducting marine research because doing so was already prohibited by the court's prior orders); *Lee v. Van Boening*, No. 94-35909, 1996 WL 145303, at *1 (9th Cir. 1996) (refusing to enjoin prison officials from opening the plaintiff's mail because doing so was already prohibited by the court's prior order). But in this action, of course, the FTC acts under Section 13(b) and does not ask this Court to duplicate a prior order.

[11] The FTC contends that the EC's investigation "accomplishes the same relief sought in the PI complaint". (MTD at 10). That is plainly untrue. The preliminary injunction complaint seeks to prevent the transaction from closing during the pendency of the administrative proceeding, the resolution of which is not expected until 2022. By contrast, we anticipate resolving any concerns raised by the EC at or about the time the TRO expires in September 2021.

explanation for the basis for its request" in "an obvious effort by the plaintiff to escape the inevitable consequences of its own failures").

II. The FTC's Request for Dismissal Without Prejudice Is Inequitable and Will Impose Undue Prejudice on Defendants.

A dismissal *without prejudice* is inappropriate where it would be prejudicial or inequitable to allow the plaintiff to bring the same action again in the future. *See Burnette*, 828 F. Supp. at 1443 (explaining that the court should "order the dismissal to be with prejudice where it would be inequitable or prejudicial to defendant to allow plaintiff to refile the action"); *Evenflo Co., Inc. v. Augustine*, No. 14-CV-1630-AJB-JLB, 2015 WL 7568663, at *5 (S.D. Cal. Nov. 24, 2015); *Blue Spike*, 2015 WL 13655824, at *3; *White*, 2008 WL 4184651, at *3. Here, the FTC seeks to dismiss the case *without prejudice*, precisely so that it can file a new case seeking exactly the same relief as soon as the FTC feels the EC is closer to clearing the transaction. Allowing the FTC to do that would put the FTC in a position to terminate the transaction without adequate review by an Article III Court because it is unlikely a court could determine the merits on the timeline provided for in the merger agreement.

While Defendants believe the FTC's case and request for a preliminary injunction are meritless, they consented to a TRO and agreed to a schedule that would put the Court in a position to decide the motion before the transaction expires on September 20. All parties agreed that a decision on the FTC's motion would require substantial fact discovery, a period of expert discovery, and a substantial hearing on the merits. In an April 20, 2021 joint letter to Chief Judge Sabraw, the parties advised the Court that they expected the hearing in this matter

would require at least two weeks. (FTC's Exhibit 6.) In oral communications, the FTC has advised Defendants that they would like two weeks to present their case.[12]

Permitting the FTC to withdraw its case now and refile later would make it impossible (as a practical matter) for the Court to address the issues on the kind of schedule that the parties already agreed is appropriate. If the FTC were to withdraw and refile perhaps in August/September, there would be insufficient time for the parties to complete fact discovery on any new claims, conduct expert discovery, exchange trial exhibits and other pretrial submissions, and otherwise ready the case for a hearing before the transaction would expire on its terms. There is a significant chance a court would be unable to devote adequate time to the issues if a new motion for a preliminary injunction were thrust upon it at the eleventh hour. Thus, dismissal *without prejudice* would give the FTC the unchecked power to block this pro-competitive, life-saving combination without regard to its merits, simply by running out the clock.[13]

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[12] Defendants believe they can put on their case in approximately five to six trial days and intend to ask the Court to establish a chess clock allocating time evenly between the parties in a trial to last approximately 10-12 trial days.

[13] To obtain a preliminary injunction, a plaintiff must act equitably and with dispatch. *See Sequa Corp. v. Gelmin*, No. 91 CIV. 8675 (DAB), 1995 WL 404726, at *9 n.7 (S.D.N.Y. July 7, 1995) ("[D]elay may reflect tactical maneuvering by the movant with the goal of maximizing the burden on his adversary. . . this delay would be relevant to an assessment of the relative harms to be endured by the parties if a proposed preliminary injunction were either granted or denied." (citing *Nassau Boulevard Shell Serv. Station, Inc. v. Shell Oil Co.*, 869 F.2d 23, 24 (2d Cir. 1989)); *see also Oakland Tribune, Inc. v. Chronicle Publ'g Co.*, 762 F.2d 1374, 1377 (9th Cir. 1985) ("Plaintiff's long delay before seeking a preliminary injunction implies a lack of urgency and irreparable harm."). The FTC's claim that it should be allowed to start the process of seeking a preliminary injunction, withdraw its application, and then start again later at its convenience is incompatible with the conduct expected of a party seeking equitable relief. A later-filed application for a preliminary injunction could nonetheless occasion the

A recent court filing by the EC further supports Defendants' view that the FTC is working to run out the clock on this transaction. In its observations to Illumina's motion to expedite its challenge to the EC investigation, although the EC did not formally oppose expedition it noted to the European General Court that U.S. proceedings were ongoing, and that they were a relevant factor for the General Court's decision on expedition. In particular, the EC stated that it is in contact with the FTC which has told it that the administrative process would last at least until March 2022. Essentially, the EC is arguing to the European General Court that the case need not be decided because there is a U.S. proceeding. Meanwhile, the FTC is arguing in the U.S. that the case need not be decided because there is an EC proceeding. This ploy has broad implications. If the Court allows the FTC to withdraw its request for preliminary injunction *without prejudice*, then any transaction that is subject to investigations in both the U.S. and EC would never qualify for review by a federal district court.

Ordinarily, no plaintiff wants its case dismissed unless there is some clear advantage in dismissal, and no defendant opposes dismissal of a case against it unless there is some real disadvantage. So it is here. The FTC seeks to obtain by dismissal what it cannot achieve by litigating the case on the merits: preventing the transaction from closing. Defendants oppose dismissal without prejudice to avoid a re-filed suit that will run the clock and by that means alone preclude closing of the transaction. That Defendants oppose the dismissal of claims against them speaks volumes about where the prejudice lies in the event the FTC is allowed to drop this case only to start another case months down the road.

The FTC contends that Defendants would not suffer legal prejudice because they intend still to pursue an administrative trial on the merits. As the FTC

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expense, delay, and uncertainty associated with litigation, allowing the FTC to scuttle the transaction using tactics unrelated to the merits.

knows, however, the FTC's continued prosecution of the administrative proceeding will do nothing to avoid prejudice to Defendants, the transaction and the public, because no decision will be taken in the administrative proceeding until 2022.

Courts have rejected motions for dismissal *without prejudice* in similar circumstances where dismissal would be prejudicial to defendants. *See Diamond State Ins. Co. v. Genesis Ins. Co.,* 379 F. App'x 671, 673 (9th Cir. 2010) (affirming Rule 41(a)(2) dismissal *with* prejudice where dismissal *without* prejudice would "essentially allow [plaintiff] to 'revoke its promise'" with respect to a settlement agreement with defendant); *Neville*, 2019 WL 4242502, at *2 (Bencivengo, J.) (dismissing the case with prejudice where "[p]laintiff ha[d] engaged in forum-shopping" and dismissal *without prejudice* would, in fact, prejudice defendants); *Burnette*, 828 F. Supp. at 1443 (explaining that the court should "order the dismissal to be with prejudice where it would be inequitable or prejudicial to defendant to allow plaintiff to refile the action"); *Blue Spike*, 2015 WL 13655824, at *3 (denying request for dismissal with prejudice where dismissal was "a transparent attempt to circumvent the impact of [the judge's] ruling"); *Evenflo*, 2015 WL 7568663, at *5 ("The timing of this motion, filed on the heels of the close of fact discovery, is suspicious.").

III. Dismissal Without Prejudice Would Be Inefficient and Impractical.

Finally, while dismissal is favored when it secures the "just, speedy, and inexpensive determination" of an action (MTD 8), that would not be the result of the FTC's motion to dismiss *without prejudice*. *See Hanginout, Inc. v. Google*, No.13cv2811 AJB (NLS), 2015 WL 11254668, at *2 (S.D. Cal. April 22, 2015) ("[R]ules of civil procedure 'should be construed and administered to secure the just, speedy and inexpensive determination of every action and proceeding.'"); *White*, 2008 WL 4184651, at *3 (denying request for dismissal *without prejudice* where there was a pending claim dispositive motion so dismissal would be wasteful

and inefficient). Contrary to the FTC's contention (MTD 12), requiring the FTC to go forward with the preliminary injunction action would not "waste the resources of the court, third parties, and taxpayers". The opposite is true.

Inefficiency. The parties have already engaged in extensive fact discovery. As explained above, Defendants have produced more than 34 million pages in response to the FTC's requests[14]; made more than 20 witnesses available for investigatory hearings or deposition; and obtained discovery from at least 25 third parties, including, for example, Exact Sciences Corporation, Foundation Medicine, Inc., Freenome Holdings, Inc., Guardant Health, Morgan Stanley, Natera, Inc., Omniome, Inc., Quest Diagnostics, Singlera Genomics, Inc., Singular, StageZero Life Sciences, Inc., and Ultima Genomics.[15] Fact discovery is set to end on June 4, and the first wave of expert reports is due on June 8. Illumina and GRAIL (and presumably also the FTC) have made substantial progress in preparing for trial, and witnesses have blocked their calendars and are ready to go. If the preliminary injunction hearing goes forward, all of the discovery taken (and to be taken) in this matter will be available to the parties in the separate administrative proceeding before the FTC, which the FTC has said it will pursue irrespective of whether the Court dismisses the present case (with or without prejudice). The scheduling order in the administrative proceeding specifically contemplates that the

[14] The FTC has had access to the vast majority of this discovery prior to March 1, 2021, when the Defendants substantially complied with the FTC's second request in connection with its investigation of the transaction.

[15] Additional third parties that have been subpoenaed include: Ariosa Diagnostics, Inc., Caris Life Sciences, Inc., Element Biosciences, Inc., Emory Healthcare, Genapsys, Inc., Labcorp, Luminex Corporation, Pacific Biosciences of California, Personal Genome Diagnostics, Inc., PreventionGenetics, LLC, Progenity, Inc., Roche Sequencing Solutions, Inc., Thermo Fisher Scientific, Inc., ThirdRock Ventures, LLC, and Thrive Earlier Detection Corp.

discovery taken in this action may be used in that case. So, nothing done here will be wasted no matter the outcome of the present motion.

By contrast, allowing the FTC to withdraw and refile this case would waste significant resources and impose unneeded burden and expense on the parties and the Court. When the FTC files a new (and with the benefit of months of discovery, possibly revised) complaint, the litigation will start over—in many ways from square one. The case would be assigned to a new judge or return to this Court. Defendants would need to prepare and file a new answer. A new CMSO would need to be negotiated and entered. Fact discovery would be required as to any new allegations and updated discovery would be required as to old allegations. New subpoenas would need to issue. The parties would need also to prepare and exchange expert reports (revised and updated for the new preliminary injunction case) and take expert depositions. The parties would need to exchange deposition designations, proposed exhibits, and other pre-trial submissions. And there is no guarantee that there will be time for all of this or that the Court would be able to accommodate a trial of at least two weeks prior to the termination date for the transaction.[16] Proceeding according to the current agreed-upon and so-ordered schedule avoids all of this duplicative waste and averts the likely self-inflicted chaos that would follow from allowing the FTC the option of a belated redo.[17]

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[16] In footnote 20 of its Brief, the FTC states that it is willing to "stipulate to the use of evidence gathered post-dismissal in a subsequent filing for a temporary restraining order of preliminary injunction." But the FTC could bring the TRO long after discovery is closed in the administrative action (June 24), and so there would likely be a need for interim discovery.

[17] Defendants do not believe the FTC's present theories of anticompetitive harm have any merit. Nor do Defendants believe any later-filed claims of harm would have any more merit. But the FTC will no doubt seek to shroud itself in the trappings of government authority and argue it should be given deference in matters of antitrust enforcement. Defendants expect no court would want to address the

That the FTC is pursuing an administrative proceeding in parallel does not make this case duplicative. The FTC concedes in its brief that different standards apply across the two proceedings. (MTD at 11.) As the FTC knows, it cannot obtain a preliminary injunction barring closing of the transaction in the administrative proceeding; the ALJ is not empowered to do that. Only a district court can issue a preliminary injunction to determine whether the transaction can close. If the FTC seeks to prevent Defendants from closing, it will come right back to this Court to seek a preliminary injunction.[18]

Delay and expense. The FTC argues that the case should be dismissed *without prejudice* and without the imposition of any conditions because, it says, it "acted quickly and the explanation for dismissing the PI Complaint is clear." (MTD 14.) Not so, for all the reasons discussed above. The FTC suggests that it would have acted more quickly but for Defendants refusing to provide a clear answer regarding the impact of the EC proceedings on this case. That is false. Defendants promptly and repeatedly advised the FTC that "[t]he European Commission's assertion of jurisdiction is unprecedented and unlawful and you should make no assumptions regarding what the parties can or cannot do in closing the transaction, either in whole or in part". (MTD Ex. 4.) In any case, as shown above, the FTC not only knew about the EC proceedings long before it acknowledges in its opening brief, but also there is reason to believe the FTC played a role in the initiation of the investigation.

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issues presented by this transaction, which all agree have life-saving consequences, on a rushed schedule, especially when the parties have already agreed to a process that will allow for an orderly resolution.

[18] While injunctive relief is available to the FTC, such relief can only be obtained after a final decision is issued—something that will only occur many months after the expiration of the transaction.

The FTC contends that "Defendants have incurred minimal expense that they would have otherwise not incurred in the administrative process" which they claim will be the more expansive proceeding. (MTD 15.) This too is incorrect. Defending against the FTC's request for a preliminary injunction and preparing for a trial beginning on August 9 has resulted in significant expense to Defendants that they would not have otherwise incurred, including the preparation of expert reports, discovery responses and other filings specifically focused on the legal standard applicable in the district court proceedings. Moreover, it is this case, not the administrative proceeding, that will determine the outcome of this transaction. If this Court issues a preliminary injunction, then Defendants will abandon the transaction. If the Court denies the preliminary injunction, then Defendants will close and the FTC will have to decide whether to proceed with the administrative case. If history is any guide, the FTC will not proceed. But in any case it will not be able to stop the closing. The administrative proceeding will not resolve until long after the termination date of the transaction.

Courts routinely deny motions to dismiss *without prejudice* where, as here, doing so would be wasteful, inefficient and impractical. *Hanginout*, 2015 WL 11254688, at *2 (noting upon denying dismissal *without prejudice* that the "rules of civil procedure 'should be construed and administered to secure the just, speedy and inexpensive determination of every action and proceeding'"); *Peck Ormsby Const. Co. v. City of Rigby*, No. 1:10–00545 WBS, 2013 WL 5274221, at *2 (D. Idaho Sept. 17, 2013) (declining to dismiss claim without prejudice where there would be "further delay and the duplication of costs and efforts already expended"); *Cent. Montana Ry. Co. v. BNSF Ry. Co.*, No. CV-05-116-GF-RKS, 2010 WL 11534149, at *3 (D. Mont. Apr. 13, 2010) (denying Rule 41(a)(2) motion to dismiss where "[i]f voluntary dismissal were granted, the result would be great delay and duplication"); *IXIA v. Mitchell*, No. CV 08–07076 RGK (AJWx), 2009 WL

10674095, at *2 (C.D. Cal. July 8, 2009) (denying Rule 41(a)(2) motion to dismiss where, *inter alia*, the case was "only two and one-half months from trial"); *White*, 2008 WL 4184651, at *3 (denying request for dismissal *without prejudice* where it would impair "the timely final adjudication" of plaintiff's claims).

In seeking dismissal *without prejudice*, the FTC seeks to have its cake and eat it too. It seeks to put a pin in its obligation to show that there is any basis for a preliminary injunction, while continuing to deploy the threat of one to influence the European process and dissuade the parties from closing. In a proceeding about equity, the FTC should have to pick. The FTC chose to sue and to pursue injunctive relief. It negotiated a TRO and a schedule to determine its entitlement to injunctive relief. If the FTC still wants to hold open the possibility of such relief, then this case should proceed according to the agreed-upon schedule. If not, then the Court should dismiss this case *with prejudice* so that the transaction can close and Defendants can get about the business of saving lives.

CONCLUSION

For the foregoing reasons, Defendants respectfully submit that the Court should deny FTC's motion to dismiss *without prejudice*.

Dated: May 26, 2021

By:

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that he caused a copy of the foregoing documents to be served on the following via ECF on May 26, 2021:

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Exhibit I

PUBLIC

United States District Court

SOUTHERN DISTRICT OF CALIFORNIA

Federal Trade Commission

Plaintiff,

V.

Illumina Inc.; GRAIL, INC.

Defendant.

Civil Action No. 21-cv-00800-CAB-BGS

JUDGMENT IN A CIVIL CASE

Decision by Court. This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

IT IS HEREBY ORDERED AND ADJUDGED:

Motion Hearing held on 5/28/2021 re 120 Ex Parte MOTION to Dismiss the Complaint without prejudice filed by Federal Trade Commission. Hearing argument and for reasons stated on the record, the Court grants the motion to dismiss. Case closed.

Date: 6/1/21

CLERK OF COURT
JOHN MORRILL, Clerk of Court
By: s/ A. Hazard
A. Hazard, Deputy

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

In the Matter of	
Illumina, Inc., a corporation, and and GRAIL, Inc., a corporation, Respondents	Docket No. 9401

[PROPOSED] ORDER GRANTING UNOPPOSED MOTION FOR LEAVE TO AMEND ANSWER

Upon the unopposed motion of Respondents Illumina, Inc. and GRAIL, Inc., for an order granting Respondents leave to amend their Answer originally filed on April 13, 2021,

IT IS ORDERED THAT Respondents are granted leave to amend the Answer to plead the following additional affirmative defenses: (1) violation of the Appointments Clause in Article II, Section 2 of the United States Constitution, (2) violation of the President's removal powers, as vested in Article II of the United States Constitution and as outlined in *Myers v. United States*, 272 U.S. 52, 117 (1926), and (3) violation of the Due Process and Equal Protection Clauses of the Fifth Amendment of the United States Constitution. Respondents shall file their Amended Answer by [●].

ORDERED:

D. Michael Chappell
Chief Administrative Law Judge

Date: