UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, Plaintiff, v. ILLUMINA, INC. AND GRAIL, INC., Defendants.	Civil Action No. 1:21-cv-00873-RC **FILED UNDER SEAL**

ANSWER OF DEFENDANTS ILLUMINA, INC. AND GRAIL, INC.

Defendants Illumina, Inc. ("Illumina") and GRAIL, Inc. ("GRAIL") (together, "Defendants") answer the Complaint for temporary restraining order and preliminary injunction (Dkt. No. 14) (the "Complaint") filed by the Federal Trade Commission (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 a preliminary injunction 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 plans to launch 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'

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

"'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'").

The FTC bears the burden to show that issuing a preliminary injunction is in the public interest based on an assessment of (1) the FTC's likelihood of success on the merits, and (2) the balance of the equities. That burden is substantial, 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 this life-saving technology, and at lower prices. A preliminary injunction will prevent the transaction from ever being consummated and, consequently, these benefits from being realized. Thus, it is "an extraordinarily drastic remedy". *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 290 (D.D.C. 2020). A mere "showing of a fair or tenable chance of success on the merits will not suffice for injunctive relief." *Id.*

The FTC does not contest that the proposed merger is a purely vertical transaction. Because it is purely vertical, 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 in development 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

[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.

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 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.

[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.

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] 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 tissue 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 tissue 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]

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

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

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 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.

The Balance of Equities Favors the Transaction. If the Court issues a preliminary injunction, the transaction will collapse. The Merger Agreement provides for termination rights in the event that the transaction is not consummated on or before September 20, 2021, subject to a three-month extension period, and both parties have stated that they will not go forward with the transaction in the event that a preliminary injunction is issued. And with the collapse of the transaction, an important opportunity to save tens of thousands of lives would be lost. The equities plainly favor allowing this transaction to go forward.

RESPONSE TO THE SPECIFIC ALLEGATIONS OF THE COMPLAINT

Except to the extent specifically stated herein, Defendants 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 90 numbered paragraphs.

The first paragraph of 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, Defendants state that the FTC has petitioned this Court for a preliminary injunction enjoining the Transaction and in all other respects denies the allegations in the first paragraph of the preamble to the Complaint.

The second paragraph of 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, Defendants state that the FTC has filed an administrative complaint before the FTC and in all other respects denies the allegations in the second paragraph of the preamble to the Complaint. Specifically, Defendants deny that competition will be harmed if the Court denies the FTC's request for a preliminary injunction enjoining the Transaction; and Defendants deny that the FTC's administrative hearing will determine the legality of the acquisition or will provide all parties a full opportunity to conduct discovery and present testimony and other evidence regarding the likely competitive effects of the acquisition.

To the contrary, Defendants aver that administrative proceedings before the Commission frequently take years to complete and that the administrative proceeding against Defendants would conclude long after the transaction's deadline, given a weeks-long trial, post-trial briefing, a months-long window for the Administrative Law Judge to issue an opinion, an appeal to the Commissioners and an appeal to the United States Court of Appeals. Given the

commercial realities surrounding the transaction, this Court's determination with respect to this preliminary injunction action will decide the fate of the transaction on the merits.

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

NATURE OF THE CASE

1. Defendants state that the allegations in paragraph 1 purport to describe this action, and do not require a response. To the extent a response is required, Defendants deny the allegations in Paragraph 1.

2. Defendants deny the allegations in Paragraph 2, and state that GRAIL's Galleri test in development 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. Defendants deny the allegations in Paragraph 3, and state that GRAIL's Galleri test in development 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 in development, 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. Defendants 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. Defendants deny the allegations in Paragraph 4, and state that GRAIL is working to develop and commercialize its Galleri test in development for early-cancer screening for asymptomatic patients; GRAIL plans to launch its Galleri test as a laboratory developed test in the United States in April 2021; 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. Defendants further state that Plaintiff purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents. Defendants 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. Defendants 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 in development 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. Defendants further state that Defendants 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. Defendants 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. Defendants 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. Defendants 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 Defendants refer to the underlying agreements for their contents. Defendants further state that Plaintiff purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents.

8. Defendants 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 Defendants refer to the underlying agreements for their contents.

9. Defendants 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]

[redacted] GRAIL plans to launch its Galleri test as a laboratory developed test in the United States in April 2021 and GRAIL anticipates submitting an application for single-site premarket approval with the U.S. Food and Drug Administration ("FDA") for Galleri.

10. Defendants 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] Defendants further state that Plaintiff purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents. Defendants further state that Defendants 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. Defendants deny the allegations in Paragraph 11, and state that Plaintiff purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents. Defendants 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. Defendants 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 in development, Galleri. Defendants state that Plaintiff purports to reference unidentified written materials and refer to the referenced unidentified written materials for their contents. Defendants 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. Defendants deny the allegations in Paragraph 13.

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

15. Defendants deny the allegations in Paragraph 15.

16. Defendants 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.

17. Defendants deny the allegations in Paragraph 17, 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.

JURISDICTION AND VENUE

18. Defendants state that because Paragraph 18 states conclusions or characterizations of law, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 18, except refer to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b); 28 U.S.C. §§ 1331, 1337 and 1345; and the unidentified Act of Congress for their contents. Defendants further state that because this case centers on a proposed transaction between two companies headquartered in California and because the majority of third-party witnesses are all located in California, this case should be transferred to the United States District Court for the Southern District of California for the convenience of parties and witnesses, in the interest of

justice under 28 U.S.C. § 1404(a). Defendants have separately moved this Court for transfer under that section.

19. Defendants deny the allegations in Paragraph 19, and state that Plaintiff purports to describe Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to which no response is required. To the extent a response is required, Defendants refer to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), for its contents.

20. Defendants state that because Paragraph 20 states conclusions or characterizations of law, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 20. Defendants further refer the Court to Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12, for their contents.

21. Defendants state that because Paragraph 21 states conclusions or characterizations of law, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 21 except refer to the FTC Act, 15 U.S.C. § 53(b); Fed. R. Civ. P. 4(k)(1)(C); 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1391(c)(2) for their contents. Defendants further state that because this case centers on a proposed transaction between two companies headquartered in California and because the majority of third-party witnesses are all located in California, this case should be transferred to the United States District Court for the Southern District of California for the convenience of parties and witnesses, in the interest of justice under 28 U.S.C. § 1404(a). Defendants have separately moved this Court for transfer under that section.

THE PARTIES AND THE PROPOSED ACQUISITION

22. Defendants deny the allegations in Paragraph 22 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.

23. Defendants deny the allegations in Paragraph 23, 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.

24. Defendants deny the allegations in Paragraph 24, and state that Defendant, GRAIL, is a private pre-commercial 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.

25. Defendants deny the allegations in Paragraph 25, 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. Defendants

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

26. Defendants deny the allegations in Paragraph 26, 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.

27. Defendants state that because Paragraph 27 states conclusions or characterizations of law, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 27 and state that the FTC filed its administrative complaint on March 30, 2021. Defendants further state that Defendants 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. Defendants further refer to 16 C.F.R. § 3.41 for its contents.

28. Defendants state that because Paragraph 28 states conclusions or characterizations of law, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 28. Defendants further state that Defendants 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, including the Commission.

INDUSTRY BACKGROUND

29. Defendants deny the allegations in Paragraph 29 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.

30. Defendants deny the allegations in Paragraph 30 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.

31. Defendants deny the allegations in Paragraph 31, 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. Defendants 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 31.

32. Defendants deny the allegations in Paragraph 32.

33. Defendants deny the allegations in Paragraph 33 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. Defendants further state that Plaintiff purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents.

34. Defendants deny the allegations in Paragraph 34, and state that GRAIL's Galleri test in development 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. Defendants further state that Defendants 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 34.

35. Defendants deny the allegations in Paragraph 35, 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. Defendants further state that Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 35.

THE ALLEGED RELEVANT ANTITRUST MARKET IS MCED TESTS

36. Defendants state that because Paragraph 36 states conclusions or characterizations of law, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 36.

37. Defendants deny the allegations in Paragraph 37 and state that GRAIL's Galleri test in development 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. Defendants further state that Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 37.

38. Defendants deny the allegations in Paragraph 38, 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 in development 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. Defendants 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 38.

39. Defendants deny the allegations in Paragraph 39, and state that polymerase chain reaction ("PCR") technology can be used to look for changes in a gene or chromosome.

40. Defendants deny the allegations in Paragraph 40, and state that GRAIL's Galleri test in development for early-cancer screening for asymptomatic patients can improve patient compliance. Defendants further state that Plaintiff purports to quote from unidentified written materials and refer to the referenced unidentified written materials for their contents.

41. Defendants deny the allegations in Paragraph 41, 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.

42. Defendants state that because Paragraph 42 states conclusions or characterizations of law, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 42.

43. Defendants deny the allegations in Paragraph 43.

44. Defendants deny the allegations in Paragraph 44, and state that no NGS-based multi-cancer test is currently commercialized in the U.S. Defendants further state that Plaintiff purports to quote from GRAIL's amended Form S-1 Registration Statement and refer to that document for its contents.

45. Defendants deny the allegations in Paragraph 45, 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] Defendants further state that Defendants 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 Plaintiff purports to quote from unidentified written materials and Defendants refer to the referenced unidentified written materials for their contents.

46. Defendants deny the allegations in Paragraph 46, 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.

Defendants further state that Plaintiff purports to quote from [redacted] and refer to the referenced document for its contents. Defendants 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.

47. Defendants deny the allegations in Paragraph 47, 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 plans to launch its Galleri test as a laboratory developed test in the United States in April 2021 and [redacted]

48. Defendants deny the allegations in Paragraph 48, and state that [redacted] and state that Defendants 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.

49. Defendants deny the allegations in Paragraph 49, and state that Defendants 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.

50. Defendants deny the allegations in Paragraph 50, and state that Defendants 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.

51. Defendants deny the allegations in Paragraph 51, and state that Defendants 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.

52. Defendants deny the allegations in Paragraph 52, and state that Illumina's internal projections reflect that no other multi-cancer screening test for use in asymptomatic patients will launch this year. Defendants 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 plans to launch its Galleri test as a laboratory-developed test in the United States in April 2021.

ALLEGED ANTICOMPETITIVE EFFECTS

53. Defendants state that because Paragraph 53 states conclusions or characterizations of law, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 53, except refer to the Vertical Merger Guidelines for their contents.

54. Defendants deny the allegations in Paragraph 54, 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. Defendants 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.

55. Defendants deny the allegations in Paragraph 55, 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.

56. Defendants deny the allegations in Paragraph 56, and state that GRAIL uses a sequencing platform to analyze methylation patterns in DNA fragments.

57. Defendants deny the allegations in Paragraph 57.

58. Defendants deny the allegations in Paragraph 58, and state that certain NGS platforms can be used for de novo whole-genome sequencing or detecting large structural rearrangements.

59. Defendants deny the allegations in Paragraph 59.

60. Defendants deny the allegations in Paragraph 60 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.

61. Defendants deny the allegations in Paragraph 61, and state that Thermo Fisher is an NGS platform manufacturer in the United States. Defendants 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. Defendants state that Plaintiff purports to quote and/or reference unidentified written materials and refer to the referenced unidentified written materials for their contents.

62. Defendants deny the allegations in Paragraph 62, and state that BGI is an NGS platform provider. Defendants further state that Plaintiff 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.

63. Defendants deny the allegations in Paragraph 63, and state that Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 63.

64. Defendants deny the allegations in Paragraph 64.

65. Defendants deny the allegations in Paragraph 65, and state that Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 65.

66. Defendants deny the allegations in Paragraph 66, and state that Plaintiff 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. Defendants 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 66.

67. Defendants deny the allegations in Paragraph 67, 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. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 65.

68. Defendants deny the allegations in Paragraph 68, 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.

69. Defendants deny the allegations in Paragraph 69, 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. Defendants 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.

70. Defendants deny the allegations in Paragraph 70, 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. Defendants 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.

71. Defendants 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.

72. Defendants deny the allegations in Paragraph 72, 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. Defendants further state that Plaintiff's quotation from unidentified written material is taken out of context and is misleading. Defendants 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.

73. Defendants deny the allegations in Paragraph 73. Defendants 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. Defendants 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.

74. Defendants deny the allegations in Paragraph 74, and state that Plaintiff's quotation from unidentified written material is taken out of context and is misleading. Defendants 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. Defendants 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.

75. Defendants deny the allegations in Paragraph 75, 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.

76. Defendants deny the allegations in Paragraph 76, 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. Defendants 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.

77. Defendants deny the allegations in Paragraph 77, and state that Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations related to unidentified third parties in Paragraph 77.

78. Defendants deny the allegations in Paragraph 78, and state that GRAIL plans to launch its Galleri test as a laboratory developed test in the United States in April 2021.

79. Defendants deny the allegations in Paragraph 79.

80. Defendants deny the allegations in Paragraph 80, and state there are no multi-cancer non-invasive screening tests on the market today.

81. Defendants deny the allegations in Paragraph 81, 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] Defendants further state that Plaintiff purports to quote and/or reference unidentified written materials and refer to the referenced unidentified written materials for their contents. Defendants 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

82. Defendants deny the allegations in Paragraph 82, 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.

83. Defendants deny the allegations in Paragraph 83, and state that Plaintiff's quotation from unidentified written material is taken out of context and is misleading. Defendants 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

84. Defendants state that a separate response to paragraphs 1 through 83 is not required. To the extent that a separate response is required, Defendants incorporate their responses to paragraphs 1 through 83 as though fully stated herein.

85. Defendants deny the allegations in Paragraph 85 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.

86. Defendants state that because Paragraph 86 states conclusions or characterizations of law, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 86.

LIKELIHOOD OF SUCCESS ON THE MERITS, BALANCE OF EQUITIES AND ALLEGED NEED FOR RELIEF

87. Defendants state that because Paragraph 87 states conclusions or characterizations of law, no response is required. To the extent a response is required, Defendants deny the

allegations in Paragraph 87 and refer to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b) for its contents.

88. Defendants state that because Paragraph 88 states conclusions or characterizations of law, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 87. Defendants 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.

89. Defendants state that because Paragraph 89 states conclusions or characterizations of law, no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 89.

90. Defendants state that Paragraph 90 purports to set forth Plaintiff's prayer for relief and contain a request for relief as to which no response is required. To the extent a response is required, Defendants deny that Plaintiff is entitled to the requested relief in Paragraph 90.

DEFENSES

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

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

2. The combination of Defendants' 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. Plaintiff'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. Plaintiff has failed to define any appropriate relevant market or markets.

6. Plaintiff has failed to establish that Defendants exercise market power with respect to any relevant market.

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

8. Plaintiff'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 injunctive relief that Plaintiff seeks is inconsistent with the public interest, the equities favor consummation of the Transaction and alternative remedies are available to the Court.

Defendants reserve the right to assert any other available defenses.

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

Dated: April 5, 2021

Respectfully submitted,

/s/ Christine A. Varney

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