

**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

MOTION FOR LEAVE TO ALLOW TWO ADDITIONAL TESTIFYING EXPERTS

Pursuant to Rule 3.31A(b) of the Commission Rules of Practice, Respondents Illumina, Inc. (“Illumina”) and GRAIL, Inc. (“GRAIL”) (collectively, “Respondents”), through undersigned counsel, respectfully request that the Court permit Respondents to present testimony from two additional expert witnesses.

Rule 3.31A(b) allows a party to seek leave to call more than five experts “due to extraordinary circumstances”. 16 C.F.R. § 3.31A(b). Respondents submit that this case presents such circumstances. As set forth below, this case involves numerous, complex issues and technical areas giving rise to extraordinary circumstances that require the designation of two additional experts. Each of Respondents’ expert witnesses offers a distinct area of expertise that is critical to Respondents’ defense against Complaint Counsel’s allegations and affirmative arguments in support of the proposed merger.

PUBLIC**I. BACKGROUND**

Respondent Illumina is a leading provider of sequencing products for genetic and genomic analyses. (*See* Respondents' Answer to Administrative Complaint dated April 13, 2021 (Answer) at 2.) Illumina was founded in 1998 in San Diego. (*Id.* at 20.) Its mission is to improve human health by unlocking the power of the genome. (*Id.* at 2.) Illumina originally founded Respondent GRAIL in 2016 with the goal of developing a screening test for multiple cancers to detect cancer at an early stage, when it can most easily be cured. (*Id.*) GRAIL was spun out as a standalone company in 2017 to invest in the extensive, population-scale clinical trials needed to develop its multi-cancer screening test, Galleri. *Id.* Illumina retained a 14.5% equity interest in GRAIL and the right to receive a percentage royalty on GRAIL's future revenues. *Id.*

On September 20, 2020, Illumina and GRAIL announced that they had reached an agreement to fully reunify the two companies. (*Id.* at 2–3.) Through this administrative action, the FTC has sought to block the proposed transaction, a purely vertical one, alleging that it will have anticompetitive effects in an alleged relevant product market of “multi cancer early detection” or “MCED” tests. (Administrative Complaint dated March 30, 2021 (Compl.) ¶ 1.) However, the reunification of Illumina and GRAIL will not have any adverse effects on competition, and, to the contrary, will result in enormous pro-competitive efficiencies that will save thousands of lives. (Answer. at 12–13.) Any theoretical competitive concerns are resolved by Illumina's offer to current and prospective oncology customers of contract terms (an “Open Offer”) that include a 12-year commitment to enter into a supply agreement that provides robust

PUBLIC

pricing, supply and service guarantees, which directly address the FTC's competitive concerns. (Answer at 3–4, 10–11 & ¶ 49.)¹

This case presents complex and novel issues because the FTC is suing to block a vertical merger pertaining to a nascent technology that is many years from reaching commercial scale and faces many hurdles to achieving broad adoption. Respondents submit that the consequences of the FTC's actions are enormous—acceleration of GRAIL's test, Galleri, through the merger will save thousands of lives. Given the complex issues and subject matters at issue, Respondents preliminarily designated fifteen expert witnesses. *See* Respondents' Expert Witness List (May 21, 2021). Following the close of fact discovery and review of Complaint Counsel's expert report, Respondents submitted eight expert reports and declarations in support of Respondents' defense and in rebuttal to the FTC's expert. Respondents have since further narrowed their proposed list to seven testifying experts, each of whom Respondents intend to present at trial.

II. LEGAL STANDARD

Under Rule. 3.31A(b), if “extraordinary circumstances” warrant, parties may call more than the standard five expert witnesses. 16 C.F.R. § 3.31A(b).² The Rule does not define the phrase, “extraordinary circumstances”, but in enacting Rule 3.3 1A(b), the Commission referred to this exception as a “safety valve that allows a party to seek leave to call additional

¹ The Open Offer 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>. The *Oncology Contract Terms* webpage provides a high-level summary of the Open Offer and links to Illumina's proposed standard supply contract and proposed IVD agreements for oncology customers.

² Rule 3.31A(b) states in full: “No party may call an expert witness at the hearing unless he or she has been listed and has provided reports as required by this section. Each side will be limited to calling at the evidentiary hearing 5 expert witnesses, including any rebuttal or surrebuttal expert witnesses. A party may file a motion seeking leave to call additional expert witnesses due to extraordinary circumstances”. 16 C.F.R. § 3.31A(b).

PUBLIC

expert witnesses” when the five-expert limit is insufficient. 74 Fed. Reg. 1804, 1813 (Jan. 13, 2009).

This Court has previously granted respondents leave to add experts pursuant to Rule 3.31A(b) in circumstances that are analogous to this case. In *In re POM Wonderful, LLC*, 2011 WL 734462 (2011), the Court permitted respondents to exceed the five-expert limit with three additional experts in light of the complexity of the scientific issues and the “broad and comprehensive defense” necessitated by the complaint’s allegations. *Id.* at *4. Additional experts were warranted because the case involved multiple products, advertisements and areas of science as well as “at least two theories of liability”. *Id.* Similarly, in *In re 1-800 Contacts, Inc.*, Docket No. 9372 (Feb. 22, 2017), the Court permitted respondents to exceed the five-expert limit with one additional expert where the case involved the technical areas of both antitrust law and trademark law and presented “technical issues regarding Internet search advertising, keyword usage, and extensive related data”. *Id.* at 4.

III. THE EXTRAORDINARY CIRCUMSTANCES OF THIS CASE WARRANT TWO ADDITIONAL TESTIFYING EXPERTS.

The Court should allow Respondents to designate seven expert witnesses because of the sheer breadth of complex, novel issues in this case, which include, among other things, private payor and Medicare reimbursement, antitrust economics, healthcare economics, cancer screening test development (including their development through clinical trials and the various performance attributes that can differentiate them, such as the cancer biomarkers they can detect and their ability to minimize false positives and false negatives), the efficacy of long-term contractual constraints in the industry and the upstream and downstream markets for clinical diagnostic platforms, including next generation sequencing and the rapid technological innovation and investment in the space. Each of Respondents’ expert witnesses offers a distinct

PUBLIC

area of expertise that will be helpful to the Court in evaluating these critical issues.³

Respondents seek leave to present testimony from Dr. Richard Abrams, a primary care physician who is the only expert in this case who has prescribed a multi-cancer screening test to a patient and Mr. Robert Rock, a certified public accountant who will testify regarding compliance audit issues. Dr. Abrams' report is attached hereto as Exhibit B, and Mr. Rock's report is attached hereto as Exhibit C. As discussed below, Dr. Abrams and Mr. Rock each possess unique expertise that will be valuable to elucidating the complex issues to this Court.

The scope of discovery that the parties have taken to date helps to demonstrate the extraordinary circumstances. As part of the FTC's investigation of the proposed transaction, the FTC demanded that Respondents produce documents from an unprecedented 253 custodians. (Ex. D, Dec. 24, 2020 Letter from S. Goswami to D. Naegele.) For 40 of those 253 custodians, the FTC required that their files be collected back to 2010, more than ten years before the proposed transaction was announced. (Ex. E, Feb. 11, 2021 Letter from S. Goswami to D. Naegele.) Once litigation commenced, the parties together participated in 49 depositions of party and third-party witnesses, following an initial 33 hearings of party and third-party witnesses by the FTC during its investigation. More than six million documents and more than ten terabytes of data have been produced as part of the FTC's investigation and during fact discovery.

A. The Breadth of Issues Raised in This Case Require the Expertise of Two Additional Experts.

The FTC alleges that a reunited Illumina and GRAIL would have an incentive to raise prices on sequencing instruments and reagents and otherwise disadvantage potential

³ A copy of Respondents' Proposed Final Witness List, which includes details of each expert's anticipated testimony, is attached hereto as Exhibit A.

PUBLIC

downstream rivals of GRAIL in the future (Compl. ¶ 7), even though there is no existing market for multi-cancer screening tests, and Illumina's incentives are to expand the adoption of next-generation sequencing (NGS) by current and prospective customers. To show that Illumina's incentives today are to support all test developers using NGS (and to rebut the contentions of the FTC to the contrary), Respondents intend to present testimony from Dr. Dennis Carlton, an industrial organization and antitrust economics expert.

With respect to the FTC's contentions on market definition, Respondents intend to present testimony from Dr. Robert Willig, an economics expert who will primarily focus on rebutting Dr. Scott Morton's definition of the relevant product market from an economics standpoint, and will also address Dr. Scott Morton's opinions relating to bargaining theory and anticompetitive effects. Respondents also intend to present testimony from Dr. Richard Cote, a clinical pathologist and cancer researcher who will opine on the development of cancer screening tests. (*See Ex. A at 7.*)

Respondents seek leave to call Dr. Abrams, an expert in the field of primary and preventative care, as an additional expert beyond the default number. (*See Ex. B.*) The parties agree that multi-cancer screening tests are likely to be prescribed through primary care physicians. (*E.g.*, Expert Report of Fiona Scott Morton at ¶ 157.) Dr. Abrams is a practicing primary care physician who will testify about current and potential cancer screening options and the factors clinicians would consider prior to using a multi-cancer early detection test. (*See Ex. A at 8–9.*)

The FTC alleges that Illumina has the ability to foreclose competition because it is the "dominant" provider of NGS platforms in the United States (Compl. ¶ 6), even though Illumina faces increasing competition in the upstream market and not all test developers rely on

PUBLIC

NGS to perform cancer screening tests. The FTC makes numerous other allegations, including that the merger will discourage innovation (*id.* ¶ 14), even though new investment has poured into the cancer screening space since the announcement of the proposed transaction and Illumina's vertical integration will lead to more innovation, not less. Dr. Willig will also address the significance of continuing investment and innovation in the cancer screening space from an economics perspective. (Ex. A at 8.) Dr. Cote will also address important technical issues relating to alternative NGS platforms and their suitability for oncology screening test development. (*Id.* at 7.)

Contrary to the FTC's allegations, the evidence that Respondents have amassed show that the merger will revolutionize cancer care, saving tens of thousands of lives. (Answer at 3.) Illumina is uniquely situated to use its experience and substantial resources to accelerate the widespread adoption of Galleri and reach more patients faster. (*Id.*) GRAIL projects that, if it can get the help this transaction will provide, the test could save many thousands of lives annually.⁴ Specifically, the merger will produce numerous pro-competitive efficiencies, including: (1) accelerating the commercialization of GRAIL's test at scale; (2) eliminating double marginalization; (3) accelerating private and Medicare reimbursement, and accelerating regulatory approval; (4) accelerating international expansion of GRAIL's test (which will also benefit US consumers); and (5) R&D efficiencies. (Answer at 12–13.)

These efficiencies are substantial and merger-specific. The expert testimony Respondents intend to proffer will help the Court assess these efficiencies and their magnitude. For example, Dr. Patricia Deverka, an expert in payor reimbursement, health economics and outcomes research who focuses on the clinical adoption of genomics will testify about the

⁴ Acceleration by just one year could save between 18,037 and 25,349 lives over a 10-year period.

PUBLIC

process for obtaining private payor and Medicare/Medicaid coverage. (Ex. A at 7.) She will also opine on Illumina's ability to accelerate the potential pathways for reimbursement for GRAIL's Galleri test. (*Id.*)

In addition, Respondents also show that each of the purported anticompetitive effects of the proposed transaction are addressed by the Open Offer. Under the Open Offer, Illumina has committed to not raise prices for the entire 12-year term of the agreement, to lower sequencing costs by at least 43% by 2025 and to provide uninterrupted supply and services to all oncology test developers. The Open Offer also provides for a "firewall" between Illumina and GRAIL to prevent information sharing and ensure the protection of confidential customer information. Illumina's compliance with the Open Offer will be subject to regular audits by an independent, third-party auditor and a binding arbitration provision. Respondents will present testimony from Ms. Margaret Guerin-Calvert, who will opine as to the efficacy of the Open Offer in addressing the FTC's allegations of anticompetitive harm. Ms. Guerin-Calvert is an economist with years of experience with consent decrees and antitrust remedies.

Respondents seek leave to call Mr. Rock to testify about the efficacy of the auditing processes contemplated by the Open Offer at monitoring compliance with long-term contractual commitments such as those in the Open Offer. (Exhibit A at 8; *see also* Ex. C.) The FTC's primary attack on the Open Offer is the purported inability to effectively monitor Illumina's compliance with its terms. Unique among the parties' experts, Mr. Rock has performed over forty compliance audits and brings an important perspective to understanding this charge and why it is unfounded.

B. Testimony from Dr. Abrams and Mr. Rock Will Not Prejudice Complaint Counsel.

Allowing Respondents to designate an additional two experts for trial testimony will not prejudice Complaint Counsel. Their opinions are discrete and narrowly tailored in scope but address important issues that are best elucidated by experts in the relevant fields. The importance of these issues is illustrated by the report submitted by Complaint Counsel's economic expert, Dr. Scott Morton, which includes several pages focused on regulatory, payor and technical issues. Respondents respectfully submit that the opinions of antitrust economic experts on such issues would be unhelpful to the Court, whereas testimony from experts in these fields will provide significant value to the Court's evaluation of the FTC's challenge. Respondents' motion is limited to their request that they be permitted to designate more than five expert witnesses in order to preserve the right to call such experts at trial. *See* Rule 3.31A(b) ("No party may call an expert witness at the hearing unless he or she has been listed . . ."). Respondents believe each of these witnesses will be necessary to testify to distinct issues at trial. However, expert discovery is still ongoing, and there are other remedies available to Complaint Counsel to limit expert testimony if they believe it is appropriate at trial.⁵

IV. CONCLUSIONS

For the reasons set forth above, Respondents respectfully request that this Court grant leave to designate two additional experts, Dr. Richard Abrams and Mr. Robert Rock.

⁵ *See In re POM WONDERFUL*, 2011 WL 7344452, at *5 (granting respondents leave to designate three additional experts and noting that expert testimony at trial would be restrained by (1) Rule 3.43(b), which allows for the exclusion of "needless presentation of cumulative evidence"; (2) the right to move *in limine* to preclude or limit expert testimony; and (3) and the time limits for trial under Rule 3.41(b)).

PUBLIC

Dated: July 24, 2021

Respectfully submitted,

/s/ Sharonmoyee Goswami

Christine A. Varney
Richard J. Stark
David R. Marriott
J. Wesley Earnhardt
Sharonmoyee Goswami
CRAVATH, SWAINE & MOORE LLP
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019
(212) 474-1000
cvarney@cravath.com
rstark@cravath.com
dmarriott@cravath.com
wearhardt@cravath.com
sgoswami@cravath.com

*Attorneys for Respondent
Illumina, Inc.*

Michael G. Egge
Marguerite M. Sullivan
Anna M. Rathbun
David L. Johnson
LATHAM & WATKINS LLP,
555 Eleventh Street NW
Suite 1000
Washington, D.C. 20004
Telephone: (202) 637-2200
Facsimile: (202) 637-2201
michael.egge.lw.com

Alfred C. Pfeiffer
505 Montgomery Street
Suite 2000
San Francisco, CA 94111-6538
Telephone: (415) 391-0600
Facsimile: (415) 395-8095
Al.pfeiffer@lw.com

*Attorneys for Respondent
GRAIL, Inc.*

PUBLIC

CERTIFICATE OF SERVICE

I hereby certify that on July 24, 2021, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

April Tabor
Acting Secretary Federal Trade Commission 600
Pennsylvania Ave., NW, Rm. H-113
Washington, DC 20580
ElectronicFilings@ftc.gov

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, DC 20580

I also certify that I caused the foregoing document to be served via email to:

Complaint Counsel

U.S. Federal Trade Commission

Susan Musser
Dylan P. Naegele
David Gonen
Jonathan Ripa
Matthew E. Joseph
Jordan S. Andrew
Betty Jean McNeil
Lauren Gaskin
Nicolas Stebinger
Samuel Fulliton
Stephen A. Mohr
Sarah Wohl
William Cooke
Catherine Sanchez
Joseph Neely
Nicholas A. Widnell
Daniel Zach
Eric D. Edmonson

Counsel for Respondent Illumina, Inc.

Cravath, Swaine & Moore LLP

Christine A. Varney
Richard J. Stark
David R. Marriott
J. Wesley Earnhardt
Sharonmoyee Goswami

PUBLIC

Jesse M. Weiss
Michael J. Zaken

Counsel for Respondent GRAIL, Inc.

Latham & Watkins LLP

Michael G. Egge
Marguerite M. Sullivan
Alfred C. Pfeiffer, Jr.
Anna M. Rathbun
David L. Johnson
Marcus Curtis

July 24, 2021

/s/ Sharonmoyee Goswami

Sharonmoyee Goswami

PUBLIC

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.

July 24, 2021

By: /s/ Sharonmoyee Goswami
Sharonmoyee Goswami

PUBLIC

**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

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 Respondents’ Motion for Leave to Present Two Additional Expert Witnesses.
3. Attached hereto as Exhibit A is a true and correct copy of Respondents’ Final Witness List, which was served on July 23, 2021.
4. Attached hereto as Exhibit B is a true and correct copy of the Expert Report and Declaration of Robert J. Rock, which was served on July 16, 2021.
5. Attached hereto as Exhibit C is a true and correct copy of the Expert Report and Declaration of Richard Abrams, M.D., which was served on July 16, 2021. The final report is redacted pursuant to ongoing discussions between the parties regarding an issue unrelated to this motion.

PUBLIC

6. Attached hereto as Exhibit D is a true and correct copy of the December 24, 2020 Letter from S. Goswami to D. Naegele et al.

7. Attached hereto as Exhibit E is a true and correct copy of the February 11, 2021 Letter from S. Goswami to D. Naegele et al.

Dated: July 24, 2021

Respectfully submitted,

/s/ Sharonmoyee Goswami
Sharonmoyee Goswami

Exhibit A

Filed In Camera

Exhibit B

Filed In Camera

Exhibit C

Filed In Camera

Exhibit D

Filed In Camera

Exhibit E

Filed In Camera

PUBLIC

**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 ON RESPONDENTS' MOTION FOR LEAVE TO ALLOW
TWO ADDITIONAL TESTIFYING EXPERTS**

On July 24, 2021, Respondents filed a Motion for Leave to Allow Two Additional Testifying Experts pursuant to Rule 3.31A(b). Having considered Respondents' Motion and attached Exhibits, it is hereby ORDERED that Respondents' Motion is GRANTED. Respondents shall be permitted to present testimony from two additional expert witnesses.

ORDERED:

D. Michael Chappell
Chief Administrative Law Judge

Date:

PUBLIC

**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

**STATEMENT IN SUPPORT OF RESPONDENTS' MOTION FOR LEAVE TO ALLOW
TWO ADDITIONAL TESTIFYING EXPERTS**

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 telephonically and by email to resolve in good faith issues raised by the motion and has been unable to reach such an agreement. The parties met and conferred by phone on July 20, 2021 and in subsequent email correspondence, but were unable to reach an agreement with respect to the issues that Respondents raise in this Motion.

Dated: July 24, 2021

Respectfully submitted,

/s/ Sharonmoyee Goswami
Sharonmoyee Goswami