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

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

RESPONDENTS' MOTION *IN LIMINE* TO EXCLUDE EXPERT TESTIMONY OF DR. FIONA SCOTT MORTON

Respondents Illumina, Inc. ("Illumina") and GRAIL, Inc. ("GRAIL") (collectively, "Respondents"), respectfully move to exclude certain opinions and testimony[1] offered by Complaint Counsel's expert witness Fiona Scott Morton because (1) she lacks the expertise to opine on multi-cancer early detection ("MCED") technology, the viability of alternative next generation sequencing ("NGS") platforms, and on issues relating to regulatory and reimbursement issues; (2) she improperly summarizes the testimony and documentary evidence from third parties; and, (3) she improperly weighs the evidence.

I. BACKGROUND

As this tribunal has recognized (in allowing Respondents to present testimony from seven expert witnesses), the Complaint "involves numerous, complex issues and technical

[1] *See* Scott Morton Opening Rpt. (Ex. A) ¶¶ 14–59; 62–126; 141–149; 151–163; and 174–180; Scott Morton Rebuttal Rpt. (Ex. B) ¶¶ 6; 22–36; 53–65. The FTC's experts Dr. Dov Rothman and Dr. Amol Navathe also rely on these improper opinions (*See* Rothman Rpt. ¶¶ 14–16 n.18, 19, 21, 22; Navathe Rpt. ¶ 13, n.7) and such opinions should be excluded as well. *See In re Baycol Prod. Litig.*, 532 F. Supp. 2d 1029, 1055–56 (D. Minn. 2007).

areas, which may include private payor and Medicare reimbursement, antitrust economics, healthcare economics, cancer screening test development (including their development through clinical trials and the various performance attributes". (Order Granting Respondents' Motion for Leave to Allow Additional Expert Witnesses at 3.)

Despite the breadth of issues raised in the Complaint, the FTC offered only one affirmative expert report from a single expert (Dr. Scott Morton)—spanning 159 pages—which purported to address all aspects of this extraordinarily complicated case. (Ex. A.) Dr. Scott Morton purports to address not only issues relating to scientific topics relating to MCED[2] tests (Ex. A ¶ 63)) and NGS (Ex. A ¶ 70)), but also relating to regulatory requirements (Ex. A ¶ 154)). But Dr. Scott Morton admits that she does not possess expertise relating to MCED tests, NGS technology, regulatory or reimbursement issues, or any field outside of economics. Instead, she improperly summarizes third party documents and testimony (Ex. A ¶ 121 (summarizing Natera's testimony)) and weighs the evidence (Ex. C[3] 212:12-16 ("So you rejected some statements by witnesses in their deposition and IH testimony; correct? A. No. I weighed them according to the information they had, the role they play in the company and the type of competition in which they are engaged.") For these reasons, certain opinions and testimony of Dr. Scott Morton should be excluded.

II. ARGUMENT

A. Legal Standard

To be admissible under Rule 3.43(b)(1), evidence must be relevant, material, and reliable. When ruling on the admissibility of expert opinions, this tribunal routinely considers

[2] Respondents refer to "MCED tsts" or the "MCED test market" because Dr. Scott Morton used such terminology; these references are not an adoption by Respondents of the FTC's or Dr. Scott Morton's opinions regarding the relevant markets here.

[3] Transcript of the August 3, 2021 Deposition of Dr. Scott Morton.

whether the expert is qualified in the relevant field and examines the methodology the expert used in reaching the conclusions at issue. *See, e.g.*, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 588 (1993); *In re McWane, Inc.*, 2012 FTC LEXIS 142, at *8 (Chappell, J.) (FTC Aug. 16, 2012) (citing *Daubert*).

This Court routinely relies upon *Daubert* and Federal Rule of Evidence ("FRE") 702 in assessing the potential exclusion of expert testimony.[4] *See, e.g.*, *In re Evanston Northwestern Healthcare Corp.*, 2005 FTC LEXIS 10, at *4–6 (FTC Jan. 13, 2005). Therefore, expert testimony should comport with the admissibility requirements of FRE 702:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if [among other requirements]:
>
> > (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue[.]

In assessing whether an expert opinion complies with the requirements of *Daubert* and Federal Rule of Evidence 702, the Court must consider: (1) the qualifications of the proposed expert; (2) whether each proposed opinion is based upon reliable data and reliable methodology; and (3) whether the proposed testimony would be helpful to the trier of fact. *See, e.g.*, *Nimely v. City of New York*, 414 F.3d 381, 396–97 (2d Cir. 2005).

B. Dr. Scott Morton Lacks the Expertise to Opine On Technical, Regulatory and Reimbursement Issues and These Opinions Should Be Excluded.

It is black letter law that experts must be qualified to offer the opinions that they seek to express. *Daubert*, 509 U.S. at 588; *Arista Records LLC v. Lime Group LLC*, No. 06-CV-5936-KMW, 2011 WL 1674796, at *2 (S.D.N.Y. May 2, 2011); *see also United*

[4] The FTC has also relied on the Federal Rules of Evidence in motion in limine briefing. *See, e.g.*, *In the Matter of LabMD, Inc.*, 2014 FTC LEXIS 123, at *5–6 (Complaint Counsel's MIL Opposition) (May 1, 2014).

States v. Tin Yat Chin, 371 F.3d 31, 40 (2d Cir. 2004) (noting that experts should only be allowed to testify in areas within their field of expertise).

Courts routinely exclude expert opinions and testimony from economic experts who do not have the requisite expertise to opine on such topics, including based on the expert's own testimony about their respective expertise. *See In re Whirlpool Corp. Front-Loading Washer Prods. Liab. Litig.*, 45 F. Supp. 3d 724, 758 (N.D. Ohio 2014) ("The Court will not permit Bresnahan (or any other **economist/damages expert**) to offer any opinion suggesting a washer does not have a design defect or has a 'superior design' or is 'innovative.' **Bresnahan is not an engineer and has no expertise to render such a conclusion**." (emphases added)); *Nat'l Communs. Ass'n v. AT&T*, 1998 WL 118174, at *42–49 (S.D.N.Y. Mar. 16, 1998) (excluding an economic expert's testimony because he conceded he was not an expert in the technical area where he was offering an opinion).

The same fate should meet Dr. Scott Morton's improper opinions. It is undisputed that Dr. Scott Morton does not have expertise in MCED tests, NGS platforms, regulatory approval or reimbursement. Dr. Scott Morton, by her own admission, is not an expert in any field other than economics. (Ex. D (OttoBock Tr.) 3967:13–15.)

- She does not have a degree in any biological or chemical sciences. (Ex. A, App'x A; Ex. C 22:19–21; 22:24–23:3; 25:5–9 ("Q. Are you a pathologist or medical doctor of any kind? A. No. Q. You have no medical training? A. That's correct.").)

- She has never been involved in the development of any diagnostic or screening test of any kind, including diagnostic or screening tests for cancer. (Ex. C 26:10–13; 27:9–15 ("Q. And you don't have any expertise in the functions of features of different MCED tests; correct? A. That's correct. Q. Is it also correct that you don't have any personal experience in bringing any form of medical diagnostic test to market? A. That's correct.").)

- She has no experience in the clinical diagnosis of any form of cancer. (Ex. C 25:13–15.)

- She has never received training on how to decide what forms of cancer screening are best for a particular patient and has never been trained to detect what indications may call for different forms of cancer screening. (Ex. C 25:16–22 ("Q. Have you ever prescribed or interpreted any form of cancer screening? A. No. Q. Ever received any training on how to decide what forms of cancer screening are best for a particular patient? A. No.").)

Similarly, she was not even familiar with NGS before being engaged on this matter. (Ex. C 26:18–20.) She has no personal experience choosing between sequencing technologies in any context. (Ex. C 25:2–4.) Further, Dr. Scott Morton is not an expert in regulatory approval, private or public reimbursement of MCED tests, or sequencing technologies. (Ex. C 22:4–18.)

Despite her admitted lack of any training or expertise in any scientific or medical field or in regulatory or reimbursement issues, Dr. Scott Morton purports to opine on both the MCED test market and the NGS market. For example, Dr. Scott Morton claims that MCED tests "all have a similar intended use" and appears to base this opinion entirely on third party lay witness testimony and publicly available documents from the American Cancer Society website. (Ex. A ¶ 145.) But Dr. Scott Morton is unqualified to interpret such documents, let alone opine on them. Dr. Scott Morton offers a litany of conclusions on matters beyond her expertise, including:

- The technical features of MCED tests, including the specific biomarkers that are interrogated using such MCED tests. (*See, e.g.*, Ex. A ¶¶ 22–36; 85–149; 155–163.)
- The regulatory requirements for different types of MCED tests, and the regulatory and reimbursement pathways for MCED tests, including the requisite clinical trials and clinical data for such tests. (*See, e.g.*, Ex. A ¶¶ 45–59.)
- The technical aspects of NGS platforms, including the applicability of NGS to MCED tests and the relative benefits of various NGS platforms for MCED applications. (*See, e.g.*, Ex. A ¶¶ 60–62; 63 (discussing the importance of "sequencing a large number of loci" and/or "sequence each locus to great depth" in the detection of multiple types of cancer); 64–70

(evaluating short-read versus long-read sequencing, and ability of a test developer to address non-random versus random errors); 71–84; 151–53; 174–80.)

- The steps needed to switch between NGS platforms for MCED tests, including the need to conduct "an equivalency or registrational study to maintain FDA approval". (Ex. A ¶ 154.)

Dr. Scott Morton's improper opinions relating to technical, regulatory and reimbursement issues build to one of her most important ones: that "MCED tests constitute a relevant market because they are likely to be close substitutes for each other". (Ex. A ¶ 147.) Dr. Scott Morton has no training as an oncologist or pathologist who works with cancer patients, no experience developing cancer screening tests, no experience developing guidelines for cancer screening and no experience prescribing cancer screening tests. (Ex. C 25:13–22; 26:10–13; 27:9–15.) She therefore lacks any expertise on which to base her conclusion that all MCED tests in development are "close" substitutes for each other.

The same fundamental lack of expertise should be the basis for excluding Dr. Scott Morton's opinions that only Illumina's NGS technology is suitable for supporting MCED tests, including her opinions about the purported technical deficiencies of competing platforms. (*See, e.g.*, Ex. A ¶¶ 62; 174.) Given Dr. Scott Morton's lack of any scientific credentials regarding NGS technology or their suitability for the performance of MCED tests, including her lack of familiarity with NGS before this litigation (Ex. C 26:18-20), this Court should exclude any opinions provided by Dr. Scott Morton on these issues.

C. The Portions of Dr. Scott Morton's Report Which Merely Selectively Rehash Documentary and Testimony Evidence Should Be Excluded.

Additionally, much of Dr. Scott Morton's report simply presents certain facts in a light most favorable to the Complaint. These "opinions," too, should be excluded.

It is inappropriate for an expert to "be presented to the [fact finder] solely for the purpose of constructing a factual narrative based upon record evidence". *Highland Capital Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 468–69 (S.D.N.Y. 2005); *In re Rezulin Products Liab. Litig.*, 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004) (rejecting expert's factual narrative because "such material, to the extent it is admissible, is properly presented through percipient witnesses and documentary evidence"); *LinkCo, Inc. v. Fujitsu Ltd.*, 2002 WL 1585551, at *1–*2 (S.D.N.Y. July 16, 2002) (noting that where expert's report was based on a "documents, computer documents, computer files, deposition transcripts and exhibits," the "testimony by fact witnesses familiar with those documents would be far more appropriate" (internal quotations omitted)).

Throughout her report, Dr. Scott Morton merely selectively summarizes the testimony and documentary evidence provided by the parties and third parties in this case.[5] For example, in paragraph 64, Dr. Scott Morton summarizes third party testimony, [REDACTED] However, [REDACTED] testimony is already part of the record and the finder of fact is better suited to interpret the testimony. In addition, Dr. Scott Morton selectively highlights portions of [REDACTED] testimony, but fails to highlight the record evidence that contradicts the cited assertions. Therefore, Dr. Scott Morton's improper narrative opinions should be excluded as they usurp the domain of the fact finder by providing nothing more than a factual narrative pieced together from record evidence.

[5] *See* Ex. A ¶¶ 22–59, 62–126, 141–149, 151–163, and 174–180.

D. This Court Should Exclude the Portions of Dr. Scott Morton's Testimony that Improperly Weigh the Credibility of Witnesses.

Finally, Dr. Scott Morton's opinions should be excluded where she usurps the role of the fact finder by opining on the credibility of witness testimony or weighs the evidence. "The credibility of witness testimony is a matter left to the [fact finder] and generally is not an appropriate subject for expert testimony." *Wilson v. Muckala*, 303 F.3d 1207, 1218 (10th Cir. 2002); *United States v. Adams*, 271 F.3d 1236, 1246 (10th Cir. 2001) ("The offered testimony does little more than vouch for the credibility of another witness and thereby encroaches upon the [fact finder's] vital and exclusive function to make credibility determinations." (internal quotations omitted)). Dr. Scott Morton repeatedly weighs the evidence in the course of offering her opinions here. (Ex. C 193:17–25; 212:12-16.) For example, she accepts the testimony of complainants at face value without interrogating their testimony or even citing to contrary authority. (Ex. A ¶ 310 (citing exclusively to deposition testimony of [REDACTED] [REDACTED]).) She also takes at face value the FTC's arguments and disregards efficiencies sworn to by Illumina fact witnesses. (Ex. C 242:11-18 ("Q. . . . No one has shared with you any deposition testimony concerning supply chain and operational efficiencies expected because of the transaction; correct? A. I asked for everything important. Therefore, there isn't anything of importance for my report that falls in the category you are talking about, or I would've seen it.").

CONCLUSION

For the reasons stated above, Respondents respectfully request that the Court exclude certain opinions and testimony of Dr. Scott Morton.

Dated: August 5, 2021

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CERTIFICATE OF SERVICE

I hereby certify that on August 5, 2021, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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

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Respectfully submitted,

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CERTIFICATE FOR ELECTRONIC FILING

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

August 5, 2021

/s/Sharonmoyee Goswami
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PUBLIC

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

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

STATEMENT IN SUPPORT OF RESPONDENTS' MOTION *IN LIMINE* TO EXCLUDE EXPERT TESTIMONY OF DR. FIONA SCOTT MORTON

Pursuant to Paragraph 4 of the Scheduling Order entered on April 26, 2021, Respondents hereby represent that counsel for the moving parties has conferred with Complaint Counsel by email in an effort in good faith to resolve by agreement issues raised by the motion. The parties corresponded by email on August 4 and August 5, 2021 to discuss a potential agreement with respect to the evidence that Respondents seek to exclude in this motion, but were unable to reach an agreement.

Respectfully submitted,

/s/ Sharonmoyee Goswami
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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 in Limine to Exclude the Expert Testimony of Dr. Fiona Scott Morton.

3. Attached hereto as Exhibit A is a true and correct copy of the opening report submitted by Dr. Scott Morton, which was served on July 2, 2021.

4. Attached hereto as Exhibit B is a true and correct copy of the rebuttal report of submitted by Dr. Scott Morton, which was served on July 23, 2021.

5. Attached hereto as Exhibit C is a true and correct copy of the transcript of the August 3, 2021 deposition of Dr. Scott Morton.

6. Attached hereto as Exhibit D is a true and correct copy of the transcript of Dr. Scott Morton's trial testimony in *In the Matter of Otto Bock HealthCare North America, Inc.*, Docket No. 9378.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 5th day of August, 2021 in New York, NY

/s/ Sharonmoyee Goswami
Sharonmoyee Goswami

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Exhibit A

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Filed In Camera

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Exhibit B

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Filed In Camera

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Exhibit C

Filed In Camera

Exhibit D

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

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

[PROPOSED] ORDER ON RESPONDENTS' MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. FIONA SCOTT MORTON

Upon consideration of Respondents' Motion In Limine To Exclude Expert Testimony of Dr. Fiona Scott Morton, and in consideration of the entire Record in this matter, Respondents' Motion is GRANTED.

IT IS HEREBY ORDERED that Dr. Scott Morton's testimony and opinions (1) relating to multi-cancer early detection ("MCED") technology; (2) relating to the viability of next-generation sequencing platforms; (3) relating to regulatory and reimbursement issues; (4) summarizing the testimony and documentary evidence from third parties; and (5) weighing the evidence, including those opinions contained in ¶¶ 14–59; 62–126; 141–149; 151–163; and 174–180 of the July 2, 2021 Expert Report of Dr. Scott Morton; and ¶¶ 6; 22–36; 53–65 of the July 26, 2021 Expert Report of Dr. Scott Morton, and any opinions relying on such paragraphs, as outlined in the Motion, are hereby stricken from the record and excluded.

ORDERED:

Date:

____
D. Michael Chappell
Chief Administrative Law Judge