

**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 TO EXCLUDE PORTIONS OF COMPLAINT COUNSEL'S
REBUTTAL EXPERTS' REPORTS**

Respondents respectfully move for an order to exclude portions of the expert reports of two of Complaint Counsel's rebuttal experts, Dr. Dov Rothman and Dr. Amol Navathe. Both experts purport to rebut the testimony of Respondents' consulting expert, Mr. George Serafin, which was excluded from the record. Because Mr. Serafin's testimony was excluded, there is nothing for Complaint Counsel's experts to rebut. Their rebuttal opinions should therefore be excluded. Complaint Counsel, however, has agreed only to redact explicit references to Mr. Serafin and has refused to redact the entirety of Dr. Rothman's and Dr. Navathe's opinions addressing the FDA acceleration that Mr. Serafin's declaration described. Respondents seek an order striking all portions of Dr. Rothman and Dr. Navathe's expert reports that purport to rebut the content of Mr. Serafin's declaration and excluding those portions from evidence.

BACKGROUND

Pursuant to the scheduling order, Complaint Counsel was to provide its expert witness reports by July 2, 2021; Respondents' expert reports were to be served on July 16, 2021 and Complaint Counsel was to identify and provide rebuttal expert reports, if any, by July 26, 2021. As set forth in the scheduling order, "[a]ny such reports are to be limited to rebuttal of matters set forth in Respondents' expert reports." (Apr. 26, 2021 Scheduling Order at 2.)

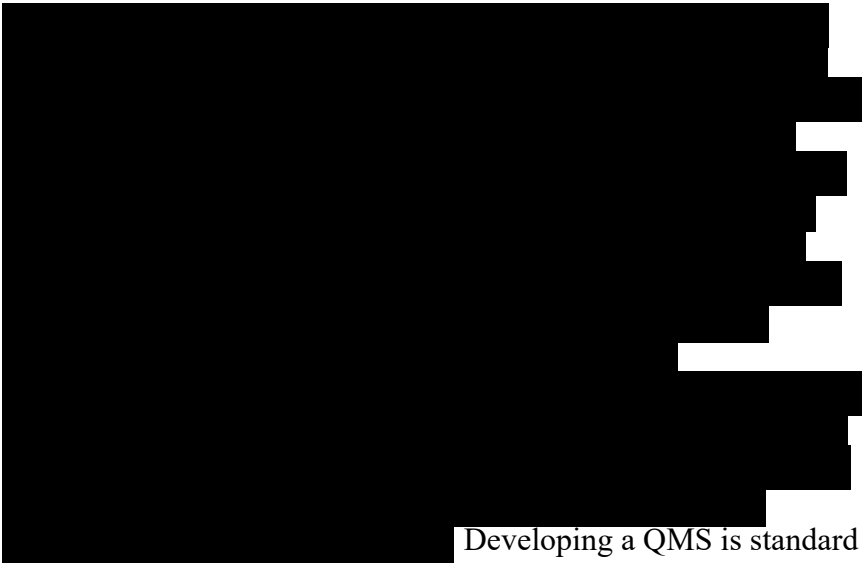
In accordance with the scheduling order, Respondents served their expert reports on July 16, 2021, including expert reports for economic expert, Dr. Dennis Carlton, payor reimbursement expert, Dr. Patricia Deverka, and a declaration of FDA expert, Mr. George Serafin. (RX3864, RX3867.) Complaint Counsel then served its rebuttal expert reports on July 26, 2021. In addition to the rebuttal report of its economic expert, Dr. Scott Morton, Complaint Counsel identified two additional experts, Dr. Dov Rothman and Dr. Amol Navathe, as rebuttal experts to respond to the expert opinions of Dr. Carlton, Dr. Deverka and Mr. Serafin. (PX6092, PX6093.)

On August 5, 2021, Complaint Counsel moved to exclude the expert declaration of Mr. Serafin on the basis that Mr. Serafin was identified as a consulting but not a testifying expert. (Aug. 5, 2021 Mot. in Limine re: George J. Serafin.) Respondents opposed the motion. On August 23, 2021, the Court granted Complaint Counsel's motion to exclude Mr. Serafin's declaration and deposition transcript from the record. (Aug. 25, 2021 Order Memorializing Bench Rulings.)

Because Mr. Serafin's declaration and deposition were excluded from the trial record, Dr. Navathe's and Dr. Rothman's opinions purporting to "rebut" Mr. Serafin's opinions are no longer relevant or within the proper scope of the record. As such, on September 21, 2021, Respondents requested that Complaint Counsel agree to redact portions of Dr. Navathe's and

Dr. Rothman's reports that purported to respond to Mr. Serafin's declaration. Complaint Counsel provided its redactions on September 27, 2021. (*See* Exs. 1, 2.)

In its proposed redactions, however, Complaint Counsel failed to fully redact opinions in its experts' reports that purported to rebut Mr. Serafin's testimony concerning FDA acceleration. For example, within the same paragraph Complaint Counsel redacted only the bolded sentences, while leaving the un-bolded sentences unredacted:


Developing a QMS is standard practice for medical/biotechnology companies developing new technologies and products, including IVDs. Numerous small companies that have received PMA for IVDs have successfully navigated it.

(*Compare* PX6093 ¶ 14 to Ex. 1 ¶ 14.)

On September 29, 2021, Respondents requested that Complaint Counsel fully redact portions of its rebuttal experts reports that purport to rebut Mr. Serafin's declaration. (Ex. 3 at 1-2.) On October 7, 2021, Complaint Counsel stated that it did not intend to make any further redactions and would oppose any motion to exclude portions of Dr. Rothman's and Dr. Navathe's reports. (Ex. 3 at 1.)

ARGUMENT

Pursuant to Rule 3.31A(a), “a rebuttal report shall be limited to rebuttal of matters set forth in a respondent’s expert reports.” 16 C.F.R. § 3.31A(a). As this Court has explained, “the scope of fair rebuttal . . . is that which is offered to disprove or contradict the evidence presented by an opposing party.” *In re N. Carolina Bd. of Dental Examiners*, F.T.C. Dkt. No. 9343, 2011 WL 479902, at *3 (Jan. 28, 2011) (citing *Black's Law Dictionary* 639 (9th ed. 2009)). “[E]vidence is outside the scope of fair rebuttal where it includes opinions on subjects not mentioned in opposing report or introduces new matters.” *Id.* Where a party includes material “outside the scope of fair rebuttal . . . a respondent may file a motion . . . seeking appropriate relief with the Administrative Law Judge, including striking all or part of the report”. 16 C.F.R. § 3.31A(a).¹

When the opinions that a rebuttal report purports to rebut are excluded, “there is no expert testimony to rebut” and a motion to strike the rebuttal expert is appropriate. *Great Am. Ins. Co. of N.Y. v. Vegas Constr. Co.*, No. 2:06-cv-911, 2007 WL 2375056, at *4 (D. Nev. Aug 15, 2007). Where affirmative expert reports are excluded, courts routinely exclude the rebuttal opinions responding to excluded reports as moot. *See Citizen Fin. Grp., Inc. v. Citizens Nat’l Bank of Evans City*, No. CIV.A. 01-1524, 2003 WL 24010950, at *12 (W.D. Pa. Apr. 23, 2003), *aff’d in part, rev’d in part*, 383 F.3d 110 (3d Cir. 2004) (“[T]o the extent that I am excluding the report of [the affirmative expert], any corresponding rebuttal of [rebuttal experts] is necessarily excluded as moot.”); *Huskey v. Ethicon, Inc.*, No. 2:12-CV-05201, 2014 WL

¹ As explained *supra*, the issues with Complaint Counsel’s rebuttal reports only arose once Complaint Counsel’s motion to exclude Mr. Serafin’s declaration was granted, and Complaint Counsel stated that it did not intend to make any further redactions to their rebuttal reports. Respondents’ motion is timely because they made an objection to Dr. Rothman’s and Dr. Navathe’s reports “at the earliest possible opportunity.” *In re N. Tex Specialty Physicians*, F.T.C. Dkt. No. 9312, 2004 WL 1720022, at *2 (July 20, 2004) (citations omitted) (denying motion to exclude filed two weeks after the close of the record).

3861778, at *5 (S.D.W. Va. Aug. 6, 2014) (excluding plaintiff’s rebuttal expert’s opinion that was responsive to a now-excluded portion of defendant’s affirmative expert); *Barry v. Medtronic, Inc.*, No. 1:14-CV-104, 2016 WL 11731493, at *1 (E.D. Tex. Sept. 21, 2016) (excluding plaintiff’s rebuttal expert on patent practice and procedure since “the majority of his opinions are now irrelevant because the court has excluded [defendant]’s patent law expert”); *Syneron Med. Ltd. v. Invasix, Inc.*, No. 8:16-CV-00143-DOC-KES, 2018 WL 4696969, at *15 (C.D. Cal. Aug. 27, 2018) (plaintiff’s rebuttal expert’s report would be rendered moot by the exclusion of defendant’s expert’s report); *Papin v. Univ. of Miss. Med. Ctr.*, No. 3:17-CV-763-KHJ-FKB, 2021 WL 4316949, at *5 (S.D. Miss. Sept. 22, 2021) (excluding defendant’s rebuttal expert to the extent opinions specifically rebut plaintiff’s withdrawn expert).

There is no question that the reports of Dr. Navathe and Dr. Rothman were intended to rebut Mr. Serafin’s declaration. Both Dr. Navathe and Dr. Rothman identified that they were retained solely to evaluate the opinions of Respondents’ experts, including Mr. Serafin. *See* PX6092 ¶ 5 (“Three of Respondents’ experts have offered opinions that the proposed transaction would result in efficiencies: [REDACTED]

[REDACTED] The FTC has asked me to evaluate these opinions to determine if they have identified any cognizable efficiencies that would result from the proposed transaction”); PX6093 ¶ 6 (“Two of the Respondents’ experts have offered opinions that Illumina, Inc. (“Illumina”) provides regulatory and commercial expertise that GRAIL, Inc. (“Grail”) lacks . . . : Mr. George Serafin and Dr. Patricia Deverka. The FTC has asked me to evaluate these opinions to determine if these regulatory and market acceptance acceleration claims are substantiated.”). Both confirmed in their depositions that their task was to rebut Mr. Serafin and that neither Dr. Rothman nor Dr. Navathe undertook any independent assessment of

Illumina’s regulatory capabilities outside of responding to Mr. Serafin’s declaration. (*See, e.g.*, RX3853, Navathe Dep. Tr. 22:23-23:6 (“Q: Again, just to be clear, you’ve made no conclusion of your own as to whether the proposed acquisition of GRAIL by Illumina can accelerate GRAIL getting PMA for Galleri? . . . A. Correct, my assignment was not to make that judgment.”); RX3854, Rothman Dep. Tr. 76:21-25 (“I didn’t do my own affirmative analysis of the claimed efficiencies. I evaluated what [Respondents’ experts] had offered as substantiation for certain of the claimed . . . efficiencies”).) In light of their testimony and the scope of Dr. Navathe’s and Dr. Rothman’s assignments, it is indisputable that any opinions they expressed concerning FDA acceleration and whether Illumina had the capabilities necessary to accelerate FDA approval of Galleri were in response to Mr. Serafin’s declaration and are now moot.

Complaint Counsel, however, attempts to maintain portions of their rebuttal experts’ opinions concerning FDA acceleration despite these opinions having been offered in rebuttal to Mr. Serafin’s declaration. As to Dr. Navathe, Section III of his report is titled “*Mr. Serafin* fails to demonstrate that the merger will accelerate FDA approval for Galleri”. (PX6093 at 5 (emphasis added).) Dr. Navathe confirmed under oath in his trial deposition that Section III “contains [his] response to Mr. Serafin” (Ex. 6, Navathe Trial Dep. 87:22-24), and that the entirety of that section, paragraphs 12 through 33, responds to Mr. Serafin’s report (*id.* 89:19-90:21). Nonetheless, Complaint Counsel has refused to redact significant portions of Section III.

Complaint Counsel took a different, yet equally inappropriate, approach to Dr. Rothman’s report, redacting the direct references and sections responding to Mr. Serafin while attempting to leave summary opinions relating to FDA acceleration and Illumina’s FDA capabilities unredacted. For example, Complaint Counsel has not redacted portions of Dr.

Rothman’s summary of opinions stating that [REDACTED]

[REDACTED]

(PX6092 ¶ 28 (emphasis added).)² Similarly, Complaint Counsel has not redacted Dr.

Rothman’s statement that “[t]he capabilities that Illumina purportedly could supply to Grail are largely human capital based—i.e., Illumina employs personnel who purportedly have more experience and expertise with *FDA and* payer approval.” (*Id.* (emphasis added).) Obviously, such statements constitute, in part, Dr. Rothman’s response to Mr. Serafin’s declaration, which discussed the experience and expertise with FDA approval that Illumina would provide to GRAIL.

Complaint Counsel cannot seriously contend that the offending opinions in Dr. Navathe’s and Dr. Rothman’s reports were in response to Dr. Deverka’s report. Section III of Dr. Navathe’s report contains only a single reference to Dr. Deverka’s report referring to FDA approval, and that footnote merely states that Dr. Deverka was relying on Mr. Serafin’s declaration for that opinion. (PX6093 ¶ 71 n.184 (“Dr. Deverka also relies heavily on Mr. Serafin’s report for the propositions that Illumina possesses FDA-related resources, infrastructure, and experience to accelerate FDA approval for Galleri”).) This does not change the fact that the entirety of Section III of his report is a rebuttal of Mr. Serafin and should be excluded. (*See* PX6093.) And, while Dr. Rothman’s report sometimes blends his opinions concerning FDA acceleration with his opinions on payor reimbursement, it is clear that the opinions concerning payor reimbursement are in response to Dr. Deverka, Respondents’ market access expert, and that opinions concerning FDA acceleration are in reference to Mr. Serafin.

² *See also, e.g., id.* ¶ 69 (“Respondents’ experts do not explain why—if billions of dollars are at stake—Grail would not hire personnel from Illumina and/or elsewhere. . . . Illumina and Grail compete in labor markets for personnel with expertise relating to *FDA and* payer approval.”) (emphasis added).

(See PX6092 ¶ 45 (explaining his opinions as “I then address [REDACTED] opinion that the proposed transaction will accelerate Galleri’s FDA approval and [REDACTED] opinion that [REDACTED].³ His opinions should be excluded to the extent they relate to FDA acceleration.

To allow Complaint Counsel to retain its experts’ opinions purporting to rebut Mr. Serafin, while Mr. Serafin’s declaration remains excluded from the record, would inappropriately allow Complaint Counsel to transform its rebuttal experts’ reports into affirmative reports. If Complaint Counsel wanted affirmative—as opposed to rebuttal—expert opinions on Illumina’s ability to accelerate FDA approval for Galleri, it would have had to identify such experts and submit reports by July 2, 2021. Complaint Counsel did not do so. Permitting Complaint Counsel now to submit Dr. Navathe’s and Dr. Rothman’s reports as affirmative opinions concerning FDA acceleration would violate the scheduling order and deny Respondents the opportunity to respond.

In sum, Respondents respectfully request that the Court strike and exclude portions of Dr. Navathe and Dr. Rothman’s rebuttal expert reports that purport to rebut Mr. Serafin’s declaration. Complaint Counsel has not identified any basis on which either expert has to form affirmative opinions concerning Illumina’s FDA capabilities that would not have been in response to Mr. Serafin. With Mr. Serafin’s declaration now excluded from the record, any opinions rebutting Mr. Serafin should be excluded as moot.

³ For instance, in attempting to rebut “Dr. Deverka’s specific claim that Grail could not obtain the capabilities it needs through external consultants” (PX6092 ¶ 71), Dr. Rothman relies on Dr. Navathe’s opinions regarding FDA consultants which, in turn, respond to Mr. Serafin. (*Id.* ¶ 71 nn.109-10.) Dr. Deverka’s opinion was about *market access*, not FDA, consultants. (See RX3867 ¶¶ 145-46.) This portion of Dr. Rothman’s rebuttal must therefore be disregarded, since it cannot be considered within the scope of Dr. Deverka’s report.

CONCLUSION

For the reasons stated above, Respondents respectfully request that the Court grant Respondents' motion to strike paragraphs 9 and 12-33 (including footnotes within those paragraphs) from Dr. Navathe's report (PX6093) and paragraphs 13-18, 50-59, and portions referencing FDA acceleration from paragraphs of 26-28, 44, 45, 68, 69, 71 and 72 (including footnotes within those paragraphs) from Dr. Rothman's report (PX6092). All redacted and stricken portions of Dr. Navathe's and Dr. Rothman's reports should be excluded from evidence. Respondents have prepared proposed redacted versions attached to its proposed order.

Dated: October 25, 2021

/s/ Richard J. Stark

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CERTIFICATE OF SERVICE

I hereby certify that on October 25, 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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The Honorable D. Michael Chappell
Administrative Law Judge
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I also certify that I caused the foregoing document to be served via email to:

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October 25, 2021

Respectfully submitted,

/s/ Richard J. Stark

Richard J. Stark

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.

October 25, 2021

/s/ Richard J. Stark

Richard J. Stark

**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

DECLARATION OF RICHARD J. STARK

I, Richard J. Stark, declare and state:

1. I am a partner at Cravath, Swaine & Moore LLP and counsel for Respondent Illumina, Inc. (“Illumina”) in this matter. I make this declaration in support of Respondents’ Motion to Exclude Portions of Complaint Counsel’s Rebuttal Experts’ Reports.

2. Attached as Exhibit 1 is a true and correct copy of Complaint Counsel’s proposed redactions to the Rebuttal Expert Report of Dr. Amol Navathe attached to a September 27, 2021 Email from Jordan Andrew to Molly Jamison.

3. Attached as Exhibit 2 is true and correct copy of Complaint Counsel’s proposed redactions to the Rebuttal Expert Report of Dr. Dov Rothman attached to a September 27, 2021 Email from Jordan Andrew to Molly Jamison.

4. Attached as Exhibit 3 is a true and correct copy of an October 7, 2021 Email from Jordan Andrew to Molly Jamison.

5. Attached as Exhibit 4 is a true and correct copy of the Rebuttal Expert Report of Dr. Amol Navathe containing Respondents’ proposed additional redactions.

6. Attached as Exhibit 5 is a true and correct copy of the Rebuttal Expert Report of Dr. Dov Rothman containing Respondents' proposed additional redactions.

7. Attached as Exhibit 6 is a true and correct copy of an excerpt of the trial deposition transcript of Dr. Amol Navathe, dated October 1, 2021.

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

Executed on this 25th day of October, 2021 in Scottsdale, Arizona.

/s/ Richard J. Stark

Richard J. Stark

EXHIBIT 1

Filed In Camera

EXHIBIT 2

Filed In Camera

EXHIBIT 3

Filed In Camera

EXHIBIT 4

Filed In Camera

EXHIBIT 5

Filed In Camera

EXHIBIT 6

Filed In Camera

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BEFORE THE FEDERAL TRADE COMMISSION
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In the Matter of

Illumina, Inc.,
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Docket No. 9401

**[PROPOSED] ORDER GRANTING RESPONDENTS' MOTION TO EXCLUDE
PORTIONS OF COMPLAINT COUNSEL'S REBUTTAL EXPERTS' REPORTS**

On October 25, 2021, Respondents filed a Motion to Exclude Portions of Complaint Counsel's Rebuttal Experts' Reports. Having considered Respondents' Motion and attached Exhibits, it is hereby ORDERED that Respondents' Motion is GRANTED. Paragraphs 9 and 12-33 (including footnotes within those paragraphs) from Dr. Navathe's report (PX6093) and paragraphs 13-18, 50-59, and portions referencing FDA acceleration from paragraphs of 26-28, 44, 45, 68, 69, 71 and 72 (including footnotes within those paragraphs) from Dr. Rothman's report (PX6092) are hereby excluded from the record.

ORDERED:

Date:

D. Michael Chappell
Chief Administrative Law Judge