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

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In the Matter of

Illumina, Inc., a corporation,

and

GRAIL, Inc., a corporation,

Respondents.

Docket No. 9401

ORDER DENYING RESPONDENTS' MOTION TO EXCLUDE PORTIONS OF COMPLAINT COUNSEL'S REBUTTAL EXPERT WITNESS REPORTS

I.

On October 25, 2021, Respondents Illumina, Inc. ("Illumina") and GRAIL, Inc. ("GRAIL") filed a motion to exclude portions of the expert witness reports of two of Complaint Counsel's rebuttal expert witnesses, Dr. Amol Navathe and Dr. Dov Rothman. ("Motion"). Federal Trade Commission ("FTC") Complaint Counsel filed an opposition on November 4, 2021 ("Opposition"). For the reasons set forth below, the Motion is DENIED.

II.

Pursuant to the Scheduling Order, Respondents served expert witness reports on July 16, 2021, including expert witness reports for an economic expert witness, Dr. Dennis Carlton, and a payor reimbursement expert witness, Dr. Patricia Deverka, and a declaration of an FDA expert, Mr. George Serafin. In summary, Mr. Serafin offered opinions on whether Illumina's acquisition of GRAIL would accelerate FDA approval of the Galleri test, compared to if GRAIL had to pursue FDA approval independently. Complaint Counsel served its rebuttal expert witness reports on July 26, 2021. In addition to the rebuttal expert witness report of its economic expert witness, Dr. Fiona Scott Morton, Complaint Counsel identified two additional experts, Dr. Navathe and Dr. Rothman, as rebuttal expert witnesses to respond to the expert opinions of Dr. Carlton, Dr. Deverka and Mr. Serafin. On August 5, 2021, Complaint Counsel moved to exclude the declaration of Mr. Serafin on the basis that he had not been not properly designated as an expert witness and has no first-hand knowledge of any relevant facts. Respondents opposed the motion. On August 23, 2021, Complaint Counsel's motion was granted (Aug. 25, 2021 Order Memorializing Bench Rulings).

Because Mr. Serafin's declaration and deposition were excluded from the trial record, on September 21, 2021, Respondents requested that Complaint Counsel redact portions of the rebuttal expert witness reports of Dr. Navathe and Dr. Rothman that purported to respond to Mr. Serafin's declaration. Complaint Counsel agreed to an exchange of redactions, with Respondents to undertake redacting portions of the expert witness reports of Dr. Carlton and Dr. Deverka that relied on opinions of Mr. Serafin. Complaint Counsel provided its redactions on September 27, 2021.

Respondents assert that in the proposed redactions, Complaint Counsel failed to fully redact opinions in its expert witness reports that purported to rebut Mr. Serafin's testimony concerning FDA acceleration. Respondents argue that 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 expert witness reports into affirmative reports.

Complaint Counsel asserts that Respondents' expert witnesses, Dr. Carlton and Dr. Deverka, relied upon the opinions of Mr. Serafin to support portions of their expert witness reports. Complaint Counsel further asserts that its rebuttal expert witnesses responded collectively to the opinions of Dr. Carlton, Dr. Deverka and Mr. Serafin, and that the opinions of Respondents' expert witnesses, Dr. Carlton and Dr. Deverka, rely at least in part on the now-excluded opinions of Mr. Serafin. Complaint Counsel argues that it would be improper and prejudicial to compel redactions from the expert witness reports of Dr. Navathe and Dr. Rothman while allowing portions of Respondents' expert witness reports that rely on Mr. Serafin.

III.

Because Mr. Serafin's opinions were excluded, Respondents' expert witnesses are not entitled to rely on Mr. Serafin or his opinion on FDA acceleration to support their own opinions. Any material in Respondents' expert witness reports purporting to rely, directly or indirectly, on Mr. Serafin or his opinion regarding FDA acceleration, and any material in Complaint Counsel's rebuttal expert witness reports purporting to respond, directly or indirectly, to Mr. Serafin or his opinion regarding FDA acceleration, do not belong in the record. However, it is unnecessary and inefficient for the Administrative Law Judge to engage in a line by line determination of which redactions must be made to each expert witness report at issue. Respondents' request that the Administrative Law Judge undertake this endeavor at this time is rejected. This case involves a bench trial. The need for gatekeeping is lessened in a bench trial, as the judge is capable of assigning the appropriate weight, if any, to the evidence. To the extent any party cites material that relies upon or responds to Mr. Serafin's excluded declaration in post-trial findings of fact, the other side is capable of noting the issue in reply findings so that the Administrative Law Judge can determine whether to disregard or reject and, what weight, if any, to give each assertion, contention, or opinion as the issue arises.

IV.

For the reasons set forth above, the Motion is DENIED.

ORDERED:

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D. Michael Chappell Chief Administrative Law Judge

Date: November 8, 2021