PUBLIC

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**

COMPLAINT COUNSEL'S OPPOSITION TO RESPONDENTS' SUPPLEMENTAL MOTION TO REOPEN THE RECORD AND ADMIT AN ADDITIONAL EXHIBIT

Respondents make an untimely motion to admit a confusing, misleading, and unreliable document. Not only does this document fail to meet the threshold requirements of Rule 4.34(b), but Respondents also fail to meet their burden to show good cause for its late admission. Complaint Counsel respectfully requests that this Court deny Respondents' motion.

I. The Minimal Probative Value of Respondents' Exhibit Is Far Outweighed by Its Tendency to Confuse and Mislead

Respondents seek to admit a document that consists of vague, ambiguous, and unclear statements about a supply agreement between Ultima Genomics ("Ultima") and Exact Sciences ("Exact"). Resp. Mot. at 1-2. Under Rule 3.43(b), this Court excludes evidence "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or if the evidence would be misleading, or . . . needless presentation of cumulative evidence." 16 C.F.R. § 3.43. Here, the minimal probative value of this document is outweighed by its misleading nature and tendency to confuse the issues.

RX4063 is a press release that consists of a series of vague, ambiguous, and unclear statements concerning a supply agreement between Ultima and Exact. Respondents ask this Court to admit this confusing document and rely on it for the baseless proposition that the existence of the supply agreement "is probative of the fact that Ultima's UG100 platform will be viable for Exact's [CancerSEEK] MCED test." Resp. Mot. at 4. This document, however, does not even contain the word "CancerSEEK" or "MCED" and certainly does not come close to making any statements about the suitability of Ultima's UG100 sequencer for running Exact's CancerSEEK test. This is unsurprising, as {[redacted]} Instead, the press release merely says, "the companies also plan to develop one or more of Exact Sciences' advanced cancer diagnostic tests using Ultima's sequencing technology." RX4063 at 1. But CancerSEEK is a screening test, not a diagnostic test. *See* CC Post-Tr. Br. at 51–52 (explaining the difference between screening tests and diagnostic tests); *see also* PX7058 (Conroy (Exact) IHT at 22–24 (explaining the differences between Exact's screening tests and diagnostic tests). As Respondents admit, diagnostic tests are not part of this case, making an article about Exact's use of Ultima for one of its many diagnostic tests irrelevant. *See* Resp. Post-Tr. Br. at 63. Moreover, even if this document does refer to potential use with CancerSEEK, without additional context regarding when and in what capacity Exact would be able to use Ultima's NGS platform, this document lacks any probative value as to whether Ultima is a timely, likely, and sufficient alternative to Illumina that would offset the competitive harm of this acquisition.

Respondents attempt to muddy the waters by asserting that ambiguous statements about "Ultima's mission" and "applications like cancer screening, minimal residual disease, and recurrence monitoring" show that Exact intends to use Ultima's NGS platform for its CancerSEEK MCED test. Resp. Mot. at 5. But this leap of logic is not supported by the text of Respondents' exhibit. Far from referencing Exact's CancerSEEK MCED test, Exact's Mr. Conroy appears to have been discussing three general families of oncology tests, not a specific MCED test. RX4063 at 1. Cancer screening alone encompasses a range of tests, including tests like {[redacted]} Likewise, minimal residual disease tests are not MCED tests, as they are designed to determine whether remnants of cancer remain in a patient who has been treated for cancer. CCFF ¶ 155. Recurrence monitoring tests are not MCED tests, either, as they are used for detecting the recurrence of cancer in patients who have already been diagnosed. *See* CCFF ¶¶ 1909, 2191. At most, Mr. Conroy's ambiguous statement can be taken as support for the truism that lower sequencing costs are important for clinical oncology tests in general, not that Exact plans to use Ultima's NGS platform for its CancerSEEK MCED test.

Due to its tendency to confuse the issues and mislead, Respondents' proposed exhibit fails to meet the basic, threshold requirements under Rule 4.34(b) and should not be admitted for that reason alone. But, even assuming that this document meets the admissibility requirements under Rule 4.34(b), Respondents have failed to show good cause to open the record now to admit it.

II. Respondents Failed to Establish Good Cause to Reopen the Record

Under the Federal Trade Commission Rules of Practice, an "Administrative Law Judge may reopen the proceeding for the reception of further evidence for good cause shown." *In re Polypore Int'l, Inc.*, 2009 FTC LEXIS 173, at *3 (Sept. 8, 2009) (citing 16 C.F.R. § 3.51(e)). When deciding whether to reopen the record for supplemental evidence, this Court considers: "(1)

whether the moving party can demonstrate due diligence (that is, whether there is a bona fide explanation for the failure to introduce the evidence at trial); (2) the extent to which the proffered evidence is probative; (3) whether the proffered evidence is cumulative; and (4) whether reopening the record would prejudice the non-moving party." *In re Polypore Int'l, Inc.*, 2009 FTC LEXIS 207, *10–11 (Oct. 22, 2009). Here, Respondents' proposed exhibit lacks probative value and is highly prejudicial to Complaint Counsel.

A. Respondents' Untimely Exhibit Lacks Probative Value

Respondents' proposed exhibit omits crucial information, lacks context, and fails to address any of the elements for which Respondents cite the document, giving it little probative value. At most, the document supports the proposition that Ultima and Exact signed a supply agreement, not that the supply agreement was related in any way to Exact's CancerSEEK MCED test. Nothing in the document suggests that entry by Ultima will be timely, likely, or sufficient to counteract the anticompetitive effects of Illumina's acquisition of Grail, or that Ultima's NGS platform is suitable for MCED testing. As such, the document lacks probative value and should not be admitted.

Respondents bear the burden of showing that entry by Ultima will be "'timely, likely, and sufficient in its magnitude, character, and scope' to counteract" the anticompetitive effects of Illumina's acquisition of Grail. *United States v. Anthem, Inc*., 236 F. Supp. 3d 171, 222–24 (D. D.C. 2017); *see also* CC Post-Tr. Br. at 133–42. This document is not probative on any of those elements. The document contains no information about the timeliness of entry by Ultima, such as when Ultima's NGS platform will be commercially available, or when, if ever, Exact would utilize it. The document notes that "[t]here can be no assurance that Exact will enter into a development agreement with Ultima, utilize Ultima's products or services in Exact's current or future tests,"

showing that entry by Ultima fails to meet the element of likeliness. RX4063 at 2. Likewise, the document contains nothing that so much as suggests that entry by Ultima would be sufficient "to fill the competitive void" that would result from the merger. *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 73 (D. D.C. 2011). The document lacks any details about the purpose of the supply agreement beyond "improv[ing] patient access to genomics-based testing and human health," which cannot possibly be read to mean "for use with an MCED test." By failing to include any information that is probative of any of the elements which Respondent must prove, this document is without probative value and should not be admitted.

B. Reopening the Record Would Be Highly Prejudicial to Complaint Counsel

Admitting Respondents' exhibit would be highly prejudicial to Complaint Counsel, who will have no opportunity to respond to the exhibit. As explained, this document is subject to multiple interpretations. Without testimony to put this document in the proper context, this document has no probative value and can only be used to conflate and confuse the issues to the prejudice of Complaint Counsel. Under similar circumstances in *Polypore*, this Court denied admission of an exhibit the respondent sought to admit "at this late date, after the completion of all post trial briefs, proposed findings of facts, replies thereto, and closing arguments," ruling that it "would be prejudicial, as Complaint Counsel was not able to . . . respond to the exhibit." *In re Polypore Int'l, Inc.*, 2009 FTC LEXIS 173, *4 (Sept. 8, 2009). As in *Polypore*, admitting this exhibit would be highly prejudicial, as Complaint Counsel would have no opportunity to respond to it or elicit clarifying facts through competent witnesses.

C. Respondents Failed to Conduct Due Diligence

Respondents were well aware of Ultima prior to trial,[1] yet presented no witness at trial from Ultima regarding its alleged impending entry into the United States, much less its suitability for MCED testing. Respondents had ample opportunity to inquire into Ultima's plans for entry and technical characteristics and then present that information at trial, but they choose not to. Instead, against a record that reflects their lack of diligence, they now want to claim that an alleged late-breaking development warrants admitting a vague, ambiguous, and unclear document that does nothing to show that entry by Ultima will be "'timely, likely, and sufficient in its magnitude, character, and scope' to counteract" the anticompetitive effects of Illumina's acquisition of Grail. *Anthem*, 236 F. Supp. 3d at 222–24; *see also* CC Post-Tr. Br. at 133–42. As such, Respondents have not acted with due diligence. *See In re Polypore Int'l, Inc.*, 2010 FTC LEXIS 62, *3 (F.T.C. July 19, 2010) ("Respondent has not acted with due diligence in presenting evidence of the competitor's alleged entry into the … markets").

D. Respondents' Untimely Exhibit Is Cumulative

Respondents' exhibit is needlessly cumulative of evidence presented at trial regarding Ultima. *See In re Polypore Int'l, Inc.*, 2010 FTC LEXIS 62, *5 (F.T.C. July 19, 2010) (evidence purporting to show entry of new product was cumulative because evidence regarding same product had already been presented). While Respondents failed to present evidence directly from Ultima witnesses regarding their plans to commercialize NGS platforms, the record contains trial testimony and other evidence from multiple other witnesses about the Ultima platform. *See, e.g.*, CCFF ¶¶ 1684–99; {[redacted]}.

[1] *See* Resp. Pretrial Br. at 35, 37–38.

Because Respondents seek to admit an exhibit which lacks probative value, is highly prejudicial to Complaint Counsel, is needlessly cumulative, and because Respondents also have failed to act with due diligence, Respondents have failed to meet their burden of showing good cause under Rule 3.51(e) to open the record now to admit it. Accordingly, this court should deny Respondents' motion.

III. Conclusion

For the foregoing reasons, Respondents have failed to meet their burden to show good cause to open the record at this late date. Moreover, Respondents have failed to meet their threshold requirement to show that the probative value of this document outweighs its prejudicial effect. As such, Complaint Counsel respectfully requests that this Court deny Respondents' motion.

Dated: July 5, 2022

Respectfully submitted,

s/ Dylan P. Naegele

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CERTIFICATE OF SERVICE

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