**PUBLIC**

**UNITED STATES OF AMERICA**
**BEFORE THE FEDERAL TRADE COMMISSION**
**OFFICE OF ADMINISTRATIVE LAW JUDGES**

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| **In the Matter of**<br><br>**Illumina, Inc.,**<br>**a corporation,**<br><br>**and**<br><br>**GRAIL, Inc.,**<br>**a corporation.**<br><br>**Respondents.** | **DOCKET NO. 9401** |

**COMPLAINT COUNSEL'S OPPOSITION TO RESPONDENTS' MOTION TO REOPEN THE RECORD AND ADMIT ONE ADDITIONAL EXHIBIT**

Respondents make an untimely motion to admit a highly confusing and misleading document. Once again, Respondents seek to admit post-hearing evidence that lacks context and is not subject to cross examination. Like Respondents' previous attempts to reopen the record, the document they now seek to admit fails to meet the threshold requirements of Rule 4.34(b), and Respondents again fail to meet their burden to show good cause for its late admission. Complaint Counsel respectfully requests that this Court deny Respondents' latest motion to reopen the record.

## 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 statements about a temporary litigation standstill between Illumina, Inc. and Illumina Cambridge Ltd. ("Illumina") and certain entities related to the Beijing Genomics Institute ("BGI"). 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.

RX4064 is an Illumina regulatory filing announcing a litigation settlement and temporary pause in future patent litigation between Illumina and BGI.[1] Respondents ask this Court to admit this vague and confusing document and rely on it for the proposition that the temporary litigation pause "resolves all patent and antitrust claims between [Illumina and BGI]." Resp. Mot. at 1–2. This gross mischaracterization is contradicted by the document itself, which confirms that the settlement is merely a temporary standstill in Illumina's long-running litigation campaign to exclude BGI from selling NGS platforms in the United States. RX4064 at 002. Once the standstill terminates in 2025, Illumina is free to sue BGI again, as it has on five previous occasions.[2] Respondents gloss over the limited and temporary nature of the settlement, obscuring the document's misleading and confusing nature.

Likewise, Respondents misleadingly claim that the document is evidence that "BGI can launch its sequencers in the United States without concerns about patent litigation." Respondents cannot speak for whether BGI has ongoing "concerns about patent litigation." Indeed, Illumina's own executives have told investors that Illumina has additional patents that it believes can prevent entry by BGI. Dr. Aravanis, Illumina's Chief Technology Officer, explained in notes for a meeting with Illumina investors that, "[a]s we learn more about BGI's products, additional patents may become relevant," because Illumina has additional patents touching "every aspect of the sequencing workflow, including nucleotides, enzymes, reagent mixes, instruments, optics,

[1] Per this Court's request, Complaint Counsel and Respondents have worked to try to reach a stipulation regarding BGI's potential entry into the United States, but thus far have not reached agreement.
[2] *Illumina, Inc. v. BGI Genomics Co.*, No. 20-cv-1465 (N.D. Cal. filed Feb. 27, 2020); *Complete Genomics, Inc. v. Illumina, Inc.*, No. 19-CV-00970 (D. Del. counterclaims filed July 25, 2019); *Illumina, Inc. v. BGI Genomics Co.*, No. 19-cv-03770 (N.D. Cal. filed June 27, 2019); *Illumina, Inc. v. Complete Genomics, Inc.*, No. 3:12-cv-01465 (S.D. Cal. filed June 15, 2012); *Illumina, Inc. v. Complete Genomics, Inc.*, No. 1:10-cv-00649 (D. Del. filed Aug. 3, 2010)

analysis software, and bioinformatics."[3] Moreover, Dr. Aravanis noted that "[t]hese patents and pending applications have expiration dates ranging from 2023 to beyond 2030."[4] Perhaps most tellingly, in RX4064, which is a regulatory filing, Illumina does not warn its investors that as a result of the standstill it will be unable to file future patent infringement claims against BGI, but merely that it will not do so for the next three years.

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. 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, these factors all weigh against allowing Respondents to submit the proposed exhibit.

[3] PX2822 (Illumina) at 006–007 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021).
[4] PX2822 (Illumina) at 006–007 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021).

### A. Respondents' Untimely Exhibit Lacks Probative Value

Respondents bear the burden of showing that entry by BGI 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. RX4064 is not probative on any of those factors. Respondents' exhibit has no probative value in answering the relevant question of whether entry by BGI will be sufficient to counteract the anticompetitive effects of Illumina's acquisition of Grail. As a threshold matter, the question is not whether BGI will enter the U.S. market in *some* capacity (and it may fail even in that regard), but rather whether BGI would enter with a viable alternative NGS platform suitable for the complex and demanding application of MCED testing to which developers in the United States could switch. *See United States v. Anthem, Inc.*, 236 F. Supp. 3d 171, 222 (D. D.C. 2017) (explaining that entry is only sufficient if it has "the magnitude, character, and scope to counteract a merger's anticompetitive effects" and "fill the competitive void that will result"). Respondents' exhibit lacks any probative value on that crucial question. As extensive record evidence shows, the still unresolved question of BGI's freedom to operate is only one of many reasons why BGI is not a viable alternative to Illumina's NGS platform for MCED test developers. Among the other reasons cited by MCED test developers for why BGI is not a viable alternative to Illumina, MCED test developers have expressed concern about BGI's ties to the Chinese government, its involvement in human rights abuses, the poor performance of its NGS platform, and the supply chain risks of relying on a Chinese company.[5] Indeed, multiple MCED test developers stated that even if BGI's NGS platform were commercially available in the

[5] *See generally* CCFF ¶¶ 1296–1345.

United States, they would not consider it to be an alternative to Illumina's NGS platform.[6] There is no evidence that BGI would suddenly become a viable alternative merely because of a temporary pause in Illumina's patent infringement litigation campaign against BGI in the United States. As such, Respondents' exhibit lacks any probative value as to whether BGI would be a viable alternative for MCED test developers in the United States.

In addition, this document contains no information about when, if ever, any MCED test developer in the United States could rely on BGI as a viable alternative to Illumina NGS. As every MCED test developer explained, switching NGS platforms is an extremely challenging, expensive, time consuming, and risky process.[7] In particular, MCED test developers estimate that switching NGS platforms, *assuming* a suitable alternative were available, {[redacted][8] [redacted]}. Moreover, the prospect of future litigation between Illumina and BGI—either on the patents not subject to this purported agreement or after the agreement terminates—remains. As multiple MCED test developers testified, the prospect of such litigation is a significant concern.[9] For example, Dr. Gao of Singlera explained that the prospect of BGI being sued at some point in the future would expose Singlera to "business risk from a legal point of view" because Singlera could "spend 40 to 60 million dollar[s] to get FDA approval," but if BGI "were sued, we cannot use their machine."[10] Indeed, given that the litigation standstill described in RX4064 terminates before any MCED test developer would have time to change its test to run on BGI's NGS platform, and Illumina could still seek to enforce patents against BGI, some of which have expiration dates

[6] CCFF ¶¶ 1325–45. {[redacted]}
[7] *See* CC Post-Tr. Br. § II.F.1.b; CCFF ¶¶ 1768-1901.
[8] {[redacted]}.
[9] *See* CCFF ¶¶ 1286-1295.
[10] CCFF ¶ 1291.

beyond 2030, RX4064 fails to show that BGI's entry, even in theory, would counter the anticompetitive effects of the transaction. In addition, ample record evidence shows that there are many other barriers to entry by BGI beyond the patents at issue in the two cases covered in the settlement,[11] rendering RX4064 irrelevant on the question of the likelihood of BGI's entry as a viable alternative for MCED developers. Likewise, the document does not even begin to establish that entry by BGI would be sufficient "to fill the competitive void" that would result if Illumina foreclosed its NGS platform from one of Grail's competitors. *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 73 (D. D.C. 2011). Because it contains no information that is probative of any of the factors which Respondents must prove, this document 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. Without testimony to put this document in the proper context, RX4064 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.

[11] *See* CC Post-Tr. Br. § II.F.1.a; CCFF ¶¶ 1325–45.

### C. Respondents Failed to Conduct Due Diligence

Respondents were well aware of BGI prior to trial,[12] yet presented no witness at trial from BGI to testify regarding the potential of its NGS platform to enter the U.S. market, let alone its suitability for MCED testing. Indeed, Respondents elected not to pursue *any* form of discovery from BGI despite being party to two lawsuits against BGI throughout the course of this action,[13] likely because they know such evidence would not support their contention that BGI's NGS platform will be a feasible alternative for MCED developers in the United States in the foreseeable future. In one proceeding, Illumina even obtained discovery from BGI on the question of the commercial viability of BGI's technology, prompting the court to conclude that BGI's CoolMPS technology is "neither mature nor commercially viable." *Illumina, Inc. v. BGI Genomics Co., Ltd.*, No. 3:19-cv-03770, 2022 WL 899421, at *25 (N.D. Cal. Mar. 27, 2022). Nevertheless, against a record that reflects their lack of diligence, Respondents now want to claim that a late-breaking development, the timing of which was controlled (at least in part) by Illumina itself, warrants admitting an ambiguous document that does nothing to show that entry by BGI 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").

[12] *See* Resp. Pretrial Br. at 3–4, 27, 33, 35, 52, 54, 63.
[13] *Illumina, Inc. v. BGI Genomics Co., Ltd.*, No. 3:20-cv-01465 (N.D. Cal. filed Feb. 27, 2020); *Complete Genomic, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del. filed Jul. 25, 2019).

### D. Respondents' Untimely Exhibit Is Cumulative

Respondents' exhibit is needlessly cumulative of evidence presented at trial regarding BGI. *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 BGI witnesses regarding their NGS platform, the record contains trial testimony and other evidence from multiple other witnesses about the BGI platform and its lack of suitability for MCED testing.[14]

Respondents chose not to call a representative of BGI at trial. Respondents chose not to subpoena BGI documents. Respondents also chose to enter into a settlement agreement after trial and only after the record had closed. Despite this, Respondents now seek to admit an exhibit which lacks probative value, is highly prejudicial to Complaint Counsel, is needlessly cumulative. But Respondents should be bound by their choices. Because Respondents 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.

[14] CCFF ¶¶ 1269–1345.

Dated: August 3, 2022

Respectfully submitted,

*s/ Dylan P. Naegele*

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## CERTIFICATE OF SERVICE

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