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

In the Matter of

Illumina, Inc., a corporation, and

and

Docket No. 9401

GRAIL, Inc., a corporation,

Respondents.

### RESPONDENTS' MOTION TO REOPEN THE RECORD AND ADMIT ONE ADDITIONAL EXHIBIT

Pursuant to 16 C.F.R. § 3.43(b), 3.51(e)(1) and the April 26, 2021 Scheduling Order, Respondents Illumina, Inc. ("Illumina") and GRAIL, LLC ("GRAIL") ("Respondents"), respectfully request that the Court reopen the proceeding to admit RX4064 into evidence. RX4064 should be admitted because it is relevant, not cumulative and admitting it will not cause undue prejudice to Complaint Counsel. (July 6, 2022 Order on Resps.' Motions to Reopen Evidentiary Record (reopening the record to admit exhibits because they are "relevant, not cumulative", and would not cause undue prejudice to Complaint Counsel); Mar. 10, 2022 Order on Admissibility of Exhibits at 6 (admitting certain Open Offer Exhibits because they were "offered to show additional Open Offer signatories that did not exist at the time of trial" and which did not require "any additional discovery . . . to avoid undue prejudice").)

On July 14, 2022, Illumina and Illumina Cambridge Ltd. and BGI Genomics Technology Co. and its affiliates (collectively "BGI") entered into a Settlement and License Agreement (the "Settlement Agreement") that resolves all patent and antitrust claims between the two companies in the United States with the exception that the permanent injunction entered against BGI with respect to BGI's StandardMPS technology remains in effect until January 1, 2023.<sup>1</sup> (RX4064 (Illumina Form 8-K) at 2.) RX4064 is the Form 8-K filing by Illumina reporting the announcement of the Settlement Agreement. Illumina and BGI also agreed to a litigation standstill for patent and antitrust actions in the United States and its territories until October 1, 2025.<sup>2</sup> (*Id.*)

The settlement between Illumina and BGI is highly relevant to a key issue before the Court. To prove this Transaction is substantially likely to lessen competition, Complaint Counsel "must make a 'fact-specific' showing that the effect of the [Transaction] 'is likely to be anticompetitive." *United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 192 (D.D.C. 2018). Such a showing requires proving that NGS competition will not prevent Illumina from having an incentive and ability to foreclose GRAIL's putative rivals. The ability "element [cannot] be satisfied" if "rivals [can] readily switch purchases to alternatives to the related product" without a "meaningful effect on the price, quality, or availability of products or services in the relevant market". U.S. Dep't of Justice & Fed. Trade Comm'n, Vertical Merger Guidelines 2020 (withdrawn 2021) § 4 [hereinafter *Vertical Merger Guidelines*]. As Respondents have shown, to meet its burden, Complaint Counsel must account for the existing NGS alternatives as well as the surge of impending NGS entry, including BGI. (*See* Resps.' Post-Trial Reply Br. at 52–54.) Complaint Counsel has denied that BGI will enter, in part because of patent litigation with Illumina. (CC Post-Trial Reply Br. at 78–79 (citing CCFF ¶ 1276–79, 1284).) RX4064, which

<sup>&</sup>lt;sup>1</sup> Recognizing the importance of this issue, the Court requested that the parties file a joint stipulation regarding the status of BGI's entry in the United States in light of its intellectual property disputes with Illumina. (Tr. 4718–19.) The parties are working diligently to prepare this stipulation.

<sup>&</sup>lt;sup>2</sup> While the standstill covers all core sequencing patents it excludes certain other categories of patents. (*See* RX4064 (Illumina Form 8-K) at 2.)

shows that Illumina and BGI have settled the patent litigation referenced by Complaint Counsel and that BGI can launch its sequencers in the United States without concerns about patent litigation, is highly probative of this issue.

#### I. LEGAL STANDARD

Under Commission Rule 3.51(e)(1), at any time from the close of the hearing record until the filing of the initial decision, the Court may reopen the proceeding for the reception of further evidence for good cause shown. 16 C.F.R. § 3.51(e)(1); *see also In re Polypore Int'l, Inc.*, 2009 WL 3775105, at \*2 (Oct. 22, 2009). To determine whether to reopen the proceeding under Rule 3.51(e)(1), this Court has considered the same four factors the Commission considers when it must determine whether to reopen proceedings: "(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." *Polypore*, 2009 WL 3775105, at \*5 (citing *In re Brake Guard Prods., Inc.*, No. 9277, 125 F.T.C. 138, 248 n.38 (Jan. 15, 1998)).

#### II. ARGUMENT

#### A. <u>Respondents Can Demonstrate Due Diligence With Respect to RX4064.</u>

Respondents can demonstrate due diligence in seeking the admission of RX4064. Since RX4064 was published only last week, Respondents could not have included it at any earlier time despite their diligence. *See In re Otto Bock HealthCare N. Am., Inc.*, 2018 WL 4627651, at \*2 (Sept. 18, 2018) ("Respondent has demonstrated that it could not have included [the additional exhibits] on its Final Proposed Exhibit List by the [deadline] despite its diligence, and thus has established 'good cause' for adding these exhibits."); (July 6, 2022 Order at 2 ("Respondents have satisfied the requirement of due diligence for" certain "recently issues reports" because "each constitutes newly available information").)

#### B. <u>RX4064 Is Highly Probative.</u>

RX4064 is also probative. See 16 C.F.R. § 3.43(b). As discussed above, to prevail, Complaint Counsel must demonstrate that Illumina has the ability to foreclose GRAIL's putative rivals, which it cannot show if "rivals [can] readily switch purchases to alternatives to the related product" without a "meaningful effect on the price, quality, or availability of products or services in the relevant market". Vertical Merger Guidelines § 4. RX4064 provides new details about the imminence and suitability of upstream alternatives to Illumina. This is a "critical element[] for evaluating" Complaint Counsel's claims. See Polypore, 2009 WL 3775105, at \*6 ("If Daramic has, after the close of the record, potentially lost a significant customer, as proffered by Respondent, such evidence would directly bear on Respondent's market share and power to control prices -- critical elements for evaluating the Section 7 and monopolization charges."). With regard to BGI, Complaint Counsel asserted that "Respondents have failed to show that entry by BGI would be timely or likely, as it is far from clear that BGI would enter even in 2023." (CC Post-Trial Reply Br. at 81.) Complaint Counsel also stated that, despite the expiration of certain injunctive relief, Illumina might assert additional patents against BGI. (CC Post-Trial Reply Br. at 81.)

RX4064 is highly probative of BGI's ability to enter in the U.S. in August 2022, contrary to Complaint Counsel's claims. The document shows that Illumina and BGI entered into a Settlement and License Agreement resolving all claims between Illumina and BGI. It also shows that Illumina and BGI have entered into a standstill agreement relating to patent and antitrust litigation until October 1, 2025. Under the Settlement Agreement, BGI can launch in the United States its StandardMPS sequencing instruments and consumables on January 1, 2023.

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BGI's previously announced launch of CoolMPS products on August 29, 2022 (just after the expiration of the relevant patent) is unchanged by the Settlement Agreement.<sup>3</sup> (RX4062 (GenomeWeb, *MGI to Take Another Crack at US Next-Gen Sequencing Market This Summer*) at 1.) This shows that patent litigation between Illumina and BGI is not an impediment to BGI's launch in the United States and supports Respondents' statement that BGI will enter the United States market in August 2022. (*See* Resps.' June 7, 2022 Mot. to Reopen the Record at 1–2.) Reopening the record to admit RX4064 would also be consistent with this Court's prior decision to reopen the record to admit a document concerning the likely timing of BGI's entry. (*See* July 6, 2022 Order at 3 ("RX4062 is sufficiently reliable to show that BGI, in fact, intends to begin making sales as announced, which has some independent relevance on the issue of the availability of alternatives to Illumina's NGS").)

#### C. <u>RX4064 Presents New Facts.</u>

RX4064 is not cumulative, since it presents new facts that did not exist at the time of trial. *See United States v. Magleby*, 241 F.3d 1306, 1316 (10th Cir. 2001) ("Evidence is cumulative if repetitive, and if the small increment of probability it adds may not warrant the time spent in introducing it."). The announcement of the Settlement and License Agreement between Illumina and BGI is new evidence that rebuts Complaint Counsel's assertion that "it is far from clear that BGI would enter even in 2023." (CC Post-Trial Reply Br. at 81.) RX4064

<sup>&</sup>lt;sup>3</sup> Products that run on the CoolMPS chemistry include the DNBSeq-G400 sequencer (*see* RX4062 (GenomeWeb, *MGI to Take Another Crack at US Next-Gen Sequencing Market This Summer*) at 1), which has a reported throughput between the NextSeq and the NovaSeq offering from Illumina. (*Compare* PFF ¶ 590, Table 5 *with* PFF ¶ 575, Table 3.) BGI had previously announced that its high-throughput DNBSeq T Series will launch in the United States in 2023. (RX4062 (GenomeWeb, *MGI to Take Another Crack at US Next-Gen Sequencing Market This Summer*) at 4.) BGI's DNBSEQ-T7, which is among the products in the T Series, has a reported throughput of up to 6 Tb per run, run time under 24 hours and accuracy of more than 80% of bases with a quality score greater than Q30—which is over 99.9% accurate. (PFF ¶¶ 590–91, Table 5 (RX3465 (MGI Tech); RX3067 (BGI).)

shows that there is no impediment to BGI launching StandardMPS instruments—which have a reported throughput comparable to that of Illumina's NovaSeq instrument—in January 2023.

#### D. <u>RX4064 Will Not Prejudice Complaint Counsel.</u>

Finally, the admission of the RX4064 will not unfairly prejudice Complaint Counsel. Complaint Counsel took extensive discovery and elicited testimony from third parties about whether alternative NGS platforms (including from BGI) could launch in the United States, given the NGS patent landscape. (*See* CC Post-Trial Br. at 136; CC Post-Trial Reply Br. at 73–86); *see Otto Bock*, 2018 WL 4627651, at \*3 (noting that Complaint Counsel would not be prejudiced by admission of additional exhibits when they had elicited testimony about said topic). RX4064 provides additional relevant context to testimony Complaint Counsel elicited; if a customer has taken the position that entry of BGI is too remote because of pending patent litigation, new information about the status of that litigation is relevant. In contrast, disallowing this evidence and ignoring real-world facts, would prejudice Respondents. The Court should not allow Complaint Counsel to avoid these facts simply because the evidence did not manifest until now.

Because RX4064 is publicly available, it is also independently admissible to rebut Complaint Counsel's contentions about the likelihood of BGI's entry. *Now-Casting Econ., Ltd. v. Econ. Alchemy LLC*, No. 18 CIV. 2442 (ER), 2019 WL 4640219, at \*5 (S.D.N.Y. Sept. 24, 2019) ("[The court] may take judicial notice of publicly available materials—including articles, books, and reports—that show the information available to the relevant market at the relevant time."); *see also* 16 C.F.R. § 3.43(f).

This Court has previously reopened the record to admit documents similar to RX4064. The Court admitted RX4063, "a press release issued publicly and directly by Exact" and noted it was sufficiently reliable and would not prejudice Complaint Counsel. (July 6, 2022

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Order at 3.) RX4064 is an SEC filing made by Illumina.<sup>4</sup> The Court also reopened the record to admit RX4062, an internet article reciting BGI's announcement of its intent to "make its CoolMPS sequencing chemistry and DNBSeq-G400 sequencer commercially available in the US starting Aug. 29, the day a certain Illumina patent is set to expire." (*Id.*) While Complaint Counsel said that it would be prejudiced by the admission of RX4062, this Court disagreed and found that that document was "sufficiently reliable to show that BGI, in fact, intends to begin making sales as announced, which has some independent relevance on the issue of the availability of alternatives to Illumina's NGS". (*Id.*) RX4064 is similarly reliable to show that Illumina and BGI have entered into a Settlement and License Agreement.

#### III. CONCLUSION

For the foregoing reasons, Respondents respectfully request that this motion be granted and RX4064 be admitted.

<sup>&</sup>lt;sup>4</sup> The Court also admitted several SEC filings into the record after the close of discovery. (*See, e.g.*, PX0378; PX0408; RX3970; RX3971.)

Dated: July 23, 2022

Respectfully submitted,

/s/ Sharonmoyee Goswami

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Counsel for Respondent GRAIL, LLC

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

In the Matter of

Illumina, Inc. a corporation,

and

Docket No. 9401

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Respondents.

## [PROPOSED] ORDER

Upon consideration of Respondents Illumina, Inc. and GRAIL, LLC's ("Respondents")

Motion to Reopen the Record and to Admit into Evidence RX4064, it is hereby

ORDERED, that Respondents' motion is GRANTED, and it is further

ORDERED, that good cause exists for Respondents to amend its Final Exhibit List and to

admit RX4064 into evidence.

Date:

D. Michael Chappell Chief Administrative Law Judge

# **RX4064**

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

## Form 8-K

#### **Current Report**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 14, 2022



Illumina, Inc.

(Exact name of registrant as specified in its charter)

001-35406

(Commission File Number)

Delaware

(State or other jurisdiction of incorporation)

(I.R.S. Employer Identification No.)

33-0804655

5200 Illumina Way, San Diego, CA 92122

(Address of principal executive offices) (Zip code)

(858) 202-4500

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value	ILMN	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company  $\Box$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13a of the Exchange Act.

#### Item 8.01 Other Events.

On July 14, 2022, Illumina, Inc. and Illumina Cambridge Ltd. (collectively, the "Company") entered into a Settlement and License Agreement with BGI Genomics Technology Co., Ltd., BGI Genomics Co., Ltd., BGI Americas Corp., MGI Tech Co., Ltd., MGI Americas Inc., and Complete Genomics, Inc. (collectively, "BGI") (the "Agreement"). The Agreement resolves all claims in Complete Genomics, Inc. v. Illumina, Inc., Case No. C.A. No. 19-970-MN (D. Del.). The Agreement also resolves all claims in Illumina, Inc. and Illumina Cambridge Ltd. v. BGI Genomics Co., Ltd., BGI Americas Corp., MGI Tech Co., Ltd., MGI Americas Inc., and Complete Genomics, Inc., Case No. 3:19-cv-03770-WHO (N.D. Cal.) and Illumina, Inc. and Illumina Cambridge Ltd. v. BGI Genomics Co., Ltd., BGI Americas Corp., MGI Tech Co., Ltd., MGI Americas Inc., and Complete Genomics, Inc., Case No. 3:20-cv-01465-WHO (N.D. Cal.), as well as related Appeal Nos. 2022-1733, 2022-1735 and 2022-1742, 2022-1743 pending in the United States Court of Appeals for the Federal Circuit, with the exception that the permanent injunction entered on April 11, 2022 against BGI remains in effect with a revised expiration date of January 1, 2023, with respect to BGI's StandardMPS chemistry. The Agreement further resolves all antitrust claims against the Company in Complete Genomics, Inc., BGI Americas Corp. and MGI Americas, Inc. v. Illumina, Inc. and Illumina Cambridge Ltd., Case No. 21-cv-00217 (N.D. Cal.) and that complaint will be dismissed with prejudice. Pursuant to the terms of the Agreement, the Company agrees to pay Complete Genomics a one-time payment of \$325 million, with the parties agreeing that the judgment against BGI and the judgment against the Company in the above-referenced litigations are satisfied in total. In addition, the Company received from BGI a fully paid-up license to U.S. Patent Nos. 8,617,811, 9,222,132, 9,523,125, 10,662,473, 11,098,356 and 11,214,832, U.S. Patent Application Nos, 61/024,396, 61/024,110, 16/882,461, 17/407,935 and 17/523,706, and U.S. patents and patent applications related to each of the foregoing U.S. patents and patent applications until their expiration ("the 2-channel technology patents"). The Company's license allows it to use the 2-channel technology in all its current and future platforms with no additional royalties owed. BGI received from the Company a fully paid-up license to U.S. Patent Nos. 9,217,178, 9,303,290 and 9,970,055 ("the image mix patents") and U.S. patents and applications related to each of the foregoing U.S. patents until their expiration. The parties agree to a litigation standstill for patent and antitrust actions in the United States and its territories until October 1, 2025, as set forth in the Agreement. The standstill does not apply to the parties' patents or patent applications related to non-invasive prenatal testing (NIPT), nor to any intellectual property of Grail, Inc., related to multi-cancer early detection. None of the parties make any admission of liability in entering into the Agreement.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

FEDERAL TRADE COMMISSION | OFFICE OF THE SECRETARY | FILED 7/25/2022 | Document No. 605138] | PAGE Page 13 of 15 \* PUBLIC \*; PUBLIC \*;

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

#### ILLUMINA, INC.

Date: July 14, 2022

By: /s/ Charles E. Dadswell

Charles E. Dadswell General Counsel and Secretary

#### **CERTIFICATE OF SERVICE**

I hereby certify that on July 23, 2022, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

April Tabor Secretary Federal Trade Commission 600 Pennsylvania Ave., NW, Rm. H-113 Washington, DC 20580 ElectronicFilings@ftc.gov

The Honorable D. Michael Chappell Administrative Law Judge Federal Trade Commission 600 Pennsylvania Ave., NW, Rm. H-110 Washington, DC 20580

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

#### Complaint Counsel

#### **U.S. Federal Trade Commission**

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July 23, 2022

/s/ Sharonmoyee Goswami

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