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United States District Court
Northern District of California

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

ILLUMINA INC., et al.,
Plaintiffs,
v.
BGI GENOMICS CO., LTD., et al.,
Defendants.

Case No. [20-cv-01465-WHO](#)

ORDER GRANTING MOTION TO AMEND

Re: Dkt. Nos. 233, 241, 244

INTRODUCTION

Defendants BGI Genomics Co., LTD., BGI Americas Corp., MGI Tech Co., Ltd., MGI Americas, Inc., and Complete Genomics, Inc. (“BGI”) move for leave to amend to add a new inequitable conduct defense. Plaintiffs Illumina, Inc. and Illumina Cambridge Ltd., (“Illumina”) oppose the motion, arguing that BGI’s proposed defense is futile, that BGI failed to act diligently in seeking leave, and that amendment would be prejudicial to Illumina. In light of the liberal amendment standard, and for the reasons set forth below, BGI’s motion is GRANTED. In addition, Illumina’s request to file a sur-reply is GRANTED. BGI’s motion to seal documents associated with its reply brief is DENIED.

BACKGROUND

When prosecuting the ’444 patent, Illumina originally listed claims directed to a nucleotide or nucleoside modified to include an azidomethyl group bound to and blocking the 3’OH of the nucleotide or nucleoside. Dkt. No. 233 (“Mot.”) at 1. The patent examiner rejected the claims based on a paper published by Zavgorodny in 1991 (“Zavgorodny 1991”), which disclosed a method for placing an azidomethyl group on the 3’OH of a nucleoside. Mot. at 1; Dkt. No. 233-5 (“Milowic Decl., Ex. 4”). Illumina subsequently amended some of the ’444 patent claims to limit

1 them to modified nucleotides and asserted that Zavgorodny 1991 does not teach or anticipate the
 2 claimed nucleotides. Dkt. No. 233-6 (Milowic Decl., Ex. 5”). Following this amendment, the
 3 patent examiner granted the ’444 patent, including claims 1 and 3, directed to a modified
 4 nucleotide.

5 In its proposed Corrected First Amended Answer (“CFAA”), BGI seeks to allege a new
 6 inequitable conduct affirmative defense based on its claim that during this patent prosecution
 7 process, Illumina intentionally withheld or failed to disclose a reference to a paper by Terez
 8 Kovacs and Laslo Otvos title *Simple Synthesis of 5-Vinyl and 5-Ethynyl- 2’ Deoxyuridine- 5’-
 9 Triphosphates*, and published in *Tetrahedron Letters*, Vol. 29, pp 4525-4528, 1988 (“Kovacs”).
 10 See Dkt. No. 233-7 (“Kovacs”). BGI alleges that Kovacs discloses a methodology for converting
 11 nucleosides to nucleotides that is very similar to the method that two of the inventors of the ’444
 12 patent, Drs. Xiaohai Liu and XiaoLin Wu, were using to create modified nucleotides. Dkt. No.
 13 233-1 (“CFAA”) ¶ 337. It further alleges that a former Solexa employee named Sarah Lee, who
 14 worked in the same lab as Drs. Liu and Wu and who worked with them on converting nucleosides
 15 to nucleotides, made a hand notation that appears to reference the Kovacs publication in an April
 16 2001 notebook entry. *Id.* ¶¶ 332-335. Although the handwritten note is hard to decipher, it
 17 appears to state “Tet. Let. 1998, 29, 4525.” Dkt. No. 233 (“Mot.”) at 2-3. The notation matches
 18 the publication information for the Kovacs paper, except that the date is 10 years off. See Kovacs
 19 at 1.

20 BGI alleges that the Kovacs reference is material, both because it discloses the same
 21 methodology Liu and Wu used to convert nucleosides to nucleotides and also because it provides a
 22 motivation for a person of ordinary skill in the art (“POSITA”) to convert nucleosides to
 23 nucleotides. CCFA ¶ 338. Specifically, Kovacs notes that certain “nucleoside analogues” have
 24 proven useful as antivirals against herpes simplex virus infections and that “[i]nvestigations of the
 25 mechanisms by which these nucleoside analogues interfere with the cellular metabolism [] require
 26 the chemical synthesis of phosphorylated derivatives.” Kovacs at 4525. BGI asserts that “Kovacs
 27 teaches that converting nucleosides to nucleotides (a nucleoside with phosphates added) is
 28 necessary to study the mechanism that normally occurs in a cell, in a test tube instead.” CCFA ¶

1 340. It alleges that based on Kovacs, a POSITA would have been motivated to use the method
 2 Kovacs discloses for converting nucleosides to nucleotides, to convert the 3'OH blocked
 3 azidomethyl nucleoside in Zavgorodny into a nucleotide. *Id.* ¶ 341.

4 The Solexa notebook in which the alleged Kovacs reference appears was produced to BGI
 5 in April 2020. Dkt. No. 239 (“Opp.”) at 4. It is one of over 300 notebooks that have been
 6 produced to BGI. Dkt. No. 233-1 (“Milowic Decl.”) ¶ 2. BGI discovered the notation, and then
 7 the Kovacs paper, while preparing for the December 10, 2020 deposition of Dr. Wu. *Id.* ¶ 3. BGI
 8 filed its motion to amend on December 9, 2020, the last day to do so under the parties’ proposal
 9 that any amendment should happen no later than fifteen days after the Markman ruling in this
 10 case. *See* Dkt. No. 194 at 17.

11 LEGAL STANDARD

12 I. AMENDING PLEADINGS

13 Federal Rule of Civil Procedure 15(a) allows a party to amend its pleading once within: (1)
 14 21 days after serving the pleading or (2) 21 days after the earlier of service of a responsive
 15 pleading or service of a Rule 12(b) motion. Fed. R. Civ. P. 15(a). Outside of this timeframe, “a
 16 party may amend its pleading only with the opposing party’s written consent or the court’s leave.”
 17 *Id.* A court “should freely give leave when justice so requires.” *Id.* “Although the rule should be
 18 interpreted with ‘extreme liberality,’ leave to amend is not to be granted automatically.” *Jackson*
 19 *v. Bank of Hawaii*, 902 F.2d 1385, 1387 (9th Cir. 1990) (citation omitted).

20 A court considers five factors in determining whether to grant leave to amend: “(1) bad
 21 faith, (2) undue delay, (3) prejudice to the opposing party, (4) futility of amendment; and (5)
 22 whether plaintiff has previously amended his complaint.” *In re Western States Wholesale Nat.*
 23 *Gas Antitrust Litig.*, 715 F.3d 716, 738 (9th Cir. 2013) (quoting *Allen v. City of Beverly Hills*, 911
 24 F.2d 367, 373 (9th Cir. 1990). “Prejudice to the opposing party is the most important factor.”
 25 *Jackson*, 902 F.2d at 1387.

26 II. INEQUITABLE CONDUCT

27 To state a claim for inequitable conduct, a party must allege that “(1) an individual
 28 associated with the filing and prosecution of a patent application made an affirmative

1 misrepresentation of a material fact, failed to disclose material information, or submitted false
2 material information; and (2) the individual did so with a specific intent to deceive the
3 PTO.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 n.3 (Fed. Cir. 2009) (internal
4 citation omitted). Allegations of inequitable conduct must be pleaded with particularity pursuant
5 to Federal Rule of Civil Procedure 9(b), which requires that the pleadings “identify the specific
6 who, what, when, where, and how of the material misrepresentation or omission committed before
7 the PTO.” *Id.* at 1328. To meet the intent prong, the pleading “must include sufficient allegations
8 of underlying facts from which a court may reasonably infer that a specific individual (1) knew of
9 the withheld material information or of the falsity of the material misrepresentation, and (2)
10 withheld or misrepresented this information with a specific intent to deceive the PTO.” *Id.* at
11 1328–29. I have held that at the pleading stage, an inference of deceptive intent must be
12 reasonable and drawn from the allegations of underlying fact. *See Finjan, Inc. v. Check Point*
13 *Software Techs., Inc.*, No. 18-cv-02621-WHO, 2019 WL 330912, at *4 (N.D. Cal. Jan. 25, 2019).
14 “A reasonable inference is one that is plausible and that flows logically from the facts alleged,
15 including any objective indications of candor and good faith.” *Exergen*, 575 F.3d at 1329 n.5.

16 DISCUSSION

17 BGI moves for leave to amend to add a new inequitable conduct theory. *See Mot.*
18 Illumina opposes the motion on three bases: (1) BGI did not act diligently; (2) amendment would
19 be prejudicial to Illumina; and (3) amendment would be futile, focusing the bulk of its argument
20 on futility. *Opp.* at 6-13. For the reasons discussed below, I conclude that BGI has acted with
21 reasonable diligence, amendment would not be unduly prejudicial to Illumina, and BGI’s
22 proposed inequitable conduct claim is not clearly futile under the relevant pleading standards.
23 Accordingly, BGI’s motion for leave to amend is GRANTED.¹

24
25 ¹ Illumina seeks leave to file a sur-reply, arguing that BGI’s reply brief raises a number of issues
26 not included in its original motion for leave, including incorrect assertions of fact regarding the
27 prior art references Illumina submitted during the ’444 patent application process. *See Dkt. No.*
28 *244*. BGI opposes the motion, arguing that Illumina has failed to follow the Northern District
Local Rules and that a sur-reply is not appropriate. *See Dkt. No. 258*. BGI does not dispute,
however, that its reply includes new and incorrect assertions of fact regarding whether Illumina
submitted Zavgorodny 2000 as a prior art reference during the ’444 patent prosecution progress.
Accordingly, I conclude that Illumina’s proposed sur-reply, which clarifies this issue, is

1 possibly additional discovery, these potential costs do not appear so substantial as to be unduly
 2 burdensome. Accordingly, I do not believe that amendment would cause significant prejudice to
 3 Illumina.

4 **III. FUTILITY**

5 Illumina spends the bulk of its opposition and sur-reply arguing that BGI's proposed
 6 inequitable conduct claim is futile. *See* Opp. at 6-12; Dkt. No. 244-1 ("Sur-Reply") at 2-6.
 7 Specifically, it argues that BGI has failed to adequately plead intent or materiality, two key
 8 requirements to an inequitable conduct defense. Opp. at 6. While I agree with Illumina that there
 9 are weaknesses to BGI's proposed defense, I do not agree that the claim is futile at the pleading
 10 stage.

11 **A. Rule 9(b)**

12 Illumina does not dispute that BGI's allegations are sufficiently particular to meet the
 13 heightened pleading standard of Rule 9(b). BGI has adequately alleged "the specific who, what,
 14 when, where, and how of the material misrepresentation or omission committed before the PTO"
 15 as required under Rule 9(b). *Exergen*, 575 F.3d at 1328. It alleges that Drs. Liu and Wu, two
 16 inventors of the '444 and '973 patents who had a duty of candor as inventors, did not disclose
 17 Kovacs as relevant prior art to the patent office at any point during the prosecution of the '444 and
 18 '973 patents. CFAA ¶ 347. BGI also asserts specific facts to support its claim that Drs. Wu and
 19 Liu were aware of the Kovacs reference, specifically that (1) their lab mate Sarah Lee made a
 20 reference that appears to be to Kovacs in a April 2001 notebook entry; and (2) Liu, Wu, and Lee
 21 all used a methodology to convert nucleosides to nucleotides that is remarkably similar to the
 22 methodology disclosed in Kovacs. *Id.* ¶¶ 332-335. BGI further states that Kovacs is material for
 23 two reasons: (1) because it teaches a specific methodology for converting nucleosides to
 24 nucleotides; and (2) because it provides a motivation for converting nucleosides to nucleotides,
 25 noting that doing so makes it possible to investigate the mechanism by which certain nucleoside
 26 antivirals work. *Id.* ¶¶ 337-339. And it explains how these facts would have allegedly impacted
 27 the patent examination process, alleging

28 "Drs. Wu, Liu, and Illumina knew that had the examiner been informed of the

1 motivations to convert nucleotides [sic] into nucleotides as described in Kovacs, as
 2 well as a specific synthesis method for doing so, the Examiner would not have
 3 allowed a claim whose only difference from the disclosure in the Zavgorodny
 4 reference was that Zavgorodny disclosed azidomethyl blocking the 3' OH of a
 nucleoside whereas claims 1 and 3 of the '444 patent had been narrowed to cover
 azidomethyl blocking the 3' OH of a nucleotide (a nucleoside with phosphates
 added)."

5 *Id.* ¶ 343. Finally, BGI specifies that the failure to disclose Kovacs impacted the patent
 6 examiner's assessment of claims 1 and 3 of the '444 patent and claims 1 and 13 of the '973 patent,
 7 all of which claim modified nucleotides having a blocking group, Z, C(F')₂—N₃, where Z is
 8 azidomethyl. *Id.* ¶ 344. These allegations are specific and disclose the who, what, when, where,
 9 and how of its alleged inequitable conduct theory. They are sufficient to meet the particularity
 10 requirements of Rule 9(b).

11 **B. Knowledge & Specific Intent**

12 Illumina argues that BGI's inequitable conduct claim fails to adequately allege specific
 13 intent under the Federal Circuit's *Therasense* decision, which requires that intent to deceive the
 14 patent office be "the single most reasonable inference able to be drawn from the evidence." *Opp.*
 15 at 5-7. While I agree that BGI's allegations likely would not meet the standard set by *Therasense*,
 16 I have previously held, as have several other courts, that the *Therasense* standard does not apply at
 17 the pleading stage. *See iLife Techs. Inc. v. AliphCom*, No. 14-CV-03345-WHO, 2015 WL
 18 890347, at *4 n.1 (N.D. Cal. Feb. 19, 2015) ("I decline to impose a standard that requires more
 19 than that set forth in *Exergen*, and will not apply *Therasense* at this stage of the proceedings.").
 20 Accordingly, the relevant question is whether BGI's proposed allegations are sufficient under the
 21 standard set forth in *Exergen*. Under *Exergen*, a party's pleading "must include sufficient
 22 allegations of underlying facts from which a court may reasonably infer that a specific individual
 23 (1) knew of the withheld material information or of the falsity of the material misrepresentations,
 24 and (2) withheld or misrepresented this information with a specific intent to deceive the PTO."
 25 *Exergen*, 575 F.3d at 1328.

26 BGI's allegations are sufficient to support a plausible inference that Drs. Liu and Wu had
 27 knowledge of the Kovacs publication. As noted above, BGI has alleged that a reference to Kovacs
 28 appears in the notebook of Liu and Wu's lab mate Sarah Lee; that Liu, Wu, and Lee were all using

1 the same methodology to convert nucleosides to nucleotides; and that this methodology is virtually
 2 identical to the methodology disclosed in Kovacs. CFAA §§ 335-339. Reading these facts in the
 3 light most favorable to BGI, as is appropriate at the pleading stage, these allegations are sufficient
 4 to support a plausible inference that Liu and Wu were aware of the Kovacs reference. Another
 5 plausible inference is that Liu and Wu simply learned the methodology from Lee, or another
 6 scientist, and did not know of its origin. But at this stage, the relevant question is whether the
 7 facts could support a plausible inference of knowledge. I conclude that they can.

8 It is a closer question whether BGI's allegations support a plausible inference of specific
 9 intent to deceive, but I ultimately conclude that, on a permissive pleading standard, they do. As
 10 Illumina correctly notes, "[i]ntent to deceive cannot be inferred solely from the fact that
 11 information was not disclosed." *Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1321 (Fed. Cir.
 12 2010). But as the Federal Circuit has recognized, "direct evidence of deceptive intent is rarely
 13 available, and that intent may be inferred from circumstantial evidence." *Id.* "A reasonable
 14 inference [of specific intent] is one that is plausible and that flows logically from the facts alleged,
 15 including any objective indications of candor and good faith." *Exergen*, 575 F.3d at 1329 n.5.
 16 While BGI's allegations of specific intent are relatively sparse, it has not simply alleged that Liu
 17 and Wu were aware of Kovacs and failed to disclose it. Instead, it alleges that Liu and Wu copied
 18 the specific methodology used in Kovacs for converting nucleosides into nucleotides, but did not
 19 disclose Kovacs as relevant prior art. CFAA § 337. It has also asserted that in creating the '444
 20 patent, Illumina used a method very similar to a method disclosed in Zavgorodny 1991 for placing
 21 an azidomethyl group on the 3'OH of a nucleoside. *Id.* §§ 327-328. BGI argues that Illumina
 22 deceptively failed to make clear in its '444 patent application that this method came from
 23 Zavgorodny 1991, and instead presented the method as original. Dkt. No. 241-4 at 8.² In sum,

24 _____
 25 ² BGI argues at length in its reply that Illumina engaged in a pattern of concealment and failed to
 26 disclose Zavgorodny 1991 or 2000 to the patent examiner until after the '444 patent application
 27 was initially denied based on a reference to Zavgorodny 1991. Dkt. No. 4-8. These allegations
 28 are not included in BGI's CFAA. Further, in its sur-reply, Illumina disputes BGI's recounting of
 the prosecution history, and attaches a copy of Illumina's information disclosure statement from
 June 2005, which appears to show that Zavgorodny 2000, which cites to Zavgorodny 1991, was
 disclosed as a prior art reference by Illumina prior to the patent examiner's initial rejection. Dkt.
 No. 244-1, Ex. 1 at 4. As a result, I will not consider BGI's arguments regarding Illumina's

1 BGI has alleged that Illumina borrowed two specific methodologies that were key to creating the
 2 claimed nucleotides, did not make clear to the patent examiner that these methodologies had been
 3 adopted from Zavgorodny 1991 and Kovacs, and did not disclose Kovacs at all as prior art.
 4 Although these allegations are no smoking gun, similarly sparse allegations have been found
 5 sufficient, at the pleading stage, to permit an inference of specific intent. *See Capella Photonics,*
 6 *Inc. v. Cisco Systems, Inc.*, 77 F. Supp. 3d 850, 864 (N.D. Cal. 2014) (specific intent adequately
 7 pleaded where defendant alleged that plaintiff “initially refused to identify the precise flaw in its
 8 original patents when seeking reissue,” “failed fairly to disclose” a key prior art reference in a
 9 filing likely to be reviewed by the patent examiner, and defendants had significant financial
 10 incentives to deceive patent office); *Coolsystems, Inc. v. Nice Recovery Systems LLC*, Case No.
 11 16-cv-02958-PJH, 2016 WL 6091577, *4 (N.D. Cal. Oct. 19, 2016) (specific intent adequately
 12 pleaded where defendant alleged that relevant prior art – which was allegedly virtually identical to
 13 claimed invention - was “buried” on 8th page of a list of 176 other minimally relevant references).
 14 I conclude that BGI’s allegations are sufficient, at this stage, to support a plausible inference of
 15 specific intent.

16 C. Materiality

17 Illumina argues that BGI’s proposed inequitable conduct defense is also futile because the
 18 Kovacs reference is cumulative of other prior art disclosed to the patent examiner, and is thus not
 19 material. I have previously held that it is not appropriate at the pleading stage to determine the
 20 materiality of prior art allegedly withheld from the patent office. *See iLife Techs.*, 2015 WL
 21 890347, at *6 (N.D. Cal. Feb. 19, 2015) (concluding that “an analysis of the European references’
 22 materiality as prior art is not appropriate at this stage”); *see also Breville Pty Ltd. v. Storebound*
 23 *LLC*, No. 12-CV-01783-JST, 2013 WL 1758742, at *6 (N.D. Cal. Apr. 24, 2013) (“The Court
 24 does not read *Exergen* as requiring a court to determine, on the face of the pleadings, whether the
 25 allegedly missing material is in fact material and not cumulative.”). Illumina argues that many
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27 _____
 28 alleged failure to disclose Zavgorodny at the outset of prosecuting the ’444 patent. However,
 because BGI’s CFAA does include allegations that Illumina used a method very similar to the
 method disclosed in Zavgorodny, I will consider this limited portion of BGI’s argument.

1 courts do consider materiality at the pleading stage and that I considered materiality with regard to
2 BGI's prior inequitable conduct defense. *See* Sur-Reply at 4 (citing *Illumina, Inc. v. BGI*
3 *Genomics Co.*, No. 19-CV-03770-WHO, 2020 WL 571030, at *2-4 (N.D. Cal. Feb. 5, 2020)).
4 However, in reviewing BGI's prior defense, my assessment of materiality focused on whether the
5 allegedly misleading statements were material to the PTAB and Federal Circuit's decisions based
6 on those courts' written analyses. *Id.* at 3. I did not attempt to assess whether a specific prior art
7 reference would be material or cumulative in the patent prosecution process, a much more
8 technical and fact-specific inquiry. *Id.* While it may be appropriate to consider materiality in
9 some contexts, I decline to engage in a fact-intensive inquiry into the materiality of Kovacs as
10 prior art at this stage.

11 BGI's allegations are sufficient to support a plausible inference that the Kovacs reference
12 is material and not cumulative. It asserts that Kovacs discloses a motivation for converting
13 nucleosides to nucleotides because "Kovacs teaches that converting nucleosides to nucleotides (a
14 nucleoside with phosphates added) is necessary to study the mechanism that normally occurs in a
15 cell, in a test tube instead." CCFA ¶ 340. Although BGI previously argued that Zavgorodny 1991
16 also disclosed this motivation, Illumina does not dispute that the references are different. BGI
17 contends that the Kovacs discussion on this point is more detailed than any other prior art that was
18 submitted to the patent office, including Zavgorodny, and is thus not cumulative. *See* Reply at 11-
19 12. As noted above, it is not appropriate at this stage to make a factual determination whether
20 Kovacs is or is not cumulative of the other prior art references that were before the patent office.
21 BGI has made facially plausible allegations that Kovacs discloses something more and different
22 than these other references. At this stage, these allegations are sufficient to allege materiality.

23 For these reasons, I conclude that BGI's proposed inequitable conduct defense is not
24 clearly futile on a permissive pleading standard. Accordingly, BGI's motion for leave to amend is
25 GRANTED.

26 **IV. MOTION TO SEAL**

27 BGI has filed a motion to seal portions of its reply brief and supporting exhibits. *See* Dkt.
28 No. 241. In its supporting declaration, BGI explains that it has filed these documents under seal

United States District Court
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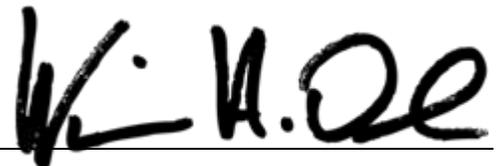
because they have been designated confidential by Illumina and takes no position on whether the documents should be sealed. Dkt. No. 241-2. Pursuant to Local Rule 79-5(e), as the designating party, Illumina had four days from the date BGI filed its motion to submit a substantive declaration providing justification for sealing these documents. Illumina did not file such a declaration. In addition, upon review, these documents do not appear to contain sensitive information suitable for sealing. Accordingly, BGI’s motion to seal is DENIED. The sealed documents will be unsealed on the docket.

CONCLUSION

For the reasons discussed above BGI’s motion to amend is GRANTED. BGI is instructed to file its proposed CFAA, currently filed at Docket No. 233-2, as a separate document on the docket. In addition, Illumina’s motion to file a sur-reply is GRANTED. BGI’s motion to seal documents associated with its reply brief is DENIED and the provisionally sealed documents will be unsealed on the docket.

IT IS SO ORDERED.

Dated: February 8, 2021



William H. Orrick
United States District Judge