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 IN PART AND DENYING IN PART MOTION FOR PARTIAL SUMMARY JUDGMENT

Re: Dkt. Nos. 408, 409, 419

Defendants BGI Genomics Co., Ltd., BGI Americas Corp., MGI Tech Co., Ltd., MGI Americas, Inc., and Complete Genomics, Inc.'s (collectively, "BGI") move for partial summary judgment on Plaintiffs Illumina Inc. and Illumina Cambridge Ltd. (collectively, "Illumina") complaint. BGI asserts that Illumina's U.S. Patent No. 7,777,973 ("'973 Patent") is invalid for failure to satisfy the enablement and written description requirements under 35 U.S.C. § 112 and that its accused product does not infringe Illumina's U.S. Patent No. 10,480,025 ("'025 Patent"). For the reasons below, BGI's motion for summary judgment on the invalidity of the '973 Patent is DENIED. BGI's motion for summary judgment on the CoolMPS products' non-infringement of the '025 Patent is GRANTED.[1]

BACKGROUND

I. PROCEDURAL BACKGROUND

Illumina filed the complaint in the present case on February 27, 2020, after it learned of

[1] Separate from this motion, the parties seek additional claim construction to determine whether the cleavable linker in the '025 Patent is a direct or indirect link between the base and detectable label. *See* Dkt. Nos. 456, 467, 468. This dispute arose from Illumina's addition of its literal infringement theory with respect to BGI's CoolMPS products. *See* Dkt. No. 415. Because the CoolMPS products do not infringe the '025 Patent, the claim construction issue is no longer relevant. *See* Dkt. No. 416. The September 3, 2021 claim construction hearing is VACATED.

new products developed by BGI called CoolMPS™ ("CoolMPS") ("Accused Product"). Dkt. No. 1 ("Compl."). In this lawsuit, Illumina asserts infringement of the '973 Patent, the '025 Patent, and U.S. Patent No. 7,541,444 (the "'444 Patent"). *Id.* ¶ 2. Illumina alleges that BGI's CoolMPS products, which are purportedly based upon new sequencing chemistry, infringe claim 13 of the '973 patent, claim 3 of the '444 patent, and claim 1 of the '025 patent. *Id.* ¶¶ 48, 65, 146, 232.

On November 24, 2020, I entered a claim construction order on disputed terms in the '973 Patent, '025 Patent, and the '444 Patent. Dkt. No. 216 ("Claim Construction Order"). On June 16, 2021, BGI filed this present motion for partial summary judgment, alleging that the '973 Patent is invalid for failure to satisfy the enablement and written description requirements under 35 U.S.C. § 112 and that its CoolMPS does not infringe the '025 Patent. Dkt. No. 409 ("Mot.").

II. THE '973 AND '025 PATENTS

The '973 Patent is titled "Modified Nucleotides." Dkt. No. 1-1 ("'973 Patent"). Claim 1 of the '973 patent recites, "A method for determining the sequence of a target single-stranded polynucleotide, comprising monitoring the sequential incorporation of complementary nucleotides wherein at least one incorporation is of a nucleotide having a removable 3'– OH blocking group covalently attached thereto, such that the 3' carbon atom has attached a group of the structure –O—Z." *Id.* at 86:24-32. Claim 13 of the '973 patent states in full, "The method of claim 1 wherein Z is an azidomethyl group." *Id.* at 88:37-38.

The '025 Patent is titled "Labelled Nucleotides." Dkt. No. 1-3 ("'025 Patent"). Claim 1 of the '025 Patent recites,

> "A nucleotide or nucleoside molecule having a ribose or deoxyribose sugar moiety and a base linked to a detectable label via a cleavable linker, wherein the sugar moiety comprises a protecting group attached via a 3' oxygen atom, and wherein said protecting group comprises an azido group that can be modified or removed to expose a 3' OH group."

Id. at 21:19-24.

LEGAL STANDARD

A party is entitled to summary judgment where it "shows that there is no genuine dispute as to any material fact and [it] is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). A

dispute is genuine if it could reasonably be resolved in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is material where it could affect the outcome of the case. *Id.*

The moving party has the initial burden of informing the court of the basis for its motion and identifying those portions of the record that demonstrate the absence of a genuine dispute of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323–24 (1986). Once the movant has made this showing, the burden shifts to the nonmoving party to identify specific evidence showing that a material factual issue remains for trial. *Id.* The nonmoving party may not rest on mere allegations or denials from its pleadings but must "cit[e] to particular parts of materials in the record" demonstrating the presence of a material factual dispute. FED. R. CIV. P. 56(c)(1)(A); *see also Liberty Lobby*, 477 U.S. at 248. The nonmoving party need not show that the issue will be conclusively resolved in its favor. *Id.* at 248–49. All that is required is the identification of sufficient evidence to create a genuine dispute of material fact, thereby "requir[ing] a jury or judge to resolve the parties' differing versions of the truth at trial." *Id.* (internal quotation marks omitted). If the nonmoving party cannot produce such evidence, the movant "is entitled to . . . judgment as a matter of law because the nonmoving party has failed to make a sufficient showing on an essential element of her case." *Celotex*, 477 U.S. at 323.

On summary judgment, the court draws all reasonable factual inferences in favor of the nonmoving party. *Liberty Lobby*, 477 U.S. at 255. "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Id.* However, conclusory and speculative testimony does not raise a genuine factual dispute and is insufficient to defeat summary judgment. *See Thornhill Publ'g Co., Inc. v. GTE Corp.*, 594 F.2d 730, 738–39 (9th Cir. 1979).

DISCUSSION

I. WHETHER THE '973 PATENT IS INVALID

BGI asserts that the '973 Patent is invalid because "nothing in the specification or within the knowledge of one skilled in the art at the time the '973 patent was filed teach how to perform" "monitoring the sequential incorporation of complementary nucleotides without a label when:

a) all four nucleotide types are brought into contact with the target simultaneously, b) three nucleotides are brought into contact with the target simultaneously, and c) two nucleotides are brought into contact with the target simultaneously." Mot. at 2. Illumina refers to this theory as BGI's "simultaneous nucleotide addition" theory. Dkt. No. 420 ("Opp.") at 3. Because the allegedly inoperable embodiment related to the simultaneous addition of nucleotides is outside the claim scope, the '973 Patent is not invalid.

A. BGI Did Not Fail to Disclose Its Invalidity Theory

As a preliminary matter, Illumina contends that BGI failed to disclose its "simultaneous nucleotide addition" theory in its contentions in violation of Patent Local Rule 3-3(d), which requires that a party's invalidity contentions disclose any grounds of invalidity based on enablement or written description. Opp. at 3–4; *see* Patent L.R. 3-3. According to Illumina, BGI only disclosed its "over-breadth" invalidity theory (that the '973 Patent was not enabled or described because it covers "the potential incorporation of millions of 3'-O-azidomethyl blocked nucleotides by millions of enzymes with unlimited sequencing read length using labeled or unlabeled nucleotides" and is therefore overbroad) and its "unlabeled nucleotide theory" (that the specification offers no guidance as to how sequencing can be accomplished using unlabeled nucleotides) in its invalidity contentions. Mot. at 4; *see* Dkt. No. 420-2 ("BGI Invalidity Contentions"). Illumina argues that BGI only now improperly asserts its "simultaneous nucleotide addition" theory because I had rejected BGI's "over-breadth" theory in my preliminary injunction order and that Dr. Floyd Romesberg, Illumina's expert, rebutted BGI's "unlabeled nucleotide" theory by showing that there are five methodologies that a person having ordinary skill in the arts ("POSITA") would have known for using the claimed method for unlabeled nucleotides. *Id.* at 3; *see* 3770[2] Dkt. No. 185 ("PI Order") at 9–13; *see also* Dkt. No. 409-6 ("Romesberg Rebuttal Rep.") ¶¶ 212–34. It also contends that BGI's "unlabeled nucleotides" theory and its "simultaneous nucleotide addition" theory are distinct because the latter focuses on the way the nucleotides are added and that BGI cannot "shift to a new theory . . . without obtaining leave to

[2] This refers to the related case 19-cv-03770-WHO.

amend its contentions." *Id.* at 4–5.

BGI asserts that its "simultaneous nucleotide addition" theory is not a new invalidity theory but rather "further evidentiary support for the theory previously disclosed," i.e., the "unlabeled nucleotide" invalidity theory. Dkt. No. 436 ("Reply") at 7–8. I agree. BGI's "simultaneous nucleotide addition theory"—that the '973 specification does not teach how to monitor the sequencing of unlabeled nucleotides when multiple nucleotides come into contact with the target simultaneously—"merely provides an evidentiary example or complementary proof in support" of its disclosed "unlabeled nucleotide" theory under which BGI asserted that the specification provided no guidance as to how sequencing can be accomplished using unlabeled nucleotides. *See Genentech, Inc. v. Trustees of Univ. of Pennsylvania*, No. 10-CV-2037-LHK, 2012 WL 424985, at *2 (N.D. Cal. Feb. 9, 2012) (evaluating whether the challenged expert report section provides an evidentiary example of a disclosed invalidity theory "or itself advances a new or alternate means by which the jury could find the claim at issue invalid" in violation of Patent L.R. 3-3). BGI did not waive its "simultaneous nucleotide addition" invalidity theory.

B. Whether Claims 1 and 13 Satisfy the Enablement Requirement

The question then is whether BGI's "simultaneous nucleotide addition" invalidity theory succeeds. First, the parties dispute whether the '973 specification enables the full scope of the claims 1 and 13 as required under 35 U.S.C. § 112. As explained in my prior order, "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012) (citations omitted); PI Order at 9–10. "Enablement serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention." *MagSil Corp.*, 687 F.3d at 1380–81.

In order to prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a POSITA would not be able to practice the claimed invention without "undue experimentation." *Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc.*, 928 F.3d 1340, 1346 (Fed. Cir. 2019). In analyzing whether an invention requires undue experimentation,

the court considers "factors such as: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* (citation omitted).

1. BGI's Contested Embodiment Is Not Part of the Claims

BGI argues that the '973 Patent is invalid because its specification does not enable the full scope of the claims by failing to teach "how to monitor sequential incorporations of complementary nucleotides without the use of labels" when "two, three, or all four nucleotides [come] into contact with the target simultaneously." Mot. at 3. In my prior Claim Construction Order, I held that claims 1 and 13 did not limit the "sequential incorporation of complementary nucleotides" to only labeled nucleotides. Claim Construction Order at 11–12.

BGI points to one section of the specification that discusses five ways that nucleotides can be brought into contact with the target: (1) four nucleotides are brought into contact with the target simultaneously ('973 Patent at 6:19-24); (2) one nucleotide is brought into contact with the target in the first step and then in a second step three are added simultaneously ('973 Patent at 6:50-61); (3) three nucleotides are added simultaneously in the first step and then in the second step one is added ('973 Patent at 50-61); (4) two nucleotides are added in the first step and then in the second step the remaining nucleotides are added ('973 Patent at 6:26-37); and (5) each nucleotide is added one at a time ('973 Patent at 6:13-18). Mot. at 1–2. It argues that "[b]ecause neither claim 1 nor 13 is limited to a particular order in which the nucleotides are brought into contact with the target, all five described ways are covered" in claims 1 and 13 and therefore "claims 1 and 13 must enable each of the five ways" for both labeled and unlabeled nucleotides. Dkt. No. 436 ("Reply") at 2. According to BGI, claims 1 and 13 only enable one out of the five ways that unlabeled nucleotides can be brought into contact with the target—i.e., adding the nucleotides one at a time—because the specification does not explain how to monitor the sequential incorporation of unlabeled nucleotides when multiple nucleotides are added at once.

Although Romesberg, Illumina's expert, contends that there are five methodologies that

can be used to monitor the sequential incorporation of unlabeled nucleotides, he admits that four of these—gel electrophoresis, pyrosequencing, intercalating dyes, and high performance liquid chromatography ("HPLC")—require that each nucleotide type be added one at a time. *See* Romesberg Rebuttal Rep. ¶¶ 212–13, 218, 223, 226–27; Dkt. No. 409-4 ("Romesberg Tr.") at 277:15-278:2, 304:9-24; 306:18-24, 307:4-6, 308:5-9. BGI explains that this is because when more than one unlabeled nucleotide, i.e., one type of base, is added and there is incorporation, "there is no way to tell which base was incorporated" if more than one nucleotide is added at a time. Mot. at 3. The fifth methodology is called mass spectrometry, under which multiple nucleotides can be added simultaneously. Romesberg Rebuttal Rep. ¶ 225. But, it asserts, the "teaching for enablement must emanate from the specification itself and not novel inventions by those of skill in the art" and in this case the specification does not mention mass spectrometry. Reply at 5; *see Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (holding that although "a specification need not disclose what is well known in the art" this rule "means that the omission of minor details does not cause a specification to fail to meet the enablement requirement" but it is "not a substitute for a basic enabling disclosure."). As a result, it argues that the '973 specification does not teach a POSITA how to make and use the full scope of the claimed invention.

BGI's enablement argument relies on a conclusion that claims 1 and 13 require that multiple unlabeled nucleotides be brought to the target simultaneously, which is not the case here. As Illumina contends, BGI's arguments are irrelevant because they concern a "small, artificial subset of 'corner case' combinations involving numerous *unclaimed* aspects" that do not "negate the fact that the full scope of the *claimed* method is sufficiently enabled and described." Opp. at 8 (emphasis in original). Claim 1 recites, "A method for determining the sequence of a target single-stranded polynucleotide, comprising monitoring the sequential incorporation of complementary nucleotides" and claim 13 recites, "The method of claim 1 wherein Z is an azidomethyl group." '973 Patent at 86:24-26, 88:37-38. As explained above, I previously held that no construction was necessary for the claim 1 language and rejected BGI's construction, which required the use of labeled nucleotides and that labeling must occur prior to incorporation.

Claim Construction Order at 10–12.

Although I rejected BGI's limitation and construed the claim to allow the use of unlabeled nucleotides, neither claim requires the use of multiple unlabeled nucleotides that are added simultaneously to determine the sequence of a single-stranded polynucleotide. BGI does not dispute that the claims are sufficiently described and enabled for all embodiments in which the nucleotides, whether labeled or unlabeled, are added sequentially. It also does not dispute that the claims are sufficiently enabled for all embodiments in which labeled nucleotides are added, whether sequentially or simultaneously. It only disputes that the claims are not enabled where unlabeled nucleotides are added simultaneously. While it argues that there does not need to be a positive recitation of elements in the claims for there to be a requirement that the elements be enabled, whether the nucleotides are added sequentially or simultaneously is not a part of the claims.

The cases on which BGI relies are distinguishable because the courts in those cases had construed the claims to require the elements at issue; in this case, the claims do not require the allegedly inoperable element (the simultaneous addition of unlabeled nucleotides). In *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1378 (Fed. Cir. 2007), the invention concerned a method for loading a syringe into a high pressure power injector to inject fluid into an animal. *Liebel-Flarsheim*, 481 F.3d at 1373. The district court had construed the asserted claims to not require a pressure jacket. *Id.* at 1374. The Federal Circuit affirmed the district court's decision that the claims were invalid because the patent did not enable an invention with a jacketless injector and such a system could not have been produced at the time of filing. *Id.* at 1380. In *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 1000 (Fed. Cir. 2008), the technology at issue involved integrating a user's audio signal or visual image into a pre-existing video game or movie. *Sitrick*, 516 F.3d at 995. The district court had construed the asserted claims to include both video games and movies. *Id.* at 999. The Federal Circuit affirmed the district court's holding that the patents at issue did not enable the full scope of the asserted claims because the patents' specifications did not teach "how the substitution and integration of a user image would be accomplished in movies." *Id.* at 1000. Likewise, in *Trustees of Bos. Univ. v. Everlight Elecs. Co.*,

896 F.3d 1357 (Fed. Cir. 2018), the embodiment at issue was claimed because the embodiment was one of six permutations from the district court's construction of two claim terms. 896 F.3d at 1360. The Federal Circuit held that embodiments that are claimed but cannot be enabled lead to an invalid claim. *Id.* at 1364.

Unlike those cases, the allegedly inoperable embodiment here is outside the claim scope. *See McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1101 (Fed. Cir. 2020) (declining to find non-enablement where the techniques at issue were outside the claim scope and distinguishing *Siltrick* and *Boston University* as cases that "involved specific identification of products or processes that were or may be within the scope of the claims"). The '973 Patent teaches how to use labeled and unlabeled nucleotides to determine a sequence, as the claims require. BGI admits that the '973 Patent describes one embodiment that fully allows for the addition of multiple unlabeled nucleotides, i.e., the sequential addition of unlabeled nucleotides. It contends that the '973 Patent does not enable four other embodiments, i.e., the simultaneous addition of unlabeled nucleotides, because adding unlabeled nucleotides all at once would make it impossible to determine the sequence of the polynucleotide, as the claims require. Mot. at 3. But if the allegedly inoperable embodiments do not satisfy the claims then they are outside the scope of the claims and do not have to be enabled. *See Application of Geerdes*, 491 F.2d 1260, 1265 (C.C.P.A. 1974) (holding that the patent enabled the scope of the claims and disagreeing with the determination "that the claims are inclusive of materials which would not apparently be operative in the claimed process" because the "use of materials which might prevent achievement of the objective (by rendering the process inoperative) can hardly be said to be within the scope of the claims"). Accordingly, BGI's argument that the specification does not enable the full scope of the claims fails.

2. There Are Genuine Disputes of Material Fact

Even if the claims required the simultaneous addition of unlabeled nucleotides, BGI's motion would fail because there are genuine disputes of material fact about whether there is such an embodiment in the specification. Illumina contends that BGI ignores an embodiment in the '973 Patent involving incorporating unlabeled nucleotides, even when they are added all at once.

Opp. at 9. Specifically, the specification "discloses examples in which the detected fluorescent label is attached to the nucleotide after incorporation." Romesberg Rebuttal Rep. ¶ 229 (citing '973 Patent at 15:52-60). Romesberg also notes that a POSITA "would have known that these detection techniques could be further adapted as needed, depending on the desired protocol being used. These adaptations would be similar to the procedures used for an ELISA (enzyme-linked immunosorbent assay) that is ubiquitously used by thousands of labs across the world." *Id.* Based on these statements, Illumina contends that a POSITA would understand that the methodology could be modified to use, for example, four antibodies specific to each nucleotide, which would help identify the nucleotide when the specific antibody attached after incorporation. Opp. at 9. Using four nucleotide-specific antibodies would allow a POSITA to add four nucleotides at once. *Id.* Therefore, Illumina argues that the '973 Patent describes a way to monitor the sequential incorporation of complementary nucleotides when multiple unlabeled nucleotides are simultaneously added.

BGI counters that the '973 Patent describes this method as using labeled nucleotides and that Romesberg's report does not describe the use of nucleotide-specific antibodies. Reply at 4. It says that the section of the '973 Patent that Romesberg relies on "defines the component that is attached to the nucleotide when it is incorporated in the multi-component label as the label, not the component added later" and therefore describes the use of labeled nucleotides. *Id.* (citing '973 Patent at 15:52-60). Illumina responds that this section describes the use of unlabeled nucleotides and therefore there is a genuine issue of what a POSITA would understand the specification to disclose.

BGI also argues that Romesberg does not state that this methodology could be modified to use four antibodies and therefore Romesberg does not find that a POSITA would understand to use the simultaneous addition of unlabeled nucleotides under the '973 Patent. *Id.* at 5. Although I agree that Romesberg does not mention the use of four antibodies, he does explain that a POSITA could further adapt the detection techniques as needed. This raises the issues of whether the disclosed embodiment could be adapted, e.g., modified by other techniques known in the art, and whether a POSITA would recognize that it could be used to incorporate unlabeled nucleotides

simultaneously. *See* Opp. at 10. Moreover, the question of whether a POSITA would be able to practice the claimed invention without "undue experimentation" remains; BGI did not address this factor, which is a necessary component to finding that a claim is invalid for lack of enablement. *Enzo Life*, 928 F.3d at 1345. BGI's motion fails because even if the claims required the simultaneous addition of unlabeled nucleotides, genuine disputes of material fact remain.

C. Whether the '973 Claims Satisfy the Written Description Requirement

The parties also dispute whether claims 1 and 13 of the '973 Patent are invalid for lack of written description. The test for written description is whether the specification would have objectively demonstrated to a POSITA that the patent applicant actually invented, or "possessed," the claimed subject matter when the patent application was filed. *See Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014). BGI asserts that the '973 Patent fails the written description requirement because there is no disclosure in the '973 specification for how to do sequential monitoring using multiple unlabeled nucleotides that were added simultaneously and at the time the '973 Patent was filed, there was no established method for doing so and no inventor would have contemplated such an approach. Mot. at 9; *see* Dkt. No. 408-6 ("Balasubramanian Tr.") at 311:6-25, 389:2-11; Dkt. No. 408-12 ("Wu Tr.") at 53:23–54:1; Dkt. No. 408-14 ("Liu Tr.") at 314:7–317:11. But for the reasons above, there is a genuine dispute of whether the specification discloses the contested combination. In addition, Illumina points out that BGI only relies on the testimony of three out of the seven inventors, which undermines BGI's assertion that no inventor contemplated the embodiment at issue. Reply at 18.

For all of these reasons, I DENY BGI's motion that the '973 Patent is invalid.

III. WHETHER BGI'S COOLMPS INFRINGES THE '025 PATENT

BGI asserts that its CoolMPS cannot infringe Illumina's '025 Patent because the CoolMPS "uses detectable antibody complexes for detection that bind to the nucleotides at *both* the base and the sugar" whereas the '025 Patent is "directed to modified nucleotides having a detectable label attached to the *base*, and *not* the sugar." Mot. at 10–11. Illumina contends that BGI's argument improperly adds an extraneous limitation to the claims: the claims recite "a ribose or deoxyribose sugar moiety and a base linked to a detectable label via a cleavable linker," '025 Patent at 21:19-

21, but BGI argues that the claims require that a detectable label be linked "only" to the base and not the sugar. Opp. at 18. The specification clearly disavows the attachment of the label to the sugar and there is no factual dispute that the CoolMPS attaches labels to the sugar. As a result, there can be no literal infringement of the '025 Patent and Illumina is estopped from pursuing its doctrine of equivalents ("DOE") claim.

A. BGI Did Not Waive Its Non-Infringement Argument

First, Illumina contends that BGI waived its non-infringement argument because it did not raise its proposed construction of "a base linked to a detectable label" at claim construction and that I should not consider BGI's "untimely claim construction argument for purposes of summary judgment." Opp. at 19. But BGI's argument is a request for an evaluation of non-infringement, not a request for claim construction. *See* Reply at 8. It does not seek a construction that "a base linked to a detectable label" means a detectable label that is linked only to the base and not the sugar. Instead, it seeks a finding of non-infringement based on the plain meaning of the claim term. *Id.* A court will not refuse to "consider the parties' summary judgment arguments merely because an apparent dispute has arisen about the scope of a term's plain and ordinary or construed meaning." *Apple, Inc. v. Samsung Elecs. Co.,* No. 12-CV-00630-LHK, 2014 WL 252045, at *4 (N.D. Cal. Jan. 21, 2014).

I will "view the parties' disputes through the lens of whether a reasonable jury, armed with the Court's claim construction as to certain terms and an instruction that the plain and ordinary meaning controls as to others, could or would necessarily conclude that the asserted claim reads on an accused device (or that a prior art reference reads on an asserted claim)."[3] *Apple*, 2014 WL

[3] Two of the cases that Illumina relies on are distinguishable because they concern parties who requested claim construction during or after summary judgment. *See, e.g.*, *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 640-41 (Fed. Cir. 2011) (affirming the district court's decision that a party "could not add new claim construction theories on the eve of trial."); *Power Integrations, Inc. v. ON Semiconductor Corp.*, 396 F. Supp. 3d 851, 864 (N.D. Cal. Aug. 22, 2019) (the defendant wanted to bind the plaintiff to a proposed construction the plaintiff made to the Patent Trial and Appeal Board but had not argued for during the claim construction hearing). The other two cases that Illumina relies on support BGI's argument because they apply the plain meaning analysis at the summary judgment stage. *See, e.g.*, *Apple*, 2014 WL 252045, at *5; *Finisar Corp. v. Nistica, Inc.*, No. 13-CV-03345-BLF, ECF 551-3 at 7–9 (Apr. 4, 2016).

252045, at *5; *see, e.g.*, *Huawei Techs., Co, Ltd v. Samsung Elecs. Co, Ltd.*, 340 F. Supp. 3d 934, 948 (N.D. Cal. 2018). In determining the plain and ordinary meaning, I will look to "[t]he written description and other parts of the specification" for "contextual light[.]" *Aventis Pharm. Inc. v. Amino Chemicals Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013).

B. The CoolMPS Does Not Infringe the '025 Patent

Illumina alleges that the CoolMPS infringes claims 1–2, 4–5, 7–8, and 14–17 of the '025 Patent. Dkt. No. 214-8 ("Illumina's Patent L.R. 3-1 Disclosures"). The asserted claims recite "a ribose or deoxyribose sugar moiety and a base linked to a detectable label via a cleavable linker." '025 Patent at 21:19-21. BGI argues that its CoolMPS cannot infringe the '025 Patent because the "claims of the '025 patent are directed to modified nucleotides having a detectable label attached to the *base*, and *not* the sugar" and the CoolMPS "uses detectable antibody complexes for detection that bind to the nucleotides at *both* the base and the sugar." Mot. at 10–11. BGI points to disclosures in the specification to support its argument that the '025 Patent does not allow for the label to be linked to the sugar. Illumina disagrees and contends that the plain meaning of the claims only requires that the "antibody label is linked to *at least* the base, which satisfies the limitation at issue." Opp. at 18; Dkt. No. 419-6 ("Romesberg Rep.") ¶¶ 180–96.

1. There Is A Clear and Unequivocal Disclaimer of Claim Scope

The parties first dispute what the correct legal standard is for disavowal. Illumina contends that the disclosures in the specification, which BGI relies on, are preferred embodiments and so for BGI to construe the claim terms in light of these preferred embodiments, BGI must describe the preferred embodiment as the invention itself. Opp. at 21 (citing *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1305 (Fed. Cir. 2003)). But BGI is not arguing for a narrow construction based on a preferred embodiment in the specification. Rather, BGI argues that under the plain meaning of the claim terms in light of the specification, the claims require the base-only limitation.

As a result, the correct legal standard for disavowal is a "clear and unequivocal" disclaimer of claim scope. It is well-established that, "[c]laims must be read in view of the specification, of which they are a part." *Markman v. Westview Instruments*, 52 F.3d 967, 979–80 (Fed. Cir. 1995),

aff'd, 517 U.S. 370 (1996). "One purpose for examining the specification is to determine if the patentee has limited the scope of the claims." *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882 (Fed. Cir. 2000). The written description and other parts of the specification "cannot be used to narrow a claim term to deviate from the plain and ordinary meaning unless the inventor acted as his own lexicographer or intentionally disclaimed or disavowed claim scope." *Aventis*, 715 F.3d at 1373. "Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001). Accordingly, BGI does not need to show that the '025 Patent describes the preferred embodiment as the invention itself; it needs to show that there is a clear and unequivocal disclaimer of the claims' scope.

The specification makes clear that the invention does not include scenarios where the detectable label is linked to the sugar. For example, the "Summary of the Invention" section of the specification recites, "In the present invention, a nucleoside or nucleotide molecule is linked to a detectable label via a cleavable linker group attached to the base." '025 Patent at 2:22-24. Specifically, "[t]he molecules of the present invention are in contrast to the prior art, where the label is attached to the ribose or deoxyribose sugar." '025 Patent at 2:35-38. The "Description of the Drawings" section of the specification says the same. *See id.* at 8:28-29 ("In contrast to the prior art, there is no detectable label attached at the ribose 3′ position."). The same section goes on to explain that, "This ensures that steric hindrance with the polymerase enzyme is reduced, while still allowing control of incorporation using the protecting group." *Id.* at 8:29-32. In the following paragraph, the specification recites:

> "The skilled person will appreciate how to attach a suitable protecting group to the ribose ring to block interactions with the 3'-OH. The protecting group can be attached directly at the 3' position, or can be attached at the 2' position (the protecting group being of sufficient size or charge to block interactions at the 3' position). Alternatively, the protecting group can be attached at both the 3' and 2' positions, and can be cleaved to expose the 3'OH group."

Id. at 8:33-40.

Illumina points to this language to argue that "[b]locks can be attached to the sugar at the 2' or 3' position (or both)." Opp. at 22. It then points to a different section of the specification that describes an embodiment where the label can "act as a block to the incorporation of a further nucleotide onto the nucleotide of the invention" "due to steric hindrance" or "to a combination of size, charge and structure." *Id.* at 6:28-33. It uses these two sections to undermine BGI's argument that the '025 Patent disavows embodiments where the label is attached to the sugar. Opp. at 22. But as BGI emphasizes, these sections "say[] nothing about the location where the label is attached as a factor for potential blocking, or that the label may be attached to the sugar group instead of just the base." Reply at 12.

In contrast, "this structural arrangement – where the label is attached to the base, and not the sugar – is repeated throughout the Summary of the Invention as a distinguishing feature." Reply at 10; *see* '025 Patent at 2:39-41, 2:42-44, 2:56-57, 3:9-10, 3:16-18, 4:9-11, 4:22-24. Illumina contends that these disclosures do not disavow embodiments where the label is attached to both the base and the sugar; at best, the disclosures only support that the label is at least linked to the base. Opp. at 21–22. But the disclaimer clearly excludes nucleotides or nucleosides with a label attached to the sugar. *See* '025 Patent at 8:28-29 ("In contrast to the prior art, there is no detectable label attached at the ribose 3′ position."); *see* Reply at 13. Further, there "is no requirement that a clear and unequivocal disclaimer include an express disavowal of every possible embodiment that falls outside the scope of the claims." Reply at 12 (citing *Astrazeneca AB v. Mut. Pharm. Co.,* 384 F.3d 1333, 1339 (Fed. Cir. 2004) (The patentee "seems to suggest that clear disavowal requires an 'expression of manifest exclusion or restriction' in the form of 'my invention does not include _____.' But again, such rigid formalism is not required.")). These disclosures constitute a clear and unequivocal disclaimer of embodiments where the label is attached to the sugar. *See SciMed* , 242 F.3d at 1341–45; *Poly-America*, 839 F.3d at 1136-37.

2. The CoolMPS Has a Label Attached to Both the Base and the Sugar

Then, if the CoolMPS has a label attached to both the base and the sugar, there would be no infringement of the '025 Patent, which disavows labels attached to the sugar. Contrary to

Illumina's assertions, there is no genuine dispute of material fact that the CoolMPS binds at both the base and the sugar. Romesberg relies on the *CoolMPS™: Advanced Massively Parallel Sequencing Using Antibodies Specific to Each Natural Nucleobase* (Feb. 20, 2020) article ("Dramanac Article"), which concludes that the label in the CoolMPS attaches to the sugar. Dkt. No. 409-9 (the "Drmanac Article") at 13. The Drmanac Article concludes that, "The monocolonal antibodies described in this report not only recognize the natural base type (whether it be A, C, G or T) but also bind to a small reversible blocking group at the 3' end of the nucleotide." *Id.* The Drmanac Article reaches this conclusion in part by relying on experiments reported in the paper and illustrated in Figure 4b, which show that the "[a]ntibody binding is dependent on both the base and the sugar with a 3'-O azidomethyl block." *Id.* at 7.

Illumina asserts that Romesberg disputes BGI's assertion that the antibody in CoolMPS is attached directly to the sugar. Opp. at 23. But when asked whether the antibody in the CoolMPS binds to the sugar, Romesberg admitted that "there must, in some way, be a direct interaction with the sugar." Romesberg Tr. at 212:21–23. In fact, Romesberg did not rebut the experimental results and conclusions in the Drmanac Article. *Id.* at 249:14-250:13 ("Q: You didn't say that statement is wrong, the antibodies are not binding to the sugar? A: No, I don't think in my – in my declaration I don't – I don't recall saying that."). BGI's expert, Dr. Michael Metzker also confirms in his report that the CoolMPS antibodies bind to both the base and the sugar. Dkt. No. 436-3 ("Metzker Rep.") at 10, 32–38. Contrary to Illumina's arguments, Romesberg's "unsupported musings at his deposition about the nature of the binding interaction between the CoolMPS antibodies and the sugar," i.e., whether the interaction is direct or indirect, does not create a genuine issue of material fact for trial. *See* Reply at 15. There is no factual dispute that the label in the CoolMPS attaches to both the base and the sugar. Therefore, the CoolMPS cannot literally infringe the '025 Patent.

3. Illumina Cannot Assert Infringement Under the Doctrine of Equivalents

BGI argues that (1) Illumina is estopped from arguing that the asserted claims of the '025 Patent encompass subject matter that was explicitly distinguished and disclaimed in the

specification and (2) Illumina cannot assert that the CoolMPS antibodies are equivalent to the claimed label because to do so would improperly vitiate the express limitation in the claims of the '025 Patent requiring the label to be attached to the base. Mot. at 11. The DOE prohibits capture of art or technology that the patent distinguishes from the claimed subject matter or criticizes in the specification. *See SciMed*, 242 F.3d at 1345–47 ("A particular structure can be deemed outside the reach of the doctrine of equivalents because that structure is clearly excluded from the claims whether the exclusion is express or implied.") (collecting cases).

As established above, the disavowal of a label attaching to the sugar is unequivocal in the specification of the '025 Patent. '025 Patent at 8:28-32. Contrary to Illumina's assertions, the disclosures in the specification are not "general statements" to improvements over the prior art but specific instructions to a POSITA what feature should be avoided, i.e., the attachment of the label to the sugar. *See* Opp. at 24; Reply at 13 n.10. As a result, Illumina "cannot now invoke the doctrine of equivalents to embrace a structure that was specifically excluded from the claims." *SciMed*, 242 F.3d at 1345 (internal quotation marks omitted).[4]

IV. MOTIONS TO SEAL

The parties have filed two motions to seal. *See* Dkt. Nos. 408, 419. A party seeking to seal court records must overcome a strong presumption in favor of the public's right to access those records. *See Ctr. for Auto Safety v. Chrysler Grp., LLC*, 809 F.3d 1092, 1096 (9th Cir. 2016), *cert. denied sub nom. FCA U.S. LLC v. Ctr. for Auto Safety*, 137 S. Ct. 38 (2016). Here, the "compelling reasons" standard applies. *See id.* at 1101. The Ninth Circuit has explained that examples of "compelling reasons" include "the use of records to gratify private spite, promote public scandal, circulate libelous statements, or release trade secrets." *Kamakana v. City & Cty. of Honolulu*, 447 F.3d 1172, 1179 (9th Cir. 2006). Other examples include "sources of business information that might harm a litigant's competitive standing." *Ctr. for Auto Safety*, 809 F.3d at

[4] Because I conclude that Illumina is estopped from pursuing its DOE theory, I will not address the vitiation argument—that Illumina's DOE argument fails because the label can be attached to both the sugar and the base under the '025 Patent, which would vitiate the limitation that the label be attached to the base as the only places that the label can be attached is the sugar or the base. *See* Mot. at 20–21.

1097. For the reasons explained in the table below, both administrative motions to seal are GRANTED in part and DENIED in part. *See* Dkt. Nos. 408, 419. The clerk shall UNSEAL Dkt. Nos. 408-4, 408-6, 408-8, 408-12, 408-14, 419-4, and 419-8.

Document	Portions to Be Filed Under Seal	Designating Party	Ruling
Dkt. No. 408 – GRANTED IN PART AND DENIED IN PART			
BGI's Motion for Summary Judgment	Highlighted portions	Illumina	**DENIED – The clerk shall UNSEAL Dkt. No. 408-4.** (Illumina does not redact these portions in its opposition.)
Exhibit 6	Entire document	Illumina	**DENIED – The clerk shall UNSEAL Dkt. No. 408-6.** (Illumina did not file a responsive declaration and the material does not appear to be sealable.)
Exhibit 7	Entire document	Illumina	**DENIED – The clerk shall UNSEAL Dkt. No. 408-8.** (Illumina did not file a responsive declaration and the material does not appear to be sealable.)
Exhibit 11	Highlighted portions	BGI	**GRANTED** (Discusses BGI's trade secrets and confidential information regarding its R&D.)
Exhibit 12	Entire document	Illumina	**DENIED – The clerk shall UNSEAL Dkt. No. 408-12.** (Illumina did not file a responsive declaration and the material does not

			appear to be sealable.)
Exhibit 13	Entire document	Illumina	**DENIED – The clerk shall UNSEAL Dkt. No. 408-14.** (Illumina did not file a responsive declaration and the material does not appear to be sealable.)
Dkt. No. 419 – GRANTED IN PART AND DENIED IN PART			
Illumina's Opposition to BGI's Motion for Summary Judgment	Portions of page 23	BGI	**DENIED – The clerk shall UNSEAL Dkt. No. 419-4.** (BGI does not seek to seal any portion of Illumina's opposition. Dkt. No. 426 at 1.)
Exhibit 5 to the Declaration of Andrew Gesior in Support of Opposition to BGI's Motion for Summary Judgment	Highlighted portions	BGI	**GRANTED** (Discusses BGI's trade secrets and confidential information regarding its R&D)
Exhibit 6 to the Declaration of Andrew Gesior in Support of Opposition to BGI's Motion for Summary Judgment	Entire Document	BGI	**DENIED – The clerk shall UNSEAL Dkt. No. 419-8.** (BGI does not seek to seal any portion of Exhibit 6. Dkt. No. 426 at 1.)

CONCLUSION

For the reasons above, BGI's partial motion for summary judgment is GRANTED in part and DENIED in part. BGI's motion for summary judgment on the invalidity of the '973 Patent is DENIED. BGI's motion for summary judgment on the CoolMPS products' non-infringement of the '025 Patent is GRANTED. The September 3, 2021 claims construction hearing is VACATED.

IT IS SO ORDERED.

Dated: August 27, 2021

William H. Orrick
United States District Judge