IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Regina M. Rodriguez

Civil Action No. 25-cv-03646-RMR-KAS

BIOMODAL LIMITED and
CHILDREN'S MEDICAL CENTER CORPORATION,

Plaintiffs,

v.

WATCHMAKER GENOMICS, INC.,

Defendant.

ORDER ADOPTING MAGISTRATE JUDGE RECOMMENDATION

This matter is before the Court on the Recommendation of United States Magistrate Judge Kathryn A. Starnella entered on September 2, 2026, ECF No. 50, addressing Defendant Watchmaker Genomics, Inc.'s ("Defendant" or "Watchmaker") Motion to Dismiss for Failure to State a Claim, ECF No. 18. Magistrate Judge Starnella recommends that Defendant's Motion be granted. Plaintiffs biomodal Limited ("biomodal") and Children's Medical Center Corporation ("CMCC") timely filed an objection to the Recommendation, ECF No. 59, and Defendant has not yet filed a response. The Court has received and considered the Recommendation, the objection, the record, and the pleadings. For the reasons stated below, the Court overrules Plaintiffs' objection and adopts the Recommendation.

I. BACKGROUND[1]

Epigenetics is the study of changes in gene expression that are not encoded in DNA. One of the most common epigenetic modifications is DNA methylation, the process where a methyl group is added to a cytosine. When a cytosine undergoes methylation, it may be converted to a 5-methylcytosine ("5mC"). This process occurs in nature, and another epigenetic modification can occur when enzymes contact and oxidize 5mC. Ten eleven translocation ("TET") enzymes exist naturally and convert 5mC to 5-hydroxymethylcytosine ("5hmC"). TET enzymes can also further oxidize 5hmC, resulting in 5-formylcytosine ("5fC") and 5-carboxylcytosine ("5caC").

Plaintiff biomodal develops, manufactures, and sells sequencing and computing platforms that provide genetic and epigenetic information. It is also the exclusive licensee of the asserted patents in this case. Plaintiff CMCC is a Massachusetts charitable corporation that legally co-owns the asserted patents by assignment. Plaintiffs' patents are directed to "a way to use catalytic fragments of TET enzymes to oxidize essentially all the naturally occurring 5mC in a polynucleotide" to "identify epigenetic methylation patterns in unmodified samples." ECF No. 50 at 3. Together, Plaintiffs allege that Defendant Watchmaker has infringed one or more claims of the asserted patents.

II. LEGAL STANDARD

The Court is required to make a de novo determination of those portions of a magistrate judge's recommendation to which a specific, timely objection has been made,

[1] The Court incorporates the "Background" section from the Recommendation, ECF No. 50 at 1-4, and the Motion, ECF No. 18 at 6-12.

and it may accept, reject, or modify any or all of the magistrate judge's findings or recommendations. 28 U.S.C. § 636(b)(1) ("A judge of the court shall make a de novo determination of those portions of the report or specified proposed findings or recommendations to which objection is made."); Fed. R. Civ. P. 72(b)(3) ("The district judge must determine de novo any part of the magistrate judge's disposition that has been properly objected to."). "[A] party's objections to the magistrate judge's report and recommendation must be both timely and specific to preserve an issue for de novo review by the district court or for appellate review." *United States v. One Parcel of Real Property*, 73 F.3d 1057, 1060 (10th Cir. 1996).

III. ANALYSIS

"Section 101 of the Patent Act defines the subject matter eligible for patent prosecution." *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014). The Supreme Court has long held that "[l]aws of nature, natural phenomena, and abstract ideas are not patentable." *Id.* (citing *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590 (2013)). In *Alice*, the Supreme Court also "set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Id.* at 217. The framework consists of two consecutive steps. First, courts must "determine whether the claims at issue are directed to one of those patent-ineligible concepts." *Id.* If the answer is "yes," the courts must "search for an 'inventive concept'—*i.e.*, an element or combination of elements that is sufficient to ensure that the patent in practice amounts to

significantly more than a patent upon the ineligible concept itself." *Id.* at 217-18 (citation omitted).

In the Recommendation, Magistrate Judge Starnella evaluates the patent eligibility of the asserted patent's claims under Section 101. First, she determines that the '320 Patent's claims are method claims directed to "identifying an epigenetic modification of a polynucleotide by taking a polynucleotide comprising an epigenetic modification, oxidizing it by bringing it into contact with an enzyme, and inducing an oxidized epigenetic modification thereby." ECF No. 50 at 8-9. Magistrate Judge Starnella notes that the process of oxidizing polynucleotides is naturally occurring and, thus, the '320 Patent claims are directed to unpatentable concepts. *Id.* at 9. She then determines that the '320 Patent claims also fail under *Alice* step two, because "Plaintiffs fail to explain why their supposedly 'innovative method' differs from simply reproducing an effect that occurs in nature under laboratory conditions." *Id.* at 13. Finally, Magistrate Judge Starnella applies largely the same analysis to the Claim 21 of the '742 Patent, with the caveat that Claim 21 is directed to a method that "converts *all* of a nucleic acid molecule's 5mC to an oxidized derivative thereof." *Id.* at 15. Ultimately, Magistrate Judge Starnella concludes that this distinction does not alter the *Alice* analysis, because (1) the '742 Claims only state "Plaintiffs' desired *result* of oxidizing all of the 5mC without providing any detail as to *how* the method is able to do so," *id.* at 16 (emphasis original), and (2) the "method asserted under the '742 Claims merely recites the mechanism that Plaintiffs' scientists observed in nature without requiring anything further," *id.* at 18. Finally, the Recommendation states that the same analysis applies to the unasserted patent claims.

Id. at 19-20. Thus, Magistrate Judge Starnella recommends Defendant's motion to dismiss be granted. *Id.* at 20.

Plaintiffs offer four objections: (1) that the Recommendation inappropriately resolved a disputed question of fact; (2) that the Recommendation's *Alice* step one analysis "fails to account for the chemically altered, non-natural state of the resulting molecule, which shows the claims are directed to a practical laboratory application rather than to the natural phenomenon itself"; (3) the Recommendation analyzed the patent's specification under 35 U.S.C. § 112, rather than patent eligibility; and (4) that the Recommendation "finds claims unpatentable without any claim-specific analysis for claims neither asserted nor argued in the Motion." ECF No. 59 at 5. The Court analyzes each objection below.

A. Disputed Question of Fact

Plaintiffs argue that, when evaluating a motion to dismiss, "the Court must accept Plaintiffs' well-pled factual allegations as true and may not resolve a genuine factual dispute against the plaintiff." *Id.* at 6 (citing *Well Master Corp. v. Flowco Prod. Sols., LLC*, 706 F. Supp. 3d 1213, 1217 (D. Colo. 2023)). Plaintiffs point to the Complaint, where they allege that "[i]n nature, TET enzymes do not convert all, or more than 98%, of the 5mC of a nucleic acid molecule to an oxidized derivative thereof." *Id.* (citing ECF No. 1 ¶ 14).

To start, the Court finds the Recommendation indeed provides the necessary support for its conclusion. *See* ECF No. 50 at 8 n.3. Magistrate Judge Starnella explains that "the focus in determining section 101 eligibility is on the language of the patent claims rather than the specification." *Id.* Indeed, the Court's Section 101 evaluation "may only

look to allegations in the sources properly considered on a motion to dismiss, such as the complaint, the patents, and materials subject to judicial notice." *Well Master Corp.*, 706 F. Supp. 3d at 1218. Thus, it was appropriate for Magistrate Judge Starnella to look beyond the Complaint and at the patent itself to determine the patent eligibility of the '320 Patent claims.

Second, the specific factual allegation Plaintiffs rely on does not entirely support their conclusion. Even if true, the fact that TET enzymes do not convert *all* of the 5mC of a nucleic acid molecule does not mean that TET enzymes do not convert *any* of the 5mC to an oxidized derivative. Viewed another way, Plaintiffs' allegation admits that, in nature, it is possible for TET enzymes to oxidize 5mC. Thus, the Recommendation did not err in finding that the '320 Patent claims are directed to natural phenomena, and Plaintiffs' first objection is OVERRULED.

B. *Alice* Step One

Next, Plaintiffs object to the Recommendation's application of *Chakrabarty* and the non-natural state of the claimed molecule. ECF No. 59 at 7-14. Indeed, in *Chakrabarty*, the Supreme Court established that claims are directed to patentable subject matter when they are "not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity having a distinctive name, character and use." *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980). Plaintiffs contend that the asserted claims "recite steps that produce a polynucleotide (or nucleic acid molecule) with 'markedly different characteristics from any found in nature and one having the potential for significant utility.'" ECF No. 59 at 7-8 (quoting

Chakrabarty, 447 U.S. at 310). Plaintiffs do not explain or identify the "markedly different characteristics." And, while Claim 1 of the '320 Patent describes "oxidized epigenetic modification," it does not recite any markedly different characteristics of the oxidized epigenetic modification. *See* ECF No. 1-1 at 173 (Claim 1 of the '320 Patent).

Plaintiffs attempt to compare the asserted claims to those described in *CellzDirect*. In *CellzDirect*, the asserted claim recited "[a] method of producing a desired preparation of multi-cryopreserved hepatocytes." *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1046 (Fed. Cir. 2016). The Federal Circuit applied *Alice* step one and determined that the claims were "directed to a new and useful laboratory technique for preserving hepatocytes," because "[t]he method requires an artisan to carry out a number of concrete steps to achieve the desired preparation." *Id.* at 1047-48. The claim in *CellzDirect* recited "hepatocytes being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw," subjecting the hepatocytes "to density gradient fractionation to separate viable hepatocytes," "recovering the separated viable hepatocytes," and "cryopreserving the recovered viable hepatocytes" without plating the hepatocytes between the first and second cryopreservation. *Id.* at 1046. In other words, the *CellzDirect* claim described steps of human intervention to achieve the desired preparation and, as a result, transformed the natural process of "multiple freeze-thaw cycles" into patentable subject matter. Here, the asserted claim language does not describe such steps of human intervention. Claim 1 of the '320 Patent is devoid of steps that describe human action,

such as "recovering," "cryopreserving" or "separating." Thus, the Court is not persuaded that the asserted claims in this case are similar to those of *CellzDirect*.

Plaintiffs argue that a person of ordinary skill in the art ("POSA") would "readily understand that "[o]xidizing the 5mC in a polynucleotide (or nucleic acid molecule) significantly alters it into something that does not occur in nature." ECF No. 59 at 9-10. However, as explained above, Plaintiffs' Complaint alleges that, in nature, TET enzymes indeed convert at least some of the 5mC of a nucleic acid molecule to an oxidized derivative thereof. ECF No. 1 ¶ 14. Thus, even considering Plaintiffs' factual allegations as true, the Court is unpersuaded by Plaintiffs' argument.

C. Component-by-Component Approach

Plaintiffs' next objection is directed to the Recommendation's consideration of each step of the asserted claims separately. ECF No. 59 at 10. Plaintiffs allege "[t]he claimed inventions are directed to a multi-step laboratory procedure wherein an existing polynucleotide (claim 1, step (a) of the '320 Patent, including by sequencing as recited in claim 4) or an existing nucleic acid molecule (claim 21 of the '742 Patent) is oxidized to create a non-naturally occurring modified polynucleotide/nucleic acid which is then exploited in a subsequent step to identify the epigenetic modification of the starting material (claim 1, step (c) of the '320 Patent) or to obtain the sequence of the nucleic acid molecule (claim 30 of the '742 Patent)." *Id.* at 11. And, according to Plaintiffs, "the Recommendation's analysis stops at the oxidation step and ignores the claim steps wherein the modified (non-naturally occurring) polynucleotide or nucleic acid is used to achieve the identification of the epigenetic pattern or sequence." *Id.* However, part (c) of

Claim 1 recites "using said oxidized epigenetic modification or derivative thereof to identify said epigenetic modification of said polynucleotide." ECF No. 1-1 at 173. As explained above, oxidized epigenetic modifications can occur in nature. Thus, without further explanation from Plaintiffs, the Court does not find that "using said oxidized epigenetic modification" to "identify said epigenetic modification" suddenly makes Claim 1 directed to patentable subject matter. The "identification" described in part (c) of Claim 1 is vague and does not describe a step of human intervention step like the *CellzDirect* claim. Therefore, the Court is similarly unpersuaded by Plaintiffs' objection regarding the Recommendation's component-by-component approach.

D. Claim Construction Preceding Section 101 Determination

Plaintiffs rely on the Federal Circuit's decision in *Bancorp Services* for the proposition that "the Court should not resolve patent eligibility before claim construction occurs." ECF No. 59 at 14. However, Plaintiffs fail to include in their explanation that the Federal Circuit also stated "we perceive no flaw in the notion that claim construction is not an inviolable prerequisite to a validity determination under § 101." *Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Canada (U.S.)*, 687 F.3d 1266, 1273 (Fed. Cir. 2012). The Federal Circuit clarified that, while "desirable—and often necessary," it is not a prerequisite to determine claim construction prior to Section 101 analysis. *Id.* Thus, the Court is unpersuaded by Plaintiffs' objection.

E. Section 112

Plaintiffs contend the Recommendation inappropriately evaluates the '320 Patent and '742 Patent disclosures under Section 112 for the Section 101 patent eligibility

analysis. ECF No. 59 at 14-15. Plaintiffs misinterpret the Recommendation's analysis. Magistrate Judge Starnella "concludes that the '742 Patent Claims, like the '320 Patent Claims, are directed at a patent-ineligible concept," because "the '742 Patent Claims neither address nor explain *how* the stated result of "all" the naturally occurring 5mC in the nucleic sample being oxidized is achieved." ECF No. 50 at 16. The Recommendation explains that a "claim must have the specificity required to transform the claim from one claiming only a result to one claiming a way of achieving it." *Id.* (citing *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1167 (Fed. Cir. 2018). Plaintiffs appear to conflate the Recommendation's reference to "specificity" as an analysis of the patent's specification under Section 112. Indeed, Section 112(a) states a patent's "specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains." 35 U.S.C. § 112. However, in this case, the Recommendation references "specificity" to explain that Plaintiffs' asserted claims lack the specificity required to be something more than abstract. *See SAP Am.*, 898 F.3d at 1167 (concluding the asserted claims "avoided being 'abstract,'" because "they had the specificity required to transform a claim from one claiming only a result to one claiming a way of achieving it."). Thus, the Court is not persuaded that the Recommendation inappropriately analyzed the patent's specification in its Section 101 analysis.

F. Unasserted Claims

Finally, Plaintiffs assert that the Recommendation erred by "neither identif[ying] nor analyz[ing] the additional elements recited in the unasserted claims of either patent,

and merely stat[ing] that the Court would nonetheless apply the same analysis and would reach the same conclusions." ECF No. 59 at 16. Plaintiffs accuse the Recommendation of "violat[ing] both § 282(a)'s claim-by-claim presumption of validity and the due-process requirement that a party have notice and an opportunity to be heard on the specific claims at issue." *Id.* Plaintiffs' argument is unsupported by case law demonstrating that the Court must evaluate unasserted patent claims. Further, the Recommendation explains that, even when reviewing the unasserted claims, the unasserted claims lack any additional step that describes human intervention that would convert the subject matter from naturally occurring 5mC to patentable subject matter. *Id.* at 19. Therefore, Plaintiffs' final objection is overruled.

IV. CONCLUSION

For the reasons set forth, the Court ORDERS:

1. Plaintiffs' Objection to the Recommendation, ECF No. 59, is OVERRULED;
2. The Recommendation, ECF No.50, is ACCEPTED AND ADOPTED;
3. Defendant's Motion to Dismiss, ECF No. 18, is GRANTED; and
4. Plaintiffs' Complaint, ECF No. 1, is DISMISSED WITHOUT PREJUDICE.

DATED: September 30, 2026

BY THE COURT:

REGINA M. RODRIGUEZ
United States District Judge