IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

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

BIOMODAL LIMITED and
CHILDREN'S MEDICAL CENTER CORPORATION,

Plaintiffs,

v.

WATCHMAKER GENOMICS, INC.,

Defendant.

RECOMMENDATION OF UNITED STATES MAGISTRATE JUDGE

ENTERED BY MAGISTRATE JUDGE KATHRYN A. STARNELLA

This matter is before the Court on the **Motion to Dismiss for Failure to State a Claim** [#18] (the "Motion") filed by Defendant Watchmaker Genomics, Inc. Plaintiffs biomodal Limited ("biomodal") and Children's Medical Center Corporation ("CMCC") filed a joint Response [#31] to the Motion [#18]. Defendant filed a Reply [#35].

For the following reasons, the Court **RECOMMENDS** that the Motion [#18] be **GRANTED** and that Plaintiffs' Complaint [#1] be **dismissed without prejudice**.

I. Background

Plaintiff biomodal is a corporation organized under the laws of the United Kingdom that develops, manufactures, and sells sequencing and computing platforms that provide genetic and epigenetic information. *Compl.* [#1] ¶ 4. Plaintiff biomodal is the exclusive licensee of the patents at issue. *Id*. Plaintiff CMCC is a Massachusetts charitable corporation, and, by assignment, it legally co-owns the patents at issue. *Id*. ¶ 5. Defendant Watchmaker is a Delaware company with a principal place of business in Boulder,

Colorado. *Id*. ¶ 6. Plaintiffs allege that Defendant Watchmaker has infringed one or more claims of the patents at issue. *Id*.

The technology at issue relates to epigenetics. *See id.* ¶ 12. "Epigenetics is the study of changes in gene expression that are not encoded in DNA—in other words, how environmental and behavioral factors impact the function of genes without changing the underlying sequence of the DNA. *See Biomodal Ltd. v. New England Biolabs, Inc.*, 757 F. Supp. 3d 182, 185 (D. Mass. 2024). Such changes can create significant impacts in the body and can signal the presence of diseases such as cancer.

"One of the most common epigenetic modifications is the methylation of DNA." *Id*. DNA methylation occurs when a methyl group is added by the cell to cytosine, one of four DNA bases. *Motion* [#18] at 9[1] (citing *Compl.* [#1] ¶¶ 12-16. When cytosine undergoes methylation, it is sometimes converted to 5-methylcytosine ("5mC"). *Id*. (citing *Compl.* [#1] ¶ 12; '320 patent at 12:53-55). This process occurs in nature, including in the human body. *Id*. (citing *Compl.* [#1] ¶¶ 12-13; '320 patent at 12:59-61). Another epigenetic modification occurs when enzymes, specifically ten eleven translocation ("TET") enzymes, contact and oxidize 5mC. *Id*. (citing *Compl.* [#1] ¶ 13; '320 patent at 12:39-45). TET enzymes also exist naturally and convert 5mC to 5-hydroxymethlcytosine ("5hmC") through this oxidization process; accordingly, 5hmC is also naturally occurring. *Id*. at 9-10 (citing *Compl.* [#1] ¶ 13; '320 patent at 12:39-45, 28:36). TET enzymes can also further oxidize 5hmC, resulting in 5-formylcytosine ("5fC") and 5-carboxylcytosine ("5caC"). *Id*. at 10 (citing *Compl.* [#1] ¶ 13).

[1] Citations to the page numbers of the parties' briefs refer to the numbering stamped at the top of each page by the court's docketing system.

The inventors of Plaintiffs' patents first discovered that 5hmC naturally occurs in the genome due to this oxidization process. *Id*. ¶ 13. However, Plaintiffs assert that in nature, TET enzymes do not convert an entire nucleic acid molecule, or polynucleotide, to an oxidized derivative thereof, and more specifically, such enzymes never convert more than 98% of the 5mC of a nucleic acid molecule. *Id*. ¶ 14.

Plaintiffs allege that based on the inventors' discovery, the inventors devised a way to use catalytic fragments of TET enzymes to oxidize essentially all the naturally occurring 5mC in a polynucleotide. *Id*. ¶ 13; *see Response* [#31] at 16. The inventors subsequently were able to utilize these modified polynucleotides to identify epigenetic methylation patterns in unmodified samples. *Compl.* [#1] ¶ 19; *Response* [#31] at 16.

Plaintiffs accordingly claimed a series of patents, two of which are at issue here: the '320 Patent and the '742 Patent (together, the "Asserted Patents"). *See Compl.* [#1] ¶¶ 33-50. Claims 1, 2, 3, 4, 6, and 11 of the '320 Patent (the "'320 Patent Claims") state as follows:

> 1. A method comprising: (a) providing (i) a polynucleotide comprising an epigenetic modification and (ii) an enzyme or a catalytically active fragment thereof and contacting said polynucleotide with said enzyme or said catalytically active fragment thereof; (b) oxidizing said epigenetic modification of said polynucleotide using said enzyme or said catalytically active fragment thereof to generate an oxidized epigenetic modification; and (c) using said oxidized epigenetic modification or derivative thereof to identify said epigenetic modification of said polynucleotide.
>
> 2. The method of claim 1, wherein, prior to (a), said polynucleotide is isolated from an extracellular fluid.
>
> 3. The method of claim 1, wherein said epigenetic modification comprises methylation.
>
> 4. The method of claim 1, wherein (c) comprises sequencing.

> . . . .
>
> 6. The method of claim 1, wherein said enzyme comprises an active ten-eleven translocation (TET) family enzyme.
>
> . . . .
>
> 11. The method of claim 1, wherein said oxidized epigenetic modification is generated by more than one oxidation reaction.

See Ex. 1 to Compl. - '320 Patent [#1-1] at col. 221 *l.* 1-col. 222 *l.* 11. Claims 21 and 30 of the '742 Patent (the "'742 Patent Claims"; together with the '320 Patent Claims, the "Patent Claims") state as follows:

> 21. A method comprising: contacting a nucleic acid molecule comprising cytosine and 5-methylcytosine with an isolated enzyme comprising a TET polypeptide, a catalytically active fragment thereof, a variant thereof, or any combination thereof in an amount effective to convert all of said 5-methylcytosine of said nucleic acid molecule to an oxidized derivative thereof.
>
> . . . .
>
> 30. The method of claim 21, further comprising conducting a sequencing reaction to obtain a sequence of the nucleic acid molecule.

See Ex. 2 to Compl. - '742 Patent [#1-2] at col. 158, *l.* 21, 30.

Plaintiffs allege that Defendant created a product that infringes the Asserted Patents. In Count One of the Complaint [#1], Plaintiffs allege that Defendant violated the '320 patent, including "at least" Claims 1, 2, 3, 4, 6, and 11. *Compl.* ¶ 35. In Count Two, Plaintiffs allege that Defendant has violated the '742 patent, including "at least" claims 21 and 30. *Id*. ¶ 44. In its Motion [#18], Defendant argues that the Asserted Patents embody unpatentable subject matter under 35 U.S.C. § 101 and that therefore, Plaintiffs' claims against Defendant must be dismissed. *See generally Motion* [#18].

II. Standard of Review

Fed. R. Civ. P. 12(b)(6) permits dismissal of a claim where the plaintiff has "fail[ed] to state a claim upon which relief can be granted." The Rule 12(b)(6) standard tests "the sufficiency of the allegations within the four corners of the complaint after taking those allegations as true." *Mobley v. McCormick*, 40 F.3d 337, 340 (10th Cir. 1994). "A complaint must contain 'enough facts to state a claim to relief that is plausible on its face.'" *Santa Fe All. for Pub. Health & Safety v. City of Santa Fe*, 993 F.3d 802, 811 (10th Cir. 2021) (quoting *Twombly*, 550 U.S. at 570). "When the complaint includes 'well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.'" *Carraway v. State Farm & Cas. Co.*, No. 22-1370, 2023 WL 5374393, at *4 (10th Cir. Aug. 22, 2023) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)).

"A pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do . . . . Nor does a complaint suffice if it tenders naked assertion[s] devoid of further factual enhancement." *Iqbal*, 556 U.S. at 678 (internal quotation marks omitted). "[D]ismissal under Rule 12(b)(6) is appropriate if the complaint alone is legally insufficient to state a claim." *Brokers' Choice of Am., Inc. v. NBC Universal, Inc.*, 861 F.3d 1081, 1104-05 (10th Cir. 2017). "The court's function on a Rule 12(b)(6) motion is not to weigh potential evidence that the parties might present at trial[.]" *Sutton v. Utah State Sch. for the Deaf & Blind*, 173 F.3d 1226, 1236 (10th Cir. 1999).

III. Analysis

A. Relevant Standard for Patent Invalidity Defense

U.S. patents are presumed valid, as are individual patent claims:

> A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

35 U.S.C. § 282(a). Further, "[w]hile 'any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,' may be eligible for patent protection, 35 U.S.C. § 101, 'laws of nature, natural phenomena, and abstract ideas' are not patentable[.]" *Biomodal Ltd.*, 757 F. Supp. 3d at 187 (quoting *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 566 U.S. 66, 70 (2012) (other citations omitted)).

Defendant principally argues that Plaintiffs' Asserted Patents are for natural phenomena instead of a new process or composition. The Court must first determine what legal standards apply in this context. The parties refer to the two-step *Alice*/*Mayo* framework set forth in *Alice*/*Mayo* to evaluate subject matter eligibility:

> First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, "[w]hat else is there in the claims before us?" To answer that question, we consider the elements of each claim both individually and "as an ordered combination" to determine whether the additional elements "transform the nature of the claim" into a patent-eligible application. We have described step two of this analysis as a 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."

Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 217-218 (2014) (quoting *Mayo*, 566 U.S. at 72-73, 78, 79); *see, e.g.*, *Motion* [#18] at 13. However, Plaintiffs imply that the Court should apply the *Myriad*/*Chakrabarty* "markedly different characteristics" test instead, *see, e.g.*, *Response* [#31] at 19-24, while Defendant argues that Plaintiffs' preferred test

applies to "composition" claims and that Plaintiffs' Patent Claims are instead "method" claims. *See, e.g.*, *Reply* [#35] at 5-8.

In support of the "markedly different characteristics" test, Plaintiffs cite *REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*, 167 F.4th 1206 (Fed. Cir. 2026). However, that court applied the markedly different characteristics test to a composition claim and, here, Plaintiffs' claims are method claims. *REGENXBIO*, 167 F.4th at 1213-15; *see also id*. at 1216 (applying *Alice/Mayo* framework, "*if* resort to [it] . . . is necessary." *Id*. at 1216 (emphasis added). Each individual Patent claim specifies clearly and without reservation that it is for "[a] method" or "[t]he method" rather than for a composition.[2] The Federal Circuit's decision in *ChromaDex, Inc. v. Elysium Health, Inc.*, 59 F.4th 1280 (Fed. Cir. 2023) reiterates that distinction. There, the Federal Circuit distinguished the composition claims before it from "method" claims, noting that in a prior case, it had "analyzed composition-of-matter claims under *Myriad* and *Chakrabarty* but analyzed *method* claims under *Mayo*." 59 F.4th at 1286 n.5 (emphasis added) (citing *In re BRCA1- and BRCA2*, 774 F.3d 755, 759-61 (Fed. Cir. 2014)). Therefore, the Court concludes based on *ChromaDex* that the *Alice*/*Mayo* framework, not the "markedly different characteristics" test, applies to method claims like the Patent Claims. Accordingly, the Court proceeds to apply the two-step framework set forth in *Alice*/*Mayo*.

B. Whether the Asserted Patents are Directed at a Natural Phenomenon

Defendant argues that the Asserted Patents are directed to naturally occurring enzymatic reactions and that Plaintiffs seek to enforce patent rights for a natural

[2] The Court contrasts this with the claims at issue in *REGENXBIO*, which were not directed at the overall method but were instead directed specifically at human-made cultured host cells. *See* 167 F.4th at 1208-09.

phenomenon by recreating that phenomenon in a laboratory environment. *See, e.g.*, *Motion* [#18] at 14-22.

In response, Plaintiffs assert that the modified polynucleotide or nucleic acid molecule that results from the Asserted Patents does not exist in nature. *See, e.g.*, *Response* [#31] at 16-18. Plaintiffs do not deny or dispute that epigenetic modifications, enzymes, and oxidation of epigenetic modifications by enzymes, including oxidation via similar or identical mechanisms to the ones asserted in the Asserted Patents, are all naturally occurring. However, Plaintiffs dispute whether the *degree* of oxidation of 5mC to 5hmC they achieve ever occur in nature, arguing that such an advanced degree of oxidization does not and will not naturally occur. *See, e.g.*, *id*. As a result, Plaintiffs assert that the modified polynucleotide achieved under their methods cannot exist in nature.

1. The ’320 Patent

a. *Alice* Step One

The Court turns first to the ’320 Patent and ’320 Patent Claims. As stated above, under the *Alice* test’s Step One, the Court must determine whether the claim at issue is “directed to” a patent-ineligible concept, such as a natural phenomenon.

The Court finds that the ’320 Patent Claims are clearly directed at natural phenomena.[3] Here, Plaintiffs seek to enforce a patent for their *method* of identifying an

[3] The Court notes that the focus in determining section 101 eligibility is on the language of the patent claims rather than the specification. *Am. Axle & Mfg.*, 967 F.3d at 1293; *see also ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 769 (Fed. Cir. 2019) (“[A]ny reliance on the specification in the § 101 analysis must always yield to the claim language. . . . [T]he specification cannot be used to import details from the specification if those details are not claimed.”); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1286 (Fed. Cir. 2015) (Lourie, J., concurring) (noting that the appropriate focus is “on the claims we have rather than those we might have had”); *Accenture Glob. Servs., GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336, 1345 (Fed. Cir. 2013) (“[Where t]he limitations of the . . . claims . . . do not provide sufficient additional features or limit the abstract concept in a meaningful way[,] . . . the level of detail in the

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. *See Ex. 1 to Compl. – '320 Patent* [#1-1] at col. 221 *l*. 1-col. 222 *l*. 13 (stating that each claim is for a "method"). However, as noted above, Plaintiffs do not dispute that in the natural world—including in the human body—polynucleotides come into contact with, and are oxidized by, enzymes, and that this process results in oxidized epigenetic modifications. The process and method that the '320 Patent is directed at therefore exists in the natural world.

Plaintiffs nonetheless raise several arguments in response to Defendant's arguments that the '320 Patent embodies unpatentable subject matter, which the Court proceeds to address below. In doing so, the Court notes that Plaintiffs' arguments almost universally suffer from two fatal flaws. First, Plaintiffs consistently refer to the Patent Claims as though they assert "composition" claims while failing to address the fact that they explicitly assert method claims instead. This distinction significantly affects how such claims are analyzed. Second, in response to Defendant's assertion that Plaintiffs have failed to include any language in the '320 Patent that speaks to the *amount* of the modified polynucleotide that is oxidized, Plaintiffs fail to identify any such language from the '320 Patent.

First, Plaintiffs argue that the '320 Patent Claims are patent eligible because they "result in" a modified, non-naturally occurring polynucleotide with markedly different characteristics from a naturally occurring one. *Response* [#31] at 19-24. More specifically, Plaintiffs argue that the '320 Patent creates something new and patentable because

specification does not transform a claim reciting only an abstract concept into a patent-eligible system or method.").

modified polynucleotides with essentially all the naturally occurring 5mC in a nucleic sample oxidized to 5hmC, 5fC, or 5caC do not exist in nature. *See, e.g.*, *Response* [#31] at 19-24.

This argument fails to address the fact that Plaintiffs explicitly assert *method* claims, rather than composition claims aimed at the product resulting from their method, in the ’320 Patent. Regardless, Plaintiffs fail to identify any language from the ’320 Patent that states anything about the amount, relative or otherwise, of the polynucleotide that is oxidized through the method outlined in the ’320 Patent. As Defendant argues, Plaintiff’s ’320 Patent is simply not “expressed in terms of chemical composition”; indeed, the ’320 Patent Claims “do[] not recite or require any particular “richness” of 5hmC, nor any specific level of 5mC or 5hmC at all.” *Reply* [#35] at 8. In other words, although Plaintiffs may now assert that the oxidized polynucleotides have “essentially all” their naturally occurring 5mC oxidized to 5hmC, the ’320 Patent and ’320 Patent Claims say nothing about this. *See id.* at 8-9. “These unclaimed features cannot function to remove [the ’320 Patent Claims] from the realm of ineligible subject matter.” *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285, 1295 (Fed. Cir. 2020).

Plaintiffs next argue that Defendant is attacking the Asserted Patents “component-by-component,” an approach that Plaintiffs state was rejected by the Federal Circuit in *REGENXBIO*, 167 F.4th 1206. *See Response* [#31] at 25-27. Plaintiffs assert that the proper question is not whether each individual component or element of the Asserted Patents independently occurs in nature, but whether the claimed composition under the Asserted Patents possesses “markedly different characteristics” from anything in nature. *Id*. at 25-26. Plaintiffs then assert that the modified polynucleotide that results from the

claimed methods under the Asserted Patents has "markedly different characteristics" that do not exist in nature and that accordingly, the Asserted Patents are valid. *Id*. at 26-27.

Again, as the Court has addressed above, Plaintiffs' Patent Claims are each method claims, and the "markedly different characteristics" standard that Plaintiffs cite applies to composition claims, not method claims. Regardless, the Court disagrees with Plaintiffs' characterization of Defendant's argument as taking "too narrow a view of the asserted claims by focusing on whether the individual components of the claim were markedly different from what is naturally occurring" rather than focusing on the composition as a whole. *REGENXBIO*, 167 F.4th at 1215. Defendant does not argue only that each individual component of the patented methods occurs in nature; it further argues that the modified polynucleotides that result from the methods described in the Asserted Patents themselves exist in nature. *Reply* [#35] at 10. Defendant asserts, and Plaintiffs acknowledge, that TET enzymes can oxidize 5mC in nature and that this results in polynucleotides that contain some amount of 5hmC existing in nature. *Id*. at 11. Defendant argues that as a result, Plaintiffs' modified polynucleotides exist in nature. Furthermore, Plaintiff fails to identify any claim language in the '320 Patent that speaks to the *amount* of the modified polynucleotide that is oxidized. Because Plaintiffs do not dispute that polynucleotides with *some* amount of 5mC oxidized to 5hmC are naturally occurring, and Plaintiffs' '320 Patent Claims do not state that most or all of the 5mC in a polynucleotide would be oxidized, Plaintiffs' '320 Patent Claims would not meet the "markedly different characteristics" standard *even if* that standard applied in this context.

Plaintiffs next argue that the '320 Patent Claims recite patent eligible subject matter because they are directed to a novel laboratory technique that achieves a new and useful

end. *Response* [#31] at 28-29. In support, Plaintiffs assert that "[t]he claimed method does not replicate the process performed in nature[ ]" because it "seeks to oxidize all existing 5mCs, not just a very select minority of 5mC bases" and because "[t]he claimed method clearly involves significantly altering and transforming the composition of the polynucleotide, as shown by the change in the information-transmitting ability of the resulting polynucleotide." *Response* [#31] at 28-29. However, Plaintiffs cite nothing to support their implicit assertion that the information-transmitting ability of a polynucleotide found in nature that becomes oxidized does *not* change, nor do Plaintiffs cite anything to support their other implicit assertion that "significant" transformation is necessary for a polynucleotide's information-transmitting ability to change dramatically. The Court is also unaware of any language in the '320 Patent referencing these factors, and Plaintiffs have failed to identify any such language. Regardless, this argument also suffers from one of the same key issues identified above: Plaintiffs have failed to identify any language from the '320 Patent that addresses what amount of the modified polynucleotide is oxidized.

For the reasons set forth above, the Court concludes that Plaintiffs' '320 Patent Claims are directed to a patent-ineligible natural phenomenon. The Court therefore concludes that Plaintiffs' '320 Patent fails Step One of the *Alice* test.

b. *Alice* Step Two

Proceeding to *Alice* Step Two, the Court considers whether the elements of Plaintiffs' '320 Patent Claims transform the nature of the claim into a patent-eligible application through, e.g., some form of inventive concept. The Court concludes that they do not.

As previously noted, Plaintiffs do not deny that polynucleotides with epigenetic modifications occur in nature, that enzymes contact and oxidize such polynucleotides in nature, or that this oxidization results in oxidized epigenetic modifications occurring in nature. Plaintiffs' method therefore cannot qualify as "innovative" in any relevant sense because, at its core, it simply replicates an event that occurs naturally. Put another way, Plaintiffs fail to explain why their supposedly "innovative method" differs from simply reproducing an effect that occurs in nature under laboratory conditions. Such a method is not inventive simply because it was performed or was created in a laboratory rather than in the human body or elsewhere in nature. *See, e.g.*, *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1378 n.3 (Fed. Cir. 2016) (noting that a claim was not "inventive" simply because it involved analysis of "*man-made* amplified DNA[]" where its sequence was identical to that of naturally occurring DNA).

Moreover, the final step included in the '320 Patent Claims under Claim One—using the oxidized epigenetic modification or derivative of a polynucleotide to "identify" said epigenetic modification of the polynucleotide—does not transform the method identified in the '320 Patent Claims into something inventive. Under the '320 Patent Claims, although Plaintiffs include a third step of identifying the epigenetic modification induced by the previous steps, Plaintiffs do not specify a method of identification and only broadly "identify" the epigenetic modification of a polynucleotide. This broadly stated step is not sufficient to confer patentability. *See, e.g.*, *Mayo*, 566 U.S. at 82 ("appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable."). Furthermore, the "claimed advance" here is "only in the discovery of [the]

natural law" that Plaintiffs' scientists discovered, and this additional step only applies a "conventional technique[]" to "detect that natural law." *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 751 (Fed. Cir. 2019). This factor, too, renders the step insufficient to confer patentability. *See id*.

Finally, as Defendant argues, *Motion* [#18] at 24-25, other techniques referenced within the '320 Patent Claims, like "isolating" a polynucleotide from extracellular fluid or "sequencing" a modified polynucleotide, were routinely and conventionally used before Plaintiffs sought the Asserted Patents. *See, e.g.*, *ChromaDex, Inc. v. Elysium Health, Inc.*, 59 F.4th 1280, 1284 (Fed. Cir. 2023) (act of isolating nicotinamide riboside, a form of vitamin B3, from its natural existence in milk "is not sufficient, on its own, to confer patent eligibility[,]" as "other than separation from some other components, the isolated [nicotinamide riboside] is no different structurally or functionally from its natural counterpart in milk."); *In re BRCA1-, BRCA2-Based Hereditary Cancer Test Pat. Litig.*, 3 F. Supp. 3d 1213, 1229-31 (D. Utah), *aff'd and remanded*, 774 F.3d 755 (Fed. Cir. 2014) (by 2014, a variety of gene sequencing techniques were "well understood, widely used, and fairly uniform" within the scientific community). Plaintiffs do not deny this and make no attempt to counter this argument.

In summary, the elements recited by Plaintiffs in asserting the '320 Patent Claims do not reflect that, in practice, the '320 Patent amounts to more than an asserted patent on the underlying natural phenomenon that Plaintiffs discovered. Given the Court's conclusion that Plaintiffs' '320 Patent fails the *Alice* test at both Step One and Step Two, the Court further concludes that the '320 Patent embodies unpatentable subject matter.

Accordingly, the Court **recommends** that Plaintiffs' Claim One be dismissed for failure to state a claim pursuant to which relief can be granted.

2. The '742 Patent

a. Alice Step One

Plaintiff's '742 Patent raises issues that largely overlap with the Court's analysis of the '320 Patent, but with one potentially relevant distinction. Claim 21 states that the method it outlines converts "*all*" of a nucleic acid molecule's 5mC "to an oxidized derivative thereof." *Ex. 2 to Compl. - '742 Patent* [#1-2] at col. 158 *l*. 21 (emphasis added). In contrast to the '320 Patent, therefore, the '742 Patent asserts that the method Plaintiffs use creates polynucleotides in which "all" of the naturally occurring 5mC from a nucleic sample is oxidized. The Court therefore turns directly to this point in analyzing whether Plaintiff's '742 Patent embodies unpatentable subject matter.

Turning to *Alice* Step One, the Court notes that Plaintiffs do not assert that the "method" outlined under the '742 Patent Claims differs in any way from what occurs in nature *except in the following two respects*: (1) the method is used in a laboratory rather than within, e.g., the body; and (2) the resultant degree or amount of 5mC in the nucleic sample is more extreme than that which occurs in nature, Plaintiffs asserting that in nature, it is never the case that "all" of the 5mC in a nucleic acid molecule is oxidized. *See Response* [#31] at 31-38. The Court has already rejected this first point in dealing with Plaintiffs' '320 Patent Claims.[4] Accordingly, the Court turns to consider Plaintiffs' argument that the degree or amount of 5mC in the nucleic sample is more extreme than

[4] As addressed above, the mere fact that the method is followed in a laboratory environment instead of occurring in nature does not affect the Court's analysis here. *See, e.g.*, *Genetic Techs.*, 818 F.3d at 1378 n.3. The Court therefore need not analyze this point further.

that which occurs in nature and that this means that the '742 Patent is not directed at a natural phenomenon. *See Response* [#31] at 31-33.

The Court concludes that the '742 Patent Claims, like the '320 Patent Claims, are directed at a patent-ineligible concept. First, as Defendant argues, 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. This is not sufficient to state a patentable claim. A claim must "ha[ve] the specificity required to transform [the] claim from one claiming only a result to one claiming a way of achieving it." *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1167 (Fed. Cir. 2018) (collecting cases); *see also, e.g.*, *Am. Axle & Mfg., Inc.*, 967 F.3d at 1296-97 (citing *SAP Am.* and collecting cases while noting that this principle applies in natural law cases); *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1343 (Fed. Cir. 2018) (summarizing prior Supreme Court holdings in which patent claims were rejected on similar grounds and noting that the claims "failed to recite a practical way of applying an underlying idea . . . [and] instead were drafted in such a result-oriented way that they amounted to encompassing the 'principle in the abstract' no matter how implemented."); *Electric Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1355-56 (Fed. Cir. 2016) ("the essentially result-focused, functional character of claim language has been a frequent feature of claims held ineligible under § 101"). Because '742 Patent 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, their '742 Patent Claims are not stated with sufficient specificity.

Additionally, even if the nucleic sample that ultimately results from the method outlined in Plaintiffs' '742 Patent Claims *did* differ from anything found in nature, and even

if Plaintiffs had sufficiently stated how to achieve this result, the *method* used to create it is nonetheless drawn directly from nature. As with Plaintiffs' '320 Patent Claims, Plaintiffs' '742 Patent Claims are for a method, not for the nucleic sample that ultimately results from the method. *See Ex. 2 to Compl. – '742 Patent* [#1-2] at col. 155 *l.* 1 through col 158 *l.* 30 (stating that each claim is for a "method"). The parties ultimately do not dispute that the *method* that Plaintiffs use to create the nucleic sample is taken directly from nature, even if Plaintiffs are correct that, for some unspecified reason, their use of the method results in a higher degree of oxidization than that which occurs in nature.

The District of Massachusetts reached an essentially identical conclusion in *Biomodal Ltd. v. New England Biolabs, Inc.*, which involved both the same Plaintiffs and highly similar patent claims arising from the same discovery referenced here. In analyzing Plaintiffs' patent claims, the court dismissed each of Plaintiffs' claims directed toward a method, although it allowed Plaintiffs' claims directed toward compositions to proceed. Specifically, in considering Plaintiffs' claim two, the court noted that Plaintiffs had asserted—as here—that the method underlying claim two creates a modified, non-naturally occurring nucleotide sequence which is unnaturally rich in 5hmC and unnaturally deficient in 5mC. *Biomodal Ltd.*, 757 F. Supp. 3d at 188. However, the court found that Plaintiffs' argument was fundamentally flawed because Plaintiffs' claims were "not directed to the allegedly new, modified nucleotide sequence identified by plaintiffs. Rather, they target the same replication of a natural process that the court earlier found ineligible." *Id*. The court then found that, regardless of whether the method created a non-naturally occurring nucleotide sequence, the method itself still replicated a natural process, and the court ultimately concluded that the patent claims at issue merely recited

a law of nature. Although the Court does not accord this decision the weight of binding precedent,[5] for the reasons stated above, the Court nevertheless agrees with the specific analysis outlined above and finds that it applies equally here.

For the reasons set forth above, the Court concludes that Plaintiffs' '742 Patent Claims are directed to a patent-ineligible natural phenomenon. The Court therefore concludes that Plaintiffs' '742 Patent fails the *Alice* test at Step One.

b. *Alice* Step Two

At Step Two of the *Alice* framework, in addressing the '742 Patent, Plaintiffs only raise arguments identical to those already dealt with above in analyzing the '320 Patent. *See Response* [#31] at 31-35. The Court rejects these arguments for the same reasons that it rejected them as to the '320 Patent. The Court does not find that the '742 Patent Claims add any potential innovation that the Court did not already address above in dealing with the '320 Patent Claims at Step Two. In fact, the '742 Patent Claims are even less complex, as there is no "identification" step under the '742 Patent Claims. The method asserted under the '742 Patent Claims therefore merely recites the mechanism that Plaintiffs' scientists observed in nature without requiring anything further. Moreover, as with the '320 Patent Claims, the Court again agrees with Defendant that other techniques referred to in the '742 Patent Claims, like "sequencing" a nucleic acid molecule, were routinely and conventionally used before Plaintiffs sought the Asserted Patents. See *In re BRCA1-*, 3 F. Supp. 3d at 1229-31. Again, Plaintiffs do not argue

[5] The Court notes that although Plaintiffs argue that this opinion should neither be relied on nor accorded any weight, Plaintiffs acknowledge that the opinion may be of interest to the Court. *See Response* [#31] at 38-39.

otherwise. The Court therefore concludes that Plaintiffs' '724 Patent also fails the *Alice* test at Step Two.

Given the Court's conclusion that Plaintiffs' '742 Patent fails the *Alice* test at both Steps One and Two, the Court further concludes that the '742 Patent embodies unpatentable subject matter. Accordingly, the Court **recommends** that Plaintiffs' Claim Two be dismissed.

3. Unasserted Patent Claims

Finally, Plaintiffs assert that this action should not be limited to the patent claims that Plaintiffs specifically reference in the Complaint [#1] because they asserted infringement of "at least" Claims 1-4, 6, and 11 of the '320 Patent and "at least" Claims 21 and 30 of the '742 Patent. *Response* [#31] at 35-37. Plaintiffs argue that because this language was not exclusive, the Court must also consider the claims not specifically identified by Plaintiffs. *Id*.

Assuming for the sake of argument that Plaintiffs are correct, the Court would nonetheless apply the same analysis set forth above to each of the claims that Plaintiffs did not specifically identify and would reach the same conclusions as with the asserted claims. The Court notes that each of Plaintiffs' claims under both the '320 Patent and the '742 Patent is explicitly for a "method" and that therefore, each of the claims run into the same issues as Claims 1-4, 6, and 11 and Claims 21 and 30 do. Moreover, the Court notes that each of the additional claims under the Asserted Patents fails to further address or explain how "all" of the naturally occurring 5mC in a nucleic sample would be oxidized under Plaintiffs' method. The Court therefore need not further analyze the patent claims

that Plaintiffs failed to specifically identify, as it finds that the analysis set forth above applies equally to those claims.

IV. Conclusion

Based on the foregoing,

IT IS HEREBY **RECOMMENDED** that the Motion to Dismiss [#18] be **GRANTED** and that Plaintiffs' Complaint [#1] be **dismissed without prejudice** in its entirety.

IT IS FURTHER **ORDERED** that Plaintiffs may file an objection **within 14 days** of service of this Recommendation. In relevant part, Federal Rule of Civil Procedure 72(b)(2) provides that, "within 14 days after being served with a copy of the recommended disposition, a party may serve and file specific written objections to the proposed findings and recommendations. A party may respond to another party's objections within 14 days after being served with a copy." "[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. 2121 E. 30th St.*, 73 F.3d 1057, 1060 (10th Cir. 1996). The objection must be "sufficiently specific to focus the district court's attention on the factual and legal issues that are truly in dispute." *Id.* "[A] party who fails to make a timely objection to the magistrate judge's findings and recommendations waives appellate review of both factual and legal questions." *Morales-Fernandez v. I.N.S.*, 418 F.3d 1116, 1119 (10th Cir. 2005).

Dated: September 2, 2026

BY THE COURT:



Kathryn A. Starnella
United States Magistrate Judge