UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

NEXTCEA INC.,	)	
Plaintiff,	)	
v.	)	No. 1:24-cv-12624-JEK
LIPOTYPE, INC.; LIPOTYPE GMBH,	)	
Defendants.	)	

MEMORANDUM AND ORDER ON DEFENDANTS' MOTION TO DISMISS

KOBICK, J.

Plaintiff Nextcea Inc. claims that defendants Lipotype, Inc. and Lipotype GmbH (collectively, "Lipotype") have induced and contributed to the infringement of its patented method of testing samples for isomers of a biomarker that is correlated with phospholipidosis and other lysosomal storage disorders. Lipotype has moved to dismiss the complaint, arguing that Nextcea's patent is directed to unpatentable laws of nature and that Nextcea's claims of induced and contributory infringement therefore fail as a matter of law. Agreeing that Nextcea's patent claims recite only patent-ineligible natural laws without supplying the necessary inventive concepts to transform Nextcea's claims into patentable applications of these natural phenomena, the Court will grant the motion to dismiss.

BACKGROUND

The following facts are recounted based on the allegations in the amended complaint and documents attached to that pleading. *Thornton v. Ipsen Biopharmaceuticals, Inc.*, 126 F.4th 76, 81 (1st Cir. 2025).

Nextcea is a Massachusetts-based business founded in 2006 by Dr. Frank Hsieh. ECF 20, ¶¶ 5, 14. It specializes in offering drug development and diagnostic services, including biomarker quantitation and safety assessments for medical conditions like lysosomal storage disorders. *Id.* ¶¶ 14-16. In a patient with a lysosomal storage disorder, the body's cells and tissues accumulate excess lipid materials, like phospholipids, that would normally be broken down. ECF 20-1, at 12 col. 1 lines 13-27. Over time, excessive storage of lipid materials can cause permanent damage to cells and organs. *Id.* at col. 1 lines 27-30. Lysosomal storage disorders can be inherited or induced by drugs. ECF 20, ¶ 16. Phospholipidosis, the lysosomal storage disorder characterized by excessive accumulation of phospholipids, can be induced by many different classes of drugs. ECF 20-1, at 13 col. 4 lines 27-60; 16 col. 10, lines 5-10. Thus, it can be useful to test for drug-induced phospholipidosis when managing the use of drugs in a patient or when determining whether a drug under evaluation for approval may cause phospholipidosis. *Id.* at 13 col. 4 lines 55-60; 16 col. 10, lines 5-10.

One of the services Nextcea offers involves determining the level of the biomarker di-docosahexaenoyl (22:6)-bis(monoacylglycerol)phosphate ("di-22:6-BMP") in samples provided by its customers. ECF 20, ¶ 15. Di-22:6-BMP is a lysosomal phospholipid that can exist in four isoforms and may be measured in non-invasively collected samples, such as urine or plasma. *Id.*; ECF 20-1, at 14, col. 6 lines 15-17. Hsieh discovered that this biomarker is correlated with certain lysosomal storage disorders, including drug-induced phospholipidosis. ECF 20, ¶ 16. Nextcea applied this correlation to create and perform tests that measure levels of di-22:6-BMP in collected samples. *Id.* These tests assess whether an individual has induced or inherited phospholipidosis or other lysosomal storage disorders. *Id.*

The patent at issue here, U.S. Patent No. 8,313,949 (the "'949 patent"), is directed towards this discovery. Historically, phospholipidosis has been identified by visually confirming the presence of myeloid bodies in tissues using electron microscopy, a process that is "invasive, relatively non-quantitative, expensive, and time consuming." ECF 20-1, at 14, col. 5 line 60 – col. 6 line 2. By contrast, the patented invention offers a "less invasive approach for detecting phospholipidosis," exploiting the "unexpected discovery" that different levels of the four isoforms of di-22:6-BMP (as well as several other biomarkers) "correlate differentially with the phospholipidosis induced by different drugs and inherited lysosomal storage disorders." *Id.* at 12, col. 1 lines 40-47; 14, col. 6 lines 5-6. As compared to electron microscopy, the methods described in the patent "provid[e] a better means of defining the temporal relationship between the onset and time course of phospholipidosis with the changes that lead to drug toxicity." *Id.* at 14, col. 6 lines 9-12. The patent, which was filed on October 14, 2009 and granted on November 20, 2012, claims priority to U.S. Provisional Application No. 61/169,789, which was filed on April 16, 2009. *Id.* at 12, col. 1 lines 7-9; ECF 20, ¶¶ 19-20.

The '949 patent contains twenty method claims, three of which—claims 1, 14, and 16—are independent. Claim 1 is addressed to "[a] method for evaluating the activity of a test compound to induce phospholipidosis in a target subject"; claim 14 to "[a] method for managing patient treatment comprising identifying a patient under a treatment suspected to induce phospholipidosis in the patient"; and claim 16 to "[a] method of diagnosing a lipid storage disorder in a human subject." ECF 20-1, at 18, col. 13 lines 64-65; 19 col. 15 lines 4-6, 26-27. Each of the three claims involves three steps: (1) obtaining a test sample; (2) determining the level of each of the four isomers of di-22:6-BMP (and, optionally, another three biomarkers) in the sample; and (3) comparing the level of each biomarker in the test sample with a corresponding pre-determined

level for the same biomarker, obtained from a control sample. *Id.* at 18, col. 13 line 66 – col. 14 line 17; 19 col. 15 lines 7-18, 28-30, col. 16 lines 1-9. For claim 1, "the test compound is determined to have the activity to induce phospholipidosis in the target subject if the level of any of the group of biomarkers is at or above the corresponding pre-determined level." *Id.* at 18, col. 14 lines 18-21. For claim 14, "the patient is determined to be not suitable for the treatment if the level of any of the group of biomarkers is at or above the corresponding predetermined level." *Id.* at 19, col. 15 lines 19-21. And for claim 16, "having a level of any of the group of biomarkers that is at or above the corresponding predetermined level indicates that the subject has or is at risk of developing the lipid storage disorder." *Id.* at 19, col. 16 lines 10-13.

Nextcea alleges that Lipotype has induced and contributed to infringement of the '949 patent. Lipotype sells, offers for sale, provides, and promotes services that use mass spectrometry to test and quantify the amounts of selected lipids in test samples sent in by its customers. ECF 20, ¶¶ 23-24. One of these services is titled "MS-based lipid analysis of BMP phospholipids" ("BMP Analysis Services"). *Id.* ¶ 25. On its website offering this service for purchase, Lipotype notes that BMPs "play a role in lysosomal storage diseases" and "are also researched as a non-invasive biomarker to monitor phospholipidosis with drug-induced toxicities." ECF 20-2, at 2; ECF 20, ¶¶ 25-26. Lipotype's "Tech Sheet," which it distributes to promote and solicit its BMP Analysis Services, also states that the test may be applied to lysosomal storage diseases and phospholipidosis, and that Lipotype's "fully quantitative results" separately report species for each "sn-isomer." ECF 20-3, at 2; ECF 20, ¶¶ 27-30. According to Nextcea, Lipotype encourages customers to use its services, provides sample preparation, and offers instructions and guidance to its customers on how to apply its analysis—which is provided to customers via data reports and an optional data visualization software—to their "diagnostic and/or drug testing applications,

services, and research." ECF 20, ¶¶ 32-35; ECF 20-2, at 10. As a result, Nextcea contends, customers purchase Lipotype's services and directly infringe Nextcea's patent. ECF 20, ¶¶ 32-35.

On August 19, 2024, Nextcea sent notice letters to Lipotype, alleging infringement of its patent. *Id.* ¶ 39. Nextcea then initiated this action in October 2024 and filed an amended complaint in December 2024. ECF 1, 20. Lipotype moved to dismiss the case for failure to state a claim, contending, among other things, that the '949 patent is directed to unpatentable laws of nature. ECF 28. After receiving Nextcea's opposition and holding a hearing, the Court took the motion under advisement. ECF 31, 36.

STANDARD OF REVIEW

In evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the Court must determine "'whether, construing the well-pleaded facts of the complaint in the light most favorable to the plaintif[f], the complaint states a claim for which relief can be granted.'" *Cortés-Ramos v. Martin-Morales*, 956 F.3d 36, 41 (1st Cir. 2020) (quotation marks omitted). The complaint must allege "a plausible entitlement to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Id.* at 679. The Court "'may properly consider only facts and documents that are part of or incorporated into the complaint.'" *Rivera v. Centro Médico de Turabo, Inc.*, 575 F.3d 10, 15 (1st Cir. 2009) (citation omitted).

DISCUSSION

Lipotype contends that the '949 patent claims unpatentable subject matter and is therefore invalid. Under Section 101 of the Patent Act, patentable subject matter encompasses "any new and

useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. Implicit in this definition is an important and long-standing exception: "'[l]aws of nature, natural phenomena, and abstract ideas' are not patentable." *Mayo Collaborative Servs. v. Prometheus Lab'ys*, 566 U.S. 66, 70 (2012) (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)). This is so, the Supreme Court has explained, because permitting the monopolization of these "'basic tools of scientific and technological work' . . . might tend to impede innovation more than it would tend to promote it." *Id.* at 71 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). Moreover, "'[a] principle, in the abstract, is a fundamental truth; an original cause; a motive[.] [T]hese cannot be patented, as no one can claim in either of them an exclusive right.'" *Alice Corp. Pty. Ltd. v. CLS Bank. Int'l*, 573 U.S. 208, 218 (2014) (quoting *Le Roy v. Tatham*, 55 U.S. 156, 175 (1862)). Still, "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 566 U.S. at 71. Thus, "[a]pplication[s] of such concepts to a new and useful end . . . remain eligible for patent protection." *Alice*, 573 U.S. at 217 (quoting *Gottschalk*, 409 U.S. at 67) (quotation marks omitted).

Courts apply a two-step inquiry, known as the *Alice*/*Mayo* test, for evaluating claims of patent subject matter ineligibility under Section 101. A court must first ask whether the claims at issue are directed to a patent-ineligible concept, like a law of nature. *See Cleveland Clinic Found. v. True Health Diagnostics*, 859 F.3d 1352, 1360 (Fed. Cir. 2017). If so, a court must next ask whether the claims nonetheless "contain an inventive concept sufficient to transform the claimed naturally occurring phenomena into a patent-eligible application." *Id.* at 1361. If a court determines that a patent claim is directed to a patent-ineligible concept and lacks an inventive concept, the claim is invalid and therefore cannot form the basis for an infringement claim. Questions of patent eligibility "may be resolved on a Rule 12(b)(6) motion when the undisputed facts require a holding

of ineligibility." *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 749 (Fed. Cir. 2019).

I. ***Alice*/*Mayo* Step One.**

When determining whether a patent is "directed to" a patent-ineligible concept, "'it is not enough to merely identify a patent-ineligible concept underlying the claim.'" *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1134 (Fed. Cir. 2018) (quoting *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016)). "Indeed, to preclude the patenting of an invention simply because it touches on something natural would 'eviscerate patent law.'" *CellzDirect*, 827 F.3d at 1050 (quoting *Mayo*, 566 at 71). The Federal Circuit has instead clarified that the "'directed to' inquiry focuses on the claim as a whole," *Athena*, 915 F.3d at 750, scrutinizing whether it "amount[s] to nothing more than observing or identifying the ineligible concept itself," *CellzDirect*, 827 F.3d at 1048. Courts should examine "both the written description and the claims" themselves to determine "whether the claimed advance improves upon a technological process or merely an ineligible concept." *Athena*, 915 F.3d at 750. Where, for example, method claims "star[t] and en[d] with naturally occurring phenomena with no meaningful non-routine steps in between," they are "directed to a natural law." *Cleveland Clinic*, 859 F.3d at 1361. Thus, "claiming a new treatment for an ailment, albeit using a natural law, is not claiming the natural law," but "[c]laiming a natural cause of an ailment and well-known means of observing it is not eligible for [a] patent because such a claim in effect only encompasses the natural law itself." *Athena*, 915 F.3d at 752-53.

Several recent decisions illustrate the distinction. In *Vanda*, the Federal Circuit found that the patent claims at issue were not directed to a natural law because they were "directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome." *Vanda*, 887 F.3d at 1136. The patent claims outlined a treatment

regimen for patients with schizophrenia, which provided for different dosages of the medicine iloperidone based on the patient's genotype for an enzyme known to metabolize that drug. *Id.* at 1121. The Court emphasized that the claims at issue recited "treatment steps" and were directed to an application of the natural relationship between the enzyme genotype and the potential complications associated with iloperidone, not the natural relationship itself. *Id.* at 1135. Likewise, in *CellzDirect*, the Federal Circuit concluded that the method claims were not directed to a natural phenomenon—namely, the "ability of hepatocytes to survive multiple freeze-thaw cycles"—because they did not merely "observ[e] or identif[y] the ineligible concept itself." *CellzDirect*, 827 F.3d at 1048. Instead, the Court explained, the claims outlined "a new and useful laboratory technique" that went beyond the inventors' initial discovery of the hepatocytes' capacity to survive multiple freeze-thaw cycles. *Id.*

By contrast, in *Cleveland Clinic*, the Federal Circuit found that the patent claims were "directed to multistep methods for observing [a] law of nature" because the invention "involve[d] 'seeing' [an enzyme] already present in a bodily sample and correlating that to cardiovascular disease," a relationship that "'exists in principle apart from human action.'" *Cleveland Clinic*, 859 F.3d at 1360-61 (quoting *Mayo*, 566 U.S. at 77). There, the patents concerned the enzyme myeloperoxidase ("MPO"), which is released "[w]hen an artery is damaged or inflamed" and is "an early symptom of cardiovascular disease." *Id.* at 1355. The patents at issue disclosed "ways of detecting MPO" and "methods for characterizing a test subject's risk for cardiovascular disease by determining levels of MPO in a bodily sample and comparing that with the MPO levels in persons not having cardiovascular disease." *Id.* at 1356. Noting that the plaintiff "ha[d] not created a new laboratory technique" and instead, according to the patent specification, only "use[d] well-known

techniques to execute the claimed method," the Court determined that the claims were directed to ineligible subject matter. *Id.* at 1361.

Similarly, in *Mayo*, the Supreme Court concluded that the patent claims, which "set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm"—were patent ineligible because they did not add enough to the naturally occurring phenomenon "to qualify as patent-eligible processes that *apply* natural laws." *Mayo*, 566 U.S. at 77. Instead, they simply told doctors to "(1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law." *Id.* at 82. The Court explained that "[t]hese instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field," which have the effect of merely "tell[ing] doctors to apply the law somehow when treating their patients." *Id.*

Lipotype argues that Nextcea's patent is directed to ineligible natural phenomena—i.e., "the relationship between [species] of BMP and lysosomal storage disorders"—and ineligible mental processes—i.e., "simple comparisons between measured levels of BMP species to reach mental conclusions about lysosomal storage disorders, without any actions to be taken as a result." ECF 29, at 9. The Court agrees. Nextcea's patent claims are more akin to those in *Cleveland Clinic* and *Mayo* than in *Vanda* and *CellzDirect*. The claims are directed to little more than "multistep methods for observing" natural phenomena, *Cleveland Clinic*, 859 F.3d at 1360—namely, the correlation between elevated BMP levels and lipid storage disorders (claim 16), and the correlation

between elevated BMP levels and phospholipidosis, induced by either administration of a test compound (claim 1) or another unspecified "treatment" (claim 14), ECF 20-1, at 18-19.

On their face, claims 1 and 16 recite methods of observation and diagnosis, not methods of treatment. Under claim 1, the "wherein" step only yields the conclusion that "the test compound is determined to have the activity to induce phospholipidosis in the target subject." ECF 20-1, at 18, col. 14 lines 18-21. Similarly, in claim 16, the "wherein" step merely states that having an elevated BMP level "indicates that the subject has or is at risk of developing the lipid storage disorder." *Id.* at 19, col. 16 lines 10-13. And claim 14, though described as a "method for managing patient treatment," *id.* at 19, col. 15 line 4, lacks the necessary specificity and detail to transform it into an application of the natural law rather than an observation of that law with "nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients." *Mayo*, 566 U.S. at 79. In that claim, the "wherein" step states only that "the patient is determined to be not suitable for the treatment" if the biomarkers exceed the predetermined level; it does not recite any further action to be taken as a result of that indication. ECF 20-1, at 19, col. 15 lines 19-21. Unlike the claims in *Vanda*, for example, claim 14 does not prescribe any specific treatment method. *See Vanda*, 887 F.3d at 1134-35 (noting that the eligible claims were directed at "treatment steps," not a "diagnostic method").

Nextcea protests that its claims are directed to specific applications of the natural phenomena, not to the patent-ineligible natural laws themselves. Claim 1, it says, is "directed to evaluating a specific property of a test compound, a laboratory procedure undertaken in preclinical settings such as the unnatural process of drug development," not "methods for making a determination about a natural process or reaction occurring within a patient." ECF 31, at 12. Because it "achieves the tangible result of evaluating the properties of a test compound, such as a

drug candidate," Nextcea claims, it is "not a diagnostic procedure that merely observes natural phenomena." *Id.* But whether a natural phenomenon occurs in clinical settings or within a patient's body does not affect its patentability. And in any case, Nextcea's argument is belied by the language of the patent, which explains that claim 1 recites a method of observing whether "the test compound is determined to have the activity to induce phospholipidosis *in the target subject*." ECF 20-1, at 18, col. 14 lines 18-19 (emphasis added); *see id.* at 12, col. 2 line 7 ("A 'subject' refers to either a human or non-human animal."). Nor does the fact that claims 1 and 14 "tak[e] a human action . . . to trigger a manifestation of this relation" in the test subject affect this analysis: the correlation "exists in principle apart from human action," and thus the claims simply "se[t] forth a natural law." *Mayo*, 566 U.S. at 77.

The Court is also unpersuaded by Nextcea's argument that claim 1 is directed to an "innovative laboratory technique" rather than a law of nature. *See Athena*, 915 F.3d at 751. Citing the patent specification, Nextcea argues that "isoform level analysis itself was an unconventional activity as evidenced by the 'unexpected results' disclosed in the '949 Patent that different isoforms of di-22:6-BMP were differently correlated with particular treatments." ECF 31, at 13. But Nextcea fails to distinguish between groundbreaking methods of discovery and groundbreaking discoveries of natural phenomena. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013) ("Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."). The "unexpected results" described in the patent—i.e., the correlations—refer only to the latter, which are not patentable. Claim 1 does not introduce a new or non-routine manner of determining the level of each of the four biomarkers—indeed, it does not specify any particular method of determination at all. Instead, the specification explains that evaluation of the individual isoforms may occur through "a number of methods," including "thin layer chromatography, liquid

chromatography, gas chromatography, mass spectrometry, florescence or UV detection, scintillation counting, ELISA, NMR, imaging techniques, and labeling with a dye, antibody, florescence tag, or chemical modifier." ECF 20-1, at 15, col. 8 lines 34-40.[1] According to the specification, mass spectrometry is "a common tool to profile specific phospholipid species," and gas chromatography with mass spectrometry and tandem mass spectrometry "are used in many lipid studies." ECF 20-1, at 16, col. 9 lines 1-2, 16-18. At bottom, the claim merely recites a law of nature that may be observed through "well-known techniques" and, accordingly, is directed to patent-ineligible material. *Cleveland Clinic*, 859 F.3d at 1361; *see Mayo*, 566 U.S. at 88-89 (patent subject matter eligibility inquiry does "not distinguis[h] among different laws of nature according to whether or not the principles they embody are sufficiently narrow").

Nextcea next asserts that claim 14 is directed to a patent-eligible method of managing treatment. Claim 14, Nextcea argues, is more specific than the claims described in *Mayo*, *Vanda*, and *Endo* because it is "directed to managing treatment for a specifically identified condition, phospholipidosis, suspected to be induced by a particular treatment in a particular patient receiving that treatment." ECF 31, at 10. But here, unlike the claims in *Vanda* and *Endo*, no particular treatment or patient is specified. In *Vanda*, the patients were people with schizophrenia who were being treated with iloperidone, and the treatment steps were more specific than the claims at issue here, instructing doctors to "internally administe[r]" iloperidone "in an amount of 12 mg/day or less" or "an amount that is greater than 12 mg/day, up to 24 mg/day," depending on the patient's genotype. *Vanda*, 887 F.3d at 1121. Similarly, in *Endo*, the patients were people receiving

[1] ELISA stands for enzyme-linked immunosorbent assay. *See Athena*, 915 F.3d at 748 n.2. NMR standards for nuclear magnetic resonance. *See Fonar Corp. v. Gen. Elec. Co.*, 107 F.3d 1543, 1546 (Fed. Cir. 1997).

oxymorphone to treat pain from impaired kidney function. *Endo Pharms Inc. v. Teva Pharms. USA, Inc.*, 919 F.3d 1347, 1348 (Fed. Cir. 2019). The patent claims referred to specific dosages of oxymorphone and instructed doctors to "orally administe[r]" different amounts of the drug based on patients' creatine clearance rates, which were sorted into four ranges, and ensure that the "'average [amount in the patient's body] of oxymorphone over a 12-hour period is less than about 21 ng hr/mL.'" *Id.* at 1350-51. Claim 14, by contrast, is described in more general terms and is not limited to any particular treatment or dosages. *See* ECF 20-1, at 19, col. 15 lines 5-6 (referring merely to "a patient under a treatment suspected to induce phospholipidosis in the patient"); ECF 31, at 2 (Nextcea noting that "[m]any antidepressants, such as citalopram and fluoxetine, as well as antipsychotics like haloperidol and chlorpromazine, are known to cause phospholipidosis"). Like the claims in *Mayo*, which stated that certain levels of a metabolite "indicate[d] a need" to either increase or decrease dosage of thiopurine drugs, the "wherein" clause of claim 14 merely recites that "the patient is determined to be not suitable for the treatment" when certain biomarkers meet or exceed the predetermined level set by a control sample. ECF 20-1, at 19, col. 15 lines 19-20; *see Mayo*, 566 U.S. at 73-75.

Nextcea nevertheless contends that claim 14 is more specific than the claim at issue in *Mayo* because the phrase "the patient is determined to be not suitable for the treatment" necessarily requires that the treatment be reduced to a dosage of zero if levels of any of the isoforms of di-22:6-BMP exceed those in the control sample. ECF 20-1, at 19, col. 15 lines 19-20. In Nextcea's view, this "tangible and specific outcome" qualifies as a patent-eligible application of the natural law, not a mere observation of the natural law itself, because it recites a particular treatment. ECF 31, at 11. Lipotype counters that a plain reading of the claim reveals that this language does not

"require a practitioner to specifically stop treatment of a drug" or prescribe any particular treatment at all. ECF 37, at 10:8-10.

On a motion to dismiss, a district court may either "proceed by adopting the non-moving party's constructions" or "resolve the disputes to whatever extent is needed to conduct the § 101 analysis, which may well be less than a full, formal claim construction." *UTTO Inc. v. Metrotech Corp.*, 119 F.4th 984, 994 (Fed. Cir. 2024) (quotation marks omitted) (noting that while "[s]ome courts have found it useful to hold hearings and issue orders comprehensively construing the claims in issue, . . . [s]uch a procedure is not always necessary"). Applying the claim construction principles set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), the Court concludes that Nextcea's proposed construction finds no foothold in the words of the patent. Claim 14 stops short of prescribing any particular treatment at all—much less a dosage of zero. Rather, its use of the term "determined" suggests only that the results of the claimed method will divulge whether the patient is "suitable for the treatment"; it does not instruct a doctor to take any particular step after making this determination or to reduce a treatment dosage to zero. ECF 20-1, at 19, col. 15 lines 19-20. The use of "determined" here also mirrors its use in the "wherein" clause in claim 1, in which the term simply specifies the significance of an observation, without implying any further action. *Id.* at 18, col. 14 lines 18-21.

The Court thus concludes that, like the claim in *Mayo*, claim 14 "simply tell[s] a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient." *Mayo*, 566 U.S. at 78. Accordingly, claims 1, 14, and 16 are each directed to patent-ineligible material.

II. ***Alice*/*Mayo* Step Two.**

Even if patent claims are directed to patent-ineligible material, they may still be valid if they contain an "inventive concept"—that is, 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 [the ineligible concept] itself.'" *Vanda*, 887 F.3d at 1133 (quoting *Alice*, 573 U.S. at 217-18). Courts must "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." *Id.* (citation omitted). "[M]ore is required than 'well-understood, routine, conventional activity already engaged in by the scientific community,' which fails to transform the claim into 'significantly more than a patent upon the' ineligible concept itself." *CellzDirect*, 827 F.3d at 1047 (quoting *Mayo*, 566 U.S. at 83). And "[f]or process claims that encompass natural phenomenon, the process steps are the additional features that must be new and useful." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377 (Fed. Cir. 2015).

"Simply appending conventional steps, specified at a high level of generality, [is] not enough to supply an inventive concept." *Alice*, 573 U.S. at 222 (quotation marks and italics omitted); *see Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 F. App'x 1013, 1019 (Fed. Cir. 2019) (the Federal Circuit has "consistently rejected" the argument "that using a known technique in a standard way to observe a natural law can confer an inventive concept"). Viewed individually, each step of claims 1, 14, and 16 only recites conventional methods, described in very general terms. ECF 20-1, at 18, col. 13 line 66 – col. 14 line 17; 19 col. 15 lines 7-18; 19 col. 15 line 28 – col. 16 line 9 (instructing users to "obtai[n]" test samples, "determin[e]" the level of the four isoforms, and "compar[e]" the levels to a predetermined level taken from a control sample with phospholipidosis or a lipid storage disorder). The specification explains that obtaining test samples may occur through conventional means, such as sampling blood or urine. ECF 20-1, at 14 col. 6 lines 65-67. And the patent does not, for example, describe new methods for determining the levels of the di-22:6-BMP isoforms. *See* ECF 20-1, at 15 col. 9 line 32 – 16 col. 9 line 40

(describing the array of methods that may be used to measure the isoforms, characterizing one as "a common tool" and another as a method "used in many lipid studies").

Nextcea claims, however, that measuring the levels of the di-22:6-BMP isoforms was not conventional activity and that, when viewed as a whole, the patent supplies an inventive concept because "[t]he information that is being 'determined,' levels of individual isoforms of di-22:6-BMP, is not something that was conventional in the prior art." ECF 31, at 15-17 (distinguishing between "disclosure related to techniques to identify 'phospholipids' generally" and "techniques for individual isoforms of di-22:6-BMP" specifically). It is true that in some cases, the Federal Circuit has held that a novel combination of conventional steps provides an inventive concept. *See CellzDirect*, 827 F.3d at 1051 (though individual freezing and thawing steps described in the patent were not novel, the "process of preserving hepatocytes by repeating those steps was itself far from routine and conventional"; prior art only disclosed methods with one freeze-thaw cycle and taught away from the method described in the patent); *BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016) (an "inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces," such as where "claims do not merely recite the abstract idea of filtering content along with the requirement to perform it on the Internet," but rather "recite a specific discrete implementation of the abstract idea of filtering content"). But here, the Court "cannot hold that performing standard techniques in a standard way to observe a newly discovered natural law provides an inventive concept." *Athena*, 915 F.3d at 754. "[T]o supply an inventive concept the sequence of claimed steps must do more than adapt a conventional [method] to a newly discovered natural law; it must represent an inventive application beyond the discovery of the natural law itself." *Id.* Nextcea's patent amounts to no more than instructing users to adapt conventional methods to the di-22:6-BMP isoforms.

Taken together, the "process steps here merely tell those 'interested in the subject about the correlations that the researchers discovered,'" and accordingly do not supply an inventive concept. *Cleveland Clinic*, 859 F.3d at 1362 (quoting *Mayo*, 566 U.S. at 78).

Finally, Nextcea argues that dependent claims 13, 15, and 18 recite a further limitation: separation of the isomers from each other. But stated at such a high level of generality and absent any more specifics regarding the method of separation, these claims simply do not contain an inventive concept sufficient to show that the "patent in practice amounts to significantly more than a patent upon the [the ineligible concept] itself." *Vanda*, 887 F.3d at 1133 (citation omitted). Accordingly, the claims in the '949 patent are unpatentable, and Nextcea's infringement claim must be dismissed.

CONCLUSION AND ORDER

For the foregoing reasons, Lipotype's motion to dismiss, ECF 28, is GRANTED.

SO ORDERED.

/s/ Julia E. Kobick
JULIA E. KOBICK
UNITED STATES DISTRICT JUDGE

Dated: February 6, 2026