IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CHROMADEX, INC. and TRUSTEES OF DARTMOUTH COLLEGE Plaintiffs, v. ELYSIUM HEALTH, INC. Defendant.	Civil Action No. 18-1434-CFC-JLH

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MEMORANDUM OPINION

September 21, 2021
Wilmington, Delaware

COLM F. CONNOLLY
CHIEF JUDGE

Plaintiffs ChromaDex, Inc. and Trustees of Dartmouth College (collectively, ChromaDex) have sued Defendant Elysium Health, Inc. for infringement of U.S. Patent Numbers 8,197,807 (the #807 patent) and 8,383,086 (the #086 patent). Pending before me is Elysium Health's Motion for Summary Judgment (No. 1) of Invalidity Under 35 U.S.C. § 101. D.I. 182. Elysium argues that claims 1, 2, and 3 of the #807 patent and claim 2 of the #086 patent are invalid under 35 U.S.C. § 101 for claiming patent-ineligible subject matter.

I. BACKGROUND

The asserted patents claim compositions containing isolated nicotinamide riboside (NR), a naturally occurring form of vitamin B3. Isolated NR facilitates production of "NAD^+," a coenzyme associated with various biological activities.

The asserted claims of the #807 patent read as follows:

> 1. A composition comprising isolated nicotinamide riboside in combination with one or more of tryptophan, nicotinic 60 acid, or nicotinamide, wherein said combination is in admixture with a carrier comprising a sugar, starch, cellulose, powdered tragacanth, malt, gelatin, talc, cocoa butter, suppository wax, oil, glycol, polyol, ester, agar, buffering agent, alginic acid, isotonic saline, Ringer's solution, ethyl alcohol, poly- 65 ester, polycarbonate, or polyanhydride, wherein said composition is formulated for oral administration and increases NAD+ biosynthesis upon oral administration.

> 2. The composition of claim 1, wherein the nicotinamide riboside is isolated from a natural or synthetic source.
>
> 3. The composition of claim 1, wherein the formulation comprises a tablet, troche, capsule, elixir, suspension, syrup, wafer, chewing gum, or food.

#807 patent at claims 1–3.

Asserted claim 2 of the #086 patent depends from independent claim 1, which is not asserted.[1] Those two claims read as follows:

> 1. A pharmaceutical composition comprising nicotinamide riboside in admixture with a carrier, wherein said composition is formulated for oral administration.
>
> 2. The pharmaceutical composition of claim 1, wherein the nicotinamide riboside is isolated from a natural or synthetic source.

#086 patent at claims 1, 2. I have construed the phrase "pharmaceutical composition" to mean "a composition that can be used to improve or prolong the health or well-being of humans or other animals." D.I. 152 at 3.

[1] The Patent Trial and Appeal Board has already held that claim 1 of the #086 patent is invalid. *See Elysium Health Inc. v. Trustees of Dartmouth College*, No. IPR2017-01795, Paper No. 39 (P.T.A.B. Jan. 16, 2019), *aff'd*, 796 Fed. App'x 745 (Fed. Cir. 2020).

II. LEGAL STANDARDS

A. Summary Judgment

A court must grant summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Material facts are those "that could affect the outcome" of the proceeding. *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011). "[A] dispute about a material fact is genuine if the evidence is sufficient to permit a reasonable jury to return a verdict for the non-moving party." *Id.* (internal quotation marks omitted). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations, . . . admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute . . . ." Fed. R. Civ. P. 56(c)(1). The non-moving party's evidence "must amount to more than a scintilla, but may amount to less (in the evaluation of the court) than a preponderance." *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460–61 (3d Cir. 1989).

B. Patent-Eligible Subject Matter

Section 101 of the Patent Act defines patent-eligible subject matter. It provides: "Whoever invents or discovers any new and useful process, machine,

manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101.

There are three judicially created limitations on the literal words of § 101. The Supreme Court has long held that laws of nature, natural phenomena, and abstract ideas are not patentable subject matter. *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014). These exceptions to patentable subject matter arise from the concern that 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.* (internal quotation marks and citations omitted).

"A claim to otherwise statutory subject matter does not become ineligible simply because it recites a natural law," *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, 760 Fed. App'x 1013, 1018 (Fed. Cir. 2019), since "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 71 (2012). But in order "to transform an unpatentable law of nature [or natural phenomena] into a patent-eligible application of such law [or natural phenomena], one must do more than simply state the law of nature [or natural phenomena] while adding the words 'apply it.'" *Id.* (emphasis omitted).

In *Alice*, the Supreme Court established a two-step framework by which courts are to distinguish patents that claim eligible subject matter under § 101 from patents that do not claim eligible subject matter under § 101. The court must first determine whether the patent's claims are drawn to a patent-ineligible concept—i.e., are the claims directed to a law of nature, natural phenomenon, or abstract idea? *Alice*, 573 U.S. at 217. If the answer to this question is no, then the patent is not invalid for teaching ineligible subject matter. If the answer to this question is yes, then the court must proceed to step two, where it considers "the elements of each claim both individually and as an ordered combination" to determine if there is 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 (alteration in original) (internal quotations and citations omitted).[2]

[2] The Court in *Alice* literally said that this two-step framework is "for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." 573 U.S. at 217. But as a matter of logic, I do not see how the first step of the *Alice/Mayo* framework can distinguish (or even help to distinguish) patents in terms of these two categories (i.e., the categories of (1) "patents that claim laws of nature, natural phenomena, and abstract ideas" and (2) patents "that claim patent-eligible applications of [laws of nature, natural phenomena, and abstract ideas]"). *Both* categories *by definition* claim laws of nature, natural phenomena, and abstract ideas; and only one of *Alice*'s steps (i.e., the second, "inventive concept" step) could distinguish the two categories. I therefore understand *Alice*'s two-step framework to be the framework by which courts are to distinguish patents that

Issued patents are presumed to be valid, but this presumption is rebuttable. *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 96 (2011). Subject-matter eligibility is a matter of law, but underlying facts must be shown by clear and convincing evidence. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018).

III. DISCUSSION

Applying the two-step framework from *Alice*, I find that the asserted patent claims are invalid under § 101.

A. *Alice* Step One

"[C]laims are considered in their entirety [at step one] to ascertain whether their character as a whole is directed to excluded subject matter." *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015). Elysium argues in its briefing that the asserted claims are directed to "compositions comprising isolated nicotinamide riboside ("NR")[,] . . . a naturally-occurring vitamin present in cow milk." D.I. 183 at 1. ChromaDex does not dispute this description of the asserted claims' subject matter. And Elysium's description of the claims' subject matter is entirely consistent with the language of the claims and

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claim eligible subject matter under § 101 from patents that do not claim eligible subject matter under § 101.

the patents' shared written description. Accordingly, the asserted claims are directed to a natural phenomenon.

ChromaDex counters that "the mere fact that NR is found in nature does not establish that the claimed compositions are directed to patent-ineligible subject matter." D.I. 278 at 2. Quoting language from *Natural Alternatives International, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338 (Fed. Cir. 2019), ChromaDex argues that the "correct inquiry under *Alice* step 1 is . . . whether compositions of the Asserted Claims 'have different characteristics and can be used in a manner that [NR] as it appears in nature cannot.'" D.I. 278 at 3 (citing *Natural Alternatives*, 918 F.3d at 1348) (alterations in the original). According to ChromaDex:

> The characteristics of the claimed compositions dramatically distinguish those compositions from naturally occurring NR. The claimed compositions contain isolated NR that is stable, bioavailable, and sufficiently pure that the compositions can be administered orally to deliver NR to the cells of an animal and exert therapeutic effect. Elysium's motion contains no showing that the NR in milk even reaches the bloodstream after the milk is consumed, let alone enters cells and provides therapeutic effect.

D.I. 278 at 6.

But even if I were to apply the *Alice* step one test as framed by ChromaDex, its argument fails. As an initial matter, the characteristics of the isolated NR in the claimed compositions that ChromaDex has identified as being different from the

characteristics of NR in milk—i.e., stability, bioavailability, sufficient purity, and therapeutic efficacy—are immaterial to the *Alice* inquiry because none of these characteristics are required by the claims. *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1149 (Fed. Cir. 2016) ("The § 101 inquiry must focus on the language of the Asserted Claims themselves."). Nothing in the language of the asserted claims or the patent's intrinsic evidence suggests that the claims require these characteristics. And, indeed, ChromaDex does not allege in its briefing that the claims impose such requirements. ChromaDex expressly states in its briefing that the asserted claims require that the recited compositions be capable of improving a patient's health and of enhancing NAD^+ synthesis. *See* D.I. 278 at 7 (stating that "the claims do require that the compositions have the capability to improve health and well-being (the [#]086 Patent) [and] enhance NAD^+ biosynthesis (the [#] 807 Patent)"). But those requirements have no bearing on the *Alice* step one test articulated by ChromaDex, since it is undisputed that NR in milk improves health and well-being and enhances NAD^+ biosynthesis, and thus those characteristics do not distinguish isolated NR in the claimed compositions from NR found in milk.

The crux of ChromaDex's position seems to be that stability, bioavailability, purity, and therapeutic efficacy are implicitly required by the claims' "isolation" limitation. ChromaDex states, for example, that "[t]he use of isolated NR in the

Asserted Claims requires that the NR in the claimed compositions be stable and bioavailable, allowing it to reach the bloodstream, enter the cell, and provide therapeutic effect." D.I. 278 at 4. And it argues that "[b]ecause the NR in the claimed compositions is isolated—and therefore stable, bioavailable, and pure—the claimed compositions can be used to deliver effective amounts of NR to cells." D.I. 278 at 6–7. But the Supreme Court unanimously rejected this line of argument in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 580 (2013). The Court held in *Myriad* that "a naturally occurring DNA segment is a product of nature and not patent-eligible merely because it has been isolated." *Id.* And it expressly rejected the argument that the asserted claims in that case were "saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule," because "Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA." *Id.* at 593.

In this case, the asserted claims are simply not expressed in terms of stability, bioavailability, or purity; nor do they rely in any way on changes that result from the isolation of NR. ChromaDex consented to my construction of "isolated [NR]" as NR "that is separated or substantially free from at least some of the other components associated with the source of the [NR]." Tr. of Dec. 17,

2020 Hr'g at 32:1–6. And that construction in no way requires that the NR in the claimed composition be stable, bioavailable, sufficiently pure, or have a therapeutic effect.

Accordingly, I decline to import details not claimed and find that the asserted claims are directed to a natural product. *See ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 769 (Fed. Cir. 2019) (focusing § 101 analysis on the asserted claims because "the specification cannot be used to import details from the specification if those details are not claimed."), *cert. denied*, 140 S. Ct. 983 (2020).

B. *Alice* Step Two

Having found that the claims are directed to a product of nature, I consider next whether they contain an "'inventive concept' sufficient to 'transform' the claimed [ineligible concept] into a patent-eligible application." *Alice*, 573 U.S. at 221 (quoting *Mayo*, 566 U.S. at 77). It is insufficient for the patent to "simply state the law of nature while adding the words 'apply it.'" *Mayo*, 566 U.S. at 72. A claim directed towards a natural product must include "additional features to ensure that the claim is more than a drafting effort designed to monopolize the [natural product]." *Alice*, 573 U.S. at 221 (quotation marks and alterations omitted) (quoting *Mayo*, 566 U.S. at 77).

There are no such additional features here. The patents' shared written description acknowledges, and ChromaDex does not dispute, that compositions containing NR "can be prepared by methods and contain carriers which are well-known in the art." #807 patent at 29:24–35; #086 patent at 28:49–60. Nor does ChromaDex dispute that the physical act of isolating NR is not an inventive concept. *See* #807 patent at 27:45–54 ("Isolated extracts of the natural sources can be prepared using standard methods."); #086 patent at 27:3–12 (same); D.I. 292-1, Ex. 1 ¶ 164 (ChromaDex's expert stating that "[i]t is not the specific techniques of isolation that transform the Asserted Claims beyond a law of nature or natural phenomenon"); *see also Myriad*, 569 U.S. at 591, 595 (stating that "the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad's patents" and that "separating th[e] [BRCA1 or BRCA2] gene from its surrounding genetic material is not an act of invention").

ChromaDex argues initially in its briefing that the "inventive step" of the asserted claims is the "recogni[tion] [of] the utility of NR for enhancing health and well-being." D.I. 278 at 9. But "[t]he inventive concept necessary at step 2 of the *Mayo/Alice* analysis cannot be furnished by [an] unpatentable law of nature (or natural phenomenon or abstract idea)." *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1376 (Fed. Cir. 2016). Perhaps because it realized the futility of its argument, ChromaDex abandoned it in the very next paragraph of its brief, stating

there that "[t]he inventive concept of the Asserted Claims is not the *discovery* of the NR vitamin pathway, but rather therapeutic *applications* of this discovery in inventive ways beyond that of the prior art." D.I. 278 at 9–10 (emphasis in the original). Its expert agrees with this latter position. In the expert's words:

> [T]he inventive concept is the pioneering decision to create a composition comprising isolated NR formulated for oral administration. This was not well-understood, routine, and conventional activity at the time of the invention; . . . it was not until [the inventor] Dr. Brenner's work in 2004 that the scientific community even became aware of the importance of NR as an orally available vitamin or what it would do in the body.

D.I. 292-1, Ex.1 ¶ 164.

This revised articulation of the putative inventive concept fails too. Because NR's oral bioavailability is an inherent property of NR and thus is itself a natural phenomenon, ChromaDex did not alter NR to create this property. It simply uncovered it. ChromaDex is essentially arguing that the idea of making an oral formulation of NR was inventive. But the decision to create an oral formulation of NR after discovering that NR is orally bioavailable is simply applying a patent-ineligible law of nature. And the Supreme Court has made clear that more than "apply it" is needed to "transform an unpatentable law of nature into a patent-eligible application of such a law." *Mayo,* 566 U.S. at 72.

ChromaDex disagrees and cites the Federal Circuit's decision in *Rapid Litigation Management, Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050–51 (Fed.

Cir. 2016) for the proposition that "a claim that 'applies the discovery' to achieve something new and useful suffices to provide an inventive concept." D.I. 278 at 10 (citing *CellzDirect*, 827 F.3d at 1050–51). But the Court in *CellzDirect* stressed that the patent-eligible asserted claims at issue in that case were "directed to a new and useful method," as opposed to a product claim. 827 F.3d at 1048–49 (noting that the asserted claims "are like thousands of others that recite *processes* to achieve a desired outcome, e.g., *methods* of producing things or, *methods* of treating diseases") (emphasis added)); *id.* at 1049 (stating "the claims are directed to a new and useful process of creating [the] pool [of cells], not to the pool [of cells] itself"); *id.* at 1049 (stating that the method claims before it were "distinguishable from [the composition claims] held unpatentable in *Myriad*"). The asserted claims here are composition claims, and thus they are governed by *Myriad*. *See Myriad*, 569 U.S. at 595 (noting that the claims the Court found to be patent-ineligible were not method claims purporting to create an inventive method of manipulating genes).

IV. CONCLUSION

For the reasons discussed above, I find that claims 1, 2, and 3 of the #807 patent and claim 2 of the #086 patent are invalid under 35 U.S.C. § 101 for claiming patent-ineligible subject matter. Accordingly, I will grant Elysium's motion for summary judgment (D.I. 182).

The Court will issue an Order consistent with this Memorandum Opinion.