APPENDIX

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APPENDIX A

United States Court of Appeals for the Federal Circuit

CHROMADEX, INC., TRUSTEES OF DARTMOUTH COLLEGE,
Plaintiffs-Appellants

v.

ELYSIUM HEALTH, INC.,
Defendant-Appellee

2022-1116

Appeal from the United States District Court for the District of Delaware in No. 1:18-cv-01434-CFC-JLH, Chief Judge Colm F. Connolly.

Decided: February 13, 2023

WILLIAM L. MENTLIK, Lerner, David, Littenberg, Krumholz & Mentlik, LLP, Cranford, NJ, argued for plaintiffs-appellants. Also represented by RUSSELL W. FAEGENBURG, STEPHEN F. ROTH; ROBERT JASON FOWLER, CHRISTOPHER NEIL SIPES, ASHLEY MARIE WINKLER, Covington & Burling LLP, Washington, DC.

JEREMY YOUNKIN, Foley Hoag LLP, Boston, MA, argued for defendant-appellee. Also represented by DONALD ROSS WARE.

Before PROST, CHEN, and STOLL, *Circuit Judges*.

PROST, *Circuit Judge*.

ChromaDex, Inc. ("ChromaDex") and the Trustees of Dartmouth College ("Dartmouth") (collectively, "Appellants") appeal the decision of the U.S. District Court for the District of Delaware granting Elysium Health, Inc.'s ("Elysium") motion for summary judgment that the asserted claims of U.S. Patent No. 8,197,807 ("the '807 patent") are directed to unpatentable subject matter under 35 U.S.C. § 101.[1] We affirm.

BACKGROUND

I

The '807 patent is directed to dietary supplements containing isolated nicotinamide riboside ("NR"), a form of vitamin B3 naturally present—in non-isolated form—in cow's milk and other products.[2] *See* '807 patent col. 27 ll. 42–45. Animal cells convert ingested NR into the coenzyme nicotinamide adenine dinucleotide, or NAD+. NAD+ deficiencies can cause diseases in both animals and humans.

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[1] Appellants also sought review of the district court's invalidation of claim 2 of U.S. Patent No. 8,383,086. The voluntary dismissal of a related appeal mooted that part of the case.

[2] For the sake of brevity, we use the word "milk" in the rest of this opinion to describe natural cow's milk.

The asserted claims are claims 1–3 of the '807 patent.

Representative claim 1 recites:

> 1. A composition comprising isolated nicotinamide riboside in combination with one or more of tryptophan, nicotinic 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, polyester, polycarbonate, or polyanhydride, wherein said composition is formulated for oral administration and increased NAD+ biosynthesis upon oral administration.

II

ChromaDex sells, among other products, dietary supplements in the form of pharmaceutical compositions of NR embodying the '807 patent. It licenses the patent from Dartmouth. Appellants sued Elysium, a former ChromaDex customer, for patent infringement in September 2018. The district court construed several claim terms; relevant here, the court construed "isolated [NR]" to mean "[NR] that is separated or substantially free from at least some other components associated with the source of [NR]." J.A. 22.

Elysium moved for summary judgment, arguing that the asserted claims were invalid under 35 U.S.C.

§ 101, and the district court granted the motion. *See ChromaDex, Inc. v. Elysium Health, Inc.*, 561 F. Supp. 3d 460 (D. Del. 2021). The district court concluded that the claims were directed to a natural phenomenon, namely, "compositions comprising isolated [NR], a naturally occurring vitamin present in cow milk." *Id.* at 464 (cleaned up). It rejected ChromaDex's argument that the characteristics of isolated NR purportedly different from naturally occurring NR—stability, bioavailability, sufficient purity, and therapeutic efficacy—render the claims patent-eligible, observing that none of those characteristics were part of the claims. *Id.* at 465. It concluded that "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." *Id.* at 467.

The district court entered judgment of invalidity, and this appeal followed.[3] We have jurisdiction under 28 U.S.C. § 1295(a)(1).

[3] Appellants also challenge the district court's orders granting-in-part Elysium's motion to dismiss for lack of standing and denying its motion for leave to amend, as well as one of its claim constructions. The district court's standing order only dismissed claims of infringement based on activities alleged to have occurred on or after March 13, 2017, *see* J.A. 16–17, so the eligibility issue remained live. Because we affirm the district court's invalidity judgment, we do not reach either the standing or the claim construction issues.

DISCUSSION

I

We review the district court's grant of summary judgment under the law of the regional circuit, here the Third Circuit, which reviews such issues de novo. *Junker v. Med. Components, Inc.*, 25 F.4th 1027, 1032 (Fed. Cir. 2022) (citing *Gonzalez v. Sec'y of Dep't of Homeland Sec.*, 678 F.3d 254, 257 (3d Cir. 2012)). Summary judgment is appropriate when, drawing all reasonable inferences in the nonmoving party's favor, "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); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Eligibility under § 101 may involve questions of fact but is, ultimately, a question of law that we review de novo. *Nat. Alts. Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1342 (Fed. Cir. 2019); *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1342 (Fed. Cir. 2018).

"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. "Laws of nature, natural phenomena, and abstract ideas," in contrast, "are not patentable." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013).

II

The parties agree that NR is naturally present in milk. It is undisputed that milk is a naturally

occurring product that is not patent eligible. The parties also acknowledge that milk contains tryptophan and lactose, a sugar. And no one disputes that the tryptophan in milk treats NAD+ deficiencies. The claims are very broad and read on milk with only one difference as shown:

Element	**Milk**
[1p] "A composition comprising"	Milk is a composition.
[1a] "isolated [NR]"	Milk contains NR, but the NR is not isolated. J.A. 10095.
[1b] "in combination with one or more of tryptophan, nicotinic acid, or nicotinamide"	Milk contains tryptophan and nicotinamide. J.A. 10095.
[1c] "wherein said combination is an 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, polyester, polycarbonate, or polyanhydride"	Milk is an admixture containing a sugar (lactose). J.A. 10096

[1d] "wherein said composition is formulated for oral administration"	Milk is formulated for oral administration. *See* J.A. 10096.
[1e] "and increases NAD+ biosynthesis upon oral administration."	Milk (through tryptophan) increases NAD+ biosynthesis upon consumption. *See* J.A. 10096.

So the only difference between at least one embodiment within the scope of the claims and natural milk is that the NR in the former is isolated.

The Supreme Court's decisions in *Myriad* and *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980), apply here. In *Chakrabarty*, the Court found eligible claims to a genetically engineered bacterium "capable of breaking down multiple components of crude oil." 447 U.S. at 305, 318. No naturally occurring bacteria possessed the same property. *Id.* Accordingly, in the Court's view, the "claim [was] 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." *Id.* at 309–10 (cleaned up). Because "the patentee ha[d] produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility," the Court upheld the claims. *Id.* at 310.

As in *Myriad*, under the circumstances presented here, the act of isolating the NR compared to how NR naturally exists in milk is not sufficient, on its own, to

confer patent eligibility. *See Myriad*, 569 U.S. at 590–93. The claimed compositions remain indistinguishable from natural milk because, other than separation from some other components, the isolated NR is no different structurally or functionally from its natural counterpart in milk. *Chakrabarty* defines the inquiry: to be patentable, the claimed composition must "ha[ve] markedly different characteristics and have the potential for significant utility." 447 U.S. at 310. Milk, like the claimed compositions, undisputedly "increase[s] NAD+ biosynthesis" upon oral administration. The claimed compositions do not exhibit markedly different characteristics from natural milk and are, therefore, invalid for claiming a patent-ineligible product of nature. *Cf. Myriad*, 569 U.S. at 579 (concluding "that a naturally occurring DNA segment is *a product of nature* and not patent eligible merely because it has been isolated" (emphasis added)).

Our *Natural Alternatives* decision is particularly instructive. There, we upheld, at the motion-to-dismiss stage, claims directed to dietary supplements containing beta-alanine. *See* 918 F.3d at 1341. We concluded that the patents there claimed "specific treatment formulations that incorporate[d] natural products" and that those formulations "ha[d] different characteristics and c[ould] be used in a manner that beta-alanine as it appears in nature cannot." *Id.* at 1348. Specifically, the "natural products ha[d] been isolated and then incorporated into a dosage form"—"between about 0.4 grams to 16 grams"—"with particular characteristics"—namely, to "effectively increase[] athletic performance." *Id.* at 1348–49. Those markedly different characteristics

distinguished the claimed supplements from natural beta-alanine and preserved the claims' validity. *Id.* at 1349.

Here, in contrast, the asserted claims do not have characteristics markedly different from milk. Both the claimed compositions and milk "increase[] NAD+ biosynthesis upon oral administration." Appellants argue that the claimed compositions are advantageous over milk because the isolation of NR allows for significantly more NAD+ biosynthesis than is found in milk and that the large quantity of NR itself *can alone* increase NAD+ biosynthesis. But the asserted claims do not require any minimum quantity of isolated NR. Nor do these claims attribute the claimed increase in NAD+ biosynthesis to the isolated NR, requiring only that the *composition* increase NAD+ production. Because milk increases NAD+ biosynthesis, the claimed compositions do not possess characteristics markedly different from those found in nature. To be sure, the claims cover several different composition embodiments, some of which are structurally different from milk. However, as noted above, the claims also encompass—as both parties agree—at least one embodiment that covers milk, except that the NR element is "isolated." Because the claims are broad enough to encompass a product of nature, it is invalid under § 101.

Appellants nonetheless argue that the claims, in fact, possess markedly different characteristics that render them patent-eligible. *See* Appellants' Br. 28–31. They base this argument on two main points: (1) "NR is found in milk in only trace amounts," *i.e.*, one part per million; and (2) "what little NR is found in

milk is not bioavailable" because it is bound to the lactalbumin whey protein. *Id.* at 29.[4] The problem for Appellants is two-fold. First, as discussed above, milk increases NAD+ biosynthesis (albeit because it contains tryptophan rather than because of the trace amounts of NR), and that is the only therapeutic effect that the claims require. Second, the claims simply do not reflect the distinctions Appellants rely on: they do not require any specific quantity of isolated NR, and the district court's construction for "isolated [NR]," which Appellants do not challenge on appeal, does not require that the NR be separated from the lactalbumin whey protein but only from "*some* of the other components associated with the source of [NR]." J.A. 22 (emphasis added). The claims, therefore, do not necessarily require that the isolated NR be bioavailable, meaning that the claimed compositions do not necessarily possess markedly different characteristics from milk, as they must to be patent-eligible.

[4] Appellants also identify a factual error in the district court's opinion. The court stated that it was "undisputed that NR in milk . . . enhances NAD+ biosynthesis." *ChromaDex*, 561 F. Supp. 3d at 465. Appellants correctly point out that the NR in milk does not enhance NAD+ biosynthesis, that it argued as much to the district court, and that Elysium conceded the point. *See, e.g.*, J.A. 10245 (Elysium admitting that "one can't eat enough of anything [containing trace amounts of NR] to boost NAD+ levels"). That error was harmless, however, because the claims do not require that the NR, specifically, increase NAD+ biosynthesis; it is enough if the claimed composition accomplishes that objective, and milk does so.

We conclude that the asserted claims lack markedly different characteristics from milk. They claim a product of nature and are not patent eligible.

III

The inquiry could end here—the Supreme Court in *Myriad* relied on *Chakrabarty*'s "markedly different characteristics" framework for analyzing whether the claimed compositions there were directed to a natural phenomenon; the Court never applied the *Alice*/*Mayo* two-step framework despite deciding the case after *Mayo*. *See Myriad*, 569 U.S. at 593–95; *see also Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 77–80 (2012). But if resort to *Alice*/*Mayo* is necessary, then at step one we conclude the asserted claims are directed to a product of nature for the reasons stated above, and at step two the claims lack an inventive step because they are directed to nothing more than compositions that increase NAD+ biosynthesis, which is the very natural principle that renders the claims patent-ineligible.[5]

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[5] In *Natural Alternatives*, we purported to analyze the patent-eligibility of the claimed compositions under *Alice*/*Mayo*'s two-step framework. *See Nat. Alts.*, 918 F.3d at 1342, 1348–49. But because we concluded that factual allegations relating to the claimed compositions' markedly different characteristics from natural beta-alanine precluded judgment on the pleadings, the analysis functionally examined only the *Chakrabarty* question. *See id.* at 1348. Indeed, in one prior case, we analyzed compositionof-matter claims under *Myriad* and *Chakrabarty* but analyzed method claims under *Mayo*. *Compare In re BRCA1 and BRCA2*, 774 F.3d 755, 759–61 (Fed. Cir. 2014), *with id.* at 761–765.

Appellants identify only two possible inventive steps: "[1] recognizing the utility of NR for enhancing health and well-being and [2] the wisdom of *isolating* the NR to provide concentrations higher than what occur naturally." Appellants' Br. 31 (emphasis original). But recognizing the utility of NR is nothing more than recognizing a natural phenomenon, which is not inventive. *See Myriad*, 569 U.S. at 591. And the act of isolating the NR by itself, no matter how difficult or brilliant it may have been (although the specification makes clear that it was conventional), similarly does not turn an otherwise patent-ineligible product of nature into a patentable invention. *See id.* So the claims would likewise fail at step two.

CONCLUSION

We have considered Appellants' remaining arguments and find them unpersuasive. As Appellants conceded at oral argument, our resolution of the patent-eligibility issue moots the standing question. For the reasons set forthabove, we affirm the district court's judgment that the asserted claims of the '807 patent are invalid under 35 U.S.C. § 101.

AFFIRMED

APPENDIX B

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

Adam Poff, Pilar Kraman, YOUNG, CONWAY, STARGATT & TAYLOR LLP, Wilmington, Delaware; James Haley, HALEY GUILIANO LLP, New York, New York; Jason Fowler, COVINGTON & BURLING LLP, Washington, District of Columbia

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Counsel for Defendant.

MEMORANDUM OPINION

September 21, 2021
Wilmington , Delaware

/s/ Colm F. Connolly
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.

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

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[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).

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]

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).

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

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 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.

APPENDIX C

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

CHROMADEX, INC., TRUSTEES OF DARTMOUTH COLLEGE,
Plaintiffs-Appellants

v.

ELYSIUM HEALTH, INC.,
Defendant-Appellee

2022-1116

Appeal from the United States District Court for the District of Delaware in No. 1:18-cv-01434-CFC-JLH, Chief Judge Colm F. Connolly.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before MOORE, *Chief Judge*, NEWMAN, LOURIE, DYK, PROST, REYNA, TARANTO, CHEN, HUGHES, STOLL, and CUNNINGHAM, *Circuit Judges*.[1]

PER CURIAM.

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[1] Circuit Judge Stark did not participate.

O R D E R

ChromaDex, Inc. and Trustees of Darmouth College filed a combined petition for panel rehearing and rehearing en banc. A response to the petition was invited by the court and filed by Elysium Health, Inc. The petition was referred to the panel that heard the appeal, and thereafter the peti- tion was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue May 17, 2023.

FOR THE COURT

May 10, 2023
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court