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UNITED STATES PATENT AND TRADEMARK OFFICE

EBORE THE PATENT TRIAL AND APPEAL BOARD

ELYSIUM HEALTH INC.,
Petitioner,

v.

TRUSTEES OF DARTMOUTH COLLEGE,
Patent Owner.

Case No. IPR2017-01796
Patent 8,197,807 B2

Before SUSAN L. C. MITCHELL, CHRISTOPHER G. PAULRAJ, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Elysium Health Inc., ("Petitioner") filed a Petition requesting *inter partes* review of claims 1–3 of U.S. Patent No. 8,197,807 B2 ("the ''807 patent"). Paper 1 ("Pet."). The Trustee of Dartmouth University ("Patent Owner") filed a Preliminary Response contending that the Petition should be denied as to all the challenged claims. Paper 8 ("Prelim. Resp.").

We have authority under 37 C.F.R. § 42(a) and 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Having considered the arguments and the evidence presented, for the reasons described below, we determine that Petitioner has not demonstrated that there is a reasonable likelihood that it would prevail with respect to at least one of the claims challenged by the Petition. Accordingly, we decline to institute an *inter partes* review.

B. Additional Proceedings

Petitioner represents that the '807 patent is at issue in *ChromaDex, Inc., v Elysium Health, Inc.*, Case No. 16-cv-02277-KES (C.D.Cal.). Pet. 29. Petitioner also represents that a petition for *inter partes* review has been filed challenging related U.S. Patent No. 8,383,086, which is now IPR 2017-001795. *Id*. at 29–30.

C. The ’807 Patent (Ex 1001)

The ’807 patent, titled “Nicotinamide Riboside Kinase Compositions and Methods for Using the Same” purports to disclose a dietary supplement composition containing nicotinamide riboside wherein the nicotinamide riboside is obtained from a natural or synthetic source. Ex. 1001, col. 4, ll. 8–23.

D. Illustrative Claim

Of the challenged claims, claim 1 is independent. Claims 2 and 3 depend from claim 1. Claim 1 is illustrative of the claimed subject matter and reads as follows:

> 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 increases NAD+ biosynthesis upon oral administration.

Ex. 1001 col. 53, l. 59–col. 54, l. 59.

E. The Alleged Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable on the following grounds[1]:

[1] Petitioner supports its challenge with the Declaration of Joseph A. Baur, Ph.D. Ex 1002 (“Baur Decl.”).

References	Basis	Claims Challenged
Goldberger et al.[2]	§ 102	1–3
Goldberger and Tanner[3]	§ 102	1–3

II. CLAIM CONSTRUCTION

A. Legal Standard

"A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). When applying that standard, we interpret the claim language as it should be understood by one of ordinary skill in the art in light of the specification. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). Under that standard, the claim terms are generally given their ordinary and customary meaning as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("The ordinary and customary meaning 'is the meaning that the term would have to a person of ordinary skill in the art in question.'"). Only terms which are in controversy need to be construed and only then to the extent necessary to resolve the

[2] Goldberger et al., *A Study of the Blacktongue-Preventative Action of 16 Foodstuffs, With Special Reference to the Identity of Blacktongue of Dogs and Pellagra of Man,* 43 Pub. Heath Reports 1385 (1928) ("Goldberger et al."). Ex. 1005.
[3] Goldberger and Tanner, *A Study of the Treatment and Prevention of Pellagra,* 39 Pub. Health Reports 87 (1924) ("Goldberger and Tanner"), Ex. 1006.

controvery, *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

B. Isolated

Claim 1 recites a composition comprising "isolated nicotinamide riboside." Ex. 1001, col. 53, l. 59. Claim 2 state that the nicotinamide riboside "is isolated from a natural or synthetic source." *Id.* at col. 54, ll. 60–61.

Petitioner contends that the term "isolated" should be interpreted to mean "separated or substantially free from at least some of the other components of the naturally occurring organism." Pet. 6. Similarly, Petitioner contends that the phrase "is isolated" in claim 2 should be construed to mean "is separated from at least some of the other components of the naturally occurring organism." *Id.* at 7.

In support of its proposed constructions, Petitioner cites in part to the following teaching in the Specification:

> The present invention is an isolated nucleic acid containing a eukaryotic nucleotide sequence encoding a nicotinamide riboside kinase polypeptide. As used herein, an isolated molecule (e.g., an isolated nucleic acid such as genomic DNA, RNA or cDNA or an isolated polypeptide) means a molecule separated or substantially free from at least some of the other components of the naturally occurring organism, such as for example, the cell structural components or other polypeptides or nucleic acids commonly found associated with the molecule. When the isolated molecule is a polypeptide, said peptides is at least about 25%, 50%, 60%, 70%, 75%, 80%, 85%, 90%, 95%, 97%, 98%, 99% or more pure (w/w).

Ex. 1001, col. 9. ll. 21–32; Pet. 6.

Patent Owner contends that the term "isolated" should be construed to mean substantially free from other molecules. Prelim. Resp. 7. Patent owner contends that the term "is isolated" as used in claim 2 should be construed to mean "fractionated from other molecular components." *Id.*

In support of its contention regarding the term "isolated" as used in claim 1, Patent Owner relies upon the same passage in the Specification cited above. *Id.* at 8. Patent Owner also emphasizes the Specification's teaching that the nicotinamide riboside "can be from a natural or synthetic source identified by the method of the instant invention, or can be chemically synthesized using established methods." *Id.* at 9 (citing Ex. 1001, col. 28 ll. 58–63). Patent Owner argues that "the claims do not cover natural sources of nicotinamide riboside," but "[i]nstead, the patent specification identifies various natural and synthetic sources for the compound and then teaches a person of ordinary skill in the art how to isolate nicotinamide riboside *from those sources*, including from cow's milk." *Id.* at 11 (emphasis added). Patent Owner also contends that its proposed construction is consistent with the language of the claims insofar as independent claim 1 refers to the isolated nicotinamide riboside molecule itself (which may be chemically synthesized), while dependent claim 2 is narrower and "further specifies that nicotinamide riboside 'is isolated from a natural or synthetic source,' to the exclusion of chemically synthesizing the compound." *Id.* at 12–13. Patent Owner argues that Petitioner's proposed constructions are inconsistent with the Specification and claims and are unreasonably broad insofar as they encompasses cow's milk as the claimed composition whereas the Specification only identifies cow's milk as a

natural source from which nicotinamide riboside may be isolated. *Id.* at 14–18.

The term "isolated" as defined and used in the Specification embraces compositions containing nicotinamide riboside in which only some of the other naturally occurring components associated with the nicotinamide riboside have been removed. Ex. 1001, col. 9, ll. 23–26. Nonetheless, the question that remains is how much of those other components must be removed to meet the "isolated" claim limitations. In other words, how *pure* must the nicotinamide riboside be in order for it to be considered "isolated"?

The Specification provides guidance concerning the required purity of an "isolated molecule" in the paragraph recited above indicating that an isolated polypeptide is at least about 25% pure (w/w). Ex. 1001, col. 9, ll. 31–33. We recognize that the claims of the '807 patent refer to "isolated nicotinamide riboside" and not "isolated nicotinamide riboside kinase," the polypeptide to which the Specification refers in describing the meaning of an "isolated molecule" as set forth above. *Compare id.* at col. 53, ll. 59–60, *with id*. at 9:21–33. Although the Specification only refers to the purity of polypeptides, we find that, when read in the broader context of the entire patent, the person of ordinary skill in the art would also understand that a minimal level of purity would also be required for other types of "isolated" molecules, including specifically nicotinamide riboside. We find that it would be unreasonable under the broadest reasonable interpretation standard to construe "isolated" to only require separation from "some"—no matter how insignificant—amount of other components of the natural source of nicotinamide riboside (e.g., cow's milk). We find that in light of the Specification, "some amount" requires a measure, which is not answered by

Patent Owner's assertion that "isolated" means "substantially free from other molecules."

Thus, based on our consideration of the claim language, the Specification, and the parties' arguments, we determine that the broadest reasonable interpretation of the term "isolated" requires that the nicotinamide riboside is separated or substantially free from at least some of the other components associated with the source of the molecule such that it constitutes at least 25% (w/w) of the composition.

ANALYSIS

Petitioner contends that claims 1–3 are anticipated by Goldberger et al. and by Goldberger and Tanner. Pet. 5. As discussed more fully below we conclude that, on the record before us, Petitioner has not demonstrated that there is a reasonable likelihood that it will prevail on either ground.

A. Anticipation by Goldberger et al.

Goldberger et al. discloses a study of foodstuffs for the prevention of blacktongue in dogs. Ex. 1005, 1385. Blacktongue is a canine condition similar to pellagra in humans. *Id.* at 1385–86. Like pellagra, blacktongue is caused by a deficiency of NAD+. Ex. 1010, 2. In the study, dogs were fed a pellagra producing diet along with several candidates for preventing pellagra. Ex. 1005, 1387–88. Among the candidates evaluated by Goldberger et al. was milk, including skim milk. *Id.* at 1402–05. Goldberger et al. concluded that skim milk exercised a blacktongue preventative action. *Id.* at 1404.

"Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." *Gechter*

v. Davidson, 116 F.3d 1454, 1457 (Fed. Cir. 1997). "A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference." *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958(Fed. Cir. 2014) citing *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

Petitioner argues that all of the limitations of claims 1–3 are disclosed by Goldberger et al. Pet. 7–16. Specifically, Petition asserts that "[t]he milk disclosed in Goldberger et al. inherently comprises a composition comprising isolated nicotinamide riboside in combination with tryptophan and nicotinamide" as shown by Trammell I.[4] Pet. 13 (citing Ex. 1002 (Baur Decl.) ¶¶ 11, 31). Petitioner further asserts that the nicotinamide riboside in the Goldberger et al.'s skim milk is "isolated" because it is removed from the cow and further isolated during the process of converting the whole milk from the cow to skim milk by removing fat. *Id*. at 12 (citing Ex. 1002 ¶ 30).

We are not persuaded that Petitioner has shown sufficiently, on the present record and for purposes of the present decision, that Goldberger et al. discloses all of the limitations of claims 1–3.

Claim 1 is directed to a composition comprising isolated nicotinamide riboside. Ex. 1001, col. 53, ll. 59–60. The nicotinamide is in combination with one or more of tryptophan, nicotinic acid, or nicotinamide. *Id.* at col. 53, ll. 60–61. The combination is in an admixture of a carrier which may comprise a sugar. *Id.* at col. 53, l. 62. The composition is formulated for

[4] Trammell et al., *"Nicotinamide Riboside Is a Major NAD+ Precursor Vitamin in Cow Milk,"* 146 J. Nutrit. 965 (2016). ("Trammell I) Ex. 1007.

oral administration and increases NAD+ biosynthesis upon oral administration. *Id.* at col. 53, l. 66 – col. 54, l. 59.

As discussed above, we have construed the claim term "isolated" when read in light of the Specification of the '807 patent to require that the nicotinamide riboside be separated or substantially free from at least some of the other components associated with the source of the molecule such that it constitutes at least 25% (w/w) of the composition. Although Petitioner has offered evidence that the skim milk disclosed in Goldberger et al. comprises nicotinamide riboside that has been separated from fat, it does not teach that the nicotinamide riboside comprises at least 25% of the skim milk, nor do the other Trammell references on which Petitioner relies to show the inherent presence of nicotinamide riboside in Goldberger et al.'s skim milk. *See* Pet. 10. In fact Trammell I suggests that the amount of nicotinamide riboside present in raw cow's milk is less than 25%. *See* Ex. 1007, 3 (Milk samples contain 4.3 ± 2.6 µmol of nicotinamide riboside/liter.). Thus on the record before us, Petitioner has not shown that nicotinamide riboside in skim milk is "isolated" as required by claim 1.

Claims 2 and 3 depend from claim 1 and include the limitation "isolated nicotinamide riboside." For the reasons discussed above, Petitioner has not shown a reasonable likelihood that it will prevail in showing that claims 2 and 3 are anticipated by Goldberger et al.

B. Anticipation by Goldberger and Tanner

Goldberger and Tanner reports a study as to whether certain foods could be used to treat and prevent pellagra. Ex. 1006, 87. One of the foods

found to be effective in treating and preventing pellagra was buttermilk. Ex. 1006, 93. Subsequent research revealed that the buttermilk used by Goldberger and Tanner contains significant amounts of nicotinamide riboside, a precursor of NAD+. Ex. 1007 at 3, 5, and 6.

Petitioner contends that all of the limitations of claims 1–3 are disclosed by Goldberger and Tanner. Pet. 18–28. We are not persuaded that Petitioner has shown sufficiently, on the present record and for purposes of the present decision, that Goldberger and Tanner discloses all of the limitations of claims 1–3. In particular, although Petitioner has offered evidence that the buttermilk disclosed in Goldberger and Tanner comprises nicotinamide riboside that has been separated from fat, it does not teach that the nicotinamide comprises at least 25% of the skim milk, nor do the other Trammell references on which Petitioner relies to show the inherent presence of nicotinamide riboside in Goldberger and Tanner's buttermilk. *See* Pet. 20. In fact, as set forth above, Trammell I suggests that the amount of nicotinamide riboside present in raw cow's milk is less than 25%. *See* Ex. 1007, 3 (Milk samples contain 4.3 ± 2.6 μmol of nicotinamide riboside/liter.). Thus on the record before us, Petitioner has not shown that nicotinamide riboside in buttermilk is isolated as required by claim 1.

Claims 2 and 3 depend from claim 1 and include the limitation isolated nicotinamide riboside. For the reasons discussed above, Petitioner has not shown a reasonable likelihood that it will prevail in showing that claims 2 and 3 are anticipated by Goldberger and Tanner.

CONCLUSION

For the forgoing reasons, we conclude that Petitioner has not established a reasonable likelihood of prevailing on its assertion that claims 1–3 of the ’807 patent are anticipated by Goldberger et al. We also conclude that Petitioner has not established a reasonable likelihood of prevailing on its assertion that claims 1–3 of the ’807 patent are anticipated by Goldberger and Tanner.

ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied as to all challenged claims of the ’807 patent and no trial is instituted.

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