UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELYSIUM HEALTH, INC.,
Petitioner

v.

TRUSTEES OF DARTMOUTH COLLEGE,
Patent Owner

Case IPR2017-01795

Patent 8,383,086

PATENT OWNER RESPONSE

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EXHIBIT LIST

Exhibit No.	Description
2002	Declaration of Zhaohui Sunny Zhou, PhD. ("Zhou Decl.")
2003	Transcript of Joseph A. Baur deposition taken on April 26, 2018 ("Baur Tx.")
2004	Excerpt from McGraw-Hill Dictionary of Scientific and Technical Terms (2003) ("McGraw-Hill 2003")
2005	Excerpt from New Oxford American Dictionary (2005) ("New Oxford American 2005")
2006	Excerpt from Remington: The Science and Practice of Pharmacy, Alfonso R. Gennaro, editor, 20th ed. Lippingcott Williams & Wilkins: Philadelphia, Pa., 2000 ("Remington")
2007	Raats, et al., *Molecular analysis of bacterial communities in raw cow milk and the impact of refrigeration on its structure and dynamics*, Food Microbiology, Vol. 28, pp. 465-71 (2011)
2008	Rasolofo, et al., *Molecular analysis of bacterial population structure and dynamics during cold storage of untreated and treated milk*, Int'l J. Food Microbiology, Vol. 138, pp. 108-18 (2010)
2009	Kurnasov, et al., *Ribosylnicotinamide Kinase Domain of NadR Protein: Identification and Implications in NAD Biosynthesis*, J. Bacteriology, Vol. 184, No. 24, pp. 6906-17 (Dec. 2002)
2010	Johnson, et al., *Characterization of NAD salvage pathways and their role in virulence in Streptococcus pneumoniae*, Microbiology, Vol. 161, pp. 2127-36 (2015)
2011	Holsinger, et al., *Milk pasteurisation and safety: a brief history and update*, Rev. sci. tech. Off. int. Epiz, Vol. 16(2), pp. 441-51 (1997)

Pursuant to 35 U.S.C. § 316(a)(8) and 37 C.F.R. § 42.120, Trustees of Dartmouth College ("Patent Owner") responds to the Petition filed by Elysium Health, Inc. ("Petitioner") regarding U.S. Patent No. 8,383,086 (Ex. 1001, "the '086 patent").

I. SUMMARY OF ARGUMENT

Petitioner bears "the burden of proving a proposition of unpatentability by a preponderance of the evidence." 35 U.S.C. § 316(e). Petitioner has failed to meet that burden here.

The '086 patent claims require a pharmaceutical composition containing nicotinamide riboside as the active agent. The asserted prior art, Goldberger et al. (Ground 1) and Goldberger and Tanner (Ground 2)[1], discloses milk and buttermilk, respectively. Petitioner has not established that either milk or buttermilk is a

[1] The Board instituted review of claims 1, 3, 4 and 5 on Ground 1 (anticipation), but did not institute review of claim 2, nor did the Board institute review on Ground 2 (anticipation). Paper 9, at 19. After the Board announced it would institute review on all claims and all grounds (see Paper 22, "Modified Institution Decision"), Patent Owner filed a Request for Rehearing (Paper 24), which is currently pending. The Board has indicated that the Patent Owner Response should address all grounds in the Petition. Paper 25.

pharmaceutical composition containing nicotinamide riboside as the active agent. Because all claims of the ’086 patent require the same pharmaceutical composition containing nicotinamide riboside as the active agent, Petitioner has failed to establish that the prior art anticipates any claim of the ’086 patent. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”); *see also* M.P.E.P. § 2131 (“To anticipate a claim, the disclosure must teach every element of the claim.”).

Additionally, claim 2 depends from claim 1 and further requires nicotinamide riboside “isolated from a natural or synthetic source,” which the Board has already properly concluded is not disclosed in either of Petitioner’s asserted prior art references. Specifically, with respect to claim 2, the asserted prior art references do not disclose nicotinamide riboside that is isolated from a natural or synthetic source. Paper 9, at 13-14.

Finally, Petitioner has failed to establish that the prior art discloses dependent claim 5, which covers the pharmaceutical composition of claim 1 “which increase[s] NAD+ biosynthesis upon oral administration.” In fact, Petitioner’s expert expressly admits there is no proof that milk leads to such an increase. Ex. 2003, Baur Tx., at 45:22-47:17.

For the reasons set forth herein, Petitioner has failed to meet its burden to establish by a preponderance of the evidence that any claim of the ’086 patent is anticipated by either Goldberger et al. or Goldberger and Tanner.

II. THE ’086 PATENT

A. The Nicotinamide Riboside-Containing Pharmaceutical Compositions of the ’086 Patent Increase NAD+ Biosynthesis Upon Oral Administration

Prior to the ’086 patent invention, the gene products and pathways to nicotinamide adenine dinucleotide (NAD+), a co-enzyme found in cells, were understood to include *de novo* synthesis, nicotinic acid import, and nicotinamide salvage. ’086 patent, at 2:20-29, Scheme 1. The ’086 patent inventor, however, discovered that nicotinamide riboside is “an NAD+ precursor in a previously unknown but conserved eukaryotic NAD+ biosynthetic pathway,” and, importantly, that oral pharmaceutical formulations of nicotinamide riboside as the active agent could be used to treat conditions that are connected to NAD+ biosynthesis. *Id.* at 2:62-3:3, 8:39-41. As described in the specification:

> [A]gents (e.g., nicotinamide riboside) that work through the discovered nicotinamide riboside kinase pathway of NAD+ biosynthesis could have therapeutic value in improving plasma lipid profiles, preventing stroke, providing neuroprotection with chemotherapy treatment, treating fungal infections, preventing or reducing neurodegeneration, or in prolonging health and well-being. Thus, the present invention is further a method for preventing or

> treating a disease or condition associated with the nicotinamide riboside kinase pathway of NAD+ biosynthesis by administering an effective amount of nicotinamide riboside composition.

Id. at 27:60-28:3.

In light of the discovery that nicotinamide riboside is an effective active agent, the ’086 patent claims oral pharmaceutical compositions containing nicotinamide riboside. Contrary to Petitioner’s arguments, the ’086 patent does not cover any composition that happens to include nicotinamide riboside. Instead the ’086 patent claims cover oral compositions specifically formulated with nicotinamide riboside as the active agent.

B. All of the ’086 Patent Claims Require an Oral Pharmaceutical Composition Wherein Nicotinamide Riboside is the Active Agent

Each of dependent claims 2 through 5 depend from independent claim 1, which claims pharmaceutical compositions comprising nicotinamide riboside as the active agent, wherein the nicotinamide riboside is in admixture with a pharmaceutically acceptable carrier, and the composition is formulated for oral administration. *See* ’086 patent, at claim 1.

Dependent claim 2 further specifies that the nicotinamide riboside of the claimed pharmaceutical composition “is isolated from a natural or synthetic source.” *See id.* at claim 2. The ’086 patent specification includes examples of

such sources, and further describes methods for isolating nicotinamide riboside from a natural source such as cow's milk. *See id.* at 26:64-27:12.

Dependent claim 3 identifies a subset of forms that oral formulations of the nicotinamide riboside-containing pharmaceutical composition can take, including "a tablet, troche, capsule, elixir, suspension, syrup, wafer, chewing gum, or food." *Id.* at claim 3. As explained in the '086 specification, regardless of which of these oral dosage forms the composition takes, an amount of active agent (*i.e.*, nicotinamide riboside) is also present. *See id.* at 29:43-53.

Dependent claim 4 recites pharmaceutically acceptable components that may be optionally added to the pharmaceutical composition, including "tryptophan, nicotinic acid, or nicotinamide." *Id.* at claim 4. As described in the specification, these additional components may optimize NAD+ metabolism for certain conditions, but are in addition to the operative active agent, nicotinamide riboside. *Id.* at 28:36-48.

Finally, dependent claim 5 claims the pharmaceutical composition of claim 1 which further "increase[s] NAD+ biosynthesis upon oral administration." *Id.* at claim 5. This claimed increase in NAD+ biosynthesis is based on the inclusion of nicotinamide riboside as the active agent and leads to the therapeutic result of preventing or treating a wide range of diseases and conditions due to an increase in NAD+ biosynthesis when administrated orally. *See id.* at 28:3-15.

C. Level of Ordinary Skill in the Art

Patent Owner contends that a person of ordinary skill in the art with respect to the ’086 patent would be someone with a Ph.D. in biochemistry or similar field in the pharmaceutical sciences, with familiarity and experience with pharmacokinetics. Ex. 2002, Zhou Decl., at ¶ 17. Although Petitioner’s proposed level of ordinary skill in the art does not specify any particular experience in the pharmaceutical sciences or pharmacokinetics, Petitioner’s proposal is not materially different for purposes of this review. *See* Pet. at 6. Patent Owner’s analysis and conclusions presented here would not change based on any differences between Patent Owner’s and Petitioner’s proposed level of ordinary skill in the art. Ex. 2002, Zhou Decl., at ¶ 18.

III. CLAIM CONSTRUCTION

In an *inter partes* review, claim terms are interpreted according to their “broadest reasonable construction in light of the specification of the patent in which it appears.” *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136 (2016); *see also id.* at 2144-45; 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48764, 66 (Aug. 14, 2012).[2] The broadest reasonable

[2] The Patent Office issued a Notice of Proposed Rulemaking on May 9, 2018, which proposes replacing this “broadest reasonable construction” standard with the standard applied in federal district courts, “including construing the claim

construction of the terms must be consistent with the patent specification. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1259-60 (Fed. Cir. 2010) ("[C]laims should always be read in light of the specification and teachings in the underlying patent."). As the Federal Circuit has explained:

> The correct inquiry in giving a claim term its broadest reasonable interpretation in light of the specification is not whether the specification proscribes or precludes some broad reading of the claim term adopted by the examiner. And it is not simply an interpretation that is not inconsistent with the specification. It is an interpretation that corresponds with what and how the inventor describes his invention in the specification, *i.e.*, an interpretation that is "consistent with the specification."

In re Smith Int'l, Inc., No. 2016-2303, 2017 WL 4247407, at *5 (Fed. Cir. 2017) (quoting *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997)).

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in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art." Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 21221, at 21223 (proposed May 9, 2018) (to be codified at 37 C.F.R. pt. 42). Petitioner's analyses and conclusions presented herein would remain the same under either claim construction standard.

Terms should also be construed in light of the express language of the claims in which they appear. *See Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016) ("Construing individual words of a claim without considering the context in which those words appear is simply not 'reasonable.'").

A. "Pharmaceutical composition comprising nicotinamide riboside"

A person of ordinary skill in the art would understand that the '086 patent is directed to nicotinamide riboside, and specifically, to its use as an active agent in the claimed pharmaceutical compositions. Petitioner's proposed interpretation of the "pharmaceutical composition" term should be rejected because it does not provide any meaningful definition for the term and instead focuses only on the physical forms the claimed composition may take based on the language of dependent claim 3. Pet. at 7. In doing so, Petitioner ignores the disclosure of the '086 patent itself and the specification's focus on nicotinamide riboside compositions. Patent Owner proposes that the Board construe the phrase "pharmaceutical composition comprising nicotinamide riboside" consistent with the way a person of ordinary skill in the art would understand that phrase, namely as "a composition containing nicotinamide riboside as the active agent."

1. Patent Owner's Proposed Construction is Consistent with the Specification

The '086 patent consistently and repeatedly emphasizes nicotinamide riboside and its use as an active agent in the claimed pharmaceutical compositions. For example, the specification discloses, among other things:

- Methods of treating diseases or conditions with "an effective amount of ***a nicotinamide riboside composition*** so that the signs or symptoms of the disease or condition are prevented or reduced." '086 patent, at 4:22-24 (emphasis added).
- The diseases and conditions that "can be prevented or treated by supplementing a diet or a therapeutic treatment regime with ***a nicotinamide riboside composition***." '086 patent, at 27:60-28:15 (emphasis added); *see also* 8:57-59 (improve lipid profiles), 8:61-62 (stroke), 27:32-36 (Alzheimer's Disease, Parkinson's Disease and Multiple Sclerosis), 27:45-47 (neurotoxicity before, during or after cytotoxic chemotherapy), 27:57-59 (fungal infections), and 28:12 (aging).
- A definition for the "effective amount of nicotinamide riboside," which can be adjusted based on clinical evaluation "before and after ***treatment with the nicotinamide riboside***." '086 patent, at 28:36-43 (emphasis added).

- Optional combinations, including other NAD+ precursors, with the "***nicotinamide riboside treatments***." '086 patent, at 28:44-48 (emphasis added).

These are but a few examples of portions of the specification that confirm to a person of ordinary skill in the art that the claimed '086 patent invention is a pharmaceutical composition in which nicotinamide riboside is the active agent, rather than just an inactive excipient. Ex. 2002, Zhou Decl., at ¶¶ 23-28.

These disclosures also reflect the understanding of a person of ordinary skill in the art that a pharmaceutical, at its most basic level, contains an active ingredient. Ex. 2002, Zhou Decl., at ¶ 31. Even the compendium identified in the '086 patent specification ('086 patent, at 28:56-60) repeatedly refers to the inclusion of an active agent in a pharmaceutical. Ex. 2002, Zhou Decl., at ¶¶ 30-31; Ex. 2006, Remington, at 700-01, 858, 860; *see also* Ex. 2004, McGraw-Hill 2003, at 1571 (defining "pharmaceutical" as "[a] chemical produced industrially (medicinal drug), which is useful in preventive or therapeutic treatment of a physical, mental, or behavioral condition"); Ex. 2005, New Oxford American 2005, at 1275 (defining "pharmaceutical" as "a compound manufactured for use as a medicinal drug").

Accordingly, the construction for this phrase should be consistent with the patentee's clear intent to identify nicotinamide riboside as the active agent of the

claimed compositions. *See In re Smith Int'l*, 2017 WL 4247407, at *5 (broadest reasonable interpretation must be the one that "corresponds with what and how the inventor describes his invention in the specification, *i.e.*, an interpretation that is consistent with the specification") (internal quotations omitted).

Moreover, the specification describes the claimed compositions in terms of "the active agent," and specifically identifies the active agent of the invention to be nicotinamide riboside. For example, in the context of describing pharmaceutically acceptable carriers, the specification states:

> "Polypeptides, nucleic acids, vectors, dietary supplements (i.e. ***nicotinamide riboside***), and nicotinamide riboside-related prodrugs produced or identified in accordance with the methods of the invention can be conveniently used or administered in a composition containing ***the active agent*** in combination with a pharmaceutically acceptable carrier."

'086 patent, at 28:49-54 (emphasis added). Similarly, in the claimed compositions, a pharmaceutically acceptable carrier "is involved in carrying or transporting ***the subject compound*** from one organ, or portion of the body, to another organ, or portion of the body." '086 patent, at 28:62-64 (emphasis added); *see also id.* at 29:43-53 (disclosure of the "active compound" in oral forms), 30:4-7 (disclosure of "active compound" in syrups or elixirs), 30:9-12 (disclosure of "active compound" in sustained-release preparations). In light of the specification, a person of

ordinary skill in the art would understand the subject compound (*i.e.*, the active agent) of the ’086 patent to be nicotinamide riboside. Ex. 2002, Zhou Decl., at ¶¶ 29, 33.

2. Patent Owner’s Proposed Construction is Consistent with the Express Claim Language

Indeed, the above passages from the ’086 patent specification are the same as those the Board relied on to define the “carrier” term in the Institution Decision. Paper 9, at 6-7 (quoting ’086 patent, at 28:61-67). As defined by the Board, the claimed carrier must carry or transport “the subject compound.” *Id.* In the first sentence of the paragraph the Board relied upon for its definition, the specification also refers to this compound as “the active agent.” ’086 patent, at 28:49-54. In both cases, “the subject compound” and “the active agent” refer to the compound that is transported by the carrier. That compound is indisputably the active agent, *i.e.* nicotinamide riboside. The Board’s construction of the “carrier” limitation, which also appears in claim 1, further confirms that the “pharmaceutical composition” phrase must be construed consistently to reflect the requirement for an active agent, that agent being nicotinamide riboside. *See ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003) (“While certain terms may be at the center of the claim construction debate, the context of the surrounding words of the claims also must be considered in determining the ordinary and customary meaning of those terms”).

The remaining dependent claims also confirm that the active agent of the pharmaceutical composition of claim 1 is nicotinamide riboside. Claim 2 specifically recites nicotinamide riboside and its isolation from a natural or synthetic source. *See* '086 patent, at claim 2, 26:64-27:12. Claim 3 recites the different oral dosage forms the composition can take, all of which must also include an amount of active agent (*i.e.*, nicotinamide riboside). *See id.* at claim 3, 29:43-53. Claim 4 recites additional NAD+ precursors that may be added to the composition to optimize NAD+ metabolism for certain conditions, but those are in addition to the active agent nicotinamide riboside. *See id.* at claim 4, 28:36-48. Finally, claim 5 recites a therapeutic effect (*i.e.*, increasing NAD+ biosynthesis) resulting from the inclusion of nicotinamide riboside as the active agent. *See id.* at claim 5, 28:3-15.

Accordingly, consistent with the express claim language, including the Board's definition of carrier, "pharmaceutical composition comprising nicotinamide riboside" should be construed as a "composition containing nicotinamide riboside as the active agent." Ex. 2002, Zhou Decl., at ¶¶ 32-33.

3. Petitioner's Proposed Interpretation of "pharmaceutical composition" Should Be Rejected

Petitioner does not offer an explicit construction of "pharmaceutical composition" and instead relies only on claim 3 to propose that the term "should be understood to include at least a tablet, troche, capsule, elixir, suspension, syrup,

wafer, chewing gum, or food." Pet. at 6-7. However, as expressed in the specification, this phrase from claim 3 does not define the composition, but rather identifies some of the specific forms the composition of claim 1 (*i.e.*, containing nicotinamide riboside as the active agent) can take when used for oral therapeutic administration:

> For oral therapeutic administration, the compound can be combined with one or more carriers and used in the form of ingestible tablets, buccal tablets, troches, capsules, elixirs, suspensions, syrups, wafers, chewing gums, foods and the like.

'086 patent, at 29:43-47. The very next sentence in the specification confirms that such compositions must include the "active compound" and that "[t]he amount of active compound in such compositions is such that an effective dosage level will be obtained." *Id.* at 29:47-53. In other words, even if a composition takes the form of food, such food would not be necessarily considered a "pharmaceutical composition" of the '086 patent unless the composition also included the active compound nicotinamide riboside.

Contrary to this teaching, Petitioner's proposed interpretation would lead to the absurd result that any food would qualify as a "pharmaceutical composition" under the '086 patent. Petitioner's expert, Dr. Baur, confirmed that under Petitioner's interpretation "any food would qualify" as a pharmaceutical composition of the '086 patent, without exception. Ex. 2003, Baur Tx., at 21:10-

24. This result is particularly nonsensical given that Petitioner's expert also understands that pharmaceutical compositions generally should "be interpreted to always mean something that doesn't harm the molecule being administered." *Id.* at 19:21-20:6. Moreover, Petitioner's expert repeatedly confirmed that, in the context of the '086 patent, the molecule being administered is the active agent nicotinamide riboside. *See id.* at 19:21-20:16 ("Q: And in this case, that active agent would be nicotinamide riboside, correct? A: Yes."), 23:4-23 ("Q: And the formulation that you're referring to there, in paragraph 30, is the pharmaceutical composition of claim 1, where nicotinamide riboside is the active agent, correct? A: Yes."), 25:11-14 ("Q: You're referring to the nicotinamide riboside because that's the active agent in the '086 patent, correct? A: That's correct.").

Petitioner's proposed interpretation ignores and is inconsistent with the surrounding claim language of claim 1 and the language of the dependent claims, all of which confirms that the pharmaceutical composition must include nicotinamide riboside as the active agent. *See supra* Section II.B. Petitioner's proposed construction can be rejected on this basis alone because it unreasonably seeks to "constru[e] individual words of a claim without considering the context in which those words appear." *Trivascular*, 812 F.3d at 1062; *see also ACTV*, 346 F.3d at 1088 ("the context of the surrounding words of the claims also must be considered in determining the ordinary and customary meaning of those terms").

Petitioner's proposal would also result in the claims being construed to cover milk. However, milk was explicitly disclosed as a prior art "source" of the active agent nicotinamide riboside. *See* '086 patent, at 4:8-20 (describing an embodiment where cow's milk is a natural source of nicotinamide riboside). This disclosure makes clear that the inventor did not intend the invention to cover milk as it occurs naturally, so adopting Petitioner's proposal would not be a reasonable construction. *See In re Smith*, 2017 WL 4247407, at *6 (reversing the Board's anticipation findings for lack of substantial evidence because giving a disputed term "such a strained breadth in the face of the otherwise different description in the specification was unreasonable").

Accordingly, Petitioner's proposed interpretation of the claimed pharmaceutical compositions should be rejected because it does not account for the understanding that first and foremost, the pharmaceutical composition must contain the specified active agent, which in the '086 patent is nicotinamide riboside. *See* Ex. 2003, Baur Tx., at 19:21-20:16, 23:4-23, 25:11-14. This understanding, which is reflected in Patent Owner's proposed construction, is consistent with the interpretation of a person of ordinary skill in art in light of the entire disclosure of the '086 patent. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007); Ex. 2002, Zhou Decl., at ¶¶ 29-33.

Accordingly, the phrase "pharmaceutical composition comprising nicotinamide riboside" should be construed as a "pharmaceutical composition containing nicotinamide riboside as the active agent."

B. "is isolated from a natural or synthetic source"

Claim 2 covers "[t]he pharmaceutical composition of claim 1, wherein the nicotinamide riboside is isolated from a natural or synthetic source." '086 patent, at claim 2. Petitioner proposed a construction only for the term "isolated" and proposed that the term be construed to mean "is separated or substantially free from at least some of the other components of the naturally occurring organism." Pet. at 7. Petitioner relied on a single, incomplete, phrase from the specification in support of its proposed construction. *Id.* (citing '086 patent, at 9:3-10).

Patent Owner requested that the Board construe the complete phrase "is isolated from a natural or synthetic source" to mean "fractionated from other cellular components." Paper 8, at 10-11. As explained in Patent Owner's Preliminary Response, this proposed construction is consistent with the specification and the express claim language. *Id.* at 11-16. First, the '086 patent specification discloses the sources of nicotinamide riboside (28:16-21), methods for identifying natural or synthetic sources (26:37-63), specific natural or synthetic sources from which nicotinamide riboside can be isolated (26:64-27:3), and methods for isolating extracts from the natural sources (27:3-12, 32:54-33:2, 19:5-

28), including cow's milk (26:64-27:3, 27:3-12, 32:54-33:2). Second, the construction of "isolated" must be consistent with the scope of claim 2, which specifies that the nicotinamide riboside "is isolated from a natural or synthetic source," to the exclusion of the third option of chemically synthesizing the compound. *See* '086 patent, at 27:3-12, 28:16-21, 53:41-43. Patent Owner also explained that Petitioner's proposed construction was inconsistent with the specification and claims and was unreasonably broad. Paper 8, at 16-20. The portion of the specification that Petitioner relied on addresses nucleic acids (rather than nicotinamide riboside) and includes additional information regarding the meaning of "isolated" in that context. '086 patent, at 9:3-10. The specification also discloses cow's milk as a source from which nicotinamide riboside can be isolated, and standard methods for isolating nicotinamide riboside from that cow's milk. '086 patent, at 4:8-20, 26:32-34, 32:54-33:2, 26:67-27:12. Petitioner's proposed construction is unreasonably broad in light of these teachings because it would read on milk that has been removed from a cow.

The Board agreed that Petitioner's proposed construction was unreasonable because it would permit "separation from 'some' – no matter how insignificant – amount of other components of the natural source of the nicotinamide riboside (e.g., cow's milk)." Paper 9, at 8-9. The Board further concluded that the proper construction must include guidance regarding the purity of the nicotinamide

riboside, and relied on the ’086 patent specification to construe “isolated” to mean “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.” *Id.*, at 8-9.

IV. PETITIONER HAS NOT MET ITS BURDEN OF SHOWING THAT ANY OF THE CLAIMS OF THE ’086 PATENT ARE UNPATENTABLE OVER EITHER GROUNDS 1 OR 2

A. Anticipation Standard

A claim is not anticipated unless each limitation of that claim is found in a single reference, either expressly or inherently. *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006). Anticipation requires a disclosure of “the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art and that such existence would be recognized by persons of ordinary skill in the field of the invention.” *Crown Operations Int’l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002).

A finding of inherent anticipation “is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation.” *Atofina*, 441 F.3d at 1000. “The mere fact that a certain thing may result from a given set of circumstances is insufficient to prove anticipation.” *Electro Med. Sys., S.A. v. Cooper Life Scis., Inc.*, 34 F.3d 1048, 1052, 32 U.S.P.Q.2d 1017 (Fed. Cir. 1994) (internal citations omitted). While a patent challenger may rely on evidence

extrinsic to the prior art reference to show a missing element, "such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991); *see also HTC Corp. v. Cellular Commc'ns Equip., LLC,* 877 F.3d 1361, 1368 (Fed. Cir. 2017) (affirming finding of no inherent anticipation where there was no evidence that the secondary reference taught the missing descriptive matter).

B. Goldberger et al. Does Not Anticipate the '086 Patent Claims Because it Does Not Teach a Pharmaceutical Composition Containing Nicotinamide Riboside as the Active Agent

Goldberger et al., which is a 1928 Public Health Report article discussing the administration of a variety of foodstuffs to dogs and the ability of the foodstuffs, if any, to prevent blacktongue, does not disclose any pharmaceutical compositions containing nicotinamide riboside as the active agent. *See* Ex. 1005. Accordingly, Petitioner has failed to establish that Goldberger et al. discloses each and every element required by claim 1. Because all of the '086 patent claims require a pharmaceutical composition containing nicotinamide riboside as the active agent, Petitioner has failed to establish that Goldberger et al. anticipates any of the claims. Moreover, the extrinsic references upon which Petitioner relies do not cure the deficiencies in Goldberger et al.'s disclosure because they do not

establish that the milk recited in Goldberger et al. necessarily is a pharmaceutical composition containing nicotinamide riboside as the active agent.

1. Goldberger et al. Does Not Anticipate Claim 1 of the ’086 Patent

a. Goldberger et al. Does Not Disclose a “pharmaceutical composition comprising nicotinamide riboside”

Goldberger et al. does not disclose nicotinamide riboside, let alone nicotinamide riboside as the active agent in a pharmaceutical composition. Petitioner’s arguments regarding claim 1 are a result of reading out the claim’s requirement for the active agent (*i.e.*, nicotinamide riboside) and boil down to the illogical conclusion that all food, without limitation or other characteristics, would qualify as a pharmaceutical composition. Petitioner’s expert confirmed as much, and further testified that (1) all milk qualifies as a pharmaceutical composition, “unless it has actually spoiled” (Ex. 2003, Baur Tx., at 21:10-22:22); and (2) chewing gum, “on its own,” qualifies as a pharmaceutical composition “based on it being recited in the dependent claim” (*Id.* at 22:24-23:3). Petitioner’s expert further stated that a prior art reference disclosing a child drinking milk would be sufficient to anticipate claim 1 of the ’086 patent. Ex. 2003, Baur Tx., at 45:22-47:4. These conclusions bear no relationship to, and contradict, the teachings of the ’086 patent.

Petitioner offers no evidence that Goldberger et al. discloses any pharmaceutical composition as that term would be understood by a person of ordinary skill in the art of the '086 patent. Ex. 2002, Zhou Decl., at ¶ 34. Instead, Petitioner redirects its arguments to the language of claim 3 to conclude that the milk disclosed in Goldberger et al. is a pharmaceutical composition because it is a food. Pet. at 12. However, Petitioner's arguments are logically flawed and contrary to the teachings of the '086 patent, which provide that an oral formulation of a pharmaceutical composition of the claimed invention can take the form of food, provided it also includes "the active compound." *See* '086 patent, at 29:43-53. The '086 patent does not teach that all food is a pharmaceutical composition.

In fact, a person of ordinary skill in the art would readily understand that the '086 patent requires more than just food on its own and that nicotinamide riboside must be more than just an inactive excipient. *See* Ex. 2002, Zhou Decl., at ¶ 28. In fact, the nicotinamide riboside must be *the* active agent. *Id.* at ¶¶ 29-33. But, Petitioner and its expert concede that Goldberger et al. does not even disclose whether the milk contained nicotinamide riboside. *See* Pet. at 12-13; Ex. 1002, at ¶ 31. They instead rely on a separate reference, Trammell 1, to try to support their conclusion that "nicotinamide riboside is naturally present in skim milk." Pet. at 12. As an initial matter, Petitioner's expert confirmed that Trammell I does not

provide any disclosure concerning whether the milk used in Goldberger et al. contained any nicotinamide riboside. Ex. 2003, Baur Tx., at 12:24-13:3.

Trammell I also fails to establish whether any nicotinamide riboside is therapeutically active in light of its disclosure that nicotinamide riboside binds to some other molecule in milk ("bound NR"). *See* Ex. 2002, Zhou Decl., at ¶ 35; Ex. 1007. The other references upon which Petitioner and its expert rely report data on an *unbound* form of nicotinamide riboside, so they cannot be used to draw conclusions about its activity as *bound* NR within milk. *See* Ex. 2002, Zhou Decl., at ¶ 36. Petitioner also has not shown that any alleged nicotinamide riboside in the milk was not degraded by naturally occurring bacteria. Ex. 2002, Zhou Decl., at ¶ 37; Exs. 1007, 2007-2011. Accordingly, Petitioner has not presented any evidence that would make clear to a person of ordinary skill in the art that the missing element of nicotinamide riboside as the active agent of a pharmaceutical composition was necessarily present in Goldberger et al. Ex. 2002, Zhou Decl., at ¶¶ 34, 38; *see HTC Corp.*, 877 F.3d at 1368 (finding of no inherent anticipation appropriate where there is no evidence that the secondary reference taught the missing descriptive matter).

b. Goldberger et al. Does Not Disclose Nicotinamide Riboside "in admixture with a carrier"

Petitioner's conclusion that Goldberger et al. discloses nicotinamide riboside that "is in a mixture with other components of the milk" does not establish that any

nicotinamide riboside contained in the milk is "in admixture with a carrier" as required by the claim. *See* Pet. at 13 (emphasis added). Pursuant to the Board's construction of both pharmaceutically acceptable carriers and carriers, such a compound "is involved in carrying or transporting *the subject compound* from one organ, or portion of the body, to another organ, or portion of the body." Paper 9, at 6 (quoting '086 patent, at 28:61-67) (emphasis added). This has not been established by Petitioner.

As explained above, the first half of the paragraph that the Board cited in support of its "carrier" definition confirms that:

> Polypeptides, nucleic acids, vectors, dietary supplements (i.e. nicotinamide riboside), and nicotinamide riboside-related prodrugs produced or identified in accordance with the methods of the invention can be conveniently used or administered in a composition containing the active agent in combination with a pharmaceutically acceptable carrier. Such compositions can be prepared by methods and contain carrier with are well-known in the art. A generally recognized compendium of such methods and ingredients is Remington: The Science and Practice of Pharmacy, Alfonso R. Gennaro, editor, 20th ed. Lippingcott Williams & Wilkins: Philadelphia, Pa., 2000.

'086 patent, at 28:49-60. This disclosure, including the methods described in Remington, confirms to a person of ordinary skill in the art that a pharmaceutical

composition of the ’086 patent would be prepared by purposefully mixing the carrier with the active agent (*i.e.*, nicotinamide riboside). Ex. 2002, Zhou Decl., at ¶ 39.

A person of ordinary skill in the art would also readily understand that the milk disclosed in Goldberger et al. was not prepared as an admixture of nicotinamide riboside and a carrier. Ex. 2002, Zhou Decl., at ¶ 39. Petitioner’s expert Dr. Baur concludes that the nicotinamide riboside in the milk in Goldberger et al. “is in admixture with other components of the milk, including components that are demonstrated in Trammell I to bind and stabilize the compound.” Ex. 1002 at 17, ¶ 32. However, this conclusory statement does not establish that any nicotinamide riboside was prepared as an admixture with a carrier as described in the ’086 patent. Ex. 2002, Zhou Decl., at ¶ 39. Accordingly, there is no evidence that the milk disclosed in Goldberger et al. contains nicotinamide riboside in admixture with a carrier.

2. Goldberger et al. Does Not Anticipate Claim 3 of the ’086 Patent

Claim 3 covers the pharmaceutical compositions of claim 1, “wherein the formulation comprises a tablet, troche, capsule, elixir, suspension, syrup, wafer, chewing gum, or food.” ’086 patent, at claim 3. As discussed above, Petitioner has failed to establish that Goldberger et al. anticipates claim 1 of the ’086 patent,

from which claim 3 depends, so Petitioner has failed to establish that Goldberger et al. anticipates claim 3.

Specifically, and as discussed above, the group recited in claim 3 does not define the pharmaceutical composition per se, but rather identifies some of the specific forms the composition can take when used for oral therapeutic administration. *See* '086 patent, at 29:43-47. As explained above, even if a composition takes the form of food, such food would not be considered a "pharmaceutical composition" of the '086 patent unless the composition also included the active compound nicotinamide riboside. *See supra* Section III.A.3.

Petitioner argues that Goldberger et al. anticipates claim 3 only on the basis that the reference discloses milk and "milk is a food." Ex. 1002, at ¶ 31; Pet. at 15. Petitioner's arguments would lead to the nonsensical conclusion that, any food, regardless of any other variable, would anticipate claim 3. In fact, defining milk as a food is not the end of the inquiry for claim 3 because, according to the claim language itself, the food must also qualify as a pharmaceutical composition of claim 1. Petitioner has failed to establish that the food disclosed in Goldberger et al. (*i.e.* milk) is a pharmaceutical composition containing nicotinamide riboside as the active agent as required by claim 1. Accordingly, Petitioner has also failed to establish that Goldberger et al. anticipates claim 3.

3. Goldberger et al. Does Not Anticipate Claim 4 of the ’086 Patent

Claim 4 covers the pharmaceutical compositions of claim 1, “further comprising one or more of tryptophan, nicotinic acid, or nicotinamide.” ’086 patent, at claim 4. As discussed above, Petitioner has failed to establish that Goldberger et al. anticipates claim 1 of the ’086 patent, from which claim 4 depends, so Petitioner has also failed to establish that Goldberger et al. anticipates claim 4.

As discussed above, the specification identifies the pharmaceutically acceptable components recited in claim 4 as optional components that may be added to the pharmaceutical composition to optimize NAD+ metabolism for certain conditions. ’086 patent, at 28:36-48. These optional components, however, must be in addition to the active ingredient (*i.e.*, nicotinamide riboside). *Id.* In other words, any prior art reference that does not disclose nicotinamide riboside as the active agent cannot disclose a composition with the additional components of claim 4. Accordingly, because Petitioner failed to present any evidence that Goldberger et al. discloses a pharmaceutical composition containing nicotinamide riboside as the active ingredient, there is also no evidence that Goldberger et al. discloses the required elements of claim 4.

4. Goldberger et al. Does Not Anticipate Claim 5 of the ’086 Patent

Claim 5 covers the pharmaceutical compositions of claim 1 “which increase NAD+ biosynthesis upon oral administration.” ’086 patent, at claim 5. As discussed above, Petitioner has failed to establish that Goldberger et al. anticipates claim 1 of the ’086 patent, from which claim 5 depends, so Petitioner has also failed to establish that Goldberger et al. anticipates claim 5.

Moreover, there is no evidence that the alleged nicotinamide riboside in the milk of Goldberger et al. actually increased NAD+ biosynthesis upon administration to dogs. Ex. 2002, Zhou Decl., at ¶ 40. Indeed, Petitioner’s own expert confirmed that a prior art reference showing a child drinking a glass of milk would not anticipate claim 5 because “there’s no proof the milk drunk by that child was used to synthesize NAD.” Ex. 2003, Baur Tx., at 45:22-47:17. The same is true of Goldberger et al.

The evidence suggests any alleged increase in NAD+ biosynthesis occurring in Goldberger et al. could be due to the presence of other naturally occurring components of milk. Ex. 2002, Zhou Decl., at ¶ 43; Exs. 1011, 2006. Petitioner’s own expert agrees that the data reported in Goldberger et al. do not show that nicotinamide riboside increased NAD+ biosynthesis. Ex. 2003, Baur Tx., at 15:3-10. One of the reasons for this lack of evidence is that the other NAD+ precursors, including nicotinamide and tryptophan, which are also found in milk, are sufficient

to lead to any increase in NAD+ caused by ingestion of milk. *See* Ex. 2003, Baur Tx., at 15:3-15; *see also* Ex. 2002, Zhou Decl., at ¶ 43; Exs. 1011, 2006. Not only is there no evidence in Goldberger et al. that NAD+ biosynthesis increased, there is no way to determine what, if anything, could have been responsible for that hypothetical increase. *See* Ex. 2003, Baur Tx., at 15:3-15; *see also* Ex. 2002, Zhou Decl., at ¶ 43.

Petitioner attempts to account for the deficiencies in Goldberger et al.'s disclosure by pointing to other references regarding nicotinamide riboside's ability to increase NAD+ biosynthesis. In particular, Petitioner's expert points to the Tummala (Ex. 1017), Cantó (Ex. 1018), and Gong (Ex. 1019) references in support of the theory that nicotinamide riboside in milk must have led to NAD+ biosynthesis in Goldberger et al. Ex. 1002, at ¶13, 36. However, none of these three references report any data on the activity of nicotinamide riboside in milk, let alone its ability to increase NAD+ levels as one of many ingredients in the milk fed to dogs in Goldberger et al. *See* Ex. 2003, Baur Tx., at 27:22-29:24; *see also* Ex. 2002, Zhou Decl., at ¶¶ 36, 42. Accordingly, this reliance on Tummala (Ex. 1017), Cantó (Ex. 1018), and Gong (Ex. 1019) is insufficient to demonstrate anticipation by Goldberger et al.

Petitioner's expert also relies on the Trammell II (Ex. 1008) reference for the proposition that nicotinamide riboside is more orally available than other NAD+

precursors. Ex. 1002, at ¶14. Again, however, Trammell II does not report any data on the oral availability of nicotinamide riboside in milk, or for that matter, the milk fed to dogs in Goldberger et al. Ex. 2002, Zhou Decl., at ¶ 41. As further confirmed by Petitioner's expert, Trammell II also does not account for whether or to what extent nicotinamide riboside binds to other molecules in milk in a manner that would impact its ability to increase NAD+ levels. *See* Ex. 2003, Baur Tx., at 37:12-38:8; *see also* Ex. 2002, Zhou Decl., at ¶¶ 35-36, 41.

In other words, Petitioner's additional references do not establish that the information missing from Goldberger et al. is necessarily present in milk. *See HTC Corp.*, 877 F.3d at 1368 (finding of no inherent anticipation appropriate where there is no evidence that the secondary reference taught the missing descriptive matter). At most, Petitioner suggests that it "may" be the case that the nicotinamide riboside in milk increased NAD+, which is insufficient to establish anticipation. *Electro Med. Sys.*, 34 F.3d at 1052 ("The mere fact that a certain thing may result from a given set of circumstances is insufficient to prove anticipation.").

C. The Modified Institution Decision Does Not Change the Result that Petitioner Has Failed to Establish Unpatentability of Any Claim of the '086 Patent Over Grounds 1 or 2

The Board did not institute review of claim 2 in its Institution Decision, nor did it institute on Ground 2 – anticipation based on the Goldberger and Tanner

reference. Paper 9, at 19. However, in an April 27, 2018 Order of the Conduct of the Proceedings, the Board stated that it would institute review on all clams and all grounds. Paper 22. As explained in Patent Owner's Request for Rehearing, which is currently pending, the Modified Institution Decision should be vacated. However, in the event the Board reviews the patentability of claim 2 in Ground 1 and the patentability of all claims in Ground 2, the Board should find all claims not unpatentable.

1. Petitioner Has Failed to Establish Unpatentability of Claim 2

First, claim 2 depends from claim 1, and Petitioner has thus not established that claim 2 is unpatentable over Goldberger et al. for the same reasons outlined herein with respect to claim 1. Second, as explained in the Institution Decision, "Petitioner has offered no evidence to show that nicotinamide riboside constitutes at least 25% by weight of the remaining composition." Paper 9, at 13-14. Based on the Board's construction of "isolated" and its analysis of Petitioner's failure to present sufficient evidence to establish anticipation of claim 2, Petitioner has failed to establish that claim 2 is unpatentable in view of Goldberger et al. *See* Paper 9, at 13-14.

2. Petitioner Has Failed to Establish Unpatentability of Any Claim over Ground 2

Petitioner's arguments for Ground 2 are substantially the same as those for Ground 1, although the reference of Ground 2 (Goldberger and Tanner) discloses buttermilk instead of milk. Petitioner relies on the buttermilk disclosed in Goldberger and Tanner in the same fashion as it unsuccessfully relied on the milk in the prior art of Ground 1. *See* Pet. at 18-29; Paper 9, at 18 ("The generalized teachings of Goldberger and Tanner that Petitioner relies upon for this challenge are similar to the teachings of Goldberger et al."). As the Board acknowledged in the Institution Decision, "Petitioner has not pointed to any material differences between this challenge and the challenge based on Goldberger et al. to justify the use of Board and party resources to proceed on both challenges." Paper 9, at 18-19.

As an initial matter, a person of ordinary skill in the art would not find any material difference between the disclosure of Goldberger et al. in Ground 1 and that of Goldberger and Tanner in Ground 2 for purposes of analyzing the patentability of the '086 patent claims. Ex. 2002, Zhou Decl., at ¶ 34, n.1. In any event, Petitioner has not established that the claims of the '086 patent are unpatentable over Goldberger and Tanner.

Specifically, Petitioner has not established that Goldberger and Tanner discloses a pharmaceutical composition where nicotinamide riboside is the active

agent, as required by claim 1 of the ’086 patent. Ex. 2002, Zhou Decl., at ¶¶ 34, 38. Because all claims include this limitation, Petitioner has failed to establish the unpatentability of any claim of the ’086 patent over Goldberger and Tanner.

There is no disclosure of nicotinamide riboside in the buttermilk of Goldberger and Tanner, and Petitioner and its expert concede that there is no such disclosure. *See* Pet. at 23; Ex. 1002, at ¶ 37. There is no disclosure in Goldberger and Tanner of whether any nicotinamide riboside contained in the buttermilk is therapeutically active. Ex. 2002, Zhou Decl., at ¶¶ 34, 38. Any nicotinamide riboside in buttermilk may be bound to other molecules, and there is no evidence that any such bound nicotinamide riboside would be available as an active agent. Ex. 2002, Zhou Decl., at ¶ 35. In fact, the references that Petitioner cites in an attempt to establish the activity of nicotinamide riboside reflect the compound in its unbound form, and so cannot be used to draw any conclusions regarding its activity in the buttermilk of Goldberger and Tanner. Ex. 2002, Zhou Decl., at ¶ 36. Moreover, any nicotinamide riboside in buttermilk may have been degraded by naturally occurring bacteria, and neither Petitioner nor its expert takes this into account. Ex. 2002, Zhou Decl., at ¶ 37; Exs. 1007, 2007-2011.

Petitioner also fails to present any evidence that NAD+ biosynthesis increased in Goldberger and Tanner, as required in claim 5. Not only is there no evidence in Goldberger and Tanner that NAD+ biosynthesis increased, there is no

way to determine what, if anything, is responsible for that increase based on the evidence reported. Ex. 2002, Zhou Decl., at ¶ 43. As explained above with respect to milk, any alleged increase in NAD+ biosynthesis occurring in Goldberger and Tanner could be due to the presence of other naturally occurring components of buttermilk, including nicotinamide and tryptophan. Ex. 2002, Zhou Decl., at ¶ 43; Exs. 1011, 2006. So Petitioner has provided no evidence that nicotinamide riboside is the active agent in the buttermilk of Goldberger and Tanner or that nicotinamide riboside in the buttermilk of Goldberger and Tanner increased NAD+ biosynthesis. Ex. 2002, Zhou Decl., at ¶ 44.

Additionally, for the same reasons identified above with respect to Ground 1 (*supra* Section IV.C.1), Petitioner has not established that Goldberger and Tanner anticipates claim 2. Because Goldberger and Tanner does not disclose isolated nicotinamide riboside, Petitioner has also failed to establish that claim 2 is unpatentable in view of Goldberger and Tanner.

Accordingly, for the same reasons presented above with respect to Ground 1, the ’086 patent is also patentable over Goldberger and Tanner.

V. CONCLUSION

For the foregoing reasons, the Board should reject all grounds in the Petition and find all of the ’086 patent claims patentable.

Respectfully submitted,

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CERTIFICATION UNDER 37 C.F.R. §42.24

Under the provisions of 37 C.F.R. §42.24, the undersigned hereby certifies that the foregoing document contains 7,599 words, and thus complies with the word-count limits of 37 C.F.R. § 42.24.

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e), the undersigned hereby certifies that a copy of the foregoing PATENT OWNER RESPONSE was served on June 4, 2018 by filing this document through the Patent Trial and Appeal Board End to End as well as by delivering a copy via the delivery method indicated to the attorneys of record for the Petitioner as follows:

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