NO. 19-1630

United States Court of Appeals for the Federal Circuit

ELYSIUM HEALTH, INC.

Appellant,

v.

TRUSTEES OF DARTMOUTH COLLEGE,

Appellee.

Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in proceeding No. IPR2017-01795

APPELLEE'S RESPONSIVE BRIEF

John L. Abramic
(Lead Counsel)
jabramic@steptoe.com
STEPTOE & JOHNSON LLP
115 S. LaSalle Street, Suite 3100
Chicago, IL 60603
Telephone: (312) 577-1264
Facsimile: (312) 577-1370

Jamie L. Lucia
STEPTOE & JOHNSON LLP
One Market Plaza,
Spear Tower, Suite 3900
San Francisco, California 94105
Telephone: (415) 365-6711
Facsimile: (415) 365-6681

Counsel for Appellee,
Trustees of Dartmouth College

August 28, 2019

CERTIFICATE OF INTEREST FOR APPELLEES

Pursuant to Federal Circuit Rules 26.1 and 47.4, counsel for Appellee hereby certifies the following:

1. The full name of every party represented by me is:

Trustees of Dartmouth College

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None

3. All parent corporations and any publicly-held companies that own 10% or more of the stock of any party represented by me are:

None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

Harold H. Fox
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, NW
Washington, DC 20036-1795

James R. Nuttall
STEPTOE & JOHNSON LLP
115 South LaSalle Street, Suite 3100
Chicago, IL 60603

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal:

ChromaDex, Inc. v. Elysium Health, Inc., Case No. 16-cv-02277-CJC (C.D. Cal.);
ChromaDex, Inc. et al. v. Elysium Health, Inc., Case No.18-cv-01434-CFC (D. Del.)

Dated: August 28, 2019

/s/ John L. Abramic

John L. Abramic
STEPTOE & JOHNSON LLP

115 S. LaSalle Street, Suite 3100
Chicago, IL 60603
Telephone: (312) 577-1264
Facsimile: (312) 577-1370

Counsel for Appellee,
Trustees of Dartmouth College

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TABLE OF ABBREVIATIONS

"the '086 patent"	U.S. Patent No. 8,383,086
"NR"	nicotinamide riboside
"NAD+"	Nicotinamide adenine dinucleotide
"Dartmouth"	Trustees of Dartmouth College
"Elysium"	Elysium Health, Inc.
"the Board"	Patent Trial and Appeal Board
"PTO"	U.S. Patent and Trademark Office
"IPR"	*inter partes* review
"AIA"	Leahy-Smith America Invents Act
"Goldberger et al."	Joseph 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," *Public Health Reports*, 43(23):1385-1454 (1928)
"Goldberger and Tanner"	Joseph Goldberger and W.F. Tanner, "A Study of the Treatment and Prevention of Pellagra," *Public Health Reports*, 39(3):87-107 (1924)

STATEMENT OF RELATED CASES

Appellee accepts Appellant's Statement of Related Cases.

COUNTER STATEMENT OF THE ISSUES

1. Whether the Board properly construed the term "is isolated" to require the nicotinamide riboside to 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," where the '086 patent specification provides guidance to a person of skill in the art as to how pure a molecule must be to be deemed "isolated."

2. Whether the Board properly found that Goldberger et al. does not render claim 2 of the '086 patent unpatentable.

3. Whether the Board properly found that Goldberger and Tanner does not render claim 2 of the '086 patent unpatentable.

COUNTER STATEMENT OF THE CASE

I. BACKGROUND

Appellee Trustees of Dartmouth College ("Dartmouth") is a non-profit educational research institution based in New Hampshire, and is the assignee of the '086 patent at issue in this appeal. The inventions of the '086 patent relate to nicotinamide riboside ("NR"), and more specifically, to pharmaceutical compositions comprising isolated NR. NR is a form of vitamin B3 that can produce nicotinamide adenine dinucleotide ("NAD+"), which in turn is critical to healthy cellular function in humans. Dartmouth has licensed its inventions, and as a result, isolated NR has been commercialized as an ingredient (under the name NIAGEN®) for use in oral dietary supplements. *See* Appx1597.

Appellant Elysium Health, Inc. ("Elysium"), is a dietary supplement company that filed the petition for *inter partes* review of the '086 patent. Following the Board's determination that claim 2 of the '086 patent is not anticipated by Elysium's asserted prior art references, Elysium filed the instant appeal.

Dr. Charles M. Brenner, the inventor of the '086 patent, was an Associate Professor (2003-2007) and Professor (2007-2009) of Genetics and of Biochemistry at Dartmouth's Medical School, and assigned his inventions in the '086 patent to Dartmouth. People of skill in the art at the time of the invention of the '086 patent

believed that NR was part of the NAD+ biosynthetic pathway only in bacteria, and were not aware that NR could also synthesize NAD+ in humans. Dr. Brenner made this discovery. In fact, scientific literature in this area reveals that those of skill in the art attributed the discovery of nicotinamide riboside as an NAD+ precursor in humans to Dr. Brenner. *See* Appx809 ("Recently, a 'new' NAD^+ precursor—NAM riboside (NR)—that also enhances NAD^+ levels through the salvage pathways was described (Bieganowski and Brenner, 2004)"); Appx964 ("NR was recently identified as a NAD+ precursor, with conserved metabolism from yeast to mammals (Bieganowski and Brenner, 2004)."); Appx979 ("Evidence shows that extracellular NR application could increase intracellular NAD levels…(Bieganowski and Brenner, 2004).").[1] These references also confirm that persons of skill in the art understood that Dr. Brenner did not purport to discover or claim milk, but that milk was a ***source*** for the NR compositions made possible by the discovery of NR as a precursor to NAD+.

Indeed, the exemplary source for NR disclosed in the '086 patent is cow's milk. As described in the specification, once NR is isolated from cow's milk, it

[1] Dr. Brenner is a co-author of the "Bieganowski and Brenner, 2004" paper referenced in all of the cited articles. The full citation to that 2004 paper, which was not made part of the record below, is: Pawel Bieganowski & Charles Brenner, "Discoveries of nicotinamide riboside as a nutrient and conserved NRK genes establish a Preiss-Handler independent route to NAD+ in fungi and humans," Cell, 117:495-502 (2004).

can be used effectively in pharmaceutical compositions for treating the wide range of diseases and conditions that are implicated by the NAD+ biosynthetic pathway in humans, including for example, improving lipid profiles, protecting against stroke, and protecting tissue from toxicity during cancer treatment. *See* Appx50 (8:57-67).

Despite the significance of the '086 patent invention and its impact on the advancements in the NAD+ supplement market, Elysium filed an *inter partes* review petition at the Board seeking to render these important inventions unpatentable. Moreover, notwithstanding the extensive disclosures of how the inventor isolated NR from cow's milk, the sole prior art references presented by Elysium in the IPR proceedings relate to milk and buttermilk, respectively, and not isolated NR.

Accordingly, the fundamental question on appeal is whether claim 2 of the '086 patent, which requires NR to be isolated from a natural (*e.g.*, cow's milk) or synthetic source, can be read to cover that same milk or buttermilk. The '086 patent specification discloses cow's milk as a ***source*** of NR and discloses how to isolate NR from that cow's milk so that it may be effectively used in the claimed pharmaceutical compositions. In short, claim 2 of the '086 patent cannot cover either the milk or buttermilk of Elysium's proffered prior art references and, as a

result, the Board was correct to conclude that claim 2 of the '086 patent is not anticipated over those references.

II. THE '086 PATENT

A. Nicotinamide Riboside

The '086 patent describes NAD+ as a co-enzyme, or helper molecule, that is critical for many biological processes in humans. Appx47 (1:63-2:18). Prior to the '086 patent invention, the gene products and pathways to NAD+ were understood to include *de novo* synthesis, nicotinic acid import, and nicotinamide salvage. Appx47 (2:20-29, Scheme 1). Dr. Brenner discovered, however, that in addition to the known pathways based on nicotinic acid and nicotinamide—vitamin forms of NAD+ collectively known as niacins—NR is also "an NAD+ precursor in a previously unknown but conserved eukaryotic NAD+ biosynthetic pathway." Appx47-50 (2:62-3:3).

Based on this discovery of NR as a third pathway to NAD+ biosynthesis, the '086 patent teaches that oral pharmaceutical formulations containing NR as an active agent could be used to treat conditions that are connected to NAD+ biosynthesis. Appx48 (4:17-24); Appx50 (8:39-41). The potential conditions particularly well-suited for treatment using pharmaceutical formulations of NR are wide-ranging, as summarized in the '086 patent 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.

Appx60 (27:60-28:3).

B. Pharmaceutical Compositions of the ’086 Patent

The claims of the ’086 patent recite the pharmaceutical formulations of NR described in the specification. There are five claims in the ’086 patent, with claim 1 being the only independent claim. *See* Appx73. Claim 1 recites “[a] pharmaceutical composition comprising nicotinamide riboside in admixture with a carrier, wherein said composition is formulated for oral administration.” *Id.* at 53:38-40. Dependent claim 2 further recites that the nicotinamide riboside of the claimed pharmaceutical composition “is isolated from a natural or synthetic source.” *Id.* at 53:41-43.

C. Isolated NR Disclosures

1. “isolated”

The terms “isolated” and “isolating” appear nearly fifty times in the ’086 patent specification. The specification includes an explanation of “isolated molecules” generally that:

> 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.

Appx51 (9:3-10). The specification then explains what it means for a molecule to be "separated or substantially free" (*i.e.*, "isolated), using a polypeptide as an example: "When the isolated molecule is a polypeptide, said polypeptide is at least about 25%, 50%, 60%, 70%, 75%, 80%, 85%, 90%, 95%, 97%, 98%, 99% or more pure (w/w)." *Id.* at 9:10-12.

2. Isolated NR

With respect to NR that "is isolated from a natural or synthetic source" according to claim 2, the specification includes descriptions for identifying such sources of NR (Appx59 at 26:37-63) and then, critically, isolating that NR from the original source (Appx60 at 27:3-12) to achieve the desired purity level.

The '086 patent identifies various synthetic and natural sources from which NR can be isolated:

> Synthetic sources of nicotinamide riboside can include any library of chemicals commercially available from most large chemical companies. . . .
>
> Natural sources which can be tested for the presence of [] nicotinamide riboside include, but are not limited to, cow's milk, serum, meats, eggs, fruit and cereals.

Appx59-60 (26:64-27:3). The patent emphasizes one particular natural source of NR: milk. For example, the '086 patent discloses that, with respect to the above-described method for identifying a natural or synthetic source of NR from which the NR can be isolated for use in the claimed pharmaceutical compositions, "[i]n one embodiment, the natural source [of NR] is cow's milk." Appx48 (4:12-23); *see also id.* at 3:12-13 ("yeast mutants of defined genotype were used to identify sources of nicotinamide riboside and it is shown that milk is a source of nicotinamide riboside").

Once a source of NR is identified using the '086 patent teachings, the specification further includes a description of standard methods for isolating that NR:

> Isolated extracts of the natural sources can be prepared using standard methods. For example, the natural source can be ground or homogenized in a buffered solution, centrifuged to remove cellular debris, and fractionated to remove salts, carbohydrates, polypeptides, nucleic acids, fats and the like before being test on the mutant[] strains of the invention. Any source of nicotinamide riboside that scores positively in the assay of the invention can be further fractionated and confirmed by standard methods of HPLC and mass spectrometry.

Appx60 (27:3-12); *see also* Appx62-63 (32:54-33:2, Example 2 describing "Nicotinamide Riboside and Whey Preparations"); Appx56 (19:5-28, describing purification techniques for NR kinases).

III. ELYSIUM'S ASSERTED PRIOR ART

In its Petition, Elysium presented only two prior art references as allegedly anticipating the '086 patent claims: (1) Joseph 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," *Public Health Reports*, 43(23):1385-1454 (1928) ("Goldberger et al."); and (2) Joseph Goldberger and W.F. Tanner, "A Study of the Treatment and Prevention of Pellagra," *Public Health Reports*, 39(3):87-107 (1924) ("Goldberger and Tanner"). Appx189. Both references are from the 1920s and report, *inter alia*, the results of experiments using milk and buttermilk, respectively.

A. Goldberger et al.

Goldberger et al., which reports the results of an experiment in which dogs were fed skim milk in 1928, is silent as to any particular ingredient in that milk. Appx673-676. In fact, the authors do not even identify nicotinamide riboside by name, instead theorizing that "[i]t thus appears that milk contains the preventive for both blacktongue and pellagra, but, considered in relation to effective quantity, contains it in relatively small amount." Appx676. The authors ultimately concluded this unidentified "preventive" was present in such a small amount in milk that other food items were more appropriate for the treatment of pellagra. Appx719 ("On the basis of the indications afforded by the test in the dog, liver,

salmon, and egg yolk are recommended for use in the treatment and prevention of pellagra in the human.").

B. Goldberger and Tanner

Goldberger and Tanner reports the results of treating women housed at the Georgia State Sanitarium in the 1920s with buttermilk in an effort to treat pellagra symptoms. Appx732-739. Like in Goldberger et al., Goldberger and Tanner does not identify nicotinamide riboside by name. Instead, inexplicable conflicting results using buttermilk led Goldberger and Tanner to conclude that until they could resolve the conundrum of the results, "it seems warranted to hold that the primary etiological dietary factor in pellagra is either a faulty protein (amino acid) mixture, or a deficiency in some as yet unrecognized complex, or some combination of these." Appx738. In other words, Goldberger and Tanner did not identify any specific ingredients in the buttermilk used at the sanitarium, let alone report on any properties of those ingredients.

IV. CLAIM CONSTRUCTION OF "IS ISOLATED"

A. Elysium's Petition and Proposed Construction of "Is Isolated"

Elysium first proposed its construction for "is isolated" in its Petition, arguing that "is isolated" in claim 2 of the '086 patent should mean "is separated or substantially free from at least some of the other components of the naturally occurring organism." Appx190.

Elysium further explained the scope of this proposed construction when applying the definition in its anticipation arguments with respect to both Goldberger et al. and Goldberger and Tanner. Specifically, for Goldberger et al., Elysium argued that NR in the skim milk of Goldberger et al. "is isolated (*i.e.*, separated or substantially free from at least some of the other components of the naturally occurring organism) from a natural source: the cow." Appx197-198. Elysium similarly argued that the NR in the buttermilk of Goldberger and Tanner "is isolated" when milk is removed from a cow. Appx208.

Elysium's expert also explicitly stated that Elysium's proposed construction of "is isolated" is so broad as to encompass any NR contained in milk that is removed from a cow:

- "the NR in skim milk is isolated from a natural source, first, from the cow and later from the whole milk when the fat elements of whole milk are separated from the non-fat elements, including the NR." Appx266 (¶33).
- "the NR in buttermilk is isolated from a natural source, first, from the cow, and later from the whole milk or cream, when the fat elements that are churned into butter are separated from the water-soluble elements, including NR." Appx268 (¶38).

In other words, under Elysium's proposed definition, the NR contained in milk that is still inside of a cow would not be "isolated" as that term is used in the '086 patent, but as soon as that same milk has been removed from the cow's udder, the NR in that milk would be "isolated." Moreover, in applying its construction to the prior art, Elysium did not address how its proposed construction could be reconciled with the explicit teachings of the '086 patent specification regarding isolating NR ***from*** cow's milk.

B. The Board's Construction of "Is Isolated"

The Board construed the phrase "is isolated from a natural or synthetic source" of claim 2 of the '086 patent 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." Appx1152.

1. Institution Decision

In construing the term "isolated" in the '086 patent, the Board rejected both parties' proposed constructions and adopted its construction based on the express definition of "isolated" and the teachings regarding isolated NR in the '086 patent.[2]

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[2] Dartmouth's proposed construction, which is not at issue on appeal, was "fractionated from other cellular components." Appx1150.

Appx1150-1152. In particular, the Board referred to the following portion of the specification discussing "isolated molecules" (Appx51 at 9:3-12):

> 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 polypeptide is at least about 25%, 50%, 60%, 70%, 75%, 80%, 85%, 90%, 95%, 97%, 98%, 99% or more pure (w/w).

Appx1150. From the plain language of this disclosure, the Board concluded that while "the Specification embraces compositions containing nicotinamide riboside in which only some of the other components of the naturally occurring organism have been removed," it also "provides guidance concerning the required purity of an 'isolated molecule.'" Appx1151. Based on the Board's review of the specification and conclusion that nothing in the '086 patent limited the purity requirement to any specific molecule, the Board included the exemplary 25% purity level in the construction of "isolated." Appx1152.

The Board also rejected Elysium's argument that the 25% purity level disclosed in the patent specification should be excluded, stating 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)." Appx1151-1152.

2. Final Written Decision

Following Elysium's request for the Board to reconsider its construction of "isolated" and to "adopt its broader proposed construction," the Board reiterated its original construction and provided additional explanation for why that construction is appropriate under the broadest reasonable interpretation standard. Appx12-14.

First, the Board reiterated its view that Elysium's proposed construction must be rejected because "construing the term 'is isolated' as suggested by Petitioner would render the term unreasonably broad in that it would encompass separation of even an insignificant amount of other components." Appx13. Second, the Board emphasized the '086 patent's teachings regarding the isolation of NR from natural sources such as milk (Appx59-60 at 26:64-27:12) and concluded "that isolating NR is more than simply separating or rendering it substantially free from ***any amount*** of the other components of the naturally occurring organism." Appx13-14 (emphasis added). Third, the Board acknowledged that the '086 patent's definition of "isolated" would lead a person of ordinary skill in the art to consider how pure a molecule must be in order to be sufficiently "isolated," and would be guided in that inquiry by the remainder of the specification. The Board acknowledged that the specification included an express

reference to polypeptides in its explanation of the "at least 25% (w/w)" purity level, but did not find any evidence to support Elysium's argument that such a purity level applies ***only*** to polypeptides. Appx14. In fact, the Board could "find no reason why one skilled in the art would have viewed the term 'isolated' differently for nucleic acids than for polypeptides." *Id.*

Accordingly, the Board concluded that the '086 patent specification taught that "the same minimum percentage is also appropriate for the measure of isolation of NR." *Id.*

SUMMARY OF ARGUMENT

There is no dispute that Elysium's proposed construction for "is isolated" in the '086 patent is broader than that adopted by the Board in the IPR proceedings below. There is also no dispute that under this Court's precedent for construing terms under the broadest reasonable interpretation standard, a construction that is unreasonably broad must be rejected. Elysium's proposed construction suffers from this very problem. It is so unreasonably broad that it would to lead to an interpretation squarely contradicted by the '086 patent. On this basis alone, Elysium's proposed construction should be rejected.

In contrast to Elysium's unreasonable construction, the Board's construction of "is isolated" complies with the requirements of the broadest reasonable interpretation standard. The Board's construction incorporates the definition supplied by the '086 patent for "isolated molecules," and includes the purity level that further elucidates that definition. Moreover, the remainder of the '086 patent specification supports the conclusion that a person of ordinary skill in the art would understand that a purity level of at least 25% would apply to all molecules, including NR, and that one could utilize the standard isolation and purification methods disclosed in the specification to achieve that level for the claimed NR. Even in the absence of a 25% purity level requirement, the specification makes

clear that to achieve isolated NR, one must do more than simply milk a cow or skim the fat off of milk.

Applying the Board's construction for "is isolated," there is no dispute that Elysium's asserted prior art references do not anticipate claim 2 of the '086 patent. Under either construction, however, the prior art references do not contain any disclosure of NR, let alone any disclosure of the purity of the NR with respect to the source of the molecule.

Accordingly, because the Board correctly construed "is isolated" as used in claim 2 of the '086 patent, the Court should affirm both the Board's claim construction of that term and its conclusion that claim 2 of the '086 patent is not unpatentable in light of either Goldberger et al. or Goldberger and Tanner.

ARGUMENT

I. STANDARD OF REVIEW

Claim construction is a question of law that can involve factual inquiries. *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347, 1360 (Fed. Cir. 2018). This Court reviews "the Board's claim construction based solely on intrinsic evidence *de novo*." *Id*. Anticipation is a question of fact, and this Court "uphold[s] the Board's factual determinations unless they are not supported by substantial evidence." *In re Rambus, Inc.*, 694 F.3d 42, 46 (Fed. Cir. 2012); *see also Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1068 (Fed. Cir. 2017) ("anticipation is a question of fact subject to substantial evidence review").

"Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *In re Applied Materials, Inc.*, 692 F.3d 1289, 1294 (Fed. Cir. 2012) (internal quotation marks omitted); *In re Morsa*, 713 F.3d 104, 109 (Fed. Cir. 2013) ("Substantial evidence is less than the weight of the evidence but more than a mere scintilla of evidence."). "If two inconsistent conclusions may reasonably be drawn from the evidence in record, the PTAB's decision to favor one conclusion over the other is the epitome of a decision that must be sustained upon review for substantial evidence." *Elbit Sys. of Am., LLC v. Thales Visionix, Inc.*, 881 F.3d 1354, 1356 (Fed. Cir. 2018) (internal quotation marks and bracketing omitted).

II. THE BOARD'S CONSTRUCTION OF "IS ISOLATED" SHOULD BE AFFIRMED BECAUSE IT IS THE BROADEST REASONABLE INTERPRETATION

The Board's construction of "is isolated" as used in claim 2 of the '086 patent should be affirmed because it comports with the requirement that, in an *inter partes* review filed before November 13, 2018, claim terms are construed 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 Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51,340, 51,344 (Oct. 11, 2018) ("The [Board] will continue to apply the BRI standard for construing unexpired patent claims . . . in AIA proceedings where a petition was filed before the effective date of the final rule.").

A. The '086 Patent Specification Supports the Board's Definition of "Is Isolated" in Claim 2 of the '086 Patent

Elysium's appeal on the construction of "is isolated" boils down to its argument that the term should be limited to a single sentence from the '086 patent specification regarding that term, regardless of the breadth of that single sentence and regardless of the remainder of the specification that informs a person of ordinary skill in the art regarding the level of purity encompassed by that definition. But the result of adopting Elysium's proposal would be a violation of this Court's precedent concerning the broadest reasonable interpretation in *inter*

partes review proceedings. "While the Board must give the terms their broadest reasonable construction, the construction cannot be divorced from the specification and the record evidence." *In re Man Machine Interface Techs., LLC*, 822 F.3d 1282, 1286 (Fed. Cir. 2016) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)). Specifically, "[t]his court's cases on BRI make clear that the proper BRI construction is not just the broadest construction, but rather the broadest *reasonable* construction *in light of the specification*." *Id.* at 1287 (emphasis in original). Thus, "a construction that is unreasonably broad and which does not reasonably reflect the plain language and disclosure will not pass muster." *Regeneron Pharms., Inc. v. Merus N.V.*, 864 F.3d 1343, 1351-52 (Fed. Cir. 2017) (citing *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015)).

During the IPR proceedings below, the Board properly rejected the same arguments that Elysium makes here, and the Board did so based on its review of the '086 patent's definition of "isolated molecules," including the remainder of the specification that informs a person of ordinary skill in the art about the purity level meant by the definition's "separated or substantially free" phrase. The term "isolated" is defined in the below paragraph from the '086 patent specification:

> 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 polypeptide is at least about 25%, 50%, 60%, 70%, 75%, 80%, 85%, 90%, 95%, 97%, 98%, 99% or more pure (w/w).

Appx51 (9:3-12). As explained by the Board, this passage does provide language defining "isolated molecules," which necessarily includes the exemplary molecules discussed in the passage—nucleic acid, DNA, RNA, cDNA, polypeptides—as well as the other molecules discussed in the rest of the specification. Appx12-14. Importantly, given that the claims are directed solely to pharmaceutical compositions of NR, and the specification's extensive disclosures concerning NR, there can be no dispute that NR should be considered a "molecule" that is governed by the teachings of the above-cited passage.

The Board's analysis of the specification's disclosures concerning isolated NR and its inclusion of the 25% (w/w) limitation to further define how pure a molecule must be in order to be "separated or substantially free" are appropriate under this Court's precedent. For example, in *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340 (Fed. Cir. 2010), this Court affirmed a lower court's construction of the term "static," where the lower court adopted the specification's express definition, but made two changes to that definition based on the teachings in the specification. *Id.* at 1353. While the Court acknowledged that such a definition "may seem narrower than the inventors' express definition at first glance . . . the rest of the specification, and the prosecution history support the

district court's definition." *Id.* Like in *Trading Techs.*, the '086 patent specification "strongly suggests" that isolated molecules require at least some level of purification, and therefore supports the Board's inclusion of the 25% purity level for NR. *See id.* at 1353-54; *see also ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 540-42 (Fed. Cir. 1998) (affirming construction of "embossments" that included both the express definition and additional language from the specification describing the function of the embossments).

Elysium focuses only on the first sentence of the passage discussing isolated molecules as being "definitional" (Op. Br. 14), to the exclusion of the rest of the specification, which provides further clarification on the level of purity required for a molecule—including NR—to be "separated or substantially free" under that definition. Elysium also ignores the Board's findings regarding the following passage, which is a part of the '086 patent's teachings concerning the isolation of NR specifically:

> Synthetic sources of nicotinamide riboside can include any library of chemicals commercially available from most large chemical companies including Merck, Glaxo, Bristol Meyers Squibb, Monsanto-Searle, Eli Lilly and Pharmacia. Natural sources which can be treated for the presence of a nicotinamide riboside include, but are not limited to, cow's milk, serum, meats, eggs, fruit and cereals. Isolated extracts of the natural sources can be prepared using standard methods. For example, the natural source can be ground or homogenized in a buffered solution, centrifuged to remove cellular debris, and fractionated to remove salts, carbohydrates, polypeptides, nucleic acids, fats and the like before being tested on the mutant[] strains of the invention. Any source of nicotinamide riboside that

> scores positively in the assay of the invention can be further fractionated and confirmed by standard methods of HPLC and mass spectrometry.

Appx59-60 (26:64-27:12); *see also* Appx62-63 (32:54-33:2, Example 2 describing "Nicotinamide Riboside and Whey Preparations"); Appx56 (19:5-28, describing purification techniques for NR kinases). In other words, and as the Board recognized, these teachings would convey to a person of ordinary skill in the art "that isolating NR is more than simply separating or rendering it substantially free from any amount of the other components of the naturally occurring organism." Appx14.

This is analogous to *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370 (Fed. Cir. 2006), where this Court analyzed the specification's disclosures, including specific references to EDTA salts, when determining whether to modify the specification's express definition of EDTA—"EDTA and derivatives thereof"—to add additional language defining "derivatives." 467 F.3d at 1376-77. This Court concluded that the additional language was appropriate, stating that "[w]hen reading these statements in the context of the entire specification, it is evident that the listing of various EDTA salts defines the term 'derivatives.' At the very least, 'derivatives' does not include structural analogs." *Id.* at 1377. Like in *Abraxis*, whatever definition is used for "isolated," at the very

least it must require more than just removing some amount—no matter how little—of other components of milk. *See Abraxis*, 467 F.3d at 1377.

Because the techniques described for "isolating" NR include steps that would remove significant portions—and likely much more than 25%—of the source material (*e.g.*, "the natural source can be ground or homogenized in a buffered solution, centrifuged to remove cellular debris, and fractionated to remove salts, carbohydrates, polypeptides, nucleic acids, fats and the like"), it is therefore reasonable to include the 25% purity level in the definition of "isolated" as applied to NR—and unreasonable not to.

B. Elysium's Alternative Construction Should Be Rejected Because it is Unreasonably Broad

Despite the '086 patent teachings, Elysium proposes that "is isolated" should instead be construed to mean "is separated or substantially free from at least some of the other components of the naturally occurring organism." Op. Br. 15-16. However, the Board understood that "construing the term 'is isolated' as suggested by [Elysium] would render the term unreasonably broad in that it would encompass separation of even an insignificant amount of other components." Appx13. Because such a result would be contrary to the teachings of the specification, this Court's precedent dictates that Elysium's proposed construction must be rejected as unreasonably broad. *In re Power Integrations, Inc.*, 884 F.3d 1370, 1377 (Fed. Cir. 2018) (explaining that a proper BRI analysis "endeavors to

assign a meaning to a disputed claim term 'that corresponds with . . . how the inventor describes his invention in the specification.'") (quoting *In re Smith Int'l*, 871 F.3d 1375, 1383 (Fed. Cir. 2017)). The intrinsic record repeatedly emphasizes that cow's milk is a source of NR, meaning that NR can be isolated from that milk and purified using the techniques taught above so that the NR can then be used in the claimed pharmaceutical compositions:

- Natural sources which can be tested for the presence of [] nicotinamide riboside include, but are not limited to, cow's milk, serum, meats, eggs, fruit and cereals. Appx59-60 (26:67-27:3).
- "In one embodiment, the natural source [of NR] is cow's milk." Appx48 (4:12-13).
- "Further, yeast mutants of defined genotype were used to identify sources of nicotinamide riboside and it is shown that milk is a source of nicotinamide riboside." Appx48 (3:9-12).

Elysium's proposed construction, which requires virtually no separation from other components, cannot be squared with the definition of "isolated molecules," particularly when read in the context of these additional teachings regarding sources of NR. Elysium conceded that its construction is so broad that it would cover cow's milk, which is the very substance that the specification repeatedly discloses as a ***source*** from which NR is isolated:

- "the ***NR in skim milk is isolated from a natural source, first, from the cow*** and later from the whole milk when the fat elements of whole milk are separated from the non-fat elements, including the NR." Appx266 (¶33); *see also* Appx197-198 (citing same in Petition) (emphasis added).
- "the ***NR in buttermilk is isolated from a natural source, first, from the cow***, and later from the whole milk or cream, when the fat elements that are churned into butter are separated from the water-soluble elements, including NR." Appx268 (¶38); *see also* Appx208 (citing same in Petition) (emphasis added).

In other words, under Elysium's proposed construction, milk inside of a cow's udder ***is not*** "isolated," but that same NR found in milk immediately after removing it from the cow ***is*** "isolated." Elysium offers no explanation for why the teachings of the '086 patent should be ignored in favor of an unreasonably broad construction that would lead to such an absurd result. Nothing in the '086 patent, let alone the definition of "isolated molecules" as encompassing purity of at least 25% (w/w), supports the result that Elysium seeks. Because Elysium's proposed construction is overly broad under the broadest reasonable interpretation standard, Elysium's construction should be summarily rejected and the Board's construction should be affirmed.

C. Elysium Offers No Basis to Depart from the Board's Construction of "Is Isolated" Under This Court's Precedent on the Broadest Reasonable Interpretation

In the absence of any intrinsic evidence to support its unreasonably broad construction for "is isolated," Elysium offers three other arguments, all of which should be rejected.

1. Elysium's Cited Cases Confirm that Elysium's Unreasonably Broad Construction Should Be Rejected

None of Elysium's cited cases dictates a reversal of the Board's correct construction for "is isolated." Op. Br. 16-18 (citing *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363 (Fed. Cir. 2009), *Braintree Labs, Inc. v. Novel Labs, Inc.*, 749 F.3d 1349 (Fed. Cir. 2014), and *Google LLC v. Network-1 Tech., Inc.*, 726 F. App'x 779 (Fed. Cir. 2018)). In fact, *Martek*, *Braintree*, and *Google* confirm that where, as here, a broader proposed interpretation is ***unreasonable***, then it must be rejected under the broadest reasonable interpretation standard.

In *Martek*, the Board's construction was unreasonable because it actually modified the otherwise undisputed scope of "the kingdom Animalia" recited in the patent's express definition of the disputed term. *Martek*, 579 F.3d at 1380. No such circumstance exists here because the Board adopted the definition of "isolated" without changing any of the terms or language expressly recited in that definition. Nothing in *Martek* prohibits the Board's construction here, which only adds a purity level that also comes directly from the patent specification.

Similarly, in *Braintree*, the Board edited the disjunctive word "or" in the express definition to be the conjunctive phrase "both . . . and" such that the preferred embodiment would not be excluded from the definition. *Braintree*, 749 F.3d at 1355-56. The same is not true here, where the Board kept the definitional language for "isolated molecule," identified a phrase requiring additional explanation ("separated or substantially free"), and used the specification's teachings to identify the proper scope of that phrase ("25% (w/w)"). Such additional explanations are proper under this Court's precedent, particularly where the specification would lead a person of ordinary skill in the art to additional features not expressly recited in a definition. *E.g.*, *Abraxis*, 467 F.3d at 1375-78 (adopting specification's definition of "edetate"—"EDTA and derivatives of EDTA"—and adding further clarification defining "derivatives" in concluding that "the proper construction of 'edetate' is EDTA and derivatives of EDTA, such as salts, but not including structural analogs").

Finally, in *Google*, the broader of two constructions was selected following this Court's analysis of the specification and extrinsic evidence and its conclusion that all of that evidence was "inconclusive" as to which alternative construction was correct. *Google*, 726 F. App'x at 786. Here, quite the opposite is true. The intrinsic evidence of the '086 patent, including its definition of "isolated," the enumerated minimum purity level required for a molecule to be considered

"isolated," and the explanations for how to isolate and purify NR from natural sources (*e.g.*, from milk), are all conclusive evidence that Elysium's proposed construction is unreasonably broad—even under the broadest reasonable interpretation standard—and should therefore be rejected.

2. The 25% Purity Limitation is Supported By the Disclosure of Isolation Techniques for the NR Used in the Claimed Pharmaceutical Compositions

As an initial matter, Elysium's argument that the inclusion of the 25% purity limitation is somehow incorrect simply because Dartmouth did not initially propose it during the IPR proceedings is nonsensical. Op. Br. 19-20. While it is true that Dartmouth initially proposed that "isolated" be construed to mean "fractionated from other cellular components" (Appx1115), there is no dispute that this proposal is not at issue in this appeal. Even if it were, Dartmouth's proposed construction in its Preliminary Patent Owner Response, which was based on the disclosures concerning isolating NR from synthetic or natural sources (*e.g.*, milk), is actually fully consistent with the Board's inclusion of the 25% purity level in its construction of "isolated."

As the Board recognized, the '086 patent counsels against adopting a construction that would permit the NR of the claimed pharmaceutical compositions to be merely an ingredient among many, without any purification of NR at all. Appx13. In fact, the Board relied on the disclosures concerning fractionation and

purification that Dartmouth originally presented in its Preliminary Patent Owner Response (*see* Appx1117 (citing Appx60 at 27:3-12)), and concluded that:

> [C]onstruing the term 'is isolated' as suggested by [Elysium] would render the term unreasonably broad in that it would encompass separation of even an insignificant amount of other components. . . . The teachings in the Specification of the '086 patent counsel against such a broad construction when defining the term 'isolated' with respect to NR.

Appx13. In other words, the '086 patent's teachings regarding purification techniques, including "standard methods" of centrifugation, fractionation, HPLC, and mass spectrometry would lead a person of ordinary skill in the art to at least the minimum purity level identified in the paragraph that contains the definition of "isolated molecules." Appx60 (27:3-12). This alone is a sufficient basis for the Board's inclusion of that purity level in its construction of "is isolated."

Given that the disclosed purification techniques include "standard methods" for isolation, it is reasonable to conclude that a person of ordinary skill in the art would read the disclosed purity levels in conjunction with this discussion to answer the question the Board posed in determining the proper construction of "is isolated": "how *pure* must the nicotinamide riboside be in order for it to be considered 'isolated'?" Appx1151 (emphasis in original). In other words, a person of ordinary skill in the art would use the guidance from the specification concerning "isolated molecules," including the purity level of at least 25% (w/w), and would use the disclosed "standard methods" to achieve that purity level. It is

unreasonable to assume that a person of ordinary skill in the art would read the '086 patent specification as disclosing purity levels for only a single type of molecule—polypeptides—and conclude that all other molecules disclosed in the specification, including NR, nucleic acids, vectors, and prodrugs, do not require any purification whatsoever. It would be even more unreasonable to conclude from those teachings that NR in particular could be used without any purification, when NR is the subject of the claims to pharmaceutical compositions that can be used to treat humans suffering from conditions associated with NAD+ biosynthesis.

3. The Board's Construction of "Is Isolated" Properly Applies the Relationship Between the Source of the Molecule and the Desired Purity Level

Elysium's argument that the Board's "is isolated" construction "focuses on the wrong relationship" is not supported by the record. Op. Br. 23. Elysium's argument seems to be that the Board's construction somehow requires the NR to be 25% (w/w) of the final pharmaceutical composition. To the contrary, the Board's construction for "is isolated" focuses on the NR in relation to the source from which that NR was obtained. Starting with the construction itself, the Board's construction includes the phrase "nicotinamide riboside is separated or substantially free from at least some of the other components associated with the ***source*** of the molecule . . . ." Appx14 (emphasis added).

Elysium's misinterpretation may be wrapped up in its attempted application of a prior art reference (*i.e.*, Goldberger et al.) disclosing the very source—cow's milk—that the specification emphasizes as the source from which NR can be isolated and purified for use in the claimed pharmaceutical compositions. But the Board was not confused by the interplay of these concepts, which it explained when rejecting Elysium's unreasonably broad construction in its Institution Decision: "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***)." Appx1151-1152 (emphasis added). In other words, the Board's construction is squarely based on the correct relationship, namely, the required purity level of NR when it is isolated from the source of that molecule.

III. THE BOARD DID NOT ERR IN FINDING THAT PETITIONER FAILED TO PROVE THAT THE PRIOR ART RENDERED CLAIM 2 OF THE '086 PATENT UNPATENTABLE

The Board did not err in finding that neither Goldberger et al. nor Goldberger and Tanner discloses "isolated" NR under either the Board's adopted construction or Elysium's proposed construction. Appx26-27.

A. The Prior Art Does Not Anticipate Claim 2 of the '086 Patent Under the Board's Construction of "Is Isolated"

As an initial matter, Elysium does not dispute that that if the Board's construction of "isolated" is affirmed then neither Goldberger et al. nor Goldberger and Tanner anticipate claim 2. Op. Br. 27-28. That is because, as the Board correctly found, neither reference discloses that the NR in skim milk (Goldberger et al.) or buttermilk (Goldberger and Tanner) constitutes at least 25% (w/w) of the composition. Appx26. In fact, the record evidence establishes that NR constitutes 0.0001097% (w/w) of raw cow milk, and that skimming fat from that milk only increases the NR concentration in skim milk to 0.0001143%.[3]

Accordingly, there is no dispute that if this Court affirms the Board's construction of "isolated" then neither Goldberger et al. nor Goldberger and Tanner anticipates claim 2.

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[3] Table 1 in Trammell I shows that raw cow milk contains 4.3±2.6 µmol/L NR. Appx750. NR has the chemical formula $C_{11}H_{15}N_2O_5$ (*see* Appx752), which equates to a molar mass of 255.2 g/mol. Applying that molar mass, and assuming that milk has a density of 1.0 g/mL, this equates to only 0.0001097% (w/w) NR in raw cow milk. Fresh milk contains 4% (w/w) fat, such that removal of the fat to produce skim milk removes 4% of the mass from the milk, resulting in NR content of 0.0001143% (w/w). *See* Appx746.

B. The Record Demonstrates Ample Support for the Board's Conclusion that the Prior Art Does Not Disclose "Isolated" NR

With respect to the Board's analysis of Goldberger et al., Elysium disputes only whether separating "the non-fat elements of whole milk (including NR) . . . from the fat" satisfies the "isolated" requirement under Elysium's proposed construction. Op. Br. 27. Similarly, with respect to Goldberger and Tanner, Elysium disputes only whether separating the milk or cream from the buttermilk as it is churned into butter satisfies the "isolated" requirement under Elysium's proposed construction. *Id.*

But, as the Board correctly found, the NR in the skim milk of Goldberger et al. is not "isolated" from the components of the skim milk (Appx26), and the NR in the buttermilk of Goldberger and Tanner is not "isolated" from the components of buttermilk (Appx38). And, contrary to Elysium's argument, these findings are supported by substantial evidence.

As the Board explained, the record evidence establishes that even though skim milk has most, if not all, of its fat content removed, it still retains vitamins, minerals, and proteins, such as lactose. Appx27. The Board also explained that the record evidence establishes that even though buttermilk has most, if not all, of its butter content removed, it still retains other minerals, carbohydrates, and proteins, such as tryptophan and tyrosine. Appx38. Elysium does not dispute either of these findings. Op. Br. 27. Instead, Elysium simply argues that requiring

the "isolated NR" to be separated from "***every one*** of the 'salts, carbohydrates, polypeptides, nucleic acids, fats, and the like' present in a natural source of NR" is unnecessary. Op. Br. 25.

But, as the Board recognized, the '086 patent explains that each of the categories of salts, carbohydrates, polypeptides, nucleic acids, and fats should be removed during the isolation process. Appx27. Specifically, the Board recognized that the '086 patent discloses that during the isolation process the natural source of the NR could be "fractionated to remove salts, carbohydrates, polypeptides, nucleic acids, fats, ***and*** the like." Appx13 (citing Appx59-60 at 26:64-27:12). Thus, the '086 patent does not disclose that one or another of these components could be removed for the NR to be "isolated." Instead, as the Board found, each of them must be removed. Appx27. As neither Goldberger et al. nor Goldberger and Tanner disclose removing each of these components from the whole milk when creating the skim milk and buttermilk, and as the evidence in fact establishes that each of these components are still present, the Board's finding that the two prior art references proffered by Elysium do not anticipate claim 2 should be affirmed. *See Elbit*, 881 F.3d at 1356 (affirming Board's finding regarding prior art disclosures where supported by substantial evidence).

C. Claim 2 of the '086 Patent Cannot Be Read to Cover Milk or Buttermilk

The Board's anticipation analysis described above further confirms why a purity level is so important to the term "isolated"; without a purity level, the results would be nonsensical. Most alarmingly, it would lead to the absurd result that NR in milk inside of a cow would not be "isolated," but that same milk removed from a cow would be "isolated." Similarly, it would lead to the result that simply skimming the fat off of milk would render the NR in that milk "isolated," which is no more logical than drawing a distinction between NR in milk inside and outside of a cow. Based on the record evidence, simply skimming fat from fresh milk only increases the concentration of NR from 0.0001097% (w/w) in the fresh milk to 0.0001143% (w/w) in the resulting skim milk.[4]

Accordingly, even if there is no specific purity limitation to "isolated," the specification makes clear that one cannot achieve isolated NR simply by skimming fat off of milk. Like in *Abraxis*, the '086 patent disclosures provide an explanation of the words (*i.e.*, "separated or substantially free") included in the specification's definition of "isolated." *See Abraxis*, 467 F.3d at 1377 (finding that the

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[4] As explained in Argument Section III.A. above (*see* n.3), fresh milk contains 4% (w/w) fat. *See* Appx746. Similarly, buttermilk contains 0.5% (w/w) fat. *See id.* Accordingly, simply skimming fat from milk or buttermilk would not sufficiently increase the amount of NR to render it more than 25% (w/w) of the remaining milk or buttermilk.

specification's identification of EDTA salts provided definitional guidance for the word "derivatives" in the express definition of EDTA). Accordingly, whatever definition is used for "isolated," at the very least it must require more than just removing milk from a cow or removing fat from the cow's milk. *See, e.g.*, *Abraxis*, 467 F.3d at 1377 (stating that "[a]t the very least, 'derivatives' does not include structural analogs" based on the specification's statement regarding EDTA salts). Accordingly, because Elysium's prior art references are limited to a disclosure of milk and buttermilk, it would be illogical to render claim 2 of the '086 patent unpatentable over those references.

Moreover, the specification's description of the method of identifying and isolating NR from milk is unequivocal that milk cannot fall within the scope of claim 2. As explained above, the '086 patent explicitly states that the "present invention" relates to a method of identifying NR and isolating that NR from cow's milk (a natural source of NR). Appx59-60 at 26:37-27:12. In doing so, the specification distinguishes the "isolated NR" of claim 2 from cow's milk and therefore disavows the scope that cow's milk could include isolated NR. *See Poly-Am., L.P. v. API Indus., Inc.*, 839 F.3d 1131, 1136 (Fed. Cir. 2016) (stating that "an inventor may disavow claims lacking a particular feature when the specification describes 'the present invention' as having that feature"); *see also SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343 (Fed. Cir.

2001) (holding that a patent's characterization of a particular feature "as part of the 'present invention' is strong evidence that the claims should not be read to encompass the opposite structure").

Moreover, where a patent distinguishes the prior art, "the claims should not be read so broadly as to encompass the distinguished prior art structure." *SciMed*, 242 F.3d at 1343. This is precisely the situation here because the '086 patent distinguishes the prior art—milk—from the present invention by explaining how NR can be isolated from that milk for use in the claimed pharmaceutical formulations. *See* Appx59-60 at 26:37-27:12. Because Elysium has offered only prior art that the '086 patent expressly distinguishes from the invention, those references cannot render claim 2 of the '086 patent unpatentable.

CONCLUSION

As explained herein, the Board properly construed the "is isolated" term in Claim 2 of the '086, and properly applied that construction to find that Elysium failed to show that Claim 2 of the '086 patent is unpatentable. Accordingly, and for the foregoing reasons, the Court should affirm the Board's determination that Claim 2 is not unpatentable.

Dated: August 28, 2019

/s/ John L. Abramic

John L. Abramic
STEPTOE & JOHNSON LLP
115 S. LaSalle Street, Suite 3100

Chicago, IL 60603
Telephone: (312) 577-1264
Facsimile: (312) 577-1370

Counsel for Appellee,
Trustees of Dartmouth College

CERTIFICATE OF SERVICE

I hereby certify that, on the 28th day of August, 2019, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which thereby served a copy upon all counsel of record via email or electronic means.

Upon notification of the Court indicating paper copies are requested, the required number of copies of the brief set by Clerk will be sent to the Court via Federal Express, priority overnight, within the time provided in the Court's instructions.

Dated: August 28, 2019

/s/ John L. Abramic

John L. Abramic
STEPTOE & JOHNSON LLP
115 S. LaSalle Street, Suite 3100
Chicago, IL 60603
Telephone: (312) 577-1264
Facsimile: (312) 577-1370

Counsel for Appellee,
Trustees of Dartmouth College

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitations of Fed. Cir. R. 32(a). This brief contains 8,278 words (including diagrams and images), excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b), as counted by Microsoft® Word 2016, the word processing software used to prepare this brief.

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Dated: August 28, 2019

/s/ John L. Abramic

John L. Abramic
STEPTOE & JOHNSON LLP
115 S. LaSalle Street, Suite 3100
Chicago, IL 60603
Telephone: (312) 577-1264
Facsimile: (312) 577-1370

Counsel for Appellee,
Trustees of Dartmouth College