

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CHROMADEX, INC. and TRUSTEES
OF DARTMOUTH COLLEGE,

Plaintiffs,

v.

ELYSIUM HEALTH, INC.,

Defendant.

Civil Action No. 18-1434-CFC



**PLAINTIFFS' RESPONSE TO ELYSIUM'S MOTION FOR SUMMARY
JUDGMENT (NO. 2) OF NON-INFRINGEMENT OF CLAIM 2
OF EACH ASSERTED PATENT (D.I. 190)**

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Elysium baldly mischaracterizes how it obtains NR for its Basis product.

[REDACTED]

As this Court explained during the *Markman* hearing, there is a distinction between chemical synthesis in which “you are creating a synthetic source,” and the separate “instance when you’re having isolation from a synthetic source.” Ex. 1, 36:9-19. Under the Court’s construction, chemical synthesis is outside the scope of each claim 2. *See* D.I. 152, 2. In contrast, “isolation from a synthetic source” is within the scope. *Id.* [REDACTED]

[REDACTED]

Elysium’s motion for summary judgment is predicated on mischaracterization intended to disguise a disputed question of fact: [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] XSF-21. Because a reasonable jury could find that it is, Elysium’s motion should be denied.

BACKGROUND

I. Claim Construction

As relevant to this motion, claim 2 in each of the Dartmouth Patents recites that the claimed composition contain “nicotinamide riboside isolated from a natural or synthetic source.” The Court construed this term to mean “the nicotinamide riboside is isolated from a natural or synthetic source and is not chemically synthesized.” D.I. 152, 2. The Court explained that a POSA would understand the Dartmouth Patents to describe “that NR can be obtained in three different ways — [1] from a natural source, [2] from a synthetic source, or [3] from chemical synthesis described in the articles like Tanimori and Franchetti.” Ex. 1, 48:7-10; *see also id.*, 36:9-19.

II. Elysium's Basis Product

Elysium's Basis product is a dietary supplement that contains NR (as NR chloride)¹, which it calls "NR-E." *See* Ex. 10, 15:9-16:3. [REDACTED]

[REDACTED]

[REDACTED]. *See* XSF-1.

[REDACTED]

[REDACTED]

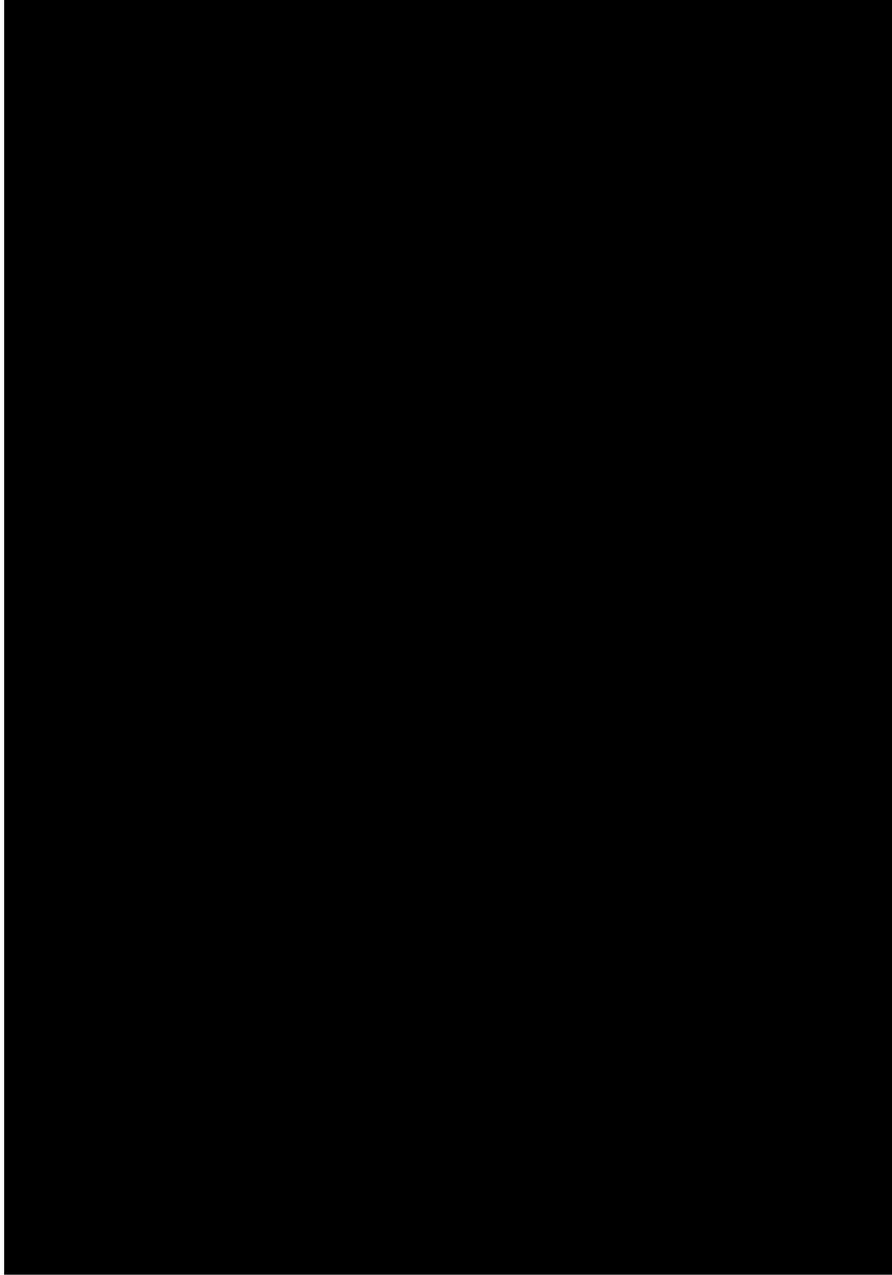
[REDACTED] (Ex. 3, ELY_DEL0017829-833). *E.g.*, Ex. 5, ¶ 42; Ex. 2, 167:18-168:8, 180:16-181:3; Ex. 10, 66:9-23.

[REDACTED]

[REDACTED] Ex. 3, ELY_DEL0017830, 831.

¹ NR chloride is a salt form of NR. *See* Ex. 3, ELY_DEL0017829. Elysium uses the terms "NR" and "NR chloride" interchangeably. *Id.*

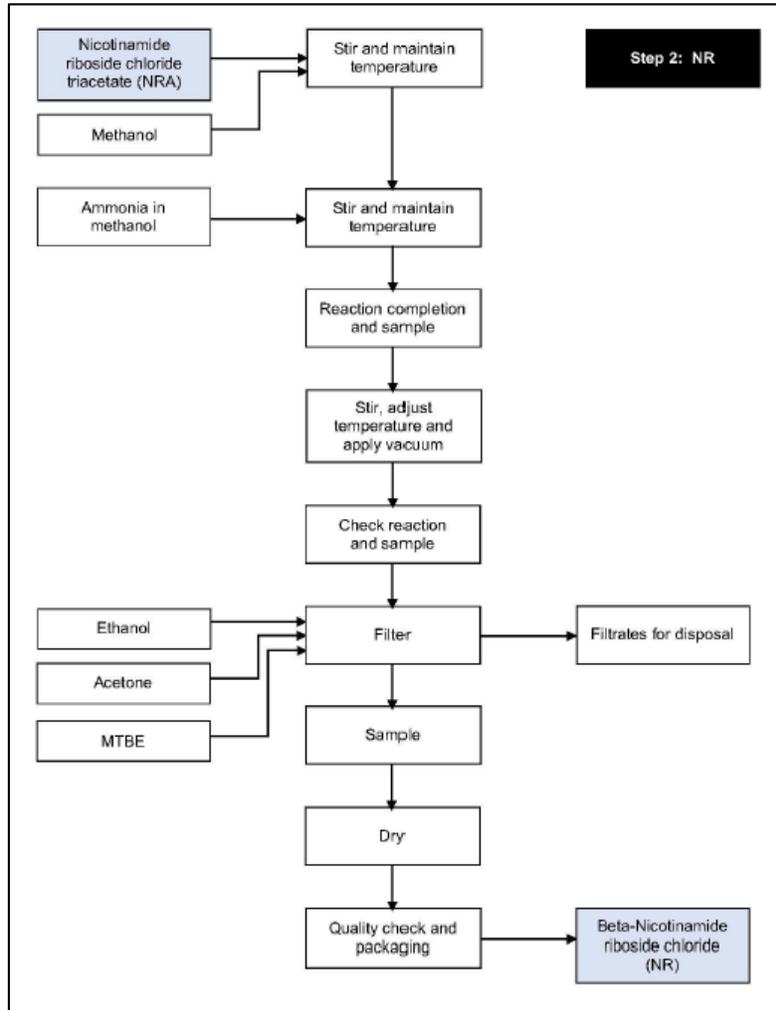
² [REDACTED]



[REDACTED]

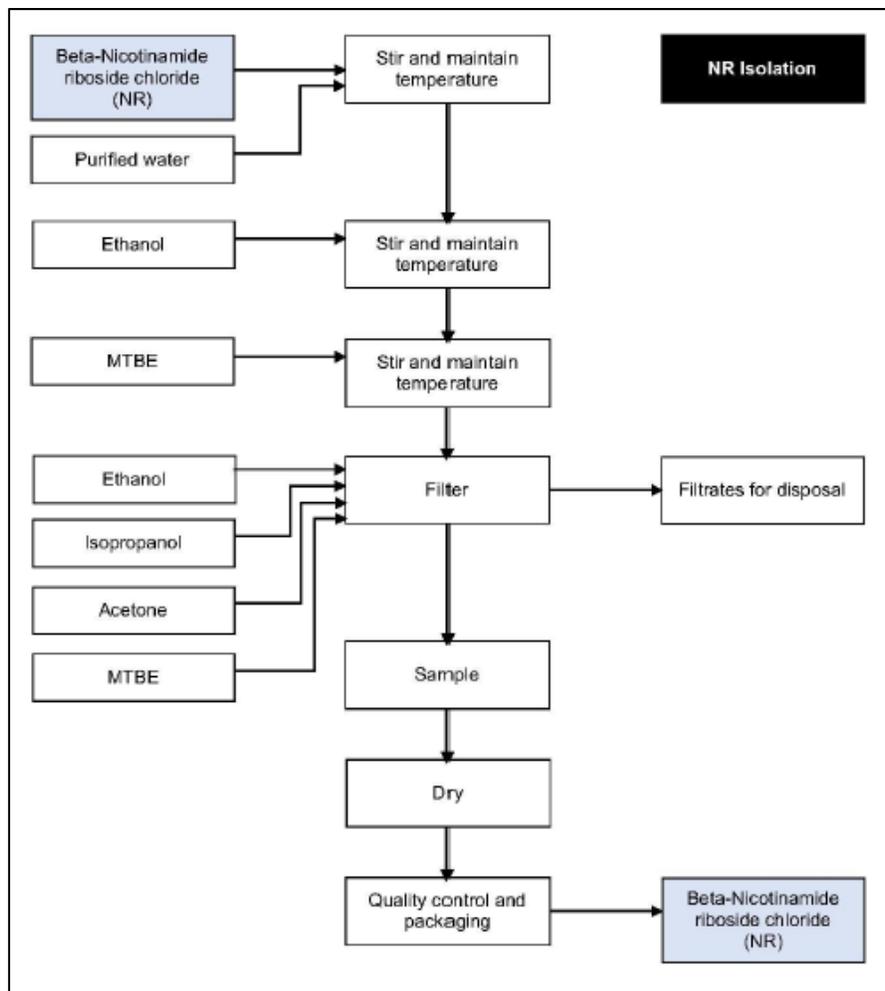
[REDACTED]

to completion, after which the NR is isolated (purified), quality checked, and packaged. XSF-11; XSF-12.³



³ Dr. Adams, Elysium’s technical expert, admits that the NR obtained at the end of Step 2 is purified, dried, quality checked, and packaged. Ex. 10, 79:12-20. He declines to call the purification step an isolation because he asserts “isolation” applies only to natural, not synthetic, sources. Ex. 10, 73:8-24. Dr. Adams’ restricted use of the term “isolation” is contrary to ordinary usage, as demonstrated by batch records for Elysium’s NR, Ex. 6, ¶¶ 25-26, and Elysium’s own representations in its GRAS Notification, Ex. 10, 74:2-5.

Importantly, Elysium does not use the NR obtained from this two-step process in its product, but instead, uses it as the synthetic source from which it isolates higher purity NR for inclusion in Basis. Ex. 3, ELY_DEL0017830 (“NR is further isolated to remove impurities such as acetamide.”); XSF-13. As shown below, Elysium’s own GRAS Notification describes this additional, later step as an “isolation.” Ex. 3, ELY_DEL0017833.



No chemical reactions are conducted during the separate isolation of NR, which has a higher purity as a result of being separated from impurities and by-

products associated with its source. Ex. 5, ¶ 42; Ex. 10, 74:6-20. It is this isolated NR that Elysium uses in Basis—NR isolated from a synthetic source rather than obtained from a chemical synthesis.

B. Bontac’s Process for Obtaining NR

Although Elysium requires its NR to be manufactured according to its GRAS Notification, in 2019 Elysium used four lots of NR that were manufactured by Bontac using an enzymatic process. XSF-7. This enzymatic process requires a living organism to produce the enzyme used to make NR. XSF-22. Once the enzyme has catalyzed the reaction to produce NR, Bontac then isolates and packages it. Ex. 5, ¶ 92. Bontac’s NR is thus isolated from a natural source.

ARGUMENT

I. A genuine dispute of material fact exists with respect to the isolation of NR in the Basis product

A. Elysium’s NR manufactured according to its GRAS Notification is isolated from a synthetic source

A genuine dispute of material fact exists regarding whether isolation of high-purity NR from a source of NR that has previously been synthesized, isolated, quality checked, and packaged is “isolated from a synthetic source,” rather than obtained from a chemical synthesis. XSF-21. As described above, Elysium’s source of NR is made in a two-step process that yields synthetic NR that has been isolated, quality tested, packaged, and stored. XSF-10; XSF-11; XSF-12. This marks the end

of the chemical synthesis. As Dr. Larsen, an expert in process chemistry, opines, a POSA “would understand that checking the quality and packaging the [NR] is indicative of a completed synthetic process. Packaging the material permits the [NR] to be stored for some period of time. The testing and packaging of the material serves to separate the process before and after packaging, permitting the later steps to be conducted on multiple or blended lots an indefinite time *after* the synthesis step(s) has been completed.” Ex. 8, ¶ 45; *see also* XSF-15.

Following the end of the chemical synthesis, Elysium performs a separate isolation process on the previously packaged NR to obtain the high-purity NR it uses in its product. A POSA would not understand this separate isolation step as part of the synthesis. As Dr. Sobol explained, the separate isolation “serves, as Elysium’s GRAS Notification states and as a POSA would readily appreciate, not to complete a chemical synthesis, but rather to take existing, packaged NR and further purify it.” Ex. 6, ¶ 28; *see also* Ex. 8, ¶ 42; *see also* XSF-14; XSF-15.

Notably, the later isolation process need not be conducted immediately, and the chemically synthesized source of Elysium’s NR may be may be stored for months before the later isolation is performed to create the NR that is used in the Basis product. In addition, multiple different NR batches, made at different times in different syntheses, can be—and sometimes are—combined for isolation. Ex. 5, ¶¶ 88-91. The isolation is thus not conducted as part of Step 2, but rather may occur

later—sometimes months later—and on material collected from different synthetic batches of NR. Ex. 8, ¶¶ 48-49. Elysium’s process for obtaining NR is thus indistinguishable from obtaining NR from a chemical library and conducting an isolation to further purify it—a process this Court identified, as Elysium acknowledges, as an example of NR that would be isolated from a synthetic source as recited by claim 2. XSF-16.

Elysium misleadingly asserts that its process is the same as the chemical synthesis in Tanimori, which is outside the scope of claim 2. D.I. 190, 7-8. Elysium is wrong. XSF-17. As Dr. Larsen explained, Tanimori describes “a simple and efficient” synthesis beginning with starting reagents and ending with NR conducted in a “one-pot manner.” Ex. 9, ELY_DEL0000583; Ex. 8, ¶ 46; *see also* Ex. 6, ¶¶ 41-43. Tanimori does not package or store the NR and then conduct a second isolation; instead, the synthesis and purification of the NR proceed immediately one after the other. XSF-18; XSF-19. The NR in Basis is not isolated in a “one-pot manner” like Tanimori, but instead a synthesis is carried out and the NR is isolated, quality checked, packaged, and stored indefinitely. *See* XSF-5. Only later does a subsequent process isolate the high-purity NR from that source for use in the Basis product.

Elysium is incorrect that “[i]f Elysium’s process is not chemical synthesis, then the exclusion of chemical synthesis from the scope of the claim [2] is meaningless.” D.I. 190, 6-7. The Court’s construction distinguishes between

isolation from a synthetic source and chemical synthesis as two different sources of NR. *See* Ex. 1, 36:9-19, 48:7-10; *see also* Ex. 8, ¶ 35. It is thus Elysium’s position—which excludes from claim 2, higher purity NR obtained by isolating from synthesized, isolated, and packaged NR—that would render the Court’s construction meaningless, since nothing would remain of NR that is “isolated from a synthetic source.”

Elysium also argues that because its NR was at one point synthesized, then it is necessarily “outside the scope” of claim 2. D.I. 190, 6. But all NR that is “isolated from a *synthetic* source,” and within the scope of claim 2, must be *synthesized* at one point. *See* Ex. 6, ¶ 46. It is the chemically synthesized source of NR that is outside the scope. A POSA would understand that, under the Court’s construction, the distinction between infringing and non-infringing NR is whether an isolation has been conducted *separate from* the original synthesis. *Id.* Elysium’s process entails precisely this separate isolation.

Elysium believes the Court has already concluded that Elysium’s NR is not “isolated from a synthetic source,” because at the *Markman* hearing, the Court stated that “with chemical synthesis, ‘you are creating a synthetic source, but it’s anticipated that at the last step you’re going to have some isolation.’” D.I. 190, 8 (quoting Ex. 1, 36:11-20). Elysium, however, ignores that its two-step process for making NR has an isolation step before the NR is packaged. Elysium does not use

that NR in Basis. Instead, that synthesized, isolated, and packaged NR serves as a synthetic source for a later, second isolation process that yields higher purity NR for use in the Basis product. This is precisely the instance in which chemical synthesis is used to provide “a synthetic source” of NR, from which a higher-purity NR is subsequently isolated. Ex. 1, 36:9-19; *see also id.*, 48:6-10. Ample evidence thus establishes—and there is at the least a genuine dispute of material fact—that the NR in Basis is isolated from a synthetic source rather than obtained from a chemical synthesis. *See* XSF-21; *see also* XSF-13.

B. Bontac’s NR is isolated from a natural source

A genuine dispute of material fact also exists regarding whether isolation of high-purity NR from Bontac’s enzymatic process using a living organism is NR “isolated from a natural source,” rather than obtained from a chemical synthesis. XSF-24. Elysium asserts that Bontac’s NR is chemically synthesized and not “isolated from a natural source.” *See* D.I. 190, 8. The record, however, supports the conclusion that Bontac’s NR has been isolated from a *natural* source. XSF-23. There is no dispute that Bontac manufactures NR using an enzymatic process. *See* D.I. 190, 4-5; XSF-7. And while the record does not identify the specific organism that produces the enzyme required for Bontac’s process, there appears to be no dispute that a bacteria or other living organism is required to produce the enzyme that catalyzes the reaction to yield Bontac’s NR. XSF-22. *See Crown Operations Int’l*,

Ltd. v. Solutia Inc., 289 F.3d 1367, 1375 (Fed. Cir. 2002) (On summary judgment doubts resolved in favor of the nonmovant.).

Elysium asserts that Bontac's NR is chemically synthesized because Bontac's enzyme "was used simply to catalyze a reaction in the process that yielded chemically-synthesized NR." D.I. 190, 8. But this makes no sense. Applying Elysium's logic, a compound that has been biosynthesized by an organism using an enzyme would always be "chemically synthesized," and never isolated from a natural source. As Dr. Sobol explained, enzymes are the tools that living organisms use to biosynthesize natural compounds. Ex. 7, 153:14-23. That is, enzymes are involved in natural processes and a natural enzymatic reaction produces Bontac's NR, which is then isolated for use in Basis. Bontac's NR is thus isolated from a natural source.

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WORD COUNT CERTIFICATION

The undersigned counsel hereby certifies that the foregoing brief complies with the type-volume limitations of paragraph 20(c) of the Scheduling Order (D.I. 40). The text of the brief, including footnotes, was prepared using Times New Roman 14-point font, and it contains 2,207 words (excluding the title, caption, tables, and signature block).

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CERTIFICATE OF SERVICE

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