

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

CHROMADEX, INC. and
TRUSTEES OF DARTMOUTH
COLLEGE,

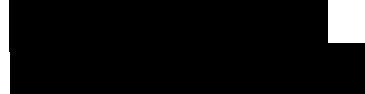
Plaintiffs,

v.

ELYSIUM HEALTH, INC.,

Defendant.

Civil Action No. 18-1434-CFC



**PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR
SUMMARY JUDGMENT THAT MILK DOES NOT ANTICIPATE
U.S. PATENT NO. 8,197,807 (MOTION NO. 3) (D.I. 213)**

Dated: May 21, 2021

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TABLE OF ABBREVIATIONS

Abbreviation	Description
The Dartmouth Patents	U.S. Patent Nos. 8,383,086 and 8,197,807
The '807 Patent	U.S. Patent No. 8,197,807
The '086 Patent	U.S. Patent No. 8,383,086
The Asserted Claims	Claims 1-3 of the '807 Patent and Claim 2 of the '086 Patent
ChromaDex	Plaintiff ChromaDex, Inc.
Dartmouth	Plaintiff Trustees of Dartmouth College
Plaintiffs	collectively, Plaintiffs ChromaDex, Inc. and Trustees of Dartmouth College
Elysium	Defendant Elysium Health, Inc.
NR	nicotinamide riboside
isolated NR	isolated nicotinamide riboside
D.I. 277	Elysium's Answering Brief in Opposition to Plaintiffs' Motion for Summary Judgment That Milk Does Not Anticipate U.S. Patent No. 8,197,807 (Motion No. 3)
D.I. 279	Defendant Elysium Health, Inc's Counterstatement of Facts in Opposition to Plaintiffs' Concise Statement Of Undisputed Facts in Support of Plaintiffs' Motion for Summary Judgment That Milk Does Not Anticipate U.S. Patent No. 8,197,807 (Motion No. 3)
PTAB's FWD	<i>Elysium Health, Inc. v. Trs. of Dartmouth Coll.</i> , IPR2017-01795, Paper No. 39 (P.T.A.B. Jan. 16. 2019)
Trammell I	Samuel A.J. Trammell et al., "Nicotinamide Riboside is a Major NAD ⁺ Precursor Vitamin in Cow Milk," <i>J. of Nutrition</i> , 146(5):965-963 (2016)

Abbreviation	Description
Trammell II	Samuel A.J. Trammell et al., “Nicotinamide Riboside is Uniquely and Orally Bioavailable in Mice and Humans,” Nature Communications, Vol. 7, Art. No. 12948 (2016)
GRAS Determination	Generally Recognized as Safe (GRAS) Determination for Niagen™ (Nicotinamide Riboside Chloride), Prepared for ChromaDex, Inc. (Dec. 21, 2015)
Bogan & Brenner	Katrina L. Bogan and Charles Brenner, “Nicotinic Acid, Nicotinamide, and Nicotinamide Riboside: A Molecular Evaluation of NAD ⁺ Precursor Vitamins in Human Nutrition,” Annu. Rev. Nutr., 28:115-30 (2008)
Cubero	Cubero, et al., “The circadian rhythm of tryptophan in breast milk affects the rhythms of 6-sulfatoxymelatonin and sleep in newborn,” Neuro Endocrinology Letters 26(6)657-61 (2005).
Exs. 1-10	Exhibit to Declaration of Adam W. Poff in Support of Plaintiffs’ Reply in Further Support of Their Motion for Summary Judgment That Milk Does Not Anticipate U.S. Patent No. 8,197,807 (Motion No. 3), D.I. 223 (April 27, 2021)
Ex. 11	Exhibit to Declaration of Adam W. Poff in Support of Plaintiffs’ Reply in Support of Their Motion for Summary Judgment That Milk Does Not Anticipate U.S. Patent No. 8,197,807 (Motion No. 3), filed concurrently (May 21, 2021)

As discussed below, no genuine issues of material fact exist and the Court should grant summary judgment that milk does not anticipate the '807 Patent.

I. The Identical Issue Was Previously Adjudicated.

Prior to arguing that milk anticipates the '807 Patent, Elysium made these same arguments before the PTAB with respect to the '086 Patent. *Orexo AB v. Actavis Elizabeth LLC*, 371 F. Supp. 3d 175, 181 (D. Del. 2019) (“The doctrine of issue preclusion ... bars successive litigation ... even if the issue recurs in the context of a different claim.”) (internal quotations omitted). Elysium argues that the issue decided by the PTAB was not identical because it employed a different construction than issued by this Court. D.I. 277, 11. This is plainly incorrect.

As Elysium acknowledges, the PTAB first rejected Elysium’s arguments regarding milk under the following construction of “isolated”: “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.” Ex. 5, 14. But the PTAB reached the same conclusion—that skim milk and buttermilk do not contain isolated NR—even under *Elysium’s* proposed construction: “Our conclusion remains the same even if we were to agree with [Elysium’s] contention that it is improper to adopt the 25% purity level included in our construction of the term ‘is isolated.’” Ex. 5, 27.

Elysium’s argument that the PTAB’s alternate construction is “significantly narrower than this Court’s construction” is baseless. As seen below, removal of the 25% language from the PTAB’s construction yields a materially identical construction to that adopted by this Court:

PTAB Construction Without 25% Limitation	Court’s Construction
<p>“the nicotinamide riboside is separated or substantially free from at least some of the other components associated with the source of the molecule”</p> <p>Ex. 5, 14.</p>	<p>“nicotinamide riboside that is separated or substantially free from at least some of the other components associated with the source of the nicotinamide riboside”</p> <p>D.I. 152.</p>

Elysium also cursorily argues that preclusion should not apply to “the public use and sale of skim milk” because it is not a printed publication capable of consideration during an IPR. D.I. 277, 11-12. But those arguments are just arguments based on printed publications about milk recast as the “public” use and sale thereof. Circumventing IPR estoppel is not so easy, and an unsuccessful IPR petitioner may not rely on patents or printed publications that could have been raised during the IPR to support such arguments. *Biscotti Inc. v. Microsoft Corp.*, 2017 WL 2526231, at *8 (E.D. Tex. May 11, 2017). Here, Elysium’s “public use and sale” arguments rely entirely on printed publications. There is nothing inherent to the use or sale of skim milk itself that prevented these very same arguments from being presented to the PTAB. Indeed, a review of Elysium’s expert’s claim chart shows that Elysium’s arguments are supported entirely by printed publications. Further all

but one¹ of the printed publications were submitted to the PTAB to support the same arguments. *Compare* Ex. 6, Ex. 1A *with* Ex. 11, iii, v (citing Trammell I, Trammell II, GRAS Determination, Bogan & Brenner). Elysium may not now cloak the arguments as “public use and sale” to avoid estoppel.

II. The PTAB’s Determination Was Necessary to the Final Decision Under Third Circuit Law.

Elysium also argues that issue preclusion does not apply because the Federal Circuit’s decision “did not identify which (if any) of the PTAB’s determinations was necessary to its summary affirmance.” D.I. 277, 12. Elysium’s analysis misstates the caselaw and renders obsolete the Third Circuit’s precedent regarding alternative findings.

Elysium acknowledges that alternative findings may be given preclusive effect under Third Circuit law. *See, e.g., Jean Alexander Cosms., Inc. v. L’Oreal USA, Inc.*, 458 F.3d 244, 255 (3d Cir. 2006) (“[W]e adopt the view of the First Restatement and the other courts of appeals that permit the application of issue preclusion to alternative findings”). The parties disagree, however, on whether this precedent applies to a summary affirmance. Elysium’s argument relies primarily on

¹ The remaining reference, Cubero, is a published article and reasonably could have been submitted to the PTAB as well.

the holdings in *United Access* and *Leyse*.² *United Access Techs., LLC v. Centurytel Broadband Servs., LLC*, 2016 WL 5745085 (D. Del. Sept. 30, 2016); *Leyse v. Bank of Am., Nat'l Ass'n*, 538 F. App'x 156 (3d Cir. 2013). But in neither of these cases did an appellate court summarily affirm where the *lower court* had reached its holding on alternative findings. Rather, in both instances, the referenced “ambiguity” was introduced by the *appellant's* new theories that the lower court *did not* address.

In *United Access*, the district court had granted partial summary judgment in the prior “EarthLink” case that the accused product did not infringe based on its claim construction. *United Access*, 2016 WL 5745085, at *3. On appeal, the defendants argued that the Federal Circuit could affirm the judgment of non-infringement either based on the court’s earlier claim construction or under the theory *introduced on appeal by the defendants* that a separate jury verdict relating to a different product warranted judgment of non-infringement as well. *Id.* Thus, *United Access* does not address the application of issue preclusion to alternative findings under Third Circuit law after a Rule 36 affirmance.

² Though Elysium also discusses *TecSec* and *Phil-Insul*, these cases do not apply Third Circuit law and are therefore irrelevant to the application of Rule 36 affirmances to alternative findings under Third Circuit law. *See TecSec, Inc. v. IBM Corp.*, 731 F.3d 1336, 1341 (Fed. Cir. 2013) (applying Fourth Circuit law); *Phil-Insul Corp. v. Airlite Plastics Co.*, 854 F.3d 1344, 1353 (Fed. Cir. 2017) (applying Eight Circuit law).

The *Leyse* court similarly does not address the question for which Elysium relies upon it. In *Leyse*, a first lawsuit was dismissed on standing grounds. *Leyse*, 538 F. App'x at 158 (3d Cir. 2013). The decision was appealed and, despite a pending motion to dismiss on *separate* grounds not addressed by the district court, the appellate court summarily affirmed the district court claim's dismissal. *Id.* Thus, this case likewise does not speak the preclusive effect of summary affirmances of decisions supported by alternative grounds.

The bedrock principles of issue preclusion are governed by Third Circuit law. *See, e.g., Voter Verified, Inc. v. Election Sys. & Software LLC*, 887 F.3d 1376, 1382 (Fed. Cir. 2018). As it explained in *Jean Alexander*, the Third Circuit has made the intentional decision to “permit the application of issue preclusion to alternative findings” even though “such determinations do not fulfill the necessity requirement for collateral estoppel in a strict sense.” *Jean Alexander*, 458 F.3d at 255. Denying preclusive effect for cases with these alternative findings, the court reasoned, “would significantly weaken the principle that later courts should honor the first actual decision of a matter that has been actually litigated.” *Id.* (internal quotation omitted). Elysium may not ignore this purposeful precedent under the same strict-necessity-requirement theory already addressed and rejected by the Third Circuit.

As the identical issue was previously litigated and the PTAB's determination was necessary to the final decision under Third Circuit law, the Court should grant summary judgment that claims 1-3 of the '807 Patent are not anticipated by milk.

Dated: May 21, 2021

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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 1,213 words (excluding the title, caption, tables, and signature block).

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CERTIFICATE OF SERVICE

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