IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CHROMADEX, INC. and TRUSTEES OF DARTMOUTH COLLEGE,	)	
Plaintiffs,	)	C.A. No. 18-1434-CFC
v.	)	
ELYSIUM HEALTH, INC.,	)	
Defendant.	)	

ELYSIUM'S REPLY BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT (NO. 1) OF INVALIDITY UNDER 35 U.S.C. § 101

ASHBY & GEDDES
Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Defendant

Of Counsel:

Donald R. Ware
dware@foleyhoag.com
Jeremy A. Younkin
jyounkin@foleyhoag.com
Marco J. Quina
mquina@foleyhoag.com
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, Massachusetts 02210
Phone: (617) 832-1000

Dated: May 21, 2021

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page**

Statutes

TABLE OF ABBREVIATIONS

Abbreviation	Description
'807 Patent	U.S. Patent No. 8,197,807
'086 Patent	U.S. Patent No. 8,383,086
Elysium	Defendant Elysium Health, Inc.
Plaintiffs	Collectively, Plaintiffs ChromaDex, Inc. and Trustees of Dartmouth College
NR	Nicotinamide riboside
DEX	Exhibit to Declaration of Marco J. Quina in Support of Elysium Health's Motion for Summary Judgment (No. 1) of Invalidity Under 35 U.S.C. § 101 (D.I. 185)
DOBr.	Elysium's Opening Brief in Support of Motion For Summary Judgment (No. 1) Of Invalidity Under 35 U.S.C. § 101 (D.I. 183)
PR-DSOF1	Plaintiffs' Counterstatement of Facts in Opposition to Elysium's Motion for Summary Judgment (No. 1) of Invalidity Under 35 U.S.C. § 101 (D.I. 288)
PABr.	Plaintiffs' Response to Elysium's Motion for Summary Judgment (No. 1) of Invalidity Under 35 U.S.C. § 101 (D.I. 278)

This is the rare summary judgment motion in which the non-moving parties ***admit*** every fact in the movant's statement of facts. Those undisputed facts establish that the asserted claims are directed to a natural product and not patentable under § 101.

In an attempt to stave off this inevitable legal conclusion, Plaintiffs disregard the Court's claim construction and read non-existent limitations into the claims. But they cannot deny that under *Myriad*, the claims as the Court construed them and the undisputed facts point to only one conclusion: the claims are unpatentable as a matter of law.

I. Step I: The Asserted Claims are Directed to Natural Products

A. Plaintiffs ignore *Myriad* and this Court's claim construction.

Plaintiffs' assertion that the claims are not directed to natural products focuses on the patents' requirement that the NR in the claimed composition be "isolated." But under the Supreme Court's *Myriad* decision, "isolating" a natural substance does not transform an unpatentable natural product into patentable subject matter, as a matter of law. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 580, 591, 595 (2013). *See* DOBr. at 6-8. Plaintiffs do not engage this argument or attempt to distinguish *Myriad*, effectively conceding the point.

Plaintiffs' failure to dispute Elysium's material facts underscores that their opposition turns on a legal question—claim construction—not an issue of fact.[1] *See ICU Med., Inc. v. Alaris Med. Sys.*, 2007 U.S. Dist. LEXIS 13156, at *41 (C.D. Cal. Jan. 22, 2007). This Court already decided claim construction. Rejecting Plaintiffs' original proposal, the Court construed "isolated nicotinamide riboside" to mean the NR is "separated or substantially free from at least some of the other components associated with the source." D.I. 152. Plaintiffs disregard this and assert that the term "isolated" "requires that the NR in the claimed composition be ***stable and bioavailable, allowing it to reach the bloodstream, enter the cell, and provide therapeutic effect***." PABr. at 4.[2] This contradicts the Court's construction, which does not include ***any*** of these requirements. *See Myriad*, 569 U.S. at 577 ("The claims… [do not] rely on the chemical changes resulting from the isolation of a particular DNA section."). On summary judgment, a court's constructions cannot "be undermined by… expert testimony that purports only to

[1] Plaintiffs also propose two additional purported material "facts," but they cannot defeat summary judgment. The Scheduling Order emphasizes that a statement of material facts "must detail each material *fact.*" D.I. 40 at 16-17 (emphasis in original). Instead of following these instructions, Plaintiffs identified general *issues* (not facts) to be decided. In any event, Plaintiffs' admission of ***all*** of Elysium's facts is more than sufficient to find an absence of disputed material facts here and, for the reasons discussed in Elysium's briefs, Plaintiffs' recitation of asserted issues does not defeat judgment as a matter of law for Elysium.

[2] Plaintiffs also add the requirement that the NR must be "sufficiently pure" or "pure." PABr. at 6, 7.

'explain' or 'provide context' to the terms, but instead logically or syntactically contradicts the Court's constructions." *ICU*, 2007 U.S. Dist. LEXIS 13156 at *42-43.

Plaintiffs advanced a different, much narrower construction of "isolated nicotinamide riboside" during *Markman*. When they failed to persuade the Court, Plaintiffs ***agreed*** to the Court's construction. DEX-G at 29. Plaintiffs cannot use their summary judgment opposition to reargue an agreed-upon claim construction. In any event, Plaintiffs' new and belated construction is baseless. Plaintiffs cite no intrinsic evidence supporting their added limitations, and instead rely on the extrinsic opinion of their expert, Dr. Sobol. But as discussed in Elysium's opening brief, even Dr. Sobol admitted that his added limitations could not be found in the claims or the Court's construction.

Plaintiffs' new interpretation of the claims contradicts their earlier arguments. In *Markman* briefing, Plaintiffs acknowledged that "the claimed 'composition'—***not any one of its particular components***—'increases NAD+ biosynthesis upon oral administration.'" D.I. 99 at 93-94 (emphasis added). Plaintiffs' expert also admitted this at his deposition. DEX-C at 204-205. Plaintiffs shamelessly ignore their prior admissions and now contend that the ***nicotinamide riboside*** in the claimed composition must itself "provide therapeutic effect." Rather than address their own about-face, Plaintiffs dismissively proclaim

that Elysium "misses the point," and assert (without citation) that the tryptophan in milk "act[s] through different pathways," as if that had anything to do with the claims. PABr. at n.1.

Plaintiffs' argument that NR in milk is neither bioavailable nor stable is immaterial because the claims do not require bioavailability or stability. Plaintiffs admit that milk treats the NAD+ deficiency diseases pellagra and blacktongue, PR-DSOF1-07, -08, and thus do not dispute that milk meets the claims' only functional limitations: it is a composition formulated for oral administration that increases NAD+ biosynthesis and can be used to improve the health/welfare of animals.

B. Plaintiffs' "utility" argument is wrong.

The purported "potential for utility" of the claimed invention does not make it patent eligible. Even useful inventions directed to natural products, such as the isolated DNA that can help detect cancer in *Myriad*, are unpatentable. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013) ("[Myriad] found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.").

Plaintiffs' utility argument ignores the full breadth of the claims. Whether one can imagine a composition falling within the scope of the claims that has "the potential for significant utility far beyond that of milk" is irrelevant. The critical question is whether the claims also extend to compositions that are not markedly

different from milk. *See Natural Alts. Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1348 (Fed. Cir. 2019) (claimed composition made from a natural product may be patentable if it has "different characteristics ***and*** the 'potential for significant utility'") (emphasis added). The claims reach such compositions, rendering them unpatentable.

C. Plaintiffs' reliance on *Natural Alternatives* is misplaced.

In its opening brief, Elysium presented a detailed analysis of *Natural Alternatives* and established that the claims in that case were very different from the claims here. Elysium also pointed out that in *Natural Alternatives*, the procedural posture was such that the court was required to accept plaintiffs' interpretation of the claims as importing non-natural limitations. In response, ***Plaintiffs do not disagree*** and make no effort to explain why *Natural Alternatives* is controlling here. Instead they seize on a single sentence in the opinion, which simply reiterates what the Supreme Court held long ago: to be patentable, a composition must have "markedly different characteristics from any found in nature." *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980). Plaintiffs make no attempt to show that *Natural Alternatives*' facts dictate the result here. Nor can they, because the claims here do not require any markedly different characteristics from those already found in natural milk. Plaintiffs bizarrely accuse Elysium of "never address[ing] [*Charkrabarty*'s] test," PABr. at 1, apparently overlooking an

entire section of Elysium's brief that discusses *Chakrabarty* and explains why the undisputed facts establish that the claims encompass compositions not markedly different from milk. DOBr. at 8-10.

II. Step 2: No Inventive Concept

There is no "inventive concept" that saves the claims from unpatentability. In two convoluted paragraphs, Plaintiffs argue that the inventive concept "is not the *discovery* of the NR vitamin pathway, but rather therapeutic *applications* of this discovery in inventive ways beyond that of the prior art." PABr. at 9-10 (emphasis in original). The claims, however, say nothing about "therapeutic applications." They are directed to compositions, not methods of treating diseases.

Moreover, it is ***undisputed*** that milk meets all functional limitations of the claims. The claimed composition of the '807 patent need only "increase[] NAD+ biosynthesis." The claimed composition of the '086 patent need only "be used to improve or prolong the health or well-being of humans or other animals." D.I. 152 at 3. Plaintiffs admit that milk can be used to prevent or treat NAD+ deficiency diseases, thus meeting both of the claims' two functional limitations. PR-DSOF1-07, -08.

Plaintiffs' reliance on *CellzDirect* is misplaced, because the claims in that case were materially different. Unlike the asserted claims here, the *CellzDirect* claims were "directed to a new and useful laboratory technique for preserving

hepatocytes," a type of liver cell. *Rapid Litig. Mgmt. v. CellzDirect, Inc.*, 827 F.3d 1042, 1048 (Fed. Cir. 2016). In finding the claims patentable, the Federal Circuit emphasized that the claims were ***method*** claims that improved an existing technological process, unlike the composition claims held unpatentable in *Myriad* and *Funk Bros. Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127 (1948). *See CellzDirect*, 827 F.3d at 1049, 1050. The claims in Dartmouth's patents are composition claims, and thus *Myriad* and *Funk* control.

Plaintiffs' argument overlooks that patent eligibility "requires more than simply stating the [unpatentable subject matter] while adding the words, 'apply it.'" *See Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 221 (2014). The specification in this case purports to disclose that animal cells naturally convert the vitamin NR into the co-enzyme NAD+. As the patent acknowledges, compositions comprising other NAD+ precursors (e.g., nicotinic acid and nicotinamide) were known in the art. DEX-A at 8:61-9:20. The patent states that compositions comprising NR can be used in the same way as the prior art compositions because NR is also an NAD+ precursor; in other words, take the natural phenomenon and "apply it." *Id.* Under governing Supreme Court precedent, claims such as these are unpatentable.

Of Counsel:

Donald R. Ware
dware@foleyhoag.com
Jeremy A. Younkin
jyounkin@foleyhoag.com
Marco J. Quina
mquina@foleyhoag.com
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, Massachusetts 02210
Phone: (617) 832-1000

Dated: May 21, 2021

ASHBY & GEDDES

/s/ Andrew C. Mayo

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Defendant

CERTIFICATE OF COMPLIANCE

This brief complies with the type, font and word limitations set forth in this Court's Standing Order Regarding Briefing in All Cases, dated November 6, 2019. This brief contains 1571 words (excluding the title page, table of contents, table of authorities, table of abbreviations, signature block, and certificate of compliance). This brief has been prepared in 14-point Times New Roman font.

Date: May 21, 2021

ASHBY & GEDDES

/s/ Andrew C. Mayo

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Defendant