

Milk Vitamin Patents Surprisingly Soured By Section 101

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On Sept. 21, 2021, the U.S. District Court for the District of Delaware granted summary judgment that two formulation patents were directed to patent-ineligible subject matter.[1] The two ChromaDex patents concern compositions and pharmaceutical formulations of nicotinamide riboside, or NR, a vitamin present in cow's milk, for oral administration.

The ChromaDex Inc. v. Elysium Health Inc. decision was particularly surprising since the compositions and formulations at issue do not exist in nature and the U.S. Court of Appeals for the Federal Circuit and district courts have generally upheld patent claims to formulations of natural compounds under Title 35 of the U.S. Code, Section 101.

Both ChromaDex patents also survived challenges in inter partes review proceedings. The Patent Trial and Appeal Board denied institution of IPR for one of the patents, and it upheld a challenged claim in the other patent as valid.[2][3]

The ChromaDex litigation goes back to September 2018, when ChromaDex filed an action alleging that Elysium's dietary supplement Basis infringed its patents. Both ChromaDex and Elysium market their products as anti-aging supplements, and NR has been touted as the "Fountain of Youth." [4][5][6]

Since the discovery of the potential anti-aging benefits of NR, ChromaDex's dietary supplement generated much enthusiasm and has been featured in publications such as Forbes, GQ, Entrepreneur and Shape. NR has been the subject of numerous studies to investigate its health benefits, including for the treatment of neurological disorders, cancer and even COVID-19.[7][8]

Elysium had taken a license to the two formulation patents but stopped making payments, which prompted ChromaDex to file a breach of contract action.[9] ChromaDex later sued Elysium for patent infringement. Elysium filed motions for summary judgment on several issues, including noninfringement, indefiniteness and invalidity under Section 101.

Two weeks before trial, the district court granted Elysium's motion for summary



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judgment under Section 101. It found the asserted claims to be patent-ineligible under the U.S. Supreme Court's 2014 two-step framework in *Alice Corp. v. CLS Bank International*.^[10]

ChromaDex Analysis of Alice Step One

The district court held the asserted claims are directed to a natural phenomenon because NR is a naturally occurring vitamin present in cow's milk.^[11]

ChromaDex argued the "correct inquiry" is "whether compositions of the Asserted Claims have different characteristics and can be used in a manner" not used "in nature."^[12]

The court disagreed, explaining that "the characteristics of the isolated NR in the claimed compositions that ChromaDex has identified as being different from the characteristics of NR in milk" are not required by the claims.^[13] It found that "[n]othing in the language of the asserted claims or the patent's intrinsic evidence suggests that the claims require these characteristics" and the characteristics "do not distinguish isolated NR in the claimed compositions from NR found in milk" in any event.^[14]

The court analogized the ChromaDex formulation claims to those in *Association for Molecular Pathology v. Myriad Genetics Inc.*, where claims to DNA isolated from its natural setting were held to be patent-ineligible.

In *Myriad*, the Supreme Court in 2013 held that the act of locating and isolating DNA from its natural environment did not render it patentable subject matter.^[15] In *ChromaDex*, the asserted claims did not cover isolated NR alone, but a "pharmaceutical composition" for "oral administration" comprising NR that included other ingredients, including a composition in the form of a tablet or capsule.^[16]

Despite the differences in the claims between *ChromaDex* and *Myriad*, the district court found the cases similar for purposes of step one of its *Alice* analysis and relied heavily on *Myriad*.^[17]

ChromaDex Analysis of Alice Step Two

The district court also held that the asserted *ChromaDex* claims did not contain an inventive concept.^[18] It relied on a statement from the specification that compositions containing NR "can be prepared by methods and contain carriers which are well-known in the art."^[19] It also found that recognizing the health benefit of a natural product is not sufficient to rise to the level of an "inventive concept."^[20]

Further, it was not convinced that therapeutic application of NR was inventive because "NR's oral bioavailability is an inherent property of NR and thus is itself a natural phenomenon," concluding that mere application of a natural phenomenon is not inventive.^[21]

Other Recent Decisions Involving Formulations of Natural Compounds

Other courts have rejected Section 101 challenges to formulations of natural compounds.

In *Natural Alternatives International Inc. v. Creative Compounds LLC*, the Federal Circuit in 2019 reversed judgment on the pleadings that claims involving beta-alanine, an amino acid, were patent-ineligible subject matter.^[22]

The claims at issue in *Natural Alternatives* included composition claims related to a dietary supplement providing beta-alanine to increase athletic performance.[23] Reversing the district court's decision, the Federal Circuit held:

We live in the natural world, and all inventions are constrained by the laws of nature. As the Supreme Court has warned, we must be careful not to overly abstract claims when performing the Alice analysis.[24]

The court explained that the mere fact that the "active ingredient in the supplement is a molecule that occurs in nature and is consumed as part of the human diet" does not affect its patentability where the claimed products have different characteristics with "the potential for significant utility," different from the natural substance itself.[25]

It held that

[a]lthough beta-alanine is a natural product, the Product Claims are not directed to beta-alanine. ... the Product Claims are directed to specific treatment formulations that incorporate natural products, but they have different characteristics and can be used in a manner that beta-alanine as it appears in nature cannot.[26][27]

Following *Natural Alternatives*, the PTAB recently upheld claims to protein supplements, including an animal protein, as patent-eligible.[28] In *Ex parte Christopher M. Lockwood* last year, the PTAB explained that "although bovine colostrum including transfer factor is a natural product, the claims are not directed to bovine colostrum." [29] Rather, as in *Natural Alternatives*, the claims are directed to specific formulations that incorporate natural products, and "can be used in a manner that the natural products, as they appear in nature, cannot." [30]

District courts also have recently found formulations of natural compounds to be patent-eligible.

For example, in *United Cannabis Corp. v. Pure Hemp Collective Inc.*, the U.S. District Court for the District of Colorado held in 2019 that the claimed liquid formulations containing cannabinoids for oral or topical administration were not directed to a natural phenomenon because they covered a liquid formulation for cannabinoids in non-naturally occurring concentrations.[31] The court noted that "it is logically possible that cannabinoids in nature might appear in a form that could ... be deemed a 'liquid,'" but the asserted claims did not cover the precise liquid form that could be present "in nature." [32]

And, in *ThermoLife International LLC v. Hi-Tech Pharmaceuticals Inc.*, claims directed to a "solid composition" comprising an isolated nitrate salt compound and at least one isolated amino acid were found to be patent-eligible by the U.S. District Court for the Northern District of Georgia in 2020.[33]

The defendants argued "that the claims merely combine two naturally occurring chemical compounds" that "can be made by the body and are present together in food." [34] The court, however, disagreed and found that the claimed compositions have "markedly different characteristics from their naturally occurring counterparts," and that the compositions exhibited properties of better circulation and distribution and improved water solubility.[35]

At the request of Congress, the U.S. Patent and Trademark Office recently solicited public comments from stakeholders regarding the state of patent-eligibility jurisprudence and its effect on investment and innovation.[36] The application of the Alice two-part test to pharmaceutical formulations of natural products was part of these discussions.

The Natural Products Association, for example, commented that "[d]ietary supplements differ from most chemical and pharmaceutical innovation because many claimed compositions are often derived or synthesized from natural ingredients" and emphasized the importance of protecting innovations relating to the use of natural ingredients.[37]

While it remains to be seen what reform may result from these comments, it is clear that greater clarity is needed as to the application of Section 101 to patents directed to formulations of natural products.

The recent decisions, however, provide important guidance both for drafting such patents and also litigating them.

The decisions reflect that there is value to drafting specific claims that set forth the particular components of the formulation in addition to the natural compound itself as well as the advantages of the formulation, such as certain stability or manufacturability benefits. There is also benefit to a specification that does not genericize or diminish the formulation but rather provides specifics and stresses the advantages of the formulation and improved properties it exhibits versus the natural compound in its natural setting.

The courts are looking for "markedly different characteristics" from the naturally occurring compounds even when no formulation of the natural compound exists and formulating the natural compound is both novel and nonobvious. Such claims, supported by a specification that emphasizes the benefits of the formulated natural compound, greatly assist in defending any Section 101 challenges in litigation in the current landscape and allow patent owners to emphasize the markedly different characteristics of the claims that they assert.

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[1] ChromaDex, Inc. et al., v. Elysium Health, Inc., No. CV 18-1434-CFC-JLH, 2021 WL 4286527 (D. Del. Sep. 21, 2021) ("ChromaDex").

[2] Elysium Health Inc. v. Trustees of Dartmouth College, No. IPR2017-01795, Paper No. 39 (P.T.A.B. Jan. 16, 2019), aff'd, 196 Fed. App'x 745 (Fed. Cir. 2020).

[3] Elysium Health Inc. v. Trustees of Dartmouth College, No. IPR2017-01796, Paper No. 9 (P.T.A.B. Jan. 18, 2018).

[4] <https://time.com/5159879/is-an-anti-aging-pill-on-the-horizon/>.

[5] <https://www.truniagen.com/>.

[6] https://www.elysiumhealth.com/products/basis/?gclid=EAlaIQobChMI5M7RuczI9AIVq_7jBx2mkwnDEAAYASAAEgJAzfD_BwE.

[7] <https://www.medrxiv.org/content/10.1101/2020.10.02.20202614v1>.

[8] <https://www.aboutnad.com/scientific-analysis> (studies relating to NR curated by ChromaDex Corp.).

[9] ChromaDex, Inc. v. Elysium Health, Inc., Case No. 8:16-cv-02277–CJC (DFMx), Dkt. No. 570, Jury Form at 2-11 (C.D. Cal. Sept. 27, 2021). In September 2021, a jury found in favor of ChromaDex on certain claims, and in favor of Elysium on counterclaims.

[10] ChromaDex at *5.

[11] *Id.* at *4.

[12] *Id.* at *3.

[13] *Id.*

[14] *Id.*

[15] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590 (2013).

[16] ChromaDex at *1.

[17] *Id.* at *4.

[18] *Id.* at *5.

[19] *Id.* at *4.

[20] *Id.*

[21] *Id.* at *5 (citing *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 72 (2012) for the proposition that more than an instruction to "apply it" is necessary to "transform an unpatentable law of nature into a patent-eligible application of such a law.").

[22] *Nat. Alternatives Int'l, Inc. v. Creative Compounds, LLC.*, 918 F.3d 1338, 1348–49 (Fed. Cir. 2019).

[23] *Id.* at 1348-49.

[24] *Id.* at 1350.

[25] *Id.* at 1346, 1348 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)).

[26] *Id.* at 1348.

[27] *Id.*

[28] *Ex parte Christopher M. Lockwood*, No. APPEAL 2020-005549, 2021 WL 2026317, *3–4 (P.T.A.B. May 20, 2021).

[29] Id. at *4.

[30] Id.

[31] *United Cannabis Corp. v. Pure Hemp Collective Inc.*, No. 18-CV-1922-WJM-NYW, 2019 WL 1651846, at *6–7 (D. Colo. Apr. 17, 2019).

[32] Id. at *7.

[33] *ThermoLife Int'l, LLC v. Hi-Tech Pharms. Inc., et al.*, No. 1:15-CV-00892-ELR, 2020 WL 9601785, at *2 (N.D. Ga. May 29, 2020), report and recommendation adopted, No. 1:15-CV-00892-ELR, 2020 WL 9602008 (N.D. Ga. June 23, 2020).

[34] Id. at *5.

[35] Id.

[36] <https://www.federalregister.gov/documents/2021/07/09/2021-14628/patent-eligibility-jurisprudence-study>.

[37] <https://www.regulations.gov/comment/PTO-P-2021-0032-0135>.