

## Methods For Using Natural Compounds Can Be Patent-Eligible

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(May 6, 2019, 3:26 PM EDT)

On March 15, 2019, in *Natural Alternatives International Inc. v. Creative Compounds LLC*,<sup>[1]</sup> the U.S. Court of Appeals for the Federal Circuit reversed a judgment on the pleadings holding patent claims directed to methods of administering the naturally occurring compound beta-alanine to increase anaerobic working activity of muscles and other tissues invalid for claiming patent ineligible subject matter § 101<sup>[2]</sup> and remanded the case back to the district court.

In reversing the district court, the Federal Circuit found that Creative Compounds had failed to demonstrate that the asserted claims were patent-ineligible in view of Natural Alternatives' proposed claim constructions.

### Background

Natural Alternatives Intl. Inc. sued Creative Compounds LLC for infringement of U.S. patent claims directed to methods of administering the naturally occurring compound beta alanine to increase anaerobic working activity of muscles and other tissues.

Together with the amino acid histidine, beta-alanine can form dipeptides that are found in muscles, which in turn are involved in the regulation of intracellular pH during muscle contraction and development of fatigue.<sup>[3]</sup> “[V]ariations in dipeptide concentrations affect the anaerobic work capacity of individual athletes.”<sup>[4]</sup> The asserted claims relate to the use of beta-alanine in a dietary supplement to increase the anaerobic working capacity of muscle and other tissues.<sup>[5]</sup>

Natural Alternatives has asserted the patents at issue against multiple defendants in the Southern District of California, including against Creative Compounds.<sup>[6]</sup> Creative Compounds moved for judgment on the pleadings under § 101, and the district court granted the motion. Natural Alternatives appealed.

### Court Analysis

Applying the Alice two-part test<sup>[7]</sup>, the district court determined that all of the asserted claims were (1)



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directed to patent-ineligible subject matter under 35 U.S.C. § 101, and (2) lacked an inventive concept sufficient to render the claims patent-eligible.[8] The district court had accepted Natural Alternatives' proposed claim constructions in performing its eligibility analysis.[9]

The Federal Circuit, applying those same proposed claim constructions, determined that "the complaint's factual allegations, together with all reasonable inferences, plausibly establish the eligibility of the representative claims." [10]

The majority opinion addressed the asserted claims as three separate types: (1) methods of treatment using beta-alanine ("the method claims"), (2) dietary supplements ("the product claims"), and (3) uses of beta-alanine in manufacturing a human dietary supplement ("the manufacturing claims").

Regarding the method claims, the Federal Circuit found that the method claims "are treatment claims and as such they are patent eligible." [11] It reasoned that "administering certain quantities of beta-alanine to a human subject alters that subject's natural state ... result[ing] in specific physiological benefits for athletes engaged in certain intensive exercise." [12]

Moreover, the method claims "require that an infringer actually administer the dosage form claimed in the manner claimed, altering the athlete's physiology to provide the described benefits," making them treatment claims, and as such, patent-eligible.

In support of its determination that the method claims are patent-eligible treatment claims, the Federal Circuit cited the court's decision in *Vanda* [13], noting that *Vanda* stands for the proposition that "claims directed to particular methods of treatment are patent eligible." [14]

The Federal Circuit explained that in *Vanda* "the claims were directed to a patent eligible method of using iloperidone to treat schizophrenia, a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome." [15] It found that the same applies to administering beta alanine to increase anaerobic working capacity of muscles in the method claims.

The Federal Circuit also distinguished *Vanda* from the Supreme Court's decision in *Mayo*. [16] It noted that "unlike the claims held ineligible in *Mayo*, which required only the observation of a natural law, the *Vanda* claims required a doctor to affirmatively administer a drug to alter a patient's condition from their natural state." [17] It explained that the *Mayo* claim did not confine its reach to particular applications of the natural laws relied upon, and accordingly "the fact that the human body responds to the treatment through biochemical processes does not convert the claim into an ineligible one." [18]

Here, according to the Federal Circuit, unlike the claims in *Mayo*, "the Method Claims at issue are treatment claims," and like the claims in *Vanda*, "the Method Claims contain specific elements that clearly establish they are doing more than simply reciting a natural law" [19] — they "set forth a particular method of treatment." [20] Therefore, the Federal Circuit concluded that the method claims at issue are not directed to ineligible subject matter. [21]

Regarding step two of the *Alice/Mayo* framework, Creative Compounds argued "that placing a natural substance into a dietary supplement for administration to a human, in order to increase the function of tissues is a conventional, well-known activity" and not a transformative application of the natural relationship. [22] It pointed to the specifications of Natural Alternatives's patents as admitting so.

The Federal Circuit court rejected this argument, stating that at most, the language in the patents

“shows that the prior art contained food supplements containing natural products” and “does not establish that the dietary supplement in the claims, which provides a dose well in excess of the normal levels of beta-alanine, would have been well-understood, routine, and conventional.”[23]

Notwithstanding the Alice/Mayo step-two analysis, the Federal Circuit thus concluded that “under Natural Alternatives’ proposed claim constructions, the Method Claims are not directed to an exception to § 101 under the first step of the Alice test.”[24] Judge Jimmie Reyna, writing separately, dissented with the claim construction that the majority used to find the claims patent-eligible, but concurred in the majority’s decision to remand for further proceedings because he expected that this would permit the district court to revisit the § 101 question under a proper claim construction.[25]

He concluded his opinion by declaring that “[t]his case, and the general development of the law concerning § 101 analysis at the pleading stage, causes me to ask whether the time has come for this court to reconsider whether a Rule 12(c) motion based on § 101 should be decided before claim construction.”[26]

When analyzing the product claims, the Federal Circuit acknowledged that “beta-alanine is a natural product” but explained that “the Product Claims are not directed to beta-alanine,” they are instead directed to “specific treatment formulations that incorporate natural products.”[27] The court explained that the “combination of glycine and beta-alanine could have synergistic effects allowing for outcomes that the individual components could not have” which distinguished the product claims from the patent-ineligible claims in Funk Brothers,[28] where the “claimed combination ‘ha[d] the same effect it always had.’”[29] Therefore, the Federal Circuit thus found that the product claims are not directed to ineligible subject matter.[30]

Lastly, the Federal Circuit held that “the Manufacturing Claims are not directed to the natural law or product of nature, but instead are an application of the law and new use of that product.”[31] The Federal Circuit emphasized that the manufacturing claims are “even further removed from the natural law and product of nature at issue in the Method Claims and Product Claims, respectively.”

The court explained that the claimed dietary supplement had “certain characteristics,” was “not a product of nature” and therefore, a “claim to the manufacture of a non-natural supplement [is not] directed to [a] law of nature or [a] natural product.”[32]

## **Conclusion**

In Natural Alternatives, the Federal Circuit court held that all of the claims at issue, including claims directed at Natural Alternatives’ dietary supplement products, its manufacture and its methods of administration, were patent-eligible under § 101. In analyzing the evolution of how courts conduct a § 101 analysis, the court emphasized that method of “treatment claims” that utilize an existing product, “specify particular results to be obtained by practicing the method,” and “require specific steps to be taken” in order to bring about that particular result, i.e., “a [physiological] change in a subject, altering the subject’s natural state,” are patent-eligible.[33]

The Supreme Court has held that methods making use of natural products are not equivalent to claims to the natural products themselves.[34] The fact that beta-alanine “occurs in nature and is consumed as part of the human diet,” did not alter the court’s analysis.[35] The Federal Circuit court emphasized that “while beta-alanine may exist in nature ... the quantities being administered do not, and that the claimed consumption greatly exceeds natural levels.”[36]

Further, the court determined that the claimed human dietary supplement has “certain characteristics,” and is “not a product of nature,” therefore, the claim to the manufacture of a “non-natural supplement” is “not directed to the natural law or product of nature, but instead are an application of the law and a new use of that product.”<sup>[37]</sup> Notably, the court added, “[w]e 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.”<sup>[38]</sup>

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[1] Natural Alternatives Int’l, Inc. v. Creative Compounds, LLC, Appeal No. 2018-1295 (Fed. Cir. Mar. 15, 2019).

[2] Natural Alternatives Int’l, Inc. v. Creative Compounds, LLC, Nos. 16-cv-02146-H-AGS and 16-cv-02343-H-AGS (S.D. Cal. 2017).

[3] Natural, 2018-1295, at 3 (Fed. Cir. 2019).

[4] Id.

[5] Id.

[6] Id.

[7] Alice Corp. v. CLS Bank Int’l, 573 U.S. 208, 217 (2014).

[8] Natural, 2018-1295, at 3 (Fed. Cir. 2019).

[9] Id. at 5.

[10] Id.

[11] Id. at 8 (internal quotations omitted).

[12] Id. at 8 (internal quotations omitted).

[13] Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int’l Ltd., 887 F.3d 1117 (Fed. Cir. 2018).

[14] Natural, 2018-1295, at 8 (Fed. Cir. 2019).

[15] Id. at 8-9 (internal quotations omitted).

[16] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012).

[17] *Natural*, 2018-1295, at 9 (Fed. Cir. 2019).

[18] *Id.*

[19] *Id.* at 11.

[20] *Id.*

[21] *Id.* at 13.

[22] *Id.* (internal quotes omitted).

[23] *Id.* at 13-14.

[24] *Id.* at 14.

[25] *Id.* at 2 (Reyna, C.J. dissenting).

[26] *Id.* (Reyna, C.J. dissenting).

[27] *Id.* at 16.

[28] *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948).

[29] *Natural*, 2018-1295, at 17 (Fed. Cir. 2019) (citing *Funk Brothers*).

[30] *Id.* at 18.

[31] *Id.* at 20.

[32] *Id.*

[33] *Id.* at 10-11.

[34] *Natural*, 2018-1295, at 12 (Fed. Cir. 2019) (citing *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 595 (2013)).

[35] *Id.* at 11.

[36] *Id.* at 12.

[37] *Id.* at 20.

[38] *Id.*