

Federal Circuit Finds Dietary Supplements Patent Eligible – Legal Analysis

March 25, 2019

In a landmark ruling, the U.S. Court of Appeals for the Federal Circuit reversed a finding by a District Court that human dietary supplement could not be patented because they were products of nature or followed natural laws. The appellate court instead found that "[w]e live in the natural world, and all inventions are constrained by the laws of nature" but courts "must be careful not to overly abstract claims" in deciding whether supplement inventions are eligible to be patented. The ruling provides greater predictability to companies to protect their significant investments in research and development for innovative products and uses that benefit consumers.

Natural Alternatives International, Inc. sued Creative Compounds LLC for infringing six of its patents covering CarnoSyn® beta-alanine and its use as a human dietary supplement popular in sports nutrition products. The District Court dismissed the lawsuit on the pleadings for lack of patent eligibility under § 101 of the patent statute. The Court ruled that Natural Alternatives' product, method of treatment and method of manufacture patents were directed toward a product of nature (beta-alanine) and a law of nature (taking beta-alanine in sufficient amounts over time would improve athletic performance). Natural Alternatives appealed and the Federal Circuit reversed and remanded. The decision revives important patent rights in Natural Alternatives' existing patent portfolio.

Section 101 provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." A series of recent U.S. Supreme Court decisions said that under § 101, patent protection does not extend to the patent ineligible concepts of laws of nature, natural phenomena, and abstract ideas, which are "building blocks of human ingenuity."

In considering the appeal, the Federal Circuit looked to the language of Natural Alternatives' patent claims and the construction of those claims that it proposed to the District Court below. For example, the method of treatment patents claimed administering certain quantities of beta-alanine as a dietary supplement over time to a human subject alters that subject's natural state. Specifically, homeostasis is overcome and will result in specific physiological benefits for athletes engaged in certain intensive exercise. The Federal Circuit majority held that "[t]he claims not only embody this discovery, they require that an infringer actually administer the dosage form claimed in the manner claimed, altering the athlete's physiology to provide the described benefits. These are treatment claims and as such they are patent eligible." The Court also rules that "using a natural product in unnatural quantities to alter a patient's natural state, to treat a patient with specific dosages outlined in the patents" are eligible for patent protections.

The Federal Circuit also found that the District Court erred in finding Natural Alternatives' product claims were patent ineligible. Judge Moore wrote that 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. In the Product Claims, beta-alanine and glycine are incorporated into particular dosage forms." For example, claim 6 of U.S. Patent No. 7,504,376 is directed to a "dietary supplement or sports drink" that uses a combination of glycine and one of the specified forms of beta-alanine in an amount effective to increase athletic performance. In addition, Creative Compounds' counsel admitted at oral argument that the combination of glycine and beta-alanine could have synergistic effects allowing for outcomes that the individual components did not have. As such, the appellate court reversed the decision below on the product claims at issue.

Finally, the Federal Circuit reversed on Natural Alternatives' method of manufacture claims because they "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.... It is directed to the manufacture of a human dietary supplement with certain characteristics. The supplement is not a product of nature and the use of the supplement to achieve a given result is not directed to a law of nature. We do not see, therefore, how a claim to the manufacture of a nonnatural supplement would be directed to the law of nature or natural product."

The Federal Circuit sent the case back to the District Court for further proceedings on Natural Alternatives' claims against Creative Compounds.

Natural Alternative's was represented in the Federal Circuit by Porzio, Bromberg & Newman P.C. attorneys, [Kevin M. Bell](#), [Scott A.M. Chambers, Ph.D.](#), [Richard J. Oparil](#), [B. Dell Chism](#), and [Caroline C. Maxwell](#). A copy of the decision is available [here](#).