



Claim Construction – Alternatives Intl. v. Creative Compounds

■ This case will potentially impact the manner in which “natural law” is applied to claim construction

■ This will most likely make cause for support of findings of patent eligibility, however this case highlights importance of claim construction

Claim Construction Paves Path for Decision on Natural Alternatives Intl. v. Creative Compounds

The Federal Circuit issued its decision regarding Natural Alternatives Intl. v Creative Compounds, potentially impacting the patentability of inventions incorporating natural law. Specifically, the Court held that the particular manner in which a natural law is applied, to achieve an identified benefit, can be sufficient to show that the invention is not simply directed at the natural law, but instead reciting a new use for the associated principles. In arriving at this decision, the Court relied heavily on the claim construction by Natural Alternatives Intl. (“NAI”), who own the patents at issue, wherein through construction the Court found its support that such application of the natural law was unconventional and atypical, to the point it was identified as a new use for an existing product.

The case was centered about a number of patents owned by NAI that relate to dietary supplements containing beta-alanine, which can aid the human body engaged in physical exercise by “increasing the anaerobic working capacity of muscle and other tissue”. The District Court, in applying the two-part Alice test, held that all the claims asserted by the NAI patents in question were directed to patent ineligible subject matter, under 35 U.S.C. § 101, and further lacked an inventive concept to render said claims as patent eligible. Although the District Court also accepted NAI’s proposed claim constructions, it held that the claims in question were directed to a natural law, specifically directed to “ingesting certain levels of beta-alanine”, thereby resulting in changes in human tissue functioning.

In reversing the District Court’s decision regarding the method claims in question, the Federal Circuit focused on the deviation from a subject’s natural state that resulted from the specified level of beta-alanine being ingested, thereby enabling “specific physiological benefits for athletes engaged in intensive exercise”. The Court further held that “the 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". In arriving at its decision, the Federal Circuit contrasted between the patent eligible claims held in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.* ("Vanda"), and the patent ineligible claims held in *Mayo Collaborative Servs. v. Prometheus Labs.* ("Mayo"). For example, in *Vanda*, the Court noted that the relationship between a medical compound and an illness was not what was claimed, but instead a "specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome". By contrast, the patent ineligible claims held in *Mayo* "did not do significantly more than simply describe the natural relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a...drug will prove ineffective or cause harm".

While the Court acknowledged certain similarities between the method claims in the NAI patents and *Mayo*, the Court found that the method disclosed by the claims in the NAI patents fell within the contours 35 U.S.C. §100(b), §101, wherein "a new use of a known...composition of matter, or material" suffices the requirement for "a new and useful process". Firstly, the Court identified the particular result set forth by the NAI patents by using a specific compound of beta-alanine, such as "regulating hydronium ion concentration in a human tissue", and "increasing anerobic working capacity in a human subject". Then, relying on the proposed claim constructions, the Court found that a specific dosage was specified in the claims via the limitation of an "effective" amount being recited in the claim language. The Court relied on the specification to determine what entailed an "effective" amount, wherein a method was provided for calculating a specific dosage, such as "calculating dosage based on a subject's weight". The Court also noted the limitation "dietary supplement" in the claim language was construed as "an addition to the human diet, which is not a natural or conventional food". As such, the Court noted, as per NAI, that such dosage "elevates beta-alanine above natural

levels", thereby altering a patient's natural state. The Court further acknowledged that although the claims recited a specific application of the natural law, which was sufficient for satisfying step 1 of the Alice test, the claim construction of the "dietary supplement" limitation provided "factual impediments" at step 2 of the Alice test, which were deemed not to be resolved on a motion for judgment on the pleadings. Nevertheless, the Court held that the claims were deemed patent eligible via step 1 of the Alice test.

Regarding the product claims, the Court again reversed the District Court's holding by indicating that "a claim to a manufacture or composition of matter made from a natural product is not directed to the natural product where it has different characteristics and the potential for significant utility". The claim constructions provided support in the Court's holding, wherein the "effective" dosage of beta-alanine was found to be part of an article of manufacture, which in combination with other chemicals provide significant utility, e.g. increase athletic performance in a way that "naturally occurring beta-alanine cannot". Similarly, the Court found that patent claims directed to the manufacturing of the dietary supplement, having a specific amount of beta-alanine, was not directed to the law of nature or natural product since "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".

In issuing a concurring-in part and dissenting-in part opinion, Judge Reyna concurred with the majority decision only to the extent that the legal analysis was based on the claim construction that was adopted. However, Judge Reyna disagreed with the claim construction, believing that it "improperly imports limitations into the claims and is contradicted by the written description"

All in all, it is apparent that the specific application of a judicial exception will provide strong support for finding of patent eligibility. However, in the case at hand, the importance of claim construction is clearly exemplified, considering that the legal analysis applied by the Court occurs with deference to the agreed-upon construction of the claims.