

Federal Circuit Weighs in on Patent Subject-Matter Eligibility of Dietary Supplements

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The Federal Circuit weighed in on patent subject matter eligibility again last week, finding certain amino-acid containing dietary supplements, and related methods of use, to be patent eligible. In *Natural Alternatives Int'l v. Creative Compounds, LLC*, the Federal Circuit vacated the decision of the district court in the Southern District of California, which held that several sets of claims issued to Natural Alternatives International (“Natural”) were not directed to patentable subject matter under 35 USC § 101. The district court found the claims not patent eligible following a motion on the pleadings. Although the claims at issue included methods of treatment, composition, and process claims, this entry looks at the court’s decision with respect to methods. The decision could put some wind in the sails of developers of supplements and nutraceuticals.

The court’s review of Natural’s method claims hinged on a method claim that read

1. A method of regulating hydronium ion concentrations in a human tissue comprising: providing an amount of beta-alanine to blood or blood plasma effective to increase beta-alanylhistidine dipeptide synthesis in the human tissue; and exposing the tissue to the blood or blood plasma, whereby the concentration of beta-alanylhistidine is increased in the human tissue.

See claim 1 of U.S. Patent No. 5,965,596.

The claim above was at risk being seen as a mere application of a natural phenomenon because beta-alanine leads to beta-alanylhistidine dipeptide synthesis in normal processes in the body. The claim’s saving move was use of the term “effective.” The court based its decision on the finding that Natural’s claim was limited to amounts that were effective to bring about certain results in the body. Natural’s claim construction—which was accepted by the court due to the early stage of litigation—proposed that the “effective” amount was that which “elevates beta-alanine above natural levels.” The court clarified that this was enough to remove the claim from the realm of natural phenomena.

The court made hay of the decision in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int’l Ltd.*, which held that method claims were patent eligible where, in the current panel’s words, the claims “required a doctor to affirmatively administer a drug to alter a patient’s condition from their natural state.” (Indeed, the court cited an expert opinion proffered by Natural stating that one would have had to eat 109 Big Macs to take in the amount of beta-alanine provided by the supplement.) This requirement for affirmative steps distinguished the claims from those found invalid by the Supreme Court in *Mayo v. Prometheus*. There, claims that merely “indicated a need” to take certain medical treatment actions were found invalid.

However, the majority seemed to be most convinced by various statements of patentee Natural that their invention was only one of a supernatural effect, so to speak. For example, the patentee’s claim constructions suggested that a dietary supplement is not a “natural or conventional food.” Natural brought data that suggested large quantities of beta-alanine might provide enhanced athletic performance; and further that synergistic effects may be realized by the combination of beta-alanine and glycine. The court seemed impressed



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by *Natural's* results, citing several statements in the patents of enhanced athletic ability. These results arising from taking a higher-than natural amount of the amino acids seemed to be key to the decision.

In all, the *Natural* decision provides a beacon of hope for applicants for patents to naturally derived medicines. However, as is always the case in the patent world, speak softly and carry a big binder.

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