

NATURAL ALTERNATIVES INTERNATIONAL, INC. v. CREATIVE COMPOUNDS, LLC,
Appeal No. 2018-1295 (Fed. Cir. March 15, 2019). Before Moore, Reyna, and Wallach.
Appealed from S.D. Cal. (Judge Huff).

Background:

Natural Alternatives owns a number of patents that relate to dietary supplements containing beta-alanine. Natural Alternatives asserted its patents in multiple suits in district court and Creative Compounds moved for judgment on the pleadings. The district court granted Creative Compounds' motion finding all of the asserted claims directed to patent ineligible subject matter under §101. Natural Alternatives appealed.

Issue/Holding:

Did the district court err in granting the motion? Yes, reversed and remanded.

Discussion:

The case essentially turned on the claim construction of key features. The method claims recited an "effective" limitation, *e.g.*, providing an amount of beta-alanine to blood or blood plasma *effective to increase* beta-alanylhistidine dipeptide synthesis in the human tissue. The product claims recited a "supplement" limitation, *e.g.*, a human *dietary supplement*, comprising a beta-alanine in a unit dosage of between about 0.4 grams to 16 grams, wherein the supplement provides a unit dosage of beta-alanine.

The district court held that the method claims were directed to the natural law that "ingesting certain levels of beta-alanine, a natural substance, will increase the carnosine concentration in human tissue and, thereby, aid in regulating hydronium ion concentration in the tissue." Natural Alternatives proposed construing the "effective" limitations to mean to elevate beta-alanine above natural levels to cause an increase in the synthesis of beta-alanyl-histidine dipeptide in the tissue. The Federal Circuit agreed with this construction reasoning that administering certain quantities of beta-alanine to a human subject alters that subject's natural state, *i.e.*, homeostasis is overcome, and the subject's body will produce greater levels of creatine. It held that this is similar to the *Vanda Pharmaceuticals* claims directed to a patent-eligible method of using iloperidone to treat schizophrenia and different than *Mayo*, which required only the observation of a natural law. According to the Federal Circuit, both the *Vanda* claims and the instant claims specified a compound to be administered to achieve the claimed result, *e.g.*, through the administration of the specific compound beta-alanine, and through the use of one of the three specified forms of beta-alanine.

Natural Alternatives proposed construing the "dietary supplement" limitations to mean an addition to the human diet, which is not a natural or conventional food, which effectively increases athletic performance and is manufactured to be used over a period of time. The Federal Circuit found that although beta-alanine is a natural product, the product claims are not merely directed to beta-alanine. It held that the product claims are directed to specific treatment formulations that incorporate natural products, but have different characteristics and can be used in a manner that beta-alanine as it appears in nature cannot, *e.g.*, beta-alanine and glycine are incorporated together into particular dosage forms. In view of evidence of combined synergistic effect, the Federal Circuit distinguished *Funk Brothers* where the claimed combination had no more than the same effect as the individual species.