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Federal Circuit Vacates Natural Product Challenge Of Dietary Supplement Claims

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In *Natural Alternatives Internat'l v. Creative Compounds, LLC*, the Federal Circuit vacated the district court decision that held the asserted claims invalid under 35 USC § 101 at the pleadings stage. The claims at issue included method of treatment, product, and manufacturing claims. Here, I focus on the product claims. While the decision provides a welcome discussion of *Chakrabarty* and *Funk Brothers*, my enthusiasm is tempered by the narrow holding and Judge Reyna's dissent.

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The Patents At Issue

The patents at issue were Natural Alternatives' U.S. Patent Nos. 5,965,596, 7,825,084, 7,504,376, 8,993,610, 8,470,865, and RE45,947.

The broadest product claim at issue was claim 1 of the '084 patent:

1. 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 court also considered claim 6 of the '376 patent, which depends from claim 5 (directly) and claim 1 (indirectly):

1. A composition, comprising:
glycine; and
a) an amino acid selected from the group consisting of a beta-alanine, an ester of a beta-alanine, and an amide of a beta-alanine, or
b) a di-peptide selected from the group consisting of a beta-alanine di-peptide and a beta-alanylhistidine di-peptide.

5. The composition of claim 1, wherein the composition is a dietary supplement or a sports drink.

6. The composition of claim 5, wherein the dietary supplement or sports drink is a supplement for humans.

For the purpose of deciding the appeal, the court accepted Natural Alternatives' proposed construction of "dietary supplement" and "human dietary supplement" as meaning "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 *Chakrabarty/Funk Brothers* Analysis

The Federal Circuit opinion was authored by Judge Moore and joined by Judge Wallach. Judge Reyna concurred-in-part and dissented-in-part.

Judge Moore began the analysis of the product claims with a reference to *Chakrabarty*:

Although beta-alanine is a natural product, the Product Claims are not directed to beta-alanine. 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." *See Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980). … [T]he 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.

With regard to claim 1 of the '084 patent, the opinion notes that the dietary supplement "uses the product beta-alanine at a dosage of "between about 0.4 grams to 16 grams" to "effectively increase[] athletic performance." With regard to claim 6 of the '376 patent, the opinion notes that product "uses a combination of glycine and one of the specified forms of beta-alanine" sufficient to "effectively increase[] athletic performance." Thus:

> In each case, the natural products have been isolated and then incorporated into a dosage form with particular characteristics.

Addressing *Funk Brothers*, the opinion explains:

[E]ven though claim 6 contains a combination … of … natural products, that is not necessarily sufficient to establish that the claimed combination is "directed to" ineligible subject matter. The Court's decision in *Funk Brothers* does not stand for the proposition that any combination of ineligible subject matter is itself ineligible.

Turning to the (limited) record, the majority finds "sufficient factual allegations" that "when combined the beta-alanine and glycine have effects that are greater than the sum of the parts."

Thus, the majority concludes that "these claims would still survive a motion for judgment on the pleadings at the first step of the *Alice* test." That is, the majority found that the product claims were not "directed to" a natural product.

The opinion goes on to state that the claims also likely would be found eligible at step two of the *Alice* test, because "the specification does not contain language supporting the idea that [the dietary supplement] limitation was well-understood, routine, and conventional."

Judge Reyna's Concerns

Judge Reyna dissented based on his view that "the majority's § 101 analysis relies on an erroneous claim construction." He concurred in "the result reached by the majority to remand for further proceedings" and invited "the district court to revisit the § 101 question under a proper claim construction."

Why Does It Have To Be This Complicated?

While I tend to agree with the result reached by the majority, I share Judge Reyna's concerns that it may rest "on a claim construction that improperly imports limitations into the claims."

Why couldn't the court invoke *Chakrabarty* and find the product claims to satisfy § 101 because they are "directed to" a man-made product, not a "natural product"?

Why did the court have to rely on the intended effect of the product and/or the possibility of synergy between the ingredients?