

Split Federal Circuit Panel Holds That Method of Medical Treatment Claims are Patent Eligible

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In *Natural Alternatives Int'l., Inc. v. Creative Compounds, LLC*, Appeal No. 2018-1295 (Fed. Cir., March 15, 2019) a divided panel of the Fed. Cir. held that claims to methods of increasing the anaerobic working capacity in a human subject by administering an amount of a dietary supplement comprising beta-alanine, its ester or amide, effective to increase beta-alanyl histidine dipeptide synthesis in the subject's tissue via the blood (Moore, Reyna and Wallach, Moore writing, Reyna concurring in part, dissenting in part.) A two-component composition claim comprising glycine and beta-alanine and these derivatives, and either beta-alanine dipeptide or beta-alanyl histidine dipeptide, that is a dietary supplement, was also found to be patent eligible. The panel found that the broadest composition claim reciting only beta-alanine was also patent-eligible:



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1. A human dietary supplement, comprising a beta-alanine in a unit dosage of between about 0.4-16 grams, wherein the supplement provides a unit dosage form of beta-alanine.

Claims to the use of beta-alanine in manufacturing a human dietary supplement for oral consumption by supplying the beta-alanine as a single ingredient or in combination with at least one other ingredient, in a manufacturing step of the human dietary supplement, whereby oral consumption of the dietary supplement in doses over a period of time increases beta-alanyl histidine levels in muscle tissue sufficient to delay the onset of fatigue in the human. See, U.S. Pat. Nos. 5,965,596; 8,933,610; 8,470,865 and RE45,947.

The panel accepted the definition of "dietary supplement" proposed by Natural Alternatives as "an additional to the human diet which is not a natural or conventional food, which effectively increases athletic performance when administered to a human over a period of time." Natural Alternative's proposed construction of "effective" was also accepted as "elevates beta alanine above natural levels to cause an increase in the synthesis of beta-alanyl-histidine dipeptide in the tissue." This is making those terms do a lot of heavy lifting, but the patents had been invalidated at the pleadings stage.

While the district court held that the method claims were natural laws, essentially reasoning that the claims were directed to correlations such as "ingesting certain levels of beta-alanine, a natural substance, will increase the carnosine concentrations in human tissue...." the panel did not agree. Rather the panel held:

"Administering certain quantities of beta-alanine to a human subject alters that subject's natural state. Specifically, homeostasis is overcome, and the subject's body will produce greater levels of creatinine.... This, in turn, results in specific physiological benefits for athletes engaged in certain intensive exercise.... The claims not only embody this discovery, they require that an infringer actually administer the dosage form as claimed, altering the athlete's physiology to provide the described benefits. These are treatment claims and as such they are patent eligible."

Of course, *Vanda* was cited and discussed with approval. The panel noted that the claims were not directed to the underlying natural relationships but "to a patent eligible method of using iloperidone to treat schizophrenia, 'a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome.'"

Mayo was distinguished on the basis that the *Mayo* claims required only the "observation of a natural law" where

nothing in the claims:

“required any application of [the discovery of the optimum metabolite range], beyond the ‘steps that must be taken in order to apply the laws in question.’...The [Mayo] claims did not, however, require any actual action be taken based on the measured level of metabolite” and so they were not treatment claims. “The fact that the human body responds to the treatment through biochemical processes does not convert the [present] claim into an ineligible one.... Unlike the claims in Mayo, the Method Claims at issue are treatment claims.”

The panel also touched on the natural product issue: “Similarly the fact that the active ingredient in the supplement is a molecule that occurs in nature and is consumed as part of the human diet also does not alter our analysis.” The Myriad decision was also cited: “The Supreme Court has also rejected the idea that claims to methods making use of natural products are equivalent to claims to the natural products themselves.” Funk Bros. was distinguished as not involving claims directed to “methods of selecting and testing the non-inhibitive strains.”

Turning to the composition claims, the panel ruled:

“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.’ [Citing Chakrabarty with approval]...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.”

This reasoning is a little hard to follow but appears to be applying the “markedly different” test that the PTO found to have its roots in Chakrabarty. The panel leaned on its construction of “dietary supplement” and its ability to “effectively increase athletic performance [in the amounts recited in the claims or disclosed in the specification as ‘effective’]” as sufficient to distinguish the composition claims, 5 and 6 of the ‘376 patent and claim 1 of the ‘084 patent, from the natural products.

Noting that claim 6 contains a combination of natural products, e.g., beta-alanine dipeptide and glycine, the panel distinguished Funk Bros. on the basis that Creative Compound’s expert had conceded that a combination of “glycine and beta-alanine could have synergistic effects allowing for outcomes that the individual components could not have.” There was some other speculative evidence of synergism that the panel found were sufficient factual allegations to permit the composition claims to survive at the pleadings stage “at the first step of the Alice test.”

The recitation in the manufacturing claim that beta-alanine is used to make a “dietary supplement” was found not to be “directed to a natural law or product of nature, but instead are an application of the law and a new use of that product...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 non-natural supplement would be directed to the law of nature or natural product.”

Judge Reyna’s dissent is primarily based on his opinion that the expansive claim construction the panel employed, particularly with respect to the term “dietary supplement”, improperly imported claim limitations such as “effectively increases the function of a tissue when administered to a human over time” from the specification. He opined that remand was proper so that the district court could do a full claim construction.

This post is already too long, but I think that it is worthwhile to compare the patent-eligible composition claims to the composition claim at issue in *re Bhagat*. Apart from the fact that the composition claim was found to be anticipated, I think it is fair to ask if, or how, the composition claim – drawn to a “lipid-containing formulation...providing controlled delivery of the formulation containing certain fatty acids to a subject, could be rewritten in view of Natural Alternatives so that it would stay patent eligible at Mayo/Alice Step 1. In any case, it would make a great law school exam question.

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