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Federal Circuit Upholds Method Of Treatment Claims Under Vanda And Distinguishes Mayo

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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. I previously wrote about the court's treatment of the product claims. Now, I consider the method of treatment claims, and the distinction the majority draws between *Vanda* and *Mayo.* This analysis may be significant now that the Supreme Court has issued a CVSG in *Vanda,* asking for the Solicitor General's views on whether *certiorari* should be granted.

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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 court treated claim 1 of the '596 patent and claim 1 of the '865 patent as representative of the method of treatment claims.

Claim 1 of the '596 patent recites:

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.

Claim 1 of the '865 patent recites:

1. A method of increasing anaerobic working capacity in a human subject, the method comprising:
a) providing to the human subject an amount of an amino acid to blood or blood plasma effective to increase beta-alanylhistidine dipeptide synthesis in the tissue, wherein said amino acid is at least one of:
i) beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide;
ii) an ester of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; or
iii) an amide of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; and
b) exposing the tissue to the blood or blood plasma,
whereby the concentration of beta-alanylhistidine is increased in the tissue,
wherein the amino acid is provided through a dietary supplement.

Due to the procedural posture, the court accepted Natural Alternatives' proposed claim construction:

- "effective" means to "elevates beta-alanine above natural levels to cause an increase in the synthesis of beta-alanylhistidine dipeptide in the tissue."
- "dietary supplement" means "an addition to the human diet, which is not a natural or conventional food, which effectively increases athletic performance when administered to the human over a period of time."
- "increasing anaerobic working capacity" means "increasing the amount of work performed by a muscle under lactate producing conditions."

As summarized in the Federal Circuit opinion, the district court held the claims invalid as directed to natural laws:

It held claim 1 of the '865 patent is 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, increase the anaerobic working capacity in a human." J.A. 22. It held claim 1 of the '596 patent is 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." J.A. 21.

Vanda* Versus *Mayo

The Federal Circuit opinion was authored by Judge Moore and joined by Judge Wallach. Judge Reyna concurred-in-part and dissented-in-part, but his dissent seems to focus on the majority's treatment of the product claims.

Although the district court had found the claims ineligible as being directed to natural laws, the majority disagreed:

> These are treatment claims and as such they are patent eligible.

The majority explained further, "Administering certain quantities of beta-alanine to a human subject alters that subject's natural state."

The majority opinion discussed the difference between method of treatment claims that are eligible under *Vanda* and method claims that are ineligible under *Mayo:*

As we explained in *Vanda* … claims that are directed to particular methods of treatment are patent eligible.
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Unlike the claims held ineligible in *Mayo*, which required only the observation of a natural law, the *Vanda* claims required a doctor to affirmatively administer a drug to alter a patient's condition from their natural state. …. In *Mayo*, the discovery underlying the claims was that when blood levels were above a certain level harmful effects were more likely and when they were below another level the drug's beneficial effects were lost. Nothing in the claim required any application of that discovery ….

The majority also cited *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, for the proposition that:

[T]he "natural ability of the subject matter to undergo the process does not make the claim 'directed to' that natural ability.

The Federal Circuit also discussed differences between the claims at issue in *Vanda* versus *Mayo*:

Unlike the claims held ineligible in *Mayo*, which required only the observation of a natural law, the *Vanda* claims required a doctor to affirmatively administer a drug to alter a patient's condition from their natural state. …. In *Mayo*, the discovery underlying the claims was that when blood levels were above a certain level harmful effects were more likely and when they were below another level the drug's beneficial effects were lost. …. The claims did not, however, require any actual action be taken based on the measured level of metabolite. …. The claim, therefore, was not a treatment claim," because "it was 'not limited to instances in which the doctor actually decreases (or increases) the dosage level.

The Federal Circuit emphasized that the Supreme Court itself had distinguished the claims at issue in *Mayo* from method of treatment claims:

This was expressly recognized in *Mayo*, which distinguished the Mayo claim from "a typical patent on a new drug or a new way of using an existing drug," because the *Mayo* claim did not "confine [its] reach to particular applications" of the natural laws relied upon.

The majority explained further:

While the Method Claims have similarities to the claims found ineligible in *Mayo*, as they utilize an underlying natural law, this is not sufficient to establish that they are directed to that law. In *Mayo*, the Court held the claims 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 thiopurine drug will prove ineffective or cause harm." …. The Method Claims similarly rely on the relationships between the administration of beta-alanine and beta-alanylhistidine dipeptide synthesis, but under Natural Alternatives' constructions, the Method Claims require specific steps be taken in order to bring about a change in a subject, altering the subject's natural state.

Referring to the "directed to" inquiry of step one of the *Alice/Mayo* analytical framework, the majority concluded:

The Method Claims at issue are treatment claims. They cover using a natural product in unnatural quantities to alter a patient's natural state, to treat a patient with specific dosages outlined in the patents. We hold, therefore,

that the Method Claims are not directed to ineligible subject matter.

The majority also left open the possibility that the claims could be found eligible at *Alice/Mayo* step two if providing "a dose well in excess of the normal levels of beta-alanine, would [not] have been well-understood, routine, and conventional."

Why Is The Easy Answer So Hard?

Despite the murky case law surrounding 35 USC § 101, I thought the eligibility of method of treatment claims still was an easy ***yes*** answer. While the majority's analysis justifies that result, it also highlights how hard it can be to apply the ***language*** of Supreme Court decisions to get to that answer. For example, the majority said of the claims held ineligible in *Mayo*:

Nothing in the claim required any application of that discovery beyond the "steps that must be taken in order to apply the laws in question."

But couldn't the same be said of any method of treatment claim? Aren't the "steps that must be taken" in order to apply any "natural law" underlying most method of treatment claims just the step(s) of administering the active agent at issue? Don't most method of treatment claims fail to go "beyond" those steps?

Even more fundamentally, the majority here emphasized that "the *Vanda* claims required a doctor to affirmatively administer a drug," but step (a) of the claims invalidated in Mayo recited "(a) administering a drug providing 6-thioguanine to a subject." The Supreme Court decided the "administering" step "simply refer[red to the relevant audience" for the "natural law" underlying the claims. If the Supreme Court grants *certiorari* in *Vanda*, how will it view the claims at issue in that case?