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A Special “Treatment” for Patent Eligibility

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Addressing the patentability of method-of-treatment claims, the US Court of Appeals for the Federal Circuit issued two decision finding such claims patent eligible. [Natural Alternatives Int'l, Inc. v. Creative Compounds, LLC](#), Case No. 18-1295 (Fed. Cir. Mar. 15, 2019) (Moore, J) (Reyna, J, concurring in part and dissenting in part); [Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.](#), Case Nos. 17-1240, -1455, -1887 (Fed. Cir. Mar. 28, 2019) (Stoll, J).

Natural Alternatives v. Creative Compounds

Natural Alternatives owns a patent directed to certain dietary supplements that increase the anaerobic working capacity of muscle and other tissue. After being sued on the patent, Creative Compounds moved for judgment on the pleadings, arguing that the asserted method, product and manufacturing claims were all directed to patent-ineligible subject matter under 35 USC § 101. The district court granted Creative Compounds’ motion, finding that the patent claims were directed to the natural law that ingesting certain levels of the dietary supplement beta-alanine, a natural substance, will increase the anaerobic working capacity in a human. Natural Alternatives appealed.

The Federal Circuit reversed, finding that the complaint plausibly established patent eligibility. Starting with the method claims, the Court found that the claims “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.” According to the Court, “[a]dministering certain quantities of beta-alanine to a human subject alters that subject’s natural state. . . . The method claims not only embody this discovery, they require that an infringer actually administer the dosage form claimed in the manner claimed, altering the athlete’s physiology to provide the described benefits.” The Court acknowledged that while the method claims rely on natural relationships, under Natural Alternatives’ proposed 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.” The fact that beta-alanine exists in nature and is consumed as part of the human diet did not alter the Court’s analysis. The Court noted that Natural Alternatives had argued that the administered amount and the claimed consumption “exceeds natural levels.”

The Federal Circuit also found the product claims patent eligible, concluding that they “are directed to specific treatment formulations” and, although they incorporate natural products, they have “different characteristics and can be used in a manner that beta-alanine as it appears in nature cannot.” The Court also found the manufacturing claims patent eligible, noting that these claims are directed to manufacture of a human dietary supplement that “is not a product of nature,” and “a claim to the manufacture of a non-natural supplement” would not be directed to a law of nature or natural product.

Judge Reyna dissented, arguing that the majority relied on erroneous claim construction, but concurred in remanding the case for further proceedings to allow the district court to revisit patent eligibility under a proper claim construction.

Endo Pharmaceuticals v. Teva Pharmaceuticals

Endo owns a patent directed to a method of treating pain in patients with impaired kidney function using oxymorphone. After being sued, Teva filed a motion to dismiss, arguing that the patent claims were directed to patent-ineligible natural law, namely, the reaction of a renally impaired individual’s body to oxymorphone. After



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the district court granted the motion, Endo appealed.

The Federal Circuit reversed, finding that the claims were directed to a patent-eligible method of using oxymorphone to treat pain in a renally impaired patient. The Court found that the claims at issue “are directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome.” The Court explained that while the inventor “recognized the relationship between oxymorphone and patients with renal impairment,” he claimed “an application of that relationship—specifically a method of treatment including specific steps to adjust or lower the oxymorphone dose.” As a result, the Court found the claims patent eligible and remanded the case for further proceedings.

Practice Note: A treatment claim employing a specific method on specific patients or subjects using a specific compound at specific doses to achieve a specific outcome may pass the patent eligibility bar.

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