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Medical Treatments Are Still Patent Eligible in the U.S.

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The Supreme Court earlier this decade issued several decisions concerning patent eligibility under 35 U.S.C. § 101. These decisions have resulted in the invalidation of patents over concerns that the patents cover and preempt the use of “laws of nature” and “abstract ideas.” For the pharmaceutical industry, the decisions concerning natural laws have been particularly impactful. Recently, the Federal Circuit has issued decisions affirming the patent eligibility of certain types of method of treatment claims.

These decisions:

- support the patent eligibility of method of treatment claims
- consider method of treatment claims as utilizing natural laws, rather than being directed to natural laws.

The *Mayo* Decision

In 2012, the U.S. Supreme Court issued its *Mayo v. Prometheus* decision,[1] which considered whether claims to a medical method were patent eligible. The claim in question was to a method of optimizing the efficacy of a treatment for a gastrointestinal disorder comprising (a) administering a thioguanine drug and (b) determining the level of the drug, wherein a level of the drug that is below a certain concentration indicates a need to increase the amount of the drug.

The Supreme Court invalidated the claims as being directed to a law of nature.[2] The Court reasoned that the administering and determining steps were "well-understood, routine, conventional activity" and further stated that "[p]urely 'conventional or obvious' '[pre]-solution activity' is normally not sufficient to transform a law of nature into a patent-eligible application of such a law."[3] The Court did express concern, however, that too broad an interpretation of ineligibility "could eviscerate patent law."[4] Following *Mayo*, many patents, particularly in the diagnostics area, have been invalidated under Section 101.

Recent Federal Circuit Jurisprudence

In March, the Federal Circuit issued two decisions that continue a trend towards patent eligibility for method of treatment claims. In the *Natural Alternatives* case, the Federal Circuit reviewed patent claims directed to a providing of beta-alanine in an amount "effective to increase beta-alanylhistidine dipeptide synthesis."[5] The Federal Circuit reasoned that, while the claims "utilize an underlying natural law, this is not sufficient to establish that they are directed to that law."[6] In holding that the claims were patent eligible, that court stated:

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.[7]

Next, the Federal Circuit issued its decision in *Endo Pharmaceuticals v. Teva Pharmaceuticals*.[8] Endo's claims concerned a method of treating pain in a renally impaired patient by providing solid, oral-controlled release doses of oxymorphone and measuring the creatinine clearance rate to determine subsequent dosages. The district court determined that the claims addressed "'the connection between the severity of renal impairment and the bioavailability of oxymorphone,' or in other words, the reaction of the human body of a renally impaired individual to oxymorphone, which is unquestionably a natural law."[9]

The Federal Circuit reversed, and focused on the claim language and the specification. The Federal Circuit explained that the claims required the steps of (a) providing oxymorphone, (b) testing for a disease state, and (c) administering a lower dose of oxymorphone based on the creatine clearance rate. The Federal Circuit also looked to the specification, which the court characterized as disclosing "a method that treats renally impaired pain patients with less oxymorphone while still treating their pain."[10] The Federal Circuit distinguished Endo's claims from the claim in *Mayo*, which "as a whole was not directed to the application of a drug to treat a particular disease."[11]

Time will tell how the Supreme Court views these developments.

Endnotes

1 *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

2 The Supreme Court distinguished Prometheus's claims from those pertaining to "a new way of using an existing drug." *Mayo*, 566 U.S. at 87.

3 *Id.* at *79.* The consideration of what is conventional or obvious by the Supreme Court introduces prior art concepts into the Section 101 analysis, but without the analytical and procedural frameworks set forth in Sections 102 and 103 and the attendant case law.

4 *Id.* at *71.*

5 *Natural Alts. Int'l, Inc. v. Creative Compounds LLC*, 129 USPQ2d 1571, 1574 (Fed. Cir. 2019).

6 *Id.* at 1575.

7 *Id.* at 1576.

8 *Endo Pharm. Inc. v. Teva Pharm. USA, Inc.,* No. 2017-1240 (Fed. Cir. Mar. 28, 2019).

9 *Id.* at *3-4.

10 *Id.* at *5.

11 *Id.* at *6.