ARE Patent Law Alert:
Federal Circuit Finds Method of Treatment Claims Patent-Eligible, Not Directed to Natural Law

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On March 28, 2019, the Federal Circuit issued a unanimous 3-0 decision finding claims covering a method of treatment—namely, treating pain in renally impaired patients using the opioid oxymorphone—to be patent-eligible under 35 U.S.C. § 101. This decision in *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 17-1240 overturned the district court's holding that the claims were merely directed to the natural law that the effective dose of oxymorphone is lower in patients with renal impairment because the bioavailability of oxymorphone is increased in such patients.

The Federal Circuit rejected the district court's conclusion at step one of the two-part *Alice /Mayo* test, finding that the claims were not "directed to" a natural law, but to "a method of using oxymorphone . . . to treat pain in a renally impaired patient." The Federal Circuit came to this conclusion based on the specification and the claim language of the following "representative" claim:

1. A method of treating pain in a renally impaired patient, comprising the steps of:

a. providing a solid oral controlled release dosage form, comprising:

i. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt thereof as the sole active ingredient; and

ii. a controlled release matrix;

b. measuring a creatinine clearance rate of the patient and determining it to be

(a) less than about 30 ml/min,

(b) about 30 mL/min to about 50 mL/min,

(c) about 51 mL/min to about 80 mL/min, or

(d) above about 80 mL/min; and

c. orally administering to said patient, in dependence on which creatinine clearance rate is found, a lower dosage of the dosage form to provide pain relief;

wherein after said administration to said patient, the average AUC of oxymorphone over a 12-hour period is less than about 21 ng·hr/mL.

The Federal Circuit compared this claim to the claims it found patent-eligible last year in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd*, 887 F.3d 1117 (Fed. Cir. 2018). Our previous report on the *Vanda* decision can be found here. The Federal Circuit found the *Endo* claim here "legally indistinguishable from the representative claim in *Vanda*" since "[b]oth claims recite a method for treating a patient" using a dosage regimen based on patient testing. Accordingly, the Federal Circuit repeated its finding from *Vanda* and found that both claims "are directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome."

The Federal Circuit also distinguished the *Endo* claims from those found patent-ineligible in *Mayo* for the same reasons as those stated in *Vanda*. For example, the Court found that the *Endo* claims "recite the steps of carrying out a dosage regimen based on the results of kidney function testing" in contrast to the non-specific claims in *Mayo* whose testing steps "'indicat[ed]' a need to increase or decrease dosage, without prescribing a specific dosage regimen or other added steps to take as a result of that indication."

The Federal Circuit's *Vanda* decision is currently the subject of a pending cert petition, in which the "Question Presented" by the Petitioners is "whether patents that claim a method of medically treating a patient automatically satisfy Section 101 of the Patent Act, even if they apply a natural law using only routine and conventional steps." On March 15, 2019, the Petitioners brought the Federal Circuit's decision in *Natural Alternatives Int'l, Inc. v. Creative Compounds, LLC*, No. 18-1295 (Fed. Cir. Mar. 15, 2019) to the attention of the Supreme Court, since it similarly found method of treatment claims to be patent-eligible. (Both *Vanda* and *Natural Alternatives* were split 2-1 decisions of the Federal Circuit.) On March 18, 2019, the Solicitor General was invited to file briefs with regard to the *Vanda* petition.

We will continue to follow developments in the above cases and the law of patent-eligibility. In the meantime, should you have any questions, please feel free to contact one of our lawyers.

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