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Client Alert: Federal Circuit Reverses District Court and Finds Method of Treatment Claims Patent Eligible

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The United States Court of Appeals for the Federal Circuit recently revisited the question of patent eligible subject matter under 35 U.S.C. § 101. In *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2017-1240, the Federal Circuit reversed the district court's finding that the claims at issue were directed to a natural law and thus patent ineligible.

At issue was U.S. Patent No. 8,808,737 (the "737 Patent") which is directed to a method of using oxymorphone to treat pain in patients with impaired kidney function. The inventor of the "737 Patent" discovered that less oxymorphone may be used in patients with moderately or severely impaired kidney function than the amount typically administered to achieve a similar level of pain management. Specifically, the inventor found that there was a correlation between plasma AUC for oxymorphone and a patient's degree of renal impairment. Claim 1 of the "737 Patent" was deemed representative and reads in part: "A method of treating pain in a renally impaired patient, comprising the steps of: a. providing a solid oral controlled release dosage form . . . ; b. measuring a creatinine clearance rate of the patient . . . ; 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 "737 Patent" was challenged under § 101, and the Federal Circuit found that the claims were not directed to patent-ineligible subject matter; therefore, the court focused solely on step one of the *Mayo* two-step test. The court determined that "the claims are directed to a patent-eligible method of using oxymorphone or a pharmaceutically acceptable salt thereof to treat pain in a renally impaired patient," and noted that its conclusion was supported by the claim language and the specification. The claim requires specific steps: providing a pharmaceutical, testing the patient for a disease state, and administering the pharmaceutical. The court also noted that the specification "predominantly describes the invention as a method that

treats renally impaired pain patients with less oxymorphone while still treating their pain.”

The court went on to compare the claims of the '737 Patent with the patent-eligible claims at issue in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd*, 887 F.3d 1117 (Fed. Cir. 2018) and found the claims to be “legally indistinguishable.” Both sets of claims recite a method for treating a patient. The claims include the steps of carrying out a dosage regimen based on the results of some form of testing. In addition, both sets of claims require specific treatment steps.

In contrast, the court found that the claims at issue differ from those addressed in *Mayo*. The court noted that “[a]lthough the representative claim in *Mayo* recited administering a thiopurine drug to a patient, the claim as a whole was not directed to the application of a drug to treat a particular disease.” The court also concluded that preemption was not a valid concern because the claims of the '737 Patent require the specific treatment steps of carrying out a dosage regimen based on the results of kidney function testing, whereas the claims in *Mayo* did not prescribe a specific dosage regimen or steps to take as a result of the testing. The court also considered other precedent and emphasized that “the claims here are directed to a *treatment* method, not a detection method.” “[T]he result of the claims here is not simply an observation or detection. . . . the claims here are directed to a new and useful method of treating pain in patients with impaired renal function.”

PRACTICE NOTE:

The court’s holding highlights the distinction between claims directed to a method of treating and claims directed to methods which merely observe or detect some relationship or correlation. The claims at issue in *Endo* and *Vanda* were directed to methods of treating, whereas the claims at issue in *Mayo* were directed to a method of optimizing therapeutic efficacy. Thus, claims directed to a method of treating a patient that contain specific treatment steps are more likely to be found patent eligible than claims lacking those specific steps.