Improved Forecast for IP Harvest

Gathering Seeds from USPTO Memo on *Vanda*

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Subject Matter Eligibility Drought Lessens: Following the Federal Circuit's decision in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*, 887 F.3d 1117 (Fed. Cir. 2018), the U.S. Patent and Trademark Office issued a memo to the patent examination corps clarifying the patent eligibility of certain method of treatment claims. In particular, the USPTO's guidance clarifies that method of treatment claims which practically apply natural relationships are not "directed to" the natural relationship. The patent eligibility of treatment claims reciting a natural relationship and conventional steps has been an open question for a number of years. This USPTO memo provides some much needed clarity, enabling inventors to harvest further patent rights from discoveries based on natural relationships.

Starting with *Mayo Collaborative Servs. v. Prometheus Labs.*, 566 U.S. 66 (2012), United States courts have been restricting the patent eligibility of natural relationships. In *Mayo*, the Supreme Court provided a two part analysis for determining the patent eligibility of a claim under 35 U.S.C. § 101, which involves (1) assessing whether the claim is directed to a patent ineligible concept, such as a natural relationship, a natural product, or an abstract idea; and (2) if so, determining whether the claim recites "significantly more" than the patent ineligible concept. The Court found the claims at issue in *Mayo* patent ineligible for being directed to a natural relationship that was the consequence of how the subject drug is metabolized by the body, without significantly more. Conversely, the U.S. Court of Appeals for the Federal Circuit applied the same two part analysis proscribed by *Mayo*, and held that the claims at issue in *Vanda* were patent eligible because they were not "directed to" a natural correlation.

The claims at issue in *Vanda* were generally directed to a method of treating a patient having schizophrenia with iloperidone, a drug known to cause QTc prolongation (a disruption of the heart's normal rhythm) in patients having a particular genotype associated with poor drug metabolism. The primary steps in the claim included a step of "determining" whether the patient has the particular genotype by using an assay, followed by a step of "administering" a certain quantity of drug based on that determination in order to "treat a particular disease." Notably, the Federal Circuit distinguished the claims from the patent ineligible claims that were the subject of *Mayo* by recognizing that the claims that were the subject of *Vanda* were not directed to a natural correlation (i.e., the relationship between the patient's genotype and the risk of QTc prolongation), but rather were directed to an application of that natural correlation.

The USPTO's memo carves out several important points regarding the subject matter eligibility analysis in the Federal Circuit's *Vanda* decision. First, the Federal Circuit evaluated the claims as a whole when determining that the claim was not "directed to" the recited natural relationship. Second, the Federal Circuit distinguished the method of treatment claims of *Vanda* that ***applied*** a natural correlation from those method claims at issue in *Mayo* that were ***directed to*** a natural correlation. In particular, the Federal Circuit noted that while the "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," (*Vanda*, at 1134). Finally, the Federal Circuit

did not consider whether or not the treatment steps were routine or conventional when making its "directed to" determination, effectively concluding the patent eligibility analysis after having determined that the claim was not directed to a judicial exception in the initial step of the patent eligibility analysis.

The USPTO's guidance confirms the subject matter eligibility of method of treatment claims that practically apply a natural correlation and provides welcome clarity to those in the life sciences industry. The ability to obtain method of treatment claims, without the need to recite unconventional method steps, should increase the crop of patent rights in the life sciences industry. For more information regarding the USPTO's recent memo or for questions regarding the patentability of your inventions, please contact **Stan Chalvire**.