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MEMORANDUM

DATE: June 7, 2018

TO: Patent Examining Corps

FROM: Robert W. Bahr
Deputy Commissioner
for Patent Examination Policy

SUBJECT: Recent Subject Matter Eligibility Decision: *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*

On April 13, 2018, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") held the claims at issue in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*, 887 F.3d 1117 (Fed. Cir. 2018), **patent eligible** under 35 U.S.C. § 101 because they are not "directed to" a judicial exception. The claims recite 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 that can lead to serious health problems) in patients having a particular genotype associated with poor drug metabolism. In particular, a representative claim is below:

> A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:
>
> **determining** whether the patient is a CYP2D6 poor metabolizer by:
>
> **obtaining** or having obtained a biological sample from the patient;
>
> and
>
> **performing** or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and
>
> if the patient has a CYP2D6 poor metabolizer genotype, then internally **administering** iloperidone to the patient in an amount of 12 mg/day or less, and
>
> if the patient does not have a CYP2D6 poor metabolizer genotype, then internally **administering** iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day,
>
> wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal administration of 12 mg/day

> or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day.

The primary steps include "determining" with a genotyping assay, and then "administering" a certain quantity of drug based on that determination, in order to "treat a particular disease." *Id.* at 1134. The Federal Circuit distinguished *Mayo*,[1] stating: "The inventors recognized the relationships between iloperidone, CYP2D6 metabolism, and QTc prolongation, but that is not what they claimed. They claimed an **application** of that relationship. Unlike the claim at issue in *Mayo*, the claims here require a treating doctor to administer iloperidone." *Id.* at 1135 (emphasis added). As a result, the Federal Circuit held the claims in *Vanda* patent eligible under the first step of the *Alice/Mayo* framework (Step 2A in the USPTO's subject matter eligibility guidance), because the claims "are directed to a method of using iloperidone to treat schizophrenia," rather than being "directed to" a judicial exception.

The Federal Circuit's decision in *Vanda* illustrates several important points regarding the subject matter eligibility analysis. First, the Federal Circuit evaluated the claims as a whole, including the arguably conventional genotyping and treatment steps, when determining that the claim was not "directed to" the recited natural relationship between the patient's genotype and the risk of QTc prolongation. The importance of evaluating the claims as a whole in Step 2A was also emphasized by the Federal Circuit in previous cases, such as *Finjan Inc. v. Blue Coat Systems, Inc.*, 879 F.3d 1299 (Fed. Cir. 2018), and *Core Wireless Licensing S.A.R.L., v. LG Electronics, Inc.*, 880 F.3d 1356 (Fed. Cir. 2018). The two prior cases are discussed in a memorandum dated April 2, 2018 to examiners titled "Recent Subject Matter Eligibility Decisions."

Second, the Federal Circuit cited the Supreme Court "[t]o further underscore the distinction between method of treatment claims and those in *Mayo*." *Id.* at 1135. Method of treatment claims (which ***apply*** natural relationships as opposed to being "directed to" them) were identified by the Supreme Court as *not* being implicated by its decisions in *Mayo* and *Myriad* because they "confine their reach to particular applications." *Id.* 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." *Id.* at 1134. That is, while the *Mayo* claims recited a step of administering a drug to a patient, that step was performed in order to gather data about the natural relationships, and thus was ancillary to the overall diagnostic focus of the claims. The *Mayo* claims were not "method of treatment" claims that practically apply a natural relationship.

Lastly, the Federal Circuit did **not** consider whether or not the treatment steps were routine or conventional when making its "directed to" determination. Since the claim was determined eligible in the step 2A "directed to" part of the test, there was no need to conduct a step 2B analysis.

The USPTO's current subject matter eligibility guidance and training examples are consistent with the Federal Circuit's decision in *Vanda*, with the understanding that: (1) "method of treatment" claims that practically apply natural relationships should be considered **patent**

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

eligible under Step 2A of the USPTO's subject matter eligibility guidance; and (2) it is not necessary for "method of treatment" claims that practically apply natural relationships to include nonroutine or unconventional steps to be considered **patent eligible** under 35 U.S.C. § 101. For example, claims 5 and 6 of USPTO Example 29 (Diagnosing and Treating Julitis) should be considered patent eligible under Step 2A of the USPTO's subject matter eligibility guidance in light of the Federal Circuit decision in *Vanda*.

This memorandum addresses the limited question of how to evaluate the patent eligibility of "method of treatment claims" in light of the Federal Circuit decision in *Vanda*. The USPTO is determined to continue its mission to provide clear and predictable patent rights in accordance with this rapidly evolving area of the law, and to that end, may issue further guidance in the area of subject matter eligibility in the future.