THE FEDERAL CIRCUIT ADDRESSES PATENT ELIGIBILITY OF METHODS OF TREATMENT FOR FIRST TIME POST-MAYO

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INTRODUCTION

On April 13, 2018, the U.S. Court of Appeals for the Federal Circuit in *Vanda Pharmaceuticals* affirmed a district court decision regarding patent eligibility under 35 U.S.C. § 101 of a method of treatment. [1] In *Vanda*, the Federal Circuit applied the eligibility test set forth by the U.S. Supreme Court in *Mayo v. Prometheus*, [2] and the majority held that the claimed therapeutic method was patent eligible subject matter. [3] This holding of eligibility by the majority, along with the reasoning behind the holding, provides noteworthy insights relevant to patent prosecution and patent litigation, particularly in view of the previous absence of Federal Circuit decisions directly related to eligibility of therapeutic methods.

THE PATENT AT ISSUE

As noted by the Federal Circuit, the patent at issue [4] "relates to a method of treating schizophrenia patients with iloperidone wherein the dosage range is based on the patient's genotype." The patent eligibility of the claimed therapeutic method was challenged on the alleged basis that the claims were directed to a natural law or phenomenon and thus indistinguishable from the invalid claims in *Myriad* [5] and *Mayo*. [6] The Federal Circuit characterized the first independent claim as a representative claim, and this claim recites the following:

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 MAJORITY OPINION

The patent eligibility of the claimed therapeutic method was specifically challenged on the alleged basis that the claimed method is directed to a natural relationship between iloperidone, CYP2D6 metabolism, and QT prolongation and "adds nothing inventive" to those natural laws and phenomena. However, the majority of the Federal Circuit disagreed, in particular asserting that the inventors indeed recognized these natural relationships but nevertheless claimed a patent eligible application of the relationships.

In making this determination, the Federal Circuit applied the two-step eligibility test set forth by the U.S. Supreme Court in *Mayo*: The first step requires determining whether the claims are "directed" to a patent-ineligible concept. The second step is undertaken only if the first step is not fulfilled, and requires determination of whether the claim includes an inventive concept, i.e., an element or combination of elements that ensures that the patent would be significantly more than a patent merely upon the ineligible concept itself.

The majority here in *Vanda* noted that the claims require a treating doctor to administer iloperidone in one of two doses, depending on the result of a genotyping assay. The specificity of the claim language was also emphasized by the majority: "the claims here are directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome." Furthermore, the specification highlights the significance of the specific dosages by disclosing that the recited doses are safer for patients. Therefore, according to the majority, the claims are directed to a new way of using an existing drug and not merely the underlying natural relationship. As a result, the majority held that the claims were not directed to a patent ineligible concept and thus satisfied step one of the two-step eligibility test from *Mayo* such that the step two analysis was not needed.

Notably, the majority clarified its understanding of *Mayo* and the claims held invalid in that case. For example, the majority stated that the claims in *Mayo* were not directed to a novel method of treating a disease but instead were directed to a diagnostic method based on the natural relationships, *e.g.*, the claim as a whole was not directed to the application of a drug to treat a particular disease.

The majority also relied upon the recent decision *CellzDirect* [7] as support for the eligibility of the claimed therapeutic method. In this regard, the majority noted that the holding in that case was that a "method of producing a desired preparation of multi-cryopreserved hepatocytes" was eligible because its end result was not merely an observation or detection, and the natural ability of the material to undergo the process did not make the claim directed to a natural law.

Finally, the majority characterized its holding that the claimed therapeutic methods were patent eligible as consistent with *Myriad*. [8] For example, in *Myriad*, the U.S. Supreme Court found that a naturally occurring DNA segment is a product of nature and, even if isolated, not patent eligible; but the U.S. Supreme Court also explicitly stated that method claims and new applications of knowledge about particular genes were "not implicated by [its] decision."

THE DISSENT

The dissent in *Vanda* asserted that the claims were directed to a law of nature and thus ineligible. In particular, the dissent agreed with the majority that the claims at issue do not solely state a law of nature, but nevertheless the dissent asserted that the claims simply direct the relevant audience to apply the law of nature. Further in this regard, the dissent characterized the claims as mere instructions directing the relevant audience to apply the natural law in a routine and conventional manner, which *Mayo* classifies as patent ineligible.

CONSEQUENCES FOR PATENT PRACTICE

The presence of the dissent in the *Vanda* opinion suggests that the patent eligibility of therapeutic methods could continue to be refined as these inventions are considered in subsequent decisions in the Federal Circuit and perhaps even the U.S. Supreme Court. Indeed, it is unlikely that therapeutic methods will be classified as *per se* patent eligible, especially when an aspect of the claim is diagnosis of the patient. However, the holding of the majority in *Vanda* indicates that claims reciting treatment "for specific patients using a specific compound at specific doses to achieve a specific outcome" have a strong position regarding patent eligibility.

Furthermore, the statements of the majority in *Vanda* distinguishing the claims at issue (and also those of *CellzDirect*) from those found ineligible in *Mayo* are insightful. In this regard, the majority in Vanda emphasized that the "end result" of the claims in Mayo was simply observation or detection, even though the claimed method there began with an "administering" step. To the contrary, the methods of *Vanda* and *CellzDirect* end with a tangible step that could not be conducted merely mentally. Accordingly, in addition to the specificity of an "administering" step, the role of the "administering" step may be critical for eligibility, *i.e*., whether it is the basis for mere observation or detection or instead a tangible application of the alleged natural law.

Moreover, the holding of the majority in *Vanda* suggests that disclosures in the specification regarding the benefits of the actual treatment, *e.g*., the administering step and its claim limitations, should be considered when determining whether the claim is directed to a patent ineligible natural law or instead an eligible application of the natural law.

CONCLUSION

The Federal Circuit's holding in *Vanda* regarding patent eligibility of claims directed to a method of treatment makes several points that should be considered by practitioners analyzing the patentability or validity of such an invention. These points may be refined further as other cases tackle the issue, but the Federal Circuit's application of the *Mayo* eligibility test to a therapeutic method in *Vanda* provides some clarity that was lacking in view of an absence of decisions directly addressing these types of claims.

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[1] *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited*, Nos. 2016-2707, 2016-2708 (Fed. Cir. Apr. 13, 2018).

[2] *Mayo v. Prometheus,* 132 S. Ct. 1289, 1294(2012).

[3] *Vanda Pharm. Inc. v. Roxane Labs., Inc*., 203 F. Supp. 3d 412 (D. Del. 2016).

[4] U.S. Patent No. 8,586,610 entitled "Methods for the administration of iloperidone."

[5] *Association for Molecular Pathology v. Myriad Genetics, Inc*., 133 S. Ct. 2107 (2013).

[6] Endnote 2

[7] *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016).

[8] *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119-2120 (2013).

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