ARE Patent Law Alert:
USPTO GUIDANCE ON SUBJECT MATTER ELIGIBILITY OF METHOD OF TREATMENT CLAIMS

Author(s): Brian Amos, Ph.D., Charles R. Macedo, Alan D. Miller, Ph.D.

On April 13, 2018, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") affirmed the district court's ruling that the claims at issue in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*, 887 F.3d 1117 (Fed. Cir. 2018), were patent eligible under 35 U.S.C. § 101. In a 2-1 split decision, the Court held that claims directed to a specific method of treatment based on a previously-performed, specified diagnosis are patentable.

The patent-in-suit in *Vanda* was U.S. Patent No. 8,586,610:

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 Federal Circuit found that the *Vanda* claim is patent-eligible subject matter (i.e., step one of a patentability analysis under 35 U.S.C. §101) and that it was therefore not necessary to proceed with further analysis to determine if the claimed subject matter includes additional elements to transform the nature of the claim from being directed to a patent-ineligible law of nature into a patent-eligible method claim. *See id.*

The *Vanda* claims were determined to be patent eligible because they were directed to a method for treating schizophrenia, and were not directed to a judicial exception. The claims were not "directed to" the natural relationship between iloperidone and an identified side effect. Instead, the claims recited more than the natural relationship by claiming an *application* of that relationship, and reciting a dosage regimen based on that relationship. *Id*. at 1135-36. The Court stated, "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. They are different from *Mayo*." *Id* . at 1136. For more information on this decision, please see our alert, Alan D. Miller, Ph.D. et al., ARE Patent Law Alert: "Diagnose And Treat" Claims Held Patentable By Federal Circuit - A Path Forward For Patentability (April 20, 2018).

Guidance - Memorandum from Robert W. Bahr, Deputy Comm'r for Patent Examination, to Patent Examining Corps (June 7, 2018)

On June 7, 2018, the U.S. Patent and Trademark Office ("PTO") issued a memorandum addressing the question of how to evaluate the patent eligibility of "method of treatment claims" in light of the Federal Circuit's decision in *Vanda*. The memorandum emphasizes that method of treatment claims can be found to satisfy 35 U.S.C. § 101 at the first step of an *Alice/Mayo* analysis, without requiring a showing of "nonroutine or unconventional steps."

The memorandum states that "method of treatment" claims that apply natural laws may be patent-eligible under the first step of the *Alice/Mayo* test. It also instructs patent examiners to skip the analysis under the second step of the *Alice/Mayo* test if a method of treatment claim is considered eligible under the first step. Thus, the guidance offers a simplified analysis for certain method of treatment claims.

The memorandum makes three specific points based on the *Vanda* decision:

1. Claims should be evaluated **as a whole, including arguably conventional steps,** when determining whether they are "directed to" a judicial exception. In *Vanda*, the Federal Circuit had evaluated the claims as a whole, including the 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.

2. The memorandum suggests that, despite the "administering" step, the claims invalidated in *Mayo* were **not** "method of treatment" claims that applied a natural relationship. Instead, 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. Thus, *Mayo* does not undermine the eligibility of "method of treatment" claims because the *Mayo* claims were not, themselves, "method of treatment" claims that practically apply a natural relationship.

3. The Memorandum instructs, when determining whether claims are directed to a judicial exception, **there is no need to consider whether the recited steps are "routine or conventional."** If the claims are not directed to a judicial exception, and thus determined to be patent-eligible, there is no need to undertake such an analysis. In other words, if the method of treatment claims are not directed to patent ineligible subject matter, the analysis ends.

Conclusion

The *Vanda* memorandum provides clarity as to the patentability of method of treatment claims. When a claim, as a whole, applies a law of nature, it should be considered patent eligible under step one of the *Alice/Mayo* test. Once the claim is considered patent eligible, there is no need to further analyze whether the claim recites additional elements that amount to significantly more than the law of nature or natural phenomenon. The memorandum provides guidance as to how claims can be drafted to methods of treatment that include a diagnostic step and clarifies how such claims will be analyzed by the PTO.

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

*Charles R. Macedo, M.S. is a Partner, Alan D. Miller, Ph.D. is a Senior Counsel, Brian Amos,

Ph.D. is an Associate, and Chandler Sturm is a Law Clerk at Amster Rothstein & Ebenstein LLP. Their practice specializes in intellectual property issues, including litigating patent, trademark and other intellectual property disputes. They may be reached at cmacedo@arelaw.com, amiller@arelaw.com, bamos@arelaw.com, and csturm@arelaw.com.