

Insights: Alerts

USPTO Guidance on Subject Matter Eligibility of Method of Treatment Claims

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On June 7, 2018, the USPTO issued a memorandum to patent examiners based on the recent Federal Circuit decision in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*, 887 F.3d 1117 (Fed. Cir. 2018). The memorandum provides subject matter eligibility guidance to patent examiners for analyzing method of treatment claims under 35 U.S.C. §101. Notably, 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. The memorandum also instructs patent examiners to skip the analysis under the second step of the *Alice/Mayo* test if a method of treatment claim is found eligible under the first step. Thus, the guidance offers a simplified analysis for certain method of treatment claims.

Federal Circuit Decision

In *Vanda*, the Federal Circuit affirmed the district court's decision that the asserted claims of U.S. Patent No. 8,586,610 (the '610 patent) were patent-eligible subject matter under the first step of the two-part *Alice/Mayo* test. The claims of the '610 patent are directed to a method of treating schizophrenia using iloperidone. In particular, claim 1 focused on the relationship between the dosage of iloperidone based on markers of CYP2D6 metabolism to manage the risk of a disrupted heart rhythm (QTc prolongation). It is important to note that the first part of claim 1 focused on a diagnostic method for determining if a patient is a poor metabolizer of CYP2D6 and the second part of claim 1 focused on administering a specific dosage of iloperidone to a patient.

The Federal Circuit analyzed the claims under the two-part *Alice/Mayo* framework. Interestingly, the Federal Circuit primarily focused its analysis on the treatment aspect of the claims under the first step of the two-part test. The first step of the two-part test requires a determination of "whether the claims at issue are directed to one of the patent-ineligible concepts of laws of nature, natural phenomena and abstract ideas." The Federal Circuit noted that, unlike the claims in *Mayo*, the '610 Patent claims were directed to a novel treatment method. The *Mayo* claims, in contrast, were directed to a diagnostic method based on the "relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of [the] drug [would] prove ineffective or cause harm." Under the first step, the Federal Circuit in *Vanda* determined that the claims, as a whole, were directed to a patent-eligible method of treatment rather than a diagnostic method.

Memorandum

The memorandum characterizes the judicial exception (i.e., natural phenomenon) in *Vanda* as the relationship between iloperidone, CYP2D6 metabolism, and QTc prolongation and reasons that the relationship itself was not claimed. The memorandum notes that claims directed to the application of the relationship were distinguishable from the diagnostic claims in *Mayo*.

The *Vanda* memorandum emphasizes several important considerations for analyzing subject matter eligibility of method of treatment claims.

- A claim should be analyzed, as a whole, to determine whether it is directed to a method of treatment or a diagnostic method.
- Method of treatment claims that practically apply natural relationships are not directed to one of the patent-ineligible concepts of laws of nature, natural phenomena and abstract ideas.
- If the method of treatment claims are not directed to patent ineligible subject matter, the analysis ends.

Takeaways

The *Vanda* memorandum provides clarity as to the patentability of method of treatment claims that include a diagnostic component. When a claim, as a whole, practically applies a law of nature, it should be considered patent eligible under step one of the *Alice/Mayo* test. This test negates the need to further analyze whether the claim recites additional elements that amount to significantly more than the law of nature or natural phenomenon. Therefore, examiners can avoid the more subjective analysis of the second step of the *Alice/Mayo* test. The memorandum provides guidance as to how claims can be drafted to methods of treatment that include a diagnostic step and improves the predictability of how such claims will be analyzed by the US Patent and Trademark Office.

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