ARE Patent Law Alert: â€œDiagnose and Treatâ€• Claims Held Patentable By Federal Circuit - A Path Forward For Patentability

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On April 13, 2018, a three-judge panel of the United States Court of Appeals for the Federal Circuit (CAFC), held in a 2-1 split decision in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*, No. 2016-2707 & 2016-2708 that claims directed to a specified method of treatment based on a previously-performed, specified diagnosis are patentable.

By way of background, since the 2012 U.S. Supreme Court decision in *Mayo* (*Mayo Collaborative Services v. Prometheus Laboratories, Inc.* 132 S. Ct. 1289 (2012)), the ability to obtain patentprotection in the United States for diagnostic methods has been greatly curtailed. Historically, judge-made law has long prohibited patents directed to a law of nature, a natural phenomenon, or an abstract idea. However, in *Mayo*, the Supreme Court indicated that something more is required to transform a newly discovered practical application of a law of nature into a valid method claim, without providing much guidance as to what that something more has to be. In May 2016, the U.S. Patent Office issued “Subject Matter Eligibility Examples: Life Sciences” taking into account the Mayo decision and other relevant judicial decisions (https://www.uspto.gov/sites/default/files/documents/ieg-may-2016-ex.pdf). The examples included hypothetical methods that could be considered as patent-eligible, in particular claims 5 and 6 of Example 29 directed to diagnosing and treating a hypothetical disease (“julitis”) in a subject. We have previously discussed enforceability issues of two-actor

diagnose and treat claims (https://www.law360.com/ip/articles/996376/exploring-viability-of-diagnose-and-treat-method-claims).

The patent-in-suit in Vanda was U.S. Patent No. 8,586,610 ("the '610 patent"). Claim 1 is directed to:

1. 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. QTc prolongation refers to prolongation of the interval between the Q and T components of the patient's electrocardiogram, and QTc indicates that the QT value has been corrected for the patient's heart rate.

The CAFC 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. The CAFC distinguished the claims in the '610 patent from those in *Mayo*. The CAFC indicated that unlike the present case, in *Mayo* "the claim as a whole was not directed to the application of a drug to treat a particular disease." In contrast, "the '610 patent claims are directed to a method of using iloperidone to treat schizophrenia." "[T]he '610 patent claims are "a new way of using an existing drug" that is safer for patients because it reduces the risk of QTc prolongation." Furthermore, to the extent that preemption is a concern, "unlike the claim in *Mayo*, ...the '610 patent claims do not "tie up the doctor's subsequent treatment decision." In contrast to the treatment steps in the '610 patent claims, "the claim in *Mayo* stated that the metabolite level in blood simply "indicates" a need to

increase or decrease dosage, without prescribing a specific dosage regimen or other added steps to take as a result of that indication." In terms of patent eligibility, the CAFC concluded:

At bottom, 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*. They recite more than the natural relationship between CYP2D6 metabolizer genotype and the risk of QTc prolongation. Instead, they recite a method of treating patients based on this relationship that makes iloperidone safer by lowering the risk of QTc prolongation. Accordingly, the claims are patent eligible.

The *Vanda* decision confirms the validity of the strategy for U.S. patent protection of pursuing claims directed to a method of treatment based on the results of a specific diagnostic test recited in the claims. However, since corresponding patent-eligibility subject matter issues have not been raised in other important jurisdictions, e.g. Europe, it would be prudent to include in patent applications intended for international filings claims directed to diagnostic methods or uses comparable to those for which patent protection could have been obtained in the U.S. prior to the *Mayo* decision.

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