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PATENT SUBJECT MATTER ELIGIBILITY UNDER 35 U.S.C. §101 IN MEDICAL TECHNOLOGY

By: Daniel A. Geselowitz, Ph.D.

On April 13, 2018, the U.S. Court of Appeals for the Federal Circuit (hereinafter, "Federal Circuit) issued a ruling in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals* holding that the claims of U.S. Patent No. 8,586,610 (hereinafter, "the '610 patent") are **not** invalid on the grounds of patent subject matter eligibility under 35 U.S.C. §101.

Vanda Pharmaceuticals owns the '610 patent and had sued West-Ward Pharmaceuticals for infringement of the patent by a New Drug Application ("NDA") for a generic version of Vanda's drug Fanapt®. The district court held that West-Ward induced infringement and that the claims of the '610 patent are not invalid. West-Ward appealed to the Federal Circuit and argued that "that the asserted claims are ineligible under [35 U.S.C.] §101 because they are directed to a natural relationship between iloperidone, CYP2D6 metabolism, and QT prolongation, and add nothing inventive to those natural laws and phenomena." (Note: A "QT" prolongation or interval is the time between the Q and T of a heart rhythm. When corrected for a patient's heart rate, it is abbreviated "QTc.")

Claim 1 of the '610 patent is representative and reads as follows:

> 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.

As written, the claimed method, recited in claim 1, comprises a **determining** step involving **obtaining** a biological sample and **performing** an assay. Based on the results of this determining step, an **administering** step is conducted in order to treat a particular disease.

The Federal Circuit distinguished this patent claim from the claims in the U.S. Supreme Court case of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, stating that:

> [t]he 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** in the amount of either (1) 12 mg/day or less or (2) between 12 mg/day to 24 mg/day, depending on the result of a genotyping assay. [Emphasis added.]

In other words, the fact that the claims have an actual treating step means that the claims are **not** directed to the natural relationship between the genotype and QTc prolongation. Rather, in this *Vanda Pharmaceuticals* case, the claims are directed to a method for treating a patient. This is **an application of a natural relationship**, and is more than the natural relationship itself. The district court's finding that the claims of the '610 patent is not invalid is therefore **affirmed**.

The U.S. Patent and Trademark Office has cited this case in a Memorandum dated June 7, 2018, regarding patent subject matter eligibility. This case is therefore extremely relevant to any patent application directed to measuring biomarkers in a patient and the applicability of biomarkers to a disease. While patent claims **only** reciting a correlation or diagnosis based on biomarkers are likely to be found non-eligible patent subject matter under 35 U.S.C. §101, patent claims reciting concrete method steps (such as, administering a drug) based on the obtained biomarker values should be patent subject matter eligible.

Washington D.C. Office:
4th Floor
1420 K Street, N.W.
Washington, DC 20005
U.S.A.
Tel: 202.659.2930
Fax: 202.962.0011
correspondence@kqhpatentlaw.com
www.kqhpatentlaw.com

Tokyo Liaison Office:
21st Floor
Shin-Marunouchi Center Building
1-6-2 Marunouchi, Chiyoda-ku
Tokyo, JAPAN 100-0005
Tel: 03.3216.7188
Fax: 03.3216.7210

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