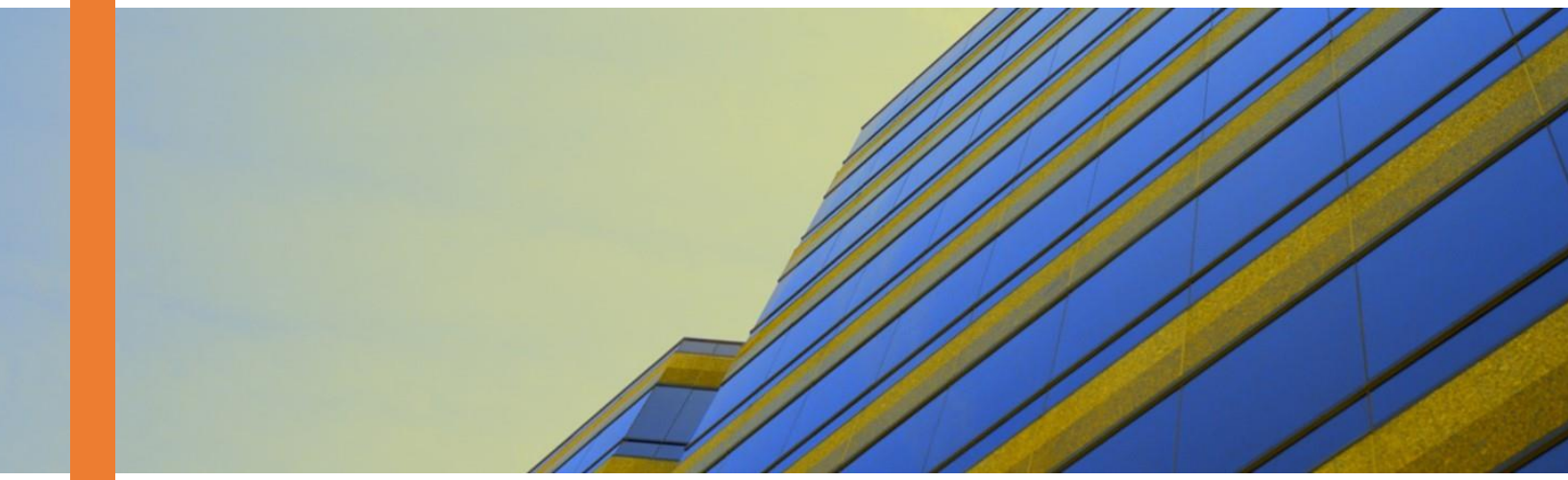
CASE SUMMARY OF *VANDA PHARMA V. WEST-WARD PHARMA*.



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Case summary of *Vanda Pharma v. West-Ward Pharma*

Background

This is an appeal to the Court of Appeals for the Federal Circuit from the U.S. District Court for the District of Delaware holding the asserted claims of U.S. Patent No. 8,586,610 (the '610 patent) to be infringed and not invalid. The Federal Circuit affirmed.

West-Ward filed an Abbreviated New Drug Application (ANDA) that substantially copied Vanda's New Drug Application, which Vanda was able to obtain approval from the FDA for treatment of patients with schizophrenia. After the '610 patent issued, Vanda filed an infringement action against West-Ward in the U.S. District Court for the District of Delaware. After a bench trial, the district court held that the asserted claims were not invalid under §101, §103, or §112 for lack of written description.

The primary dispute is whether the claims are patent eligible in view of *Mayo v. Prometheus*, or are they instead directed to a law of nature.

Patent at Issue

The '610 patent relates to a schizophrenia treatment using iloperidone. The claims require a dosage according to a patient's metabolization rate of iloperidone ("CYP2D6 activity").

Comparison of Vanda claims to Mayo claims

Vanda	Mayo
A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:	A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
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;	(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
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,	(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
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 the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

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.	wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells **indicates** a need to decrease the amount of said drug subsequently administered to said subject.

Analysis

The Federal Circuit analyzed the findings of the lower court and noted that "[t]he [district] court did conclude that 'the asserted claims depend upon laws of nature,' specifically, 'the relationship between iloperidone, CYP2D6 metabolism, and QTc prolongation." *Id* at 7. But the Federal Circuit continued by explaining that the '610 patent "addresses natural relationships to which the claims add conducting CYP2D6 genotyping tests to determine the appropriate dose of iloperidone to reduce QTc-related risks." *Id.*

The Federal Circuit held that the claims at issue were not directed to one of the patent-ineligible concepts. Since the claims were directed to patent-eligible subject matter, no step two inquiry *Alice* inquiry is needed. The Federal Circuit explained, that "at step one, 'it is not enough to merely identify a patent-ineligible concept underlying the claim; we must determine whether the patent-ineligible concept is what the claim is 'directed to.'" *Id.* at 28 (quoting *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016).

In distinguishing *Mayo*, the Federal Circuit explained that the "claims in *Mayo* were not directed to a novel method of treating a disease. Instead, the claims 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 thiopurine drug will prove ineffective or cause harm.' *Id.* This 'relation is a consequence of the ways in which the thiopurine compounds are metabolized by the body- entirely natural processes. And so a patent that simply describes the relations sets forth a natural law." *Id.* at 29 (quoting *Mayo v. Prometheus*).

The Federal Circuit distinguished the claims in *Mayo* by explaining that "the claim as a whole was not directed to the application of a drug to treat a particular disease." *Id.* As noted by the Supreme Court in *Mayo*, "the administering step was akin to a limitation that tells engineers to apply a known natural relationship or to apply an abstract idea with computers." *Id.* "To underscore the distinction between method of treatment claims and those in *Mayo*, the Supreme Court noted that '[u]nlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws.'" *Id.* (quoting *Mayo v. Prometheus*).

The Federal Circuit noted the following three distinctions in the claims of the '610 patent:

1. The claims require a doctor to administer a drug in a certain amount.

2. The claims do not tie up the doctor's subsequent treatment plan. (In *Mayo*, a doctor could infringe even if he/she did not change up his/her treatment plan).
3. The claims recite the steps of carrying out a specific dosage regimen based on the results of the genetic testing. (In *Mayo*, the claims did not prescribe a specific dosage regimen or other added steps to take as a result of the indication).

The Federal Circuit summarized that "the claims here are directed to a specific method of treatment for specific patients using a specific compound at specific doses for a specific outcome." *Id.* at 32.

The dissent disagreed, concluding that "[w]hile the claims here do not solely state a law of nature, they do no more than simply direct the relevant audience to apply it." (Dissenting Opinion, p. 2). The dissent reasoned that the claims are directed to "no more than optimization of an existing treatment of schizophrenia, just as the claims in *Mayo* concerned 'optimizing therapeutic efficacy' of thiopurine drugs.'" *Id.* at 5. "It claims no more than instructions directing the audience to apply the natural law in a routine and conventional manner." *Id.* at pp. 5-6. With regard to the difference in claiming a specific dosage, the dissent highlighted that *Mayo* considered "the 'administering' step in its search for an inventive concept, *not* as part of the determination whether the claims were directed to a natural law at the threshold." *Id.* at 6. As noted by the dissent, "the specific dosage adds nothing inventive to the claims beyond the natural law." *Id.* Similarly, the dissent noted that requiring treatment instead of indicating a dosage is not sufficient at step two of the analysis.

<u>Practice Insights</u>

It is important to be specific about a particular method of treatment, and also to be specific about a particular dosage for a specific outcome. In particular, a specific treatment should be claimed, instead of an optimization of a treatment, as in *Mayo*. The treatment should also include a specific dosage, intended for a specific outcome. Although not determinative, careful consideration should be given to drafting the preamble, as it also plays a role in finding the claims patent eligible, particularly as it related to specifying the particular method of treatment.