VANDA PHARM. INC. v. WEST-WARD PHARM. INT'L LTD., Appeal Nos. 2016-2707, -2708 (Fed. Cir. April 13, 2018). Before Prost, Lourie, and Hughes. Appealed from D. Del. (Judge Sleet).

Background:

When sued for infringement, an ANDA applicant challenged the patent's validity under §101. The representative claim was directed to a "method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia." As summarized by the Federal Circuit, the method included "(1) determining the patient's CYP2D6 metabolizer genotype by (a) obtaining a biological sample and (b) performing a genotyping assay; and (2) administering specific dose ranges of iloperidone depending on the patient's CYP2D6 genotype."

The district court held that the claims were not invalid under §101 because although the claims were directed to a law of nature (i.e., the relationship between iloperidone, CYP2D6 metabolism, and certain side effects), the claims as a whole amounted to significantly more than this law of nature. Specifically, the claims recited conducting CYP2D6 genotyping tests to determine the appropriate dosing of iloperidone to reduce specific side effects, and West-Ward had not shown that this test and the discovered results were routine or conventional.

Issue/Holding:

Did the district court err in holding that the claims were not patent ineligible? No, affirmed.

Discussion:

Unlike the district court, the Federal Circuit held that the claims were not directed to patent-ineligible subject matter, and thus did not even reach the second step of the *Alice* test. Citing its 2016 decision in *CellzDirect*, the Federal Circuit emphasized that "it is not enough to merely identify a patent-ineligible concept underlying the claim; we must determine whether that patent-ineligible concept is what the claim is 'directed to.'"

The court held that the claims here were directed to "a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome." Although the claims recited a natural relationship, the court reiterated its statement in *CellzDirect* that "the natural ability of the subject matter to *undergo* the process does not make the claim 'directed to' that natural ability." Thus, the claim's recitation of the relationship between the CYP2D6 metabolizer genotype and the likelihood of certain side effects did not amount to the claim being "directed to" that relationship.

The court specifically distinguished the claims in this case from those in *Mayo*, which recited a step of administering a drug, but did not go beyond recognizing a need to adjust the dosage based on measured concentrations of certain metabolites in the blood. The claims therefore "tied up" any future treatment decision, raising preemption concerns.

By contrast, the claims in this case recited more than the relationship between the CYP2D6 metabolizer genotype and the risk of experiencing certain side effects. They instead recited a method of treating patients based on that relationship in order to reduce the likelihood of the side effects, limiting the claim to a specific application. This specific application of the law of nature was patent eligible.