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IP Alert: Did the Supreme Court Bless Claims to Methods of Treating?



Did the Supreme Court Bless Claims to Methods of Treating?

By Sarah A. Kagan

At the U.S. Court of Appeals for the Federal Circuit oral argument in Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals (Case Nos. 16-2707 and 16-2708) on Dec. 5, Judge Lourie challenged each side to defend its position on the subject-matter eligibility of the claims in U.S. Patent 8,586,610. The claims relate to a method for personalized dosing of schizophrenia drug iloperidone (FANAPT®), employing both a diagnostic step and a treatment step. The court probed whether such hybrid claims are subject-matter eligible.

The trial court had found the ’610 claims patent eligible, applying the two-part test from Mayo Collaborative Services v. Prometheus Laboratories, Inc. , 566 U.S. 66 (2012). In step 1 of the analysis, it found a law of nature. In step 2 of the analysis, however, the trial court found that the claims contained elements that were not routine or conventional. The trial court defined the law of nature as the relationship between iloperidone, CYP2D6 metabolism, and QTc prolongation. The court found the process of using the genetic test for CYP2D6 metabolism to inform the iloperidone dosage adjustment to be the additional, non-conventional elements.

Vanda’s representative claim 1 bears some striking similarities to the Prometheus patent claim 1 at issue in the Mayo case itself, as shown below. Both involve determining drug metabolism of a patient so that the dosage administered can be adjusted for that patient.

U.S. 8,586,610

Mayo v. Prometheus –
Prometheus’ U.S. 6,680,302

A	1. A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:	1. 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:	(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
B	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	(b) determining a level of 6-thioguanine or 6-methyl-mercaptopurine in said subject having said immune-mediated gastrointestinal disorder,
C	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	
D	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,	
E	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 a level of 6-thioguanine less than about 230 pmol per 8 x 108 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein a level of 6-thioguanine greater than about 400 pmol per 8 x 108 red blood cells or a level of 6-methyl-mercaptopurine greater than about 7000 pmol per 8 x 108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

The last clause in each claim (located in row E) sets out the natural law. The evaluation of each patient is set out in row B. In the Prometheus claim, the amount of drug or metabolite is measured after the drug is administered to the patient. In the Vanda ’610 patent, a genotype of the patient is determined, which is associated with poor metabolism. The claims substantially differ from each other in rows C and D, in which the Vanda ’610 claim has a method of treating (administering a specific dosage of drug). In contrast, the Prometheus claim has no post-evaluation treatment step.

Even though the Supreme Court in Mayo found the Prometheus claim subject-matter ineligible, Judge Lourie at the Vanda v. West-Ward hearing referred to the Mayo decision as

having “exempted” methods of treatment (from subject-matter ineligibility invalidity). This is an interesting interpretation of Mayo, as the Supreme Court specifically found that the administration of drug of step (a) (row B, above) did not make the claim subject-matter eligible.[1] The Mayo court held that each claim “recites an ‘administering’ step, a ‘determining’ step, and a ‘wherein’ step. These additional steps are not themselves natural laws but neither are they sufficient to transform the nature of the claim.” Judge Lourie may be relying for his exemption on the following statement in Mayo: “Unlike, 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.”

West-Ward, the patent challenger, told the court that Vanda’s claims were just like the claims at issue in Mayo. Both Judge Hughes and Judge Prost seemed to find that assertion surprising. Judge Hughes asked, “How can you make that statement so broadly? We have dozens of cases that permit treatment.” Judge Prost countered West-Ward’s assertion of similarity between the Prometheus claims at issue in Mayo and Vanda’s ’610 claims saying, “Mayo didn’t have any specificity as to what the method of treatment was….it didn’t go to the dosing.”

Vanda latched onto Judge Lourie’s statement and reiterated without explanation that Mayo exempts method-of-treatment claims. It also advanced its own novel theory for subject-matter eligibility of its claims based on the presence of not one, but three separate laws of nature. It urged that this made it “fail” the Mayo step 1 analysis (i.e., not directed to a law of nature).[2] Vanda did not explain how three natural laws would extricate a claim from the Mayo step 1 analysis.

When Judge Prost asked Vanda what beyond the law of nature was not routine (i.e., Mayo step 2), Vanda indicated that the change in dosing of iloperidone was not routine for modulating risk of QTc prolongation. Was Vanda referring to the element in row E above, which aligns with Prometheus’ law of nature? If so, then Vanda may have pointed to the same element as both a law of nature (Mayo step 1) and “significantly more” than the law of nature (Mayo step 2). Vanda may have been referring to the steps in rows C and D. These are the treating steps, which the judges seemed to find significant. These steps also do not have direct analogues in the Prometheus claim. Alternatively, the law of nature in Vanda’s claim may be the diagnostic step itself (row B).

The panel of judges entered the oral hearing predisposed to see the Vanda claims as directed to a method of treatment. Vanda pushed the subject-matter eligibility doctrine in more exotic directions, trying to have its claims clear both steps 1 and 2 of the Mayo test.

This court may ultimately not decide the subject-matter-eligibility question because the panel of judges at the oral hearing also questioned whether the court had jurisdiction over the appeal. West-Ward characterized the appeal as relating to 35 U.S.C. §271(b) inducement to infringe, but it has not yet marketed or obtained approval of its product. Vanda maintains that the suit relates to 35 U.S.C. §271(e)(2) and West-Ward’s filing of an Abbreviated New Drug Application listing the ’610 patent with the U.S. Food and Drug Administration. Neither party argued that the appellate court did not have jurisdiction, but the court can raise the issue on its own. If the court finds that it does not have jurisdiction over the appeal, it will not reach the subject-matter eligibility issue. If the court finds that it does have jurisdiction, we may learn more of the court’s view of permissible subject matter in the personalized medicine context.

Click here to listen to the arguments in Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals.

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[1] The Court discounted Prometheus' administration step (a) as merely defining the population to treat.

[2] Note that the court and the parties referred interchangeably to "passing" the steps of the Mayo analysis [to yield patent eligible subject matter] and "failing" the steps of the Mayo analysis [to identify patent ineligible subject matter].

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