BANNER & WITCOFF, LTD.
INTELLECTUAL PROPERTY LAW

Intellectual Property Alert:
A Test That Cannot Be Applied Consistently

By Sarah A. Kagan

April 24, 2018 — The difficulty in consistently applying the prevailing test for subject matter eligibility was evident in the April 13, 2018, opinion of the U.S. Court of Appeals for the Federal Circuit in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited* (2016-2707, 2016-2708). As a result of U.S. Supreme Court decisions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012) and *Alice Corp. Pty. v. CLS Bank International*, 534 S. Ct. 2347 (2014), a two-step test has been adopted for determining patent subject-matter eligibility. The U.S. Patent and Trademark Office has operationalized the test in its guidelines (M.P.E.P. §§ 2106 through 2106.07).

The *Alice/Mayo* Test

The first *Alice/Mayo* step is to determine whether the claim is directed to a patent-ineligible concept, such as a law of nature, natural phenomenon, or abstract idea. The second *Alice/Mayo* step is to determine whether the portion of the claim that excludes the patent-ineligible concept amounts to significantly more than the patent-ineligible concept itself.[1] Between the *Vanda* district court, the Federal Circuit majority, and the Federal Circuit dissent, every possible result was elicited from the two-part test.

	Alice/Mayo step 1: Patent-ineligible concept present?	*Alice/Mayo* step 2: Substantially more?
District Court	Yes	Yes
Federal Circuit Majority	No	Yes
Federal Circuit Dissent	Yes	No

[1] The rationale for considering the claim in a piecemeal manner is not clear. The rationale for excluding the patent-ineligible concept from the step two inquiry is similarly obscure. Patent dogma considers claimed subject matter as a whole for other statutory requirements.

At step one, the district court concluded that the *Vanda* claim depends upon laws of nature and natural phenomena and therefore was directed to a patent-ineligible concept. However, it also found that the method of treating was not proven routine or conventional, *i.e.*, was inventive at step two of the test.[2]

The Federal Circuit majority hung its analysis on distinguishing the *Vanda* claim from the *Mayo* claim. While both contained a step of administering a drug to a patient, the majority characterized Vanda's claim as directed to a novel method of *treating* disease, while it characterized the *Mayo* claim as directed to a *diagnostic* method in which drug was administered in order to measure metabolite levels in the blood. The majority performed step one of the *Alice/Mayo* test, *i.e.*, determining to what the claim is directed, by characterizing the claim. Moreover, the majority distinguished the *Vanda* claim as actually *applying* the natural relationship of genetics and metabolism by administering a tailored dose, whereas the *Mayo* claim did not require any action based on the metabolite levels determined. Having found no patent-ineligible concept, the majority did not need to perform step two of the analysis. Nonetheless, it did state that the claim "provides 'a new way of using an existing' test that is safer for patients because it reduces the risk of QTc prolongation." This sounds like a favorable step two analysis.

The dissent criticized the majority's analysis as "conflat[ing] the inquiry at step one with the search for an inventive concept at step two." The dissent found a natural law in the claim at *Alice/Mayo* step one. Then, looking at the remainder of the claim, the dissent found nothing "to supply the requisite inventive concepts."

Other Factors

The majority also discussed pre-emption as it applied differentially to the *Vanda* and *Mayo* claims. Because the *Mayo* claim did not have an active step of applying the diagnostic result, the majority found that the *Mayo* claim pre-empted physician treatment choices. The majority explained that as long as a party performed the diagnostic step, it would not matter what treatment the physician employed because all would be infringing. In contrast, the *Vanda* claim did not preempt treatment options beyond the recited treatment step.

The majority pointed to a statement in *Mayo* that supported its distinction from the Vanda claim. The Supreme Court in *Mayo* had contrasted the *Mayo* claim from "a typical patent on a new drug or a new of using an existing drug," implying but not stating that those typical patents would be patent eligible. The majority found the *Vanda* claim to fit nicely into that protected niche.

Conclusions

Despite the seemingly mechanical analysis of the *Alice/Mayo* test for determining patent-ineligible subject matter, the test can yield wildly different results, as the *Vanda* litigation demonstrates. The variability

[2] The district court put the burden on the challenger to prove subject-matter ineligibility.

suggests that determination of subject-matter eligibility is subjective. Patent law is no stranger to subjectivity, as the fundamental concept of obviousness often turns on the eye of the beholder. However, it seems that the test for obviousness articulated in *Graham v. John Deere*[3] has provided a more workable decision framework than that in *Alice/Mayo*. The *Graham* factors are factual findings upon which an ultimate legal judgment rests. However, in the *Alice/Mayo* test, the underlying elements themselves seem malleable and subject to disagreement. This area of the patent law cries out for congressional intervention.

Click here to download the decision in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited*.

Click here to read our December 21, 2017, report on the *Vanda* oral arguments.

[3] 383 U.S. 1 (1966).