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Determining Patentability Of Personalized Medicine

Law360, New York (December 13, 2011, 12:43 PM ET) -- On Dec. 7, 2011, the U.S. Supreme Court heard arguments in Mayo Collaborative Services v. Prometheus Laboratories Inc. At issue is the standard for determining when certain types of medical methods are patent-eligible subject matter under 35 U.S.C. § 101, which operates as a gatekeeper to prevent patents issuing on a law of nature.

The claims at issue, licensed to Prometheus, are directed to so-called personalized medicine in which the dose of a drug for a patient is optimized by measuring the level of metabolites of the drug in the blood to determine whether the dose should be adjusted for that patient. Mayo and its amici have protested that broad patents in this area stymie research efforts and inhibit physicians from administering secondary tests.

The district court ruled the claims were invalid, finding the inventors' discovery was no more than "a natural body process ... preexisting in the patient population." The Federal Circuit reversed, holding the claims patent-eligible because they involve a physical transformation and thus are not merely an abstract idea or law of nature.

The Supreme Court remanded the case to the Federal Circuit in light of its 2010 decision in Bilski v. Kappos, which also involved subject matter eligibility. Following the remand, the Federal Circuit again ruled in favor of Prometheus, essentially reiterating its prior holding that both the "administering" and "determining" steps recited in the patent claims were transformative.

At oral argument before the Supreme Court, several themes were apparent. Both the court and the parties struggled to separate the gatekeeping role of Section 101 against the novelty and obvious requirements.

Mayo attempted to focus the court on the naturally occurring correlation between health and the metabolites, arguing that because the steps of "administering" the drug and "determining" the metabolite levels are not novel, they should not be considered in deciding the question of patent-eligibility.

Prometheus responded that dissecting claims into old and new elements when addressing the question of subject matter eligibility is improper under existing precedent. Prometheus pointed out that its claims involve a step of administering a drug to a patient, which alone would define a patent-eligible process. The solicitor general, who also participated in the arguments, agreed it is important to avoid the temptation of bringing the questions of novelty and nonobviousness into the patent-eligibility analysis.

According to Mayo, claims would need to describe specific treatment protocols to be taken upon measuring different metabolite levels for them to be patent-eligible. Prometheus disagreed, pointing to examples of patents for detecting leaks in a reactor or navigating a boat through fog that do not require additional steps of repairing the leak or steering the boat. Prometheus argued there is no rule prohibiting a claim from "ending" with a mental step.

Eligibility Versus Patentability

The parties also focused on the relative merits of applying Section 101 rigidly to regulate eligibility versus addressing patentability by enforcing the requirements for novelty under Section 102 and nonobviousness under Section 103. Mayo urged that Section 101 is an important gatekeeper that allows doctors to make judgments without fear of being sued for patent infringement.

Mayo also maintained courts are better equipped to decide eligibility as a purely legal issue. Prometheus disputed the ability of courts to efficiently implement a strict application of Section 101, pointing to the inefficiencies and difficulties in deciding close questions under § 101 as evidenced by the present litigation which has been pending for seven years.

Preemption

The court paid also significant attention to preemption — the extent to which patents have a chilling effect on research in the field. Mayo argued the patents left virtually no room for others to measure metabolite levels in the treatment of any autoimmune disease.

Prometheus responded that patents often have the effect of preempting later developments, such as a patent for the basic process of vulcanizing rubber precluding a later inventor from practicing an improvement invention involving particular timing of the process. In that example, Prometheus argued, the later research could be patented but the prior existing patent would obligate the later inventor to pay royalties through the end of the patent term.

A Law Of Nature Versus Its Application

The patent bar had anticipated that the Bilski decision would have supplied guidance to distinguish between when a claim is directed to a law of nature versus an application. Beyond recognizing the Federal Circuit "machine-or-transformation" test can be useful, however, Bilski did not provide much clarification. One question in particular left unanswered in Bilski is whether satisfaction of the machine-or-transformation test provides a safe harbor for Section 101 — a question that apparently will need to be answered in this case.

While it is unclear exactly where the court will draw the line between processes involving mere abstract ideas or laws of nature and those meriting patent protection, the court appears focused on finding factors to allow courts to distinguish between ineligible laws of nature and eligible applications thereof. Justice Stephen Breyer repeatedly probed counsel regarding "what has to be added to a law of nature to make it a patentable process?"

Notably, Justice Breyer appeared to comment that administering a drug should make claims patent-eligible as an application of a law of nature, perhaps suggesting common ground with the Federal Circuit analysis.

Overall, the justices appeared to recognize the need to tread carefully to balance the competing interests of protecting capital investments in this area and the ability of physicians to adequately care for patients.

The court is expected to issue its decision in spring 2012.

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