Patent Law Update: Mayo v. Prometheus

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Supreme Court Hears Arguments on Patent Eligibility of Personalized Medicine

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On December 7, 2011, the U.S. Supreme Court heard arguments in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* involving whether certain types of medical methods are patent-eligible subject matter. The patents at issue claim methods for optimizing patient treatment in which the level of a certain drug metabolite is measured to identify a need to increase or decrease dosage levels. 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 decision in *Bilski v. Kappos*, after which the Federal Circuit again ruled in favor of Prometheus.

During oral argument, Mayo objected to the claims as foreclosing others from using practically any method of measuring the metabolite levels to optimize dosage. Mayo argued 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. 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 argued it is improper to dissect claims into old and new elements when addressing the question of subject matter eligibility. 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 non-obviousness into the patent-eligibility analysis.

Prometheus disagreed with the asserted need for the claims to have additional steps defining treatment protocols, 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.

But Chief Justice Roberts questioned whether physical transformation alone was enough, questioning whether a process of igniting wood to produce heat would be patent-eligible under the test proposed by Prometheus.

Several questions from the justices probed into whether judicial economy favored a rigid application of 35 U.S.C. § 101, or whether the ultimate question of patentability is better addressed through enforcement of the requirements of novelty and non-obviousness. Mayo urged § 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 pointed 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 was another topic that received significant attention during the argument. Mayo argued the patents left virtually no room for others to measure metabolite levels in the treatment of any autoimmune disease, and that had Prometheus claimed different diseases separately this would not have saved the patents. Prometheus responded by explaining 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.

While it is not clear exactly where the Court will draw the line between processes involving mere abstract ideas and those

meriting patent protection, 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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