ARE DIAGNOSTIC METHOD CLAIMS PATENTABLE?
U.S. Supreme Court Decision (June 2012)

On March 20, 2012 the Supreme Court of the United States unanimously reversed the Federal Circuit in the case of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, finding that certain medical diagnosis claims are not patentable. Prometheus is the exclusive licensee of two patents for the use of drugs to treat auto immune diseases. Breakdown products (metabolites) of the drug are produced by the body after the drug is administered to a patient. The level of the metabolite indicates whether a dose of the drug is too high and risky or too low and likely ineffective. The patent claims set forth an administering step and a determining step to measure the metabolite in the blood and establish the correlation between metabolite levels and likely harm or ineffectiveness.

Mayo began marketing and selling its own diagnostic test which Prometheus alleged was infringing its two licensed patents. Prometheus sued Mayo for patent infringement and Mayo countered that the patents were invalid. The District Court determined that tests sold by Mayo infringed the Prometheus claims but the Prometheus patents were invalid under 35 USC § 101. This statute permits patenting of any new and useful process, machine, manufacture, or composition of matter so long as it is does not only include (1) laws of nature; (2) physical phenomena; and (3) abstract ideas. The Federal Circuit disagreed with the District Court and found the claims were patentable subject matter under §101.

The U.S. Supreme Court determined that the laws of nature recited by Prometheus' patent claims were not patentable. The Court reasoned that because methods for making determinations as to effectiveness or harm of a drug are well known in the art, the process as claimed merely tells doctors to engage in conventional activity previously engaged in by those in the field of science.

The Prometheus decision has far reaching implications for issued diagnostic methods and personalized medicine patent claims. For current and future diagnostic method claims a transformative step that goes beyond a law of nature will go far in avoiding a Prometheus invalidity decision. Companies who have rights in diagnostic patents may want to review whether a narrowing reissue application would rescue any claims that are directed to arguably unpatentable subject matter. Companies in diagnostics and personalized medicine may want to reevaluate the patents of their competitors and/or any freedom to operate opinions to determine if their markets can be expanded.

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