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Supreme Court Invalidates Biotech Method Patent in Mayo v. Prometheus

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On March 20, 2012, the United States Supreme Court handed down a groundbreaking decision in the field of biotechnology; however, the repercussions of this decision will be felt throughout the patent community. In a highly anticipated decision, the Court reversed the United States Court of Appeals for the Federal Circuit in **Mayo Collaborative Services and Mayo Clinic Rochester v. Prometheus Laboratories, Inc.,** unanimously finding that **process claims directed to optimizing the dosage of a drug for treatment of an immune-mediated gastrointestinal disorder are invalid because they effectively claim no more than an underlying law of nature.**

The two patents at issue are exclusively licensed to Prometheus, who sells d**iagnostic tests that employ the patented processes.** At first, Mayo bought and used these diagnostic tests; however, in 2004, Mayo decided to use and sell a slightly different diagnostic test. Prometheus responded by bringing an infringement action in the United States District Court for the Southern District of California, which found that although Mayo infringed a claim of a Prometheus-licensed patent, the asserted claims were invalid for being drawn to non-statutory subject matter. The District Court reasoned that the patents claimed “natural laws or natural phenomena,” which are not entitled to patent protection. Specifically, the District Court opined that the correlations between metabolite levels and the toxicity and efficacy of drug dosages are patent-ineligible laws of nature. The Federal Circuit reversed, and held that the claims were directed to patent-eligible subject matter because they “transform an article into a different state or thing,” and the transformation was “central to the purpose of the claimed process.” The Federal Circuit subsequently reaffirmed this decision on remand from the Supreme Court for reconsideration in view ofBilski v. Kappos.

The question presented to the Supreme Court in **Mayo v. Prometheus** was “whether the claimed processes have transformed unpatentable natural laws into patent-eligible applications of those laws.” The Court recognized that the threshold inquiry to determine whether a claim is directed to patent-eligible subject matter is governed by 35 U.S.C. § 101, which provides “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

The representative claim analyzed by the Court was directed to methods of calibrating the optimal dosage of a thiopurine drug by administering the drug, and determining the level of subsequent

metabolites, where certain metabolite levels correlate with certain results. The Court relied on case precedent, including Diamond v. Diehr and Gottschalk v. Benson, for the proposition that the meaning of “process” in § 101 has been limited to exclude fundamental principles, such as “laws of nature, natural phenomena, and abstract ideas,” but noted that “an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.” The Court concluded that the claims were not patent eligible, reasoning that the claims were merely instructions to apply a natural law, i.e., a natural correlation.

Specifically, the Court stated that the additional steps of “administering” and “determining,” along with the “wherein” clauses, “add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field.”

Although the Court recognized that in determining whether additional claim steps are routine or conventional, a § 102 novelty inquiry and a § 101 statutory subject matter inquiry “might sometimes overlap,” Justice Breyer repeatedly emphasized that from a policy perspective, a patent should not preempt natural correlations, thereby improperly inhibiting future innovation. The Court also warned that a non-statutory law of nature cannot be transformed into subject matter that is eligible for patent protection by mere clever claim drafting that amounts to no more than “insignificant post-solution activity.”

How the Supreme Court’s decision will impact medical diagnostic patents and patent applications in the future remains to be seen. We note that the Court declined to opine on the desirability of increased protection for diagnostic correlations, inviting Congress to develop “more finely tailored rules” for patent eligibility should the legislature disagree with the Court’s conclusion.

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