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Are Medical Diagnostic Tests Patentable? The Supreme Court Weighs in With Its Mayo v. Prometheus Decision

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In a widely anticipated decision, the Supreme Court reversed the Federal Circuit's decision in *Mayo v. Prometheus*, which had upheld the patentability of a medical diagnostic test that measured metabolites in human blood. This decision has wide-ranging implications for the medical diagnostic community, as it throws into question the patentability of medical diagnostic tests and may raise patentability issues for other industries as well.

Justice Breyer, writing on behalf of the unanimous Supreme Court, reiterated that "laws of nature, natural phenomena and abstract ideas are not patentable." Justice Breyer explained that "Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the laws of gravity." Justice Breyer did note, however, that the Court has held that "a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm...and added that 'an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.'"

Justice Breyer stated that this case "lies at the intersection of these basic principles...The claims purport to apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects. We must determine whether the claimed processes have transformed these unpatentable natural laws into patent eligible applications of those laws."

The Court held that the claims were unpatentable because they essentially applied only a law of nature, "[n]amely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." The Court reached this conclusion by categorizing the patents into three steps, consisting of an administering step, a "wherein" clause and a third determining step. With respect to the administering step, the Court found that this merely refers to the relevant audience, i.e., the doctors who treat patients. The "wherein" clause merely described the natural law. The third step, the determining step only tells the doctor to determine the level of the relevant metabolites in the blood. The Court found that this step merely told the doctors to engage in "well-understood, routine, conventional activity previously engaged in by scientists who work in the field." Finally, the Court found that "the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately."

The Supreme Court's decision raises more questions than it answers and it simultaneously calls into question the patentablity of diagnostic methods that have wide ranging value. While not going so far as to exclude the patentability of diagnostic methods per se, the Supreme Court did not provide clear guidance on what types of diagnostic tests may remain patentable. Given the lack of guidance from the Supreme Court's decision, we can expect further decisions from lower courts and the Federal Circuit testing the patentability requirements of medical diagnostic methods.

Mayo Collaborative Services v. Prometheus Laboratories Inc., 556 U.S. ____(2012).

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