

# OFFICE OF THE GENERAL COUNSEL

## Legal Advisory

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### SUMMARY

U.S. Supreme Court holds that medical diagnostic methods must have an inventive feature to qualify as patent-eligible subject matter.

If you have any questions regarding the issues raised by the *Mayo v. Prometheus* decision, please contact:

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## U.S. SUPREME COURT INVALIDATES COMPANY PATENTS ON MEDICAL DIAGNOSTIC METHODS

On March 20, 2012, the United States Supreme Court in *Mayo Collaborative Services v. Prometheus Laboratories, Inc. (Mayo v. Prometheus)* held that Prometheus' medical diagnostic methods lacked an inventive feature and are thus not patent-eligible subject matter under 35 USC §101 of U.S. patent law.

In 2004, Prometheus, a company marketing a medical test, sued Mayo Collaborative Services, a for-profit entity, and Mayo Clinic Rochester, a non-profit entity, (collectively, "Mayo") for patent infringement after Mayo, a former purchaser and user of the Prometheus medical test, announced that Mayo planned to sell a competing test to other hospitals. Prometheus had patented its medical test, a diagnostic method that determines the optimal dose of a thiopurine drug to give a patient who has an autoimmune disease. Specifically, the Prometheus test involves three steps: (1) administering a thiopurine drug to a patient, (2) determining the level of particular resulting metabolites in the patient's blood, and (3) if needed, adjusting the subsequent dosage of the thiopurine drug so that the resulting particular metabolite levels fall within a therapeutic range.

In 2010, the Court of Appeals for the Federal Circuit (Federal Circuit) affirmed its earlier decision in favor of the Prometheus patents, concluding that the Prometheus medical tests are patent-eligible subject matter under 35 USC §101.

In its unanimous decision, the Supreme Court reversed the Federal Circuit and invalidated the Prometheus patents. The Court focused on the difference between a law of nature, which is not patent-eligible subject matter, and an application of a law of nature, which may be patent-eligible subject matter. The Court emphasized that for an application of a law of nature to be patent-eligible subject matter, an inventive feature is required, and "one must do more than simply state a law of nature while adding the words 'apply it.'"

In contrast to the Federal Circuit's conclusion, the Court found that the Prometheus test applied a law of nature (*i.e.*, the "correlations" or "relationships" between drug dose and resulting blood metabolite levels) but lacked an inventive feature and thus failed to "transform" the application of the law of nature into patent-eligible subject matter. Specifically, the Court found that the steps of the Prometheus test involved "well-understood, routine, conventional activity previously engaged in by researchers in the field" but lacked an inventive feature. The Court noted that because doctors had been using thiopurine drugs to treat autoimmune diseases for a long time, the Prometheus test's use of those drugs was routine and lacked an inventive feature.

This decision will have a mixed impact on the University. It thwarts the University's ability to patent diagnostic methods created by University researchers if those methods do not meet the Supreme Court's criteria for patent-eligible subject matter. On the positive side, University doctors now have the freedom to choose from a broader array of diagnostic methods as the Court's decision invalidates third-party patents that previously made certain diagnostic methods unavailable or unaffordable to many patients.