

# PUBLICATION

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## Supreme Court Rejects Prometheus Method Claims

**Authors: W. Edward Ramage**

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As a follow-up to its recent *Bilski* decision, and continuing its focus on the question of patentable subject matter, the U.S. Supreme Court today issued its decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* In a unanimous decision, the Supreme Court held that method claims that involved administering a drug to a patient and determining the effect were not patentable subject matter. The Court held that the correlation between the drug being administered and the concentrations of certain metabolites in the blood of the patient was not itself patentable as a "law of nature," and the claimed processes, while not natural laws themselves, did not sufficiently transform the nature of the claims.

Prometheus Laboratories is the exclusive licensee of two patents claiming the use of thiopurine drugs to treat autoimmune diseases. When ingested, the drugs are metabolized and produce metabolites in the bloodstream of the patient. The claims are directed to processes that identify correlations between metabolite levels and likely harm or ineffectiveness of the drug with regard to that patient. The claims each recite an administering step (the physician administers the drug to the patient), a determining step (the physician measures the resulting metabolite levels), and a "wherein" step describing the metabolite concentrations above which there is a likelihood of harmful side effects, and below which there is a likelihood of ineffectiveness. The physician is informed that concentrations above or below either threshold indicate a need to decrease or increase the drug dosage.

Mayo announced that it intended to sell and market a similar diagnostic test. Prometheus sued Mayo for patent infringement, and Mayo challenged the validity of the claims. The District Court found that the claims effectively claimed natural laws or phenomena, and declared the claims invalid. On appeal, the Federal Circuit Court of Appeals initially reversed, holding that the claims met the "transformation" element of the machine-or-transformation test which had been developed as a means for testing patent eligibility. The case was remanded by the Supreme Court for further consideration in light of its *Bilski* decision, and the Federal Circuit reaffirmed its earlier conclusion. In its decision today, the Supreme Court reversed.

The Court's starting point was that the relationship between the metabolite concentrations and the likelihood that the thiopurine drug dosage would be harmful or ineffective is a "law of nature," and thus not patentable. The claimed processes were applications of a law of nature, and would not be patentable unless they have additional features that provide practical assurance that the processes are genuine applications of those laws, rather than an attempt to monopolize the correlations. In this case, the Court determined that none of the steps of the method claims met this standard.

This decision brings into question the validity of similar claims in many patents already issued, and will have an immediate impact on pending patent applications. It also may have some bearing on the issue of the patentability of parts of the human genome, an issue that the Supreme Court may consider this coming term in the *Myriad Genetics* case.

If you have any questions or want to discuss how this decision could impact your business, contact your Baker Donelson attorney or one of the attorneys in our Intellectual Property Group.

