



# Court Holds Drug Dosage Optimization Process to be Patentable Subject Matter

## Client Advisories

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*Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009).

The Federal Circuit's holding in *Prometheus* finds a method of optimizing medical drug dosage to be patentable subject matter. In *Prometheus*, patent claims were directed toward the process of administering a drug to a patient, quantifying the drug's metabolite byproducts in the human patient, comparing the concentration of the metabolites to known standards and adjusting drug dosages accordingly. In so doing, physicians can have better means to provide effective drug dosages for individual patients without inducing toxicity.

The Federal Circuit based its conclusion on an application of the "machine or transformation" test from *In Re Bilski* (currently on appeal to the U.S. Supreme Court). Based on this test, a process is properly considered eligible subject matter for patent protection as long as it either (a) is tied to a particular machine or apparatus, or (b) transforms a particular article into a different state or thing. The *Prometheus* court concluded that the drug's resultant transformation on the human body as well as the transformations on the human blood samples during the metabolite quantification analysis were not merely data-gathering steps, but central to the claimed invention's purpose. Consequently, the process claims were found to be patentable subject matter.

The decision is relevant to researchers in the medical field who are increasingly studying the utility of biomarkers in the diagnosis and treatment of diseases. Presumably, the court's rationale could be extended to other treatment or research procedures that involve similar transformations. This may provide incentives for further research in the field. At the same time, the decision's long-term impact may still depend on the U.S. Supreme Court's treatment of the "machine or transformation" test from *Bilski* on which the *Prometheus* court's holding is based.

If you have questions about the impact of this ruling please contact Jason Cotter of Archer's Intellectual Property Group at (856) 354-3126 or [jcotter@archerlaw.com](mailto:jcotter@archerlaw.com). For all or other intellectual property matters, please contact one of the Group Co-Chairs, Joseph A. Martin at (856) 354-3136 or [jmartin@archerlaw.com](mailto:jmartin@archerlaw.com), or Mark J. Sever Jr. at (856) 354-3045 or [msever@archerlaw.com](mailto:msever@archerlaw.com).

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