

## Patent Law Update: Mayo v. Prometheus

June 21, 2011

On June 20, 2011, the U.S. Supreme Court granted certiorari in *Mayo v. Prometheus*, a case which concerns personalized medicine patents. Prometheus's patents cover drug dosage adjustment methods tied to a patient's individual metabolism.

The U.S. Court of Appeals for the Federal Circuit has ruled twice in the case, which has gone up to the high court once before. In its first decision in September 2009, the Federal Circuit reversed a lower court's ruling invalidating the Prometheus patents, which are used to treat autoimmune diseases such as Crohn's disease, depending on a patient's particular metabolism.

The Federal Circuit ruling, authored by Judge Alan Lourie, held that Prometheus' inventions satisfy the requirements of the "machine or transformation" test in the Federal Circuit's decision in *In re Bilski* because the claimed methods "transform an article into a different state or thing" in a way that is "central to the purpose of the claimed process."

Thereafter, the Supreme Court issued its ruling in *Bilski*. In view of its *Bilsk*i ruling, the Supreme Court granted Mayo's petition for certiorari, ultimately vacating the Federal Circuit ruling and the Court remanded the case for review in light of its new *Bilski* decision.

In the December 2010 response to the remand, the Federal Circuit ruled again that Prometheus' patent claims pass muster under the new *Bilski* test, and the claims "do not encompass laws of nature or preempt natural correlations."

The Supreme Court's decision to again review *Mayo v. Prometheus* is big news. The case could allow the Court to review and clarify basic questions of patentable subject matter, particularly in the area of medical/diagnostic method patents. This subject has been ripe for review since a divided 2006 Supreme Court ruling in *Lab Corp. v. Metabolite*. That case was dismissed because certiorari had been improvidently granted. However, three dissenting justices argued that the court should keep the case to consider limiting the scope of patentable subject matter under Section 101 of the Patent Act.

Please click here to view the order granting cert.

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