



Prometheus Laboratories v. Mayo Collaborative Services 132 S. Ct. 1289 (2012)

628 F.3d 1347 (Fed. Cir. 2010), 581 F.3d
1336 (Fed. Cir. 2009)

Topics Covered: Patents

Outcome: Very Favorable

Issue

The issue in this case was whether a procedure for determining medically appropriate dosages of azathioprine (AZA) drugs is a potentially patentable process or whether it is inherently unpatentable because it is a manifestation of a law of nature and an application of a mental process.

AMA Interest

The AMA condemns the patenting of medical and surgical procedures.

Case Summary

Prometheus Laboratories is the exclusive licensee of two patents. These patents measure the blood metabolites of patients taking AZA for treatment of autoimmune diseases, including Crohn's disease. The patents cover a three step process: (1) administration of the AZA drugs to the patient; (2) measurement of the metabolite levels; and (3) determination, based on the metabolite levels, of whether a change in drug dosage is appropriate. The patents further specify the metabolite levels at which an adjustment in dosage would be indicated.

Mayo Collaborative Services, an affiliate of the Mayo Clinic, developed its own test to measure the same metabolites, but using slightly different metabolite levels to indicate a modification in dosages. Prometheus sued Mayo for patent infringement, and the trial court granted summary judgment for Mayo, holding that the Prometheus patents described a law of nature and were thus invalid.

Prometheus appealed to the Federal Circuit Court of Appeals. The Court of Appeals reversed, holding that the Prometheus patents pass the first test of patentability - - description of patentable subject matter. The court found that a procedure involving the transformation of "a

particular article into a different state or thing" may be patentable. Because the body's metabolic processes transform AZA into chemical byproducts, the Prometheus Laboratories patents involve such a transformation and are thus potentially valid. The court remanded to the trial court for a determination as to whether the patents satisfy the remaining criteria for validity under the Patent Act.

Mayo Collaborative Services petitioned for *certiorari* in the United States Supreme Court. The Supreme Court granted *certiorari*, summarily reversed, and remanded the case to the Federal Circuit for further consideration in light of its decision in *Bilski v. Kappos*. On remand, the Federal Circuit again held that the Prometheus patents cover patentable subject matter.

The Supreme Court again granted *certiorari*, but this time for a more substantive review. On March 20, 2012, in a unanimous opinion, the Supreme Court again reversed the holding of the Federal Circuit Court of Appeals. It found that the Prometheus patents merely described a naturally occurring process, rather than a practical application of that process. Therefore, the claimed patents were invalid.

AMA and Litigation Center Involvement

The Litigation Center, along with various other medical associations, filed an amicus curiae brief in the Federal Circuit opposing the patent.

The AMA, along with several specialty medical societies filed an *amicus* brief in support of one of the Mayo Collaborative Services petitions for *certiorari*.

The Litigation Center filed an *amicus* brief, along with various other medical associations, in the Supreme Court, regarding the merits.

United States Court of Appeals for the Federal Circuit brief

United States Supreme Court brief in support of certiorari

United States Supreme Court brief regarding the merits