

Federal Circuit's Prometheus Decision Reaffirms Patentability of Methods of Treatment

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On December 17, 2010, The U.S. Court of Appeals for the Federal Circuit decided *Prometheus Laboratories, Inc. v. Mayo Collaborative Services, et al.*, on remand from the Supreme Court. See No. 2008-1403 (Fed. Cir. Dec. 17, 2010). [Read the decision here.](#)

The Federal Circuit held that Prometheus's patents claiming methods for determining the optimal dosages of thiopurine drugs to treat certain diseases were directed to statutory subject matter pursuant to 35 U.S.C. § 101. The Court reversed and remanded the district court's grant of summary judgment of invalidity under § 101.

The Court's decision followed Supreme Court precedent in interpreting § 101 as broadly encompassing "any new and useful process, machine, manufacture or composition of matter." See 35 U.S.C. § 101. The Court reaffirmed the propriety of the "machine-or-transformation" test as one means by which to determine statutory subject matter under § 101 in light of *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). Notably, the Court held that Prometheus's asserted claims "are in effect claims to methods of treatment, which are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition." See *Prometheus*, slip op. at 17.

Background

Prometheus is the exclusive licensee of two patents, U.S. Patent Nos. 6,355,623 ("the '623 patent") and 6,680,302 ("the '302 patent"), directed to methods for determining the optimal dosages of thiopurine drugs to treat gastrointestinal and non-gastrointestinal autoimmune diseases. The drugs include 6-mercaptopurine ("6-MP") and a pro-drug azathiopurine ("AZA") that converts to 6-MP upon administration to a patient. 6-MP is broken down into metabolites by the human body. The drugs 6-MP and AZA have been used for years to treat autoimmune diseases; however, non-responsiveness and drug toxicity was said to be problematic in treating some patients. See *id.* at 4.

The patents-in-suit claim methods that seek to optimize the therapeutic efficacy of 6-MP and AZA while minimizing the toxicity of the drugs. The claimed methods comprise "administering" drug to a patient, "determining" the levels of the drug's metabolites, and comparing the measured metabolite levels to pre-determined levels wherein the measured metabolite levels indicate a need to increase or decrease the level of drug administered so as to minimize toxicity and maximize treatment efficacy. See *id.* A representative claim recites:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about $230 \text{ pmol per } 8 \times 10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about $400 \text{ pmol per } 8 \times 10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

See id. at 5 (Claim 1 of '623 patent).

In June 2004, Prometheus sued Mayo in the Southern District of California for infringement of the two patents. On March 28, 2008, the district court granted Mayo's motion for summary judgment of invalidity under § 101, holding that the patents only claimed correlations between thiopurine drug metabolite levels and therapeutic efficacy and toxicity and that these correlations were natural phenomena and not patent-eligible inventions. In particular, the district court held that the "administering" and "determining" steps are necessary data-gathering steps and that the "wherein" clauses are "warning steps" that are mental steps not requiring any actual change in dosage. The district court further concluded that the claims cover the correlations themselves, and therefore wholly preempt use of the correlations. *See Prometheus*, slip op. at 8-9.

On appeal, the Federal Circuit reversed the district court's grant of summary judgment, holding that the claims were directed to patentable subject matter pursuant to § 101. *See Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009). In particular, the Court held that the "administering" and "determining" claim steps were transformative and not merely data-gathering steps under the machine-or-transformation test, and therefore, the claims did not wholly preempt use of the recited correlations between metabolite levels and drug efficacy and toxicity. *See Prometheus*, slip op. at 9-10.

Mayo filed a petition for writ of certiorari in the Supreme Court. Without comment, the Supreme Court vacated and remanded the Federal Circuit's decision for reconsideration in light of the *Bilski* decision. *See Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 130 S. Ct. 3543 (2010). In *Bilski*, the Supreme Court held that the machine-or-transformation test, though a useful investigative tool, was not the sole determinative test in deciding statutory subject matter under § 101. The *Bilski* Court held that Bilski's claims directed to methods of hedging risk were not patentable subject matter because they were an attempt to patent abstract ideas. *See Bilski*, 130 S.Ct. 3218; *Prometheus*, slip op. at 10. The *Bilski* Court "declined to adopt any categorical rules [for statutory subject matter] outside the well-established exceptions for laws of nature, physical phenomena, and abstract ideas." *See Prometheus*, slip op. at 10.

Medical Treatment Claims Are Statutory Patentable Subject Matter

On remand, the Federal Circuit again reversed the district court's grant of summary judgment and affirmed its previous opinion upholding the patentability of the claims under § 101.

The Court cited *Bilski* in holding that although a law of nature is not patentable, an application of a law of nature to a process is patent-eligible subject matter. *See id.* at 12. The Court stated that "[i]n light of the Supreme Court's decision in *Bilski*, patent eligibility in this case turns on whether Prometheus's asserted claims are drawn to a natural phenomenon, the patenting of which would entirely preempt its use . . . or whether the claims are drawn only to a particular application of that phenomenon." *See id.* at 12-13.

The Court reiterated its pre-*Bilski* decision that Prometheus's asserted claims recited a transformation under the machine-or-transformation test. In particular, the Court held that the "administering" and "determining" steps of the asserted claims were transformative. The Court concluded that the claims are not drawn to a law of nature, but rather a particular application of naturally occurring correlations. Accordingly, the claims "do not preempt all uses of the recited correlations between metabolite levels and drug efficacy or toxicity." *See id.* at 14.

In upholding the patentability of the claimed methods of treatment, the Court stated that "the inventive nature of the claimed methods stems not from preemption of all use of these natural processes, but from application of a natural phenomenon in a series of steps comprising particular methods of treatment." *See id.* at 15-16. Moreover, under the machine or transformation test, the claimed method comprised a transformation that was the central purpose of the claimed process: "The transformation is of the human body and of its components following the administration of a specific class of drugs and the various chemical and physical changes of the drugs' metabolites that enable their concentrations to be determined." *See id.* at 16.

Significantly, the Court affirmed the patentability of method of treatment claims, stating: "**[M]ethods of treatment . . . are *always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition.***" *See id.* at 16-17 (emphasis added); *see also In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008) ("It is virtually self-evident that a process for a chemical or physical transformation of *physical objects or substances* is patent-eligible subject matter.") (emphasis in original).

The Court further stated that the "critical error" of the district court was that it failed to recognize that the first two steps of the asserted claims were not merely "data-gathering steps" under the machine-or-transformation test. *See Prometheus*, slip op. at 19. The Court explained that while the steps do gather data, the "administering" and "determining" steps are transformative and are part of the treatment protocol of the claims. The tests of the first two claim steps were not merely to obtain data, but to provide a drug for the purpose of treating disease. *See id.* at 20.

Conclusion

The *Prometheus* decision confirms that, in light of *Bilski*, method of treatment claims are patent-eligible subject matter under 35 U.S.C. § 101. The decision provides guidance regarding the Federal Circuit's continued use of the machine-or-transformation test after *Bilski*, and how method of treatment claims will be analyzed in light of *Bilski*.



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