

Client Alert

Latham & Watkins
Litigation Department

Reaffirming the Patentability of Medical Treatment Methods

On December 17, 2010, the US Court of Appeals for the Federal Circuit issued *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 2008-1403, — F.3d —, 2010 WL 5175124 (Fed. Cir. 2010), producing another significant victory for the Latham & Watkins appellate team handling the case on behalf of Prometheus. The decision reaffirms that innovative biotechnology and personalized medical treatment processes may be eligible for patent protection. And, because it is one of the first cases in the Federal Circuit to apply the US Supreme Court's recent decision in *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), it provides importance guidance for practitioners and lower courts.

The Federal Circuit had previously held that the asserted medical treatment method claims in this case recite patentable subject matter under 35 U.S.C. § 101.¹ But that decision was vacated by the Supreme Court and remanded back to the Federal Circuit for further consideration in light of the Supreme Court's intervening decision in *Bilski*.² On remand, the Federal Circuit concluded that *Bilski* did not compel a different outcome, and in doing so provided valuable insights on how companies should describe such innovative technologies to ensure their protection.³

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The Legal Landscape

Section 101 of the Patent Act outlines the scope of patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter."⁴ The Supreme Court has construed § 101 broadly, holding that "Congress plainly contemplated that the patent laws would be given wide scope."⁵ The scope of patentable subject matter is not unlimited, however, and the Court has long recognized the narrow, judicially created exception that "laws of nature, natural phenomena, and abstract ideas" are unpatentable.⁶ One frequently used test to assess patentability is the so-called "machine-or-transformation" test, under which a method passes § 101 muster if it involves specific machines or requires transformations of specific articles—and if such machines or transformations are not merely incidental to the purpose of the method.⁷

Background of this Case

Prometheus is the licensee of two method-of-treatment patents for calibrating the appropriate dosage of thiopurine drugs used to treat several serious autoimmune diseases, such as Crohn's disease and ulcerative colitis, based on the level of resulting

metabolites in the patient's body.⁸ After Mayo Medical Laboratories announced its intention to sell a competing test that relied on Prometheus's invention, Prometheus sued Mayo for patent infringement.⁹

The district court held that Mayo's test literally infringes Prometheus's patents, but subsequently concluded that Prometheus's patents were invalid under § 101.¹⁰ According to the district court, the patents fail to claim patentable subject matter and instead claim mere "natural phenomena" in the form of naturally occurring correlations between metabolite levels and therapeutic efficacy or toxicity. The district court dismissed the initial elements of the claim (administering thiopurine drugs and determining the resulting metabolite levels) as mere data gathering, and concluded that the final element (being warned of a potential need to change dosage if the metabolite levels are outside a specified range) was, standing alone, an unpatentable "mental step."¹¹ The district court also found that enforcement of the patents would preempt all practical uses of a natural correlation between metabolite levels and drug efficacy or toxicity.¹²

Prometheus retained Latham & Watkins to appeal the district court decision. In 2009, after briefing and argument, a panel of the Federal Circuit unanimously reversed the district court's judgment and upheld the claims' validity.¹³ The court of appeals found that the claims' "administering" and "determining" steps are transformative and not mere data-gathering, and held that the claims do not wholly preempt a naturally occurring phenomenon.¹⁴

Shortly afterwards, the Supreme Court granted certiorari in *Bilski* to consider the proper test for patentability of process claims under § 101. The Court's decision to review *Bilski* got widespread media attention and many observers predicted that the Court would use the case to restrict the patentability of "business method" claims. After review,

however, the Court reaffirmed that § 101's terms are "'expansive'" and that "Congress plainly contemplated that the patent laws would be given wide scope" to encourage innovation.¹⁵ Further, although the Court recognized the three "specific" (judge-made) exceptions to § 101's "broad patent-eligibility principles"—*i.e.*, for laws of nature, physical phenomena and abstract ideas—the Court reiterated that "an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."¹⁶

The Court rejected the Federal Circuit's use of the machine-or-transformation test as the *exclusive* test of patentability under § 101 as too restrictive, but at the same time confirmed that machine-or-transformation remains a very important—and potentially dispositive—"clue to the patentability of a process claim."¹⁷ The Court rejected the suggestion that business method claims are categorically excluded from patent-eligibility.¹⁸ Eschewing nonstatutory bright lines, the Court emphasized the case-by-case nature of the § 101 inquiry. Applying well-established principles, the Court limited its holding to the specific claims at issue (which pertained to a business method merely directed at the concept of risk hedging), in ruling that those claims were too abstract to be patentable.¹⁹

The Supreme Court then vacated and remanded the *Prometheus* case back to the Federal Circuit for "further consideration in light of *Bilski*,"²⁰ along with another case involving a different set of medical methods found *not* patentable under § 101.²¹

The Recent Federal Circuit Decision

After both sides filed supplemental briefs addressing the impact of *Bilski* on the case, the Federal Circuit decided once again (albeit with a different panel) that Prometheus's methods

are patentable under § 101.²² The court concluded that *Bilski* “did not undermine [the court’s] preemption analysis of Prometheus’s claims” and “did not disavow the machine-or-transformation test,” but merely rejected it as the “definitive test.”²³ The court reaffirmed that, even aside from the machine-or-transformation analysis, Prometheus’s claims do not improperly preempt natural principles or laws of nature.

First, the court explained that Prometheus’s “claims are drawn only to a particular application of [a natural phenomenon] as in *Diehr*” rather than to a natural phenomenon itself (“the patenting of which would entirely preempt its use as in *Benson* or *Flook*”).²⁴ The court rejected Mayo’s preemption argument, observing that, under Mayo’s analysis, “quite literally every transformation of physical matter can be described as occurring according to” and preempting “natural processes and natural law.”²⁵

Second, the court found that the machine-or-transformation test “leads to a clear and compelling conclusion ... that the present claims pass muster under § 101.”²⁶ The court reaffirmed its prior holding that the claims at issue “transform an article into a different state or thing” and that the transformation is “central to the purpose of the claimed process” as required by the machine-or-transformation test.²⁷ The physical step of “administering” the drug to the patient is “not merely data-gathering but a significant transformative element of Prometheus’s claimed methods of treatment.”²⁸ The key transformation, the court explained, “is of the human body and of its components.”²⁹ The court similarly held the “determining” step to be transformative, finding that “[s]ome form of manipulation” is required “to extract the metabolites from a bodily sample

and determine their concentration.”³⁰ The court also reaffirmed that the transformative processes are not “merely insignificant extra-solution activity,” but rather are “central to the claims.”³¹

Third, the court made clear that having a final mental step did not negate the patentability of the claim.³² The court found that “[n]o claim in the Prometheus patents claims only mental steps,” and, although the mental steps alone would not be patentable, they do not render an otherwise patent-eligible claim unpatentable.³³

Conclusion

The Federal Circuit’s second *Prometheus* decision confirms that, under *Bilski*, the machine-or-transformation test remains an important — and, in some cases, potentially dispositive — analytical tool for determining if a claimed method passes § 101 muster. It further confirms that innovative biotechnology and personalized medical treatment processes are eligible for patent protection, even though they rely — as all processes do — on natural laws.

The court’s analysis suggests that, in general, medical diagnosis and treatment methods should be well-suited for § 101 patentability to the extent they involve some form of “administering” or “determining” steps, even though they end not with a physical product or action but rather with information to improve patient care. The decision should provide a useful framework for companies to ensure they are able to protect the fruits of their research and development efforts and obtain a return on such investments. The decision should also provide comfort to both inventors and investors that the courts will not categorically exclude innovative medical technologies — long understood to be patentable — from commercial protection under the patent law.

Endnotes

- ¹ *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009).
- ² *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 130 S. Ct. 3543 (2010).
- ³ See *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No 2008-1403, slip op., 2010 WL 5175124 (Fed. Cir. 2010). See also *Research Corp. Techs., Inc. v. Microsoft Corp.*, — F.3d —, 2010 WL 4971008 (Fed. Cir. Dec. 8, 2010).
- ⁴ 35 U.S.C. § 101.
- ⁵ *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).
- ⁶ *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).
- ⁷ See *id.* at 192; *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972).
- ⁸ See U.S. Patents 6,355,623 and 6,680,302.
- ⁹ Mayo Collaborative Services (d/b/a Mayo Medical Laboratories) and Mayo Clinic Rochester (which was later added as a defendant) are referred to collectively, or individually, as “Mayo.”
- ¹⁰ See *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No 04-cv-1200 (S.D. Cal. Nov. 21, 2005); *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04-cv-1200, 2008 WL 878910 (S.D. Cal. Mar. 28, 2008).
- ¹¹ *Prometheus Labs.*, 2008 WL 878910, at *6.
- ¹² *Id.* at *10.
- ¹³ *Prometheus Labs.*, 581 F.3d at 1349-50.
- ¹⁴ *Id.* at 1345-50.
- ¹⁵ 130 S. Ct. at 3225 (quoting *Chakrabarty*, 447 U.S. at 308).
- ¹⁶ *Id.* at 3225, 3230 (quoting *Diehr*, 450 U.S. at 187). See also *Research Corp. Techs.*, 2010 WL 4971008, at *7 (applying *Bilski* and explaining that judicially-created exception to § 101 for abstractions will not preclude patent-eligibility unless “this disqualifying characteristic ... exhibit[s] itself so manifestly as to override the broad statutory categories of eligible subject matter” (emphases added)).
- ¹⁷ *Bilski*, 130 S. Ct. 3226-27 (quoting *Benson*, 409 U.S. at 71).
- ¹⁸ *Id.* at 3228-29.
- ¹⁹ *Id.* at 3229-31.
- ²⁰ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 130 S. Ct. 3543 (2010).
- ²¹ *Classen Immunotherapies, Inc. v. Biogen IDEC*, 304 F. App’x 866, 867 (Fed. Cir. 2008), cert. granted, vacated and remanded, 130 S. Ct. 3541 (2010). *Classen* remains pending on remand.
- ²² *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No 2008-1403, slip op., 2010 WL 5175124 (Fed. Cir. 2010).
- ²³ *Id.* at 14-15.
- ²⁴ *Id.* at 12-13; see also *id.* at 15 (claims merely “recite a patent-eligible application of naturally occurring correlations”—they “do not wholly preempt all uses of the recited correlations”).
- ²⁵ *Id.* at 18.
- ²⁶ *Id.* at 15.
- ²⁷ *Id.* at 16 (quotation and citation omitted).
- ²⁸ *Id.* at 18.
- ²⁹ *Id.* at 16.
- ³⁰ *Id.* at 18.
- ³¹ *Id.* at 19.
- ³² *Id.* at 21.
- ³³ *Id.*

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