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The Supreme Court Holds That Prometheus's Diagnostic Method Claims Are Unpatentable Under 35 U.S.C. § 101

The United States Supreme Court issued a significant, unanimous decision yesterday in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* No. 10-1150 (2012), holding that certain diagnostic patent claims were invalid for failure to recite patent-eligible subject matter under 35 U.S.C. § 101. The Court determined that the "steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field," and noted that "upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries."[1] In so holding, the Supreme Court reversed a Federal Circuit decision that the method claims were patent-eligible under the machine-or-transformation test, and do not impermissibly claim natural phenomena.[2]

The Supreme Court's opinion is of interest to pharmaceutical and biotechnology companies because the decision leaves a large number of therapeutic and diagnostic patent claims vulnerable to challenge, especially those that concern correlations resulting from natural body processes. The Supreme Court's decision states, however, that new drugs and new methods of using existing drugs remain patentable subject matter. And the decision suggests that certain patents covering diagnostic tests directed at the measurement of new or previously unknown analytes would withstand challenge under § 101.

The Supreme Court's decision also discusses broader policy concerns underlying the patent system, expressing concern that patent exclusivity "can impede the flow of information that might permit, indeed spur, invention by, for example raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing agreements."[3] In addition, the Supreme Court's decision states that it is not up to the Court to "determine here whether, from a policy perspective, increased protection for

[1] *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* No. 10-1150, slip op. at 4 (2012) ("Supreme Court Decision").

[2] *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 628 F.3d 1347 (Fed. Cir. 2010) ("Federal Circuit Decision").

[3] Supreme Court Decision, slip op. at 23.

discoveries of diagnostic laws of nature is desirable"; Congress may craft "more finely tailored rules where necessary."[4]

Diagnostic Method Claims Held Unpatentable

The two patents at issue concern the use of thiopurine drugs in the treatment of autoimmune diseases, such as Crohn's disease and ulcerative colitis.[5] When a patient ingests a thiopurine compound, his body metabolizes the drug, causing metabolites to form in his bloodstream.[6] Because the way in which people metabolize thiopurine compounds varies, the same dose of a thiopurine drug affects different people differently, and it has been difficult for doctors to determine whether for a particular patient a given dose is too high, risking harmful side effects, or too low, and so likely ineffective.[7]

Prometheus Laboratories, Inc. is the sole and exclusive licensee of the patents, and sells diagnostic tests that embody the processes described by the patents.[8] After Mayo Clinic Rochester and Mayo Collaborative Services started using its own tests, Prometheus sued for patent infringement.[9] The United States District Court for the Southern District of California held that Mayo's test infringed one of the patents, but granted summary judgment in Mayo's favor that the patents were invalid because they "effectively claim natural laws or natural phenomena—namely the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages—and so are not patentable."[10]

The Federal Circuit reversed, holding that the patents are not invalid because they satisfy the "machine-or-transformation" test.[11] The Supreme Court granted Mayo's petition for certiorari. The Supreme Court then vacated the judgment of the Federal Circuit and remanded the case for consideration in light of in *Bilski v. Kappos*, 561 U.S. ——, 130 S.Ct. 3218 (2010).[12] On remand, the Federal Circuit reaffirmed its earlier conclusion, holding that under the machine-or-transformation test, the claims "do not encompass laws of nature or preempt natural correlations."[13] The Supreme Court's decision reverses the Federal Circuit.

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[4] *Id.* at 24.

[5] *Id.* at 4.

[6] *Id.*

[7] *Id.*

[8] *Id.* at 6.

[9] *Id.*

[10] *Id.* at 7.

[11] *Id.*

[12] *Id.*

[13] *Id.* at 8 (citing Federal Circuit Decision, 628 F.3d at 1355).

A. The Diagnostic Method Claims Were Unpatentable Under The "Law Of Nature" Test, Which Trumps The "Machine-Or-Transformation" Test

The Supreme Court held that the patents here—describing relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm—set forth "a natural law." [14] The Court determined that the claims simply describe "natural relations" rather than qualifying as "patent-eligible processes that *apply* natural laws."[15] The Court reasoned that "While it takes human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exist in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes."[16] The Court thus concluded that "a patent that simply describes that relation sets forth a natural law."[17]

In so holding, the Supreme Court addressed the "machine-or-transformation" test relied on by the Federal Circuit to find the method claims patent-eligible, and noted that while the "machine-or-transformation" test is an "important and useful clue" to patentability, it does not trump the "law of nature" exclusion.[18]

B. The Diagnostic Method Claims Were Unpatentable Under § 101 Because They Include Additional Steps That Are "Well-Known"

Notably, the Supreme Court's decision relied on *Parker v. Flook*, 437 U.S. 584 (1978), which held that a method claim involving a novel mathematical algorithm was unpatentable because it is "like a law of nature."[19] In *Flook*, the Supreme Court had held that post-solution activity that is purely "conventional or obvious" cannot "transform an unpatentable principle into a patentable process."[20]

As it had in the *Flook* decision, the Supreme Court in *Prometheus* reasoned that a § 101 analysis considers whether the alleged invention is "well-known."[21] The Supreme Court thus considered in its patent eligibility analysis not only that the method claims "inform a relevant audience about certain laws of nature," but also that "any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community."[22]

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[14] *Id.*

[15] *Id.* at 8 (emphasis in original).

[16] *Id.*

[17] *Id.*

[18] *Id.* at 19.

[19] *Parker v. Flook*, 437 U.S. 584, 589 (1978).

[20] Supreme Court Decision, slip op. at 13 (quoting *Flook,* 437 U.S. at 589-90).

[21] Supreme Court Decision, slip op. at 10-11.

[22] *Id.* at 11.

For the patents in *Prometheus*, the Court determined, "those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately."[23]

Because the method claims here were well known, the Supreme Court left open the question of whether the claims would be invalid had the steps of the method been new: "We need not, and do not, now decide whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them."[24]

C. Policy Concerns Regarding The Patent System

In addition, the Supreme Court considered policy concerns regarding the patent system, emphasizing "that patent law not inhibit further discovery by improperly tying up the future use of laws of nature."[25] The Court observed that "there is a danger that the grant of patents that tie up the[ ] use [of laws of nature] will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to 'apply to natural law,' or otherwise forecloses more future invention than the underlying discovery could reasonably justify."[26]

The Supreme Court also described the method claims at issue here as unlike "a typical patent on a new drug or a new way of using an existing drug" in that these claims "tie up too much future use of laws of nature" because they "do not confine their reach to particular applications of those laws."[27] In addition, the Supreme Court stated that "the underlying functional concern here is a *relative* one: how much future innovation is foreclosed relative to the contribution of the inventor"; "even a narrow law of nature (such as the one before us) can inhibit future research."[28] As the Supreme Court noted, "Patent protection is, after all, a two-edged sword."[29]

In so holding, the Supreme Court rejected Prometheus's argument that "a principle of law denying patent coverage here will interfere significantly with the ability of medical researchers to make valuable discoveries, particular in the area of diagnostic research."[30] The Court noted that other medical experts (including doctors) argue against a legal rule that would sustain the Prometheus claims because of concerns that "a vast thicket of exclusive rights over the use of

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[23] *Id.*

[24] *Id.* at 18.

[25] *Id.* at 16.

[26] *Id.* at 17 (citing Lemley, Risch, Sichelman, & Wagner, Life After *Bilski*, 63 Stan. L. Rev. 1315 (2011) (arguing that § 101 reflects this kind of concern), C. Bohannan & H. Hovenkamp, Creation without Restraint: Promoting Liberty and Rivalry in Innovation 112 (2012), and W. Landes & R. Posner, The Economic Structure of Intellectual Property Law 305-306 (2002)).

[27] *Id.* at 18.

[28] *Id.* at 20 (emphasis in original).

[29] *Id.* at 23.

[30] *Id.* at 22.

critical scientific data" must remain widely available "if physicians are to provide sound medical care."[31]

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This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues addressed in this memorandum should be directed to:

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[31] *Id.* at 23.

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