

MARCH 2012

SUPREME COURT HOLDS THAT DIAGNOSTIC CLAIMS INCORPORATING ONLY KNOWN STEPS AND A LAW OF NATURE ARE NOT PATENTABLE

On March 20, 2012, the U.S. Supreme Court issued a decision in *Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc.*, No. 10-1150, holding that several claims drawn to measuring drug metabolite levels from patient samples were not patentable subject matter under 35 U.S.C. §101. Although the Court's decision may affect some diagnostics patents, the Court provided several clues on how to construct such claims so as to meet patentability requirements. This decision, however, represents a fundamental shift in the law of patent eligibility, and companies—especially diagnostics companies—that own or license patents and patent applications with claims incorporating “laws of nature” should review their claim strategies in light of *Prometheus*.

Overview

Section 101 of the Patent Act provides that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

Past U.S. Supreme Court cases addressing this part of the statute have ruled that the language is to be given broad scope and applicability, but that the scope of patentable subject matter is not unlimited. A longstanding limitation was provided in *Diamond v. Chakrabarty*, where the Supreme Court held that laws of nature, physical phenomena, and abstract ideas fall outside the scope of patentable subject matter. Thus,

such things as unmodified living organisms, pure elements, and mathematical algorithms are not patentable.

The Supreme Court also addressed patentable processes more recently in *Bilski v. Kappos*. Specifically, the Court rejected the “machine-or-transformation” test developed by the Federal Circuit as the only test to define a patentable process. Under the machine-or-transformation test, a process was patentable if it was tied to a machine or apparatus, or had a transformative step. The Supreme Court, however, held that the machine-or-transformation test offers “a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under §101,” but that it was not the only analytical tool for determining the patentability of process claims.

After deciding *Bilski*, the Supreme Court directed the Federal Circuit to reexamine its holding in the first *Prometheus* case, where the Federal Circuit held that the claims at issue were patent-eligible under §101. Under the *Bilski* test, the Federal Circuit reaffirmed the patentability of the claims at issue under §101, and the Supreme Court granted review.

Brief Case Summary

The *Prometheus* claims involve the analysis of levels of 6-thioguanine, a metabolite of thiopurine drugs, in a subject receiving these drugs. 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)—that were asserted against The

Mayo Clinic. The Supreme Court limited its analysis to Claim 1 of the ‘623 patent as typical of the claims at issue. The 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 pmol per 8×10^8 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 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

After the Federal Circuit held the claim to be patent-eligible following the *Bilski* decision, Mayo again petitioned the Supreme Court. Specifically, Prometheus asserted that its claims were drawn to research and therapeutic processes in personalized medicine, warning that, without patentability of such claims, the U.S. biotech industry would be harmed severely. The Mayo Clinic,

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on the other hand, portrayed the patent as an attempt to monopolize a law of nature. On behalf of the Department of Justice, the U.S. Solicitor asserted that, while the claims were patent-eligible under §101, they probably were not valid for other reasons.

Analysis of the Claims

In analyzing the claims, the Court first identified that the claims encompassed a law of nature. According to the Court, “[t]he relation [between 6-thioguanine levels and thiopurine overdose or underdose] is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.” Having determined that the claims encompassed a natural law, the Court analyzed whether the claims merely embodied that law of nature or contained sufficient additional limitations “to qualify as patent-eligible processes that *apply* natural laws” (emphasis in original).

The Court deconstructed the individual parts of the claim, namely the “administering” step, the “determining” step, and the “wherein” step. It also analyzed the steps of the claim as an ordered combination. Regarding the “administering” step, the Court held that this phrase referred only to a “relevant audience,” namely doctors treating patients with thiopurine drugs. The Court noted that such doctors were a group that existed before the assertion of these claims. Turning to the “wherein” clauses, the Court stated that these limitations merely told doctors about the “natural law” of metabolite levels, “while trusting them to use those laws appropriately where they are relevant to their decisionmaking.” Finally, the Court noted that the “determining” step tells a doctor to determine the metabolite level “through whatever process” is desired. The Court noted that, as stated in the patents, methods for determining metabolite levels were known in the art. Finally, the Court concluded that the combination of steps added nothing more to the claim than the individual steps alone, amounting “to nothing significantly more than an instruction to doctors to apply the

applicable laws when treating their patients.” For these reasons, the Court held the claims to be patent ineligible as drawn merely to a law of nature without significant modification, stating:

Beyond picking out the relevant audience, namely those who administer doses of thiopurine drugs, the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law. These instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field . . . the effect is simply to tell doctors to apply the law somehow when treating their patients.

Observations on the Holding Regarding the *Prometheus* Claims

Although the Court held these claims ineligible for patentability as insignificant modifications of a law of nature, the decision should not be read as a death knell for all diagnostics claims. In light of this decision, future cases will develop the boundaries of the minimum threshold for meeting the requirements of §101. Specifically, the Court cautioned that its decision did not determine whether the correction of any single problem present in the claims at issue would satisfy §101; however, the Court did leave open that possibility. As the Court warned, to meet the requirements of §101, a claim must recite particular steps to differ significantly from one that merely reads, “apply the ‘law of nature.’” Thus, we expect that several approaches to drafting diagnostic claims can be utilized to address the concerns raised by the Court and still meet patent eligibility for claims involving “laws of nature.”

The Court repeatedly noted that the claims involved previously known and widely utilized

steps. However, citing various precedent, the court reaffirmed that a “new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.” Thus, claims covering new combinations would be capable of meeting the test for patentable subject matter following the *Prometheus* decision. Furthermore, where a new “law of nature” is discovered—such as new associations between known biomarker(s) and disease status, associations between new biomarker(s) and disease status, or metabolite-level determinations for a new drug—and incorporated into a diagnostic claim, such claims should meet the patent eligibility requirements of §101.

Additionally, the Court noted that the steps included in the claims, in addition to the “law of nature” step, did not limit the claims to a particular application of the law of nature. Thus, claims including a clause limiting the natural law to a specific application—such as a particular analytic methodology—could meet the *Prometheus* requirements. Based on prior decisions, however, limiting claims to a single field of use, such as a single disease, is not likely to suffice.

The Court also noted that the “determining” step was so generally worded that the claims would cover future and presently unknown methods of determining metabolite levels. Thus, such claims might impede innovation by blocking others from developing future technologies for metabolites. Therefore, it is possible that the inclusion of a specific method or set of methodologies limiting any “determination” steps in a claim arguably incorporating a “law of nature” could satisfy the patent eligibility requirements.

Finally, nothing about this decision indicates that DNA, RNA, proteins, or other naturally occurring biomarkers should be considered a “natural law.” More clarity on the impact of this decision on the patentability of DNA/RNA-based diagnostic methods will be obtained once the Federal Circuit and other courts have applied the *Prometheus* decision to future cases. In fact, just yesterday in the

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Myriad case, the Supreme Court granted certiorari, vacated the Federal Circuit decision, and remanded the case back to the Federal Circuit for further proceedings consistent with the Court's decision in the *Prometheus* decision. The outcome of the Federal Circuit's application of the *Prometheus* decision to the *Myriad* case likely will be instructive to the patentability of DNA/RNA-based diagnostic methods. Even if later case law developments determine that such molecules fall under the "natural law" category, the above approaches could be used to meet patent eligibility requirements.

Summary

This decision represents a shift in the current legal paradigm of patent eligibility for method claims incorporating a "law of nature," and the full effects are not yet known. It should be remembered that this decision is only relevant to process or method claims that actually incorporate these laws. The decision also points to potential ways to achieve patent eligibility for such claims. First, process or method claims incorporating new methods, new laws of nature with a specific application, or new combinations of known steps should meet the requirements set forth in *Prometheus*. Second, limiting method

claims incorporating natural laws to particular methodologies could satisfy these requirements. Finally, drafting claims that require a particular application of a law of nature, and do not merely recite an unspecified application of the natural law, could satisfy §101.

The implications of this decision for the patentability of diagnostic claims readily are apparent based on the particular facts of the case. It also is important to note that this decision, while dealing directly with a diagnostic claim, is broadly applicable across technologies. Thus, process or method claims in other technology areas should be reviewed to determine whether they incorporate "laws of nature." If so, similar claim strategies can be considered in order to meet the patent eligibility test put forth in *Prometheus*.

Wilson Sonsini Goodrich & Rosati was and is counsel of record before the lower court in this matter.

Further Guidance

For further guidance on how to evaluate your patent portfolio and patent strategy in light of this decision and its potential implications, please contact Vern Norviel, Peter Munson,

Mike Hostetler, Esther Kepplinger, Samir Elamrani, Larry Shatzer, Doug Carsten, or one of the other attorneys in the intellectual property practice at Wilson Sonsini Goodrich & Rosati.



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