

# Patent Claims Must Recite “Significantly More” than a Law of Nature

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Speaking through Justice Breyer, a unanimous Supreme Court of the United States (reversing the U.S. Court of Appeals for the Federal Circuit) held that claims directed to a blood-testing method are invalid because they do not define patent-eligible subject matter. ***Mayo Collaborative Services v. Prometheus Laboratories, Inc.***, Case No. 1150 (Supr. Ct., March 20, 2012)(Breyer, Justice). Starting from the premise that laws of nature, natural phenomenon and abstract ideas are not patentable, the Supreme Court explained that in order to transform an unpatentable law of nature into a patent-eligible method, the claims must do more than simply recite the law of nature while adding the words “apply it.” Rather, the scope of the claims must be limited by a “particular inventive application of the [natural] law.” In this instance, the Supreme Court concluded the claims embody natural relations, but fail to do “significantly more than simply describe ... [the] natural relations” and do not “add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws” (emphasis in original).

## Background

Prometheus sells diagnostic tests covered by patent and, for a time, Mayo purchased these tests from Prometheus. In 2004, however, Mayo began to use and sell its own version of the test. Prometheus filed suit and the district court found Mayo’s test to infringe, but ultimately found the patents to be invalid on the grounds that it was drawn to subject-matter ineligible for patenting under 35 USC § 101.

On appeal, the Federal Circuit reversed, finding that the claims were patentable because they recited steps that met the Federal Circuit’s “machine or transformation” test. Mayo appealed to the Supreme Court, which granted *certiorari*, but then vacated the Federal Circuit’s holding and remanded the case for reconsideration in light of its then recent holding in *In re Bilski* (*IP Update*, Vol. 14, No. 1). In *Bilski*, the Supreme Court held that the “machine or transformation” test was not the definitive test for patentable subject matter, but merely an informative tool for determining the patentability of subject matter within the context of a more holistic approach.

On remand, the Federal Circuit again found the claims to recite patentable subject matter. Mayo again appealed to the Supreme Court.

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The claims recite methods physicians may use to determine if a patient’s administered dose of a thiopurine drug is too low and thus ineffective or too high and thus potentially toxic. Because different patients metabolize drugs differently, it is not always easy for a physician to initially prescribe the correct dose. Claim 1 of the Mayo patent is exemplary and states:

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
  - (a) administering a drug ... to a subject having said immune-mediated gastrointestinal disorder; and
  - (b) determining the blood level of [the drug] in said subject having said immune-mediated gastrointestinal disorder, wherein the level of [the drug] less than about [a lower limit] indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of [the drug] greater than about [an upper limit] indicates a need to decrease the amount of said drug subsequently administered to said subject.

As viewed by the Supreme Court, this claim essentially recites a two-step method: an “administering” step, in which a drug is administered in any possible way; and a “determining” step, in which levels of a metabolite of the drug are measured, again in any possible way. The claim concludes with “wherein” clauses that do not recite an actual step of modifying the dosage level, but merely specify observation of certain metabolite levels “indicates a need” to either increase or decrease the dosage of the drug during the administering step. In other words, the Supreme Court found claims do not require dose modification to occur, but merely what a treating physician might learn from observing the metabolite levels.

The Supreme Court concluded the claims do not sufficiently transform a natural law, *i.e.*, the correlation between a metabolite level and the need to increase or decrease drug dose, into a patent-eligible *application* of the law because “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.” As Justice Breyer explained: “If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.”

The Supreme Court analyzed whether the claims include the requisite “additional features” by examining each part of the claim individually and the claim as a whole. The Supreme Court found the steps of the claim “simply tell doctors to gather data from which they may draw an inference in light of the correlations” and ultimately concluded “the steps are not sufficient to transform unpatentable natural correlations into patentable applications ... .”

The Supreme Court explained that, when a patent claim involves reliance on a natural law or correlation, the claim must contain “significantly more” than that natural law alone. It concluded that Prometheus’ claims fail in this regard because the claimed method steps “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” and simply “tell doctors to apply the law somehow when treating their patients.”

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## Patent Claims Cannot Monopolize Laws of Nature

A theme running through Justice Breyer's opinion is the policy concern that the "patent law not inhibit further discovery by improperly tying up the future use of laws of nature." The Supreme Court acknowledged that, on one hand, discovery of new natural laws is important and should be encouraged. On the other hand, however, "those laws and principles, considered generally, are 'the basic tools of scientific and technological work,'" and denying the scientific community access to those tools will stifle future innovation (quoting *Gottschalk v. Benson*).

The Supreme Court reviewed several *amici curiae* on both sides of the issue and ultimately concluded "the underlying functional concern here is a *relative* one: how much future innovation is foreclosed relative to the contribution of the inventor." In *Prometheus*, the Supreme Court found the claims tip the balance too far in the direction of stifling innovation by tying "up the doctor's subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the correlations."

Indeed, the Supreme Court contrasted two prior cases it heard relating to the patentability of claims involving laws of nature, *Diamond v. Diehr* (*upholding* claims involving natural laws) and *Parker v. Flook*, (*invalidating* claims involving natural laws). The Court likened *Prometheus* to the situation in *Flook*, stating the claims in both cases simply recited laws of nature and instructions to apply those laws in known, conventional ways.

### 35 USC § 101 Should Not Be Conflated with Other Patentability Provisions

In its *amicus* brief, the U.S. government argued that almost any step beyond a simple recitation of the law of nature should suffice to meet the § 101 standard and that other sections of the code (e.g., 35 USC §§ 102, 103 and 112) are sufficient to screen claims for patentability. The Supreme Court rejected this argument, noting that such an approach "would make the 'law of nature' exception to 35 USC §101 patentability a dead letter."

While acknowledging that sometimes the §§ 101 and 102 inquiries "sometimes overlap," the Supreme Court concludes the inquiries are different, "[a]nd to shift the patent eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do."

The Supreme Court expressly declined the invitation of the U.S. government to simply discount or ignore a law of nature, to the extent it is recited in a claim, when evaluating novelty (§ 102) or obviousness (§ 103) as a whole or when evaluating compliance with § 112, noting that such an approach would "not [be] consistent with prior law;" citing to *Bilski*, *Diehr*, *Flook* and *Benson*.

**Practice Notes:** The Supreme Court did not completely shut the door on all claims involving laws of nature. It confirmed that claims to novel compositions or methods of treatment will still constitute patentable subject matter, even if they involve laws of nature. Nevertheless, this decision may have substantial implications for the fields of personalized medicine and medical diagnostics, potentially affecting their business models. Patent owners and licensees may wish to review and analyze their claims in view of *Prometheus*, and might consider taking actions (e.g., through reexamination or reissues) to address any perceived weaknesses.

*Prometheus* stands for the proposition that there are no absolute bright-line rules for determining patent-eligible subject matter under § 101. While the precise claim language is important for determining whether claims are patent eligible, the Supreme Court expressed concern with too-clever practitioners trying to draft around the § 101 requirement, stating that patent eligibility should not “depend simply on the draftsman’s art.” Thus, the particular law of nature, the method steps in applying the law of nature, and the scope and field of the claim are all relevant factors that should be considered when determining whether claims define patent-eligible subject matter. At a minimum, it is appropriate for claim drafters to parse out the law of nature in the claim from the other claim language and ensure the remaining claim language recites substantial additional features that go beyond a mere instruction to apply the law of nature. What is not absolutely yet clear is what language will suffice to meet the *Prometheus* standard.

In the wake of its decision in *Prometheus*, the Supreme Court (on March 26, 2012) remanded the so-called breast cancer gene case, ***The Association for Molecular Pathology v. Myriad Genetics***, Case No. 10-725 (*IP Update*, Vol. 14, No. 8), back to the Federal Circuit for reconsideration in view of the *Mayo* decision. In July, the Federal Circuit (in a 2-1 decision reversing the SD NY) ruled that the isolated BRCA1 and BRCA2 genes were patentable because they were “markedly different” from naturally occurring molecules.

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