

## Supreme Court Strikes Down A Diagnostic Method in *Prometheus*: Laws of Nature Coupled With “Well-Understood, Routine [And] Conventional” Steps Not Patent Eligible

On March 20, 2012, the United States Supreme Court issued a unanimous decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, holding the claimed diagnostic methods ineligible for patent protection under Section 101 of the Patent Act. Justice Breyer wrote the opinion for the Court, which held that the treatment methods for optimizing therapeutic efficacy merely “set forth laws of nature” and that the additional steps of the claims were too “well-understood, routine, [and] conventional” to bridge the gap between an unpatentable law of nature and a patent-eligible *application* of those laws. Recognizing that the Section 101 patent-eligibility inquiry and the validity inquiry under Sections 102/103/112 “might sometimes overlap,” the Court nevertheless declined the invitation of the Government to do away with a separate 101 inquiry. A machine or manufacture may be inventive but it is not necessarily patent eligible.

The claims at issue were directed to an application of a natural phenomenon – namely, the relationship between the concentration in the patient’s blood of certain metabolites following treatment with thiopurine drugs and the likelihood that the drug dosage will be ineffective or induce harmful side-effects. In particular, the claims required “administering” thiopurine drugs to a patient, “determining” the level of the metabolites, and “wherein” clauses that suggested to physicians that they perhaps modify the drug dosage depending on whether the level of metabolites were too high or too low.

In analyzing the claims, the Court first held that the “administering” step simply referred to “a pre-existing audience” of doctors who used thiopurine drugs to treat patients prior to the patented claims. By contrast, the Federal Circuit, which twice held the *Prometheus* claims patent eligible, pointed to that step as transformative in the context of the patient to whom the drug was administered. Such a transformation, the Court held, was “irrelevant.” The Court also rejected the notion that limiting the use of the method to a particular technical environment could circumvent the prohibition against patenting abstract ideas. Second, the Court held that the “wherein” clauses simply told a doctor about the relevant law of nature, here the known correlation of metabolite levels and drug efficacy and toxicity, and added a suggestion to “take those laws into account when treating [a] patient.” Third, the Court held that the “determining” step was only an instruction “to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field.” The Federal Circuit had also found this step transformative in terms of the blood sample collected for analysis. The Court, however, hypothesized that methods might exist or be developed to “determine” without transformation. While affirming that the Federal Circuit’s machine-or-transformation test is a “useful clue” to patentability, the Court held that the test did not trump the law of nature exclusion and simply “fails” with regard to the *Prometheus* claims at issue.

When viewed in combination, the Court held, the three claimed steps “consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.” Notably, the Court reaffirmed the notion that “[p]urely ‘conventional or obvious’ ‘[pre]-solution activity’ is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.”

In supporting its decision, the Court pointed to many of its 35 U.S.C. § 101 precedents. Justice Breyer contrasted the *Prometheus* claims to the patentable process for applying a mathematical equation to the molding and curing of rubber in *Diamond v. Diebr*, holding that the *Diebr* claims, but not the *Prometheus*

claims, had multiple additional steps that were not “in context obvious, already in use or purely conventional.” He then found the Prometheus claims more similar to the unpatentable process for applying a mathematical equation to update alarm limits in *Parker v. Flook* where any additional steps were “all ‘well known’ to the point where, putting the formula to the side, there was no ‘inventive concept’ in the claimed application of the formula.” Justice Breyer also observed, “[i]f 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.” He concluded that “[t]he claim before us presents a case for patentability that is weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*.”

The Court emphasized concerns that patents must not interfere with future uses of laws of nature. The Court seemed particularly concerned with interfering with a physician’s treatment decisions. Justice Breyer referred to *Bilski v. Kappos*, where the Court concluded that allowing “petitioners to patent risk hedging would preempt use of this approach in all fields.” The Court, however, suggested that in other cases a different balance might be struck between the risk of foreclosing future innovation and the relative contribution of the inventor to a technical field. And, it pointed to Congress as the best able to craft finely tailored rules applicable to specific fields of endeavor (for example, the special rules for plant patents).

For those who own or seek method patents that are based on the application of laws of nature, the Court’s decision may have a significant impact. The Court, however, did not do away with these patents. In fact, the Court expressly stated, “[w]e 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,” meaning that such patents incorporating an “inventive application” or “inventive concept” in a particular application of the law of nature could still be patent-eligible. The Court also contrasted the Prometheus claims with “a typical patent on a new drug or a new way of using an existing drug,” implying that the patentability of such claims is not in question. Ultimately, it will be up to patent applicants, the Patent and Trademark Office, litigants, and the courts to determine which methods claim unpatentable principles or abstract ideas and which are sufficiently inventive applications of those principles or abstract ideas to merit a patent.

The profound effects of this decision are already apparent. *Certiorari* is pending before the Supreme Court in *Association for Molecular Pathology, et al. v. USPTO, et al.* (the Myriad Genetics case), where Myriad’s patents cover breast cancer genes as well as related method claims. In *Myriad*, the Federal Circuit held that claims to diagnostic methods reciting “comparing” and “analyzing” steps were not patent eligible as being directed to abstract mental processes. Indeed, it contrasted those steps with the “administering” and “determining” steps of Prometheus, which it held were transformative and breathed patentability into the claims. The Supreme Court’s decision today would seem to bode poorly to the Court’s granting *certiorari* on those claims. The question of the patent eligibility or ineligibility of Myriad’s claims to DNA molecules as mere products of nature or as changed chemical compounds as the result of an “isolating” step remains for the Court.

To find out how the Supreme Court’s decision in *Prometheus* affects your interests, please contact your usual Ropes & Gray attorney or one of the following Ropes & Gray IP attorneys:

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