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Patentability of Personalized Medicine Under Attack by Unanimous Supreme Court

On March 20, 2012, the U.S. Supreme Court unanimously held in *Mayo Collaborative Services v. Prometheus Laboratories* that a method for administering a drug and determining a personalized medicine dosing level constituted patent ineligible subject matter because it fell within the prohibition against patenting laws of nature. The decision was surprising to many observers, given recent guidance by the Supreme Court in *Bilski v. Kappos* (2010), which suggested that including transformative steps would qualify a method of using a natural law or abstract idea as a patentable application. The Court also relied on the well-known and conventional nature of the drug's administration to invalidate the claims.

On March 26, the first aftershocks of this decision were felt when the Court issued an order vacating the U.S. Court of Appeals for the Federal Circuit's decision and remanding the case of *Association for Molecular Pathology v. Myriad*, directed to patent eligibility of genes, mutated gene fragments and diagnostic tests, back to the Federal Circuit for further consideration in view of its opinion in *Mayo*.¹ The lower courts must now determine whether a claimed invention that encompasses a law of nature includes significantly more inventive features to qualify for patentability.

The two patents at issue, of which Prometheus is the sole and exclusive licensee, were related to the use of thiopurine drugs to treat autoimmune diseases.² The inventors had identified precise correlations between metabolite levels that occur when the drug is ingested by a patient and the likelihood that a particular dosage could cause harm or prove ineffective. The resulting patent claims recited processes for using these correlations to determine subsequent thiopurine dosing. As characterized by the Supreme Court,

[e]ach claim recites (1) an "administering" step—instructing a doctor to administer the drug to his patient—(2) a "determining" step—telling the doctor to measure the resulting metabolite levels in the patient's blood—and (3) a "wherein" step—describing the metabolite concentrations above which there is a likelihood of harmful side-effects and below which it is likely that the drug dosage is ineffective, and informing the doctor that metabolite concentrations above or below these thresholds "indicate a need" to decrease or increase (respectively) the drug dosage.³

Mayo bought and used Prometheus' diagnostic tests that embody the claimed processes, but later announced it would begin using and selling another similar diagnostic test. Prometheus then sued Mayo for patent infringement.

The district court found that Mayo's test did infringe Prometheus' patents, but granted summary judgment to Mayo on the basis of subject matter ineligibility, holding that the three-step claims effectively recite laws of nature and were therefore not patentable. The Federal Circuit reversed and later reaffirmed the

¹ *Association for Molecular Pathology v. Myriad*, 566 U.S. ___, Case No. 11-725 (2012).

² U.S. Patents No. 6,355,623 and 6,680,302.

³ *Mayo Collaborative Services*, 566 U.S. ___, Syllabus at 1.

reversal on remand, finding the claimed processes to be sufficiently transformative under the “machine-or-transformation test,” which the Supreme Court recently clarified as an important clue—but not a definitive test—of patent eligibility.⁴ Because the claimed processes involved the transformation of the human body or of blood taken from the body, the Federal Circuit reached the “clear and compelling conclusion ... that the ... claims ... do not encompass laws of nature or preempt natural correlations.”⁵

A unanimous Supreme Court disagreed. Writing for the Court, Justice Stephen Breyer emphasized that the “machine-or-transformation test” does not trump the “law of nature” prohibition on patent eligible subject matter.⁶ Rather, “[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.”⁷

Applying this analysis to the patents-at-issue, the Court concluded that

the claims inform a relevant audience about certain laws of nature; any additional 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.⁸

Thus, because the patent claims at issue “effectively claim the underlying laws of nature themselves,” the claims are not directed to patentable subject matter and are therefore invalid.⁹ The Court, however, declined to comment on what “additional features” might be sufficient to transform the claims into a patentable application of natural law, noting that “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.”¹⁰

Although the effects of this holding remain to be seen, the case has the potential to affect thousands of existing patents directed to personalized medicine and other practical applications that may be construed as being a natural law. In addition, the Court’s opinion may have upset the careful balance struck between industry and academic research that has helped stimulate the development and commercialization of numerous medical innovations. The opinion also may discourage future investment and funding of innovation in biotechnology, in particular the field of diagnostic medicine, due to the uncertainty surrounding the patent protection that is considered by many to be necessary to offset the significant risks in biotechnology.

Until the ramifications of the Court’s decision become apparent, patent applicants, owners and licensees should begin to review and reevaluate existing patents and patent applications to determine whether *any*

⁴ *Bilski v. Kappos*, 130 S.Ct. 3218 (2010).

⁵ *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 628 F.3d 1347, 1355 (2010).

⁶ *Mayo Collaborative Services*, 566 U.S. ___ (slip op. at 19).

⁷ *Id.* (slip op. at 8-9).

⁸ *Id.* (slip op. at 11).

⁹ *Id.* (slip op. at 24).

¹⁰ *Id.* (slip op. at 18).

of their claims may lack patent-eligible subject matter. If so, owners of issued patents may want to consider pursuing reissues of narrower claims while applicants of pending patent applications should consider whether any claim amendments can be made to add “additional features” sufficient to transform the claims into a patentable application of a natural law.

As patent applicants, owners and licensees of new inventions move ahead with new patent applications, practitioners should pay particular attention to the transformative nature of the claims in view of the Court’s decision. Companies also should consider whether the Court’s decision provides another weapon to defend against or invalidate the potentially troublesome patents of their competitors.



If you have any questions about this Legal Alert, please feel free to contact any of the attorneys listed below or the Sutherland attorney with whom you regularly work.

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