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Law of Nature or Patentable Discovery?

Supreme Court's *Mayo v. Prometheus* Decision Raises More Questions for Personalized Medicine

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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 very 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 harnessing a natural law or abstract idea into a patentable application.

The first aftershocks of this decision were felt on March 26 when the Court vacated and remanded the Federal Circuit's decision in *AMP v. Myriad*, directed to patent eligibility of genes, mutated gene fragments, and diagnostic tests. The surprising *Mayo* decision prompts method patent owners to re-evaluate their existing patents and applications and to consider pursuing narrowing re-issues or claim amendments to add "additional features" sufficient to render the claims valid.

The Prometheus Patents

The two patents at issue were related to the use of thiopurine drugs to treat autoimmune diseases. The inventors had identified precise correlations between metabolite levels that occur when the drug is ingested 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.

The claims recite (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.

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 U.S. Court of Appeals for the Federal Circuit reversed and later reaffirmed the reversal on remand, finding the claimed processes to be sufficiently transformative under the "machine-or-transformation test," which the Supreme Court had clarified as an important clue—but not a definitive test—of patent eligibility. 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."

A unanimous Supreme Court disagreed with the Federal Circuit. 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. 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."

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."

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. The Court, however, declined to comment on what "additional features" might be sufficient to transform the claims into a patentable application of natural law.

Diagnosis for the Biomedical Industry

The *Mayo* decision has the potential to affect thousands of existing patents directed to personalized medicine and other practical applications that may be construed as being impermissibly drawn to a natural law.

Unfortunately, the Court's opinion may have upset the careful balance between industry and academic research that has helped stimulate the development and commercialization of numerous medical innovations through 30 years of Bayh-Dole sponsored technology transfer. This decision could discourage private investment in and funding of innovations in biotechnology, particularly in the field of diagnostic medicine, due to the uncertainty surrounding the availability of patent protection.

The Court recognized, however, that too broad an application of its exclusionary principle could eviscerate all patents, for all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.

On its face, the Court's conclusion would seem to mean that the application of a discovery is only patentable if the application is itself novel and not obvious, altogether apart from the novelty of the discovery. Fortunately, the Court did specifically acknowledge that the exclusionary rule ought not to be interpreted to cover newly discovered first or subsequent medical indications for a known substance.

The U.S. Patent and Trademark Office issued a memorandum providing preliminary guidance to patent examiners on the subject matter eligibility standard set forth in *Mayo*. The Patent Office will likely wait for the Federal Circuit's decision in *AMP v. Myriad*, which the Supreme Court remanded in view of *Mayo*, to issue more detailed examination guidelines on determining subject matter eligibility.

At issue in *Myriad* is the patent eligibility of not only diagnostic methods but also genes and gene fragments. The Federal Circuit previously found the isolated genes covered by Myriad's patent claims to be directed to patentable subject matter, but will have to reconsider whether this too is unpatentable naturally occurring subject matter.

Until the effects of the Court's decision become manifest, patent applicants, owners, and licensees should consider pursuing re-issues of narrower method 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.

Unfortunately, the Court's test for patentability expressed as "doing significantly more" or "adding enough" beyond the recitation of a natural law is merely a matter of degree rather than of kind, and therefore fails to provide reliable guidance for the industry. Companies also should consider whether the Court's decision provides another weapon to defend against or invalidate potentially troublesome patents of their competitors.

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