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Supreme Court Holds Diagnostic Method Claims Unpatentable in *Mayo v. Prometheus*

On March 20, 2012, a unanimous Supreme Court held that patents claiming methods for refining the dosage of drugs used to treat autoimmune diseases were directed to laws of nature and therefore not eligible for patent protection. *Mayo Collaborative Servs. v. Prometheus Labs.*, No. 2010-1150 (March 20, 2012). This is a signficant decision that is expected to have important implications in the medical and biotechnology industries.

The *Prometheus* Patents

The two patents at issue were directed to an application of the correlation between the concentration of metabolites (byproducts created when the body breaks down a drug) and the toxicity and efficacy of that drug. If the concentration of byproducts in the bloodstream of a patient is too low, the current dosage of the drug may not be effective; if the concentration is too high, the dosage might be toxic.

The claims of the patents involve two steps: (i) an "administering" step in which the drug is given to patients suffering from an autoimmune disease; and (ii) a "determining" step in which the concentration of the metabolites in the patient are determined. The patient's metabolite concentration is then compared to claimed ranges, and the physician can increase or decrease the amount of drug given to the patient depending on the comparison.

The History of *Prometheus v. Mayo*

Prometheus Laboratories is the exclusive licensee of the two patents at issue, and it sells diagnostic tests that embody the process the patents describe. The Mayo Clinic initially purchased and used the tests sold by Prometheus, but in 2004 Mayo announced that it would begin using and selling its own, slightly modified, test. Prometheus promptly sued Mayo for patent infringement in the Southern District of California.

The district court held that while Mayo's test did indeed infringe, the patents both claimed natural laws or natural phenomena and were therefore invalid under section 101 of the Patent Act. Specifically, the court determined that the correlation between the concentration of metabolites and the efficacy or toxicity of the drug was a law of nature.

On appeal, the Federal Circuit reversed in *Prometheus Labs. v. Mayo Collaborative Serv.*, 581 F.3d 1336 (Fed. Cir. 2009). Applying the "machine-or-transformation test," the court held that claimed administering and determining steps were "transformative" and involved more than just data gathering. The Federal Circuit reasoned that the administering step resulted in a transformation of the human body, and the determining step resulted in a transformation because the levels of metabolite could not be determined by mere inspection.

Mayo applied for writ to the Supreme Court, which was granted. The Court vacated the Federal Circuit's decision and ordered that the case be reconsidered in light of the Supreme Court's recent ruling in *Bilski v. Kappos*, which broadened the section 101 test beyond just the machine-or-transformation test. On remand, the Federal Circuit came to the same conclusion and Mayo once again applied for writ to the Supreme Court.

The Supreme Court's Decision

In its decision, the Supreme Court held that the claimed methods were directed to laws of nature. Specifically, the claims recited the natural and pre-existing relationship between the concentration of metabolites in the blood and the likelihood that the dosage of the drug that resulted in that concentration would be ineffective or harmful. This relationship, the Court commented, is purely a consequence of the natural processes by which the human body metabolizes the drug.

With respect to the patents at issue, the Supreme Court viewed the "administering" step as simply referring to the relevant audience – doctors who treat patients with the drug. Similarly, the "determining" step simply tells the doctor to engage in conventional and routine activity that doctors had been doing long before the patent. Lastly, the "wherein" clauses only inform the doctor about the relevant natural laws and how to apply them when making a decision about drug dosage.

"Well-Understood, Routine, Conventional Activity"

According to the Supreme Court, "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." "To put the matter more succinctly, 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."

The Supreme Court explained that a law of nature will typically not be patent-eligible if elements already well-known in the art are simply applied to that law of nature. Instead, the application of elements to the law of nature must involve an "inventive concept" which is not conventional or obvious. Accordingly, Prometheus could not transform a law of nature into patent-eligible subject matter simply by adding the well-known and routine step of measuring metabolite levels in a patient.

Justice Breyer, who authored the decision, summarized the Court's analysis as follows:

> 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.

In other words, the Supreme Court appears to be saying "don't dress a law of nature in sheep's clothing" – such as claiming it with well-known elements or as part of a prior art process – and expect it to be patent eligible. A patent eligible claim must include more than than a general instruction to "apply a law of nature" – it must include activity that transforms a process "into an inventive application of the formula." However, the Supreme Court's decision does not provide clear guidance as to what types of activities will "transform" a process into an inventive concept that goes beyond a law of nature.

The Supreme Court's decision is available at the following link:
http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf.

If you have any questions about this Information Memo, please feel free to contact any of the attorneys listed below or the Bond attorney with whom you regularly work:

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