

US Supreme Court Holds Diagnostic Patents Invalid for Claiming Laws of Nature

On March 20, 2012 the United States Supreme Court invalidated two diagnostic patents for reciting no more than laws of nature. In its unanimous opinion by Justice Breyer, the Court held that claims reciting laws of nature and no more are not patentable subject matter. See *Mayo Collaborative Services v. Prometheus Labs., Inc.*, slip op. (Case No. 10-1150, Mar. 20, 2012).

According to the Court, Section 101 of the Patent Act broadly defines patentable subject matter as “any new and useful process, machine, manufacture, or composition of matter.” The Court’s precedent, however, long ago established an exception: “[L]aws of nature, natural phenomena, and abstract ideas are not patentable.” This exception has in turn been refined such that claims reciting *applications* of laws of nature might be deserving of patent protection. In *Prometheus*, the Court provides guidance in distinguishing between claiming laws of nature and claiming applications of such laws.

The patents-in-suit (U.S. Patent Nos. 6,355,623 and 6,680,302) related to methods for optimizing the treatment of a gastrointestinal disorder involving the administration of drugs known as thiopurine compounds. When a patient ingests these drugs, they metabolize into new compounds. Because different people metabolize the drugs differently, determining whether the doses of the drugs were too high or too low had often provided doctors with some difficulty. The patents-in-suit were directed to the alleged discovery of new ways for optimizing the doses of these thiopurine compounds by measuring the amount of one or more metabolites.

The Court identified the following claim as typical of all claims in the two patents:

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
 - (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
 - (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

See U.S. Patent No. 6,355,623 at claim 1. This process or method claim has four potential elements, or limitations. The first is step (a), administering the drug. The second is step (b), determining the level of a metabolite of the drug known as 6-thioguanine. The third and fourth potential elements are the two clauses beginning with the term “wherein.” These so-called “wherein” clauses recite features or results of the active step (a) or (b), or both. So why does this claim recite no more than a law of nature?

According to the Court, the claim recites a law of nature because the relationship between concentrations of 6-thioguanine in the blood of a patient and the likelihood that the dosage of a drug will be ineffective (i.e., the dose is too low) or cause harm (i.e., the dose is too high) is the consequence of natural processes in which the drugs are metabolized in the body. When the drugs, which had been known and used for years, are administered to a patient, the drugs are naturally metabolized to 6-thioguanine. The relation between the dosage and the metabolite is thus no more than a natural law, according to the Court.

Because the claims recite a natural law, the Court had to determine whether the claims include enough additional subject matter to qualify as patent-eligible *applications* of the natural law. The Court decided that they do not.

The additional steps include step (a), the administering step, step (b), the determining step and the two wherein clauses. According to the Court, the administering step (step [a]) did no more than identify the relevant audience of the patent claim. That audience includes doctors who treat patients with the thiopurine drugs – an audience that existed long before the patent’s priority date.

Further, the Court held, the two “wherein” clauses simply inform a doctor of the natural laws discussed above.

Finally, the determining step (step [b]) is old, the Court held. In particular, methods for determining metabolite levels were well known in the art. Purely conventional or obvious pre-solution activity is not sufficient to transform an unpatentable law of nature into a patent-eligible *application* of such law.

Put more simply, a claim reciting a law of nature must recite more than well-known, routine additional steps.

The Court’s decision helpfully cites to precedent that can guide the drafting of claims that are patent-eligible *applications* of laws of nature. In *Diamond v. Diehr*, 450 U.S. 175 (1981), the Court held that the application of a known mathematical equation was patentable. On its own, the equation would have been unpatentable. The patent claims in that case, however, applied the equation through additional claimed steps that were not already in use and were not purely conventional. In other words, the added further steps transformed the equation into a patent-eligible *application* of the mathematical formula.

In *Parker v. Flook*, 437 U.S. 584 (1978), on the other hand, the patentee claimed a process that combined a mathematical formula with well-known additional steps. The Court held that purely conventional or obvious post-solution activity cannot transform an unpatentable principle into a patentable process.

The take-away from the Court’s holding in *Prometheus* is that a patent claim reciting a law of nature may be found patent-eligible provided that it *applies* the law of nature using additional steps that are neither well-known nor routine.

While *Prometheus* may have applications for other diagnostic tests, it may also have broader application in the biotechnology field generally. Indeed, the Court now has before it another case, *Association for Molecular Pathology, et al. v. Myriad Genetics, Inc.*, No. 11-725, in which the petitioner seeks review of the Federal Circuit’s decision holding that isolated DNA molecules constitute patentable subject matter. The Court will consider whether to grant *certiorari* in the case this coming Friday, March 23, with an order issued in all probability on Monday, March 26. If the Court accepts review, it may well remand the case to the Federal Circuit for reconsideration in light of *Prometheus*. In any event, we can expect on-going debate about the scope and application of *Prometheus* and its reaffirmation of the importance of Section 101 in determining the validity of US patents.

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