



Supreme Court saves medical profession from diagnostic patents

By Timothy B. Lee
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The Supreme Court today unanimously invalidated a broad patent covering a method for determining the proper dose of a drug used to treat autoimmune disorders, saving the medical profession from a [new breed of patents](#) on medical diagnostic tests.

The patent focused on the process of administering a class of drugs, called thiopurines, that are used to treat autoimmune disorders. Doctors adjust the dosage by measuring the concentration of a chemical called a metabolite in the patient's blood. The patent didn't cover the drugs themselves, nor any particular method for measuring metabolite levels—these were already widely used in the medical profession. Instead, the patent covered the concept that particular metabolite levels "indicate a need" to raise or lower drug dosage.

A firm called Prometheus Labs sold a thiopurine testing product, but in 2004 the Mayo Clinic decided to stop using Prometheus's product and begin selling its own competing thiopurine testing product. Prometheus sued, arguing that if a doctor used Mayo's test and then thought about the correlations described in Prometheus's patent, the doctor—and, indirectly, Mayo—would be infringing the Prometheus patent. Prometheus had its patent upheld by an appeals court.

The prospect of allowing patents on what amounts to human thought prompted a broad range of interest groups, including the ACLU, the Cato Institute (disclosure: I contributed to Cato's brief in the case), and the American Medical Association, to file briefs urging the Supreme Court to invalidate the patent. On Tuesday, the Supreme Court did so in a unanimous vote.

The courts have long held that laws of nature—like the correlation between thiopurine metabolites and appropriate drug dosages—are not, by themselves, eligible for patent protection. But the application of a law of nature to a particular problem may be patentable. Prometheus argued that the steps specified by the patent—administering the

drug and measuring the level of the metabolites—were sufficient to avoid violating the rule against patenting laws of nature.

But the high court wasn't convinced. In the court's opinion, Justice Stephen Breyer wrote that the patent simply instructs doctors to "engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field."

"To transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words 'apply it,'" he wrote.

Patentability rules still unclear

The opinion focused heavily on a trio of [software patent cases](#) from the 1970s and early 1980s. In the first two of those cases, the Supreme Court struck down patents on software, holding that they were unpatentable "mathematical algorithms." In the final case, decided in 1981, the high court allowed a patent on a software-controlled rubber-curing machine, holding that the mere inclusion of a software element did not preclude an otherwise patentable rubber-curing machine from getting patent protection.

The court, Justice Breyer wrote, has "endorsed a bright-line prohibition against patenting laws of nature, mathematical formulas and the like."

Yet over time, this supposedly bright line has become increasingly dull. In some sense, computer programs are nothing more than extremely complex mathematical formulas, which suggests that software might not be eligible for patent protection at all. Yet lower courts have upheld a number of software patents, and have [struggled to define](#) exactly when a mathematical formula becomes complex enough to be eligible for patent protection.

And Tuesday's decision, like a [similar 2010 ruling](#), failed to give lower courts much new guidance on the boundaries of what can be patented. We now know that you can't get a patent on the correlation between metabolite levels and drug dosages, just as we learned in 2010 that you can't get a patent on the concept of hedging against the risk of commodity price changes. But the narrowness of Justice Breyer's ruling means that it will provide little guidance on what can be patented in other fields.