On March 20, 2012, the United States Supreme Court held unanimously that a method consisting of "well-understood, routine, and conventional" steps for applying a naturally-occurring process is not eligible for patent protection. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Court addressed an increasingly complex issue: what distinguishes unpatentable natural phenomena from patentable human invention.

Laws of nature, physical phenomena, and abstract ideas are not patentable. But novel *applications* of natural laws or processes can be afforded patent protection. The need to distinguish between natural laws and patent-eligible applications—between natural phenomena and human invention—is fundamental to the patent system. Natural phenomena and abstract concepts are basic tools of scientific research and technological advance. Monopolization of them through patent protection would impede the innovation the patent laws seek to promote. But denying patents to new discoveries simply because they recite or derive from natural laws—as most technologies do—would limit the economic incentives essential to their discovery. As the Supreme Court recognized:

*Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention.*

In *Prometheus*, the Court drew the line against patentability, holding that patents covering a diagnostic method for optimizing certain drug dosages "effectively claimed the underlying laws of nature themselves," not a separate application. According to the Court: the patent added "nothing significant" beyond the natural phenomena—nothing other than "well-understood, routine, conventional activity already engaged in by the scientific community."

The legal and marketplace implications of the *Prometheus* holding remain to be seen. Medical groups supported it, arguing that claims to exclusive rights over the body’s natural responses to illness and medical treatment would impede quality medical
care. Biotechnology and pharmaceutical industry groups opposed it, fearing that a ruling against patentability would undermine current and future patent protection for—and curtail investment in—diagnostic medical techniques and other personalized medicine applications. If nothing else, Prometheus will promote future legal arguments against patentability of technologies both in and outside the life sciences.

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