

SCIENCE AND LAW

When Patents Threaten Science

Lori Andrews,^{1*} Jordan Paradise,² Timothy Holbrook,¹ Danielle Bochneak¹

What if each generation of scientists was forbidden to use—or even think about—the theorems, principles, and natural phenomena that had been discovered or proven by the previous generation of scientists? Researchers may soon find themselves in that position as the U.S. Patent and Trademark Office (USPTO) comes dangerously close to issuing patents on the basic building blocks of science itself. A U.S. Supreme Court decision in June 2006, *Laboratory Corporation v. Metabolite Laboratories* (1), and a solicitation by the USPTO in July 2006 for comments on proposed guidelines for patent examiners (2–4) have raised questions about the delicate balance between a common body of knowledge and the exclusive rights over scientific information embodied in a patent.

The patent at issue in the *Metabolite* case covered the following process: Use any test (whether patented or unpatented) to measure the level of the amino acid homocysteine in a body fluid and then, if the level is elevated above the norm, conclude that vitamin B deficiency is likely. The Court of Appeals for the Federal Circuit held that LabCorp induced infringement of that patent (and thus was liable for over \$2 million in damages) based on the publication to physicians of a law of nature—the relation between levels of homocysteine and vitamin deficiency (5). Astonishingly, the Federal Circuit also held that physicians (or researchers) would infringe the patent merely by thinking about the relation between homocysteine and vitamin deficiency when they analyzed an alternative homocysteine test (5).

As the Supreme Court contemplated the merits of the *Metabolite* case, legal scholars wrote commentaries (6, 7), and major newspapers ran editorials (8, 9) addressing the problems in the current interpretation of patentable subject matter by the USPTO and federal courts. In June 2006, the Supreme Court dismissed the appeal for procedural reasons (1), which allowed this patent on a biological fact to stay in effect.

Patents on Scientific Building Blocks and Processes

The USPTO has issued various patents that could interfere with the work of basic scientists, social scientists, and engineers. These range from correlation patents, such as the one in the *Metabolite* case, to patents on certain ways of analyzing data. Patents can chill research if the patent holder forbids other researchers from using the scientific fact or natural phenomenon, or charges an excessive fee for access to that knowledge.

One patent claims the use of a computer to derive a solution to any optimization algorithm. Optimization problems have traditionally been expressed in terms of the hypothetical traveling salesman who has to travel his route with the minimum expenditure of time and money. Commentators expressed the opinion that no one would ever attempt to patent such an obvious and important method of problem-solving (10). But in 2005, a patent was issued for the process of solving the trav-

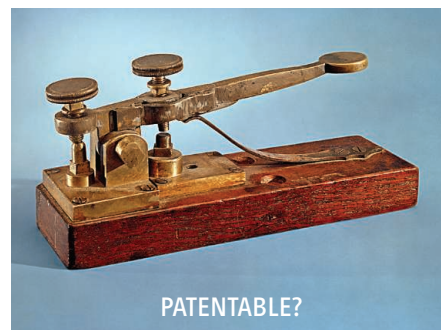
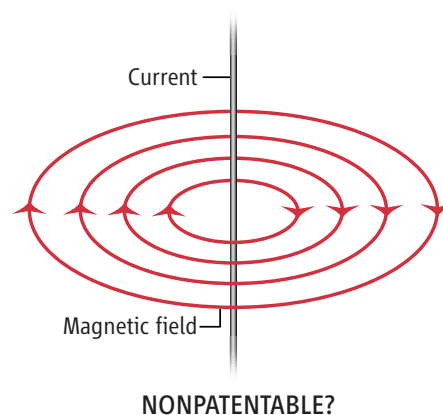
Patents should not be used to protect laws of nature, products of nature, or mathematical formulas.

eling salesman problem with a computer program that used a standard statistical algorithm outputting a set of optimal data points given certain inputs and constants (11). Although the inventor includes superficial language referencing a machine, what is actually claimed is the first step to solving any optimization or linear programming problem. The patent holder can, until the patent expires in 2021, demand a royalty from any industrial engineer, facilities planner, telecommunications analyst, or other researcher who uses this algorithm with computer assistance.

Another patent claims “a method of psychological testing of a person, comprising: (a) instructing the person to produce a drawing which includes at least one pictorial representation of each of at least a majority of the following items: a hand, an eye, a tree, a fish, a star, a spiral; a half-circle, and a zigzag; and (b) subjecting to psychological interpretation the drawing produced in response to step (a)” (12). Although the patent mentions specific pictures, a cognitive science researcher who substitutes his own drawings may be found liable of infringement under the doctrine of equivalents (13). The patent thus covers a basic psychological research evaluation technique.

The patent entitled “[d]atabase and system for storing, comparing and displaying genomic information” encompasses the very manner in which a computer user may access genomic libraries for viewing (14). Included in the claims is the “method of comparing genetic complements of different types of organisms” by means of electronic sequence libraries (14). Such a broad patent may restrict meaningful access to and analysis of genetic sequence information that would otherwise be freely available to researchers who wish to compare, for example, the genes of mice to the genes of humans.

Patents that claim the correlation between the existence of a genetic mutation and the predisposition to a disorder are also problematic (15). One patent claims the process of assessing a patient’s risk of developing certain neurological or neuropsychiatric disorders based on the presence of specific polymorphisms (16). However, mutations are natural occurrences and, if patients have the mutation,



What can be patented? (Top) Natural relationship between magnetic field and electrical current. (Bottom) Samuel Morse’s telegraph machine.

¹Institute for Science, Law, and Technology, Chicago-Kent College of Law, Chicago, IL 60661, USA. ²Consortium on Law and Values in Health, Environment, and the Life Sciences, University of Minnesota Law School, Minneapolis, MN 55455, USA.

*Author for correspondence. E-mail: landrews@kentlaw.edu

they necessarily have the predisposition. Similar to the patent at issue in *Metabolite*, a patent covering a natural correlation could apply to researchers who study the mutation and its effects, or who design tests aimed at targeting the mutation, or who even think about this relation.

Ignoring Supreme Court Precedent

A close look at patent policy and U.S. Supreme Court jurisprudence—as well as an understanding of the nature of the scientific enterprise—provides a foundation for assuring that the laws of nature and products of nature remain freely available to all. Not every discovery or innovation is entitled to patent protection. U.S. patent law dictates that patent applicants must satisfy a number of requirements in order to be issued a patent by the USPTO. An invention must be of eligible subject matter (17).

In the 1854 *O'Reilly v. Morse* case, the U.S. Supreme Court expressed its concern that granting Samuel Morse broad rights to a law of nature, beyond its particular application (the telegraph), would afford Morse the right to exclude others from making new innovations that Morse himself did not invent or even contemplate. Accordingly, the Court stated that Morse's claim to "a monopoly in [electro-magnetism's] use, however developed, for the purpose of printing at a distance" was "too broad, and not warranted by law" (18). The Court explained that patent law did not support overly broad patent rights to scientific principles because such monopolies "would be unjust to the public...and defeat the manifest object of the law" (18).

The Supreme Court continued to police the line between invention and scientific principle in *Parker v. Flook*, rejecting a patent that claimed a method for calculating updates in the catalytic conversion process as merely a mathematical formula (19). The Court reasoned that such a scientific principle, though useful, simply "reveals a relationship that has always existed" (19). Likewise, the Supreme Court in *Gottschalk v. Benson* held that a claim to the conversion of numerical data into binary code in any type of general-purpose digital computer was unpatentable because it was "so abstract and sweeping" that it was an attempt at patenting an idea rather than an inventive process (20).

In 1980 the Supreme Court handed down a seminal decision in *Diamond v. Chakrabarty* (21). Often mischaracterized as opening the door for patents claiming isolated and purified versions of naturally occurring products, including human ge-

netic material, the Court actually distinguished between a product of nature and a patentable genetically modified bacterium cell that did not exist in nature. The Court reiterated that "a new mineral discovered in the earth or a new plant found in the wild is not patentable.... Likewise, Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of . . . nature, free to all men'" (21).

Even if a patent applicant exercised considerable innovation discovering a law of nature or product of nature, neither is patentable under existing Supreme Court precedent. A person might expend money and creativity building a telescope, but he should not be able to patent the new planet he discovers through the telescope.

Justices Breyer, Stevens, and Souter, dissenting in the *Metabolite* case, said: "The justification for the principle does not lie in any claim that 'laws of nature' are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time-consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race. Rather, the reason for the exclusion is that sometimes *too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection" (1).

The idea that a patent could block future innovation, to the detriment of the public, is pertinent because the USPTO is granting patents that could block scientific inquiry. Although the discoveries of natural phenomenon may be necessary precursors to invention, improperly tying up these discoveries with patent rights will only drive up the costs of such subsequent innovations, if not thwart them altogether.

The USPTO and lower courts are responsible for granting and enforcing patent rights that run contrary to U.S. Supreme Court precedent (22). Merging the U.S. Court of Claims and the U.S. Court of Customs and Patent Appeals to create the Federal Circuit in 1982 seems to have accelerated this expansion by creating a specialized, arguably pro-patent court.

Patent applicants who seek to patent laws of nature often point to a Federal Circuit opinion, *State Street Bank & Trust Co. v. Signature Financial Group*, which suggests that a law of nature is patentable if it produces a "useful, concrete, and tangible

result" (23). However, this is clearly over-inclusive and in direct conflict with existing Supreme Court precedent (1). To be patentable, there must be something more—a human invention that produces a result beyond the law of nature or product of nature itself.

Conclusion

Scientists may not have paid sufficient attention to the privatization of common knowledge because, in the past, they felt that research activities did not require approval from patent holders. The 2002 *Madey v. Duke* decision put an end to such protection (24). Scientists can be influential by helping policy-makers understand that open access to basic laws of nature, products of nature, and mathematical formulae is necessary for scientists to explore and innovate. The U.S. Supreme Court has recognized that fact, but, increasingly, the USPTO in granting such patents and the Federal Circuit in upholding them seem to have forgotten it.

References and Notes

- 126 S. Ct. 2921 (2006).
- "Request for comments on interim guidelines for examination of patent applications for patent subject matter eligibility," *Fed. Reg.* **70**, 75451 (2006).
- Fed. Reg.* **71**, 34307 (2006).
- See also "Interim guidelines for examination of patent applications for patent subject matter eligibility," *Off. Gaz. Pat. Office* **1300**, 142 (15 November 2005).
- Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354 (Fed. Cir. 2004).
- R. S. Eisenberg, *Nat. Biotechnol.* **24**, 317 (2006).
- L. Andrews, *Chron. Higher Educ.* **52**, (24), B20 (17 February 2006).
- Wall Street Journal*, 1 March 2006, p. A14.
- New York Times*, 22 March 2006, p. A24.
- B. Klemens, *Math You Can't Use* (Brookings Institution Press, Washington, DC, 2006), pp. 46–61.
- U.S. Patent 6,904,421 (2005).
- U.S. Patent 5,190,458 (1993).
- Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 609 (1950).
- U.S. Patent 5,966,712 (1999).
- J. Paradise et al., *Science* **307**, 1566 (2005).
- U.S. Patent 6,660,476 (1999).
- 35 U.S. Code § 101.
- O'Reilly v. Morse*, 56 U.S. 62 (1854).
- Parker v. Flook*, 437 U.S. 584 (1978).
- Gottschalk v. Benson*, 409 U.S. 63, 68 (1972).
- Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
- S. Merrill et al., Eds., *A Patent System for the 21st Century* (National Research Council, National Academies Press, Washington, DC, 2004), pp. 25–27.
- State Street Bank & Trust Co. v. Signature Fin. Group* 149 F.3d 1368, 1373 (Fed. Cir. 1998), cert. denied 525 U.S. 1093 (1999).
- Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).
- Funded by the Robert Wood Johnson Foundation Investigator Awards in Health Policy Research Program; the Office of Science, U.S. Department of Energy under award number DE-FG02-06ER64276; and an NSF grant, SES 0508321.