

# The Patent Office as Thought Police

By LORI B. ANDREWS

The boundaries of academic freedom may be vastly circumscribed by the U.S. Supreme Court this term in a case that is not even on most universities' radar. *Laboratory Corporation of America Holdings v. Metabolite Laboratories Inc.* is not a traditional case of academic freedom involving professors as parties and raising First Amendment concerns. In fact, nobody from a university is a party in this commercial dispute, a patent case between two for-profit laboratories. But at the heart of the case is the essence of campus life: the freedom to think and publish.

The saga began when researchers from Columbia University and the University of Colorado Health Sciences Center developed a test to measure the level of homocysteine, an amino acid, in a patient's body. In research on thousands of people, the investigators learned that a high level of homocysteine is correlated with a vitamin deficiency: low levels of cobalamin or folate.

Other tests for homocysteine existed and were used for a variety of medical disorders. But considering theirs to be an improvement, the researchers applied for a patent. In their application, they also claimed that, because they were the first to recognize that a high level of homocysteine is connected to a vitamin deficiency, they should be allowed to patent that basic physiological fact. Thus they would be owed a royalty anytime anyone used any test for homocysteine and concluded that an elevated level signified a vitamin deficiency. They received U.S. Patent No. 4,940,658 — known as the '658 patent — and later licensed it to Metabolite Laboratories.

Laboratory Corporation of America, called LabCorp, in turn licensed from Metabolite the right to perform the test, and it paid royalties every time it used the patented method. But then Abbott Laboratories developed a homocysteine test that LabCorp considered more efficient; the new test was sufficiently novel that it did not infringe Metabolite's patent. LabCorp began using the new test.

That did not infringe the patent, either. But after LabCorp published an article stating that high homocysteine levels might indicate a vitamin deficiency that could be treated by vitamins, Metabolite sued LabCorp for patent infringement and breach of contract, and was awarded more than \$5-million in damages.

LabCorp appealed to the U.S. Court of Appeals for the Federal Circuit, which hears all patent appeals. Astonishingly, it held that LabCorp had induced doctors to infringe the patent by publishing the biological fact that high homocysteine levels indicate vitamin deficiency. The court also ruled that the doctors had directly infringed the patent by merely thinking about the physiological relationship. (Metabolite had not sued the doctors, probably because such lawsuits would have cost more than they would have netted the company and would have produced negative publicity.)

By considering publishing and thinking about a law of nature to be

actionable under patent law, the Federal Circuit court has severely threatened academic freedom. Professors everywhere should be concerned about the case, and how the Supreme Court will rule on LabCorp's appeal.

The decision has set off a rush to the patent office to assert ownership over other scientific facts and methods of scientific and medical inquiry. In an amicus brief to the Supreme Court, a group called Patients Not Patents quoted a recent application seeking to patent "a method of evaluating a risk of occurrence of a medical condition in a patient, the method comprising: receiving a patient dataset for the patient; and evaluating the dataset with a model predictive of the medical condition." The holder of such a patent could sue any doctor who was engaging in the practice of medicine, or any researcher who was trying to develop new ways to diagnose or treat an illness.

It has been a quarter-century since the Supreme Court's last landmark patent case, *Diamond v. Chakrabarty*, which allowed the patenting of genetically engineered bacteria. But that case contains a clue as to how the justices might decide this one. The court said: "The laws of nature, physical phenomena, and abstract ideas have been held not patentable. ... Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. 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 and reserved exclusively to none.'"

Further, in a 1948 case, *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, the court considered a patent on the biological properties of certain bacteria used in the inoculation of seeds. While noting that the discovery was "ingenious," the court held that "he who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes."

There are good policy reasons for not granting patents on laws of nature, which the Supreme Court articulated in 1853 in *O'Reilly v. Morse*. Samuel F.B. Morse had received a patent granting him not only the rights to the telegraph, which he had invented, but also broad rights to a law of nature: the use of electromagnetic waves to write at a distance. The court invalidated those broad rights, saying: "If this claim can be maintained, it matters not by what process or machinery the result is accomplished. ... Some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. His invention may be less complicated — less liable to get out of order — less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee."

Upholding the '658 patent would discourage the sharing of scientific information through publication, impede innovation, and give the patentee the type of broad rights to future inventions that troubled the Supreme Court in the Morse case. But it would also threaten medical research in a more fundamental way.

Many patients served as subjects and gave generously of themselves so that researchers could recognize an inherent biological phenomenon — the association between high homocysteine levels and vitamin deficiency. More than 300 of those patients were subjected to full clinical evaluations, including risky neurological evaluations, blood and bone-marrow smears, and repeated serum tests for antibodies over a period of two years. Almost 8,000 patients were studied and tested to discover the phenomenon. Yet neither the patent nor the researchers' publications contain any evidence that the patients were informed that medical information from their bodies would be patented.

If the Supreme Court upholds the '658 patent, it would not be unreasonable for patients in the future to refuse to participate in medical research at academic institutions. Why should people donate their time and subject themselves to potential physical risks if the result is a patent that would ultimately increase health-care costs and deter innovation?

The case was sufficiently troubling to me that I helped a patients' advocacy group, the People's Medical Society, prepare an amicus brief for the Supreme Court. As I worked on it, an old adage popped into my head: What goes around comes around.

University researchers from Columbia University and the University of Colorado were the inventors in the patent. In fact, it was originally assigned to an entity called University Patents, whose goal was to commercialize the discoveries of university professors. But by greedily going beyond their invention — a medical test — to claim rights to a basic fact of human physiology, those professors and their institutions set in motion a patent nightmare that could limit their own academic freedom as well as that of everybody else.

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