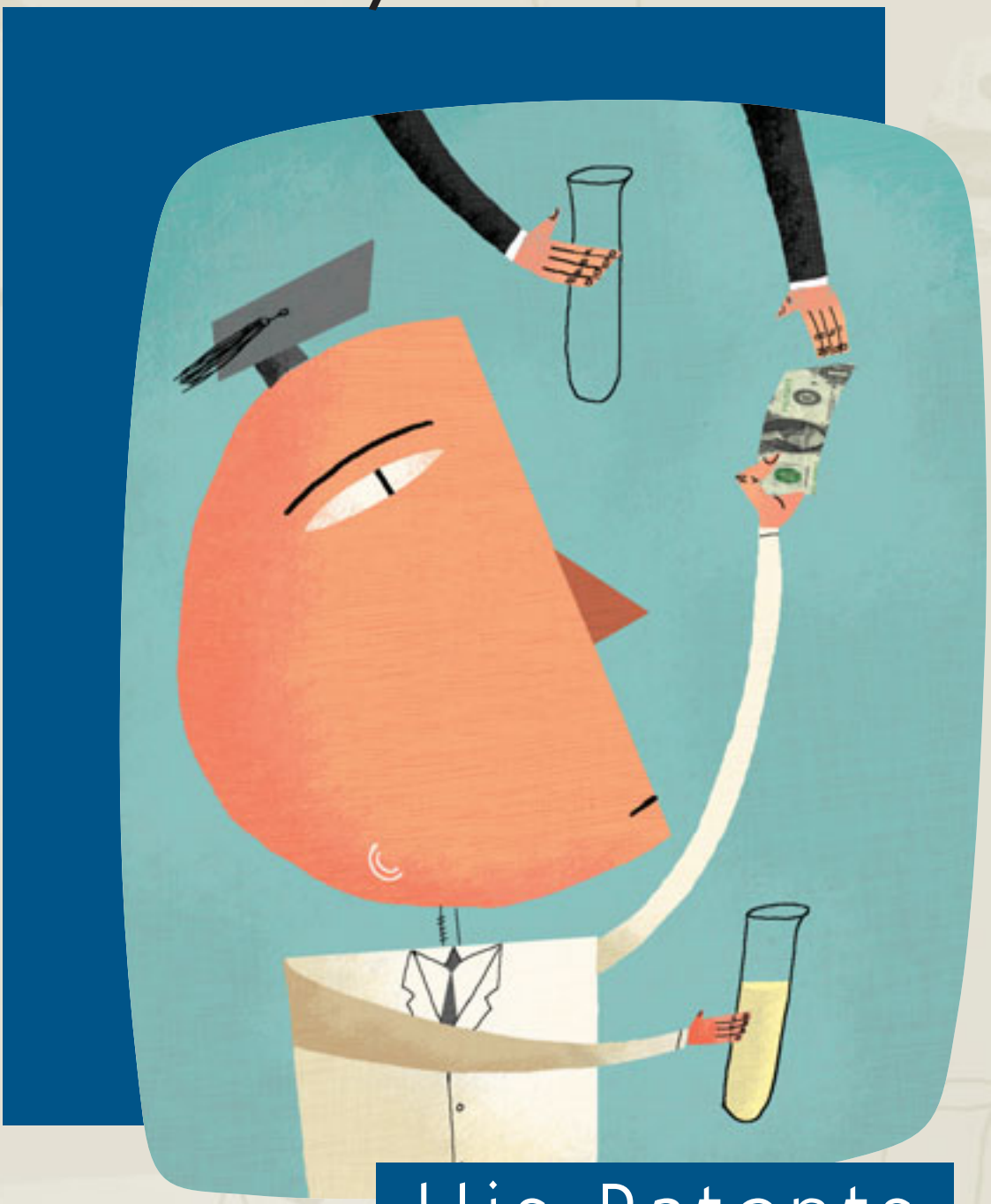
The Physicist *and*



His Patents

Cheryl M. Harris

A federal court ruling may force university researchers and officials to be more careful using technology in their own laboratories.

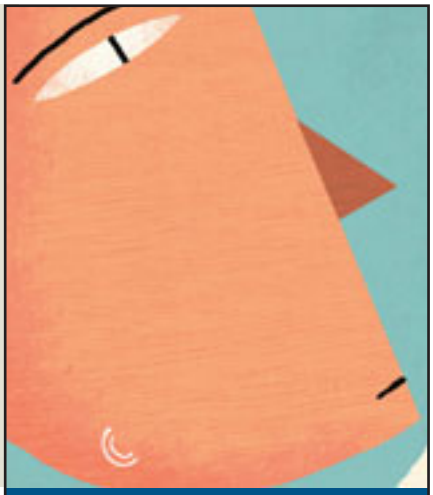
Most analytical chemists probably don't give a second thought to using, for example, a particular surface acoustic wave device or mass spectrometer in their laboratories. But now maybe they should. An October 2002 ruling in the U.S. Court of Appeals for the Federal Circuit (CAFC) may force university researchers and officials to be more vigilant about how and when they use equipment that is protected by patents.

In *Madey v. Duke University*, the CAFC ruled that a district court had improperly applied the "experimental use" doctrine in a 1999 judgment that sided with Duke University in Durham, N.C. The lower court had ruled, in effect, that the university had not committed patent infringement when it used a physicist's patented technology in research funded by the Office of Naval Research. But the CAFC concluded the university was not entitled to the "experimental use" defense—even as a nonprofit—and remanded the case to the district court for reconsideration. Duke and its supporters argue that the experimental use defense has been practiced for almost 170 years, especially by universities, and allows researchers to use patented technology for scientific research, not for commercial gain.

But the CAFC ruled that because Duke is not using John Madey's technology "solely for amusement, to satisfy idle curiosity, or strictly philosophical inquiry", it had engaged in "legitimate business objectives" and could not claim an experimental use exemption. "For example," wrote CAFC Judge Arthur Gajarsa, "major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students, and faculty."

ILLUSTRATION BY JAMES YANG

Duke University officials have petitioned the U.S. Supreme Court to hear the case. The university and its supporters claim that the ruling, if left standing, will generate unnecessary costs in patent research and legal services. Opponents of the CAFC decision argue that universities are not corporations; instead, they have conducted basic science and made new discoveries. "We're concerned that a very narrow reading of that ruling could really constrain the academic research that is out there," says David Jarmul, associate vice president of news and communications at Duke. "If that line is drawn too narrowly, it has the potential of hindering academic science."



We're concerned that a very narrow reading of that ruling could constrain academic research.
—David Jarmul

When this article went to press in May, Duke officials were awaiting word on whether the Supreme Court would hear the case this year. In April, the Supreme Court had invited the solicitor general to file a brief expressing the views of the U.S. government in the case. Whatever the outcome, attorneys and researchers see *Madey v. Duke University* as a powerful platform of debate about how universities can use patented technology and whether they should be held just as accountable as companies if they do use it without a license from the patent owner.

Reason to worry?

In January, *Science* reported that attorney Estelle Fishbein of Johns Hopkins University, which is among the universities supporting Duke's position, had told scientists that if the ruling stands, "Asia is going to be the only place where you can do cutting-edge research without facing oppressive regulation." To some, Fishbein's statement wasn't excessive at all.

The Association of American Medical Colleges (AAMC), whose membership includes 125 medical schools and 92 academic societies, has submitted a "friends of the court" brief to the U.S. Supreme Court supporting Duke's petition for review. "By effectively eliminating the exemption for even noncommercial academic scientific research, the decision erects a significant roadblock to the advancement of science," according to the AAMC brief. The brief cites an 1813 case that established a federal common law experimental use exemption. Because of that decision, according to the AAMC brief, the courts historically drew the line between commercial and noncommercial use. Thirty-one universities and member organizations have put their names on the petition.

David Korn, a physician and the AAMC senior vice president for biomedical and health sciences research, says the CAFC "created new law" in its ruling. It means that universities will have to engage in burdensome patent searching and licensing negotiations as companies do, which can cost millions of dollars, says Korn. In the last 20 years, he says, universities have intensified the patenting of their faculties' discoveries, licensing those discoveries, and getting revenue when the license pays off, and that has implications that concern him. Although the universities are patenting and licensing discoveries, the faculty is not working on "a business plan" or "business objectives or research targets," says Korn. University scientists do what they do in order to gain knowledge and solve problems for the public, he explains. "That's what drives—that's what thrills them; that's what frustrates them. That's what they teach their students. And there is a bloody difference!"

Of course, not everyone agrees that university research is in jeopardy. "The law didn't change, so the ruling didn't change the landscape," says Madey's attorney, Randall Roden of Tharrington Smith in Raleigh, N.C. "It's true that academics never understood the experimental use [rule]." On the basis of existing precedents in court, Duke was not entitled to the "experimental use" defense, says Roden, and the small differences between academic research and commercial laboratories are becoming more narrowly defined. "Why should they be allowed to infringe patents when small businesses and individuals can't?" Roden adds. "You have to have permission. . . . It doesn't matter what your purpose was."

Madey's case has created sympathy among those who have personally disputed a university's use of their technology. For about seven years, Nobel Prize winner John Fenn has been in a legal battle with former employer and alma mater Yale University over title to a patent on his method of electrospray ionization, which won him the esteemed award last year. Fenn, who now teaches at Virginia Commonwealth University in Richmond, Va., says he is in settlement discussions with Yale, which is among the universities supporting Duke's position. Fenn says universities are allowed to retain title to inventions and consequent patents resulting from research sponsored by federal agencies as long as they fulfill certain obligations spelled out in the *Code of Federal Regulations*. But Yale failed to fulfill some of those obligations, he says. Yale officials would not comment about the specifics in Fenn's case. Says Yale spokeswoman Karen Peart, "The university disagrees emphatically with Prof. Fenn's assertions."

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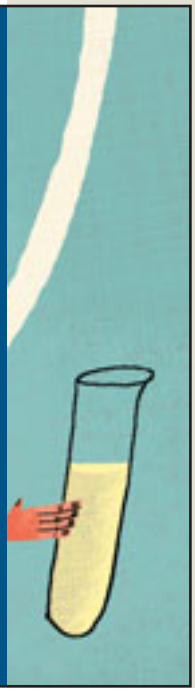
> —John Fenn



Fenn says his experience working at universities over the years has made him distrustful of the objectives of universities overall. "What the university is really selling is the research expertise and the knowledge of its faculty members, and they collect fees for that." To Fenn, universities do operate like businesses. One has only to read the advertisements for open positions on university faculties, he says. "More often than not those ads will say something to the effect that candidates will be expected to develop an externally supported research program."

Fred Regnier of Purdue University, who holds several patents, had some ambivalence after hearing about the case. "Universities license information, knowledge. They're not selling an actual product, and only in that sense can they be considered . . . to be a business." Regnier says universities sell knowledge, but, he asks, is that truly a business? "That's the question. What defines a business?" But Fenn argues that the definition of a business doesn't necessarily mean that it has to sell a packaged product. "Prostitutes sell 'love', yet everyone admits that prostitution is a business, especially for the pimp!"

Ted Pitcher, an attorney who practiced patent law for 30 years, says the appeals court ruled according to what has always been the law and that the courts don't make a distinction between how nonprofits and corporations use patented technology or methodology. He'll be surprised if the Supreme Court hears the case, he says. "This is old, old law. There's nothing startling in the opinion. What's startling is that Duke spins this as a drastic change that alters the nonprofit research environment," says Pitcher, who is now an investor for Flagship Ventures, a venture capital firm in Cambridge, Mass., that focuses on financing and building companies in the life science, information technology, and communications sectors.

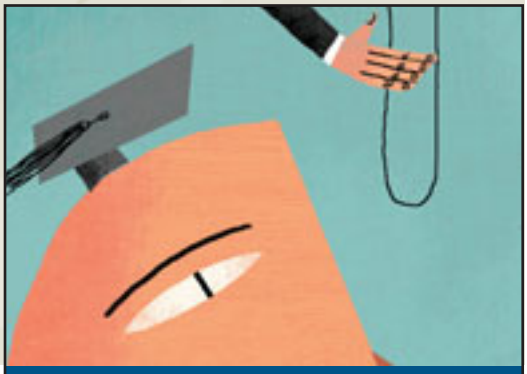
Ironically, adds Pitcher, it's the district court decision that purported to change the law. He does, however, see a political gain for Duke and other institutions if the ruling is overturned. "There're lots of people out there who don't like the patent system," he says. "They see it as 'anti-competitive'." It's in universities' interests to take Duke's position because a ruling in Duke's favor would give them more power and freedom to use patented technology at a lower cost, says Pitcher.

The ruling itself has caught the curiosity of Herb Hart of McAndrews, Held & Malloy, Ltd., a Chicago law firm that exclusively deals in intellectual property cases. Some of its clients are listed in the AAMC brief to the Supreme Court. In March, Hart presented a talk on intellectual property law at the American Chemical Society's (ACS) national meeting in New Orleans under its Division of Chemistry and the Law. Hart hasn't yet concluded whether the CAFC was wrong or right, but he was intrigued when he read its ruling. "It was very interesting to see how the district court handled these issues, and the Court of Appeals said the [district] judge didn't do his homework."

The CAFC has basically told Duke that the case needs to go back to the district court, and the district court needs to make a new ruling consistent with its opinion, explains Pitcher. If that happens, he says, it's likely that Duke will lose in the district court, and as a result, it could face an injunction and be forced to pay Madey royalties as damages for past use. And there's a whole body of law for determining "reasonable royalties", adds Hart. What makes this case so rare is that the court has addressed patent infringement issues raised by research activities at a major university, explains Pitcher. But the ruling is consistent with the law, and Duke and its supporters should know that, he says. "They make this sound like it's the end of the world."

The man behind the case

When Roden read the January *Science* article that contained



> The Federal Circuit Court created a new definition of what a university is all about.
> —David Korn

Fishbein's quote, he wasn't at all happy for his client. "All that hysteria is completely unjustified," says Roden. "It was hugely damaging to [Madey] and completely unfair." But Korn says the CAFC ruling *does* cause extreme alarm, and justifiably so. "It means the experimental use [common law] is not available to any researcher in any research university," he says. "[The Federal Circuit Court] created a new definition of what a university is all about."

The factors that have made Madey an unlikely challenger against one of the largest research universities in the country include a history of disputes with how universities were using his technology. In 1977, his research group designed the first free-electron laser (FEL) at Stanford University, which Madey had conceived as early as 1970 in his Stanford doctoral dissertation. The FEL has an electron beam source, a periodic transverse magnetic field (an "undulator" magnet), and an optical resonator. The magnet forces a beam of electrons to follow an undulating path, allowing the researcher to generate light at different frequencies. The laser has important applications in medical and materials science research in the mid-IR region.

UNIVERSITY OF HAWAII

John Madey

Madey built the first prototype with his own money, more than $100,000, because he initially couldn't get other financial support, explains Roden. When his device began capturing the attention of university and federal officials, Madey was given funding that helped improve his original design. In 1984, the physicist constructed the Mark III IR-FEL. He later gained full control of two patents based on his device and created an entire research program around it. In 1988, Duke University recruited Madey, who wanted to leave Stanford after clashing with officials over how they were charging his FEL grant money, says Roden. Madey left and brought with him to Duke about $40 million in research grants and his FEL research laboratory. After the federal government awarded North Carolina Central University (NCCU) a contract to study microwave guns, Madey's team at Duke built what is described as the "Microwave Gun Test Stand", a separate instrument, as a subcontractor to NCCU.

For almost 10 years, Madey was the director of Duke's FEL laboratory, and he lured more research funding with his device for Duke. But the relationship between Duke and Madey began to sour when, according to the CAFC ruling, Duke claimed that Madey was "ineffectively managing the lab." Madey and his attorney disagree with Duke's claims and argue that Duke sought to use the FEL equipment for research "outside the allocated scope of certain government funding," according to the CAFC ruling. In 1997, Duke removed Madey as director of the lab, and in 1998, he resigned and went to the University of Hawaii in Manoa. Duke, however, continued to operate some of the equipment in the laboratory, according to court records. Madey then claimed, among other things, that Duke was infringing on two of his patents involving the Mark III IR-FEL and sued the university.

In 1999, when the case was brought before the U.S. District Court for the Middle District of North Carolina, the lower court ruled on Duke's side. The court said that the "experimental use" defense applied to the university using Madey's patented laser technology. The lower court, according to the CAFC records, "acknowledged a common law 'exception' for patent infringement liability for uses that, in the district court's words, are 'solely for research, academic or experimental purposes.'" In the second set of alleged infringing acts that Madey presented, the district court also ruled that Duke was not infringing on patented technology because a third party, NCCU, owned and controlled the equipment. The Federal Circuit sided with the lower court on the later ruling.

But on the first set of alleged infringing acts, the CAFC reversed the lower court's decision, saying that "the district court erred in its partial dismissal, erred in applying the experimental use defense." According to the CAFC, use "does not qualify for the experimental use defense when it is undertaken in the 'guise of scientific inquiry' but has 'definite, cognizable, and not insubstantial commercial purposes.' . . . Use is disqualified from the defense if it has the 'slightest commercial implica-

tion.'" Duke had committed patent infringement after it continued to use Madey's instrument for research after he left, according to the CAFC.

Among its many lines of defense, Duke argued that it was also protected under the Bayh–Dole Act, which was adopted in 1980 and sponsored by then Senators Robert Dole and Birch Bayh. The act allows universities and businesses that operate with federal contracts to have exclusive control over many government-funded inventions. It wasn't until 1987, however, that provisions outlining the rules and obligations under the act were finalized. Madey counter-argued that the provisions under the Bayh–Dole Act cited by Duke were enacted into law after his two patents were issued. "Thus," wrote Judge Gajarsa, "some other provision may have generated the 'government rights' notation on the two patents. In sum, this discussion serves to illustrate that the government license issue needs further development before the district court if it is to ultimately provide Duke the defense it seeks."

Finally, Roden says that Duke has been ordered to send Madey the original laser system he brought with him to the university because there are still patented pieces of technology that make up the instrument. Jarmul confirms that Duke has not returned Madey's original laser system to him. "We're standing behind the government's own work that says the equipment remains here," he says. "We think the equipment properly belongs to Duke. We think we have strong legal standing that the equipment belongs to Duke."

Being patent savvy

Hart estimates that more than 90% of researchers, especially university researchers, don't truly understand patent law. Most of those who attended his talk on intellectual property at the ACS national meeting in March were industrial researchers, he adds. "Scientists don't understand patent law," agrees Gary Christian, a chemistry professor at the University of Washington–Seattle. Occasionally, they understand, "but it goes over people's heads . . . unless they have a real vested interest," he says. But times are changing, adds Christian; he believes a younger generation of scientists is becoming more attuned to patent law, and many universities now have experts to assist faculty, he says.

Pitcher adds that it's not unusual for workers in university labs to do acts that constitute patent infringement, whether deliberately or not. Researchers seem to have a good understanding of citing other researchers in written work, says Roden, but they tend to completely ignore or be unaware of when they're using patented technology in their laboratories, he adds.

Hart says researchers believe many myths about patent law. For example, some believe that mailing a description of an invention or idea to yourself is a good way to prove a date of invention, but that's not the kind of evidence that will win a case for you in the federal court, he says. Many believe that an "inventor" is any person who helps to show that an invention is workable, adds Hart, though only those who contribute to the conception of an invention can be co-inventors under the patent law. Unfortunately, researchers routinely name others, such as technicians or people who only aided in making the invention, as inventors on their patent applications. "I think managers and supervisors are named inventors on patents because it's a point of honor. Someone insists that they're named."

Understanding patent law is complex, says Hart, but the first place researchers can go if they have questions is to the university's legal department. Seeking advice from patent attorneys and doing patent searches can help ensure whether technology being used in the laboratory is patented. Some companies, such as MicroPatent in East Haven, Conn., or Thomson Delphion in Lisle, Ill., for example, offer subscriptions to updated patent searching databases via the Internet for researchers.

Scientists can also go to the U.S. Patent and Trademark Office (USPTO) for information. The USPTO grants patents for inventions, and currently the term of a new patent is generally 20 years from the date on which the application for the patent was filed in the United States or its territories. In special cases, the term of a patent can be granted from the date of an earlier, related application that was filed if the patentee pays maintenance fees. According to federal officials, patent infringement includes "the unauthorized making, using, offering for sale, or selling [of] any patented invention within the United States or U.S. Territories." The government can use any patented invention without the patentee's permission, but the patentee is entitled to obtain compensation for the use by or for the government, according to officials.

"There are a lot of misconceptions about what the patent law is and what it requires," says Hart. The people who are most savvy about patent law are the ones who've been through "the wars"—that is, adds Hart, litigation of the sort between Madey and Duke.

Cheryl M. Harris is an associate editor of Analytical Chemistry.