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SCIENCE AND THE LAW

Patent Swords and Shields

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The recent rejection by the Court of Appeals for the Federal Circuit of an "experimental use defense" to a patent infringement lawsuit against Duke University (*1*) comes as no surprise to those who follow U.S. patent law, but it is an alarming wake-up call to the academic community. Ever since Congress affirmed the right of universities to patent the results of government-sponsored research in the Bayh-Dole Act of 1980 (*2*), academic researchers and university administrators have blithely assumed that they may enforce patents on their own inventions while avoiding liability for using the patented inventions of others. This rests on a belief, widespread in the scientific community, that patent infringement requires use for commercial purposes, and does not arise in "pure" academic research.

This view finds more doctrinal support outside the United States than within it. The European Commission's recently proposed Council Regulation on the Community Patent excludes from the effects of a European community patent "acts done privately and for non-commercial purposes" and "acts done for experimental purposes relating to the subject-matter of the patented invention." (*3*). The national patent laws of many E.U. member states contain similar provisions, as does Japanese law (*4*).

The U.S. Patent Act has no statutory exemptions for noncommercial or research uses of an invention, apart from a specific provision on clinical testing of generic drugs (*5*). The academic community can nonetheless claim a whiff of authority for its vaunted experimental use defense in a line of cases going back to the 1813 opinion of Justice Story in *Whittemore* v. *Cutter* (*6*). In approving a jury instruction that defined patent infringement as "the making of a machine fit for use, and with a design to use it for profit," Justice Story speculated that "it could never have been the intention of the legislature to punish a man, who constructed a [patented] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."

As a formal matter, gratuitous statements of this sort (called dicta in legalese) are not binding authority in subsequent cases. But Justice Story's experimental use defense has enjoyed extraordinary longevity. Subsequent courts have acknowledged the availability of the defense, but have almost never applied it to the cases before them.

This is hardly surprising. Few patent holders will notice or care if someone makes a patented invention "merely for philosophical experiments." Most judicial decisions considering the scope of the experimental use defense have resolved disputes between commercial competitors. Within this universe of cases, the defense is rarely sustained, leaving its boundaries unclear.

Justice Story's early-19th-century picture of a gentleman scientist driven by idle curiosity predates the rise of the modern research university. Later courts seem to have had something closer to contemporary academic research in mind. Yet only one case, *Ruth* v. *Stearns-Roger Manufacturing Co.* (*8*), generated a published opinion holding that use of a patented invention in a university laboratory qualifies for the defense. The defendant in that case was not a university but a commercial firm that sold replacement parts for patented machines; consequently, the firm was vicariously liable for infringement by its customers. In calculating damages, the court followed a recommendation of a magistrate that excluded sales of replacement parts to the Colorado School of Mines on the grounds that these parts "were for use in laboratory machines used for experimental purposes, and consequently did not contribute to an infringing use."(*9*). Fifty years later, in 1985, a commentator who was skeptical of the experimental use defense nonetheless approved the *Ruth* decision, writing that "few would deny the experimental use exception for research on patented technology performed at a university in furtherance of its educational function." (*10*).

But 1985 seems like ancient history when it comes to universities and patents. Today, universities have become players in the patent system in a way that could hardly have been imagined before the Bayh-Dole Act. Universities owned 1.1% of U.S. corporate-owned patents issued between 1969 and 1986; by 1999 that number had risen to 4.8% (*11*). As their patent portfolios have grown, universities have become more aggressive about enforcing their patents in court. The University of California's $200 million settlement with Genentech (*12*) and the University of Minnesota's $300 million settlement with Glaxo-Wellcome (*13*) have emboldened others to follow with their own lawsuits, including Baylor College of Medicine, Cornell University, Columbia University, University of Rochester, and the Massachusetts Institute of Technology (*14*). Columbia University has further emulated commercial patent holders by petitioning Congress to extend the term of its patents (*15*). As universities shed their noncommercial innocence to reach deeper into the pockets of commercial firms, one might expect to see firms strike back with their own infringement claims, urging courts to reject the experimental use defense as a nostalgic fantasy.

But that is not what happened. Instead, the experimental use defense was taken out in an inside job, a casualty of an intra-academy squabble over control of resources. John Madey was recruited to join the physics department at Duke as a tenured professor in the late 1980s. In a previous position at Stanford, Madey had designed equipment for his research on free electron lasers. Stanford had no interest in patenting this technology itself and yielded title to Madey, as the Bayh-Dole Act permits (*16*). Duke constructed new laboratory space to house the equipment, and the Office of Naval Research (ONR) awarded Duke a grant with Madey as Principal Investigator. After some years

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the relationship soured, Duke and ONR agreed to replace Madey on the grant, and Madey resigned.

Madey sued Duke on a variety of legal theories, including patent infringement. The trial court granted summary judgment for Duke on the patent infringement claims, finding that Duke's use of the patented equipment was protected by the experimental use doctrine. Madey appealed to the Court of Appeals for the Federal Circuit (*17*).

The Federal Circuit has been signaling its discomfort with the experimental use defense for almost 20 years. That court takes very seriously its mandate from Congress to bring about greater uniformity and predictability in patent law decisions. The Federal Circuit has also consistently taken a restrictive view of judge-made, common law rules not incorporated into the language of the statute.

In the 1984 case of *Roche* v. *Bolar* (*18*), the Federal Circuit rejected the argument of a generic drug manufacturer that the experimental use defense applied to its use of a patented drug to conduct clinical trials, even as Congress was in the process of enacting a statutory defense for exactly this use as part of the Hatch-Waxman Act (*19*). The court observed that the use was "no dilettante affair such as Justice Story envisioned" but had a commercial purpose. Sixteen years later, the Federal Circuit relied on *Roche* v. *Bolar* in rejecting the defense in *Embrex* v. *Service Engineering* (*20*), noting that the defendant had "performed the tests expressly for commercial purposes." One member of the panel would have gone further to hold that "the Patent Act leaves no room for any *de minimis* or experimental use excuses for infringement." (*21*).

By the time the *Madey* case arrived before the Federal Circuit there were warning signs that the experimental use defense was not as robust as universities might hope, yet prior decisions had always seemed to leave the defense intact for pure scientific inquiry with no commercial motivation. The principal cause for concern for universities under the language of prior opinions thus appeared to be the growing difficulty in distinguishing commercially motivated research from pure academic research in the Bayh-Dole era. The most surprising move that the Federal Circuit made in *Madey* was to sidestep this issue entirely.

Sweeping aside almost 200 years of opinions that had stressed the commercial character of defendants' activities in refusing to apply the defense (including its own prior opinions in *Roche* and *Embrex*), the Federal Circuit declared the noncommercial character of the research in *Madey* irrelevant to its analysis of the case. What matters, in the Federal Circuit's revisionist account of the defense, is whether the research "is in keeping with the alleged infringer's legitimate business, regardless of commercial implications." In the case of a major research university, noncommercial research projects "unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects." Activities that further these "business objectives," including research projects that "increase the status of the institution and lure lucrative research grants, students and faculty," are ipso facto ineligible for the experimental use defense. Academic research is not "philosophical inquiry," in the court's 21st-century understanding of that term, but rather a means to advance the "legitimate business objectives" of a university. In other words, playing with the laboratory equipment might qualify for the defense, but using it in the course of serious academic research would require a license. Although the *Madey* decision did not extinguish the experimental use defense entirely, it eviscerated it to the point that it is essentially useless to research universities.

In a footnote, the court revealed that it was fully aware that "Duke … like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream." (*22*). It is hard to believe that this awareness did not inform the court's assessment, and regrettable that the court was unwilling to say so. The result is a seemingly disingenuous opinion that neither conforms to the implications of precedent nor explains the reasons for steering the law in a different direction, but pretends that prior courts never meant to give research science special treatment.

Universities have embraced the patent system as patent owners and have been in the vanguard of claimants seeking patents on "upstream" research discoveries that would have looked too far removed from the commercial marketplace to qualify for patent protection just a generation ago. Universities have barely begun to contemplate the patent system's implications for their interests as users of the patented technology of others. Generally, it is only when scientists have sought access to materials and data that they could not readily duplicate themselves that universities have entered into negotiations. Although they have haggled over the terms of material transfer agreements, they have largely ignored the growing number of patents covering technology that their scientists use without license and without apology.

As universities have become increasingly aggressive as patent owners, they have compromised their claim to disinterested stewardship of knowledge in the public interest, leaving themselves more vulnerable to patent infringement claims as defendants. With their large endowments and habits of documenting their activities in scientific publications, universities would make easy targets. Perhaps the experimental use defense could have evolved on a case-by-case basis as a tool for mediating between the private interests of patent owners and the public interest in unfettered scientific progress, but the Federal Circuit has shown no appetite for such a nuanced role. If universities are unhappy with the current state of the law, they may need to go to Congress to fix it.

References and Notes

1. *Madey* v. *Duke University*, 307 F.3d 1351 (3 October 2002).
2. Act of 12 December 1980, Pub. L. No. 96-517, Section 6(a), 94 Stat. 3015, 3019–28 (1980) [codified as amended at 35 U.S. Code § 200–212 (1994)].
3. Commission of the European Communities, Proposal for a Council Regulation on the Community Patent, art. 9 (1 August 2000), *Off. J. Eur. Communities* **43** (C 337E), p. 278 (28 November 2000); available at europa.eu.int/eur-lex/pri/en/oj/dat/2000/ce337/ce33720001128en02780290.pdf.
4. J. Mueller, *Wash. Law Rev.* **76**, 1 (2001).
5. 35 U.S.C. § 271(e).
6. 9 F. Cases 1120 (D. Mass. 1813).
7. For example, *Radio Corp. of Am.* v. *Andrea*, 15 F. Supp. 685, 687 (E.D.N.Y. 1936), *modified on other grounds*, 90 F.2d 612 (2d Cir. 1937) (assembling parts of patented combination to test them was infringement where assembly was "not a scientific research or an engineering inquiry" but rather "a step which the defendants apparently deemed necessary in the manufacture and sale of their product").
8. 13 F. Supp. 697 (D. Colo. 1935).
9. (*8*) at 703.
10. R. Hantman, *Experimental Use as an Exception to Patent Infringement*, *J. Pat. Off. Soc.* **67**, 617 (1985).
11. U.S. Patent and Trademark Office, *U.S. Colleges and Universities—Utility Patent Grants, Calendar Years 1969–2000* (U.S. Patent and Trademark Office, Washington, DC, accessed 15 December 2002); available at www.uspto.gov/web/offices/ac/ido/oeip/taf/univ/asgn/table_1.htm.
12. M. Barinaga, *Science* **286**, 1655 (1999).
13. Univ. of Minnesota, "Fact sheet on Glaxo-Wellcome AIDS discovery settlement" (5 October 1999); available at www1.umn.edu/urelate/newsservice/newsreleases/99_10glaxofacts.html.
14. M. Fisk, *National Law Journal*, 26 August 2002, p. A1.
15. "Some senators cry foul over inclusion of patent extension rider in spending bills," *Daily Report for Executives* 23 June 2000 (no. 122), p. A-41 (Bureau of National Affairs, www.bna.com, accessed 23 June 2000).
16. 35 U.S.C. § 202(d).
17. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 [codified as amended at 28 U.S.C. sections 41 et seq. (1982)].
18. 733 F.2d 858 (Fed. Cir. 1984).
19. 35 U.S.C. § 271(e).
20. 216 F.3d 1343 (Fed. Cir. 2000).
21. 216 F.3d at 1352-53 (J. Rader, concurring).
22. 307 F. 3d 1351, at n.7.

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