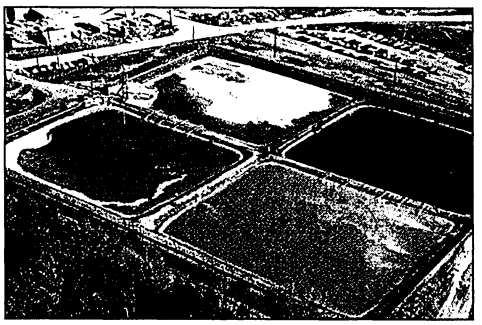

Test case. DOE will try out its bioremediating bugs at this site at Oak Ridge National Laboratory, contaminated with radionuclides and heavy metals.

At Stanford University, in as-yet-unpublished work, environmental engineer Craig Criddle and colleagues have also designed bioremediating microbes fit for a witch's brew. Criddle's team has taken a gene from a carbon tetrachloride–metabolizing bacterium known as *Pseudomonas stutzeri* strain KC and transferred it into a heavy-metal metabolizer called *Shewanella oneidensis*. Now, says Criddle, they have a recombinant strain that can both degrade carbon tetrachloride and immobilize heavy metals. But there's a catch: In lab tests, when the strain metabolizes carbon tetrachloride, it leaves behind chloroform—"and that can leave you worse off than you were before," says Criddle. So that's the next problem his team is tackling, with funding from NIEHS.

At Michigan State University in East Lansing, James Tiedje is trying a combination approach to degrade polychlorinated biphenyls, or PCBs. He starts with a natural bacterium that can consume PCBs. Then he adds genetically altered strains of two other bacteria, *Rhodococcus* RHA1 and *Burkholderia* LB400, both designed to remove chlorine and break the phenyl rings in PCBs. The mop-up effort by the engineered strains "can remove the majority of the remaining PCBs, but not all" in lab tests, says Tiedje about his as-yet-unpublished work.

In theory, says Tiedje, these PCB-eating bacteria should be ready for field-testing "by the next warm season," when they would be most effective. But strict regulations on recombinant bugs mean that these and other engineered microbes are unlikely to see the light of day anytime soon. The Environmental Protection Agency must approve any field tests of recombinant organisms. So far, out of 35 recombinant microbes approved for a variety of agricultural and other uses, only one bioremediator—a *Pseudomonas* species that fluoresces when it contacts naphthalene—has made the grade.

Suk of NIEHS and Burlage chafe at the sluggish pace with which the field is moving; in particular, they would like DOE and other funding agencies to push harder to bring recombinant bacteria to the field. "There are plenty of toxic waste sites far away from population centers that would be ideal for testing," asserts Suk. "Those are the sites to do demonstration research. We need to take some chances to restore [toxic sites] faster, better, and cheaper than we are now."

But DOE, which has some 3000 sites to clean up, is not budging. Says Patrinos: "If we rush into field-testing of recombinant microbes and it fails, we may be worse off in the long run." **–TODD ZWILLICH**

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INTELLECTUAL PROPERTY

Critics Say Rulings Give State U. License to Steal

U.S. Supreme Court rulings that give states more protection from patent infringement suits could be a potential windfall for research universities

The U.S. patent system is supposed to level the playing field for inventors. But recent Supreme Court decisions may have given states, including research universities, a leg up on the competition by making them immune from suits over patent infringement. Some lawmakers and biomedical executives are pushing Congress to pass legislation closing what they see as a potential multibillion-dollar loophole in the patent laws. But some academics and state officials say that Congress should wait to see if a problem develops before acting.

At stake is the ability of private software, biotech, and publishing companies—and even poets and musicians—to recover lost profits from state universities, hospitals, and other agencies that have copied or used their work without paying a fee. Critics say the rulings, issued last October, will tempt states to become intellectual property pirates, helping themselves to everything from patented genes to copyrighted textbooks, while at the same time shielding their own increasingly valuable patent portfolios from infringement claims. "It's inequitable … states are now in the enviable position of having their cake and eating it, too," says Q. Todd Dickinson, head of the U.S. Patent and Trademark Office (PTO). But law professor Peter Menell of the University of California (UC), Berkeley, predicts that the rulings "will have more of a symbolic than substantive impact." So far, he notes, states have claimed immunity in only a few cases, with mixed results.

"Bizarre" judgment

The debate centers on two highly technical constitutional rulings. In the cases, collectively known as Florida Prepaid, a private bank charged that a college savings program run by the state of Florida infringed on a financial patent it had obtained. In narrow 5–4 votes last October, however, the high court upheld the state's claim that it was immune from the federal lawsuit under the 11th Amendment to the U.S. Constitution, which shields states from many kinds of claims. The justices also declared unconstitutional the Patent Protection Act, which Congress had passed in 1990 to overturn an earlier Supreme Court ruling that questioned the long-standing policy of treating state patent holders the same as private entities.

The decisions sparked fierce criticism. "Truly bizarre," Charles Fried, President Ronald Reagan's solicitor general and now a professor at Harvard Law School in Cambridge, Massachusetts, wrote in *The New York Times*. If the decision stands, he and other critics claim, research labs and hospitals could use patented tests without paying royalties. They could also get into the manufacturing business, producing cheap knock-offs of popular biomedical products without fear of paying damages. State officials could even buy a single copy of a software program and copy it, while state university professors could do the same with chemistry textbooks—perhaps while offering the politically popular justification that the rip-off saved

Diet doctor. Patent commissioner Q. Todd Dickinson says states are wrongly "having their cake and eating it, too."

CREDITS: OAK RIDGE NATIONAL LABORATORY; U.S. PATENT AND TRADEMARK OFFICE

money for taxpayers. "The temptation to play Robin Hood may prove irresistible," patent attorney James Gardener of Portland, Oregon, warned in the January issue of *Nature Biotechnology*. At the same time, states could use the rulings to protect their own patent hoards from court challenge, notes Dickinson. Immunity represents "a potential windfall for the states," he believes, noting that state universities acquired at least 13,000 patents between 1969 and 1997, accounting for nearly 60% of the patents granted to all institutions of higher education. Overall, PTO statistics suggest that about 2% of all "utility patents"—the most valuable type of patent—have gone to state institutions in recent years (not counting those awarded to labs and agencies of the federal government). The University of California, for instance, last year held nearly 2000 U.S. patents that earned the school nearly $80 million, with just five inventions garnering nearly 70% of the total. State schools will face an overwhelming incentive to claim immunity to protect the income that flows from such valuable patents, the critics say.

Even some legal scholars who doubt that states will become patent thieves agree that some public universities may wield immunity to avoid paying royalties on previously patented research methods that—intentionally or unintentionally—become embedded in their own science patents. Under pressure to protect every potential source of basic research funding, "state institutions may toe and possibly cross the line," Menell concludes in a paper to be published in the *Loyola Law Review*.

So far, no one can say how many state institutions are already crossing the line. Indeed, statistics are so scarce that Senator Orrin Hatch (R–UT), chair of the Senate Judiciary Committee, has asked the General Accounting Office, Congress's investigative arm, to examine the issue. In the meantime, critics of Florida Prepaid point to a quartet of recent cases that raise potential complications. In one, the state of Texas last year successfully used the Supreme Court rulings to fend off a copyright infringement claim by an artist who accused state officials of stealing his idea for a license plate design. In another, the University of Houston got a federal judge to throw out an academic's claim that the school's press had improperly reprinted her work.

The results were less clear-cut in two science-related cases involving the University of California. In one, involving lucrative gene-engineering patents held by the biotech giant Genentech and the university, the school won a court ruling that it could claim immunity, but its impact was unclear as the parties settled out of court (*Science*, 26 November 1999, p. 1655). In the other case, in which New Star Lasers of Roseville, California, tried to invalidate a university patent, a federal district judge rejected the university's claim of immunity. In a withering opinion, Judge William Shubb noted that the school's overseers wished "to take the good without the bad. The court can conceive of no other context in which a litigant may lawfully enjoy all the benefits of a federal property right, while rejecting its limitations."

University officials decline to comment directly on the New Star Lasers case, noting that they are discussing a settlement. But Marty Simpson, an attorney in the UC General Counsel's office, says he "strongly disagrees" with the notion that state universities should be treated like any other patent holder. Instead, he believes they should be treated more like the federal government, whose liability is limited. For instance, while a losing company may have to pay triple damages in a traditional infringement case, the federal government's liability is limited only to documentable losses. Given that reality, "it becomes hard for federal legislators to argue that it's somehow shocking and highly impractical for states to be allowed to do the same thing," Eugene Volokh, a law professor at UC Los Angeles, writes in a recent *Southern California Law Review* article.

No immunity. Judge slams University of California's patent defense in case involving medical laser (*above*).

CREDIT: NEW STAR LASERS

Risking backlash

In general, Menell believes state infringement of others' intellectual property rights will be "unintentional, episodic, and relatively rare" due to a broad array of political, economic, and legal factors. States that aggressively infringe, for instance, are likely to face an intense political backlash and lose potential marketing partners. In addition, although they can't win damages in federal court, patent holders can still ask federal judges to order specific state officials to stop infringing and file damage claims in state courts.

Many industry executives, however, say pursuing such remedies would be cumbersome and expensive. "We don't have the time or money to become—or hire—experts on the property law of 50 states," says the staff attorney for one small biotechnology company. As a result, several coalitions of patent attorneys and businesses have been urging the PTO and Congress to craft legislation that would nullify the Florida Prepaid decisions. But Dickinson says a "daunting legal landscape" may make it difficult to devise a solution that will survive scrutiny by the Supreme Court.

One option is to require states to waive their right to immunity in exchange for seeking federal research grants. But skeptics say that approach—modeled on existing laws that force states receiving federal highway funds to strengthen transportation safety rules—would be unwieldy and could undermine government efforts to encourage public-sector researchers to innovate by promising them patent rights. "I would not support legislative action that would penalize our colleges and universities by withholding needed funds simply because state legislatures are unwilling to waive their sovereign immunity," says Marybeth Peters, head of the PTO's copyright office. She also worries that the court could strike down the conditions as coercive and, thus, unconstitutional.

A more promising approach, say some constitutional scholars, is legislation introduced by Senator Patrick Leahy (D–VT) that would reverse the rulings. Believing "it would be naïve" to rely on the "commercial decency" of state governments to avoid problems, Leahy proposes to allow states to obtain new patents, trademarks, and copyrights only if they renounce immunity and accept an infringement liability scheme similar to the federal government's. Each state "would be given a real choice," says Peters: "whether it is better to be a player in the system or an outlaw." The bill stagnated this year, but a Leahy aide predicts quick passage next session. The House Judiciary Committee, which held hearings on the issue this summer, is working on its own version.

Even that solution, however, could be rejected by some states and voided by an increasingly skeptical Supreme Court majority, observers warn. "The initial 'fix' failed miserably," says Gardener, referring to the 1990 Patent Protection Act, "and it is unclear that a second 'fix' will fare any better." He would prefer to see a nationwide campaign to convince state legislatures that it is in their long-term business interests to renounce immunity. "Persuading states to waive their sovereign immunity," he says, "is the only surefire method."

—DAVID MALAKOFF