Federal court raises the bar for overturning patents

A US federal appeals court ruling will make it harder for patent holders to lose their intellectual property protection because of charges—often based on small errors or omissions in patent applications—that they engaged in misconduct by misleading or deceiving the patent office. Now, except in egregious cases, such legal challenges can only succeed if the missing information would have affected whether the patent was issued in the first place.

The ruling, issued by the US Court of Appeals for the Federal Circuit in Washington, DC in late May, pivoted around a patent for the design of disposable blood glucose test strips held by the Chicago drugmaker Abbott Laboratories. Several drug companies, including a subsidiary of Germany's Bayer, had argued that Abbott's patent was unenforceable because contradictory information had been filed with the US and European patent offices. In 2008, a lower court agreed and overturned the patent license, but the latest ruling reverses that decision and establishes a new legal precedent.

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Copyright of way: New legal precedent.

The case could still find its way up to the US Supreme Court. Even so, the appeals court decision is "a very big deal," says Christian Mammen, a patent attorney in private practice who also lectures at the University of California Hastings College of the Law in San Francisco.

Mammen, together with eight other intellectual property law professors, filed a friend-of-the-court brief last year supporting the move to narrow the scope of legal challenges based what are often trivial technicalities. Last year, Mammen calculated that as many as 60% of patent lawsuits in the US center around challenges based on this so-called 'inequitable conduct', taking the focus away from more substantive issues such as a patent's novelty (*Berkeley Tech. Law J.* **24**, 1329–1398, 2009).

Inequitable conduct "has certainly gummed up patent litigation, and it has made patent litigation more expensive and time consuming," as well as caused applicants to overwhelm the patent office with extraneous information to cover their bases in the case of future lawsuits, Mammen says.

Good intentions

The old legal standard was "well intentioned," says Hans Sauer, a lawyer at the Biotechnology Industry Organization, a trade association based in Washington, DC. But the number of lawsuits based on insignificant omissions has spun out of control, he argued in an amicus brief BIO filed in the case.

As an example, Sauer points to one lawsuit, settled in 2006, in which a patent examiner had asked Ferring Pharmaceuticals to provide input from outside experts to help define certain wording before approving the filing for an antidiuretic drug. A court declared the patent unenforceable because the Swiss drugmaker did not disclose in its patent application that some of the experts had financial ties to the company. Sauer hopes that the new ruling will boost investor confidence that drug companies' intellectual property will not be shot down by such difficult-to-anticipate legal arguments.

According to Kevin Noonan, a partner at McDonnell Boehnen Hulbert & Berghoff, an intellectual property firm based in Chicago that also filed an amicus brief in the recent case, the ruling should also make it harder for generic drug companies to win favorable settlements in patent disputes with pharmaceutical firms, as such disputes often center around inequitable conduct. The Washington, DC–based Generic Pharmaceutical Association in a statement said it was "disappointed" in the decision.

Mammen and Sauer say that the ruling is unlikely to be affected by patent reform legislation now working its way through the US Congress.

Charlotte Schubert

Supreme Court decision on patent for HIV test unlikely to set major precedent

In the late 1980s, a postdoc researcher at Stanford University by the name of Mark Holodniy collaborated with Cetus Corporation, the primary patent holder of PCR, to develop a blood test for HIV that is now used in labs around the world. At the time, Holodniy signed a contract with both Cetus and Stanford; little did he know that by doing so he would set off a legal battle decades later. Roche Molecular Systems acquired marketing rights to the test from Cetus in 1991, and although Stanford applied for and received patents for the test its requests for a cut of the profits were ignored. When the California university sued for patent rights in 2005, the district court ruled in its favor, but, after Roche appealed, the Federal Circuit overturned the verdict.

Finally, on 6 June, the US Supreme Court handed down a decision, leaving some specialists aghast about its implications for government-funded discovery. The 7-2 ruling in favor of Roche came down to contractual wording, with Holodniy's agreement with Cetus stating that he "will assign and do[es] hereby assign" his "right, title and interest" in discoveries made at Cetus to the company, whereas his contract with Stanford was less committal. Detractors argue that the decision undermines the Bayh-Dole Act, which permits universities such as Stanford that receive federal grants for research to apply for patents themselves instead of turning their discoveries over to the government. If this case sets a precedent and universities aren't guaranteed patents to their discoveries, some worry that the incentive to encourage faculty to innovate will be lost, collaborations outside academia will be discouraged and contracts will have to be stricter.

Others are less bothered. "I don't think this is an earthshaking decision," says Robert Cook-Deegan, director of Duke University's Center for Genome Ethics, Law & Policy in Durham, North Carolina. The details are too specific to generalize to other cases, he argues, adding that "there is no reason this should have gone to court."

If it has any implications, it's that universities need to keep better track of their researchers, says David Resnick, a biotech patent attorney at Nixon Peabody in Boston. "If your researchers are doing projects on the side, you'd better know about it and look at those agreements," he says.

Hannah Waters

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