When the "reach-through" exceeds the grasp

Court rulings on a COX-2 inhibitor patent lead others to consider alternatives for protecting early-stage technology.

BY PHILLIP B. C. JONES

Universities and companies have often tried to maximize return on investment in early-stage drug discovery technology by filing patent applications with so-called reach-through claims. Reach-through claims aim to capture the value of downstream—and yet unidentified—products or methods. For example, a reach-through claim may cover all candidate drugs identified with a new screening method, or it could cover methods for using drugs discovered with the screening technique. David L. Nocilly, a patent attorney with Bond, Schoeneck & King, suggests that "claims of this sort were, and probably still are, inserted into most patent applications disclosing basic biotechnology research."

In February 2004, the Court of Appeals for the Federal Circuit published its *University of Rochester v. Searle* decision ruling against the university's attempted reach-through claim on COX-2 inhibitors. Mark J. Nuell, a partner in Birch, Stewart, Kolasch & Birch, thinks that the opinion significantly impacts the reach-through claim strategy. "It pretty much kills it," he says.

Reach-through claiming, often based on discoveries of new drug targets such as a receptor or enzyme, seemed like a good tactic, especially for universities and small start-up companies that lacked the means to expand on their initial work. These organizations are simply not set up to perform expensive and labor-intensive drug screening, says Debra Leith, an attorney with Heller Ehrman White & McAuliffe's IP Transactions group.

"The idea was to leverage the discovery involving the receptor or enzyme to obtain rights to yet-to-be-discovered drug products," says Michael S. Greenfield, a partner in the Chicago office of McDonnell Boehnen Hulbert & Berghoff.

"And, as opposed to the discoverer of a single drug product, the patentee who successfully obtained a reach-through claim would have rights to *all* drug products affecting the receptor or enzyme," Greenfield adds. He says the patentee would effectively control research in the area, because "only licensees would expend the time, effort, and money necessary to discover and bring drug products to market."

At least, that was the theory.

UR v. Searle

In 1992, University of Rochester researchers filed a patent application based on their discovery of the existence and distinct functions of cyclooxygenases, designated as "COX-1" and "COX-2." The inventors devised a screening assay to determine whether a particular nonsteroidal compound specifically targeted COX-2. They anticipated that such a compound would provide relief from pain and inflammation without the gastrointestinal side effects associated with most nonsteroidal anti-inflammatory drugs.

The U.S. Patent and Trademark Office issued patent no. 6,048,850 to the university on April 11, 2000, with claims to methods for inhibiting COX-2 activity in humans by administering a nonsteroidal compound that selectively inhibits the activity of the COX-2 gene product. On the same day, the university sued G.D. Searle, Monsanto, Pharmacia, and Pfizer, alleging that the sale of the blockbuster COX-2 inhibitors Celebrex (celecoxib) and Bextra (valdecoxib) infringed the patent.

Searle had developed both COX-2 drugs. The company was once part of Monsanto and was later acquired by Pharmacia, which Pfizer then purchased.

A Rochester press release offered a prediction that "over the 17-year life of the patent, royalty payments could yield the University royalties in the billions of dollars, making it the most lucrative pharmaceutical patent in history." But there was more at stake than filling Rochester's coffers, according to university officials. In a 2002 interview for *The Chronicle of Higher Education*, Thomas H. Jackson, Rochester's president, asserted that the university's lawsuit could help to establish legal precedents important to university inventors who make discoveries in fundamental science

However, a New York district court judge decided in March 2003 that the patent is invalid. While acknowledging the importance of a COX-2-specific inhibitor, the judge wrote that the inventors had not taken the "last, critical step of actually isolating such a compound, or at least of developing a process through which one skilled in the art would be directly led to such a compound." Without that step, he warned, the discoveries did not blossom into a complete invention.

PHOTO: WAYNE SCARBERRY

A University of Rochester patent based on the COX-2 enzyme research of scientists (from left) Donald Young, Virginia Winn, and Kerry O'Banion didn't have the potency the university expected.

Rochester appealed to the Federal Circuit, but in February a three-judge panel agreed with the lower court that the patent failed to adequately describe the claimed invention.

Several days later, Jeffrey Kindler, Pfizer's general counsel, said that "while Pfizer

recognizes the valuable contributions made by academic research into diseases and potential new treatments, this decision makes clear that the University played no role in the development of Celebrex." Kindler stressed that Searle had invested millions of dollars in research and development costs for Celebrex.

By the end of February, Rochester petitioned the Federal Circuit to have the entire court reconsider the panel decision. Regardless of whether the court grants the request, one party may appeal to the U.S. Supreme Court. Nonetheless, attorneys are advising alternatives to the reach-through approach for protecting early-stage discoveries.

Collaboration solution?

The University of Rochester does have another patent covering methods for identifying COX-2 inhibitors. Rochester could protect its early-stage technology with these assay claims and sue any company that attempts to sell compounds identified by the patented method.

The problem with this approach is in policing infringement, warns Stephen R. Albainy-Jenei, an attorney in the Cincinnati office of Frost Brown Todd. For example, a defendant company could assert that it identified the activity of a candidate using targets or effects not covered by the patentee's claims. "Screening patents are difficult to enforce," Nuell adds. "The processes are done behind closed doors, and it's usually expensive to find out what's going on."

There are other options for protecting embryonic technology. David J. Aston, a partner with the Palo Alto, CA, law firm of Peters, Verny, Jones & Schmitt, advises that a "company should always be aware of trade secret protection for its technology."

And Nuell agrees that companies can maintain valuable technical information as a trade secret. "But keeping secrets like that is difficult," he says, "and the inventor must act quickly before another person independently discovers the same thing."

Acting quickly is also important for protecting early-stage technology with a patent. Albainy-Jenei observes that there's a race to discover compounds that affect new drug targets and to file patent applications on them. Winning the race, he says, may necessitate partnering with a larger company.

The apparent demise of the reach-through claim strategy encourages small companies with pharmaceutical screening technology to seek co-development arrangements with companies that have high-throughput drug-screening resources. A successful collaboration generates information about candidate drugs, which will support a patent application. Aston says it may not be possible to secure patent coverage on products obtained with a new technology unless the application includes a description of at least one such product.

Albainy-Jenei agrees: "One needs to find at least one drug, if not a class of drugs, that does work on the identified target." The *University of Rochester* case might have gone the other way, he says, if the patent application had included a formula for a class of COX-2 inhibitors.

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Although Leith agrees that a small company can extract value from its early-stage technology through collaborative arrangements, she emphasizes the need for true collaboration, as opposed to an out-licensing agreement. "If the company with the secret technology can keep its hands in the project, there is the opportunity to make an inventive contribution to later discoveries," she says. And such a contribution should provide additional revenue.

Reach-through royalties

"Reach-through royalties" are another alternative to reach-through claims, Greenfield says. In this approach, a licensee makes royalty payments for using the licensed research tool or platform technology when the application of that technology results in a new product candidate. Reach-through licensing solves the problem of setting a price on basic research discoveries.

J. Scott Elmer, director of the Office of Technology Licensing at St. Jude Children's Research Hospital in Memphis, says he prefers reach-through royalties. "I know of no better way to make the compensation proportional to the benefit received from the use of the tool," he says. An alternative to a reach-through royalty is to require the licensee to pay a large up-front fee. But as a practical matter, Elmer suggests, "a non-royalty deal tends to make one side or the other look bad depending on the outcome, whereas a royalty deal tends to allow both parties to hedge their bets."

Elmer says his organization has offered licenses on its proprietary research tools with and without reach-through royalties. Offering a choice of valuation is a practice worth noting. In the October 2002 *Bayer AG v. Housey Pharmaceuticals, Inc.* case, Bayer accused Housey of committing patent misuse by attempting to acquire royalties on products not covered by patent claims. The patent misuse doctrine alleges that the patentee has extended the economic benefit beyond the scope of the patent grant. But a judge in Delaware's U.S. District Court decided that Housey had not committed an act of patent misuse by conditioning a license on royalty payments for an unpatented compound, because the company had been willing to consider other licensing terms. "It is perfectly acceptable," Greenfield says, "to base royalties on an unpatented product for the parties' mutual convenience."

There is still the possibility that a court may decide that the Rochester patent does support reach-through claims. During the past several years, however, the U.S. Patent Office's Biotechnology and Chemical Pharmaceutical Customer Partnership conferences have provided a forum for officials to assert that reach-through claims can fail to meet several patentability requirements. Thus, it seems less and less likely that the Rochester strategy will be an acceptable one. When courts and the patent office view reach-through claims with a jaundiced eye, it's worthwhile considering other options.

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