The Evolution of Patent Infringement:

High Court Addresses Reining In Scope Of Experimental Use Exemptions

By Amy I. Stickel

The U.S. Supreme Court is grappling with several high-profile issues in the second half of its current term, including the health of Chief Justice William Rehnquist, displaying the Ten Commandments on government property and the legality of the juvenile death penalty.

Merck v. Integra LifeSciences may not have received the same attention from some observers, but the High Court's ruling in that case will have important ramifications for the pharmaceutical industry and basic scientific research, according to William (Bill) L. Warren, partner and co-chair of Sutherland Asbill & Brennan LLP's biotechnology and life sciences practice.

At the heart of the *Merck* case, which the justices are expected to rule on later this summer, lies the definition of "safe harbor" under the Hatch-Waxman Act. In other words, how much protection drug developers have from patent infringement liability while conducting research to win Food and Drug Administration regulatory approval.

Since bringing new drugs to market is a very expensive and lengthy process, pharmaceutical companies need to know their legal standing when relying on the patented work of others for research. "This is a very critical issue in the age of new drug discovery," says Warren. "We need to know whether preclinical activities will be non-infringing."

The *Merck* case is an appeal from the U.S. Court of Appeals for the Federal Circuit, which has issued several surprising rulings recently broadening the definition of patent infringement.

Defining "Reasonably Related"

According to Warren, Congress basically passed Hatch-Waxman to encourage pharmaceutical companies to develop new drugs while allowing generic drug manufacturers to bring cheaper versions of drugs to market once patents expire.

The safe-harbor provision of the act, formally known as 35 U.S.C. § 271(e)(1) of the Drug Price Competition and Patent Term Restoration Act of 1984, protects competitors from patent infringement claims during the experimental phase of drug development, as long as their activities are "reasonably related to the development and submission of data under a Federal Law."

As Warren points out, while Hatch-Waxman was written with the generic drug industry in mind, the language of the act doesn't explicitly limit the safe-harbor provision to companies and research groups developing generic drugs. Any organization can claim safe harbor to make, use or sell a patented product, as long as the product's use is "reasonably related" to developing and submitting information for FDA approval.

And in recent years, district courts have tended to interpret the language of the safe-harbor provision broadly. But when ruling in the *Merck* case, the Federal Circuit opted for a much more narrow interpretation of the exemption. That ruling, along with the court's recent ruling in *Duke v. Madey*, has raised concerns in the pharmaceutical industry about whether research activities that once seemed legal will now infringe on the patents of others.

The Supreme Court's ruling on *Merck*, whether it affirms or overturns the Federal Circuit decision, will at least provide pharmaceutical companies some guidance, according to Warren. "There has been a 10-

year history of expanding the safe-harbor provision," he says. "The pharmaceutical industry is dependent on basic research, and there needs to be some clarity on what defines non-infringing preclinical research."

The *Merck* case revolves around a scientist from the Scripps Research Institute who was working with certain compounds, called RGD peptides, which showed great promise in treating cancer, rheumatoid arthritis and other diseases. Merck KGaA, a German pharmaceutical company, hired Scripps and the scientist, David Cheresh, to identify potential drug candidates using those peptides.

However, Integra held the patent on the peptides. At first, Integra offered Merck a licensing agreement for the peptides, according to the Federal Circuit decision. When Merck ultimately rejected the licensing agreement offer, Integra sued. During the July 1996 trial in the Southern District of California, Merck claimed its use of the peptides fell under the safe harbor provision—a claim the jury rejected.

On appeal, the Federal Circuit upheld the lower court ruling, finding that the safe-harbor provision of Hatch-Waxman specifically relates to research regarding generic drugs, which Merck was not involved with. According to the June 2003 ruling, Congress explicitly intended the safe-harbor provision to aid generic drug manufacturers in finding a bioequivalent generic substitute for name-brand drugs.

"The express objective of the 1984 Act was to facilitate the immediate entry of safe, effective generic drugs into the marketplace upon expiration of a pioneer drug patent," Judge Randall R. Rader wrote for the divided panel.

The court also found that Merck's clinical testing with the peptides was not done to supply information to the FDA, as the act requires. Rather, it was for "only general biomedical research to identify new pharmaceutical compounds," Judge Rader wrote. "The FDA has no interest in the hunt for drugs that may or may not later undergo clinical testing for FDA approval."

The End of Experimental Use

And in the *Duke* case, the Federal Circuit also took a narrow view of what had been a more broadly interpreted concept—in this case, the experimental use exemption of patent infringement.

The experimental use exemption is based on common law and first appeared in 1813, in *Whittemore v. Cutter*. It has rarely been invoked as a defense. When it has been used, it has been limited to defendants whose purposes are theoretically loftier than mere commercial gain.

But when John Madey sued Duke for patent infringement, the university, as a non-profit, research-driven institution, attempted to claim entitlement to the experimental use exemption. The Federal Circuit rejected that argument in October 2002 and the Supreme Court has denied certiorari, allowing the broadened definition of patent infringement to stand.

While a tenured research professor at Stanford University, Madey oversaw a "highly regarded" and "innovative" free electron laser research program, and before leaving Stanford he obtained a re-assignment of his two patents involved with the lab. Duke recruited Madey, who in 1989 moved his research lab to Duke's Durham, N.C., campus. After nearly a decade at Duke, Madey became embroiled in a dispute with university officials—he claimed the university wanted to use the laser equipment for areas that were outside the scope of its government funding, and Duke said Madey was mismanaging the lab.

After his removal as director of the lab, Madey left in 1998. However, Duke continued to use some of the lab equipment, and Madey sued for patent infringement. The District Court for the Middle District of North Carolina ruled in favor of Duke. But on appeal, the Federal Circuit overturned, saying the district court's research exemption ruling was too broad.

"In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense," Judge Arthur J. Gajarsa wrote in his opinion. "Moreover, the profit or non-profit status of the user is not determinative." The court also noted that despite the not-for-profit tax status of the university, it is clearly in business competing for grants, faculty, students and patents, and thus, the infringing activity was not purely for philosophical experimental purposes.

> The pharmaceutical industry is dependent on basic research, and there needs to be some clarity on what defines non-infringing preclinical research.
>
> **– Bill Warren, Sutherland Asbill & Brennan LLP**

"That ruling represents a sea-change for research universities and the pharmaceutical companies that rely on their basic research for new products," Warren says. "The court reasoned that even not-for-profit institutions like Duke are in business. They still have to play by the rules." This may require more university in-licensing of necessary patent rights, although there will always be corporate resistance to suing a not-for-profit. This resistance will become thinner the more universities assert their own patent rights and act like the businesses they are. "The trend toward fewer patent infringement exemptions also presents a growing opportunity for universities to license-out patents on their basic research inventions and related services," according to Warren.

So whether at an international pharmaceutical company or a research university, in-house counsel need to stay abreast of developing federal court rulings regarding patent infringement—and they need to make sure their researchers understand how the impact of those rulings can now affect their work. ■