

April 30, 2008

Patent Law Battle a Boon to Lobbyists

By [ROBERT PEAR](#)

WASHINGTON — A fight has erupted in Congress over the question of whether drug makers and other companies should be allowed to keep patents they obtained by misrepresentation or cheating.

The issue has emerged as a contentious point in legislation to overhaul patent laws. In several cases, the courts have voided patents after finding that companies intentionally misled the Patent and Trademark Office.

The legislation, affecting a wide swath of the American economy, has been a boon to lobbyists. In 15 months, two dueling business coalitions have spent \$4.3 million lobbying on the legislation, which calls for the biggest changes in United States patent law in more than 50 years. Companies from almost every major industry have joined the battle.

Patents can protect an invention for up to 20 years. But federal judges can void patents after finding that companies engaged in “inequitable conduct,” meaning that they misrepresented or concealed information with an intent to deceive the patent office. In such cases, judges can declare the patents unenforceable.

Robert A. Armitage, a senior vice president and general counsel of [Eli Lilly & Company](#), said, “This is like imposing the death penalty for relatively minor acts of misconduct.”

Brand-name drug companies are urging Congress to eliminate the penalty — or to curtail it as proposed under a bill passed by the House.

Debra S. Barrett, a vice president of the American unit of [Teva Pharmaceutical Industries](#), the world’s largest maker of generic drugs, said the changes sought by brand-name drug companies “would make it easier for them to cheat and get away with it, easier for them to defend their patents and more difficult for us to get generic products onto the market in a timely way.”

Consumer groups like [AARP](#) share that concern. They want to speed access to generic

medicines, which can cost 30 percent to 80 percent less than the equivalent brand-name drugs.

The House has approved a comprehensive patent bill that would make it harder to prove inequitable conduct. Senators are haggling over a companion bill, approved by the Senate Judiciary Committee, and hope to take it to the floor this summer.

In the last 15 years, the United States Court of Appeals for the Federal Circuit, which handles patent cases, has affirmed findings of inequitable conduct in at least 40 cases, including 14 that involved pharmaceutical or health care products. Similar findings have been issued by federal district judges in an unknown number of cases that were not appealed.

Courts have found that drug makers knowingly submitted false statements to the patent office, inaccurately described experiments and concealed information that contradicted their claims.

In one case, the appeals court said that Novo Nordisk Pharmaceuticals improperly failed to disclose that it had not performed an experiment described in its application for a patent related to synthetic human growth hormone. In another case, the court said Pharmacia had used an “inaccurate and misleading” affidavit in obtaining a patent for a glaucoma medication.

Brand-name drug companies say that generic drug makers routinely attack their patents by accusing them of inequitable conduct when they are blameless or guilty of no more than honest mistakes.

The aggressive use of such accusations has become “a plague on the patent system,” the Biotechnology Industry Organization, a trade group, told Congress.

Harry F. Manbeck Jr., who was commissioner of patents and trademarks under the first President Bush, said the existing penalty was a powerful deterrent to misconduct.

“Patents can be very valuable,” Mr. Manbeck said. “There are strong incentives to want to get them. Cheating occurs from time to time. The inequitable conduct doctrine says that if you cheated to get a patent, you should not be able to enforce it.”

Under federal regulations, people applying for a patent have a duty to deal with the patent office in “candor, good faith and honesty.” They are supposed to disclose if their invention was previously known or used by others, offered for sale or described in a publication. In that case, it may not be innovative enough to warrant a patent.

In reviewing an application, patent examiners can search the relevant literature, but may not find all the pertinent information, so they depend on applicants to be forthright.

“If Congress eliminated or reduced the penalty for inequitable conduct, applicants would no longer have a reason to disclose all the information they are aware of,” said Robert D. Budens, president of the Patent Office Professional Association, which represents 5,500 examiners.

Mr. Armitage, the Lilly executive, said: “The doctrine of inequitable conduct is used so aggressively in litigation that it has unintended consequences. Applicants give the Patent and Trademark Office too much information, to avoid allegations that they concealed anything, and they refuse to explain the information, to avoid later allegations that they engaged in some form of misrepresentation.”

[James C. Greenwood](#), president of the Biotechnology Industry Organization, said, “The poor patent examiner gets a dump truck full of information that he has to pore over without any assistance from the applicant.”

The number of patent applications — 467,243 in 2007 — has nearly doubled in the last 10 years and has more than tripled since 1987.

Jon W. Dudas, the under secretary of commerce for intellectual property, said: “We are getting more and more unpatentable ideas, worse and worse quality applications. Historically, in the last 40 years, the allowance rate — the percentage of applications ultimately approved — hovered around 62 percent to 72 percent. It went up to 72 percent in 2000, but dropped to 43 percent in the first quarter of this year.”

A major impetus for the patent legislation is the desire of technology companies to limit the damage awards and legal costs they sometimes face when they are accused of infringing patents. Companies like [Cisco](#) and Palm say the disputes drain resources that could be better spent on research and innovation.

Many of these companies have banded together in the Coalition for Patent Fairness, which in the last 15 months has spent \$2.5 million for a small army of lobbyists including Mark W. Isakowitz, a Republican, and Steven A. Elmendorf, a longtime Democratic strategist.

A rival group, the Coalition for 21st Century Patent Reform, consists of about 50 companies that zealously guard their intellectual property and are more likely to file suit to protect their patents. It includes pharmaceutical and biotech companies like [Genzyme](#), Lilly, [Merck](#) and [Pfizer](#). This coalition has paid \$1.8 million to lobbyists, much of it to the law firm of Akin Gump.

6