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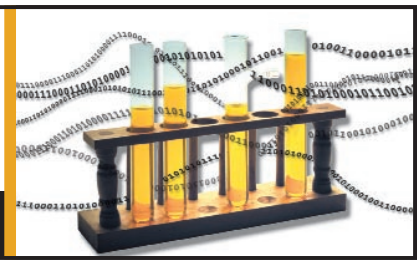
Biotech *A Practice Focus*

Patents 'R' Us?

Government grab of patent rights is possible, but dicey, undertaking.



BY RAYMOND A. KURZ AND CELINE JIMENEZ CROWSON

As we watched the terror of Sept. 11 unfold, it seemed improbable that the nation's patent laws would take center stage in the weeks to follow. Yet, as the ruins of the World Trade Center still smoldered in Manhattan, and members of Congress fled anthrax on Capitol Hill, the improbable became reality: Those same politicians began to talk about the largely arcane realm of patent law. The issues they raised are important and of constitutional proportions, although by no means new.

The focus of the debate has most recently been the drug Cipro, a leading (but not the only) antibiotic for treating anthrax. Cipro is the brand name for ciprofloxacin, for which Germany-based Bayer holds the patent. Thus Bayer has the exclusive right to sell ciprofloxacin in the United States (and elsewhere in the world). Due to alleged shortages of Cipro, as well as allegations that the price of obtaining sufficient quantities of Cipro is too high, some have urged the U.S. government to curtail that patent exclusivity. Some have proposed that the government buy less expensive generic versions of Cipro from sources other than Bayer.

The U.S. government has apparently reached agreement with Bayer to charge less for certain Cipro purchases by the government. Nevertheless, perhaps now more than ever patent holders face this critical question: Can the government—in times of crisis or otherwise—contravene a patent holder's exclusive rights, essentially mandating that the owner grant licenses to others under the patent?

The short answer is yes, but . . . . Particularly with respect to biotechnology products, a taking is complicated. Biotech products, such as pharmaceuticals, are subject to Food and Drug Administration and other regulations, which have to be considered. And the fact that pharmaceutical products can generate revenues on the order of millions of dollars a day makes calculating payments under mandatory licenses all the more difficult.

TAKE AND COMPENSATE

Patent rights are derived from Article I of the Constitution, which provides that Congress has the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors, the exclusive Right to their respective Writings and Discoveries." It is this exclusivity that forms the basis of the patent laws and serves the constitutional purpose of promoting progress by propelling U.S. scientific discoveries to ever greater heights. It is this very same exclusivity that was directly challenged by calls from some members of Congress to obtain generic versions of Cipro notwithstanding Bayer's rights.

The foundation upon which such calls are based is the government's power of eminent domain, which derives from the Fifth Amendment. Specifically, the Fifth Amendment provides that the government may appropriate real and personal property where that appropriation is for "public use" and "just compensation" is provided. While most of us are more acquainted with the government's right to appropriate real property, such as a house that blocks a new highway, the government's legal right to appropriate intellectual property is also fairly well settled.

This right is clarified with respect to intellectual property in 28 U.S.C. §1498(a), enacted in 1948, which provides: "Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture."

In other words, the patent owner cannot prevent the government's taking, but can make a claim for "reasonable and entire" compensation. In rare instances even before the enactment of §1498(a), the U.S. government and courts specifically consid-

ered the issue of mandatory patent licenses. During World War II, the owner of patents to Vitamin D (important in preventing rickets) came under public, governmental, and judicial pressure to expand its licensing policies. The company did so although such action was never affirmatively ordered by a court.

What's 'Reasonable'?

While the government's right of eminent domain with respect to patents is clear, much of what follows from that right is not. One area fraught with controversy is what constitutes the "reasonable and entire" compensation required by §1498(a).

In this context, courts have applied a "reasonable royalty" analysis. The reasonable royalty is typically based either on an established royalty for the patent or on a royalty that would result from a hypothetical negotiation between a "willing buyer" and "willing seller" conducted at the time of the taking.

In the present circumstances, the hypothetical negotiation would take place after the anthrax scare had begun. Where a government taking would be based on such a perceived dire need, it might be that, as a practical matter, the very right to obtain "reasonable and entire" compensation would preclude the taking, because the cost of such compensation would be prohibitive.

A more fundamental question is whether a reasonable royalty is the only appropriate measure of "reasonable and entire" compensation. In patent infringement litigation involving private parties, a reasonable royalty is the bare *minimum* of damages to which a patent owner is entitled. Lost profits are often deemed to be a more appropriate measure of damages.

But "lost profits" can include allegations of price erosion and lost sales on related products. That means that if a lost-profits analysis were followed in §1498(a) cases, "reasonable and entire" compensation could approach or even surpass the retail cost of the brand name product. (Courts have commented that an award of lost profits under §1498(a) would require a higher burden of proof than an award of reasonable royalties.)

Various reported cases have considered the issue of reasonable compensation by the government under §1498(a) for technologies such as camouflage screens, spin-stabilized satellites, ballistic and laser protective eye wear, and the tranquilizer meprobamate. Some have suggested these cases show that the government in the past has readily invoked its power of eminent domain over patent rights. But it is also worth noting that a number of these previous cases seemingly arose from the government (or its licensee) unwittingly infringing a patent rather than the government intentionally taking patent rights.

In addition to the power of eminent domain, there are other avenues for government access to certain intellectual property rights. For example, the Bayh-Dole Act of 1980, 35 U.S.C. §§200, *et seq.*, was written to encourage the participation of small businesses, universities, and other entities in government-funded research and development of inventions. The act also provides that the government funding agency will have certain rights in any inventions arising from this funded activity. These so-called march-in rights allow the agency to require the developer, for example, to grant licenses to the resulting inventions on reasonable terms.

The U.S. government has not generally rushed to enforce its march-in rights in the past. In 1997, for example, Cellpro filed a petition with the secretary of health and human services requesting that the government exercise its march-in rights in connection with certain patents owned by the Johns Hopkins University. Cellpro asserted, among other things, that such action was necessary to alleviate health and safety needs that had arisen because a court had found that the stem-cell separation device developed by Cellpro infringed two of the patents in question and had enjoined the sale of that device. The National Institutes of Health declined to initiate march-in procedures.

Other federal acts permit mandatory licensing of patent rights or inventions in certain circumstances—although these authorities too have rarely been used. The Clean Air Act, 42 U.S.C. §7608, provides for mandatory licensing of air pollution prevention inventions where required to enable compliance with the act. Atomic-energy-related provisions at 42 U.S.C. §2183 authorize the government to use patented inventions if the invention is of primary importance in the production or utilization of special nuclear material or atomic energy.

Compulsory licenses to patent rights have also been granted as remedies for anti-competitive activity under antitrust laws. For example, biotech companies have been required by the Federal Trade Commission to license patent and trade secret rights to competitors and other third parties in order to proceed with mergers. But compulsory licensing as a merger condition or a remedy for past anti-competitive conduct is not the kind of compulsory licensing that has created the public debate here and abroad.

The Debate Expands

In addition to existing laws, there have been other attempts to establish compulsory licensing for medicines and other biotechnologies. As early as 1959, the Senate Judiciary Subcommittee on Antitrust and Monopoly proposed that a patentee's exclusivity for patented medicines be limited to three years, followed by a period of compulsory licensing. This year, the proposed Affordable Prescription Drugs and Medical Inventions Act, H.R. 1708, would establish compulsory licensing for prescription drugs, such that brand-name companies would have to license others to sell generic versions of products in exchange for a reasonable royalty. The Cipro debate is likely to stoke such efforts.

The discussion of mandatory licensing could also widen considerably as other perceived public needs arise for patented biotech products ranging from sensing devices for biological and chemical substances to vaccines.

Finally, action by the federal government is not the only challenge to biotech patent rights. State governments now find themselves immune from intellectual property lawsuits. In the *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank* line of cases, the Supreme Court held that state governments are not liable for patent infringement under 11th Amendment principles of state sovereign immunity. Accordingly, even if the federal government does not invoke §1498(a) to mandate licensing of patent rights for certain medicines, a given state government could conceivably act.

Recent events have reordered our nation's priorities, redirected foreign policy, and shaken economies. The development of and access to new drugs and other biotechnologies to fight a host of perceived threats will remain a high priority. So we should not be surprised if the patent laws also remain a focus for national debate. ■

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