Health-Care Reform and Intellectual Property

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The Clinton administration's health-care reform legislation was introduced to Congress in July 1993, as H.R. 2624, a bill entitled "Comprehensive Health Care and Cost Containment Act of 1993." Discussions of the impact of that legislation have been widespread and will continue throughout 1994. One feature of this legislation would create a Prescription Drug Review Board in the U.S. Executive Branch responsible for taking punitive measures against the intellectual property holdings of companies that are found to be charging excessive prices for prescription drugs. A separate bill, introduced in 1993 by U.S. Congressman Fortney Stark (D-CA) (H.R. 916), is unrelated to other aspects of health-care reform, but would create a similar drug price review board within the Food and Drug Administration (FDA, Rockville, MD). Some of the powers that would be granted these boards could have a significant impact on the patent protection available to prescription drugs, which in turn could affect the availability of funding for pharmaceutical and biotechnology research.

The board that would be created by Clinton's health-care reform bill would have five members appointed by the President with the advice and consent of the U.S. Senate. It would be empowered to require each manufacturer of prescription drugs to provide detailed information on the price at which each drug is sold in any country and the cost of manufacturing and marketing the drug. That information would be used to determine whether excessive prices or excessive price increases had been imposed in the U.S. by the manufacturer. If the board finally determines that a price or price increase is excessive, it would, unless the price is sufficiently reduced, "revoke" the patent for that drug or, if the drug is not patented, revoke the patent on any other drug owned by that same manufacturer. The legislation does not require, in the latter situation, a relationship between the drug that is excessively priced and the patented technology that is "revoked."

The board created by Congressman Stark's bill would also be empowered to take away patent rights on a drug found to be priced excessively high. That board could decrease the length of a patent covering the overpriced drug or could decrease the term of any other patent in the drug manufacturer's portfolio. Unlike the Clinton administration's health-care reform bill, Congressman Stark's board could also recapture tax benefits provided to the patentee for the development of that drug, and it could either directly or by contract manufacture and sell the drug. Licensing others to manufacture a patented drug, without the permission of the patent owner, of course, would be a compulsory license that materially reduces, if not eliminates, the value of any patent held on the drug.

Congressman Stark's bill would appear to implement a compulsory licensing system similar to one that was, until recently, used by Canada. The Canadian compulsory licensing system had allowed generic manufacturers to import, make, use, or sell a patented drug in return for royalty payments established by the government to the patent holder. The Canadian parliament has now ended this system.

In the U.S., patents have often been important to investors in biotechnology companies because they help assure a return on investment by providing, for a limited time, a right to exclude infringers from the market place. The exclusivity afforded by patent protection provides research-and-development-based companies and their financiers with an incentive to risk time and money in discovering and developing new products by creating a period when the patent owner can be the only source of the patented product. Amgen's (Thousand Oaks, CA) experience provides an example of the role this incentive has played for biotechnology in the past. Before marketing its first product, Amgen needed $300-$400 million in capital. Daniel Vapnek, Amgen's senior vice president for research, felt that "the only reason we could raise that money was people thought we could get a significant patent with Epogen."[1] Even after initial financing is obtained, the value of biotechnology shares often closely reflects the value placed on the company's patent portfolio.[2]

Those who oppose the creation of a price regulatory board have characterized such legislation as an attempt to treat drug companies much like a crucial social service or public utility rather than as a private profit-seeking business and have expressed concern that the proposals to indirectly control

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prices would cripple research budgets for critical drugs. G. Kirk Raab, chief executive of Genentech (S. San Francisco, CA), was reported to say that price constraints could slow down or eliminate the volume of research by making it harder for young companies to raise money from investors. Investors supply approximately 80 percent of the working capital for biotechnology companies and there are more than 1000 companies. But the biotechnology industry still has only a small number of drugs on the market.

The Biotechnology Industry Organization (Washington, D.C.), which represents companies and academic institutions involved in the development of biotechnology products, predicts serious adverse consequences to biotechnology funding from other indirect price controls mechanisms that would be imposed by the Clinton administration's legislation. That organization has said that "[t]he prescription drug cost-containment provisions of the President's health-care reform plan will operate on the biotechnology industry as *de facto* price controls, threatening the industry's ability to continue to develop innovative and breakthrough therapies...."[3] The organization suggests that any job loss needed to lower health-care costs should be the result of improved economies in the health-care system resulting from such reforms as reduced insurance sales and administrative costs. It should not occur as a result of public policies that discourage innovation and research.

The detailed cost and pricing information required by the boards will also raise concern in many companies, as will the fairness of the analysis performed by the board on that information to reach its conclusions. The information looked at by the board would include such factors as foreign pricing, which would almost certainly apply pressure for lower prices. Many countries use compulsory licensing or other regulatory mechanisms to control prices. Canada, for instance, until recently, approved compulsory licenses from drug patents unless there was a good reason not to grant them. Canadian officials, when setting a drug royalty, believed that the Canadian market was too small to influence investment in research and development. Even if true for Canada, the same probably cannot be said for the U.S. market.[4] By comparing the U.S. price of the drug with the price it and its therapeutic cousins are sold for abroad, the board will often be comparing the U.S. price with prices that are the result of price controls.

The board may also consider the price of drugs in the same therapeutic class. The biotechnology industry may be particularly vulnerable to such side-by-side comparisons because they may have a more acute need to begin recovering the development costs as soon as possible. For example, a single injection of genetically engineered TPA, used to dissolve blood clots, was sold at an original cost of about $2000 per injection. Other agents in the therapeutic class of drugs used to dissolve blood clots would not be as expensive but may not be as effective, or the research and development costs on those other drugs may already have been recovered.

Moreover, the proposal to place pharmaceutical patent rights at risk to control prices occurs at a time when the U.S. has tried to strengthen the value of intellectual property rights in other countries through international negotiations. The North American Free Trade Agreement, the General Agreement on Tariffs and Trade (GATT), and the 1988 Omnibus and Competitiveness Act have attempted to enhance the intellectual property rights for U.S. innovations abroad. During the recent GATT negotiations, agreement was reached requiring many countries to eventually adopt laws giving pharmaceutical products and therapies greater intellectual property protection than currently exists.

The legislation proposed by the Clinton administration is apparently a compromise between direct control of prices by the U.S. Federal government and a totally free marketplace. Whatever philosophy animates the creation of a price control board, requiring that board to either eliminate or reduce the patent life of an "excessively priced" drug or any other patented drug within the company's patent portfolio may reduce the reliability of future patent protection. Jeopardizing the availability of patent exclusivity for new products compromises the financial benefits from patents and may therefore reduce the incentive to risk capital on research and development. The return investors want from the enormous risk and expense associated with developing new drugs will be even less certain. Without the security of adequate patent exclusivity in the future, biotechnology companies may therefore encounter even more difficulties in raising the necessary capital for research and product development.

Although examples of excessively priced drugs have been widely publicized, there has been little discussion of the effect on the incentive system provided by patent rights on pharmaceutical research and on the availability of risk capital for the biotechnology industry. The pharmaceutical industry's concern is most acute in connection with new drugs that have just completed their approval process before the FDA. Without the ability to charge prices that will permit recovery of their investment both in that drug and in failed attempts to find alternative drugs, the willingness to fund extensive research by biotechnology companies may be diminished. Passing this portion of the health-care reform package may therefore have far-reaching effects on the incentives provided by patent rights to the financing of biotechnology industries. Those effects should at least be considered carefully before health-care reform legislation is finalized.

References

1. The Washington Post, June 16, 1992.
2. The Washington Post, March 7, 1991.
3. January 1994 written communication of positions of the Biotechnology Industry Organization to Mr. Kjeldgaard. The price control mechanisms referred to by the Biotechnology Industry Organization were an advisory committee on the reasonableness of prices for breakthrough drugs and granting authority to HHS to exclude excessively priced drugs from Medicare. The creation of a board thst can revoke patent rights for excessively priced drugs is plainly another indirect control on prices.
4. Reported in F.M. Schere, *Pricing, Profits and Technological Progress in the Pharmaceutical Industry*, 7 Journal of Economic Perspectives, 97-115.