**BRIEF ANALYSIS**

No. 380

For immediate release:
Thursday, November 15, 2001

Cipro and the Risks of Violating Pharmaceutical Patents

By Frank R. Lichtenberg

When the threat of anthrax became a widespread concern, the Canadian government said it had serious doubts that Bayer, the owner of the patent for the anti-anthrax drug Cipro, could meet Canadian needs. Canada ignored the patent and ordered generic copies. In the United States, Sen. Charles Schumer expressed the same concerns and proposed that the U.S. government do the same. After Bayer said it could meet the needs of both nations, and after other drugs that are effective against anthrax were identified, Canada reversed its decision, and the issue was dropped in the United States for the time being.

But the proposal to override patents is certain to come up again as other drugs are needed, and as the population ages and demands drug treatment for an increasing range of illnesses and ailments. While overriding a patent might lead to a temporary increase in the supply of a drug, a great deal of evidence suggests that this policy would lead, in the long run, to a lower supply of innovative drugs, and poorer public health.

Research and development investment in general, and pharmaceutical R&D in particular, has made enormous contributions to the economic well-being and health of Americans. To have the incentive to undertake research and development, a firm must be able to get sufficient returns to make the investment worthwhile. The patent system is one of the most important ways in which the government can provide this incentive. Weakening patent protection (e.g., by government violation of patents) may have a chilling effect on private R&D investment, and therefore reduce the health and wealth of future generations.

Value of Medical Research. A host of academic studies speak to both the value of medical research and the important role of economic incentives. For example, a major project sponsored by the Mary Woodard Lasker Charitable Trust addressed the question, "What is the true economic value of our national investment in medical research?" and found, "It provide[d] a surprisingly dramatic answer: the returns are exceptional." The pharmaceutical industry performs about one-third of U.S. biomedical research. Some of my own academic research has estimated the benefits to consumers from the introduction of new drugs at the patient level, disease level and national level. These benefits include longer life, better quality of life, and reductions in total medical expenditure.

R&D Investment Is Responsive to Incentives in General. Economic research on a number of industries (including pharmaceuticals) has demonstrated that the rate of private R&D investment is very sensitive to expected returns.

■ In his influential study of almost a thousand inventions in four different industries, the late economist Jacob Schmookler found that the expected profitability of inventive activity determined the pace and direction of industrial innovation.

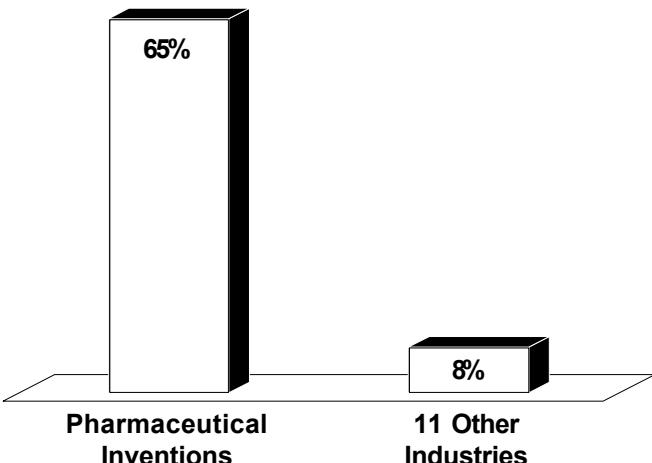
■ In response to the enormous increases in energy prices during the

1970s, firms significantly stepped up spending on energy-R&D projects, in a targeted attempt to reduce energy consumption.

■ Whenever the government offers to award a significant defense contract, potential military contractors make large investments of their own funds in R&D for the types of products the government is seeking to buy.

■ According to the Food and Drug Administration, passage of the Orphan Drug Act in 1983 led to a twelvefold increase in the number of drugs for rare diseases brought to market.

Percent of Inventions Introduced Because of Patent Protection



Source: Edwin Mansfield, "Patents and Innovation: An Empirical Study," *Management Science*, February 1986.

- Both firm-level and industry-level evidence are consistent with the hypothesis that the threat of pharmaceutical price controls in the Clinton administration's 1992-93 health care reform proposals had a significant negative effect on pharmaceutical R&D investment.

Economic theory and evidence indicate that, in general, a firm's incentive to invest is positively related to its market value (relative to the replacement costs of its assets).

- My research has indicated that a 10 percent decrease in market value is associated with a 2.25 percent decrease in R&D expenditure, holding constant tangible assets, past R&D investment and cash flow.
- In a National Bureau of Economic Research paper, economists Sara Ellison and Wallace Mullin estimated that the threat of Clinton health care reform reduced the market value of pharmaceutical firms by 44 percent during the period from September 1992 to October 1993.

We would therefore expect to observe an industry-wide decline in the rate of growth of pharmaceutical R&D investment at the time of (or soon after) the threat of pharmaceutical price controls. The facts bear this out: the growth rate of pharmaceutical industry R&D investment was much lower during the period 1993-95 than it was during any other period since 1987.

Responsiveness to Intellectual Property Protection in Particular. Economists Robert Hall and Charles Jones concluded from their research, "A country's long-run economic performance is determined primarily by the institutions and government policies that make up the economic environment within which individuals and firms make investments, create and transfer ideas, and produce goods and services."

Some economists, such as 1993 Nobel Laureate Douglass North, opine that the invention of intellectual property and its protection caused an explosion in creativity that was the basic force behind the Industrial Revolution. As Jones observes, "sustained economic growth is a very recent phenomenon" — it began with the Industrial Revolution in Britain in the 1760s — and "the thesis of Douglass North and a number of other economic historians is that the development of intellectual property (IP) rights, a cumulative process that occurred over centuries, is responsible for modern economic growth....[H]istory suggests that it is only when the *market* incentives were sufficient that widespread innovation and growth took hold."

In the long run, even imitators (such as generic drug companies) can benefit from stronger intellectual property protection. Imitators survive by copying innovators' inventions. If invention declines (e.g., due to weakening of IP protection), there is less for imitators to copy. Weaker IP protection makes it easier for imitators to dip into the pool of innovations, but it also shrinks the size of that pool; the latter effect may dominate the former. (Imitators always favor weaker protection for innovations that have already been produced, but may benefit from stronger protection for innovations yet to be produced.)

The Importance of Patent Protection of Drugs. All of this evidence suggests that, across industries, a high average level of intellectual property protection is economically beneficial. But the benefits of strong IP protection are even greater in the pharmaceutical industry than they are in other industries, because pharmaceutical firms rely more on patents to protect IP than firms in other industries.

- Richard Levin and others surveyed high-level R&D executives in more than 100 manufacturing industries, and found that "*In only one industry, drugs, were product patents regarded by a majority of respondents as strictly more effective than other means of appropriation....Comparatively clear standards can be applied to assess a drug patent's validity and to defend against infringement,*" whereas such standards cannot be applied to assess other kinds of patents (e.g., patents on components of complex systems).
- As the figure shows, Edwin Mansfield found that 65 percent of pharmaceutical inventions would not have been introduced if patent protection could not have been obtained; for the 11 other industries he studied, this percentage was only 8 percent.
- Congress has recognized the importance of patent protection as an incentive to pharmaceutical R&D. For example, as part of the Hatch-Waxman Act, Congress provided for patent term extensions to offset some of the time that drugs spend in clinical testing and in the FDA review process.

Conclusion. There appears to be widespread agreement that the war on terrorism cannot succeed in a few weeks or months — we need to have a long-term perspective. Promotion of public health should also be pursued with a long-term perspective. Government expropriation of valuable inventions today is very likely to diminish their future supply.

Frank R. Lichtenberg is Courtney C. Brown Professor of Business at the Columbia University Graduate School of Business and a Research Associate of the National Bureau of Economic Research.

Note: Nothing written here should be construed as necessarily reflecting the views of the National Center for Policy Analysis or as an attempt to aid or hinder the passage of any legislation.

The NCPA is a 501(c)(3) nonprofit public policy organization. We depend entirely on the financial support of individuals, corporations and foundations that believe in private sector solutions to public policy problems. You can contribute to our effort by mailing your donation to our Dallas headquarters or logging on to our website at www.ncpa.org and clicking "An Invitation to Support Us."