IP Protection Increases R&D Worldwide

BY GERALD J. MOSSINGHOFF*

Pharmaceutical patent protection has risen dramatically; so has local R&D and foreign investment

The history of human progress is keyed to encouraging invention and innovation through protection of intellectual property. In particular, patent protection for pharmaceuticals sharply increases local pharmaceutical research and development, attracts foreign investment in countries working to develop their own industries, and fosters technology transfer in what is one of the most successful worldwide high-technology industries. It produces high-technology employment and the potential for exports. Perhaps most important of all, patent protection for pharmaceuticals facilitates the availability of modern medicines to improve the health and well-being of people everywhere.

The defining characteristic of the pharmaceutical industry is enormous financial commitment to research and development. Since 1985, the industry's investment in research and development has been multiplied by four. It went from $4.1 billion in 1985 to almost $16 billion in 1996.

The pharmaceutical industry is the most research-intensive of the high-technology industries in terms of R&D investment as a percentage of sales, or revenues. In 1994 — the last year for which data are available for comparison — pharmaceutical companies devoted an average of 18.6% of revenues from sales to research and development.

In the electronics and electrical industry — clearly a major high-technology industry worldwide — the percentage of revenues devoted to R&D was less than 6%. Aerospace and defense companies — another very high-technology area — devoted only 4% of sales to R&D.

For the telecommunications industry, the figure was 3.3%. The all-industry composite was, according to the *Business Week* Scoreboard, at 3.5%, less than one-fourth the percentage of pharmaceutical R&D.

One reason for the enormous commitment of resources is the fact that the pharmaceutical industry is a very high-risk industry. The experts who have studied very closely the development of a drug estimate that for one drug approved by the Food and Drug Administration for use by patients, 5,000 chemicals had to be synthesized in a laboratory. Of those, 500, or one-tenth, were tested in organ preparation, half of those in rodents, five in early human clinical studies, finally resulting in only one drug being approved by the Food and Drug Administration

ROLE OF PATENTS

There are many misunderstandings about what a patent in the area of pharmaceuticals does and does not do. Clearly, patent protection is necessary in the research-based pharmaceutical industry. Perhaps in no other industry can an invention that costs so much to discover and develop — now estimated by government and academic experts as somewhere between $350 million and $500 million per drug — be copied so inexpensively, often at a mere fraction of the amount that it costs to develop. If there were no patent protection for pharmaceuticals worldwide, there would simply be no research-based industry. Worse, from a public policy view, there would be no new medicines for patients who need them. Nevertheless, there is a common misconception that somehow patents create monopolies. The opposite is true.

*Senior Counsel, Pharmaceutical Research and Manufacturers of America, Washington, D.C. Paper presented to the Intellectual Property Conference of the Americas, July 1996.

World Bank Study
Intellectual Property and Investments

Without Pharmaceutical Patent Protection, What Foreign Direct Investments Will Be Made?

Type of Investment	% of Companies Willing to Invest
Facilities to Manufacture Formulations	29%
Bulk to Final Product Manufacture	13%
Research and Development Facilities	0%

Source: IFC Discussion Paper: *Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer, Edwin Mansfield, 1994,* The World Bank

Figure 1

At one time, pharmaceutical companies enjoyed relatively long periods of exclusivity based on their patents. Inderal, for example, a breakthrough beta blocker patented in 1968, enjoyed 10 years of exclusivity. But in recent times, for well-known drugs such as Tagamet, Capoten, Seldane, AZT, Mevacor (the cholesterol-lowering drug), Prozac, Difulcan, Recombinate and Invirase, not long after an original drug was put on the market, a second drug came to the market to provide real competition even though both the original drug and the second drug were covered by valid patents. Patents do clearly establish exclusivity, but they do not establish monopolies.

The World Bank, in a major study in 1994, polled a range of companies to find out what kind of environment they needed to prompt them to invest in pharmaceutical efforts in other countries (Figure 1). Without pharmaceutical patent protection, they were asked, what foreign direct investment would you make? The responses were exactly what one would expect: 29% — less than one-third, but still a substantial number of companies — would be willing to invest in facilities to manufacture formulations. Less than half of that percentage — 13% — would be willing to invest in facilities to provide bulk material to final product manufacturing. And, very tellingly, no — zero percent — companies would be willing to invest directly in research and development facilities if there were no patent protection available for the products in the country. This fact is one of the major causes of the dramatic increases worldwide in intellectual property protection for pharmaceuticals.

PROGRESS IN PATENT PROTECTION

In the past decade, many countries have improved pharmaceutical patent protection due to bilateral efforts. In 1986, Korea enacted pharmaceutical patent protection. Numerous other countries followed suit and provided pharmaceutical product patent protection for the first time, or significantly upgraded their existing laws. These include the Czech Republic, the Slovak Republic, Bulgaria, Mexico, Chile, Belarus, Romania, Taiwan, Russia, Thailand, Ukraine, Spain, Yugoslavia, Poland, Philippines, Portugal, Macedonia, the Andean Pact, Hungary, Latvia, Turkey, and most recently in 1996, Brazil.

In the Western Hemisphere, a major development was the adoption in 1993 of NAFTA by Canada, Mexico, and the United States. This key agreement provides that countries cannot discriminate by field of technology in their patent systems, as some had discriminated against pharmaceuticals. It provides what we refer to as "pipeline" protection — that is, some exclusivity for products in the development process. And, finally, it prohibits compulsory licensing.

The Uruguay Round of negotiations resulted in the GATT Agreement, concluded in 1995. It provided for no discrimination by field of technology and established a 20-year patent term from the filing of a patent application, which the United States has now adopted. Very significantly, the Uruguay Round established the World Trade Organization to settle disputes among nations with respect to intellectual property. The pharmaceutical industry in the U.S. would wish that the provisions of GATT would apply earlier than they do in developing countries. Nevertheless, the GATT Agreement was a true breakthrough agreement, perhaps one of the most important agreements ever reached among nations.

PATENTS AND INVESTMENTS

The previously cited World Bank study is replicated by the actual investment behavior of the U.S. companies (Figure 2). Figure 2 compares for three years — 1985, 1989 and 1994 — pharmaceutical companies' R&D investments in Latin America,Canada, and Japan. For Latin America, there is very little growth. For Canada, there was dramatic growth, particularly following the strengthening in Canada of intellectual property protection for pharmaceuticals. And in Japan, which until 1978 did not protect pharmaceuticals, there were dramatic increases in growth in R&D investment by U.S. companies.

Italy provides an additional example. Once known internationally as a patent pirate country, Italy, in a move that was spurred by the Italian pharmaceutical industry, greatly strengthened patent protection in 1978. Figure 3 illustrates the results. Italy enjoyed very minor investments in research and development in 1978 of 123 billion Lira. Less than 10 years later that amount had grown almost five-fold to 592.3 billion Lira. And from the most recent data, the investment is now at more than 1.6 trillion Lira invested

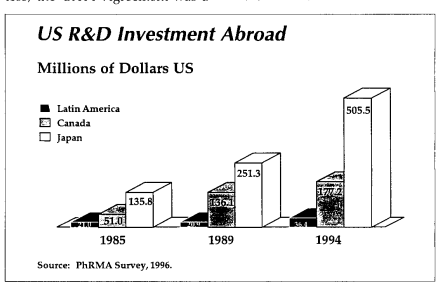

Figure 2