

LIFE SCITECH

Patent Protection – Insurance for the Health Science Industry

BY JAMIE M. LARMANN, ESQ.

Pharmaceutical and biotech companies are vital components of our health science industry, and have a strong impact on the economy and public health. These companies are among the most research-intensive in the U.S. and worldwide. Investment in research and development (R&D) has continually increased in the pharmaceutical industry over the past several decades, as shown in Fig. 1. The costs of bringing a single new drug to market reportedly range from \$500 to \$800 million and higher.

Patents operate by providing economic incentives to pharmaceutical and biotech companies that engage in R&D. According to statute, a patent provides the right to exclude others from making, using or selling an invention for 20 years from the earliest filing date of the patent application in the U.S. This period of market exclusivity permits pharmaceutical

and biotech companies to recover their R&D investments, and thereby encourages future innovation.

U.S. pharmaceutical and biotech companies rely on patents to protect their investments in developing new drugs and related technologies. Without patent protection, it would be easy for unauthorized companies to reproduce and sell the innovator's product. Moreover, unauthorized companies, which have little or no R&D costs to recover, could significantly undercut the innovator's prices.

An additional benefit is that patents foster further innovation within the pharmaceutical and biotech industries. In exchange for market exclusivity, patents require a full public disclosure of a company's product, including a description of the company's best mode for practicing the invention. This information becomes available to the public, thus further-

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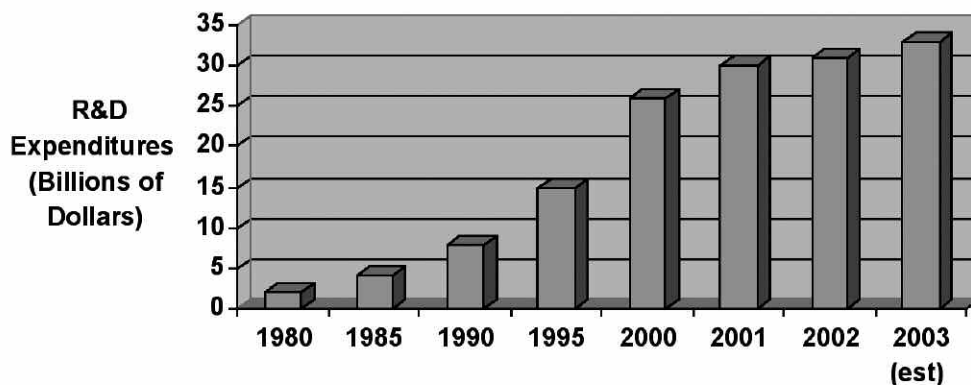


Figure 1: Source: Pharmaceutical Research and Manufacturers of America (PhRMA), Pharmaceutical Industry Profile 2004 (Washington, DC: PhRMA, 2004).

ing the overall knowledge in the industry and, in turn, encouraging additional innovation.

In the pharmaceutical industry, in particular, patent protection may be obtained for a variety of different innovations, including compounds or compositions, methods of making these compounds, and even methods of treating a specified disease or disorder. Patents that protect the new drug itself typically are the most desirable because of the ease of detecting infringement. Thus, sales of a copied drug are easily identifiable.

Determining whether that product was produced in accordance with a protected method often is more difficult. Accordingly, the pharmaceutical industry focuses much of its attention on finding and protecting new and useful chemical compounds.

Just as it did earlier for the small molecule drug industry, the patent system has fostered investment in biotech R&D. The biotech industry focuses its efforts on patenting a wide variety of technologies, including proteins, DNA, cells, assays, and research tools, among others. Such innovations may be useful in a variety of growing disciplines, including medicine, agriculture and nutrition.

While seeking patent coverage for their innovations, pharmaceutical and biotech companies also must obtain FDA approval for many of their products. Such approval is necessary prior to marketing these products in the U.S. Few innovative products, however, actually achieve FDA approval. It has been reported that only one in 5,000 newly identified drug candidates receives FDA approval. Furthermore, the approval process adds additional time and expense to the development of new products.

As shown in the typical patent/approval timeline (Fig. 2), a considerable amount of patent life is lost during the FDA approval process. Typically, only about 12 years of patent life for a new medicine remain after approval, as opposed to the 20-year full term.

In view of such concerns, Congress has provided several mechanisms for extending the term of a pharmaceutical or biotech patent. One avenue provides patent term adjustments for delays at the Patent and Trademark Office (PTO). Such adjustments are only made if the delays are caused by the PTO during normal patent

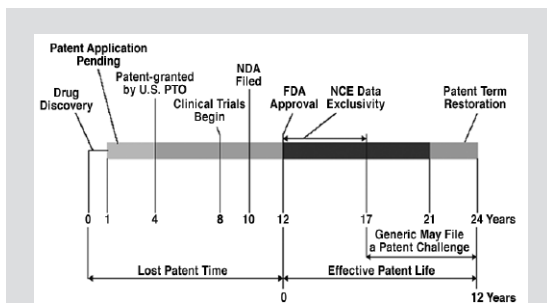


Figure 2: NCE stands for New Chemical Entity. Source: Gregory J. Glover and Bruce N. Kuhlik, "Patents and Hatch-Waxman: Understanding the Debate Between Innovative Drugs and Generic Copies," presentation to The National Governors Association (Washington, DC), 19 April 2002.

examination, and are offset by applicant delays. These adjustments are tacked onto the 20-year term. A second avenue, available to small molecules only, compensates for delays in the FDA approval process. In particular, the Drug Price Competition and Patent Term Restoration Act of 1984 (referred to as the Hatch-Waxman Act) provides patent term extensions of up to five years, with the limitation that the total term can be no more than 14 years from the time of FDA approval. Patent term extensions are extremely important to pharmaceutical and biotech companies for prolonging market exclusivity until generic manufacturers can legally enter the market. Under the Hatch-Waxman Act, generics are granted an expedited approval process, permitting market entry earlier than in the past. The Hatch-Waxman Act, therefore, struck a balance between the competing interests of innovator and generic manufacturers. Importantly, this balance protects incentives for innovator companies to engage in costly R&D by providing term extensions, while also increasing market accessibility of less expensive medicines by accelerating generics to market. Under the Hatch-Waxman Act, generics' share of the prescription drug market reportedly has risen to almost 50 percent.

Therefore, patent protection plays a critical role in the pharmaceutical and biotech industries in the U.S. It is, accordingly, important that innovations in these fields are protected internationally, as well. Although pharmaceuticals have not been granted the same intellectual property protections worldwide in the past, the international community has generally agreed that patent protection for pharmaceuticals is a necessity. Importantly, more than 140 countries have signed the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to establish minimum protection standards for pharmaceuticals. Such patent incentives encourage global R&D in pharmaceutical and biotech fields and the promotion of public health worldwide.

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