

THE NEED FOR ADEQUATE AND EFFECTIVE
PROTECTION OF INTELLECTUAL PROPERTY:
PERSPECTIVE OF THE PRIVATE SECTOR—PATENTS

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I want to elaborate on specific problems faced by the pharmaceutical industry, particularly with respect to patents, and on why improvements in patent protection are of particular importance to us. To put things into perspective, Pfizer is a U.S.-based research-based health care company with principal product lines in pharmaceuticals, medical devices and specialty chemicals. Pfizer operates in over 140 countries, has manufacturing facilities in 65 countries and approximately 50 percent of our sales come from markets outside the United States. While my remarks are from the pharmaceutical industry's perspective, they are common to other sectors of industry, particularly agricultural chemicals and also to research-based high-tech industries in the United States.

Studies have shown that the pharmaceutical industry is by far the industry most dependent on patent protection. To understand why, it is helpful to know that in 1987 Pfizer spent over \$400 million on research and development, which was over eight percent of our net sales. This is typical of our industry but significantly higher than that of industry generally in the United States. Estimates are that today it costs \$125 million and about 10 years or more from the time a new pharmaceutical product is discovered in the laboratory to the time it is brought to the market. Of every ten to fifteen thousand new compounds that are made in the laboratory, only one of these compounds will be developed into a commercial product. Many compounds will fall by the wayside even in the late stages of clinical trials. To bring a new product to the market involves enormous resources and people with diverse expertise and there are significant regulatory requirements for market entry. If a company is expected to continue to invest such time and money and to undertake the risk of development of new drugs, then it is critical that it enjoy at least some reasonable period of exclusive use of the few successful products that come out of its R&D efforts, as was intended by patent laws.

The theory of patent law is that in return for the disclosure of the invention to the public, the innovator receives a limited period

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of exclusivity during which he can recoup his investment in research and development. In many countries, however, the patent laws are inadequate either in the protection afforded or the enforcement of those laws. In some countries they are non-existent, where the pirate companies can freely enter the market and often take over significant shares of the market. In some instances, the copied product will appear in the foreign market before we can even market our own product. Such pirate companies pay none of the costs of the research and development, but wait until we have spent the money and then pick off our most successful products. Obviously they can always undercut us in price because they do not need to factor the enormous R&D cost into their market price.

In connection with exclusivity, it is worth mentioning that people like to talk about the "monopoly" that is provided by the patent. Bear in mind that it is not a true monopoly because a pharmaceutical product rarely, if ever, is the only product in the particular market. For example, one of our major products is an antiarthritic drug. There are about one hundred antiarthritic drugs, some patented, and many unpatented. Therefore, we cannot charge any price that we like and expect to dominate the market through the sale of one drug. In other words, there are significant market forces that prevent a monopoly position in any one product.

In the United States, Japan and Europe there are good patent laws that generally provide adequate protection for our industry. Conversely, in many developing countries there are inadequate degrees of protection. Looking at those countries, they can be categorized in the following ways:

First, there are countries with no patent laws at all, such as Indonesia (which just drafted a patent law that is under review) and Turkey. Next, some countries have laws that provide that certain classes of subject matter cannot be patented; pharmaceuticals are often among those excluded. An example of such a country is Brazil. A more widespread form of inadequacy exists where countries provide only process patent protection, as opposed to product patent protection for the compound itself. A product patent gives the owner the right to exclude others from making, using or selling the compound regardless of how it is made. A process patent only protects that specific method of manufacture, and it is always possible to find alternative methods of making a compound once the innovator has disclosed his invention and demonstrated the valuable properties of the compound.

There are also significant difficulties in enforcing a process patent because there is no way of knowing how the infringer is in fact making the product. One cannot go inside his plant to inspect to find the process. The patentee usually has the burden of proving infringement and most countries have no discovery procedures whereby you can determine how the manufacturer is making your product.

A further deficiency, which is common, is an inadequate term of protection. India is a prime example of a country presenting this problem. India provides only process patents for pharmaceuticals, and the term of the patent is only five years. As I indicated earlier, it usually takes us ten years to bring such a product to market. A patent that expires five years before we can bring the product to market is of very little assistance to us.

In the United States the term of a patent is seventeen years from grant, while in Europe it is twenty years from the date of filing the patent application. These terms are generally considered to be a normal standard which we would accept for the term of the patent. We do not, however, enjoy a twenty-year period of marketing exclusivity. The patent application is necessarily filed soon after the time the compound is initially discovered in research, and it takes us ten years to develop the product to the point where we can bring it to the market. Typically we end up with a period from five to ten years left on the patent life, significantly less than in other fields of technology. This has been recognized in the United States and Japan, for example, by provisions for patent term restoration which are designed to compensate for periods lost in regulatory review. Similar provisions are under consideration in Europe.

A further problem is unreasonable compulsory licensing or lapse provisions. Typically the laws in many countries require, as authorized by the Paris Convention, that a patent be worked locally within three years from grant. In other words you have to manufacture the bulk drug in each and every country where you have a patent, within three years from the time the patent is granted. As I have indicated before, that is impossible for us to do because it takes us ten years before we are in a position to manufacture and market that product. Economic realities also make it impossible for us to work in every country. While we have manufacturing facilities in sixty-five countries, we cannot make bulk drugs in all of those. We can only make bulk drugs in a few centralized facilities. Many pharmaceuticals contain only ten milligrams of active drug in a tablet or a pill and a few hundred kilos of the active drug are enough to satisfy the worldwide

demand. You cannot split that up into manufacturing facilities in every country in which you plan to market.

The last deficiency is in the enforcement area. Obviously any patent is of no use if there is not an adequate judicial system that will enforce that patent for you. We have litigation in countries like Spain that afford process patent protection where the suit typically goes on for ten or more years, during which time the generic manufacturer continues to sell in the market. Until very recently there have been no provisions in Spanish law whereby preliminary injunctions can be granted. The slow and tedious nature of Spanish litigation is typical of many countries, where litigation goes on forever. It is an exercise in frustration to try to enforce your patent rights.

The Paris Convention, which is the principal international treaty concerning patents, contains no standards of protection for the issues I have discussed. There is nothing concerning the term of the patent. There is nothing concerning protection of any specific subject matter, whether by a product or process patent. There are provisions relating to compulsory licensing, but as I have indicated those criteria are unrealistic in the commercial world that we face today. The principal requirement of the Paris Convention is national treatment, but the fact that Brazil, for example, does not give its own citizens adequate protection of patents for pharmaceuticals is of no consolation to us when we are denied protection for our products.

The GATT offers what we see as a preferred opportunity for addressing the problems in a multilateral agreement. The concept is that there would be a code of minimum standards of substantive levels of protection which would be a floor level above which the laws of all signatories would have to rise in order to be in accord with the treaty. For patents, then, the code would include a requirement that product patents be granted for all classes of subject matter without discrimination. It would provide an adequate term which we would consider to be twenty years from filing. It would have to place some reasonable, realistic criteria for compulsory licenses.

It is worth emphasizing that what is proposed is a code of minimum standards. As such, it stands or falls in total. You cannot provide half of a product patent. You cannot say, "I will give you a product patent but I will only give you half the term you want"—or "I will give you a product patent but I will take it away from you by unrealistic compulsory license provisions." From our perspective, a watered down code which would result from negotiations trying to satisfy the competing needs of large numbers of countries to get them to sign the code would be of no value. Our perception would then

be that if you cannot achieve it in the GATT, we should achieve it outside the GATT. This means that there would be more bilateral actions of the type that have been described earlier.

In the short term we expect that there will be bilateral actions and that major benefits can come from such actions in the short term. Our hope is that the GATT will proceed quickly and that our long-term problems will be resolved through the GATT.

In terms of transition provisions, I must point out that if a country were to change its laws tomorrow to provide adequate protection (let us say it provides product patent protection for the first time and I have a compound newly discovered in the lab and I file for a product patent the day after the new law goes into effect), it will be ten years before that compound is marketed. We are talking about a market effect of these changes in the early 2000s.

There are benefits to the developing countries. It may be argued that there are some disadvantages of somebody having exclusive rights to a particular compound, but those should be offset in the longer term by stimulation of innovation in the country. Without such protection, U.S. companies are reluctant to invest in developing countries and to transfer technology to those countries, for fear it will be lost and taken over by others.

Local inventors will find out that they will have their inventions stolen just the same as U.S. inventors are finding in the foreign markets. A good example is in the bio-tech area where there is very little required in initial investment to get started. Many developing countries have good scientists and expertise in these areas and have the basis for having a good industry. Those people are going to want to protect their own inventions but will find that they are unable to do so. Developing countries are going to realize that it is in their own interest to provide that protection to their industries.

The patent laws are designed to stimulate innovation. They should not be used to solve every social problem that one can associate with the use of pharmaceuticals. There are difficult issues involved in the pharmaceutical area. Every government has its rules and regulations which relate to the approval and marketing of drugs. It is not appropriate to graft those concerns into a patent law. The patent laws should be left to the purpose for which they were intended.

To complete the picture, the pharmaceutical industry also has interests in similar improvements in trademark, copyright and trade secret protection, particularly with respect to the recognition of the proprietary nature of data that is submitted to the regulatory authorities. It takes enormous amounts of time, effort and money to

develop the clinical trial and other data that are necessary to establish the safety and efficacy of a drug. That data should be used for the benefit of the innovator alone for at least a reasonable amount of time and should not be made available to generic competitors. In some countries, competitors have free access to the innovator's data and need to submit no clinical data or studies of their own. All of these are areas that are being considered in the GATT and in some bilaterals. We hope that these efforts will result in improvement, hopefully in the short term.