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Pharmaceutical Pricing and Patent Law

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SUMMARY

Rapid increases in the prices of pharmaceuticals over the last decade raise questions whether and to what degree this phenomenon is the result directly, or indirectly, of patent law provisions and practices. For example, is the term of 17 years of patent law protection effectively shortened for pharmaceuticals, thereby shortening the period for financial recovery of investments in R&D? Was the alleged effective reduction of on-patent time (caused by the multi-year testing process required to meet FDA standards) not completely restored by the Drug Price Competition and Patent Term Restoration Act of 1984? Foreign patent pirates, plus increases in the cost of research and development are also said to have contributed to rising current brand name price levels.

ARE ON-PATENT DRUGS QUASI-MONOPOLIES?

How can a monopoly be said to exist in an industry in which the largest U.S. market share held by any company is 9.4 percent? The fact is, however, that each on-patent medication is, from the consumer's standpoint, a monopoly, created as such by the patent laws, and sustained as such by the way our health care system operates.

Typically, in the United States, once a medication is prescribed, there is no effective competition for the patronage of the consumer (the patient) except the generic imitator, if there is one. Typically, the patient accepts the prescription the doctor gives him as the best treatment for his complaint. The doctor, typically, doesn't tell the patient the price of the medication, nor does he, typically, tell the patient that there are alternative drugs for his condition, but that for specific reasons, the doctor has chosen the one prescribed. Often it is only at the pharmacy counter where the patient is likely to learn that there is (or isn't) a generic version of his doctor's choice. In some States, he may then choose whether to pay more for the name brand or try the generic, if one exists. But the average patient never gets a chance (for valid reasons, many would argue) to consider alternative medications at various prices for treating his condition.

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The monopoly provided a prescription drug by the patent is not accidental. Congress established that monopoly in the form of a patent because, in a market economy, capital invested in creating a product must be returned to the investor with a profit. Failing that, capital for development of new products will not become available. In the case of the pharmaceutical companies, the period of monopoly sale for such return on investment is shortened by the regulatory process. In consideration of pricing of brand name drugs, the pharmaceutical companies insist that that factor be taken into account.

Economic theory has long recognized that a monopoly seller sets his price at what he estimates is the highest price he can sustain without stimulating excessive buyer resistance; i.e., declining demand. In the case of medications, viewed by many as necessities, this price may be the highest price the buyer can pay.

LIMITED PROTECTION OF U.S. PATENT LAW FOR PHARMACEUTICAL INNOVATIONS

The congressional framers of U.S. patent law intended that during the life of a patent, the patent owner should have a monopoly on production and sale of his product. In the two spheres where U.S. patent law now most affects the pharmaceutical industry, however, a case can be made that the U.S. system has not provided that monopoly, and has not protected the investments of pharmaceutical innovators as completely as an inventor would hope. These two areas are:

- protection of the exclusive right to produce and sell a patented pharmaceutical product for a full term of seventeen years; and,
- protection from foreign patent pirates whose national laws do not require them to observe U.S. patent protections.

PROTECTION OF EXCLUSIVE RIGHTS FOR SEVENTEEN YEARS

For most inventions, U.S. patent law provides a flat seventeen years of patent protection, after which the patented invention or process may be adopted by any manufacturer. Patenting of pharmaceuticals, however, is complicated by two factors:

- In order to preserve its right to profit from its new invention or drug in a highly competitive industry, a pharmaceutical company usually applies for a patent immediately after making its discovery;
- Before marketing the drug, the company may have to invest from two to twelve years in further research, development, and testing processes

before gaining Food and Drug Administration (FDA) approval for sale, during which time the patent is running out.

For these reasons and others, the pharmaceutical companies often face erosion of the patent-protected period during which an inventor can expect to profit most. By the time the FDA has approved a product for marketing, the expected seventeen years of patent life may have been reduced by half or more.

In 1984, in an effort to balance the interests of brand-name and generic drug makers, Congress amended drug patent law by enacting the Drug Price Competition and Patent Term Restoration Act (P.L 98-417). This legislation made a number of changes that would allow some drug patent holders to regain some of the sales monopoly time lost on some of their patents, depending on when their product received FDA approval. This was done by lengthening the period of patent protection beyond 17 years after the original filing. The Act effectively limited the time that could be regained to five years maximum, and for drugs already under development in 1984, the time to be restored could not exceed two years. "Through May 1990, the U.S. Patent and Trademark Office has granted 77 restorations of patents for human or animal drug products, resulting in an average of 10 years and 7 months of effective patent protection for these drug products," according to a drug company study.[1] To critics, the new law modified rather than fully corrected a problem already burdening the industry.

Enactment of the 1984 Drug Price Competition and Patent Term Restoration Act aided the development of generic versions of a number of previously patented medications by making testing required for the generic much less time consuming than that needed for innovator drugs. The patent on the original drug discloses the ingredients of the compound as well as the process by which it is made. Testing of a generic drug is done to establish bioequivalency with the fully tested original. The process of testing a generic usually takes from 24 to 30 months.[2] The intent here was to make safe, equivalent medications available to the public at competitive market prices.

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[1] Dr. P. Roy Vagelos. Are Prescription Drug Prices High? *Science*, v. 252, May 24, 1991, p. 1080-1084. Dr. Vagelos, Chairman and CEO of Merck & Co., bases his statement on an unpublished study done by Merck.

[2] Under FDA regulations, makers of generic medications must test the comparability of their products with the innovator products by meeting certain bioequivalence and bioavailability tests. These tests compare the rate and effect of the absorption of the generic in the bloodstream with the rate and effect for the innovator drug. Under the regulation, bioavailability may vary by up to 20 percent. FDA testing of 225 generic products, however, established that the bioavailability of the presently available generics varies from that of the innovator drug only 3.5 percent on average.

Recent data concerning the sale of generic drugs as compared with sales of original versions of medications indicate that within two years (on the average) after patent expiration, fifty percent of sales of a given medication go to generics.[3] Thus, owing to the shortened life of their patents, pharmaceutical companies may lose a considerable portion of the profit they might have hoped for from medications.

PROTECTION FROM FOREIGN PATENT PIRACY

In 1988, an International Trade Commission report estimated that ten U.S. pharmaceutical companies had—as of 1988—lost nearly $2 billion to patent and trademark piracy.[4] In some countries, many located in Asia and Latin America, laws and government policies are said to encourage patent piracy. Attempts by the U.S. Government to insure intellectual property protection to pharmaceutical companies and other U.S. innovators through the General Agreement on Tariffs and Trade (GATT) have had a mixed record of success. Hopes for correction of these abuses now rest upon Section 301 of the 1974 Trade Act as amended by the 1988 Omnibus Trade Act. Section 301 "requires the United States Trade Representative to identify countries that do not adequately protect U.S. intellectual property rights and initiate investigations of these countries for possible retaliatory measures."[5]

Recently, the Pharmaceutical Manufacturers Association petitioned the U.S. Trade Representative to initiate an investigation of pharmaceutical patent abuse in Thailand. This may in time prove an effective method of stemming patent piracy, but it has to date been a slow and unreliable path to results.

THE RELATIONSHIP BETWEEN PATENTS AND PRICES

Table 1 provides price data about the six prescription pharmaceuticals a major Washington D.C. area pharmacy reports as most frequently prescribed and purchased in recent months. Displaying dollar and percentage increases in the average wholesale prices of the six medications from 1989 to 1991, the table provides a brief illustration of the extensive variation in price streams among prescription pharmaceuticals.

Here the six brand name drugs were manufactured by five different pharmaceutical companies. The range of price changes over the three–year period (from -11 percent for Diazide to +54.7 percent for Premarin) is an indicator that each company has its own pricing policy.

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[3] Source: Pharmaceutical Manufacturers Association, September 1991.

[4] Senator Dennis DeConcini. Patent Protection. *Roll Call*, September 12, 1991.

[5] DeConcini.

TABLE 1. Comparison of Average Wholesale Prices (AWP) for Six Frequently Bought Pharmaceuticals 1989, 1990, 1991

Trade Names	Originating Company	1989 Price	1990 Price	1991 Price	Percent Price Change 1989–1991
Amoxil	Smith Klein Beecham	$21.07 AWP for 100 capsules, 250 mg.	same as 1989	same as 1989	0%
Lanoxin	Burroughs Wellcome	$7.91 AWP for 100 capsules, .25 mg.	8.62 AWP for 100 capsules, .25 mg.	9.40 AWP for 100 capsules, .25 mg.	18.8%
Xantac	Glaxo	$73.63 AWP for 60 capsules, 150 mg.	$78.79 AWP for 60 capsules, 150 mg.	$84.23 AWP for 60 capsules, 150 mg.	14.4%
Premarin	Wyeth Ayerst	$19.57 AWP for 100 capsules, .625 mg.	$25.74 AWP for 100 capsules, .625 mg.	$30.81 AWP for 100 capsules, .625 mg.	57.4%
Xanax	Upjohn	$30.35 AWP for 100 capsules, .25 mg.	$38.33 AWP for 100 capsules, .25 mg.	$43.65 AWP for 100 capsules, .25 mg.	43.8%
Diazide	Smith Klein Beecham	$35.45 AWP for 100 capsules (50/25)	same as 1989	$31.55 AWP for 100 capsules (50/25)	-11%

Source: *Drug Topics Redbook* for 1989, 1990, 1991.

Industry analysts suggest that the reasons for Premarin's 57.4 percent price increase between 1989 and 1991 is that Premarin, an estrogen product which is now off–patent, has a new application: osteoporosis. The new application provides a new (though overlapping) market for the drug. Thus it appears that its manufacturer, Wyeth Ayerst, has priced it as though it were still on patent. Xanax, an anti–depressant medication that is still under patent by the Upjohn Company, has been shown, since its FDA approval as an antidepressant, to be particularly effective in the treatment of panic disorder. This fact, when added to its on–patent status, may explain the increase in its price of 43.8 percent between 1989 and 1991. Xanax, under patent from 1976 to 1993, was first offered for sale in 1981. The 17–year period of exclusive exploitation granted by the framers of patent law was thereby reduced to 12 years; as of 1991, only 2 on–patent years remain for Xanax. Diazide, an off–patent medication introduced many years ago by Smith Kline Beecham, on the other hand, has been reduced in price. Its target, hypertension, is now treated by a host of new drugs. Diazide's price appears to have been reduced to meet the competition.