The Heritage Foundation Issue Bulletin

No. 66 | The Heritage Foundation • 513 C Street • N.E. • Washington, D.C. • 20002 • (202) 546-4400

June 16, 1981

THE PATENT TERM RESTORATION ACT
(S.255, H.R. 1937)

PATENTS AND THE DRUG INDUSTRY

As a means of encouraging innovation and the disclosure of new products, Congress passed The Patent Act in 1936. The Act granted the inventor of a product or process a seventeen-year period of exclusive rights to the invention, during which time he could enjoy the commercial rewards flowing from the development. After the seventeen-year patent period, other producers are allowed to market competing versions of the product or process, using the formula specified in the patent.

It is rare, of course, for any product to be marketed immediately after it is invented. Normally, a development and pre-marketing period is necessary before it can be put into commercial use, and so part of the patent period may be used up before revenue can be expected. Nevertheless, an inventor usually has good reason to suppose that he will enjoy most of the seventeen-year period provided for in the Act.

The situation is often very different in the case of the drug industry, because an extensive testing and evaluation process must be undertaken before a patented substance can be marketed. When a potentially useful pharmaceutical substance is synthesized or isolated, the company will apply for a patent. The patent is usually received within four or five years, at which point the seventeen-year clock begins to run. Meanwhile, the substance must undergo animal and pre-clinical tests, and a further period of clinical testing and assessment, under the auspices of the Food and Drug Administration (FDA). The drug cannot be marketed to the public until the FDA has concluded that it is both safe and effective.

Because the FDA-required testing and evaluation period applies to these new substances, the so-called effective patent

life (EPL), that is the period during which the inventor has the exclusive right to market the drug, may be much less than seventeen years. The EPL will depend on the duration of three periods -- the pre-clinical and clinical testing period, the FDA approval period, and the period between the application and the granting of the patent.

THE EROSION OF THE EFFECTIVE PATENT LIFE

The average EPL of drugs has been declining steadily for several years. As Table I indicates, the period of effective protection for marketed drugs declined by almost seven years between 1960 and 1978, and there is every indication that the downward trend is continuing. In other words, the length of time in which a new drug can be marketed with the protection of a patent is now about one-half of the seventeen-year period specified in the Patent Act. It should be remembered, moreover, that Table I represents the average EPL, and that the EPL is not known with much precision when the drug is first patented and the development decisions are made. It can vary widely; it has even been known in extreme cases for a company to discover that no patent time remains at all when its discovery was finally approved for use.[1]

To some extent, this decline in the EPL has been due to changes in the length of the pendency period (the time between the patent application and the issuance of the patent) and the pre-clinical testing period. Eisman and Wardell have shown that between 1968 and 1979, for instance, the pending period decreased by 1.1 years and the period between the patent applications and the start of the FDA approval process increased by an average of 0.5 years -- decreasing the EPL by 1.6 years.[2] But more importantly, there has been the growth in duration of the FDA approval process. Until this is complete, a drug cannot be marketed, even though the patent "clock" is running. Between 1968 and 1979, Eisman and Wardell found, the clinical testing and evaluation period increased by an average of 2.4 years.

The lengthy FDA evaluation process has been a source of concern in the drug industry for some time, since it cuts deeply into the EPL. The Federal Food, Drug and Cosmetic Act requires the FDA to process and approve all new drug applications within 180 days of filing, or to give the applicant notice of an opportunity for a hearing on the application's deficiencies. If more time is needed, there must be mutual agreement between the FDA and the company.[3] In an analysis of drugs first submitted for

---

1 National Review, May 23, 1981, p. 935.

2 Martin Eisman and William Wardell, "The Decline in Effective Patent Life," Research Management, 21 (1) 1981, pp. 18-21.

3 In its application, the company must include a full report of animal and clinical tests which show that the drug is safe and effective; a statement of the drug's composition; and processing and marketing information.

TABLE I

Expected Effective Life of Drug Patents
(1960-1978)

Year of Introduction into U.S. Market	Expected Effective Patent Life (Years)
1960	16.5
1961	16.1
1962	15.7
1963	15.4
1964	15.0
1965	14.6
1966	14.2
1967	13.9
1968	13.5
1969	13.1
1970	12.7
1971	12.4
1972	12.0
1973	11.6
1974	11.2
1975	10.9
1976	10.5
1977	10.1
1978	9.7

Source: Meir Statman "The Effect of Patent Expiration on the Market Position of Drugs," in Robert Helms (ed.), Drugs and Health (Washington, D.C.: American Enterprise Institute, 1981), p. 142.

approval in 1975, however, the General Accounting Office (GAO) found that the average time necessary for approval was twenty months, comprising seventeen months of FDA time and three months of industry time. The GAO found only a small variation in the time taken to process important new drugs and that needed for other drugs. It also discovered that in the case of small companies (with research budgets of less than $10 million) the average approval time was four to five months longer than for larger companies, and the EPL was correspondingly shorter.[4]

---

[4] FDA Drug Approval (Washington, D.C.: General Accounting Office, May 1980), p. 5. In recent years the FDA has concentrated on speeding up the approval time for the more important drugs, but in 1978 this still occupied an average of twenty months -- down from twenty-four months in 1976. Over the same period the approval time for less important drugs increased by twelve months.

The GAO pointed out that the United States has a much longer approval period than most European countries or Canada. The average time for approval in Switzerland, for instance, was twelve months (for drugs approved between 1974 and 1977); in Canada it was sixteen months; and in the United Kingdom five months. This shorter approval time meant that many very important new drugs were available in Europe and Canada months or years ahead of their availability here. While the differences in evaluation time are due partly to more stringent requirements for the U.S. market, the GAO concluded that a significant part of the delay was due to imprecise FDA guidelines, lack of FDA promptness in notifying drug companies of deficiencies in applications, and other shortcomings in the approval process.[5]

EFFECTS OF THE DECLINE IN EFFECTIVE PATENT LIFE

a) New Introductions

TABLE II

New Single Entity Drug Introductions to U.S. Markets (1959-1979)

Year	Introductions
1959	65
1960	50
1961	45
1962	24
1963	16
1964	17
1965	25
1966	13
1967	25
1968	12
1969	9
1970	16
1971	14
1972	10
1973	17
1974	18
1975	15
1976	14
1977	16
1978	23
1979	15

Source: New Chemical Entity Data Base (Pharmaceutical Manufacturers Association)

---

5 Ibid., pp. 12-28.

As Table II indicates, the number of new drugs entering the American market has fallen dramatically during the last twenty years -- the period during which the average EPL was almost halved. The United States is now lagging behind other major European pharmaceutical-producing countries, such as the United Kingdom and West Germany, in bringing new drugs onto the market.[6]

The drug industry maintains that this fall in the rate of new introductions is related closely to the erosion of the EPL. This does not mean the drug industry is suffering financially, but rather that it is moving away from innovative research into safer areas of business. As Lewis Engman, President of the Pharmaceutical Manufacturers Association, explained before House Health Subcommittee chairman Henry Waxman, the reduction in effective patent protection has led to a situation where in 1960:

> a $3.5 billion industry with 16 year effective patent lives produced 50 new medicines. In 1980 a $22 billion industry with effective patent lives of less than 10 years produced only 12 new medicines.[7]

As the FDA approval period has lengthened, and the EPL has declined, the cost of developing new products has risen sharply. In 1960, the industry estimates, a new drug cost approximately $6.5 million to develop: today the price tag is over ten times that figure.

b) Research Patterns

The increasing costs and risk associated with the erosion of the EPL has had important effects on the level and type of research undertaken by drug companies in the United States. Analysis of the research expenditures of firms shows that although outlays on research have risen during the past twenty years as a percentage of sales, the "real" percentage has fallen, since the cost of research (salaries, equipment etc.) has risen much faster than the cost of marketed drugs.[8]

In addition to the decline in the intensity of research, compared with sales, there has been a shift in the type of research undertaken. According to Dr. Richard Faust, director of research at Hoffman-La Roche, as much as 25 percent of the research and development budget of even the larger research-oriented firms is now allocated to what he calls "defensive" research, aimed at

---

6 Henry Grabowski, "Regulation and the International Diffusion of Pharmaceuticals," in Robert Helms (ed.), The International Supply of Medicines (Washington, D.C.: American Enterprise Institute, 1980), pp. 5-36.

7 Hearings held April 1, 1981.

8 Henry Grabowski and John Vernon, "The Determinants of Research Development Expenditures in the Pharmaceutical Industry," in Robert Helms (ed.), Drugs and Health (Washington, D.C.: American Enterprise Institute, 1981), pp. 3-20.

extending the marketable life of profitable, existing drugs, rather than to create new products. This, he argues, is at least partly a reaction to the increased risk attributable to FDA regulation and patent erosion.[9] The complex testing and approval procedures required by the FDA have also tended to shift the emphasis away from longer-term research to short-term development work.

The cumulative effect of these research trends has been to reduce the rate of return on drug innovation. Extensive analysis by Meir Statman on post-patent competition reached the conclusion that the rate of return on drug innovation has fallen from approximately 20 percent in 1958 to 10 percent for drugs introduced in 1978.[10]

The response of the drug companies to this change in the market has been two-fold. First, there has been a tendency to seek "big winners" and to market them very strongly, rather than to bring a stream of new products onto the market. Second, there has been a significant shift in activity into non-pharmaceutical business. A survey of the major firms by Virts and Weston, for example, showed that for eight leading firms, the percentage of sales revenue coming from pharmaceuticals declined by 3.6 percent (down to 55.3 percent between 1973 and 1978) -- representing $0.5 billion in 1978.[11]

THE PATENT RESTORATION ACT OF 1981

Background

The drug industry argues that until the full effective patent period is restored for new drugs, there will be no improvement in the number of drugs entering the American market, and that the United States will continue to lag behind European countries regarding the availability of innovative medicines for patients. In particular, companies have maintained, the lengthy and often unpredictable FDA approval process should not be included in the patent period, so that the seventeen-year patent period agreed by Congress would apply in practice for drugs, not just in theory.

Identical bills have been introduced in the House and Senate to restore the effective patent period for new drugs by excluding the FDA approval period from the patent life. The Senate bill (S. 255) is sponsored by Senator Charles Mathias (R-Md.), and the House bill (H.R. 1937) by Representative Robert Kastenmeier (D-Wis.).

---

9 Richard Faust, "The 1962 Drug Amendments," American Pharmacy, April 1979, p. 12.

10 Meir Statman, "The Effect of Patent Expiration on the Market Position of Drugs," in Helms, Drugs and Health, p. 151.

11 John Virts and Fred Weston, "Expectations and the Allocation of Research and Development Resources," in Helms, Drugs and Health, p. 42.

The Senate Judiciary Committee held hearings on the measure on May 19, 1981 and reported out the legislation unanimously. Hearings have not yet been scheduled in the House on the bill itself, but the patent issue was explored before Representative Waxman's Subcommittee on Health and the Environment.

The bill has considerable support in the Congress and the nation. Senator Mathias has been joined on the bill by Senators Thurmond, Robert Byrd, Percy and others, and the House bill has about three dozen co-sponsors. Secretary Schweiker has endorsed the measure's objectives, and the bill has the support of both the Commerce Department's Patent Office and the EPA.

Provisions of the Bill

The Patent Term Restoration Act would add a new section 155 to the patent law, which would have the effect of extending the patent term of products subject to the federal approval process by the length of time consumed by regulatory review -- up to a maximum of seven years. The regulatory review period is not considered to begin, for the purposes of the Act, until a patent is actually granted, so if part of the FDA approval period precedes the granting of the patent, that element of the period would not be included in the calculation. If a drug is undergoing review when the measure is enacted, the period of extension would be calculated from the effective date of the Act. Drugs already on the market at that point would not be eligible for an extension.

The bill covers new drugs, new animal drugs, food additives and color additives subject to the Federal Food, Drug and Cosmetic Act; human and veterinary biological products; pesticides; and chemicals subject to the Substance Control Act.

ARGUMENTS SUPPORTING THE BILL

Supporters of the bill contend that the measure will spur innovation and increase the number of useful drugs reaching the market. This will result in a downward pressure on drug prices, they maintain, because there will be an increase in competition between companies. At present, the erosion of the effective patent period tends to discourage the development of drugs which might compete with those dominating the market. In addition, say supporters, the measure will be of particular help to smaller, research-based companies, which now face longer average FDA approval periods than major companies as well as the brand loyalty barrier. The bill should encourage more product competition and reduce the emphasis on marketing competition.

A full patent life will not improve the availability of drug innovation by increasing profits as such, supporters maintain, but rather by making research and innovation more attractive in comparison with other uses of investment capital.

ARGUMENTS OPPOSING THE BILL

It would be more accurate to say that the bill has attracted skepticism rather than outright opposition. Critics of the measure do not, in general, deny that the effective life of drug patents has declined in recent years, or that the intent of the Patent Act has been undermined with respect to drugs. What they say is that the reduction in the patent life may be, on balance, beneficial to the public, and that restoring the patent life may not be in the best interest of patients. The arguments put forward to support this contention include the following.

a) Barriers to Competition

Critics argue that the patent awarded to a drug allows that pharmaceutical company not merely to reap the just rewards of innovation -- which is the intended purpose of a patent -- but also to build up such a powerful market position around its brand name that its monopoly continues, in practice, long after the patent expires.

There is some evidence to support this contention. Brand-name drugs do seem to be successful in holding off competition and retain a high proportion of the market after the patent expires -- although generic and brand-name competitors have a good deal of success in breaking into the market in the case of antibiotics and hospital drugs generally.[12]

Some supporters of the legislation reply that the strong market position of brand name drugs after patent expiration is a reflection of the understandable tendency of physicians and patients to stay with a drug they know and trust. If, on the other hand, brand loyalty is due to an unreasonably long period of patent protection, the solution would seem to be to amend the patent law by reducing the seventeen-year period in the case of drugs, not to rely on the slowness of FDA approval procedures to do so in an indiscriminate manner.

b) Too Many Drugs?

It has been argued by the bill's critics that although the number of new drugs coming on the market has fallen dramatically during the last twenty years, the number of "breakthrough" drugs has been reasonably constant. The effect of the reduction in the effective patent life, in other words, has been to reduce the number of what have been described as "lousy drugs" by Ben Gordon of the Health Research Group.[13] The reduction in the number of duplicates and molecular modifications is said to be actually beneficial to the patient, since it reduces dangerous confusion and wasteful marketing costs.

---

12 Statman, "Patent Expiration," p. 145.

13 National Journal, November 22, 1980, p. 1981.

While there is truth to the claim that the reduction in the number of new drugs coming onto the market has not involved a significant drop in the number of breakthrough drugs, it would be very wrong to assume that non-breakthrough drugs are necessarily not significant developments. Modifications of the basic chemical often have very different side-effects from those of the original drug, and for certain patients that may lead to a dramatic improvement in the drug's effectiveness. A decline in the number of these modifications is very much against the interest of patients.

c) Cost of Drugs

Related to the claim that extending the effective patent life of a drug will help it to dominate the market is the contention that it will also drive up the prices of prescription drugs, because a company will be able to enjoy a monopoly price for a longer period. This argument, however, assumes that the only source of price competition experienced by a drug company stems from generics entering the market when the patent expires.

The point which is overlooked by those who see patents as leading to higher general drug prices is that an encouragement to experiment and produce modifications and innovations means a flow of substitutes onto the market -- which serves to exert downward pressure on prices. The guarantee of a full patent life would spur research to develop competitors to breakthrough drugs by making research more attractive. Not only would this increase price competition, to the benefit of consumers, but it would also increase the range of drugs available.

CONCLUSION

The Patent Term Restoration Act would provide a full patent life to new drugs by adding the FDA approval period, during which time the drug cannot be marketed, to the period of protection. There is strong evidence that the erosion of the effective patent life in the past twenty years has had a detrimental effect on the supply of new drugs and the level of competitive innovation. The bill is a simple and probably very effective way of reversing this trend in a manner which will increase the range and improve the rate of development of drugs -- to the benefit of patients.

Stuart M. Butler, Ph.D.
Policy Analyst