THE IMPORTANCE OF PATENT TERM RESTORATION TO PHARMACEUTICAL INNOVATION

by Peter Barton Hutt

During the past thirty years, pharmaceutical innovation in the United States has declined dramatically. As a result of the increased time needed for testing and other regulatory requirements, the effective patent life of a new pharmaceutical product has been reduced to less than half of the seventeen-year patent term set by Congress for all inventions. Legislation to restore this lost patent protection is urgently needed to reinvigorate investment in pharmaceutical research.

A recent report of the National Academy of Sciences defined "innovation" in the following way:

> Economists define technological innovation as the initial commercial application of a new product or process. From the standpoint of the industrial firm, the activities leading to innovation involve a long-term investment decision process. This process incorporates the various stages of research, development, capital investment, and commercialization. A firm's investment in these activities are influenced by the same basic forces that govern outlays on other investment projects. Thus, investments for R&D and innovation will be determined by their perceived profits and risks relative to alternative investment opportunities as well as the cost and availability of funds for investment.[1]

In the pharmaceutical industry, innovation is thus best measured by the number of new chemical entity (NCE) drugs approved by the Food and Drug Administration (FDA) for marketing during any particular time. These NCE drugs represent, in the words of the National Academy, "the initial commercial application of a new product or process."

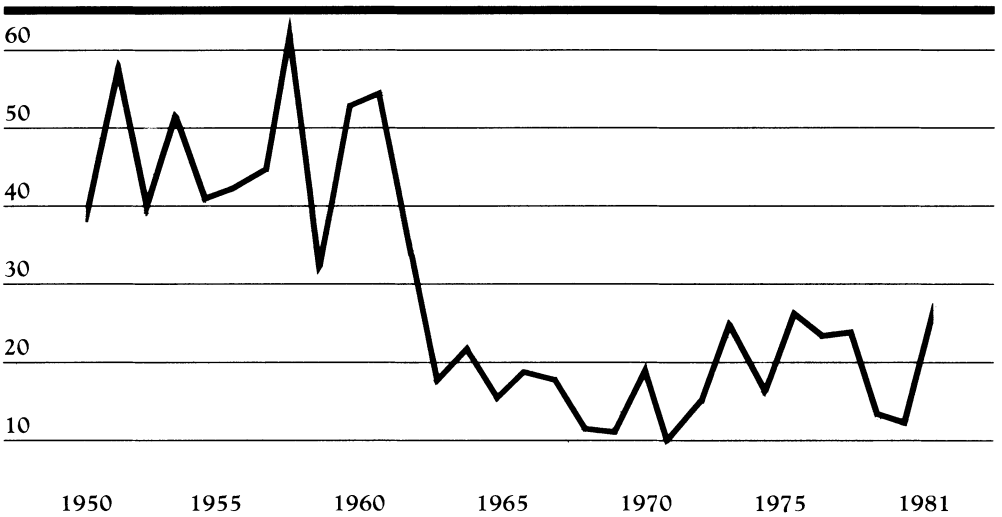
Mr. Hutt testified in support of patent term restoration on behalf of the Pharmaceutical Manufacturers Association before the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology on February 4, 1982. The author wishes to thank Thi D. Dao, Ph.D., Director of Economic Studies for the Pharmaceutical Manufacturers Association, for her assistance with the figures and tables and the economic analysis.

During the period from 1950 to the present, pharmaceutical innovation in the United States has declined substantially. Figure 1 shows the dramatic reduction in yearly FDA approvals of NCE drugs for use in this country. This reduction in pharmaceutical innovation is attributable to two interrelated factors.

First, drug research is lagging behind the growth rate of the drug industry. Pharmaceutical research and development (R&D) expenditures continue at a fairly steady rate of 12 percent of drug sales. But when these figures are adjusted for inflation, as shown in Figure 2, it becomes apparent that the rate of pharmaceutical R&D in relation to drug sales has been reduced by about one-third in the past fifteen years, because drug research costs have increased dramatically in relation to drug prices.

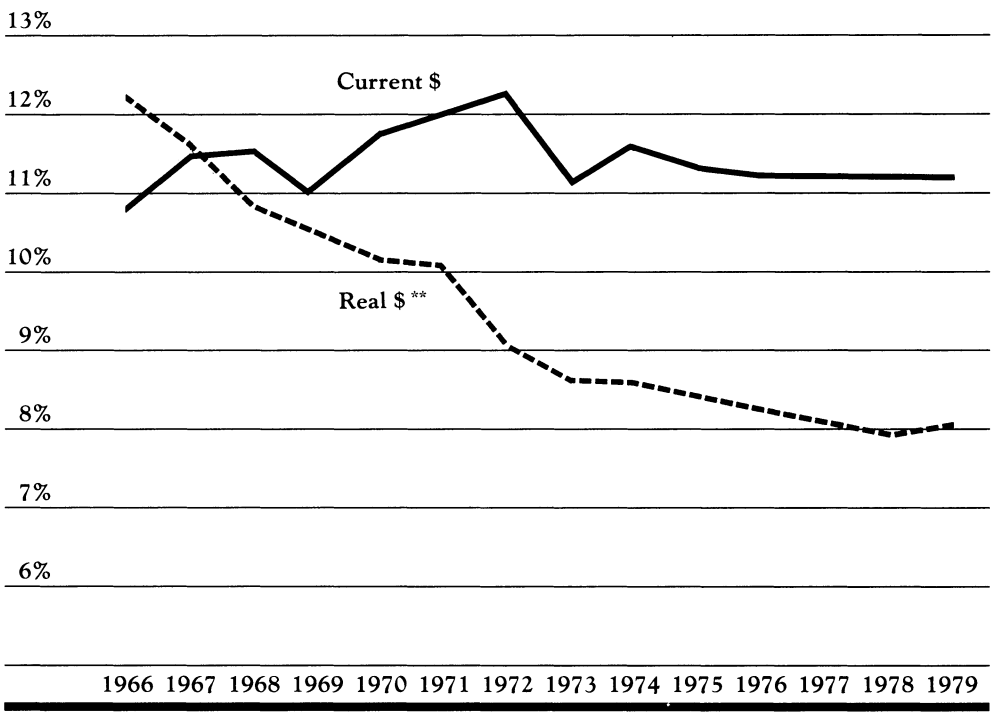
Second, the cost of developing and obtaining approval of an NCE drug has also risen dramatically. It is estimated that about ten thousand candidate drugs are synthesized for every one that actually gets to market. For every ten drugs that reach the very expensive and time-consuming clinical investigation (IND) stage, only one is ultimately marketed.[2] The cost of chemical, animal, and clinical testing of NCE drugs has soared. The time required for FDA approval is more than three times longer than it was twenty years ago. The cost of money has escalated. As a result, the total amount of investment needed to produce a single approved NCE drug has increased dramatically.

Figure 1
Number of New Chemicals Entities Approved by FDA: 1950-1981



Source: U.S., Congress, House, Committee on Energy and Commerce, Subcommittee on Health and the Environment, *Health and the Environment: Miscellaneous, Part 2,* 97th Cong., 1st sess., 1981, p. 292; and *FDC Reports,* January 11, 1982, p. 16.

Figure 2
U.S. Pharmaceutical R&D Expenditures As A Percentage of U.S. Pharmaceutical Sales: 1965-1979*



*R&D as a percentage of sales is computed by dividing human and veterinary R&D expenditures in the United States by domestic production (*i.e.*, domestic sales and exports, including subsidiaries abroad) times 100.
**Sales Deflator Producer Price Index for Ethical Pharmaceuticals, Bureau of Labor Statistics: 1967 = 100. R&D Deflator: Biomedical R&D deflator used by the National Institutes of Health, Department of Health, Education, and Welfare: 1967 = 100. *PMA Annual Survey* (various years).

The economic literature discloses some six studies of the increase in the cost of an NCE drug in real dollars during this time period. Each uses a different methodology and data base, but together they document this major increase in the cost of an NCE drug.

- Schwartzman found the R&D cost per NCE drug to be $1.3 million in 1960 and $24.3 million in 1973, excluding the cost of capital.[3] Adjusting these figures to 1980 dollars ($3.7 million and $48.6 million), this reflects a 13-fold increase in the real cost of an NCE drug in this ten-year period.
- Sarett found the cost per approved drug (not per NCE drug) in one pharmaceutical firm to be $1.2 million in 1962, $3.0 million in 1967, and $11.5 million in 1972, excluding the cost of unsuccessful projects, capital, and discovery research.[4] Adjusting the 1962 and 1972 figures to 1980 dollars ($3.4 million and $25.9 million), they reveal a 7.6-fold increase in this ten-year period.

- Mansfield[5] and Schnee[6] jointly studied some seventy-five drug research projects undertaken in one pharmaceutical firm during the period 1950 to 1957. For the period prior to 1962, R&D cost per marketed NCE was $1.1 million, or $3.1 million in 1980 dollars, excluding the cost of capital and discovery research.
- Clymer found that the R&D cost for a marketed NCE drug in one pharmaceutical company in 1971 was $12 million.[7] Clymer also found that the R&D discovery cost amounts "to at least as much as the development costs" for an NCE drug, thus making the total costs approximately $24 million in 1971 or $56.5 million in 1980 dollars, excluding the cost of capital.[8]
- Hansen, using an accounting approach, directly studied R&D expenditures based on a sample of NCE drugs from a number of drug companies.[9] He found the average cost between 1963 and 1975 to be $54 million. Expressed in 1980 dollars, this amounts to $70 million including the cost of capital and $47.6 million excluding the cost of capital.
- Baily developed a model of new product development and applied it to the pharmaceutical industry on the basis of aggregate industry figures.[10] He projected $6 million per NCE drug before 1962, or $16 million in 1980 dollars.

The following table summarizes these six studies:

Table 1
Real Research and Development Costs per NCE Drug: 1962-1972

(adjusted to 1980 dollars)	Pre-1962	Post-1962
Schwartzman	3.7	48.6
Sarett	3.4	25.9
Mansfield/Schnee	3.1	–
Clymer	–	56.5
Hansen	–	47.6
Baily	16.0	–
Average	6.5	44.7

These figures do not, of course, show the increase in real R&D cost per approved NCE drug for the past ten years. They show only the increase during the ten-year period from about 1962 to 1972. If figures were available during the past ten years, they would undoubtedly show still another increase in the real R&D cost per approved NCE. Nonetheless, they show an average cost of an approved NCE drug before 1962 of $6.5 million and after 1962 of $44.7 million, in 1980 dollars. This represents a real 6.9-fold increase even without including the cost of capital.

The recent report by the Office of Technology Assessment (OTA) on patent term restoration shows that domestic R&D investment by U.S. pharmaceutical firms has increased in current dollars from $304 million in 1965 to $1,089 million in 1978.[11] Applying the standard deflator used by OTA, these figures must be restated as an increase from $328.8 million in 1965 to $543.8 million in 1978, or a 1.6-fold increase during that time period. During the ten-year period from 1962 to 1972, however, the real cost of an NCE drug rose at a substantially greater rate—at least 6.9-fold and probably much higher, as documented earlier. The net result is that the U.S. pharmaceutical industry is investing in fewer NCE drug research projects than it once did. That total R&D investment is being applied to a much smaller number of NCE drug research projects, because the real cost of each such project has increased at a much faster rate than the rate of increase of total real R&D.

Thus, from any given level of R&D investment by the pharmaceutical industry today, the country realizes fewer NCE drugs than it once did. Because of this decrease in real R&D investment by the industry, it is not surprising that the statistics show a substantial decline in pharmaceutical innovation in the United States.

The Importance of Pharmaceutical Innovation

New chemical entity drugs represent our major hope as a society for reducing the burden of morbidity and mortality in this country. Pharmaceutical innovation is also a primary means through which the skyrocketing costs of health care can be brought under control and perhaps eventually even reduced.

The infectious diseases that took such a heavy toll at the turn of the century now cause less than 2 percent of the deaths they caused then.[12] Diseases dreaded as recently as thirty years ago now largely are under control. New pharmaceutical products have played a key role in the declining rates of death and disease shown in Table 2 and Table 3 for a wide variety of serious disease categories.

Medicine to achieve the same dramatic results against our current leading causes of death, heart disease and cancer, are now major targets for the pharmaceutical industry.

It is not true that only major new "breakthrough" drugs contribute to this reduction in morbidity and mortality. We must pursue progress in small as well as large increments. A new drug is not uniformly safe and effective throughout the entire population. Biological variations among people require development of a large armamentarium of drugs to assure that the benefits of pharmaceutical science reach as many people as possible.

Whoever argues that a drug offers little or no therapeutic advantage is talking about an average over millions of people, not about a single patient. A drug that seems to offer little therapeutic advantage to the entire population may well be, and often is, the only drug that offers *any* therapeutic benefit to a small subpopulation. And if *you* happen to be one of the individuals in that subpopulation, that particular drug has an enormous therapeutic advantage, rather than the small therapeutic advantage attributed to it by others. Indeed, for *you* it is the only

Table 2
Decline in Death Rates (per 100,000 in specified group)

	1960	1980	% Change
Measles	380	10	−97.4
Meningitis	2,316	1,320	−43.0
Rheumatic Fever and Rheumatic Heart Disease	18,411	7,950	−56.8
Streptococcal Sore Throat, Scarlatina, and Erysipelas	108	10	−90.7
Syphilis	2,945	180	−93.9
Tuberculosis	10,866	1,770	−83.7
Ulcer of Stomach and Duodenum	10,830	5,750	−46.9
Whooping Cough	120	10	−91.7

Note: The death rate for mumps also declined 93.00 percent from 1968 to 1978; for acute rheumatic fever, declined 81.2 percent from 1960 to 1978; and for rubella, declined 58.3 percent from 1968 to 1978.

Source: National Center for Health Statistics, *Monthly Vital Statistics Reports. Annual Summary of Births, Deaths, Marriage and Divorce: United States, 1980* 29, no. 13 (Washington, D.C.: Government Printing Office, 1981) p.20; National Center for Health Statistics, *Vital Statistics of the United States, 1960,* Vol. 2, pt. A (Washington, D.C.: Government Printing Office, 1961) p. 5-102.

Table 3
Decline in Disease Rates

	1960	1970	1980	% Change
Measles	441,703		13,506	−96.9
Mumps		104,953	8,576	−91.8
Rheumatic Fever, Acute	9,022		432	−95.2
Rubella		56,552	3,904	−93.1
Tuberculosis	55,494		27,749	−49.9
Whooping Cough	14,809		1,730	−88.3

Source: U.S., Department of Health and Human Services, *Morbidity and Mortality Weekly Report: Annual Summary, 1981,* 29, no. 56 (September 1981): 10, 12; and *Morbidity and Mortality Weekly Report: Annual Supplement, 1961* 29, no. 54 (September 1961): 4.

important drug. Classification of a drug as an important or unimportant innovation is therefore arbitrary and ignores the specific needs of individual patients.

This concept deserves much wider recognition than has been given to it in the past. It is at the heart of the development of a number of new drugs which, although not broadly classified as "breakthrough" products for society as a whole, are nonetheless of crucial importance to individual patients for the alleviation and cure of their disease. That is why the availability of a wide variety of drugs for any particular disease is so vital to the public health.

Drug prices have been one component of health care costs that have remained relatively stable over the last twenty years. While the consumer price index has risen 178 percent and health care costs have increased 629 percent, the cost of prescription drugs has increased only 34 percent.[13] The drug share of national health expenditures has declined every year during this past decade.[14]

The continual introduction of new drugs thus not only can improve therapy but can, at the same time, help keep down the price of all medicine and make drug therapy more cost effective.

In an era when the cost of Medicare and Medicaid threatens the stability of our entire economy, one need only look at the savings from new drug introductions to appreciate how better therapy can produce lower costs. Tagamet, SmithKline Beckman's new ulcer drug—if used by all those who could benefit from it—could save some $250 million a year in foregone surgery and physician visits.[15] Antipsychotic medicine for the control of mental illness has shortened treatment periods and reduced the need for expensive hospitalization. In 1973, only 35 percent of mental illness patients required inpatient service, down from 77 percent in 1955.[16]

Pharmaceutical innovation thus saves lives, improves the quality of life, and reduces the cost of health care—all at the same time.

The Crucial Role of Patents in Pharmaceutical Innovation

Nearly two hundred years ago, Congress—pursuant to the specific authority set forth in Article I, Section 8, of the Constitution—created our patent system for the purpose of encouraging innovation.

The Supreme Court has repeatedly recognized and reinforced "the policy of stimulating invention that underlies the entire patent system."[17] Chief Judge Markey of the U.S. Court of Customs and Patent Appeals has remarked that:

> No institution has done so much for so many, with so little public and judicial understanding, as the American patent system. . . . Yet

> there are *very few Americans* who understand the American patent system. If in our ignorance we destroy the effectiveness of that system, we and our children will pay a tremendous price for generations to come.[18]

Without the stimulus of the temporary period of exclusivity provided under the patent law, there would be far less incentive for pharmaceutical companies to invest their funds in risky pharmaceutical R&D ventures than in other competing investment opportunities.

The importance of patent protection obviously increased with the size of the investment needed to achieve innovation in any field. If innovation can be purchased cheaply, patent protection is relatively unimportant. As the investment cost escalates, however, patent protection becomes far more important. In the pharmaceutical industry, where the cost of an NCE drug has escalated so dramatically, the assurance of strong patent protection has become increasingly crucial to the future of the industry. This fact was explicitly recognized in the recent OTA report,[19] in the Patent Amendments of 1980,[20] and in a 1968 General Accounting Office report on pharmaceutical research.[21] Without an adequate patent system, innovation in the pharmaceutical industry would wither and the public health would correspondingly suffer.

In 1861, Congress selected seventeen years as the period of patent exclusivity.[22] Since 1861, the seventeen-year patent year term has remained unchanged. No one can prove empirically that seventeen years was then, or is now, the perfect patent term. But no one can deny that the patent system, as it has existed for more than a hundred years, has contributed enormously to innovation generally, and to pharmaceutical innovation in particular.

The Drug Research, Investigation, and Approval Process

A report prepared in 1980 by the House Subcommittee on Science, Research and Technology demonstrates the major impact of FDA regulatory requirements throughout the drug development process—from the moment a new chemical entity is synthesized until final FDA approval of a new drug application (NDA).[23] That process is divided into three major stages: preclinical research, clinical investigation, and NDA approval.

Preclinical Research. Before clinical investigation of a new chemical entity may begin, substantial research must be undertaken on the chemical, pharmacologic, and toxicologic properties of the chemical in order to meet FDA prerequisites for clinical research. As the report of the House Subcommittee states, the FDA requirements "... affect the type and direction of research and other development activities which

must be done once a new chemical entity is identified."[24] The FDA investigational new drug (IND) regulations require that such preclinical research include sufficient chemical information about the drug to set exact specifications, using sophisticated analytical methodology, to assure little or no variation in the entity.[25] The IND regulations also require that before clinical investigation may begin, sufficient animal testing data must exist to justify use of the chemical in humans.[26] The FDA requirements for good laboratory practices (GLP) in conducting preclinical research for a new drug have substantially added to both the cost and the time for this type of research.[27]

Accordingly, it is not surprising that the House Subcommittee report found that preclinical research can take one to four years to complete.

Clinical Investigation. Once adequate preclinical research is completed, an IND can be filed to justify clinical investigation of the new chemical entity in humans. The amount of information required by FDA to be filed with an IND is extensive. The IND regulations, including the requirements for protection of human subjects, currently comprise some twenty-five pages in the Code of Federal Regulations.

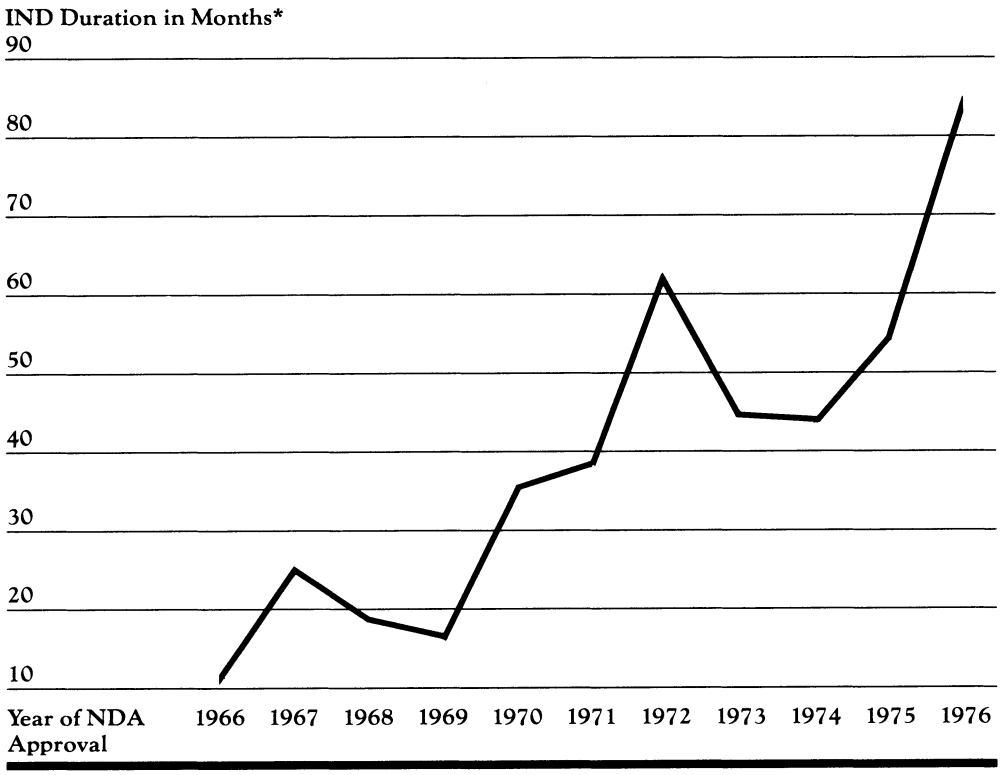
Just as the IND provisions impose regulatory requirements on preclinical research, the NDA provisions impose regulatory requirements on the clinical investigation conducted pursuant to an IND. Lengthy and detailed FDA regulations and guidelines establish what the agency demands on the nature of evidence of safety and effectiveness for a new drug. It is well-known that these requirements are rigorous and demanding. They exceed what is required in other countries.[28] The time spent on clinical investigation has therefore increased dramatically, as shown in Figure 3. The House Subcommittee report found that it takes about four to six years to conduct this IND research in accordance with FDA requirements.

NDA Approval. After the FDA requirement for preclinical research and clinical investigation are completed, an NDA is submitted to the agency to obtain approval of the drug for marketing. Until that approval is obtained, the drug may not be commercialized.

The statute requires FDA to act upon an NDA within six months. The House Subcommittee report found that the *average* NDA approval time was 14 months in 1963, rose to 37.3 months in 1971, dipped to 20 months in 1978, and climbed back up to 35.2 months in 1979. The vast majority of these NDAs are eventually approved, but the amount of time taken by FDA to review them, during which the drugs cannot be marketed, is very significant.

The number of new chemical entities (NCEs) approved during the past few years has dipped and peaked, with no apparent trend. During the past eight years, for example, there were five years during which

Figure 3
Trends in IND Duration



*IND duration is defined as the mean time from IND filing to NDA submission.

Source: Wardell, DiRaddo, and Trimble, "Development of New Drugs Originated and Acquired by United States-Owned Pharmaceutical Firms, 1963-1976," *Clinical Pharmacology and Therapy* 28 (1980): 272

more than twenty NCEs were approved, and three years during which twelve to fifteen NCEs were approved. This fluctuation appears to depend upon the number of NCEs in the pipeline and ready for approval during a particular year.[29] This level of NCE approvals sharply contrasts, however, with the much larger numbers of NCEs approved in the 1950s, as shown in Figure 1.

Attempts at Improvement. In 1980, the time from IND submission to NDA approval averaged 8.3 years for NCE drugs. During the past few years, numerous studies have been conducted to determine how the regulatory process governing new drugs could be improved. While all of these studies offer suggestions for improvement, none is optimistic that such improvement will be substantial. Dr. Richard Crout, Director of the FDA Bureau of Drugs, summed it up by stating that:

> While it would not be easy, I believe there are some opportunities to reduce this time in the future—but, in my judgment, not more than

a year or so—by modification of certain regulatory requirements and by continuing our emphasis on efficient management of the review process.[30]

The Gradual Erosion of Pharmaceutical Patent Protection

Although Congress has not changed the seventeen-year patent term for pharmaceutical products, the government research, testing, and approval requirements just described have substantially reduced the effective length of that term.

When a drug firm discovers a promising new chemical compound, the first thing it does, even before making the investment to develop it into a marketable medicine, is to file for a patent. Once that patent is issued, its seventeen-year term immediately begins to run. But at the time the patent is issued, the innovating firm may be far from sure it will ever have a marketable drug. For that assurance the government requires substantial chemical, animal, and human testing, and then FDA approval of a new drug application (NDA) for the product. This testing and approval usually takes about seven to thirteen years.[31]

For pharmaceutical products, therefore, the seventeen-year patent term has become a legislative figment. In reality, a drug patent has a much shorter effective life. As a result, incentives to invest in pharmaceutical R&D have been substantially reduced.

The erosion of effective patent life for pharmaceuticals began about twenty years ago. It coincides with the erosion in pharmaceutical innovation, as measured by the yearly FDA approval of NCE drugs. It is readily apparent that the public has been the loser. The sick and particularly the elderly—the people with diseases for which medicine has not yet been developed—have been the real victims of lost patent life and reduced pharmaceutical innovation.

Studies on Effective Patent Life of NCE Drugs

A number of studies have been conducted, each using a somewhat different methodology and data base, to study the precise reduction that has occurred in the effective patent life for NCE pharmaceutical products during the past twenty years. All studies show the same trend. Both individually and in combination, they confirm a substantial decrease in effective drug patent terms. The effective patent life of the NCE drugs approved by FDA in 1980 and 1981 was *less than half* the seventeen years provided by Congress.

- The Pracon Study. A study conducted by Pracon, Inc., an independent consulting firm, for Hoffmann-La Roche, Inc., found that the

average effective patent life of NCE drugs approved by FDA during the period 1950 to 1977 was reduced from 18.2 years to 8.8 years.[32]

- The Schwartzman Study. Professor David Schwartzman of the New School for Social Research in New York City studied the NCE drugs approved by FDA during 1966 to 1973.[33] He calculated the arithmetic mean of the effective patent life of NCEs during this time to be 13.1 years. Moreover, he found a progressive reduction in the effective patent life during that period, from 13.9 years between 1966 and 1973 to 12.4 years between 1970 and 1973.
- The Statman Study. Professor Meir Statman of the University of Santa Clara studied a sample of 126 NCE drugs approved by FDA between 1949 and 1975.[34] He found "a continuous decline in the effective life of drug patents" and developed an equation to estimate the effective life of drug patents for 1960 to 1978.
- The Eisman and Wardell Study. Professors Martin Eisman and William Wardell of the University of Rochester studied the effective life of NCE drug patents during 1966 to 1979.[35] They found the effective patent life declined from 13.6 years in 1966 to 9.5 years in 1979.
- The PMA 1980 Study. The Pharmaceutical Manufacturers Association obtained additional data for the year 1980.[36] They show that for NCE drugs approved by FDA in 1980, the effective patent life decreased still further, to 7.4 years.
- The Wardell 1981 Study. Professor Wardell recently obtained the patent data for NCE drugs approved by FDA in 1981. They show an even lower effective patent life of 6.8 years.[37]
- All studies combined. In order graphically to illustrate the results of these studies, they are plotted on the chart shown in Figure 4. The congruence of these studies is striking.

The Role of Compound, Composition, Use, and Process Patents

Under existing law, every patent application—whether for a pharmaceutical product or for some other invention—must disclose the product, a method of using the product, and a process for making the product.[38] (For a drug patent, the product itself may be described as either a single chemical compound or group of compounds or as a composition of chemicals.) All patent applications must then specify which aspects of the *disclosed* information are *claimed* as part of the invention. Only those aspects claimed as the invention can be patented.

Once a patent application is filed or granted—whether for a pharmaceutical product or for some other invention—additional patent applications may also be filed to cover related new inventions. For example, an entirely new use may be found for a product that had not been described

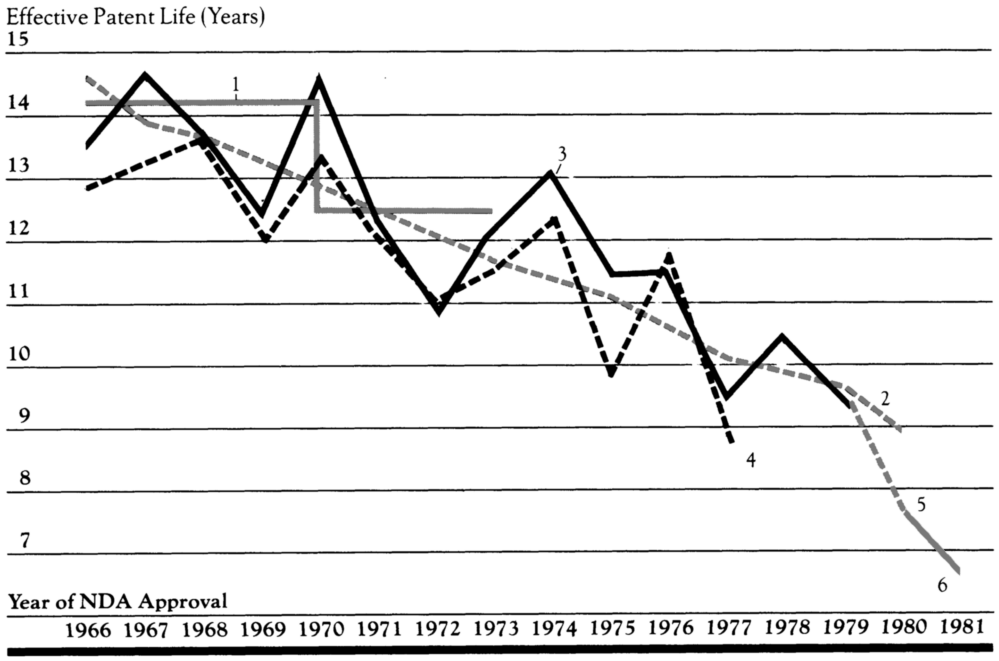
before, or a new process may be found to make the product more cheaply, or with fewer impurities, or in some other useful way.

These subsequent patents, including use patents and process patents, are also important to innovation. Companies must invest substantial resources to develop new uses and methods of manufacturing for existing products. Without the incentives provided by the patent system, these investments surely would be less attractive and perhaps would never be made at all.

Use patents in particular are exceedingly important to encourage innovation. As the Supreme Court recently pointed out:

> The number of chemicals either known to scientists or disclosed by existing research is vast. It grows constantly, as those engaging in "pure" research publish their discoveries. The number of these chemicals that have known uses of commercial or social value, in contrast, is small. Development of new uses for existing chemicals is thus a major component of practical chemical research. It is extraordinarily expensive. It may take years of unsuccessful testing before a chemical having a desired property is identified, and it may take several years of further testing before a proper and safe method for using that chemical is developed.[39]

Figure 4
Trends In Effective Patent Life From Various Sources



1. Schwartzman 2. Statman 3. Eisman & Wardell 4. Pracon 5. PMA 6. Wardell.

In 1972, the FDA issued a proposed policy statement expressing concern about unapproved uses of approved new drugs.[40] FDA urged physicians and manufacturers to cooperate in obtaining the data necessary to substantiate such uses. Without the possibility of a use patent, there would be no incentive for any company to expend the resources necessary for such an effort.

New processes can be equally important. Not infrequently they will produce a product that is safer or more effective through reduction of impurities, increased stability, or other important attributes. Of equal significance, new processes may well result in substantially lower manufacturing costs, thus permitting the company to hold the line on, or even reduce, prices to the consumer, even in the face of major inflationary pressures. Process patents have undoubtedly contributed to the superb record of the pharmaceutical industry in holding down price increases during the past twenty years.

Nor can the industry continually protect a product from competition once the basic compound or composition patent has expired. As already explained, that patent must disclose the compound or composition, a method of use, and a method of manufacturing. Once the patent expires, any competitor is free to market that compound or composition, made in the way disclosed in that patent, for any use disclosed in that patent.[41]

To the extent that the original patent holder makes further investments resulting in new inventions relating to that compound or composition, for which additional patents are in fact granted, those specific new uses and processes would remain the exclusive property of the patent holder for the length of the patent period that covers them. Those new patents could not, however, prevent a competitor from making the product and marketing it in accordance with the specifications and for the uses disclosed in the original expired compound or composition patent.

The Patent Term Restoration Act

Legislation designed to restore, at least in part, the effective patent life originally intended by Congress is now being considered in Congress.[42] It has been supported by the Patent and Trademark Office,[43] the General Accounting Office,[44] and the Food and Drug Administration.[45] The Patent Term Restoration Act would restore to patent owners up to seven years of the patent life lost to government premarket research, testing, and approval requirements. Although not limited to any particular class of products, the bill would have the greatest impact on those products, such as drugs, which are subject to the most rigorous and time-consuming regulatory requirements.

Upon application to the Patent and Trademark Office, the owner of a patent subject to one of the regulatory review periods specified in the bill would receive a limited extension of the patent term. For a new drug, the extension would generally equal the time from the investigational new drug (IND) filing with FDA to approval of the new drug application (NDA), but no more than a maximum of seven years. If the patent is granted after the IND is submitted but before the NDA is approved, the extension would be measured from the date of the patent to the date of the NDA approval. If the patent is granted after the NDA is approved, there would be no patent term extension. Accordingly, no patent could be extended beyond the statutory seventeen years.

This legislation provides a new climate of restored incentives for pharmaceutical innovation. It is justified on grounds of both fundamental equity and protection of the public health.

First, it is plainly inequitable for an NCE drug, once approved by FDA, to have only an average patent life of 6.8 years, when other inventions can obtain an effective patent life of seventeen years. This is not a question of industry asking for special treatment. The bill is designed simply to provide for drugs the same consideration Congress has given to other inventions.

Even if the Patent Term Restoration Act is enacted into law, drug patents will continue at a disadvantage. As noted, the legislation allows a maximum of only seven years patent extension. In 1980, the time from IND submission to NDA approval averaged 8.3 years for NCE drugs, but an average of only 5.7 years would have been restored under the legislation. Thus, if it were applied to the NCE drugs approved by FDA during 1980, it would have increased the average effective patent life to 13.1 years, but would not have fully restored the seventeen years intended by Congress.

The legislation provides no windfall for the pharmaceutical industry. It merely provides some, but not all, of what has been lost as a result of increased governmental research, testing, and approval requirements during the past twenty years. On the basis of equity alone, the legislation is fully justified.

Second, this legislation is vitally needed to reinvigorate pharmaceutical investment and thus to help return pharmaceutical innovation to its former stature. The public interest is best served when new therapies that are safe and effective become available as quickly as possible. For this to happen, incentives to invest in pharmaceutical research and development must be adequate. The current downward trend in real R&D investment in the pharmaceutical industry and in pharmaceutical innovation can only be halted, and hopefully reversed, if the industry perceives that a major change in policy has provided new incentives.

Investment decisions are not made on the basis merely of mathematical computations. Intangible factors, such as the perception of business managers about current governmental and public attitudes toward the industry, play an important role. During the past twenty years pharmaceutical executives have perceived an increasing indifference toward the drug industry, indicated by substantially more burdensome governmental requirements and the decrease in effective patent life. In such an atmosphere, it is not surprising that investment and innovation have declined. They will continue to decline if this atmosphere prevails.

With a restored patent term for pharmaceutical products, the real cost of safe and effective therapy should not increase, and is likely to decrease. But for consumers, the most important question is whether, without patent restoration, the new therapy will exist at all.

From the public viewpoint, the critical factor is not patent lives or research investment—it is safe and effective new medicine. The erosion in NCE drugs parallels the erosion in patent life and research investment. In 1960, a $3.5 billion industry with effective patent lives averaging sixteen years produced fifty NCE drugs. In 1980, a $22 billion industry with effective patent lives averaging less than eight years produced only twelve NCE drugs.

This unfortunate situation is not the product of congressional design. Nor has FDA set out to reduce the effective patent lives and the industry investment in pharmaceutical innovation. No one could have anticipated that a testing and approval process which took about two years in the early 1960s would take seven to thirteen years in 1980. Reduced patent protection for drugs has evolved by accident, and until recently with little notice.

Innovation and price competition are not mutually exclusive. They are complementary. The experience with our patent system for over a century has demonstrated that a seventeen-year patent life provides for innovation and competition for all products in all industries. For pharmaceutical products, the effective patent life has been eroded to less than half what it once was and what Congress intended it to be. The balance between innovation and price competition struck by Congress has therefore been upset, and the public health is suffering as a result.

NOTES

1. National Academy of Sciences, *The Impact of Regulation on Industrial Innovation* (Washington, D.C.: National Academy Press, 1979) p. 8.
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