

Chapter 4

The Implications of Patent-Term Extension for Pharmaceuticals

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This chapter examines the possible impact of patent-term extension on the numerous factors that affect pharmaceutical innovation. The first portion of the chapter concentrates on whether patent-term extension will result in beneficial

pharmaceutical innovation; the second explores the costs associated with patent-term extension and the implications of patent-term extension for the patent owner, the research- and production-intensive firm, and the consumer.

PATENT-TERM EXTENSION AND INNOVATION

A patent provides the right to exclude others from making, using, or selling an invention. The primary incentive provided by this right is the opportunity to derive economic benefits that result from an exclusive market position. By extending the patent term, Congress would extend the period in which these benefits could be derived, and thereby increase the incentives for research and development (R&D) activities.

Whether R&D activities actually increase as a result of these incentives will depend on decisions made in the private sector, and patent terms are but one consideration in these decisions. Patent-term extension will not provide a mechanism for reducing R&D costs, it will not enhance the likelihood of research breakthroughs, and it will not ensure that the results of innovative activity will meet with commercial success. Nor will it stem the trend of domestic companies conducting pharmaceutical R&D overseas.

To the extent that patent-term extension demonstrates Government support for R&D activities, it will provide psychological encouragement to decisionmakers; the effects of such encouragement might, however, be temporary. Since patent-term extension cannot provide firms with additional revenues before the extensions actually begin and the first extensions will not, under the proposed legislation, begin until the 1990's, the immediate incentive provided to the research-intensive firms by patent-term extension is the opportunity to obtain greater returns on R&D investment in the long term.

Although an exclusive market position for a drug can exist beyond the expiration of the original patent term, patent-term extension provides a longer and more certain period in which exclusivity can be assured.

Whether firms will actually increase R&D expenditures on the basis of anticipated increases in returns is, however, highly speculative. On the one hand, the increased economic attractiveness of R&D investment could encourage firms to reallocate corporate funds or obtain external funds in order to increase R&D expenditures. On the other hand, the historic stability of the relationship between R&D expenditures and revenues would suggest that R&D expenditures would not increase unless revenues increased.

In the long term, firms obtaining additional revenues in the extended period will have additional funds available for R&D investment. If historic trends prevail, they will spend on average 8 or 9 percent of these additional revenues for R&D. A major portion of the additional revenues will be used for purposes other than R&D. Taxes will need to be paid, production costs allocated, and dividends distributed. The funds may be used for product promotion or diversification. In talking about additional revenues, it should be noted, however, that such revenues will never be able to be quantified since we can never know what revenues would have been generated if the patent term had not been extended.

Despite the fact that revenues generated by the extension cannot be measured, firms with drugs whose patents are extended will probably derive additional revenues since they will have a longer period of exclusivity in which to market their products at premium prices. Therefore, both sales and prices should be greater than they would have been if no extension existed unless the supply of new drugs increases and exerts a downward pressure on prices. After extensions lapse, sales by research-intensive firms may continue to be higher than they would have been had competition entered the market when the original patent expired. In some cases, second entrants may consider the remaining product lives of drugs coming off extended patents insufficient to justify start-up costs and thus may not enter the market. Furthermore, by the time the extensions end, the patented products may be so firmly established in the market that generically equivalent products could not obtain as great a market share as they would have obtained if the extension had not occurred.

Thus, the revenues of research-intensive firms, particularly firms having high-income drugs, should receive a boost from patent-term extension. Nonetheless, pricing pressures are exerted by other patented drugs and nondrug therapies. Whether these pressures will override the research-intensive firms' ability to charge premium prices will depend on circumstances in the relevant therapeutic markets.

The distribution of additional revenues among firms can affect both the level of research activities that will be undertaken and the types of innovation that may result.

The bulk of additional revenues probably will be earned by high-income drugs. The possibility exists that the relatively few firms who develop those drugs will develop more sophisticated research techniques and more extensive research programs than other firms since they will have more funds available for research and development. Their successes may particularly encourage them to undertake additional R&D activities, some of which may be directed at therapeutic areas that go beyond their present expertise. Under these circumstances, innovation would be expected to increase.

On the other hand, other firms may be discouraged from conducting research in the areas pursued by these successful firms which have been able to increase their research dominance in these areas. In such cases some forms of innovation may suffer.

Furthermore, as a result of patent-term extension, specific types of innovation may be delayed. An originator of a drug may have little incentive to improve his product while it is benefiting from patent protection. Second entrants, when they engage in R&D activities, concentrate on manufacturing processes, drug formulations, combinations of active ingredients, or minor, unpatentable modifications of existing drugs. By delaying the entry of firms who engage in such activities, patent-term extension may delay the introduction of this type of innovation.

On balance, there is a reasonable likelihood that firms may undertake or increase pharmaceutical R&D activities because of the increased incentives provided by the longer effective patent term. If this occurs and drugs are developed more rapidly, a downward pressure might be exerted on the price of some drugs and the product lives of some drugs might decrease.

Although R&D expenditures are expected to increase, they will not increase evenly across all therapeutic areas. Since high-income drugs will derive the greatest benefits from patent-term extension, the tendency of firms to direct their research efforts toward developing drugs for large markets will be reinforced.

To the extent that patent-term extension affects the potential rate of return, drugs that might otherwise be economically marginal may become economically attractive. But this will occur only occasionally, particularly if opportunities exist for developing drugs with greater profit potential. For the many marginal drugs that do not have generic competition after their patents expire, patent-term extension will not generate additional revenues.

Patent-term extension could be a significant factor in encouraging certain types of pharmaceutical R&D. In some therapeutic areas, the loss of effective patent term due to the drug ap-

proval process can be great, and research-intensive firms may not initiate R&D activities in these areas. Patent-term extension may reduce or eliminate the discrepancy between the effective patent terms of drugs in these therapeutic areas and drugs in other areas.

Patent-term extension may also encourage second uses for existing drugs. Not infrequently an existing drug is discovered to have a therapeutic use other than the one approved by the Food and Drug Administration (FDA). FDA approval must be secured for the additional use before the drug can be sold for that use. Because of the period of exclusivity provided by the ex-

tended patent term, the development of the additional use of the drug may be financially attractive.

The balance between research spending and development spending is not likely to be significantly changed by patent-term extension. Generally, the results of research activities are less certain than the results of development activities, and patent-term extension will not alter the relative levels of uncertainty. However, if additional revenues are generated because of patent-term extension, the firms may be more willing to undertake the risk involved with research activities.

PATENT-TERM EXTENSION AND THE COST OF PHARMACEUTICALS

Drugs whose patents are extended are expected to command higher prices during the extension period than they would have, had their patents been allowed to expire. Despite these higher prices, the drugs may cost less than alternative therapies.

This section, however, does not evaluate the cost-benefit relationship of drug therapies, but is solely concerned with the additional costs of drugs during the extended period. The benefits of innovation that might result from patent-term extension are not taken into account in evaluations of cost. Furthermore this section does not take into account the fact that the prices of drugs with extensions can influence the prices of competitive drugs nor the fact that patent-term extension can affect the prices of drugs after extensions end.

There is a distinction between the additional costs to the consumer due to patent-term extension, and the additional revenues to the innovator firm. First, the additional costs to the consumer due to patent-term extension may not be directly comparable to the additional costs at the wholesale level. The drug is dispensed to the consumer by the pharmacist who assesses a prescription fee or a percentage markup. Nonetheless, substantial price benefits could be gained

by the consumer from the purchase of generic drugs. Second, generic competition will have a greater effect on the additional revenues to the innovator firm than on the costs to consumers: when a consumer purchases a low-cost equivalent drug, he saves the difference between the cost of the generically equivalent drug and the cost of the branded drug; but the innovator firm, receives no revenues for the drug he might have sold.

The degree of difference between investment revenues to the innovator firm and increased costs to the consumer cannot be estimated and may vary widely, depending on the portion of the market that would have been captured by generic competition, and whether the innovator firm would have lowered its price in view of the competition. A portion of the revenues derived by the innovator firms can be viewed as the recovery of revenues that would have been generated had the historic postpatent periods of market exclusivity continued to exist.

Projections of the costs of patent-term extension based on historic trends alone overlook some important factors that may influence costs in the future. Some of the determinants of costs are currently undergoing changes, but the magnitude of these changes is not yet known. This

section discusses the uncertainties in the factors determining the costs of patent-term extension and the sensitivity of cost projections to variations in assumptions about the determinants.

Numerous uncertainties limit attempts to predict the increased costs to the public of pharmaceuticals under patent-term extension. The revenues that drugs would have generated without an extension and the revenues they will generate with an extension are not known. The number of drugs that have product lives sufficiently long to extend into the extension period and the average duration of the patent-term extension are not known. Revenues from patented drugs after original patent terms expire depend to some degree on whether competition enters the market. The length of the extension is another unknown factor. There are a number of proposals (discussed in ch. 6) for limiting the duration of the extended patent term.

The general effect of variations in these uncertainties on the costs of patent-term extension can be derived from a sensitivity analysis with three variables: 1) the duration of the average extension; 2) the percentage of drugs, on a sales weighted average, having product lives continuing into the extension; and 3) the percentage by which total sales revenues would have been reduced because of generic competition if patent-term extension did not exist.

The following assumptions have been made to simplify this analysis: the innovator firm charges the same price for drugs during the extension that he charged before the extension; the number of units sold is constant throughout the extension period; the effective patent life for all drugs is 10 years; and the supply of new drugs is continuous, providing the same revenue each year. These assumptions are not intended to reflect actual conditions; the sensitivity analysis is, therefore, not a proper basis for projecting actual costs of patent-term extension to the consumer. However, recognizing this bias, some understanding can be developed from the sensitivity analysis of the effects of the uncertainties on the costs associated with patent-term extension.

For the sensitivity analysis, the values for the duration of the average extension are 3 years, which approximates the average time between the filing of a new drug application for a new chemical entity (NCE) and the FDA approval; 7 years, which approximates the loss of effective patent term now experienced by patented NCEs; and an intermediate value of 5 years. The values for the percentage of drugs, on a sales weighted average, having product lives continuing into the extension are 75 and 100 percent. This variable indirectly reflects the rate of innovation in that as more drugs are developed, product lives are expected to decline. The values for the reduction in total sales revenues that would exist because of generic competition if patent-term extension did not exist are 10, 30, 50, and 70 percent. The 50 and 70 percent values are within the range of the maximum potential wholesale savings projected by the Federal Trade Commission if generic-named products were dispensed instead of more expensive branded drugs.

The results of the sensitivity analysis are provided in table 15. The results are provided per \$1,000 of yearly wholesale sales of patented drugs during the original term of the patent. Thus, if it is assumed that: 1) the average extension will be 7 years, 2) 100 percent of the patented drugs will be sold during the extension, and 3) the average total sales revenue would have been 70 percent less without patent-term extension; then the additional cost to consumers of patent-term extension will be \$490 per \$1,000 of unextended, patented-drug sales or about 140 percent of the cost without patent-term extensions. If the average extension is 3 years, if only 75 percent of patented drugs are sold during the extension, and if the average revenue reduction is 10 percent; then the additional costs would be \$22.50 per \$1,000 of unextended, patented drug sales, or less than 5 percent of the costs in the preceding example.

Evident from the sensitivity analysis is the fact that the additional cost to consumers due to patent-term extension will be highly dependent

on assumptions made about generic competition. Unless the total sales revenues for the drugs would have been significantly reduced without patent-term extension, the increased revenue to the innovator firms may be relatively insignificant on an aggregate basis.

Table 15.—Sensitivity of the Consumer Cost of Patent-Term Extension to Three Variables¹

Variable 1: Average extension (years)	3	5	7			
Variable 2:						
Percentage of drugs that have product lives during the extension period (sales weighted average)	75	100	75	100	75	100
Annual sales revenues of drugs under patent extension (dollars).	225	300	375	500	525	700
Variable 3:						
Average total sales revenue reduction with competition, percent	Additional cost to consumers					
10	\$ 22.5	\$ 30	\$ 37.5	\$ 50	\$ 52.5	\$ 70
30	67.5	90	112.5	150	157.5	210
50	112.5	150	187.5	250	262.5	350
70	157.5	210	262.5	350	367.5	490

^aThe sensitivity analysis is based on an annual \$1,000 worth of wholesale purchases of patented drugs during the original term of the patent. The following assumptions are used in this table: The innovator firm charges the same price for drugs during the extension as before, the number of units sold per year is constant throughout the extension period, the effective patent term for all drugs during the original patent period is 10 years, and the supply of new drugs is continuous, providing the same revenues each year.
^bIt is assumed that \$100 worth of new drugs were introduced annually to maintain \$1,000 worth of revenues per year of drugs in their original patent term. The amount of sales of drugs during patent extension would be (\$100) x (the sales weighted average) x (the average extension).
^c(Sales of drug under patent extension) x (percentage reduction in revenue).

SOURCE: Office of Technology Assessment

IMPLICATIONS OF PATENT-TERM EXTENSION FOR SOCIETY

The major groups in society that will be directly affected by patent-term extension are the patentee, the research-intensive firm, the production-intensive firm, and the consumer. Although in most cases the research-intensive firm is the patentee, in some instances the patentee is a separate entity who grants a license to the research-intensive firm to develop and produce the patented drug. In this section we define the consumer as the person for whom the drug is prescribed whether or not payment for the drug is made by a third party (e.g., insurance company or the Government).

The Patentee

Patent-term extension would benefit the patentee by providing a longer effective patent term. If the patentee develops and markets the drug, patent-term extension provides the patentee with the benefits of an exclusive market position during the extension period. If the patentee licenses the patent to another, the

patentee can benefit from royalty revenues during the extension period.

Because decisions to develop or market drugs are often based on the length of time remaining in the patent term, the patentee may find that patent-term extension allows him more time to develop a drug or arrange with someone else to develop the drug. In this regard, patent-term extension may be particularly beneficial to universities, medical centers, research foundations, small firms, or foreign companies that may not be able to develop drug candidates in the United States. Therefore, they may arrange for licensees to develop and market the drug candidates. These organizations typically pursue drug candidates only to the preclinical phase; hence the innovator firm is faced with considerable expense and risk should it decide to develop the drug. Finding someone willing to develop the product and working out a licensing arrangement frequently requires up to 2 years. Without patent-term extension, the time spent

on licensing activities may reduce the expected patent term to such a degree that the candidate is no longer commercially attractive.

The Research-Intensive Firm

The research-intensive firm may be a patentee, in which case the effects described for the patentee apply. The primary benefit of patent-term extension will be additional revenue obtained due to the exclusive market position during the extension. Although the pharmaceutical industry traditionally has relied on internal funding for R&D activities, patent-term extension could be a favorable factor in securing external funding. This may be of particular advantage to the smaller company.

The costs of patent-term extension to the research-intensive firm are two-fold and appear to be nominal. First, many research-intensive firms market generic and branded-generic drugs. For firms which have not developed new drugs with regularity, these products can be a significant source of income. Patent-term extension may delay the entry of these firms into the generic and branded-generic markets. Second, if patent-term extension increases the rate of innovation, it is possible that the additional competition in innovative drugs could result in some downward pressure on prices and a reduction in the sales of the patented product.

The Production-Intensive Firm -

Patent-term extension offers benefits to production-intensive firms only if the rate of innovation is greater than it would have been without patent-term extension and product lives continue beyond the extension period. Production-intensive firms have conflicting interests with respect to patent-term extension. On the one hand, these firms must rely on research-intensive firms as sources of new products. A favorable environment for R&D could benefit them. On the other hand, patent-term extension delays their entry into the market.

The effect of the delay on the production-intensive firm will be particularly acute when the effects of patent-term extension first take

hold and the supply of drugs coming off patent protection dwindles. Later, when extended patent terms expire, production-intensive firms may find that the number of drugs with sufficient markets to justify investment has decreased. For those drugs worth marketing, sales potentials will have been reduced, since, in most cases, their remaining product lives will have been shortened. Furthermore, the longer period of exclusive marketing provided by patent-term extension may increase the strength of nonpatent barriers such as brand loyalty and thus reduce the ability of the production-intensive firms to establish their drugs in the market. Thus patent-term extension may have a negative psychological impact on the production-intensive firms.

The Consumer

The consumer will benefit from patent-term extension if more and better drugs are commercialized with patent-term extension than would have been commercialized in its absence. If this happens, the consumer will get better therapy earlier. However, an increase in drug innovation does not necessarily result in improved drug therapies.

An increased supply of new medicines could exert downward pressure on the price of existing drugs. But during the extension, consumers will pay more for most drugs whose patents are extended. Thus, the net effect of patent extension on consumer expenditures is unclear. Furthermore, some groups of consumers, the elderly and chronically ill, will be disproportionately affected, and these groups may be less capable than the population as a whole of bearing the increased costs.

Besides the obvious cost to the consumer of the delayed entry of lower priced generic drugs, patent-term extension may also provide two more subtle costs. The magnitude of these ancillary costs are difficult to ascertain, and they may occur only in isolated cases. First, in some instances, production-intensive firms develop new formulations or compounds which are therapeutically advantageous. These developments may be delayed. Second, to the extent that the

innovator firm is reluctant to market improvements of the patented drug until the patent

is about to expire, the consumer will have longer to wait for these improvements.

SUMMARY OF FINDINGS

Patent-term extension will enhance the incentives provided by patents for pharmaceutical research and development. Although patent-term extension lacks a mechanism that would assure increases in R&D activities, the incentives it provides may be sufficient to encourage additional R&D expenditures.

Chief among these incentives are the increased revenues that will occur when extensions begin to run. However, the first extensions will not begin for at least a decade. Thus, in the immediate future, patent-term extension will have no effect on revenues. Although historic trends indicate that R&D expenditures are closely related to revenues, research expenditures could increase before extensions begin if decisionmakers base their funding decisions on anticipated rates of return.

The extension will be most beneficial to firms selling high-income drugs and will therefore encourage research on drugs with potentially large markets. However, it will not increase the economic attractiveness of research on drugs with small markets. More research efforts may be directed toward second uses for existing drugs and towards drugs subject to extensive testing requirements as a result of patent-term extensions.

The bulk of revenues generated by patent-term extension will go to a relatively small number of firms who have a history of success in particular research areas. The successes could increase their dominance in these areas and discourage other firms from conducting similar types of research.

Competition from generically equivalent drugs will be delayed by patent-term extension. In some instances, the remaining product lives on drugs whose patents are expiring may not be sufficient to attract competition from generically equivalent drugs.

The prices of drugs whose patents are extended will be higher during the extension period. The magnitude of the increased costs of these drugs to consumers will depend on the extent to which generic competition would have existed had patent terms not been extended. Generic competition will have a greater effect on the revenues of innovator firms than on consumer costs.

Patent-term extension will benefit the research-intensive firm and the patent owner. However, to the extent that research-intensive firms rely on branded generics for revenues, the benefit will be diminished.

Production-intensive firms have the most to lose as a result of the extension. Although they cannot expand their lines of products if innovation does not occur, patent-term extension will delay their entry into markets and reduce their revenues. In the case of some drugs, production-intensive firms will not enter the market since the remaining product lives after the extensions expire will be insufficient to justify startup costs.

The consumer will benefit if new and better products are developed; however, some drugs will cost more, and the costs will fall disproportionately on the elderly and the chronically ill.