Chapter 1
Executive Summary

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INTRODUCTION

Patents were designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.

Although the patent term in the United States is 17 years, the period during the patent term in which products are marketed (the effective patent term) is usually less than 17 years because patents are obtained before products are ready to be marketed.

Effective patent terms are influenced by many factors, including Federal premarketing and premanufacturing regulations. The products covered by these regulations include pharmaceuticals, medical devices, food additives, color additives, chemicals, and pesticides. These products are subject to different regulations that have had varying impacts on effective patent terms.

The regulations governing the pharmaceutical industry have contributed to a decline in the average effective patent term of prescription drugs. Pharmaceuticals cannot be marketed in the United States until they have been approved by the Food and Drug Administration (FDA). To obtain such approval, drugs must undergo extensive testing to prove they are both safe and effective. While the pharmaceutical awaits approval, its patent term keeps running.

Concern exists that the decline in the average effective patent term of pharmaceuticals may result in diminishing profits, decreased research and development (R&D) expenditures, and an eventual decline in the introduction of new drugs. Furthermore, to many, it appears inequitable that products subject to premarketing or premanufacturing requirements are marketed under patent protection for briefer periods than products that are not subject to such regulation.

To address the concerns that have arisen about innovation and equity, legislation has been proposed that would extend the patent terms for products affected by premarketing and premanufacturing regulations.

Although this report briefly describes the equity issue, its focus is on the relationship between patent-term extension and innovation in the prescription drug industry. The effects of patent-term extension on the members of the industry and on consumers are also examined.

THE CONTROVERSY

Pharmaceutical firms that are heavily involved in basic research (research-intensive firms) support legislation to extend patent terms. These firms claim that the costs of R&D are rising, effective patent terms are declining, and the rates of return to pharmaceutical expenditures are becoming unattractive. They maintain that, under these circumstances, a decline in innovation would not be unlikely and point out that future health care in the United States would suffer if pharmaceutical innovation declines.

Research-intensive firms believe that patent-term extension will provide encouragement for research activities, raise the profitability of drug research for successful innovations, and ultimately result in more innovative products. They contend that the additional drugs will increase pricing competition among different

products used fox the same or similar ailments and that the consumer will actually save money as a result of patent-term extension.

The firms that derive most of their revenues from nonpatented, generically equivalent drugs (production-intensive firms) believe that patent-term extension will delay their entry into the market and that they will be economically penalized for each year that the extension prevents them from marketing drugs. They also contend that for some drugs, the product life remaining after the extension may be too short to justify their entry into the market. They believe that competition will decline as a result of patent-term extension and that the costs of drugs will therefore increase.

The production-intensive firms contend that many drugs are covered by more than one patent and that the combined patent terms often result in patent protection for the drug in excess of 17 years. They also point out that as a result of nonpatent barriers to market acceptance of generically equivalent products, patented products often maintain an exclusive market position even after their patents expire.

Production-intensive firms believe that some extensions might be equitable in certain situations in which the combined period of protection from all patents on the drug during its marketing is significantly less that 17 years due to excessive regulatory delay. They urge that any legislation for patent-term extension minimize any adverse effects on their industry and facilitate their effective entry into the market upon expiration of the extension. They are opposed to any legislation that would enable products covered by more than one patent to be protected by patents for more than 17 years, and they believe that the duration of the extension for any product should not exceed the actual marketing delay caused by premarketing regulations.

Spokesmen for consumer interest groups believe that patent-term extension will result in higher drug prices without providing better health care. They point out that increased drug costs will fall disproportionately on the elderly and chronically ill (whose incomes tend to be lower than average). They argue that the pharmaceutical industry is extremely profitable and needs no additional incentive to conduct research, These groups are concerned that the legislation proposed to date provides no guarantees that additional revenues derived during patent-term extensions will be invested in R&D activities. Concerns are also expressed that expenditures made for R&D may not be directed toward research areas that provide the greatest benefit to society. Therefore, many consumer spokesmen oppose patent-term extension.

FINDINGS

This study examines the issues raised by the various interest groups. Unfortunately, much of the data needed to differentiate between belief and fact are unavailable or unreliable. The evidence that is available neither supports nor refutes the position that innovation will increase significantly because of patent-term extension. Thus, the net effects of patent-term extension on pharmaceutical innovation cannot be ascertained. However, findings have been developed that should serve to clarify or explain many of the individual factors that have played, or will play, a role in pharmaceutical innovation.

The following is a list of our major findings, which will be discussed in more detail in the later sections.

- The costs of R&D for the average new chemical entity drug have increased.
- Since *1966,* average effective patent terms have declined; some factors influencing effective patent terms are, however, changing and there is reason to believe that the decline may be halted in the future.
- Revenues of the pharmaceutical industry have increased steadily and the relationship between revenues and R&D expenditures has remained stable.
- The effects of governmental actions that encourage use of generically equivalent drugs have thus far been minimal on the postpatent revenues of research-intensive firms but could become substantial in the future.

- The prices of drugs whose patents are extended are likely to be higher during the extended period than they would have been if patent protection had ended.
- Competitive pressures on patented drugs from generically equivalent drugs will be delayed and in some cases prevented by patent-term extension.
- The extension will increase the attractiveness of research on drugs that have large markets but will not increase the economic attractiveness of research on drugs whose potential markets are small.
- The effects of patent-term extension on innovation, the industry, and society will depend in part on the nature of the patent rights during the extension.

INNOVATION IN THE PHARMACEUTICAL INDUSTRY

Pharmaceutical innovation has resulted primarily from the activities of private industry, most of the expenditures being made by large, multinational companies.

In the pharmaceutical industry a long period exists between the initiation of research and the marketing of new products. Thus, the rate of innovation observed today may reflect decisions made 10 or 15 years ago, and decisions made today will affect innovation for the next decade.

The results of the innovative process in the pharmaceutical industry are often measured by the number of new chemical entity (NCE) drugs that are introduced into the market. By this measure, a sharp decline in innovation occurred with the adoption of the 1962 amendments to the Food, Drug, and Cosmetic Act, which substantially increased the stringency of the drug approval process. The number of NCEs judged by FDA to offer important or modest therapeutic gain has, however, been relatively stable. Although different measures produce different results, by most measures innovation does not appear to be increasing.

TRENDS IN THE FACTORS AFFECTING PHARMACEUTICAL INNOVATION

Innovation will not occur unless industry undertakes R&D activities. Many factors that influence R&D decisions appear to favor innovation: the industry continues to enjoy high and stable profits in terms of return to stockholder's equity; research techniques have improved; and competitive pressure for innovation has not diminished.

Nonetheless, there is a widespread belief that the return to R&D investment is declining, and this belief can affect R&D decisionmaking. Because data are insufficient to measure accurately the return to research investment, we have focused on the underlying factors influencing the returns. The major factors are the costs of R&D activities, the amount invested in R&D, and the revenues and profits of the firms conducting research.

The costs of R&D activities associated with an NCE drug have been increasing rapidly as a result of inflation and more stringent and time-consuming testing requirements. Because the time spent in obtaining FDA approval may be leveling off and new research techniques are being developed, R&D costs should increase more slowly in the future.

Real growth has occurred in expenditures for R&D. The relationship between revenues and R&D expenditures has remained highly stable over the past 15 years. For the years 1965 through 1978, research expenditures averaged about 8.5 percent of total sales.

The revenues and profits are influenced by the competitive pressures exerted on drugs. The competition may be from other patented drugs,

from nondrug therapies, or from generically equivalent drugs that are produced by either research-intensive firms or production-intensive firms. Of the drugs having generic competition, about 80 to 85 percent are sold by research-intensive companies.

Despite the decrease in the average effective patent term that may have allowed generic competition to enter the market earlier, the revenues and profits of research-intensive firms have thus far not been significantly affected by generic competition. But recent governmental actions could result in increased competition from generically equivalent drugs. Most States now have laws that allow or require generic equivalents to be substituted for brand-name drugs specified in prescriptions. FDA has adopted procedures to facilitate approval of generically equivalent drugs. The Federal Government now bases its reimbursements for prescriptions paid for under medicaid on the lowest wholesale price of generically equivalent drugs. Furthermore the Supreme Court has ruled that laws prohibiting the advertising of drug prices are unconstitutional.

Despite Government action to encourage use of generically equivalent drugs, barriers to the acceptance of these products still exist. Physicians, who determine the market for prescription drugs, tend to write prescriptions for the easily recalled brand-name drugs. Pharmacists fear they will be liable if they fill a prescription for a brand-name product with a generic equivalent that later causes injury. Furthermore, consumers tend to prefer drugs that look exactly the same as the drugs they are accustomed to using.

Thus, the effect of generic competition on the revenues and profits of research-intensive firms in the future is uncertain. If generic competition increases significantly, such revenues and profits could decline and R&D expenditures could be reduced. There is a possibility that additional generic competition could encourage research-intensive firms to increase their R&D expenditures in an effort to maintain their market shares through drug innovations.

IMPLICATIONS OF PATENT-TERM EXTENSION FOR PHARMACEUTICALS

Patent-term extension can encourage the development of new drugs through the incentives it provides to the patent owner (patentee). But by delaying use of the patented technology by the public, it may also delay some improvements in patented drugs.

Patent-term extension specifically addresses the prime concern of the research-intensive firms: the perceived decline in the rate of return to R&D investments attributed to the reduction in effective patent terms. Whether R&D activities actually increase as a result of longer effective patent terms will, however, depend on decisions made in the private sector.

Since patent-term extension will not provide additional revenues until original patents expire and extensions begin to run, the immediate incentive provided by extension legislation is the potential for obtaining greater returns on R&D investment in the future. Once extensions do begin, revenues for some firms will be greater than they otherwise would have been, thus providing additional incentive for R&D activity.

The price of drugs whose patents are extended will be higher during the extended period than they would have been if patent protection ended. The magnitude of the additional cost to the consumer will be significantly influenced by the extent to which generic competition would have existed had the patent term not been extended.

The bulk of revenues generated by patent-term extension will accrue to a few firms who have developed financially successful drugs. The increased revenues may serve to perpetuate their dominance in particular research areas, and other firms, lacking expertise, may be discouraged from entering these areas.

Since the economic incentives provided by patent-term extension will be greatest for drugs with high income potential, the tendency of firms to direct their research toward drugs with large market potential will be reinforced. Some therapeutic areas that are apt to produce economically marginal drugs may receive greater attention as a result of patent-term extension but patent-term extension will not affect research on drugs with small market potential.

The patent owner and the research-intensive firm will generally benefit from patent-term extension. To the extent that a research-intensive firm relies on revenues from the sale of generically equivalent drugs, its benefits may be reduced.

Patent-term extension poses risks for production-intensive firms. Although they depend on innovative new drugs to expand their product lines, the remaining product lives of drugs coming off patents will detemine their long-term revenues. In some cases product lives may be insufficient to justify their entry into the market.

Consumers will benefit if more and better pharmaceuticals are developed. These pharmaceuticals can provide substantial savings over other forms of health care. The cost of drugs for consumers will be higher than it would otherwise have been unless patent-term extension results in the introduction of more new drugs that exert a downward pressure on the prices of existing drugs. It is expected that both the benefits and the additional costs will affect the elderly and the chronically ill more than other segments of society; but patent-term extension will have no effect on either benefits or costs for at least a decade.

THE MECHANICS OF PATENT-TERM EXTENSION

The effects of patent-term extension can only be fully assessed in terms of specific proposals, because the effects will vary depending on the particular form the extension takes. This report has examined several proposed forms of patent-term extension to determine their possible implications for innovation.

Patent-term extension involves a modification of the present patent system. Therefore, in order to understand extension proposals, one must have a basic understanding of how the patent system works. In brief, a patent is granted for an invention which may be, for instance, a new drug, a new process for making a drug, or a new method for using a drug to treat an illness. A patent provides the right to the patentee to exclude others from making, using, or selling the invention in the United States for 17 years, In return, the patentee discloses his invention. Once the patent expires, anyone is permitted to use the invention.

The invention that is patented is defined by claims which establish the boundaries of the invention, much like a deed establishes the boundaries of a piece of land. A claim for a particular invention may thus include many potential products or processes. When a patentee attempts to enforce a patent, the claim is compared with the product or process against which the enforcement action is directed to determine whether it is included within the definition of the invention contained in the claims.

The effects of patent-term extension on the rights of the patentee and on the ability of others to use the invention will depend in part on whether patent protection is extended for the entire invention defined by the claims or for only a portion of the claimed invention. Effects will also differ depending on whether limitations are placed on the products, processes, and methods for use against which the patent can be enforced.

Numerous proposals that affect patent claims and their enforceability during the extension are examined in this report. Of these proposals, three enable the patentee to maintain an exclusive market position for the drug, while'

allowing others to use the invention for some purposes during the extension.

1. In the first of these proposals, the extension is provided for only those aspects of the claimed invention that involve the specific chemical contained in the drug approved by FDA and the patent is enforceable only against products, processes, or methods-for-use that must be approved by FDA. Of the three proposals, this one provides the greatest protection to the patentee.

   It permits others to use the patented invention for anything except drugs and allows others to make, use, or sell variations of the patentee's specific chemical for any drug therapy even though the variations may be included within the entire invention defined in the claims. It prohibits use of the patented invention for a drug therapy only if the patentee's specific chemical is used.

2. In the second proposal, the patent rights are extended for the entire invention defined by the claim, but enforcement is limited to the specific therapeutic use approved by FDA. This proposal is broader than the previous one in terms of the active chemicals that are protected, but the patented technology can still be used for other drug therapies.

   This proposal permits the development of the patented invention for all uses other than the specific therapy approved by FDA. Under this proposal, enforcement of the patent would be difficult. A competitor could manufacture and sell the identical drug for a different therapy; the competitor's drug might then be prescribed and used for the patentee's therapy. The only remedy available to the patentee would be to sue each of the prescribers or users for patent infringement.

3. In the third proposal, the extension is provided only for those aspects of the claimed invention which involve the specific chemical contained in the drug approved by FDA, and enforcement is limited to the specific therapeutic use approved by FDA. Of the three proposals, this one provides the least protection to the patentee.

   This proposal permits others to develop the technology for all uses and allows others to make, use, or sell variations of the patentee's specific chemical for any drug therapy. Furthermore, others can make, use, and sell drugs using the patented technology and the patentee's specific chemical for any drug therapy but the one for which the patentee obtained FDA approval. Enforcement under this proposal is difficult for the same reasons that it is difficult in proposal 2.