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REPORT
No. 97-138

THE PATENT TERM RESTORATION ACT OF 1981

JUNE 16 (legislative day, JUNE 1), 1981.—Ordered to be printed

Mr. MATHIAS, from the Committee on the Judiciary, submitted the following

REPORT

The Committee on the Judiciary, to which was referred the bill (S. 255), the Patent Term Restoration Act of 1981, having considered the same, report favorably thereon, and recommends that the bill do pass.

I. PURPOSE

The Patent Term Restoration Act will encourage American innovation by correcting a simple but serious inequity in the patent system. Under current law, the federal government requires an extended regulatory review for certain products affecting public health and the environment, involving tests and studies that must establish the safety and efficacy of the products before they can be placed on the market. For example, a new human drug cannot be marketed until it is tested extensively both in the laboratory and in a clinical setting to prove that the drug complies with the safety and efficacy standards of the Federal Food, Drug and Cosmetic Act. A new pesticide must be approved as not causing unreasonable risk to man or the environment under the Federal Insecticide, Fungicide and Rodenticide Act before it can be sold commercially.

Since the inventor usually secures the patent on these products before or during the regulatory review period, the subsequent time needed to fulfill the regulatory requirements encroaches directly on the life of the patent. S. 255 would remedy this unintended and inequitable side-effect by restoring to the term of the patent the time lost in complying with the government's premarket testing and review requirements, up to a maximum of seven years.

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The bill does not alter our commitment to insure and verify that new products are safe for public use: it does not interfere with any regulatory review mechanism. It merely corrects the anomaly under which the government grants a 17-year term of patent protection, but prohibits the patented product from being marketed while the patent life ticks away. There is no valid reason for a better mousetrap to receive 17 years of patent protection and a life-saving drug less than ten years.

In the past 15 to 20 years, several important laws have been passed to strengthen the protection of public health and the environment. These include the 1962 amendments to the Federal Food, Drug, and Cosmetic Act, the Toxic Substances Control Act of 1976, and the 1972 and 1978 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act.

As the technology for testing medicines, pesticides and other products has become more sophisticated, the required testing time and cost to industry has increased dramatically. Just as dramatically, the effective patent term has decreased.

EPA estimated that the remaining patent life for a chemical pesticide is about 12 years by the time the pesticide is licensed for marketing. For new human drugs introduced during the last few years, the average patent life remaining when the product was approved for marketing was less than ten years.

Development costs for drugs have increased from approximately $4 million in 1962 to approximately $70 million today. A typical agricultural chemical compound costs $20 to $25 million to develop today.

Thus, while industries that develop and manufacture these products face substantially higher research and development costs, they experience serious erosion of their patent protection. At hearings on S. 255, these trends and their evolution over the past 20 years were amply documented. The Committee also saw evidence of a decline in innovation in the pharmaceutical and pesticide industries, as well as a substantial increase in foreign competition.

S. 255, by putting inventors of products subject to federal regulatory review on an equal footing with all other patent holders, will help reverse these trends and restore badly needed research incentives in industries that have suffered from this disparity.

II. Text of S. 255

The text of S. 255 is as follows:

A BILL To amend the patent law to restore the term of the patent grant for the period of time that nonpatent regulatory requirements prevent the marketing of a patented product.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Patent Term Restoration Act of 1981".

Section 1. Title 35 of the United States Code, entitled "Patents" is amended by adding the following new section immediately after section 154:

"§ 155. Restoration of patent term

"(a)(1) Except as provided in paragraph (2), the term of a patent which encompasses within its scope a product, or a method for using a product, subject to a regulatory review period shall be extended by the amount of time equal to the regulatory review period for such product or method if—

"(A) the owner of the record of the patent gives notice to the Commission in compliance with the provisions of subsection (b)(1);

"(B) the product or method has been subjected to a regulatory review period pursuant to statute or regulation prior to its commercial marketing or use; and

"(C) the patent to be extended has not expired prior to notice to the Commissioner under subsection (b)(1).

The rights derived from any claim or claims of any patent so extended shall be limited in scope during the period of any extension to the product to method subject to the regulatory review period and to the statutory use for which regulatory review was required.

"(2) In no event shall the term of any patent be extended for more than seven years.

"(b)(1) Within ninety days after termination of a regulatory review period, the owner of record of the patent shall notify the Commission under oath that the regulatory review period has ended. Such notification shall be in writing and shall:

"(A) identify the Federal statute or regulation under which regulatory review occurred;

"(B) state the dates on which the regulatory review period commenced and ended;

"(C) identify the product and the statutory use for which regulatory review was required;

"(D) state the regulatory review referred to in subsection (a)(1)(B) has been satisfied; and

"(E) identify the claim or claims of the patent to which the extension is applicable and the lenght of time of the regulatory review period for which the term of such patent is to be extended.

"(2) Upon receipt of the notice required by paragraph (1), the Commissioner shall promptly (A) publish the information noticed in the Official Gazette of the Patent and Trademark Office, and (B) issue to the owner of record of the patent a certificate of extension, under seal, stating the fact and lenght of the extension and identifying the product and the statutory use and the claim or claims to which such extension is applicable. Such certificate shall be recorded in the official file of each patent extended and such certificate shall be considered as a part of the original patent.

"(c) As used in this section:

"(1) The term 'product or a method for using a product' means any machine, manufacture, composition of matter or any specific method of use thereof for which United States Letters Patent can be granted and includes the following or any specific method of use thereof:

"(A) any new drug, antibiotic drug, new animal drug, device, food additive, or color, additive subject to regulation under the Federal Food, Drug, and Cosmetic Act;

"(B) any human or veterinary biological product subject to regulation under section 351 of the Public Health Service Act or under the virus, serum, toxin, and analogous products provisions of the Act of Congress of March 4, 1913;

"(C) any pesticide subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act; and

"(D) any chemnical substance or mixture subject to regulation under the Toxic Substances Control Act.

"(2) The term 'major health or environmental effects test' means an experiment to determine or evaluate health or environmental effects which requires at least six months to conduct, not including any period for analysis or conclusions.

"(3) The term 'statutory use' means all uses regulated under the statutes identified in sections (c)(4)(A)–(D) for which regulatory review occurred for the product involved.

"(4) The term 'regulatory review period means—

"(A) with respect to a food additive, color additive, new animal drug, veterinary biological product, device, new drug, antibiotic drug, or human biological product, a period commencing on the earliest of the date the patentee, his assignee, or his licensee (i) initiated a major health or environmental effects test on such product or a method for using such product, (ii) claims a exemption for investigation or requests authority to prepare an experimental product with respect such product or a method for using such product under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of Congress of March 4, 1913, or (iii) submits an application or petition with respect to such product or a method for using such product under such statutes, and ending on the date such application or petition with respect to such product or a method for using such product is approved or licensed under such statutes or, if objections are filed to such approval or license, ending on the date such objections are resolved and commercial marketing is permitted or, if commercial marketing is initially permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings are finally resolved and commercial marketing is permitted;

"(B) with respect to a pesticide, a period commencing on the earliest of the date the patentee, his assignee, or his licensee (i) initiates a major health or environmental effects test on such pesticide, the data from which is submitted in a request for registration of such pesticide under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act, (ii) requests the grant of an experimental use permit under section 5 of such Act, or (iii) submits an application for registration of such pesticide pursuant to section 3 of such Act, and ending on the date such pesticide is first registered, either conditionally or fully;

"(C) with respect to a chemical substance or mixture for which notification is required under section 5(a) of the Toxic Substances Control Act—

"(i) which is subject to a rule requiring testing under section 4(a) of such Act, a period commencing on the date the patentee, his assignee, or his licensee has initiated the testing required in such rule and ending on the expiration of the premanufacture notification period for such chemical substance or mixture, or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or injunction is dissolved or set aside;

"(ii) which is not subject to a testing rule under section 4 of such Act, a period commencing on the earlier of the date the patentee, his assignee, or his licensee—

"(I) submits a premanufacture notice, or

"(II) initiates a major health or environmental effects test on such substance, the data from which is included in the premanufacture notice for such substance,

and ending on the expiration of the premanufacture notification period for such substance or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or such injunction is dissolved or set aside;

"(D) with respect to any other product or method of using a product that has been subjected to Federal premarketing regulatory review, a period commencing on the date when the patentee, his assignee, or his licensee initiates actions pursuant to a Federal statute or regulation to obtain such review prior to the initial commercial marketing in interstate commerce of such product and ending on the date when such review is completed,

except that the regulatory review period shall not be deemed to have commenced until a patent has been granted for the product or the method of use of such product subject to the regulatory review period. In the event the regulatory review period has commenced prior to the effective date of this section, then the period of patent extension for such product or a method of using such product shall be measured from the effective date of this section.".

III. Summary of S. 255

S. 255 restores to a patent holder the period of time during which commercialization of a patented product is prohibited because of Federal premarket testing or regulatory review requirements (referred to in the bill as "regulatory review period"). This is accomplished by extending the patent term to compensate for the lengthy testing and review process. In no case may the patent be extended for more than 7 years. A product may receive a patent extension only if the relevant regulatory agency permits it to be marketed. If a patent is not granted for a product until after a regulatory review period has begun, the restoration period would be calculated from the date of patent issuance to the completion of the regulatory review period.

Patented products eligible for extension include human drugs and biologicals, antibiotic drugs, animal drugs and biologicals, food additives, color additives, pesticides, other chemical substances,

medical devices, and any other product subject to Federal premarketing requirements.

The extension applies only to those claims of the patents which cover the product subject to regulatory review. Furthermore, if a claim of the patent covers a generic group of chemicals, the extension would apply only to the chemical of the group which has undergone the regulatory review. Finally, the extension is limited to the particular statutory use of the chemical for which the review occured. For example, a chemical may be used as a drug and it may also be used in color photography. The patent rights from an extension based on the FDA review requirement woud be violated by the manufacture, use or sale of the chemical as a drug for any pharmaceutical use but would not be violated by the manufacture, use or sale of the chemical for photography purposes.

The mechanics of applying for and receiving a restoration of the patent term are administratively simple and should not impose undue cost or burden either on the Patent and Trademark Office or on the patent holder. To obtain the restoration, the patent holder must simply notify the Commissioner of Patents and Trademarks that the patented product has undergone and successfully completed the premarket testing and regulatory review. The notice must inform the Commissioner how long the regulatory review period lasted. If the requirements of the bill have been met, the Commissioner will then issue a certificate to the patent holder extending the patent term for the claimed invention for a period equal to the regulatory review period. If the patent has expired prior to notice to the Commisssioner, the product will not be eligible for restoration.

IV. Background and Need

The patent has traditionally served as a major incentive for innovation. It provides an incentive for the costly and lengthy work of developing an invention by giving the inventor a sufficient opportunity to market a new product exclusively. In 1861, Congress selected 17 years as the period which best fulfilled this objective.

The substantial erosion of the patent term for products subject to extensive Federal premarketing testing, notification, and review requirements raises the serious question of whether the patent term continues to play its traditional role of encouraging innovation for these products. Certainly, an effective patent term of less than 10 years cannot provide the same incentive as one which is closer to the full 17-year term. S. 255, by restoring the full patent term, will help renew the incentive for research for such industries.

The erosion of the patent term has been most severe on some industries whose innovations provide important benefits to society. For example, society has a strong interest in encouraging the development of new and improved drug therapies, more effective medical devices, safer and more effective pesticides, and versatile plastic materials and textile fibres. Restoration of the patent term for such products will further society's interest.

Research and development in these areas has become increasingly costly and risky in the last twenty years. As testimony before the committee indicated, the research "deadends" are far from the exception. For example, nearly 90 percent of the drug candidates

studied in humans were dropped prior to the submission of a marketing application to FDA. An analysis of 1029 new chemical entities submitted to testing between 1963–75 showed that only 59, or six percent of the total, were eventually marketed. The agricultural chemical industry commercializes an average of one out of every 10,000 compounds that are initially synthesized.

Compared to 2 percent for U.S. industry as a whole, the U.S. pharmaceutical industry consistently invests about 11 percent of its sales on research and development. The increasing complexity of the research and required testing has reduced and will continue to reduce the number and magnitude of new research undertakings. Between 1954 and 1975, R&D expenditures in the U.S. drug industry went from $90 million to $420 million, while the average number of new chemical entities discovered and introduced in the country each year decreased from 20 to 10. While some of this decline is attributable to the changes in the drug laws, the sharp increase in cost and time required for development has encouraged a shift of the industry's resources away from basic research.

This tendency contrasts sharply with research trends in foreign countries. The annual growth rate for pharmaceutical R&D activities in America from 1973–79 was 11 percent, as compared to 25 percent in the United Kingdom, 20 percent in Germany, and 22 percent in Japan. The Committee is particularly disturbed by the declining position of the U.S. industry in the international field of pharmaceutical research, and considers it urgent to remove the handicap of reduced patent protection that burdens U.S. industry.

Adverse economic trends in the pharmaceutical industry, such as the increased duration and sharply rising costs of R&D discussed above, raise questions as to whether recent advances in basic science will be translated into new therapies as rapidly as good science permits. S. 255 will provide added cash flow to finance the costly future research efforts. Moreover, it will increase the expected returns from new drug innovations, thereby providing both the incentive and the economic capability to conduct expensive long-term research and development.

Successful research in the pharmaceutical and chemical industries is a continuous process. Firms cannot commit funds to initiate long-term research projects unless they have reasonable assurances that money will continue to be available to pay for those projects in later years.

The Environmental Protection Agency, which has responsibility for implementing and enforcing the Federal Insecticide Fungicide and Rodenticide Act, and the Toxic Substances Control Act, testified in favor of patent restoration, acknowledging that diminution of the patent life is an unintended side-effect of their regulatory review procedure and an unnecessary weakening of an important incentive to innovation. The Agency reported that the pesticide industry loses an average of 5 to 7 years of patent life due to regulatory review. The Committee was also reminded of the tremendous importance of new pesticides in the agricultural preparations for feeding the burgeoning world population in the rest of the century and beyond.

Benefits to Small Businesses

The Committee anticipates that S. 255 will have a particularly beneficial effect on small research-oriented companies. These firms are often dependent on one or two products to generate their revenue for future research. An adequate patent term on these products is critical if the small company is to be able to continue its efforts in innovation. Moreover, a full patent term on products which will be subject to regulatory review requirements is indispensable to a new firm seeking financing to help it develop a new invention. Absent the availability of meaningful patent protection for the invention, investors are likely to look elsewhere. For example, the Committee heard from one small innovative manufacturer of medical devices who testified as to the importance of adequate patent protection to the viability of his business.

Patent restoration may also contribute to increased competition within the covered industries by helping the small innovative companies. For exemple, there are substantially fewer domestic sources of pharmaceutical innovation in the United States now than there were in the decade following World War II. Small U.S. firms in particular have dropped out of discovering and developing new drugs. S. 255 may help reverse the trend toward concentration and R&D efforts in the larger companies.

Benefits to Universities

The legislation, endorsed by representatives of the university research community, (The Johns Hopkins University, Massachusetts Institute of Technology), also will benefit universities, responsible for much of this nation's basic research. Often, universities find it difficult to license their inventions because of their shortened patent lives.

Benefits to Society from Innovation

Impressive examples were presented at the hearing of the significant medical costs savings achieved when drug therapy can obviate the need for hospitalization and surgery. The treatment of glaucoma by surgery cost $590 in the mid-1970's, plus $172 per day of hospitalization, whereas the recent breakthrough drug "Timoptic" not only makes the treatment of this major disease more effective, but it reduces the cost to only 22 cents per day. Sodium valproate, a new medicine for treating epilepsy, now saves $612 million annually, in addition to sparing its victims great suffering and distress. A new ulcer drug, if used by all those who could benefit from it, could save approximately $250 million a year in foregone surgery and physicians' benefits.

The American Association of Retired Persons and National Retired Teachers Association submitted a written statement in support of the concept of patent restoration emphasizing the importance to the elderly of encouraging the development and introduction of major new drug therapies. Persons over the age of 65 account for 25 percent of all expenditures for prescription drug products. The Committee envisions that the restoration of the full patent terms will help to moderate prices by enlarging the span over which drug manufacturers will be recouping their investments.

The Committee also maintains a strong interest in the responsibilities of the pharmaceutical industry for pursuing and manufacturing drugs to treat relatively rare diseases, which can anticipate only a limited market. Clearly, the high costs of research documented at the hearing are doubly prohibitive in the case of drugs for rare diseases with little or no expectation of return on investment. At the Senate hearing, the Committee was pleased to hear from the industry that the passage of the patent restoration bill should have a positive effect on orphan drug research and development.

The Committee received testimony from the generic drug manufacturing industry, which performs a valuable service in manufacturing low cost drugs and providing price competition once drugs come off patent. Although the patent restoration effort will delay the entry of less expensive copied versions of drugs, the Committee considers that successful measures to stimulate greater development and marketing of valuable new drugs will ultimately rebound to the benefit of companies who bring low-cost generic versions to the public by enlarging the stream of innovation they exploit.

V. History of the Bill

In the Second Session of the 96th Congress, Senator Birch Bayh of Indiana introduced S. 2892, the Patent Term Restoration Act of 1980, with Senator Thurmond, Senator Mathias, Senator Morgan, and Senator Percy as cosponsors. The bill was referred to the Judiciary Committee, but no action was taken.

On January 27, 1981, Senator Charles McC. Mathias, Jr. of Maryland introduced S. 255, a slightly revised version of S. 2892, with Senator Robert C. Byrd, Senator Thurmond, Senator Percy, and Senator DeConcini as cosponsors. The bill was referred to the Judiciary Committee, which held a hearing on April 30, 1981, and ordered it reported by voice vote on May 19, 1981. Since its introduction, the following Senators have requested that they be added as cosponsors: Senator Hatch, Senator Schmitt, Senator Hollings, Senator Williams, Senator Inouye, Senator Simpson, Senator Hatfield, Senator Heflin, Senator Symms, Senator Nunn, Senator Danforth, Senator Lugar, Senator Laxalt, Senator Denton, Senator Baker, Senator Randolph, Senator Huddleston, Senator Dole, Senator Bradley, Senator East, Senator Biden, Senator Grassley, Senator Baucus, and Senator Tsongas.

VI. Cost of Legislation

In accordance with section 252(a) of the Legislative Reorganization Act (2 U.S.C. sec. 190(j)), the Committee estimates that the added costs to the government due to this Act would be negligible. The Patent and Trademark Office testified at the hearing that the volume of patents that will be affected by S. 255 would not be large, and that the processing requirements it involves would not be burdensome. On May 21, 1981, the following opinion was received from the Director of the Congressional Budget Office:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, D.C., May 21, 1981.

Hon. STROM THURMOND,
Chairman, Committee on the Judiciary,
U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: Pursuant to Section 403 of the Congressional Budget Act of 1974, the Congressional Budget Office has reviewed S. 255, the Patent Term Restoration Act of 1981, as ordered reported by the Senate Committee on the Judiciary, May 19, 1981.

This bill would allow the term of a patent to be extended to include the amount of time required to conduct certain regulatory reviews required by the federal government. The Patent and Trademark Office (PTO) would be required to review all requests for extension of a patent's life and to issue certificates of extension.

While the demand for such extensions is not currently known, the potential universe from which these requests could be made represents approximately 5 percent of the number of patents issued annually. The PTO estimates that minimal costs would likely be associated with any additional staff time or administrative costs resulting from the review of requests for certificates of extension, and that storage costs would not be affected as a result of this bill.

Should the Committee so desire, we would be pleased to provide further details on this estimate.

Sincerely,

RAYMOND C. SCHEPPACH,
for Alice M. Rivlin,
Director.

In addition, on June 8, 1981, the Committee received the following comments from Morton A. Myers, Director of the General Accounting Office:

GENERAL ACCOUNTING OFFICE,
Washington, D.C., June 5, 1981.

Hon. CHARLES MCC. MATHIAS, Jr.,
U.S. Senate, Washington, D.C.

DEAR SENATOR MATHIAS: I am writing in repsonse to the letter sent on may 12, 1981, by you and the Chairman of the Senate Judiciary Committee to the Acting Comptroller General. You requested that GAO prepare a regulatory impact statement for inclusion in the Judiciary Committee's Report on S. 255, the Patent Term Restoration Act of 1981. We are routinely asked to provide comments and views on many legislative proposals. We consider and address, to the extent feasible, regulatory impact questions in developing our comments on proposed legislation. On a request basis and within the limits of our resources, our staff will be available to work with the committees informally to assist in evaluating impact material developed by the executive agencies. It is thus very rare that we prepare original material for use in regulatory impact statements as required in Senate Rule 26.11(b), and we are making an exception in this case. A regulatory impact statement as required by Senate Rule 26.11(b) is composed of three components: economic impact, paperwork impact, and privacy impact. As agreed with your staff, we are furnishing an assessment of the economic

impact only. Also, given the short itme constraint, our assessment is not based on our own empirical work, but rather is qualitative in nature and discusses the likely effects of the bill based on economic theory and existing economic studies.

An economic evaluation of the effects of patent term restoration has two main components—the impacts of increased patent terms on the supply of pharmaceutical innovations and on the prices of new drugs.

Effects on Innovation

Economic analyses of the determinants of Research and Development (R&D) expenditures in the pharmaceutical industry indicate that these outlays are quite sensitive to both expected returns and the availabvility of internally generated cash flow. The proposed increases in patent term would have positive impacts on both these determinant variables. The average effective patent term for new product introductions is now approximately 10 years in length and declining over time. One sensitivity analysis, based on a sample of all new product introductions in the U.S. over the period 1970–76, indicates that from 12 to 19 years of product life was necessary for this group of new drugs to break even and earn a competitive return on capital.[1] The effect of increased patent terms on the expected returns to drug innovation was also highly sensitive to the degree of substitution faced by the pioneering firm's product after patent expiration. The degree of substitution has been increasing over time as a result of the enactment of State product selection laws (allowing pharmacists to substitute for prescribed brands) and the Federal Government Maximum Allowable Cost (MAC) program on medicaid and medicare reimbursements.

The current environment for drug innovation therefore combines higher R&D costs and longer development times with increased potential competition from generic products after patents expire. Given these trends and the findings of various economic studies on R&D returns, it is reasonable to expect that the term of patent protection will become and increasingly important economic incentive influencing R&D decisions in future periods. It is more difficult to say, however, what type of pharmaceutical R&D would be most stimulated by increased patent terms and what kind of new drugs would be made available (or made available sooner) from patent restoration. From a theoretical standpoint, patent restoration can be expected to have its greatest impact on R&D incentives for products with relatively long expected lives before they are made obsolete by rival innovations. If a drug has a relatively short expected life before technological obsolescence occurs, it would be essentially unaffected by patent restoration. Hence, one class of drugs that would be positively affected by patent restoration are "breakthrough" type drugs which have above average riskiness but longer expected product life before obsolescence. Quantitative effects in this regard are uncertain however.

[1] Henry Grabowski and John Vernon, "A Sensitivity Analyses of Expected Profitability of Pharmaceutical R&D" forthcoming in *Managerial and Decision Economics* (March 1982).

Effect on Prices

The effect of patent restoration on new drug prices in the extended exclusivity period is also likely to be not insignificant in magnitude. New drugs will be able to maintain an exclusive market for longer periods of time. Hence, the savings that consumers obtain through price competition will be deferred. A number of studies have shown that there is a considerable variance in both wholesale and retail prices of chemically equivalent forms of multi-source drug products. A study by the staff of the Federal Trade Commission, for example of 60 multi-source products indicated the wholesale prices of generic equivalent products were on the average 40 percent below those of the pioneering brand. Furthermore, the lowest priced generic product offered even much greater savings.[1]

Retail price comparisons are more relevant to consumers but this data is more difficult to obtain. In general the retail price disparities between brand name and generic products are somewhat less than for wholesale prices because pharmacists tend to have higher markups for their generic products. In a case study of product selection in Michigan the average price of a selected group of generics was about 20 percent lower than the average of prescribed brand names. The entry of lower priced generic products onto the market can provide additional benefits, however, in terms of price reductions by the pioneering firm in order to forestall potential losses in its market share.[2]

It is difficult to make specific quantitative comparisons of the innovation and price increase effects of patent restoration discussed above. From a distributional perspective one would clearly expect the research intensive sector of the pharmaceutical industry to gain from patent restoration while the generic firms' income would suffer. Consumers on balance would benefit to the extent that the gains on innovation stimulated by patent restoration exceeded the increased costs from increased drug prices discussed above and vice versa. Since the patent restoration law is not retrospective in effect, the increased price effects would not begin occuring until aproximately 10 years after the bill was passed and would not occur at all if a new drug become technologically obsolescent before patent restoration become effective. On the other hand, the impact of the bill in stimulating R&D outlays could occur with only short time lags because of the immediate positive effect on expectations concerning future returns from R&D. There would be additional time lags, however, before increased R&D efforts result in an increased supply of new drug innovations. The ultimate effects of patent restoration on drug innovation or drug prices are not likely to be large in magnitude for at least a decade or more. Consequently, trade-offs in this regard must be evaluated in terms of the long run trends and future condition for this and other industries affected by S. 255.

If you have any questions, please call on us.

Sincerely yours,

MORTON A. MYERS, *Director.*

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[1] Drug Product Selection; A staff Report to the Federal Trade Commission. Bureau of Consumer Protection (January 1979).

[2] Theodore Goldberg, et. al., "A Valuation of Economic Effects of Drug Product Selection Legislation." Paper presented to American Public Health Association Meeting (October 1977).

VII. Section by Section Analysis

Section 1

Section 1 adds a new section 155 to Title 35 of the U.S. Code, to provide for the extension of the patent term for products and methods of using products that are subject to regulatory review pursuant to Federal statutes and regulations before they are introduced into the market for commercial use.

Subsection (a)—Restoration Eligibility and Limitations

Subsection (a) provides that the term of a patent will be extended for a period equal to the regulatory review period for the product or method of use to which the patent applies, except that no patent term will be extended for more than seven years. The patent owner must submit a notice to the Commissioner of Patents and Trademarks, and the patent to be extended must not have expired when that notice is given.

Subsection (a)(1)

Subsection (a)(1) also sets forth the scope of the benefits available under restoration. The patent right available during the restoration period is limited in scope to the specific claimed invention which has been subject to the regulatory review period. Moreover, the patent right during the restoration period is limited to the nature of use, *e.g.,* pesticide, drug, medical device, for which the regulatory review occured.

The Committee recognizes that patents covering different types of inventions will be affected differently by this legislation. In certain instances an inventor will obtain a patent on a specific chemical which has its utility as the active ingredient in a pharmaceutical product. This active ingredient will be combined with certain carriers to form the marketable product. The Committee intends that the rights from such a patent during the restoration period extend to the active ingredient regardless of the inert carrier with which it may be combined. For example, chemical X may be patented for a human drug use. It will have been formulated with specific carriers to make the pill which is subject to regulatory review. A change in the composition of the carrier would not affect the patent protection accorded chemical X during the restoration period. During this period, the active ingredient would be protected by the patent extension regardless of the inert carrier with which it was combined. The rights derived from patents covering other types of inventions would differ. For example, a patent which covers the composition of both the active ingredient and the specific components with which it is combined would provide patent protection during the restoration period only for the specific composition claimed in the patent.

Subsection (a)(2)

Subsection (a)(2) provides that no patent may be restored for more than 7 years. This 7-year cap is included to protect the public against the potential for dilatory action on the part of the patent applicant during the regulatory review period. The Committee recognizes that the potential for such dilatory action is remote for two reasons: First, because the inventor's objective is to market his

product as quickly as possible; and second, because the means by which a patent holder excludes others from making, using or selling the patented product is to sue in a court of equity. The doctrine regarding inequitable conduct could deprive any benefits to a patent holder who was intentionally dilatory for the purpose of unduly extending the patent term. Nonetheless, the Committee felt it important to provide a 7-year cap to further safeguard against any potential for dilatory action.

The boundaries of the regulatory review period in the bill are designed to include only time that is lost on the patent due to federal safety and efficacy requirements, calculated as set forth in Subsections (c)(4)(A)–(D). The preliminary research and development work (other than a major health and environmental effects test) that precedes the decision to file an IND, experimental use permit, or application for registration, which corresponds to the early research period in other industries which are not subject to a regulatory review, would not be eligible for restoration.

The Committee recognizes that certain production and marketing preparations unrelated to the regulatory review process may be pursued simultaneously with the testing period, especially during the stage following the approval of the IND, experimental use permit, or application for registration, when the company has become reasonably confident of the ultimate approval of its product for commercialization. However, these would ordinarily have been undertaken at an earlier point, possibly before the patent had been granted, except for the uncertainty of gaining federal approval.

If the patent holder seeks to enforce an invalid or improperly procured extension, the facts with respect to behavior of the applicant before the regulatory agency will become known upon discovery. If it finds inequitable conduct on the applicant's part, the court is in a position to protect the public's interest by refusing to enforce the patent.

Subsection (b)—Notice to Patent and Trademark Office

Subsection (b) specifies the information that must be contained in the notice to the Commission and states that the notice must be submitted within 90 days after the regulatory review period is completed. The Commission is required to publish information concerning the notice and to issue the patent owner a certificate of extension setting forth the length of the extension and identifying the claimed invention and the statutory use for which the patent is extended.

Subsection (c)—Definition Section

Subsection (c) contains definitions of the terms used in the bill.

Subsection (c)(1)

The term "product or a method for using a product" means any machine, manufacture, composition of matter or any specific method of use thereof for which United States letters patent can be granted. The term specifically includes, but is not limited to, the following products and any method of use of such products: any new drug, antibiotic drug, new animal drug, device, food additive or color additive subject to regulation under the Federal Food, Drug and Cosmetic Act; any human or veterinary biological prod-

uct subject to regulation under the Public Health Service Act or the Act of Congress of March 4, 1913; any pesticide regulated under the Federal Insecticide, Fungicide and Rodenticide Act; and any chemical substance or mixture subject to regulation under the Toxic Substances Control Act.

Subsection (c)(2)

The term "major health or environmental effects test" means an experiment to determine or evaluate health or environmental effects which requires at least 6 months to conduct. For purposes of determining the 6-month period, time spent analyzing or evaluating the test results or drawing conclusions therefrom will not be considered part of the testing time.

Subsection (c)(3)

The term "statutory use" means the use (e.g., pesticide, drug, medical device) of the product identified in the statute or regulation requiring regulatory review. For example, the Federal Insecticide, Fungicide and Rodenticide Act requires that pesticides be submitted for approval to the Environmental Protection Agency prior to marketing. An inventor may submit for EPA approval an herbicide to be used on corn. Subsequently, EPA approval may be obtained to use the same herbicide on other crops such as rice or soybeans. However, the patent rights derived from the extension would be violated by the manufacture, use or sale of the chemical for use as an herbicide whether for use on corn, rice, soybeans, or any other crop, or for any other pecticidal use regulated under FIFRA.

Subsection (c)(4)

The final term defined in the bill is "regulatory review period". This term sets out the beginning and the ending dates of the regulatory review period for each product which may be eligible for restoration under the legislation, defined in accordance with the regulatory review procedures that apply to different kinds of products.

The most powerful safeguard against deliberate delays or procrastination during any major tests conducted prior to and in preparation for the federal review period is the natural competitive forces of the marketplace. The company's predominant object is to reach the market before its competitors devise an equivalent or superior product. In addition, as noted before, dilatory tactics at any stage of the compensable regulatory review period for the purpose of extending the patent term would jeopardize the validity of the patent under the doctrine of inequitable conduct.

Subsection (c)(4)(A)

With respect to a food additive, color additive, new animal drug, veterinary biological product, device, new drug, antibiotic drug, or human biological product, the regulatory review period will begin on the earliest of the following dates: (1) the date the patentee initiated a major health or environmental effects test on such product or method for using such product, (2) the date the patentee claims an exemption for investigation (IND) or requests authority to prepare an experimental product under the Federal Food, Drug and Cosmetic Act, The Public Health Service Act, or the Act of Con-

gress of March 4, 1913, or (3) the date the patentee submits an application (NDA) or petition with respect to the product or method for using the product under the above-mentioned statutes. For these same products, the regulatory review period will end on the date the application or petition is approved or licensed under the relevant statute. If objections are filed to an approval or license, then the regulatory review period will end on the date the objections are resolved and commercial marketing is initially permitted. However, if commercial marketing is initially permitted and subsequently revoked pending further proceedings as a result of objections, the regulatory review period shall be deemed to have ended on the date such proceedings become final and commercial marketing is permitted.

Subsection (c)(4)(B)

With respect to a pesticide, the regulatory review period will begin on the earliest of the following dates: (1) the date the patentee initiates a major health or environmental effects test on the pesticide, the data from which is submitted to EPA in a request for registration, (2) the date the patentee requests the grant of an experimental use permit under FIFRA, or (3) the date the patentee submits an application for registration of the pesticide. For a pesticide, the regulatory review period will end on the date the pesticide is first registered, either conditionally or fully.

Subsection (c)(4)(C)

For a chemical substance or mixture for which premarket notification is required under the Toxic Substances Control Act, the beginning of the regulatory review period will vary, depending on whether the product is subject to a testing rule prior to the notification. If the product is subject to such a rule, then the regulatory review period shall begin on the date the patentee initiates the testing required under the rule. If the chemical substance or mixture is not subject to a testing rule, then the regulatory review period will begin on the earlier of the following dates: (1) the date the patentee submits a premanufacture notice, or (2) the date the patentee initiates a major health or environmental effects test on the substance, the data from which is included in the premanufacture notice. For chemical substances and mixtures, the regulatory review period will end on the date the premanufacture notification period expires or, if an order or injunction is issued under section 5(e) or 5(f) of the Toxic Substances Control Act, the date on which such order or injunction is dissolved or set aside.

Subsection (c)(4)(D)

Products not specifically identified may still be eligible for a restored patent term if they have been subjected to a Federal premarketing regulatory review requirement. For these products or methods of using such products, the regulatory review period will begin on the date the patentee initiates the action required by the Federal statute or regulation to obtain the review prior to the first commercial marketing of such product. The regulatory review period will end on the date such review is completed.

Effective Date

The regulatory review period does not commence for purposes of the Act until an applicable patent is granted. If a regulatory review period has commenced prior to the effective date of the Act, the period of patent extension will be measured from the effective date of the Act.

VIII. Changes in Existing Law

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law, made by the bill, S. 255 as reported, are shown as follows (new material is printed in italic and existing law in which no change is proposed is shown in roman):

Title 35, Patents

Chapter 14.—Issue of Patent

Sec.
151 Time of issue of patent
152 Issue of patent to assignee
153 How issued
154 Contents and term of patent
155 Restoration of patent term.

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"§ 155. Restoration of patent term

"(a)(1) Except as provided in paragraph (2), the term of a patent which encompasses within its scope a product, or a method for using a product, subject to a regulatory review period shall be extended by the amount of time equal to the regulatory review period for such product or method if—

"(A) the owner of record of the patent gives notice to the Commission in compliance with the provisions of subsection (b)(1);

"(B) the product or method has been subjected to a regulatory review period pursuant to statute or regulation prior to its commercial marketing or use; and

"(C) the patent to be extended has not expired prior to notice to the Commissioner under subsection (b)(1).

The rights derived from any claim or claims of any patent so extended shall be limited in scope during the period of any extension to the product or method subject to the regulatory review period and to the statutory use for which regulatory review was required.

"(2) In no event shall the term of any patent be extended for more than seven years.

"(b)(1) Within ninety days after termination of a regulatory review period, the owner of record of the patent shall notify the Commissioner under oath that the regulatory review period has ended. Such notification shall be in writing and shall:

"(A) identify the Federal statute or regulation under which regulatory review occurred;

"(B) state the dates on which the regulatory review period commenced and ended;

"(C) identify the product and the statutory use for which regulatory review was required;

"(D) state that the regulatory review referred to in subsection (a)(1)(B) has been satisfied; and

"(E) identify the claim or claims of the patent to which the extension is applicable and the length of time of the regulatory review period for which the term of such patent is to be extended.

"(2) Upon receipt of the notice required by paragraph (1), the Commissioner shall promptly (A) publish the information noticed in the Official Gazette of the Patent and Trademark Office, and (B) issue to the owner of record of the patent a certificate of extension, under seal, stating the fact and length of the extension and identifying the product and the statutory use and the claim or claims to which such extension is applicable. Such certifcate shall be recorded in the official file of each patent extended and such certificate shall be considered as part of the original patent.

"(c) As used in this section:

"(1) The term 'product or a method for using a product' means any machine, manufacture, composition of matter or any specific method of use theeof for which United States Letters Patent can be granted and includes the following or any specific method of use thereof:

"(A) any new drug, antibiotic drug, new animal drug, device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act;

"(B) any human or veterinary biological product subject to regulation under section 351 of the Public Health Service Act or under the virus, serum, toxin, and analogous products provisions of the Act of Congress of March 4, 1913;

"(C) any pesticide subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act; and

"(D) any chemical substance or mixture subject to regulation under the Toxic Substances Control Act.

"(2) The term 'major health or environmental effects test' means an experiment to determine or evaluate health or environmental effects which requires at least six months to conduct, not including any period for analysis or conclusions.

"(3) The term 'statutory use' means all uses regulated under the statutes identified in sections (c)(4)(A)-(D) for which regulatory review occurred for the product involved.

"(4) The term 'regulatory review period' means—

"(A) with respect to a food additive, color additive, new animal drug, veterinary biological product, device, new drug, antibiotic drug, or human biological product, a period commencing on the earliest of the date the patentee, his assignee, or his licensee (i) initiated a major health or environmental effects test on such product or a method for using such product, (ii) claims an exemption for investigation or requests authority to prepare an experimental product with respect to such product or a method for using such product under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of Congress of March 4, 1913, or (iii) submits an application or petition with respect to such product or a method for using such product under such statutes, and ending on the date such application or petition with respect to such product or a

method for using such product is approved or licensed under such statutes or, if objections are filed to such approval or license, ending on the date such objections are resolved and commercial marketing is permitted or, if commercial marketing is initially permitted and later revoked pending further proceedings as a result of such objection, ending on the date such proceedings are finally resolved and commercial marketing is permitted;

"(B) with respect to a pesticide, a period commencing on the earliest of the date the patentee, his assignee, or his licensee (i) initiates a major health or environmental effects test on such pesticide, the data from which is submitted in a request for registration of such pesticide under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act, (ii) requests the grant of an experimental use permit under section 5 of such Act, or (iii) submits an application for registration of such pesticide pursuant to section 3 of such Act, and ending on the date such pesticide is first registered, either conditionally or fully;

"(C) with respect to a chemical substance or mixture for which notification is required under section 5(a) of the Toxic Substances Control Act—

"(i) which is subject to a rule requiring testing under section 4(a) of such Act, a period commencing on the date the patentee, his assignee, or his licensee has initiated the testing required in such rule and ending on the expiration of the premanufacture notification period for such chemical substance or mixture, or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or injunction is dissolved or set aside;

"(ii) which is not subject to a testing rule under section 4 of such Act, a period commencing on the earlier of the date the patentee, his assignee, or his licensee—

"(I) submits a premanufacture notice, or

"(II) initiates a major health or environmental effects test on such substance, the data from which is included in the premanufacture notice for such substance,

and ending on the expiration of the premanufacture notification period for such substance or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or such injunction is dissolved or set aside;

"(D) with respect to any other product or method of using a product that has been subjected to Federal premarketing regulatory review, a period commencing on the date when the patentee, his assignee, or his licensee initiates actions pursuant to a Federal statute or regulation to obtain such review prior to the initial commercial marketing in interstate commerce of such product and ending on the date when such review is completed,

except that the regulatory review period shall not be deemed to have commenced until a patent has been granted for the product or the method of use of such product subject to the regulatory review

period. In the event the regulatory review period has commenced prior to the effective date of this section, then the period of patent extension for such product or a method of using such product shall be measured from the effective date of this section.

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ADDITIONAL VIEWS OF SENATORS EDWARD M. KENNEDY AND HOWARD M. METZENBAUM ON S. 255

S. 255 responds to a superficially appealing situation: it seeks to restore years of patent life for drugs and chemical substances allegedly lost because of federal regulation. No one denies that such regulation is vital. At the same time, a case can be made for the general proposition that these two categories of products should not be unfairly penalized because of the regulatory process.

However, the Committee record has not established a satisfactory connection between that general proposition and the specific legislation before us. A number of important questions remain to be answered before such a bill is enacted.

The first argument for the bill is one of general equity: Congress having decreed that a seventeen-year patent monopoly is the appropriate incentive to elicit inventions, the Government should not take back a substantial portion of that period through the delay occasioned by regulatory approval. There is a reasonable issue of equity involved, but it should not be pushed too far. Throughout our history, the Nation's inventors have been given a fixed statutory monopoly within which to market their product. They have faced innumerable impediments to full enjoyment of that period, both public and private in origin. The Government has not undertaken an obligation to compensate for such impediments or to offset any delay. This bill would set a precedent that could open a Pandora's box of requests from industries who argue that the full enjoyment of the patent term is hindered by some Government program, policy or law. Accordingly, the specific premises of the legislation and its scope should be clearly established. That is not the case in the present situation.

The factual premises of the legislation are these: First, that the research and development resources committed by the industry to new drug development are declining because of the diminished return offered by patent terms significantly shorter than the full statutory period. Second, that as a result there has been a decline in the number of significant new drugs developed in recent years. And third, that the declining R&D and declining rate of new inventions are caused by the length of the regulatory process.

It is unclear that the drug companies are inadequately funded to perform the necessary R&D. In 1980, the drug industry earned 20.5 percent on equity, the Nation's fourth most profitable industry—behind tobacco and energy-related companies—and far above the 14.5 percent American average. The drug industry is usually among the two or three most profitable, and there are indications that even more profitable years are ahead, regardless of whether this legislation is enacted. The New York Times recently reported in an article entitled "The Drug Business Sees a Golden Era Ahead," May 17, 1981, Section 3, p. 1, that the industry anticipates enormous profits from the heavy R&D expenditures it has been making and plans to make.

There is also reason to doubt that significant drug discoveries have declined. The FDA has reported that the number of significant new drug discoveries has remained consistent ever since the 1950's and regardless of the 1962 amendments. Preliminary OTA analysis of this bill supports the FDA view and suggests that the "decline in drugs" reflects the extensive marketing during the 1960's of combination drugs and slight variations on basic breakthroughs, and the decline of such proliferation, rather than a substantial drop in the actual number of significant new drug breakthroughs.

The most unsettling ambiguity, however, surrounds the assumption that any decline in new drug development can be traced to the length of the regulatory approval process. For example, a report by the General Accounting Office indicates that the regulatory process is responsible for only some seventeen months of patent life loss. Moreover, it appears that much of the time currently used by the FDA may well be spent by the drug companies themselves in such pre-marketing activities as market research, product promotion, and the like.

It is also the fact that extensive promotion of the trademarks, brand names, characteristic shapes and colors, and similar brand name promotion techniques have significantly lengthened the period for which many drugs already maintain a de facto monopoly or near-monopoly market share beyond the technical patent life.

Even assuming the rationale for this legislation, it would support only a bill that extends the patent term for the net amount of delay in marketing caused by the FDA process. But apart from FDA requirements, phramaceutical manufacturers would, by their own admission engage in substantial testing of safety and efficacy to protect themselves against product liability and consumer fraud suits. The increase in our knowledge of potential risks and the increase in sophisticated testing capability has lengthened the time that they would take themselves, just as it has lengthened the time for FDA clearance. The bill reported by the Committee contains no mechanism to ensure that the period of the extension is actually limited to the net increase in the time for marketing actually attributable to the FDA regulatory process. The assumption made on page 31 of the Committee report that the entire "regulatory review period" defined in Subsection (c)(4)(A)–(D) of the bill equals the net delay in marketing caused by FDA is simply without support in the record. The potential for overreaching is disturbing.

A separate question is presented by the absence of any plowback provision which will assure that the public interest cited for this bill is advanced through increased commitment of research funds to new drug development, as opposed to their expenditure on market competition or diversification.

Finally, it is almost inevitable that this bill will reduce competition in drugs and will raise prices. Health costs are already astronomic and efforts at cost-reduction seem to be going nowhere. In such circumstances, promoting further drug cost increases is hardly sensible. Any additional cash flow may thus come from the already overstrained budgets of consumers and taxpayers.

Nevertheless, some kind of carefully tailored remedy for the loss of patent protection seems appropriate. The problem is how to reconcile the need for such a remedy with the very real problems cre-

ated by this particular bill. It was our understanding that many of these matters were under discussion and negotiation by industry groups when the vote was taken in the Committee; indeed, we had been led to believe that the bill would not be voted on until these issues had been thoroughly discussed and certain changes made.

We therefore urge that the interested parties meet to improve this bill with strengthening amendments before ity is taken up by the full Senate, so that these complex and technical matters need not consume the time of Senators who may be unfamiliar with many of the facts and issues. We also think it would be useful for the Senate to have the benefit of the OTA study of this legislation and particularly of the factual premises upon which it rests. The report is due soon. Just as we should do all we can to encourage the development of vital new drugs, so must we also do all in our power to improve competition and reduce costs.

In its present form, we believe this bill is not in the public interest.

EDWARD M. KENNEDY.
HOWARD M. METZENBAUM.

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