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## Senate

(Legislative day of Thursday, June 12, 1980)

By Mr. BAYH (for himself, Mr. THURMOND, Mr. MATHIAS, Mr. MORGAN, and Mr. PERCY):

S. 2892. A bill to amend the patent law to restore the term of the patent grant for a period of time that non-patent regulatory requirements prevent the marketing of a patented product; to the Committee on the Judiciary.

PATENT TERM RESTORATION ACT

● Mr. BAYH. Mr. President, today I am introducing the Patent Term Restoration Act of 1980. This bill has been drafted as a part of a package of bills that I have introduced to strengthen the patent and trademark system which is one of the greatest incentives to innovation and productivity.

The legislation that I am introducing is designed to restore up to 7 years of a patent's 17-year life that is effectively lost due to Government required premarket review requirements. The bill is in no way an attack on the necessity of making sure that new products such as drugs are safe for public consumption, but addresses the inequity of the Government's granting a 17-year patent with one hand and then saying that the product cannot be used until certain tests are completed during which time the life of the patent is ticking away.

In the past 15 to 20 years a number of laws have been enacted requiring that certain products be tested to assure that they are safe for marketing in the areas of public health and the environment. Gradually as more and more sophisticated tests are relied on, the time period needed to clear this review has grown. In 1962, for example, it took approximately 2 years and $4 million to bring a new pharmaceutical product from the laboratory to the marketplace. It now takes 8 years and $50 million to complete this testing period. Thus, it is not uncommon for a company to find itself having used up one-half of the patent's life without having recovered anything in the market. This fact coupled with the known failure rate of new products is a very real discouragement to innovation which has been the historic basis of our prosperity.

In the mid-1960's the United States was introducing about 42 new pharmaceutical entities a year; today that average is merely 16 new drugs a year which is a decline of 62 percent in 15 years. This type of trend has occurred in a number of areas where the United States was once preeminent and represents a very serious threat to our standard of living. Unless these trends are turned around we will find ourselves not only dependent on foreign sources for our oil but for our technology. Right now the importation of foreign manufactured goods is the second biggest drain on our economy behind oil imports. While the West Germans and Japanese are redoubling their research and development efforts, many of our own companies are cutting back on their research. Strengthening the patent and trademark system is one of the most effective means of turning this dangerous trend around. The present bill is a part of this endeavor.

As Thomas Jefferson said while drafting the United States' first patent law in 1793, "ingenuity should receive a liberal encouragement." The 17-year term of our patents was designed under this philosophy, but when our regulatory processes effectively cut this term in half it should be no surprise that innovation suffers. If this trend is left unchanged we will witness continuing losses of leadership in important economic field to foreign competitors who fully understand the importance of rewarding innovation.

The thrust of the present bill is that for products subject to Government premarket review requirements (which toll against the life of the patent) a period equal to the time required for this clearance will be granted to extend the patent's life up to a maximum of 7 years. If the product does not clear the review no extension of the patent will be granted. Further, such restoration of the patent will apply only to the specific product or use involved in the regulatory approval and not to the entire range of products that might result from the original patent grant.

It is my wish that next year the Senate Judiciary Committee conduct hearings on the patent and trademark system and its effect on American innovation and productivity. The patent restoration bill will be a part of this hearing. The Judiciary Committee has already reported

out and the Senate has overwhelmingly passed two pieces of legislation that I introduced; S. 414, the Bayh-Dole patent policy bill, and S. 2446, on patent reexamination. Many of my colleagues from both sides of the aisle have joined in these efforts because of overwhelming evidence that has been compiled showing patents and trademarks to be essential to innovation. The patent and trademark system has received more attention in the past 2 years than at any time since I have been in the Senate as our innovation and productivity slump has focused attention on what factors actually contribut to developing new products and inventions. This effort must continue, and I feel sure that the present bill will be an important part of this investigation. I urge my colleagues to give this legislation very serious consideration and hope that they will join me in supporting the Patent Restoration Act of 1980.

SECTION-BY-SECTION ANALYSIS OF PATENT TERM RESTORATION ACT

Overview.—The bill compensates a patent holder for time lost in which to commercialize the patented product because of Federal premarket testing or regulatory review requirements. This is accomplished by extending the patent by a period of time equal to the time spent doing the testing and undergoing the regulatory review. In no case may the patent be extended by more than 7 years. A product may receive a patent extension only if the relevant regulatory agency permits it to be marketed. Patented products eligible for the extension are human drugs and biologicals, animal drugs and biologicals, food additives, color additives, pesticides, other chemical substances, and medical devices.

The extension applies only to the specific product which is subject to the testing and review requirements. This means that if a single patent covers a generic chemical class, the extension applies only to the chemical entity which has undergone the regulatory review. Moreover, the extension is limited to the particular statutory use of the chemical for which the review was required. For example, a chemical may be used as a drug, and it may also be used in a cosmetic. Because the product does not have to undergo premarket testing and review for the cosmetic use, the patent extension would apply to the chemical when it was used as a drug but not as a cosmetic.

A patent holder obtains the extension by notifying the Commissioner of Patents that his or her patented product has just undergone premarket testing and regulatory review (this is called a "regulatory review period" in the bill). The notice tells the Commissioner how long the review period has lasted. The Commissioner then issues a certificate extending the patent by a period equal to the regulatory review period.

Following is a section by section explanation of the bill.

Section 1.—Section 1 provides that the act will be called the Patent Term Restoration Act.

Section 2.—Section 2 contains the Congressional findings and policy. They include findings relating to the importance of the patent system to provide incentives for investment in innovation and new product development. The findings recognize the importance of Federal health and environment laws, but also note that the premarket testing and regulatory review required under such laws may substantially reduce the period of commercial exclusivity for patented products. The Congressional policy is that the term of patents on products subject to premarket review and testing requirements should be extended to compensate for delays in commercialization resulting from such requirements.

Section 3 adds a new section, section 155, to Title 35 of the U.S. Code. The new section 155 contains three subsections as follows:

Subsection (a).—Subsection (a) provides that a patent applicable to a product subject to a regulatory review period, or a patent applicable to a process for use of such a product, may be extended by a period of time equal to the regulatory review period. In order to obtain the extension, three conditions must be met. First, the patentee must give notice to the Commissioner of Patents. Second, the regulatory review process must have resulted in the removal of restrictions on marketing the product commercially. Third, the patent must not have expired before the Commissioner receives the required notice.

The subsection limits the extension to the specific product subject to the regulatory review period and to the statutory use for which review was required.

In no event may the patent be extended for more than 7 years.

Subsection (b).—Subsection (b)(1) spells out what must be included in the notice to the Commissioner. The notice must be given to the Commissioner within 90 days after the regulatory review period has ended. The notice must state the date on which the regulatory review period began and ended; it must identify the product and use subject to the regulatory review period; it must contain a statement that the restrictions on marketing have been removed; and it must identify the particular claim of the patent to which the extension applies and how long the extension should be.

Subsection (b)(2) requires the Commissioner to publish the information received in the notice in the Official Gazette of the Patent and Trademark Office.

Subsection (b)(3) requires the Commissioner to issue a certificate to be recorded in the official file of the patent spelling out the details of the extension.

Subsection (b)(4) provides that any extension shall be revoked by the Commissioner if the person subject to the regulatory review period is convicted of submitting false or fraudulent data to obtain the regulatory approval.

Subsection (c).—Subsection (c) defines the products eligible for extension and it defines the regulatory review period for those products.

Products covered are human drugs, animal drugs, food additives, color additives, human or veterinary biological products, pesticides, chemical substances or mixtures, and medical devices.

The following is an explanation of the regulatory review period for each of the products:

Human drug or biological.—The regulatory review period begins on the date the patentee submits an investigational new drug application to the FDA, and it ends on the date FDA approves the drug or biological.

Animal drug.—The period begins on the date the patentee submits an investigational new drug application to FDA, and it ends on the date FDA approves the drug.

Veterinary biological.—The period begins on the date the patentee asks the USDA for permission to begin testing, and it ends on the date USDA approves the biological.

Food additive.—The period begins on the date the patentee inititaes a major health or environmental effects test on the food additive, and it ends on the date FDA issues a regulation approving the food additive.

Color additive.—The period begins on the date the patentee begins a major health or environment effects test on the additive, and it ends on the date FDA issues a regulation approving the additive.

Pesticide.—The period begins on the earlier of the date the patentee initiates a major health or environmental effects test, applies for an experimental use permit, or applies for registration, and it ends on the date EPA registers the pesticide.

Chemical substance or mixture.—If EPA has issued a testing rule for the substance or mixture, the regulatory review period begins on the date the patentee begins the required testing. If no testing rule has been issued, then the regulatory review period begins on the date the patentee either submits a premanufacture notice or begins a major health or environmental effects test. The period ends on the date the substance or mixture may be legally manufactured for commercial purposes.

If a patent has not been granted at the time the regulatory review period begins, then the extension period is measured from the time the patent is granted until the end of the regulatory review period. If a product is undergoing regulatory review at the time the bill is enacted, then the regulatory review period will be considered to have started on the effective date of the bill.