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SENATE

BILL	DATE	PAGE(S)
S. 2892	June 27, 1980 Part 2	S 8685-87

ACTION Introduced by Mr. Bayh, et al.

constructed i… ated on the North Platte … part of the North Platte … ctric Power, Pick-Sloan … program, western divisi…

This bill w… a study to determine th… f enlarging the 4,800-kil… ant to ap- proximately … ts. No new powerlines wo… d as the en- largement wo… d into exist- ing transmiss… he Missouri River Basin p… ment of the powerplant w… wer genera- tion with ir… es of water that now mus… resent plant due to its limi…

I hope the S… ort this bill. Mr. President … ous consent that the bill b… e RECORD.

There being … the bill was ordered to be … RECORD, as follows:

Be it enacted … and House of Representative… d States of America in Co… d, That the Secretary of th… by authorized to engage in a … ne the feasi- bility of expan… by Dam Pow- er Plant, Nort… Hydroelectric Power, Pick-Sl… sin program, Western Divisi… shen County, Wyoming.●

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.

I ask unanimous consent to that the text of the bill and a section-by-section analysis be printed in the RECORD.

There being no objection, the bill and analysis were ordered to be printer in the RECORD, as follows:

S. 2892

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 1980."

SEC. 2. (a) The congress finds that—

(1) the United States patent system has provided a major incentive for the investment necessary for innovation and new product development;

(2) protection of health and the environment is a necessary concern of the Federal Government and many patented products may not be marketed commercially until the product has been approved in accordance with various Federal health and environmental laws;

(3) the time necessary for the testing of such products and the regulatory review or notification period substantially reduce the period of commercial exclusivity which the Congress intended a patented product to enjoy;

(4) such a reduction in the commercial exclusivity period discourages research and innovation and prevents important new products from being made available to the public;

(5) restoration of the rights afforded by the grant of patents to their full period of exclusivity is a necessary prerequisite to restoring the United States to an innovative leadership position.

(b) It is the policy of the United States that the term of patents for products subject to premarketing regulatory review or notification should be extended to compensate for delays in commercialization of such products resulting from government regulation.

SEC. 3. Title 35 of the United States Code, entitled "Patents" is amended by adding the following new section immediately after Section 154:

"SEC. 155. RESTORATION OF PATENT TERM

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

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

"(B) the regulatory review period resulted in the removal of restrictions on the commercial marketing of such product, or device; and

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

"The rights derived from any claim of any patent so extended shall be limited in scope during the period of any extension to the chemical product or device 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 90 days after termination of a regulatory review period, the owner of record of the patent shall notify the Commissioner that the regulatory review period has ended. Such notification shall be in writing and shall:

"(A) state the date on which the regulatory review period commenced and ended;

"(B) identify the device or specify the chemical identity of the chemical product and the statutory use for which regulatory review was required.

"(C) state that the requirement of subsection (a)(1)(B) has been satisfied; and

"(D) identify the claim 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 publish the information noticed in the Official Gazette of the Patent and Trademark Office.

"(3(The Commissioner shall issue a certificate of extension, under seal, stating the fact and length of the extension and identifying the product or device and the use and the claim 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 part of the original patent.

"(4) Any patent extension granted under this section shall be revoked by the Commissioner if the person subject to the regulatory review period is convicted by a court of a criminal violation for submitting false, fictitious, fraudulent, or misleading data in support of the application, petition, request, or notification described in subsection (c)(4) on which such patent extension is based.

"(c) As used in this section:

"(1) The term 'chemical product' means—

"(A) any new drug, new animal drug, food additive, and color additive as defined in section 201 of the Federal Food, Drug, and Cosmetic Act;

"(B) any human or veterinary biological product as defined in section 351(a) of the Public Health Service Act or in regulations issued under the virus, serum, toxin and analogous products provisions of the Act of Congress of March 4, 1913;

"(C) any pesticide as defined in section 2 of the Federal Insecticide, Fungicide, and Rodenticide Act; and

"(D) any chemical substance or mixture as defined in section 3 of the Toxic Substances Control Act.

"(2) The term 'device' means any device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act and described in section 513(a)(1)(C) of such Act.

"(3) 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.

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

"(A) with respect to a new drug or a human biological product, a period commencing on the date the patentee, his assignee, or his licensee has requested an exemption for investigation with respect to such drug or biological product under section 505(i) or section 507(d) of the Federal Food, Drug, and Cosmetic Act and ending on the date an application with respect to such drug submitted under section 505(b) or section 507(f) of such Act is approved or such biological product is licensed under section 351(d) of the Public Health Service Act;

"(B) with respect to a new animal drug, a period commencing on the date the patentee, his assignee, or his licensee has requested an exemption for investigation with respect to such animal drug under section 512(j) of the Federal Food, Drug, and Cosmetic Act and ending on the date an application with respect to such animal drug submitted under section 512(b) of such Act is approved;

"(C) with respect to a veterinary biological product, a period commencing on the date the patentee, his assignee, or his licensee has requested authority to prepare an experimental product under the virus, serum, toxin and analogous products provisions of the Act of Congress of March 4, 1913 and ending on the date such biological product is licensed under such Act;

"(D) with respect to a food additive, a period commencing on the date the patentee, his assignee, or his licensee initiates a major health or environmental effects test relied upon to establish the safety of such food additive in a petition submitted under section 409 of the Federal Food, Drug, and Cosmetic Act requesting issuance of a regulation prescribing the conditions under which such additive may be safely used and ending on the date such regulation becomes effective;

"(E) with respect to a color additive, a period commencing on the date the patentee, his assignee, or his licensee initiates a major health or environmental effects test relied upon to show that such color additive will be safe for its intended uses in a petition requesting the issuance of a regulation listing such use and ending on the date such a regulation becomes effective;

"(F) with respect to a pesticide, a period commencing on the earlier of the date the patentee, his assignee, or his licensee (i) initiates a major health or environmental effects test on such pesticide, the date 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;

"(G) with respect to a chemical substance or mixture for which notification is required under section 5(a) and which is subject to a rule requiring testing under section 4(a) of the Toxic Substances Control 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;

"(H) with respect to a chemical substance or mixture for which notification is required under Section 5(a) but which is not subject to a testing rule under Section 4 of the Toxic Substances Control 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; and

"(I) with respect to a device, a period commencing on the date the patentee, his assignee or his licensee has requested an exemption for investigation with respect to such device under section 520(g) of the Federal Food, Drug, and Cosmetic Act and ending on the date an application with respect to such device submitted under section 515(c) of such Act is approved,

"except that the regulatory review period shall not be deemed to have commenced until a patent has been granted for the chemical product or device or the use of such product or device 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 commencement of the regulatory review period shall be considered to be such effective date."

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 t 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 dru 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.●

Mr. PERCY. Mr. President, I am pleased to join the Senator from Indiana (Mr. BAYH) in introducing the Patent Term Restoration Act of 1980.

This legislation extends the applicable time for patents on pharmaceutical products to make up, in part, for the delay in the marketability of such products caused by Government regulatory action. The current patentable life for drugs is 17 years. However, the patent term begins to run as soon as application is made for Government approval of the right to market the drug. The average approval period for the Food and Drug Administration is from 10 to 12 years. Thus, the marketable patent life is reduced to as little as 5 years. This legislation will credit the manufacturer with an additional year of patent life for each year of lost marketability, up to a total additional period of 7 years.

I am supporting this legislation for two reasons. First, it is critical that American businesses have the incentive to invest risk capital in the research and development of new drugs. This is important not only to the individual consumer but to our international competitive position in this industry as well.

The benefit to the consumer from the development of lifesaving, curative, and preventive drugs and medicines cannot be estimated. Drugs are really the least expensive form of health care and their cost as a percentage of the health care dollar is declining. One cannot estimate how many days in the hospital or how many days lost from work drugs have prevented, but the total is significant. With continued research this figure will increase. But the research and development of the drugs that will make a significant difference in the rate of illness and death in the years ahead will be extremely expensive. Without the possibility of sufficient return on this investment it will not be made.

Increased research and development will benefit us economically in another important way. The United States has been preeminent in pharmaceutical products in world markets. Some would say that we have lost that preeminence. Certainly most would agree that we are in danger of losing it. In either case, we will lose out to our competitors if we do not continue to develop more and better products.

My second reason for supporting this legislation is to help highlight what is referred to as the "drug lag." Is the 10 to 12 years that approval of a new drug typically takes necessary to protect the consumer, or does it instead delay the time when potentially lifesaving drugs will be available to the public? Certainly new drugs must be thoroughly tested, but if the general public were aware of the length of time that new drugs are kept off the market I think they would begin to ask their Representatives in Government some questions. I think these questions should be addressed. Where delay is the result of the necessity to protect the consumer, then we must accept it. But where it is the result of excessive Government regulation, it must be stopped.

I commend this legislation to the attention of my colleagues and look forward to early action by the Judiciary Committee.