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SENATE

BILL	DATE	PAGE(S)
S. 255	July 9, 1981	S 7354-56

Action:

Patent Term Restoration: Senate passed S. 255, encouraging American innovation by restoring the patent system as it affects certain products subject to premarket testing by the Federal government, after agreeing to the following amendment proposed theeto:

Heflin unprinted amendment No. 218, providing that, except for products approved and for which a stay of regulation granting approval pursuant to Section 409 of the Federal Food, Drug and Cosmetic Act was in effect as of January 1, 1981, the period of such patent extensions shall be measured from the date such stay was imposed until such proceedings are finally resolved and commercial marketing permitted provided the filing required by (b)(1) is made within 90 days of the termination of the regulatory review period or the effective date of the section, whichever is later.

Pages S7354-S7356

PATENT TERM RESTORATION ACT OF 1981

The PRESIDING OFFICER. The clerk will state the bill by title.

The assistant legislative clerk read as follows:

A bill (S. 255) 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.

The Senate proceeded to consider the bill.

Mr. ROBERT C. BYRD addressed the Chair.

The PRESIDING OFFICER. May we have order in the Chamber, please?

The Senator from West Virginia is recognized.

Mr. ROBERT C. BYRD. Mr. President, I believe Mr. HEFLIN has an amendment.

UP AMENDMENT NO. 218

Mr. HEFLIN. Mr. President, I send an amendment to the desk and ask for its immediate consideration. It is in the nature of a technical amendment which would correct an unintended but nonetheless egregious injustice which would result under our current regulatory framework. It applies to a small class of discoveries that have gone through the normal regulatory review process and secured approval, but then have had their marketing stayed by administrative act by the regulatory agency. My amendment provides that if such a stay is removed and marketing permitted, the patent life will be extended by the period of that stay.

The PRESIDING OFFICER. The amendment will be stated.

The assistant legislative clerk read as follows:

The Senator from Alabama (Mr. HEFLIN) proposes an unprinted amendment numbered 218.

Mr. HEFLIN. Mr. President, I ask unanimous consent that further reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment is as follows:

At the bottom of page 8 (at the end of the bill): change the period to a comma strike the quotation mark, and add the following: except that for products approved and for which a stay of regulation granting approval pursuant to Section 409 of the Federal Food, Drug and Cosmetic Act was in effect as of January 1, 1981, the period of such patent extensions shall be measured from the date such stay was imposed until such proceedings are finally resolved and commercial marketing permitted provided the filing required by (b)(1) is made within 90 days of the termination of the regulatory review period or the effective date of this section whichever is later."

The PRESIDING OFFICER. The question is on agreeing to the amendment.

The amendment (UP No. 218) was agreed to.

Mr. HEFLIN. Mr. President, I move to reconsider the vote by which the amendment was agreed to.

Mr. HUDDLESTON. Mr. President, I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. THURMOND. Mr. President, I am pleased to join today with the distinguished Senator from Maryland (Mr. MATHIAS) in supporting this legislation to amend the patent laws to restore the term of the patent that is taken up by nonpatent regulatory requirements.

It has become obvious that in recent years America's innovative capacity has been reduced substantially. In addition to backlogs in the patent application and reexamination system itself, is the added burden of regulatory requirements unrelated to the patent-seeking process. An increasing number of laws have been passed by the Congress to insure that new products are safe for the public to use. Unfortunately, the time required for this testing runs against the 17-year life of a patent. These tests are often unrelated to the patent, but have the effect of limiting the time available to market the product.

This legislation, Mr. President, simply restores to the life of a patent that amount of time required by Government testing of a new product. It in no way restricts the ability of the Government to test the safety of the product, it only gives to the patent holder the 17-year life of the patent in which to market the product once declared safe by the Government.

Mr. President, this legislation is extremely important to America's capacity to keep pace with the development of technology worldwide. I urge its adoption.

Mr. PERCY. Mr. President, as an enthusiastic cosponsor of S. 255, the Patent Term Restoration Act, I am delighted that it has moved expeditiously through the Judiciary Committee and has now reached the floor for consideration. It is a sorely needed bill and one that is absolutely vital both as an incentive and a reward for increased innovation.

For over 6 years I have been working closely with many of my Senate colleagues on comprehensive regulatory reform proposals. I am constantly reminded of the complex regulatory maze that has developed over the years through which business has been expected to find its way. It became apparent to me a very long time ago that we have succeeded only in stifling innovation, creativity, flexibility, and productivity. Other nations have surpassed us.

In our effort to eliminate wasteful and unnecessary regulatory burdens, we have had a few victories—airline, railroad and financial deregulation, to name three of them. S. 255 is another victory. Without altering our commitment to the public to make sure that new products are safe for their use, we protect the inventor from having his patent life eaten away by the necessary, but often lengthy, regulatory review procedure.

The Patent Term Restoration Act restores to the inventor, up to a maximum of 7 years, the time lost on patent life during the regulatory review/testing period. If the product does not pass review, no restoration would be granted. Further, such restoration would apply only to the specific purpose or use involved in the regulatory approval and not to the entire range of products that might result from the original patent.

It now costs an average of $70 million for a company to develop a new drug. Naturally, they have less incentive for this kind of investment when their period of exclusive ownership of the drug is eaten away by the necessary, but often lengthy, regulatory proceedings.

As the Judiciary Committee report so aptly states:

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.

I wholeheartedly agree. I support this legislation and look forward to its early consideration in the House of Representatives. I would like to commend the Senator from Maryland (Mr. MATHIAS) for his distinguished leadership on this measure and I ask my colleagues to join us in support of this very important piece of legislation.

Mr. President, at this time, I ask unanimous consent that a thoughtful editorial appearing in the Chicago Tribune of May 1, 1981, in support of this legislation, be printed in the RECORD.

There being no objection, the editorial was ordered to be printed in the RECORD, as follows:

WHERE THE PATENT LAWS DON'T WORK

Patents are intended to give investors and creators of a new product 17 years of exclusivity to reap a return on their investment and make a profit from their discovery before it can be copied freely by others. But for developers of new medical drugs, it hasn't been working out that way.

Today, the process of getting a new medication approved by the Food and Drug Administration (FDA) has become so complex that, on the average, almost half of the patent life of a drug now expires before the product can be put on the market. In some instances, a manufacturer has only three or four years left to sell a new medication before the patent runs out and it can be copied by competitors.

With less chance to earn back their initial investment—it cost an average of $80 million to develop a new drug in 1979 compared to $6 million in 1962—pharmaceutical companies are less motivated to invest in research and drug development and increasingly inclined to shift to non-drug products. Drug companies introduced an average of 53 new medications per year between 1959 and 1962, but only an average of 18 per year between 1977 and 1979.

So, Congress is considering new legislation that would stop the clock from running on the patent life of any product that must be reviewed and approved by a government agency before it can be put on the market. The bill would add to the remaining life of the patent the time elapsed between the initial application for classification as an "investigational new drug" and final FDA approval—up to a maximum of seven years. If passed, the new law would also help companies developing new chemical products, although government approval time is not quite as lengthy for these substances.

Some objections have been raised to the proposed legislation because it would lengthen the time until a drug could be copied by the developer's competitors and marketed as a generic product, presumably at a lower price. But in the long run, we all stand to benefit much more from the discovery and availability of new medications. It is far less expensive to treat patients with drugs than with surgery or long hospitalization, which may be the only alternatives. And one of the most effective ways to cut health care costs is to develop new medications. Enormous savings, for example, could be made if we had more effective drugs for heart disease, cancer, genetic disorders, respiratory diseases, and a long list of other ailments for which better treatment is urgently needed.

On the average, scientists now screen more than 10,000 possibilities for every one new medication that is eventually approved by

the FDA and put on the market. The proposed legislation would provide some inducement to pharmaceutical companies to continue risking their time and money on such long shots.

The PRESIDING OFFICER. The bill is open to further amendment. If there be no further amendment to be proposed, the question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed for a third reading and was read the third time.

The PRESIDING OFFICER. The bill having been read the third time, the question is, Shall it pass?

So the bill (S. 255), as amended, was passed, as follows:

S. 255

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".

SEC. 2. 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 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 ues; 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 certificate 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 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 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 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 of 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, except that for products approved and for which a stay of regulation granting approval pursuant to section 409 of the Federal Food, Drug and Cosmetic Act was in effect as of January 1, 1981, the period of such patent extensions shall be measured from the date such stay was imposed until such proceedings are finally resolved and commercial marketing permitted provided the filing required by section (b)(1) is made within ninety days of the termination of the regulatory review period or the effective date of this section whichever is later.".

Mr. BAKER. Mr. President, I move to reconsider the vote by which the bill was passed.

Mr. HUDDLESTON. Mr. President, I move to lay that motion on the table.

The motion to lay on the table was agreed to.

ROUTIN[illegible] BUSINESS

Mr. BAK[illegible]ident, I ask unanimous [illegible]ere be a brief period for [illegible]n of routine morning bus[illegible]

The PRE[illegible]ER. Without objection, it [illegible]

DANGERS [illegible]TEIN BOMB

Mr. PROX[illegible]sident, a brilliant young [illegible]d Don Richards, of Wis[illegible]itten a stunning satire [illegible] irony of our developmen[illegible]eapons. I ask