97TH CONGRESS
2D SESSION

H. R. 6444

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.

IN THE HOUSE OF REPRESENTATIVES

MAY 20, 1982

Mr. KASTENMEIER (for himself, Mr. BROOKS, Mr. RAILSBACK, Mr. SAWYER, and Mr. BUTLER) introduced the following bill; which was referred to the Committee on the Judiciary

---

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 1982".

SEC. 2. (a) Title 35 of the United States Code is amended by adding the following new section immediately after section 154:

"§ 155. **Restoration of patent term**

"(a)(1) Except as provided in paragraphs (2) and (3), the term of a patent which encompasses within its scope a product subject to a regulatory review period, or a method for using such a product or a method for producing such a product, subject to a regulatory review period shall be extended if—

"(A) the recipient of marketing approval gives notice to the Commissioner 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;

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

"(D) the patent to be extended was issued on or subsequent to the date of enactment of the Patent Term Restoration Act of 1982.

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)(A) Subject to subparagraph (B), the term of the patent shall be extended by the time equal to the regulatory

review period for such product or method for the period up to ten years after the date of filing of the earliest application for the patent and the time equal to one-half the regulatory review period for the period between ten and twenty years from the filing date of the earliest patent application.

"(B) In no event shall the term of any patent be extended for more than seven years. No extension of a patent may exceed twenty-seven years from the date of filing of the earliest patent application for the patent. If the term that the patent would be extended is less than one year, no extension shall be granted.

"(C) In no event shall more than one patent be extended for the same regulatory review period for the product or method.

"(3) The term of a patent which encompasses within its scope a method for producing a product may not be extended under this section if—

"(A) the owner of record of such patent is also the owner of record of another patent which encompasses within its scope the same product; and

"(B) such patent on such product has been extended under this section.

"(b)(1) Within ninety days after termination of a regulatory review period, the recipient of marketing approval shall notify the Commissioner under oath that the regulatory

review period has ended. If the recipient of marketing approval is not the owner of record of the patent, the notification shall include the written consent of the owner of record of the patent to the extension. 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; the date of filing of the earliest application for the patent; and the length of time of the regulatory review period for which the term of such patent is to be extended; and state that no other patent has been extended for the regulatory review period for the product or method.

"(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' 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 or of producing 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 March 4, 1913 (21 U.S.C. 155–158).

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

"(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 'earliest application for the patent' means the patent application providing the earliest benefit of filing date to the patent and includes patent applications under sections 119 and 120.

"(4) The term 'statutory use' means all uses regulated under the statutes identified in subparagraphs (A) through (F) of paragraph (5) for which regulatory review occurred for the product involved.

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

"(A) with respect to a drug, antibiotic drug, or human biological product, a period commencing on the earliest of the date the recipient of marketing approval (i) initiated a clinical investigation on humans for the specific method for use for which such product is approved or licensed under such statutes, or (ii) submits an application or petition with respect to such product or a method for

using or of producing such product under such statutes, and ending on the date such application or petition with respect to such product or a method for using or of producing such product is approved or licenses under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of March 4, 1913, or, if objections are filed to such approval or license, ending on the date such objections are resolved and commerical 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 food additive or color additive, a period commencing on the earliest of the date the recipient of marketing approval (i) claimed an exemption for investigation with respect to such product or a method for using such product under the Federal Food, Drug, and Cosmetic Act, or (ii) submitted a petition for regulation with respect to such product or a method for using such product is approved or licensed under such statute;

"(C) with respect to an animal drug or veterinary biological product, a period commencing on the earlier of the date the recipient of marketing approval (i) initiated a test on the animal for which the use of the product has been approved wherein the test required at least six months to conduct not including any period for analysis or conclusions and the data from which is included in the application or petition 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 March 4, 1913, or (ii) submitted an application or petition with respect to such product or method 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;

"(D) with respect to a device, a period commencing on the earlier of the date the recipient of marketing approval (i) submitted a proposed product development protocol with respect to such product or method for using such product under the Federal Food, Drug, and Cosmetic Act, or (ii) submitted an application with respect to such

product or method for using such product under such statute, and ending on the date such application with respect to such product or a method for using such product is approved under such statute;

"(E) with respect to a pesticide, a period commencing on the earliest of the date the recipient of marketing approval (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 pesiticide 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; and

"(F) 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 recipient

of marketing approval 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 recipient of marketing approval—

"(I) submits a premanufacture notice, or

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

and ending on the expiration of the premanufacture notification period for such 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 such injunction is dissolved or set aside;

except that the regulatory review period shall not b deemed to have commenced until a patent has bee granted for the product or the method of use of suc product subject to the regulatory review period.

"(d)(1) In the event that prior to the date of enactmer of this section a new drug product was approved on a dat more than seven years after the commencement of the regu latory review period and during such regulatory reviev period the patentee was notified that such product's applica tion was not approvable under section 505(b)(1) of the Feder al Food, Drug, and Cosmetic Act and as a result of which the patentee caused a major health or environmental effects test to be conducted to evaluate carcinogenic potential, then the period of patent extension for such product or the method of use of such product shall be seven years, if the filing required by subsection (b)(1) of this Act is made within ninety days of the date of enactment of this section.

"(2) Notwithstanding subsection (a)(1)(D), in the case of 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, if the filing required by subsection (b)(1) is made within ninety days

of the termination of the regulatory review period or of the date of enactment of this section, whichever is later.".

(b) The analysis for chapter 14 of title 35, United States Code, is amended by adding at the end the following:

"155. Restoration of patent term.".

O