98TH CONGRESS
1ST SESSION

H. R. 3502

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

JUNE 30, 1983

Mr. SYNAR (for himself, Mr. WRIGHT, Mr. FOLEY, Mr. ALEXANDER, Mr. MICHEL, Mr. LOTT, Mr. BROOKS, Mr. MAZZOLI, Mr. SAM B. HALL JR., Mr. SMITH of Florida, Mr. FISH, Mr. MOORHEAD, Mr. HYDE, Mr. KINDNESS, Mr. SAWYER, Mr. SENSENBRENNER, Mr. DEWINE, Mr. JONES of Oklahoma, Mr. BOLAND, Mr. FUQUA, Mr. MONTGOMERY, Mr. COELHO, Mr. CONABLE, Mr. JENKINS, Mr. ROSE, Mr. SHELBY, Mr. FROST, Mr. WHITLEY, Mr. DASCHLE, Mr. ANTHONY, Mr. HEFNER, Mr. DWYER of New Jersey, Mrs. BYRON, Mr. IRELAND, Mr. SHARP, Mr. DOWDY of Mississippi, Mr. LUKEN, Mr. TALLON, Mr. SKELTON, Mr. VALENTINE, Mr. ACKERMAN, Mr. VOLKMER, Mr. BREAUX, Mr. BRITT, Mr. JACOBS, Mr. MURPHY, Mr. SCHEUER, Mr. HUBBARD, Mr. WALGREN, Mr. KOSTMAYER, Mr. FORD of Tennessee, Mr. STENHOLM, Mr. BONER of Tennessee, Mr. HUTTO, Mrs. LLOYD, Mr. FLORIO, Mr. MCCURDY, Mr. ENGLISH, Mr. WATKINS, Mrs. HALL of Indiana, Mr. TOWNS, Mr. DERRICK, Mr. CARPER, Mr. HARRISON, Mr. NICHOLS, Mr. FLIPPO, Mr. SPRATT, Mr. WILSON, Mr. TAUZIN, Mr. ANDREWS of Texas, Mr. GEJDENSON, Mr. MADIGAN, Mr. RITTER, Mr. FORSYTHE, Mr. CHAPPIE, Mr. COURTER, Mr. SMITH of New Jersey, Mr. HILER, Mr. GRAMM, Mr. DAUB, Mr. WHITTAKER, Mrs. ROUKEMA, Mr. BLILEY, Mr. EDWARDS of Alabama, Mr. BURTON of Indiana, Mr. SOLOMON, Mr. PORTER, Mr. THOMAS of California, Mr. O'BRIEN, Mr. GREGG, Mr. COUGHLIN, Mr. OXLEY, Mr. WEBER, Mr. PASHAYAN, Mr. COATS, Mr. CORCORAN, Mr. WORTLEY, Mr. MCKINNEY, Mr. LOWERY of California, and Mr. PETRI) 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 1983".

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 (3) and (4), the term of a patent which encompasses within its scope a product subject to regulatory review, or a method for using such a product or a method for producing such a product, shall be extended from the original expiration date of the patent by the amount of time equal to the regulatory review period 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 product has been subjected to regulatory review pursuant to statute before 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).

"(2) The rights derived from any claim of any patent extended under paragraph (1) shall be limited—

"(A) in the case of any patent, to the scope of such claim which relates to the product subject to regulatory review, and

"(B) in the case of a patent which encompasses within its scope a product—

"(i) which is subject to regulatory review under the Federal Food, Drug, and Cosmetic Act, to the uses of the product which may be regulated by the chapter of such Act under which the regulatory review occurred, or

"(ii) which is subject to regulatory review under any other statute, to the uses of the product which may be regulated by the statute under which the regulatory review occurred.

"(3) In no event shall the term of any patent be extended for more than seven years or shall more than one patent be extended for the same regulatory review period for the product.

"(4) 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) To obtain an extension of the term of a patent under subsection (a), the owner of record of the patent shall notify the Commissioner under oath, within ninety days after the termination of the regulatory review period for the product to which the patent relates, that the regulatory review period has ended. Such notification shall be in writing and shall—

"(A) identify the Federal statute under which regulatory review occurred or, if the regulator review occurred under the Federal Food, Drug, and Cosmetic Act, the chapter of the Act under which the review occurred;

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

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

"(D) state that the requirements of the statute under which the regulatory review referred to in subsection (a)(1)(B) occurred have been satisfied and commercial marketing or use of the product is not prohibited; and

"(E) identify the patent and any claim thereof 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 and state that no other patent has been extended for the regulatory review period for the product.

"(2) Upon receipt of the notice required by paragraph (1), the Commissioner shall promptly publish in the Official Gazette of the Patent and Trademark Office the information contained in such notice. Unless the requirements of this section have not been met, the Commissioner shall 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 statute under which regulatory review occurred and specifying any claim to which such extension is applicable. Such certificate shall be recorded in the official file of the patent so extended and shall be considered as part of the original patent.

"(c) As used in this section:

"(1) The term 'product' means any machine, manufacture, or composition of matter of which a patent may be obtained and includes the following:

"(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 (21 U.S.C. 151–158);

"(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 'regulatory review period' means—

"(A) with respect to a product which is 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) initiates a major health or environmental effects test on such product, the data from which are submitted in an application or petition with respect to such product under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of Congress of March 4, 1913,

"(ii) claims an exemption for investigation or requests authority to prepare an experimental product with respect to such product under such statutes, or

"(iii) submits an application or petition with respect to such product under such statutes,

and ending on the date such application or petition with respect to 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 product which is 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 are 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 for such pesticide 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 under section 3 of such Act, either conditionally or fully; and

"(C) with respect to a product which is 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 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 chemical substance or mixture, the data from which are included in the premanufac-

ture notice for such substance or mixture,

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;

except that the regulatory review period shall not be deemed to have commenced until a patent has been granted for the product which is subject to regulatory review, for the method for using such product, or for the method for producing such product. In the event the regulatory review period has commenced prior to the date of enactment of this section, then the period of patent extension shall be measured from January 3, 1983, or the date the regulatory review period commences, whichever occurs 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.".

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