Union Calendar No. 432

97TH CONGRESS
2D SESSION

H. R. 6444

[Report No. 97–696]

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

AUGUST 4, 1982

Reported with amendments, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Omit the part struck through and insert the part printed in italic]

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)~~ *(3) and (4)*, 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 *from the original expiration date of the patent* if—

"(A) the ~~recipient of marketing approval~~ *product sponsor* 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~~ *before* 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.

"*(2)* The rights derived from any claim ~~or claims~~ of any patent ~~so~~ extended *under paragraph (1)* 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.—~~

"(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.

"~~(2)(A)~~ *(3)(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~~ *term of*

any extended 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)~~*(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) ~~Within ninety days after termination of a regulatory review period, the recipient of marketing approval shall notify the Commissioner under oath~~ *To obtain an extension of the term of a patent under subsection (a), the product sponsor 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. If the ~~recipient of marketing approval~~ *product sponsor* 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 *or, if the regulatory 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 ~~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~~

"(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 claim or claims of the patent~~ *the patent and any claim thereof* 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~~ *publish* in the Official Gazette of the Patent and Trademark Office~~, and (B)~~ *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 ~~statutory use and the claim or claims~~ *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 ~~each patent~~ *the patent so* 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, *or* composition of matter ~~or any specific method of use thereof for which United States Letters Patent can be granted and~~ *for which a patent may be obtained 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 addi-

tive 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~~ *151–158*).

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

"(D) ~~any~~ *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.~~

"(4) The term 'product sponsor' means any person who initiates testing or investigations, claims an exemption, or submits an application, petition, protocol, request, or notice described in paragraph (5) of this subsection.

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

"(A) with respect to a *product which is a* drug, antibiotic drug, or human biological product, a period commencing on the earliest of the date the ~~recipient of marketing approval~~ *first product sponsor* (i) ~~initiated~~ *initiates* 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~~ *the Federal Food, Drug, and Cosmetic Act, Public Health Service Act, or the Act of March 4, 1913,* 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~~ *or the product is licensed* under ~~the Federal Food, Drug, and Cos-~~

~~metic Act, the Public Health Service Act, or the Act of March 4, 1913,~~ *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* 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;~~ *the first product sponsor (i) initiates a major health or environmental effects test on the product, but only if the data from such test is submitted in a petition referred to in clause (iii) of this subparagraph, (ii) claims an exemption for an investigation with*

respect to such product, or (iii) submits a petition with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting issuance of a regulation for use of the product, and ending on the date such regulation becomes effective or, if objections are filed to such regulation, 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;

"(C) with respect to *a product which is* 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;~~ *on the earliest of the date the first product sponsor (i) claims an exemption for investigation of the product or requests authority to prepare an experimental product under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of March 4, 1913, or (ii) submits an application or petition with respect to the product under such statutes, and ending on the date such application or petition with respect to the product is approved or the product is 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;*

"(D) with respect to a *product which is a* device, a period commencing on the earlier of the date the ~~recipient of marketing approval~~ *first product sponsor* (i) submitted a proposed product development protocol with respect to ~~such product or method for using such product~~ *the product* under the Federal Food, Drug, and Cosmetic Act, ~~or (ii)~~ *(ii) initiates a clinical investigation on humans, or (iii)* submitted an application with respect to ~~such~~ *the* 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~~ *the product* is approved under such statute;

"(E) with respect to a *product which is a* pesticide, a period commencing on the earliest of the date the ~~recipient of marketing approval~~ *first product sponsor* (i) initiates a major health or environmental effects test on such pesticide, ~~the data from which~~ *but only if the data from such test* 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 *for the 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, either conditionally or fully; and

"(F) 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 ~~recipient of marketing approval~~ *first product sponsor* has initiated the testing required in such rule and ending on the expiration of the premanufacture notification period for such chemical substance or mixture, of 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~~ *first product sponsor*—

"(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~~ *but only if the data from such test* 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 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~~ *which is subject to regulatory review, for the method for using such product, or for the method for producing such product.*

"(d)(1) ~~In~~ *Notwithstanding subsection (a)(1)(D), in* the event the regulatory review period has commenced prior to the date of enactment of this section, then the period of patent extension for such product or a method of using such

product shall be measured from the date of enactment of this section. In the event that prior to the date of enactment of this section a new drug product was approved on a date more than seven years after the commencement of the regulatory review period and during such regulatory review period the patentee was notified that such product's application was not approvable under section 505(b)(1) of the Federal 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.".

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