

Union Calendar No. 432

97TH CONGRESS
2^D 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. RALLSBACK, 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.

- 1 *Be it enacted by the Senate and House of Representa-*
- 2 *tives of the United States of America in Congress assembled,*
- 3 That this Act may be cited as the "Patent Term Restoration
- 4 Act of 1982".

1 SEC. 2. (a) Title 35 of the United States Code is amend-
2 ed by adding the following new section immediately after sec-
3 tion 154:

4 “§ 155. Restoration of patent term

5 “(a)(1) Except as provided in paragraphs ~~(2)~~ and ~~(3)~~ (3)
6 and (4), the term of a patent which encompasses within its
7 scope a product subject to a regulatory review ~~period~~, or a
8 method for using such a product or a method for producing
9 such a product, ~~subject to a regulatory review period~~ shall be
10 extended *from the original expiration date of the patent* if—

11 “(A) the ~~recipient of marketing approval~~ *product*
12 *sponsor* gives notice to the Commissioner in compli-
13 ance with the provisions of subsection (b)(1);

14 “(B) the product ~~or method~~ has been subjected to
15 a regulatory review ~~period~~ pursuant to statute ~~or regu-~~
16 ~~lation~~ *prior to before* its commercial marketing or use;

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

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

23 “(2) The rights derived from any claim ~~or claims~~ of any
24 patent ~~so~~ extended *under paragraph (1)* shall be limited ~~in~~
25 ~~scope during the period of any extension to the product or~~

1 method subject to the regulatory review period and to the
2 statutory use for which regulatory review was required.—

3 “(A) in the case of any patent, to the scope of
4 such claim which relates to the product subject to regu-
5 latory review, and

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

8 “(i) which is subject to regulatory review
9 under the Federal Food, Drug, and Cosmetic Act,
10 to the uses of the product which may be regulated
11 by the chapter of such Act under which the regu-
12 latory review occurred, or

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

17 “(2)(A) (3)(A) Subject to subparagraph (B), the term of
18 the patent shall be extended by the time equal to the regula-
19 tory review period for such product ~~or method~~ for the period
20 up to ten years after the date of filing of the earliest applica-
21 tion for the patent and the time equal to one-half the regula-
22 tory review period for the period between ten and twenty
23 years from the filing date of the earliest patent application.

24 “(B) In no event shall the term of any patent be ex-
25 tended for more than seven years. No ~~extension of a term of~~

1 *any extended* patent may exceed twenty-seven years from
2 the date of filing of the earliest patent application for the
3 patent. If the term that the patent would be extended is less
4 than one year, no extension shall be granted.

5 “(C) In no event shall more than one patent be extended
6 for the same regulatory review period for the product ~~or~~
7 ~~method~~.

8 “~~(3)~~(4) The term of a patent which encompasses within
9 its scope a method for producing a product may not be ex-
10 tended under this section if—

11 “(A) the owner of record of such patent is also
12 the owner of record of another patent which encom-
13 passes within its scope the same product; and

14 “(B) such patent on such product has been ex-
15 tended under this section.

16 “(b)(1) ~~Within ninety days after termination of a regula-~~
17 ~~tory review period, the recipient of marketing approval shall~~
18 ~~notify the Commissioner under oath~~ *To obtain an extension*
19 *of the term of a patent under subsection (a), the product spon-*
20 *sor shall notify the Commissioner under oath, within ninety*
21 *days after the termination of the regulatory review period for*
22 *the product to which the patent relates, that the regulatory*
23 *review period has ended. If the recipient of marketing ap-*
24 ~~proval~~ *product sponsor is not the owner of record of the*
25 *patent, the notification shall include the written consent of*

1 the owner of record of the patent to the extension. Such noti-
2 fication shall be in writing and shall—

3 “(A) identify the Federal statute ~~or regulation~~
4 under which regulatory review occurred *or, if the regu-*
5 *latory review occurred under the Federal Food, Drug,*
6 *and Cosmetic Act, the chapter of the Act under which*
7 *the review occurred;*

8 “(B) state the dates on which the regulatory
9 review period commenced and ended;

10 “(C) identify the product ~~and the statutory use~~ for
11 which regulatory review was required;

12 “~~(D) state that the regulatory review referred to~~
13 ~~in subsection (a)(1)(B) has been satisfied; and~~

14 “(D) state that the requirements of the statute
15 under which the regulatory review referred to in sub-
16 section (a)(1)(B) occurred have been satisfied and com-
17 mercial marketing or use of the product is not prohibit-
18 ed; and

19 “(E) identify the ~~claim or claims of the patent the~~
20 *patent and any claim thereof* to which the extension is
21 applicable; the date of filing of the earliest application
22 for the patent; and the length of time of the regulatory
23 review period for which the term of such patent is to
24 be extended; and state that no other patent has been

1 extended for the regulatory review period for the prod-
 2 uct ~~or method~~.

3 “(2) Upon receipt of the notice required by paragraph
 4 (1), the Commissioner shall promptly ~~(A) publish the informa-~~
 5 ~~tion noticed~~ *publish* in the Official Gazette of the Patent and
 6 Trademark Office, ~~and (B) the information contained in such~~
 7 *notice. Unless the requirements of this section have not been*
 8 *met, the Commissioner shall* issue to the owner of record of
 9 the patent a certificate of extension, under seal, stating the
 10 fact and length of the extension and identifying the product
 11 and the ~~statutory use and the claim or claims statute under~~
 12 *which regulatory review occurred and specifying any claim*
 13 *to which such extension is applicable. Such certificate shall*
 14 *be recorded in the official file of each patent the patent so*
 15 *extended and such certificate shall be considered as part of*
 16 *the original patent.*

17 “(c) As used in this section:

18 “(1) The term ‘product’ means any machine, man-
 19 ufacture, *or* composition of matter ~~or any specific~~
 20 ~~method of use thereof for which United States Letters~~
 21 ~~Patent can be granted and for which a patent may be~~
 22 *obtained and includes the following or any specific*
 23 *method of use or of producing thereof:*

24 “(A) Any new drug, antibiotic drug, new
 25 animal drug, device, food additive, or color addi-

1 tive subject to regulation under the Federal Food,
2 Drug, and Cosmetic Act.

3 “(B) Any human or veterinary biological
4 product subject to regulation under section 351 of
5 the Public Health Service Act or under the virus,
6 serum, toxin, and analogous products provisions of
7 the Act of March 4, 1913 (21 U.S.C. ~~155-158~~
8 151-158).

9 “(C) ~~any~~ Any pesticide subject to regulation
10 under the Federal Insecticide, Fungicide, and Ro-
11 denticide Act.

12 “(D) ~~any~~ Any chemical substance or mixture
13 subject to regulation under the Toxic Substances
14 Control Act.

15 “(2) The term ‘major health or environmental ef-
16 fects test’ means an experiment to determine or evalu-
17 ate health or environmental effects which requires at
18 least six months to conduct, not including any period
19 for analysis or conclusions.

20 “(3) The term ‘earliest application for the patent’
21 means the patent application providing the earliest
22 benefit of filing date to the patent and includes patent
23 applications under sections 119 and 120.

24 “(4) ~~The term ‘statutory use’ means all uses regu-~~
25 lated under the statutes identified in subparagraphs (A)

1 through ~~(F)~~ of paragraph (5) for which regulatory
2 review occurred for the product involved.

3 “(4) The term ‘product sponsor’ means any
4 person who initiates testing or investigations, claims
5 an exemption, or submits an application, petition, pro-
6 tocol, request, or notice described in paragraph (5) of
7 this subsection.

8 “(5) The term ‘regulatory review period’ means—

9 “(A) with respect to a product which is a
10 drug, antibiotic drug, or human biological product,
11 a period commencing on the earliest of the date
12 the recipient of marketing approval first product
13 sponsor (i) ~~initiated~~ initiates a clinical investiga-
14 tion on humans for the specific method for use for
15 which such product is approved or licensed under
16 such statutes, or (ii) submits an application or pe-
17 tition with respect to such product or a method
18 for using or of producing such product under such
19 statutes the Federal Food, Drug, and Cosmetic
20 Act, Public Health Service Act, or the Act of
21 March 4, 1913, and ending on the date such ap-
22 plication or petition with respect to such product
23 or a method for using or of producing such prod-
24 uct is approved or licenses or the product is li-
25 censed under the Federal Food, Drug, and Cos-

1 ~~metic Act, the Public Health Service Act, or the~~
2 ~~Act of March 4, 1913, such statutes~~ or, if objec-
3 tions are filed to such approval or license, ending
4 on the date such objections are resolved and com-
5 mercial marketing is permitted or, if commercial
6 marketing is initially permitted and later revoked
7 pending further proceedings as a result of such
8 objections, ending on the date such proceedings
9 are finally resolved and commercial marketing is
10 permitted;

11 “(B) With respect to a *product which is a*
12 *food additive or color additive, a period commenc-*
13 *ing on the earliest of the date the recipient of*
14 *marketing approval (i) claimed an exemption for*
15 *investigation with respect to such product or a*
16 *method for using such product under the Federal*
17 *Food, Drug, and Cosmetic Act, or (ii) submitted a*
18 *petition for regulation with respect to such prod-*
19 *uct or a method for using such product is ap-*
20 *proved or licensed under such statute; the first*
21 *product sponsor (i) initiates a major health or en-*
22 *vironmental effects test on the product, but only if*
23 *the data from such test is submitted in a petition*
24 *referred to in clause (iii) of this subparagraph,*
25 *(i) claims an exemption for an investigation with*

1 *respect to such product, or (iii) submits a petition*
2 *with respect to the product under the Federal*
3 *Food, Drug, and Cosmetic Act requesting issu-*
4 *ance of a regulation for use of the product, and*
5 *ending on the date such regulation becomes effec-*
6 *tive or, if objections are filed to such regulation,*
7 *ending on the date such objections are resolved*
8 *and commercial marketing is permitted or, if com-*
9 *mmercial marketing is initially permitted and later*
10 *revoked pending further proceedings as a result of*
11 *such objections, ending on the date such proceed-*
12 *ings are finally resolved and commercial market-*
13 *ing is permitted;*

14 “(C) with respect to a product which is an
15 animal drug or veterinary biological product, a
16 period commencing ~~on~~ the earlier of the date the
17 recipient of marketing approval (i) initiated a test
18 on the animal for which the use of the product
19 has been approved wherein the test required at
20 least six months to conduct not including any
21 period for analysis or conclusions and the data
22 from which is included in the application or peti-
23 tion with respect to such product or a method for
24 using such product under the Federal Food, Drug,
25 and Cosmetic Act, the Public Health Service Act,

1 or the Act of March 4, 1913, or (ii) submitted an
2 application or petition with respect to such prod-
3 uct or method under such statutes, and ending on
4 the date such application or petition with respect
5 to such product or a method for using such prod-
6 uct is approved or licensed under such statutes;
7 *on the earliest of the date the first product sponsor*
8 *(i) claims an exemption for investigation of the*
9 *product or requests authority to prepare an experi-*
10 *mental product under the Federal Food, Drug,*
11 *and Cosmetic Act, the Public Health Service Act,*
12 *or the Act of March 4, 1913, or (ii) submits an*
13 *application or petition with respect to the product*
14 *under such statutes, and ending on the date such*
15 *application or petition with respect to the product*
16 *is approved or the product is licensed under such*
17 *statutes or, if objections are filed to such approval*
18 *or license, ending on the date such objections are*
19 *resolved and commercial marketing is permitted*
20 *or, if commercial marketing is initially permitted*
21 *and later revoked pending further proceedings as*
22 *a result of such objections, ending on the date*
23 *such proceedings are finally resolved and commer-*
24 *cial marketing is permitted;*

1 “(D) with respect to a *product which is a*
2 device, a period commencing on the earlier of the
3 date the ~~recipient of marketing approval~~ *first*
4 ~~product sponsor~~ (i) submitted a proposed product
5 development protocol with respect to ~~such product~~
6 ~~or method for using such product~~ *the product*
7 under the Federal Food, Drug, and Cosmetic Act,
8 ~~or (ii)~~ (ii) *initiates a clinical investigation on*
9 *humans, or (iii)* submitted an application with re-
10 spect to ~~such the product or method for using~~
11 ~~such product~~ under such statute, and ending on
12 the date such application with respect to ~~such~~
13 ~~product or a method for using such product~~ *the*
14 *product* is approved under such statute;

15 “(E) with respect to a *product which is a*
16 pesticide, a period commencing on the earliest of
17 the date the ~~recipient of marketing approval~~ *first*
18 ~~product sponsor~~ (i) initiates a major health or en-
19 vironmental effects test on such pesticide, ~~the~~
20 ~~data from which~~ *but only if the data from such*
21 *test* is submitted in a request for registration of
22 such pesticide under section 3 of the Federal In-
23 secticide, Fungicide, and Rodenticide Act, (ii) re-
24 quests the grant of an experimental use permit *for*
25 *the pesticide* under section 5 of such Act, or (iii)

1 submits an application for registration of such pes-
2 ticide pursuant to section 3 of such Act, and
3 ending on the date such pesticide is first regis-
4 tered, either conditionally or fully; and

5 “(F) with respect to a *product which is a*
6 *chemical substance or mixture for which notifica-*
7 *tion is required under section 5(a) of the Toxic*
8 *Substances Control Act—*

9 “(i) which is subject to a rule requiring
10 testing under section 4(a) of such Act, a
11 period commencing on the date the ~~recipient~~
12 ~~of marketing approval~~ *first product sponsor*
13 has initiated the testing required in such rule
14 and ending on the expiration of the premanu-
15 facture notification period for such chemical
16 substance or mixture, of if an order or in-
17 junction is issued under section 5(e) or 5(f) of
18 such Act, the date on which such order or
19 injunction is dissolved or set aside;

20 “(ii) which is not subject to a testing
21 rule under section 4 of such Act, a period
22 commencing on the earlier of the date the
23 ~~recipient of marketing approval~~ *first product*
24 *sponsor—*

1 “(I) submits a premanufacture
2 notice, or

3 “(II) initiates a major health or en-
4 vironmental effects test on such *chemi-*
5 *cal* substance or mixture, ~~the data from~~
6 ~~which~~ *but only if the data from such*
7 *test* is included in the premanufacture
8 notice for such substance or mixture,
9 and ending on the expiration of the premanufac-
10 ture notification period for such substance or mix-
11 ture or if an order or injunction is issued under
12 section 5(e) or 5(f) of such Act, the date on which
13 such order or such injunction is dissolved or set
14 aside;

15 except that the regulatory review period shall not be
16 deemed to have commenced until a patent has been
17 granted for the product ~~or the method of use of such~~
18 ~~product subject to the regulatory review period which~~
19 *is subject to regulatory review, for the method for using*
20 *such product, or for the method for producing such*
21 *product.*

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

1 product shall be measured from the date of enactment of this
2 section. In the event that prior to the date of enactment of
3 this section a new drug product was approved on a date more
4 than seven years after the commencement of the regulatory
5 review period and during such regulatory review period the
6 patentee was notified that such product's application was not
7 approvable under section 505(b)(1) of the Federal Food,
8 Drug, and Cosmetic Act and as a result of which the paten-
9 tee caused a major health or environmental effects test to be
10 conducted to evaluate carcinogenic potential, then the period
11 of patent extension for such product or the method of use of
12 such product shall be seven years, if the filing required by
13 subsection (b)(1) of this Act is made within ninety days of the
14 date of enactment of this section.

15 “(2) Notwithstanding subsection (a)(1)(D), in the case of
16 products approved and for which a stay of regulation grant-
17 ing approval pursuant to section 409 of the Federal Food,
18 Drug, and Cosmetic Act was in effect as of January 1, 1981,
19 the period of such patent extensions shall be measured from
20 the date such stay was imposed until such proceedings are
21 finally resolved and commercial marketing permitted, if the
22 filing required by subsection (b)(1) is made within ninety days
23 of the termination of the regulatory review period or of the
24 date of enactment of this section, whichever is later.”.

- 1 (b) The analysis for chapter 14 of title 35, United States
2 Code, is amended by adding at the end the following:
“155. Restoration of patent term.”.

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97TH CONGRESS
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H. R. 6444

[Report No. 97-6961]

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.

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