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bill 1937
I

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.

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".

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

1 **“§ 155. Restoration of patent term**

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

8 “(A) the recipient of marketing approval gives
9 notice to the Commissioner in compliance with the pro-
10 visions of subsection (b)(1);

11 “(B) the product or method has been subjected to
12 a regulatory review period pursuant to statute or regu-
13 lation prior to its commercial marketing or use;

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

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

20 The rights derived from any claim or claims of any patent so
21 extended shall be limited in scope during the period of any
22 extension to the product or method subject to the regulatory
23 review period and to the statutory use for which regulatory
24 review was required.

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

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

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

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

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

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

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

23 “(b)(1) Within ninety days after termination of a regula-
24 tory review period, the recipient of marketing approval shall
25 notify the Commissioner under oath that the regulatory

1 review period has ended. If the recipient of marketing ap-
2 proval is not the owner of record of the patent, the notifica-
3 tion shall include the written consent of the owner of record
4 of the patent to the extension. Such notification shall be in
5 writing and shall—

6 “(A) identify the Federal statute or regulation
7 under which regulatory 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 “(E) identify the claim or claims of the patent to
15 which the extension is applicable; the date of filing of
16 the earliest application for the patent; and the length of
17 time of the regulatory review period for which the
18 term of such patent is to be extended; and state that
19 no other patent has been extended for the regulatory
20 review period for the product or method.

21 “(2) Upon receipt of the notice required by paragraph
22 (1), the Commissioner shall promptly (A) publish the informa-
23 tion noticed in the Official Gazette of the Patent and Trade-
24 mark Office, and (B) issue to the owner of record of the
25 patent a certificate of extension, under seal, stating the fact

1 and length of the extension and identifying the product and
2 the statutory use and the claim or claims to which such ex-
3 tension is applicable. Such certificate shall be recorded in the
4 official file of each patent extended and such certificate shall
5 be considered as part of the original patent.

6 “(c) As used in this section:

7 “(1) The term ‘product’ means any machine, man-
8 ufacture, composition of matter or any specific method
9 of use thereof for which United States Letters Patent
10 can be granted and includes the following or any spe-
11 cific method of use or of producing thereof:

12 “(A) Any new drug, antibiotic drug, new
13 animal drug, device, food additive, or color addi-
14 tive subject to regulation under the Federal Food,
15 Drug, and Cosmetic Act.

16 “(B) Any human or veterinary biological
17 product subject to regulation under section 351 of
18 the Public Health Service Act or under the virus,
19 serum, toxin, and analogous products provisions of
20 the Act of March 4, 1913 (21 U.S.C. 155-158).

21 “(C) any pesticide subject to regulation under
22 the Federal Insecticide, Fungicide, and Rodenti-
23 cide Act.

1 “(D) any chemical substance or mixture sub-
2 ject to regulation under the Toxic Substances
3 Control Act.

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

9 “(3) The term ‘earliest application for the patent’
10 means the patent application providing the earliest
11 benefit of filing date to the patent and includes patent
12 applications under sections 119 and 120.

13 “(4) The term ‘statutory use’ means all uses regu-
14 lated under the statutes identified in subparagraphs (A)
15 through (F) of paragraph (5) for which regulatory
16 review occurred for the product involved.

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

18 “(A) with respect to a drug, antibiotic drug,
19 or human biological product, a period commencing
20 on the earliest of the date the recipient of market-
21 ing approval (i) initiated a clinical investigation on
22 humans for the specific method for use for which
23 such product is approved or licensed under such
24 statutes, or (ii) submits an application or petition
25 with respect to such product or a method for

1 using or of producing such product under such
2 statutes, and ending on the date such application
3 or petition with respect to such product or a
4 method for using or of producing such product is
5 approved or licenses under the Federal Food,
6 Drug, and Cosmetic Act, the Public Health Serv-
7 ice Act, or the Act of March 4, 1913, or, if objec-
8 tions are filed to such approval or license, ending
9 on the date such objections are resolved and com-
10 mercial marketing is permitted or, if commercial
11 marketing is initially permitted and later revoked
12 pending further proceedings as a result of such
13 objections, ending on the date such proceedings
14 are finally resolved and commercial marketing is
15 permitted;

16 “(B) With respect to a food additive or color
17 additive, a period commencing on the earliest of
18 the date the recipient of marketing approval (i)
19 claimed an exemption for investigation with re-
20 spect to such product or a method for using such
21 product under the Federal Food, Drug, and Cos-
22 metic Act, or (ii) submitted a petition for regula-
23 tion with respect to such product or a method for
24 using such product is approved or licensed under
25 such statute;

1 “(C) with respect to an animal drug or vet-
2 erinary biological product, a period commencing
3 on the earlier of the date the recipient of market-
4 ing approval (i) initiated a test on the animal for
5 which the use of the product has been approved
6 wherein the test required at least six months to
7 conduct not including any period for analysis or
8 conclusions and the data from which is included in
9 the application or petition with respect to such
10 product or a method for using such product under
11 the Federal Food, Drug, and Cosmetic Act, the
12 Public Health Service Act, or the Act of March 4,
13 1913, or (ii) submitted an application or petition
14 with respect to such product or method under
15 such statutes, and ending on the date such appli-
16 cation or petition with respect to such product or
17 a method for using such product is approved or li-
18 censed under such statutes;

19 “(D) with respect to a device, a period com-
20 mencing on the earlier of the date the recipient of
21 marketing approval (i) submitted a proposed prod-
22 uct development protocol with respect to such
23 product or method for using such product under
24 the Federal Food, Drug, and Cosmetic Act, or (ii)
25 submitted an application with respect to such

1 product or method for using such product under
2 such statute, and ending on the date such applica-
3 tion with respect to such product or a method for
4 using such product is approved under such stat-
5 ute;

6 “(E) with respect to a pesticide, a period
7 commencing on the earliest of the date the recipi-
8 ent of marketing approval (i) initiates a major
9 health or environmental effects test on such pesti-
10 cide, the data from which is submitted in a re-
11 quest for registration of such pesticide under sec-
12 tion 3 of the Federal Insecticide, Fungicide, and
13 Rodenticide Act, (ii) requests the grant of an ex-
14 perimental use permit under section 5 of such
15 Act, or (iii) submits an application for registration
16 of such pesticide pursuant to section 3 of such
17 Act, and ending on the date such pesticide is first
18 registered, either conditionally or fully; and

19 “(F) with respect to a chemical substance or
20 mixture for which notification is required under
21 section 5(a) of the Toxic Substances Control
22 Act—

23 “(i) which is subject to a rule requiring
24 testing under section 4(a) of such Act, a
25 period commencing on the date the recipient

1 of marketing approval has initiated the test-
2 ing required in such rule and ending on the
3 expiration of the premanufacture notification
4 period for such chemical substance or mix-
5 ture, or if an order or injunction is issued
6 under section 5(e) or 5(f) of such Act, the
7 date on which such order or injunction is dis-
8 solved or set aside;

9 “(ii) which is not subject to a testing
10 rule under section 4 of such Act, a period
11 commencing on the earlier of the date the
12 recipient of marketing approval—

13 “(I) submits a premanufacture
14 notice, or

15 “(II) initiates a major health or en-
16 vironmental effects test on such sub-
17 stance or mixture, the data from which
18 is included in the premanufacture notice
19 for such substance or mixture,

20 and ending on the expiration of the premanu-
21 facture notification period for such substance
22 or mixture or if an order or injunction is
23 issued under section 5(e) or 5(f) of such Act,
24 the date on which such order or such injunc-
25 tion is dissolved or set aside;

1 except that the regulatory review period shall not be
2 deemed to have commenced until a patent has been
3 granted for the product or the method of use of such
4 product subject to the regulatory review period.

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

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

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

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

“155. Restoration of patent term.”.

