

98TH CONGRESS  
1ST SESSION

# S. 1306

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.

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## IN THE SENATE OF THE UNITED STATES

MAY 17 (legislative day, MAY 16), 1983

Mr. MATHIAS (for himself, Mr. BAKER, Mr. THURMOND, Mr. BIDEN, Mr. PERCY, Mr. DOLE, Mr. LAXALT, Mr. HATCH Mr. DECONCINI, Mr. BAUCUS, Mr. HEFLIN, Mr. DENTON, and Mr. GRASSLEY) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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## 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 1983".

5       SEC. 2. (a) Section 155 of title 35 of the United States  
6 Code is amended by—

7               (1) striking out "Notwithstanding" and inserting  
8       in lieu thereof "(d) Notwithstanding"; and

1 (2) striking out

2 **“§ 155. Patent term extension”**

3 and inserting in lieu thereof the following:

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

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

11 **“(A) the owner of record of the patent gives**  
12 **notice to the Commissioner in compliance with the pro-**  
13 **visions of subsection (b)(1);**

14 **“(B) the product has been subjected to regulatory**  
15 **review pursuant to statute before its commercial mar-**  
16 **keting or use; and**

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

20 **“(2) The rights derived from any claim of any patent**  
21 **extended under paragraph (1) shall be limited—**

22 **“(A) in the case of any patent, to the scope of**  
23 **such claim which relates to the product subject to reg-**  
24 **ulatory review; and**

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

3           “(i) which is subject to regulatory review  
4 under the Federal Food, Drug, and Cosmetic Act,  
5 to the uses of the product which may be regulated  
6 by the chapter of such Act under which the regu-  
7 latory review occurred; or

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

12       “(3) In no event shall the term of any patent be ex-  
13 tended for more than seven years nor shall more than one  
14 patent be extended for the same regulatory review period for  
15 the product.

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

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

22           “(B) such patent on such product has previously  
23 been extended under this section.

24       “(b)(1) To obtain an extension of the term of a patent  
25 under subsection (a), the owner of record of the patent shall

1 notify the Commissioner, within ninety days after the termi-  
2 nation of the regulatory review period for the product to  
3 which the patent relates, that the regulatory review period  
4 has ended. Such notification shall be in writing, under oath,  
5 and shall—

6           “(A) identify the Federal statute under which reg-  
7 ulatory review occurred or, if the regulatory review oc-  
8 curred under the Federal Food, Drug, and Cosmetic  
9 Act, the chapter of the Act under which the review oc-  
10 curred;

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

13           “(C) identify the product for which regulatory  
14 review was required;

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

20           “(E) identify the patent and any claim thereof to  
21 which the extension is applicable and the length of time  
22 of the regulatory review period for which the term of  
23 such patent is to be extended; and

24           “(F) state that no other patent has been extended  
25 for the regulatory review period for the product.

1       “(2) Upon receipt of the notice required by paragraph  
2 (1), the Commissioner shall promptly publish in the Official  
3 Gazette of the Patent and Trademark Office the information  
4 contained in such notice. Unless the requirements of this sec-  
5 tion have not been met, the Commissioner shall issue to the  
6 owner of record of the patent a certificate of extension, under  
7 seal—

8               “(A) stating the fact and length of the extension;

9               “(B) identifying the product and the statute under  
10 which regulatory review occurred; and

11              “(C) specifying any claim to which such extension  
12 is applicable.

13 Such certificate shall be recorded in the official file of the  
14 patent so extended and shall be considered as part of the  
15 original patent.

16       “(c) As used in this section—

17              “(1) the term ‘product’ means any machine, man-  
18 ufacture, or composition of matter for which a patent  
19 may be obtained, and includes the following:

20                      “(A) any new drug, antibiotic drug, new  
21 animal drug, device, food additive, or color addi-  
22 tive subject to regulation under the Federal Food,  
23 Drug, and Cosmetic Act;

24                      “(B) any human or veterinary biological  
25 product subject to regulation under section 351 of

1 the Public Health Service Act or under the virus,  
2 serum, toxin, and analogous products provisions of  
3 the Act of March 4, 1913 (21 U.S.C. 151-158);

4 “(C) any pesticide subject to regulation under  
5 the Federal Insecticide, Fungicide, and Rodenti-  
6 cide Act; and

7 “(D) any chemical substance or mixture sub-  
8 ject to regulation under the Toxic Substances  
9 Control Act.

10 “(2) the term ‘major health or environmental ef-  
11 fects test’ means an experiment to determine or evalu-  
12 ate health or environmental effects which requires at  
13 least six months to conduct, not including any period  
14 for analysis or conclusions.

15 “(3) the term ‘regulatory review period’ means—

16 “(A) with respect to a product which is a  
17 food additive, color additive, new animal drug,  
18 veterinary biological product, device, new drug,  
19 antibiotic drug, or human biological product, a  
20 period commencing on the earliest of the date the  
21 patentee, his assignee, or his licensee—

22 “(i) initiates a major health or environ-  
23 mental effects test on such product, the data  
24 from which are submitted in an application  
25 or petition with respect to such product

1 under the Federal Food, Drug, and Cosmetic  
2 Act, the Public Health Service Act, or the  
3 Act of Congress of March 4, 1913;

4 “(ii) claims an exemption for investiga-  
5 tion or requests authority to prepare an ex-  
6 perimental product with respect to such  
7 product under such statutes; or

8 (iii) submits an application or petition  
9 with respect to such product under such stat-  
10 utes,

11 and ending on the date such application or peti-  
12 tion with respect to such product is approved or  
13 licensed under such statutes or, if objections are  
14 filed to such approval or license, ending on the  
15 date such objections are resolved and commercial  
16 marketing is permitted or, if commercial market-  
17 ing is initially permitted and later revoked pend-  
18 ing further proceedings as a result of such objec-  
19 tions, ending on the date such proceedings are fi-  
20 nally resolved and commercial marketing is per-  
21 mitted;

22 “(B) with respect to a product which is a  
23 pesticide, a period commencing on the earliest of  
24 the date the patentee, his assignee, or his  
25 licensee—

1                   “(i) initiates a major health or environ-  
2                   mental effects test on such pesticide, the  
3                   data from which are submitted in a request  
4                   for registration of such pesticide under sec-  
5                   tion 3 of the Federal Insecticide, Fungicide,  
6                   and Rodenticide Act,

7                   “(ii) requests the grant of an experimen-  
8                   tal use permit for such pesticide under sec-  
9                   tion 5 of such Act, or

10                   “(iii) submits an application for registra-  
11                   tion of such pesticide pursuant to section 3 of  
12                   such Act,

13                   and ending on the date such pesticide is first reg-  
14                   istered under section 3 of such Act, either condi-  
15                   tionally or fully; and

16                   “(C) with respect to a product which is a  
17                   chemical substance or mixture for which notifica-  
18                   tion is required under section 5(a) of the Toxic  
19                   Substances Control Act—

20                   “(i) which is subject to a rule requiring  
21                   testing under section 4(a) of such Act, a  
22                   period commencing on the date the patentee,  
23                   his assignee, or his licensee has initiated the  
24                   testing required in such rule and ending on  
25                   the expiration of the premanufacture notifica-



1           tion period for such chemical substance or  
2           mixture, or if an order or injunction is issued  
3           under subsection (e) or (f) of section 5 of  
4           such Act, the date on which such order or  
5           injunction is dissolved or set aside;

6           “(ii) which is not subject to a testing  
7           rule under section 4 of such Act, a period  
8           commencing on the earlier of the date the  
9           patentee, his assignee, or his licensee—

10           “(I) submits a premanufacture  
11           notice, or

12           “(II) initiates a major health or en-  
13           vironmental effects test on such chemi-  
14           cal substance or mixture, the data from  
15           which are included in the premanufac-  
16           ture notice for such substance or mix-  
17           ture,

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

24           except that the regulatory review period shall not be  
25           deemed to have commenced until a patent has been

1 granted for the product which is subject to regulatory  
2 review, for the method for using such product, or for  
3 the method for producing such product. In the event  
4 the regulatory review period has commenced prior to  
5 the date of enactment of this section, then the period of  
6 patent extension shall be measured from such date of  
7 enactment.”.

8 (b) The analysis for chapter 14 of title 35, United States  
9 Code, is amended by amending the item relating to section  
10 155 to read as follows:

“155. Restoration of patent term.”.

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