

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.

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## 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. WALGREEN, Mr. KOSTMAYER, Mr. FORD of Tennessee, Mr. STENHOLM, Mr. BONEB of Tennessee, Mr. HUTTO, Mrs. LLOYD, Mr. FLOBIO, Mr. MCCURDY, Mr. ENGLISH, Mr. WATKINS, Mrs. HALL of Indiana, Mr. TOWNS, Mr. DEBBICK, 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.

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

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

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

15               “(A) the owner of record of the patent gives  
16 notice to the Commissioner in compliance with the pro-  
17 visions of subsection (b)(1);

18               “(B) the product has been subjected to regulatory  
19 review pursuant to statute before its commercial mar-  
20 keting or use; and

1           “(C) the patent to be extended has not expired  
2 prior to notice to the Commissioner under subsection  
3 (b)(1).

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

6           “(A) in the case of any patent, to the scope of  
7 such claim which relates to the product subject to reg-  
8 ulatory review, and

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

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

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

20           “(3) In no event shall the term of any patent be ex-  
21 tended for more than seven years or shall more than one  
22 patent be extended for the same regulatory review period for  
23 the product.

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

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

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

9       “(b)(1) To obtain an extension of the term of a patent  
10 under subsection (a), the owner of record of the patent shall  
11 notify the Commissioner under oath, within ninety days after  
12 the termination of the regulatory review period for the prod-  
13 uct to which the patent relates, that the regulatory review  
14 period has ended. Such notification shall be in writing and  
15 shall—

16               “(A) identify the Federal statute under which reg-  
17 ulatory review occurred or, if the regulator review oc-  
18 curred under the Federal Food, Drug, and Cosmetic  
19 Act, the chapter of the Act under which the review oc-  
20 curred;

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

23               “(C) identify the product for which regulatory  
24 review was required;

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

6           “(E) identify the patent and any claim thereof to  
7           which the extension is applicable and the length of  
8           time of the regulatory review period for which the  
9           term of such patent is to be extended and state that no  
10          other patent has been extended for the regulatory  
11          review period for the product.

12          “(2) Upon receipt of the notice required by paragraph  
13 (1), the Commissioner shall promptly publish in the Official  
14 Gazette of the Patent and Trademark Office the information  
15 contained in such notice. Unless the requirements of this sec-  
16 tion have not been met, the Commissioner shall issue to the  
17 owner of record of the patent a certificate of extension, under  
18 seal, stating the fact and length of the extension and identify-  
19 ing the product and the statute under which regulatory  
20 review occurred and specifying any claim to which such ex-  
21 tension is applicable. Such certificate shall be recorded in the  
22 official file of the patent so extended and shall be considered  
23 as part of the original patent.

24          “(c) As used in this section:

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

4                   “(A) Any new drug, antibiotic drug, new  
5                   animal drug, device, food additive, or color addi-  
6                   tive subject to regulation under the Federal Food,  
7                   Drug, and Cosmetic Act;

8                   “(B) Any human or veterinary biological  
9                   product subject to regulation under section 351 of  
10                  the Public Health Service Act or under the virus,  
11                  serum, toxin, and analogous products provisions of  
12                  the Act of Congress of March 4, 1913 (21 U.S.C.  
13                  151–158);

14                  “(C) Any pesticide subject to regulation  
15                  under the Federal Insecticide, Fungicide, and Ro-  
16                  denticide Act; and

17                  “(D) any chemical substance or mixture sub-  
18                  ject to regulation under the Toxic Substances  
19                  Control Act.

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

25           “(3) The term ‘regulatory review period’ means—

1           “(A) with respect to a product which is a  
2 food additive, color additive, new animal drug,  
3 veterinary biological product, device, new drug,  
4 antibiotic drug, or human biological product, a  
5 period commencing on the earliest of the date the  
6 patentee, his assignee, or his licensee—

7           “(i) initiates a major health or environ-  
8 mental effects test on such product, the data  
9 from which are submitted in an application  
10 or petition with respect to such product  
11 under the Federal Food, Drug, and Cosmetic  
12 Act, the Public Health Service Act, or the  
13 Act of Congress of March 4, 1913,

14           “(ii) claims an exemption for investiga-  
15 tion or requests authority to prepare an ex-  
16 perimental product with respect to such  
17 product under such statutes, or

18           “(iii) submits an application or petition  
19 with respect to such product under such stat-  
20 utes,

21 and ending on the date such application or peti-  
22 tion with respect to such product is approved or  
23 licensed under such statutes or, if objections are  
24 filed to such approval or license, ending on the  
25 date such objections are resolved and commercial

1 marketing is permitted or, if commercial market-  
2 ing is initially permitted and later revoked pend-  
3 ing further proceedings as a result of such objec-  
4 tions, ending on the date such proceedings are fi-  
5 nally resolved and commercial marketing is per-  
6 mitted;

7 “(B) with respect to a product which is a  
8 pesticide, a period commencing on the earliest of  
9 the date the patentee, his assignee, or his  
10 licensee—

11 “(i) initiates a major health or environ-  
12 mental effects test on such pesticide, the  
13 data from which are submitted in a request  
14 for registration of such pesticide under sec-  
15 tion 3 of the Federal Insecticide, Fungicide,  
16 and Rodenticide Act,

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

20 “(iii) submits an application for registra-  
21 tion of such pesticide pursuant to section 3 of  
22 such Act,

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



1           “(C) with respect to a product which is a  
2 chemical substance or mixture for which notifica-  
3 tion is required under section 5(a) of the Toxic  
4 Substances Control Act—

5           “(i) which is subject to a rule requiring  
6 testing under section 4(a) of such Act, a  
7 period commencing on the date the patentee,  
8 his assignee, or his licensee has initiated the  
9 testing required in such rule and ending on  
10 the expiration of the premanufacture notifica-  
11 tion period for such chemical substance or  
12 mixture, or if an order or injunction is issued  
13 under section 5(e) or 5(f) of such Act, the  
14 date on which such order or injunction is dis-  
15 solved or set aside;

16           “(ii) which is not subject to testing rule  
17 under section 4 of such Act, a period com-  
18 mencing on the earlier of the date the  
19 patentee, his assignee, or his licensee—

20           “(I) submits a premanufacture  
21 notice, or

22           “(II) initiates a major health or en-  
23 vironmental effects test on such chemi-  
24 cal substance or mixture, the data from  
25 which are included in the premanufac-

1                   ture notice for such substance or mix-  
2                   ture,  
3                   and ending on the expiration of the premanu-  
4                   facture notification period for such substance  
5                   or if an order or injunction is issued under  
6                   section 5(e) or 5(f) of such Act, the date on  
7                   which such order or such injunction is dis-  
8                   solved or set aside;

9   except that the regulatory review period shall not be deemed  
10 to have commenced until a patent has been granted for the  
11 product which is subject to regulatory review, for the method  
12 for using such product, or for the method for producing such  
13 product. In the event the regulatory review period has com-  
14 menced prior to the date of enactment of this section, then  
15 the period of patent extension shall be measured from Janu-  
16 ary 3, 1983, or the date the regulatory review period com-  
17 mences, whichever occurs later.

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

“155. Restoration of patent term.”.

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