

97TH CONGRESS
1ST SESSION

S. 255

IN THE HOUSE OF REPRESENTATIVES

JULY 13, 1981

Referred to the Committee on the Judiciary

AN ACT

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 1981".

5 SEC. 2. Title 35 of the United States Code, entitled
6 "Patents" is amended by adding the following new section
7 immediately after section 154:

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

2 “(a)(1) Except as provided in paragraph (2), the term of
3 a patent which encompasses within its scope a product, or a
4 method for using a product, subject to a regulatory review
5 period shall be extended by the amount of time equal to the
6 regulatory review period for such product or method if—

7 “(A) the owner of record of the patent gives
8 notice to the Commission in compliance with the provi-
9 sions of subsection (b)(1);

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

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

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

21 “(2) In no event shall the term of any patent be ex-
22 tended for more than seven years.

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

1 . review period has ended. Such notification shall be in writing
2 and shall:

3 “(A) identify the Federal statute or regulation
4 under which regulatory review occurred;

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

7 “(C) identify the product and the statutory use for
8 which regulatory review was required;

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

11 “(E) identify the claim or claims of the patent to
12 which the extension is applicable and the length of
13 time of the regulatory review period for which the
14 term of such patent is to be extended.

15 “(2) Upon receipt of the notice required by paragraph
16 (1), the Commissioner shall promptly (A) publish the informa-
17 tion noticed in the Official Gazette of the Patent and Trade-
18 mark Office, and (B) issue to the owner of record of the
19 patent a certificate of extension, under seal, stating the fact
20 and length of the extension and identifying the product and
21 the statutory use and the claim or claims to which such ex-
22 tension is applicable. Such certificate shall be recorded in the
23 official file of each patent extended and such certificate shall
24 be considered as part of the original patent.

25 “(c) As used in this section:

1 “(1) The term ‘product or a method for using a
2 product’ means any machine, manufacture, composition
3 of matter or any specific method of use thereof for
4 which United States Letters Patent can be granted and
5 includes the following or any specific method of use
6 thereof:

7 “(A) any new drug, antibiotic drug, new
8 animal drug, device, food additive, or color addi-
9 tive subject to regulation under the Federal Food,
10 Drug, and Cosmetic Act;

11 “(B) any human or veterinary biological
12 product subject to regulation under section 351 of
13 the Public Health Service Act or under the virus,
14 serum, toxin, and analogous products provisions of
15 the Act of Congress of March 4, 1913;

16 “(C) any pesticide subject to regulation
17 under the Federal Insecticide, Fungicide, and Ro-
18 denticide Act; and

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

22 “(2) The term ‘major health or environmental ef-
23 fects test’ means an experiment to determine or evalu-
24 ate health or environmental effects which requires at

1 least six months to conduct, not including any period
2 for analysis or conclusions.

3 “(3) The term ‘statutory use’ means all uses regu-
4 lated under the statutes identified in sections (c)(4)
5 (A)–(D) for which regulatory review occurred for the
6 product involved.

7 “(4) The term ‘regulatory review period’ means—

8 “(A) with respect to a food additive, color
9 additive, new animal drug, veterinary biological
10 product, device, new drug, antibiotic drug, or
11 human biological product, a period commencing
12 on the earliest of the date the patentee, his as-
13 signee, or his licensee (i) initiated a major health
14 or environmental effects test on such product or a
15 method for using such product, (ii) claims an ex-
16 emption for investigation or requests authority to
17 prepare an experimental product with respect to
18 such product or a method for using such product
19 under the Federal Food, Drug, and Cosmetic Act,
20 the Public Health Service Act, or the Act of Con-
21 gress of March 4, 1913, or (iii) submits an appli-
22 cation or petition with respect to such product or
23 a method for using such product under such stat-
24 utes, and ending on the date such application or
25 petition with respect to such product or a method

1 for using such product is approved or licensed
2 under such statutes or, if objections are filed to
3 such approval or license, ending on the date such
4 objections are resolved and commercial marketing
5 is permitted or, if commercial marketing is
6 initially permitted and later revoked pending fur-
7 ther proceedings as a result of such objections,
8 ending on the date such proceedings are finally
9 resolved and commercial marketing is permitted;

10 “(B) with respect to a pesticide, a period
11 commencing on the earliest of the date the
12 patentee, his assignee, or his licensee (i) initiates
13 a major health or environmental effects test on
14 such pesticide, the data from which is submitted
15 in a request for registration of such pesticide
16 under section 3 of the Federal Insecticide, Fungi-
17 cide, and Rodenticide Act, (ii) requests the grant
18 of an experimental use permit under section 5 of
19 such Act, or (iii) submits an application for regis-
20 tration of such pesticide pursuant to section 3 of
21 such Act, and ending on the date such pesticide is
22 first registered, either conditionally or fully;

23 “(C) with respect to a chemical substance or
24 mixture for which notification is required under

1 section 5(a) of the Toxic Substances Control
2 Act—

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

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

18 “(I) submits a premanufacture
19 notice, or

20 “(II) initiates a major health or en-
21 vironmental effects test on such sub-
22 stance, the data from which is included
23 in the premanufacture notice for such
24 substance,

1 and ending on the expiration of the premanufac-
2 ture notification period for such substance or if an
3 order or injunction is issued under section 5(e) or
4 5(f) of such Act, the date on which such order or
5 such injunction is dissolved or set aside;

6 “(D) with respect to any other product or
7 method of using a product that has been subjected
8 to Federal premarketing regulatory review, a
9 period commencing on the date when the pat-
10 entee, his assignee, or his licensee initiates actions
11 pursuant to a Federal statute or regulation to
12 obtain such review prior to the initial commercial
13 marketing in interstate commerce of such product
14 and ending on the date when such review is
15 completed,

16 except that the regulatory review period shall not be deemed
17 to have commenced until a patent has been granted for the
18 product or the method of use of such product subject to the
19 regulatory review period. In the event the regulatory review
20 period has commenced prior to the effective date of this sec-
21 tion, then the period of patent extension for such product or a
22 method of using such product shall be measured from the
23 effective date of this section, except that for products ap-
24 proved and for which a stay of regulation granting approval
25 pursuant to section 409 of the Federal Food, Drug, and Cos-

1 metric Act was in effect as of January 1, 1981, the period of
2 such patent extensions shall be measured from the date such
3 stay was imposed until such proceedings are finally resolved
4 and commercial marketing permitted provided the filing re-
5 quired by subsection (b)(1) is made within ninety days of the
6 termination of the regulatory review period or the effective
7 date of this section whichever is later.”.

Passed the Senate July 9 (legislative day, July 8), 1981.

Attest: **WILLIAM F. HILDENBRAND,**
Secretary.