

96TH CONGRESS  
2D SESSION

# H.R. 7952

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

AUGUST 19, 1980

Mr. KASTENMEIER (for himself and Mr. SAWYER) introduced the following bill;  
which was 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 1980".

5        SEC. 2. (a) The Congress finds that—

6            (1) the United States patent system has provided  
7 a major incentive for the investment necessary for in-  
8 novation and new product development;

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1           (2) protection of health and the environment is a  
2           necessary concern of the Federal Government and  
3           many patented products may not be marketed commer-  
4           cially until the product has been approved in accord-  
5           ance with various Federal health and environmental  
6           laws;

7           (3) the time necessary for the testing of such  
8           products and the regulatory review or notification  
9           period substantially reduce the period of commercial  
10          exclusivity which the Congress intended a patented  
11          product to enjoy;

12          (4) such a reduction in the commercial exclusivity  
13          period discourages research and innovation and pre-  
14          vents important new products from being made availa-  
15          ble to the public;

16          (5) restoration of the rights afforded by the grant  
17          of patents to their full period of exclusivity is a neces-  
18          sary prerequisite to restoring the United States to an  
19          innovative leadership position.

20          (b) It is the policy of the United States that the term of  
21          patents for products subject to premarketing regulatory  
22          review or notification should be extended to compensate for  
23          delays in commercialization of such products resulting from  
24          government regulation.

1        SEC. 3. Title 35 of the United States Code, entitled  
2        “Patents” is amended by adding the following new section  
3        immediately after section 154:

4        “§ 155. Restoration of patent term

5        “(a)(1) Except as provided in paragraph (2), the term of  
6        a patent which encompasses within its scope a chemical  
7        product, a process for use of a chemical product, or a device  
8        subject to a regulatory review period shall be extended by the  
9        amount of time equal to the regulatory review period for such  
10       chemical product or device 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 regulatory review period resulted in the  
15        removal of restrictions on the commercial marketing of  
16        such product or device; and

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

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

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

1           “(b)(1) Within ninety days after termination of a regula-  
2 tory review period, the owner of record of the patent shall  
3 notify the Commissioner that the regulatory review period  
4 has ended. Such notification shall be in writing and shall:

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

7           “(B) identify the device or specify the chemical  
8 identity of the chemical product and the statutory use  
9 for which regulatory review was required.

10           “(C) state that the requirement of subsection  
11 (a)(1)(B) has been satisfied; and

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

16           “(2) Upon receipt of the notice required by paragraph  
17 (1), the Commissioner shall promptly publish the information  
18 noticed in the Official Gazette of the Patent and Trademark  
19 Office.

20           “(3) The Commissioner shall issue a certificate of exten-  
21 sion, under seal, stating the fact and length of the extension  
22 and identifying the product or device and the use and the  
23 claim to which such extension is applicable. Such certificate  
24 shall be recorded in the official file of each patent extended,

1 and such certificate shall be considered as part of the original  
2 patent.

3       “(4) Any patent extension granted under this section  
4 shall be revoked by the Commissioner if the person subject to  
5 the regulatory review period is convicted by a court of a  
6 criminal violation for submitting false, fictitious, fraudulent,  
7 or misleading data in support of the application, petition, re-  
8 quest, or notification described in subsection (c)(4) on which  
9 such patent extension is based.

10       “(c) As used in this section:

11               “(1) The term ‘chemical product’ means—

12                       “(A) any new drug, new animal drug, food  
13                       additive, and color additive as defined in section  
14                       201 of the Federal Food, Drug, and Cosmetic  
15                       Act;

16                       “(B) any human or veterinary biological  
17                       product as defined in section 351(a) of the Public  
18                       Health Service Act or in regulations issued under  
19                       the virus, serum, toxin and analogous prouducts  
20                       provisions of the Act of Congress of March 4,  
21                       1913;

22                       “(C) any pesticide as defined in section 2 of  
23                       the Federal Insecticide, Fungicide, and Rodenti-  
24                       cide Act; and

1           “(D) any chemical substance or mixture as  
2           defined in section 3 of the Toxic Substances Con-  
3           trol Act.

4           “(2) The term ‘device’ means any device as de-  
5           fined in section 201(h) of the Federal Food, Drug, and  
6           Cosmetic Act and described in section 513(a)(1)(C) of  
7           such Act.

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

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

14                 “(A) with respect to a new drug or a human  
15                 biological product, a period commencing on the  
16                 date the patentee, his assignee, or his licensee has  
17                 requested an exemption for investigation with re-  
18                 spect to such drug or biological product under  
19                 section 505(i) or section 507(d) of the Federal  
20                 Food, Drug, and Cosmetic Act and ending on the  
21                 date an application with respect to such drug sub-  
22                 mitted under section 505(b) or section 507(f) of  
23                 such Act is approved or such biological product is  
24                 licensed under section 351(d) of the Public Health  
25                 Service Act;

1           “(B) with respect to a new animal drug, a  
2           period commencing on the date the patentee, his  
3           assignee, or his licensee has requested an exemp-  
4           tion for investigation with respect to such animal  
5           drug under section 512(j) of the Federal Food,  
6           Drug, and Cosmetic Act and ending on the date  
7           an application with respect to such animal drug  
8           submitted under section 512(b) of such Act is  
9           approved;

10           “(C) with respect to a veterinary biological  
11           product, a period commencing on the date the  
12           patentee, his assignee, or his licensee has request-  
13           ed authority to prepare an experimental product  
14           under the virus, serum, toxin, and analogous  
15           products provisions of the Act of Congress of  
16           March 4, 1913, and ending on the date such bio-  
17           logical product is licensed under such Act;

18           “(D) with respect to a food additive, a period  
19           commencing on the date the patentee, his assign-  
20           ee, or his licensee initiates a major health or envi-  
21           ronmental effects test relied upon to establish the  
22           safety of such food additive in a petition submitted  
23           under section 409 of the Federal Food, Drug, and  
24           Cosmetic Act requesting issuance of a regulation  
25           prescribing the conditions under which such addi-

1           tive may be safely used and ending on the date  
2           such regulation becomes effective;

3           “(E) with respect to a color additive, a  
4           period commencing on the date the patentee, his  
5           assignee, or his licensee initiates a major health  
6           or environmental effects test relied upon to show  
7           that such color additive will be safe for its intend-  
8           ed uses in a petition requesting the issuance of a  
9           regulation listing such use and ending on the date  
10          such a regulation becomes effective;

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

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



1 section 5(a) and which is subject to a rule requir-  
2 ing testing under section 4(a) of the Toxic Sub-  
3 stances Control Act, a period commencing on the  
4 date the patentee, his assignee, or his licensee has  
5 initiated the testing required in such rule and  
6 ending on the expiration of the premanufacture  
7 notification period for such chemical substance or  
8 mixture, or if an order or injunction is issued  
9 under section 5(e) or 5(f) of such Act, the date on  
10 which such order or injunction is dissolved or set  
11 aside;

12 “(H) with respect to a chemical substance or  
13 mixture for which notification is required under  
14 section 5(a) but which is not subject to a testing  
15 rule under section 4 of the Toxic Substances Con-  
16 trol Act, a period commencing on the earlier of  
17 the date the patentee, his assignee or his  
18 licensee—

19 (i) submits a premanufacture notice, or

20 (ii) initiates a major health or environ-  
21 mental effects test on such substance, the  
22 data from which is included in the premanu-  
23 facture notice for such substance,

24 and ending on the expiration of the premanufac-  
25 ture notification period for such substance or if an

1 order or injunction is issued under section 5(e) or  
2 5(f) of such Act, the date on which such order or  
3 such injunction is dissolved or set aside; and

4 “(I) with respect to a device, a period com-  
5 mencing on the date the patentee, his assignee or  
6 his licensee has requested an exemption for inves-  
7 tigation with respect to such device under section  
8 520(g) of the Federal Food, Drug, and Cosmetic  
9 Act and ending on the date an application with  
10 respect to such device submitted under section  
11 515(c) of such Act is approved,

12 except that the regulatory review period shall not be  
13 deemed to have commenced until a patent has been  
14 granted for the chemical product or device or the use  
15 of such product or device subject to the regulatory  
16 review period. In the event the regulatory review  
17 period has commenced prior to the effective date of  
18 this section, then the commencement of the regulatory  
19 review period shall be considered to be such effective  
20 date.”.