96TH CONGRESS
2D SESSION

# S. 2892

To amend the patent law to restore the term of the patent grant for the period of time that non-patent regulatory requirements prevent the marketing of a patented product.

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IN THE SENATE OF THE UNITED STATES

JUNE 27 (legislative day, JUNE 12), 1980

Mr. BAYH (for himself, Mr. THURMOND, Mr. MATHIAS, Mr. MORGAN, and Mr. PERCY) 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 non-patent regulatory requirements prevent the marketing of a patented product.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,* That this Act may be cited as the "Patent Term Restoration Act of 1980."

SEC. 2. (a) The Congress finds that—

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(1) the United States patent system has provided a major incentive for the investment necessary for innovation and new product development;

(2) protection of health and the environment is a necessary concern of the Federal Government and many patented products may not be marketed commercially until the product has been approved in accordance with various Federal health and environmental laws;

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

(4) such a reduction in the commercial exclusivity period discourages research and innovation and prevents important new products from being made available to the public;

(5) restoration of the rights afforded by the grant of patents to their full period of exclusivity is a necessary prerequisite to restoring the United States to an innovative leadership position.

(b) It is the policy of the United States that the term of patents for products subject to premarketing regulatory review or notification should be extended to compensate for

delays in commercialization of such products resulting from government regulation.

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

**"§ 155. Restoration of patent term**

"(a)(1) Except as provided in paragraph (2), the term of a patent which encompasses within its scope a chemical product, a process for use of a chemical product, or a device subject to a regulatory review period shall be extended by the amount of time equal to the regulatory review period for such chemical product or device if—

"(A) the owner of record of the patent gives notice to the Commissioner in compliance with the provisions of subsection (b)(1);

"(B) the regulatory review period resulted in the removal of restrictions on the commercial marketing of such product or device; and

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

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

"(2) In no event shall the term of any patent be extended for more than seven years.

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

"(A) state the date on which the regulatory review period commenced and ended;

"(B) identify the device or specify the chemical identity of the chemical product and the statutory use for which regulatory review was required;

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

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

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

"(3) The Commissioner shall issue a certificate of extension, under seal, stating the fact and length of the extension and identifying the product or device and the use and the claim to which such extension is applicable. Such certificate

shall be recorded in the official file of each patent extended, and such certificate shall be considered as part of the original patent.

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

"(c) As used in this section:

"(1) The term 'chemical product' means—

"(A) any new drug, new animal drug, food additive, or color additive as defined in section 201 of the Federal Food, Drug, and Cosmetic Act;

"(B) any human or veterinary biological product as defined in section 351(a) of the Public Health Service Act or in regulations issued under the virus, serum, toxin and analogous products provisions of the Act of Congress of March 4, 1913;

"(C) any pesticide as defined in section 2 of the Federal Insecticide, Fungicide, and Rodenticide Act; and

"(D) any chemical substance or mixture as defined in section 3 of the Toxic Substances Control Act.

"(2) The term 'device' means any device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act and described in section 513(a)(1)(C) of such Act.

"(3) The term 'major health or environmental effects test' means an experiment to determine or evaluate health or environmental effects which requires at least six months to conduct, not including any period for analysis or conclusions.

"(4) The term 'regulatory review period' means—

"(A) with respect to a new drug or a human biological product, a period commencing on the date the patentee, his assignee, or his licensee has requested an exemption for investigation with respect to such drug or biological product under section 505(i) or section 507(d) of the Federal Food, Drug, and Cosmetic Act and ending on the date an application with respect to such drug submitted under section 505(b) or section 507(f) of such Act is approved or such biological product is licensed under section 351(d) of the Public Health Service Act;

"(B) with respect to a new animal drug, a period commencing on the date the patentee, his assignee, or his licensee has requested an exemption for investigation with respect to such animal drug under section 512(j) of the Federal Food, Drug, and Cosmetic Act and ending on the date an application with respect to such animal drug submitted under section 512(b) of such Act is approved;

"(C) with respect to a veterinary biological product, a period commencing on the date the patentee, his assignee, or his licensee has requested authority to prepare an experimental product under the virus, serum, toxin, and analogous products provisions of the Act of Congress of March 4, 1913, and ending on the date such biological product is licensed under such Act;

"(D) with respect to a food additive, a period commencing on the date the patentee, his assignee, or his licensee initiates a major health or environmental effects test relied upon to establish the safety of such food additive in a petition submitted under section 409 of the Federal Food, Drug, and Cosmetic Act requesting issuance of a regulation prescribing the conditions under which

such additive may be safely used and ending on the date such regulation becomes effective;

"(E) with respect to a color additive, a period commencing on the date the patentee, his assignee, or his licensee initiates a major health or environmental effects test relied upon to show that such color additive will be safe for its intended uses in a petition requesting the issuance of a regulation listing such use and ending on the date such a regulation becomes effective;

"(F) with respect to a pesticide, a period commencing on the earlier of the date the patentee, his assigneee, or his licensee (i) initiates a major health or environmental effects test on such pesticide, the data from which is submitted in a request for registration of such pesticide under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act, (ii) requests the grant of an experimental use permit under section 5 of such Act, or (iii) submits an application for registration of such pesticide pursuant to section 3 of such Act, and ending on the date such pesticide is first registered, either conditionally or fully;

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

section 5(a) and which is subject to a rule requiring testing under section 4(a) of the Toxic Substances Control Act, a period commencing on the date the patentee, his assignee, or his licensee has initiated the testing required in such rule and ending on the expiration of the premanufacture notification period for such chemical substance or mixture, or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or injunction is dissolved or set aside;

"(H) with respect to a chemical substance or mixture for which notification is required under Section 5(a) but which is not subject to a testing rule under Section 4 of the Toxic Substances Control Act, a period commencing on the earlier of the date the patentee, his assignee. or his licensee—

(i) submits a premanufacture notice, or

(ii) initiates a major health or environmental effects test on such substance, the data from which is included in the premanufacture notice for such substance,

and ending on the expiration of the premanufacture notification period for such substance or if an

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

"(I) with respect to a device, a period commencing on the date the patentee, his assignee or his licensee has requested an exemption for investigation with respect to such device under section 520(g) of the Federal Food, Drug, and Cosmetic Act and ending on the date an application with respect to such device submitted under section 515(c) of such Act is approved,

except that the regulatory review period shall not be deemed to have commenced until a patent has been granted for the chemical product or device or the use of such product or device subject to the regulatory review period. In the event the regulatory review period has commenced prior to the effective date of this section, then the commencement of the regulatory review period shall be considered to be such effective date.".

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