* Would this be retroactive?
Apparently no. - limited to 90 days after completion of Regulatory delay.

Howard: We may introduce this, Any comments? Joe

PATENT RESTORATION LEGISLATION

Background

Many patented pharmaceutical and chemical products cannot be marketed commercially until they have been approved in accordance with various health and environmental laws administered by FDA and EPA. Most of these laws have been enacted within the last fifteen to twenty years. Although the laws were responses to legitimate concerns for public health and the environment, they were enacted without regard to the effect increased premarketing regulatory requirements would have on the commercial life of the patented product.

The increased premarketing review requirements imposed by these laws coupled with more sophisticated and time-consuming health and safety testing techniques have substantially reduced the period of commercial exclusivity of the patented product. For example, in 1962, it took about 2 years and $4 million to bring a new pharmaceutical product from discovery to marketing; now it takes 8 years and $50 million. To assure commercial protection and to enable publication and discussion of new discoveries so important to scientitic research, manufacturers must seek a patent well before the necessary premarketing approval is obtained. As a result, some companies are left with less than a decade of patent protection to market their products.

Similarly, the commercial life of a patented pesticide is substantially less than 17 years. According to an EPA study, a patent normally is granted well before the manufacturer has established, through long-term testing, that the chemical is safe and effective enough to be registered for commercial marketing. The study estimates that there may be only 12 or so years of patent protection remaining when the pesticide is approved for marketing. Chemicals not regulated under the drug and pesticide laws are now subject to premarket scrutiny under the Toxic Substances Control Act, passed in 1976. Under the Act, EPA has authority to issue regulations to require extensive premarket testing of potentially toxic new chemicals. Such regulations could substantially reduce the commercial exclusivity period for patented chemicals subject to the testing requirements.

The reduction in the commercial exclusivity period discourages research and innovation. A decade and a half ago new pharmaceutical entities were introduced at a rate of 42 a year on average; today, the rate has decreased by 62 percent, down to

just 16 per year. Overall research and development expenditures in the U.S. have been steadily declining. In 1964, the U.S. spent 3 percent of its GNP on research and development; in 1978 reserch and development was only 2.3 percent of the GNP. During the same time, the research and development per GNP ratio of some of our major competitors has increased, West Germany's from 1.6% to 2.3% and Japan's from 1.5% to 1.9%.

Summary of Proposed Legislation

The proposed legislation would restore the patent term to its original 17-year period for products subject to premarketing review requirements. Such a restoration of the patent term is one major prerequisite to renewing incentives for research and development in the U.S.

Under the bill, the term of a patented product would be extended by a period equal to the time required for regulatory premarket testing and review, up to a maximum of seven years. The patent restoration period would apply only to the specific product or use involved in the regulatory approval, not the entire range of products which might be covered by the patent. If a patent is not granted for a product until after the regulatory review has begun, the extension period runs from the time of the patent grant until the regulatory review is completed. If the product is not approved for marketing, no patent extension occurs.

Products covered by the bill are new human and animal drugs, human and veterinary biological products, food and color additives, pesticides, and other chemicals subject to similar regulatory review.

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 --

(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 required for premarketing approval 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 a patent to its 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 a patent for a product subject to premarketing regulatory review should be extended to compensate for delays in commercialization of such product 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:

"Sec. 155 Restoration of Patent Term

"(a) (1) Except as provided in paragraph (2), the term of a patent covering a chemical product or process for use of a chemical product subject to a regulatory approval period shall be extended by the amount of time equal to the regulatory approval period for such chemical product or process for use of a chemical product if --

"(A) the person to whom the patent was granted or assigned gives notice to the Commissioner in compliance with the provisions of subsection (b)(1); and

"(B) the regulatory approval period resulted in the removal of restrictions on the commercial mar-

keting of such product or such product for the specified use; and

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

"The rights derived from any claim so extended shall be limited in scope during the period of any extension to encompass only the chemical product or the use of such product subject to the regulatory approval period.

"(2) In no event shall the extension provided in paragraph (1) exceed seven years.

"(b)(1) Within 90 days after termination of a regulatory approval period, the patentee or his assignee shall notify the Commissioner that the regulatory approval period has ended. Such notification shall be in writing and shall:

"(A) state the date on which the regulatory approval period started and ended;

"(B) identify the chemical product or use of the chemical product for which such period was in effect;

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

"(D) identify the claims of the patent to which the extension is applicable and the amount of time 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 stating the fact and length of the extension, under seal, to be recorded in the records of patents. A printed copy thereof shall be attached to each printed copy of the patent, and such certificate shall be considered as part of the original patent.

"(c) As used in this section:

"(1) the term 'chemical product' means--

"(A) any new drug, new animal drug, food additive, and 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 and economic poison as defined in section 2 of the Federal Insecticide, Fungicide, and Rodenticide Act;

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

"(2) the term 'regulatory approval 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 finally approved or such biological product is finally 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 as-

signee, 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 finally 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 finally licensed under such Act;

"(D) with respect to a food additive, a period commencing on the date the patentee, his assignee, or his licensee has initiated the development of data 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 con-

ditions 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 has initiated the development of data 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 or economic poison, a period commencing on the earlier of the date the patentee, his assignee, or his licensee either (i) requests the grant of an experimental use permit under the provisions of section 5 of the Federal Insecticide; Fungicide, and Rodenticide Act for such pesticide or economic poison, or (ii) requests the registration of such pesticide or economic poison under section 3 of such Act, and ending on the date such pesticide or economic poison is finally registered;

"(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; and

"(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 date premanufacture notice was submitted by the patentee, his assignee, or his licensee and ending on the expiration of the premanufacture notification period for such 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,

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