PATENT TERM RESTORATION ACT OF 1981

HEARINGS

BEFORE THE

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES, AND THE ADMINISTRATION OF JUSTICE

OF THE

COMMITTEE ON THE JUDICIARY

HOUSE OF REPRESENTATIVES

NINETY-SEVENTH CONGRESS

FIRST SESSION

ON

H.R. 1937, H.R. 6444, and S. 255

PATENT TERM RESTORATION ACT OF 1981

JULY 22, SEPTEMBER 30, OCTOBER 1, 7, NOVEMBER 5, 12, AND 18, 1981

Serial No. 55

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PATENT TERM RESTORATION ACT OF 1981

WEDNESDAY, JULY 22, 1981

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES
AND THE ADMINISTRATION OF JUSTICE
OF THE COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to call, at 9:30 a.m., in room 2226, Rayburn House Office Building, Hon. Robert W. Kastenmeier (chairman of the subcommittee) presiding.

Present: Representatives Kastenmeier, Butler, Sawyer, and Railsback.

Staff present: Bruce A. Lehman, counsel, Timothy A. Boggs, professional staff member; Thomas E. Mooney, associate counsel; and Audrey Marcus, clerk.

Mr. KASTENMEIER. Last year the subcommittee processed into law legislation addressing three critical problem areas in the patent system: reexamination, Government patent policy, and patent fees.

During markup on that legislation other issues arose, including the question of loss of effective patent life due to premarket regulatory delay.

However, my distinguished colleague from Michigan, Mr. Sawyer, graciously withdrew a proposed amendment on the issue with the understanding that the question of patent term restoration would be considered separately in the 97th Congress.

In recognition of our promise to consider the patent term restoration issue, the gentleman from Michigan and I introduced earlier this year, H.R. 1937.

A similar bill, S. 255, recently passed the Senate and has been referred to this subcommittee.

In introducing the bill, I stated that my purpose was to elicit study, comment, and criticism on the merits of patent life restoration. And that process is now well underway.

In an effort to develop an impartial information base with which to evaluate H.R. 1937, the chairman of our full committee, Peter Rodino, at my request asked the Congressional Office of Technology Assessment to prepare a memorandum on the issue, using the pharmaceutical industry as a model.

The OTA, I should add, was in an excellent position to provide such a study since it is in the process of a major, 2-year assessment of the patent system at the request of both Chairman Rodino and former Senate Judiciary Committee Chairman Kennedy.

We expect the final results of this larger study later this year. The separate assessment on the patent term restoration issue is now complete and will be formally released to the public later this month.

[Copies of H.R. 1937, H.R. 6444, and S. 255 follow:]

I

97TH CONGRESS
1ST SESSION

H. R. 1937

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.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 18, 1981

Mr. KASTENMEIER (for himself and Mr. SAWYER) 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.

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 1981".

SECTION 1. 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 product, or a method for using a product, subject to a regulatory review period shall be extended by the amount of time equal to the regulatory review period for such product or method 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 product or method has been subjected to a regulatory review period pursuant to statute or regulation prior to its commercial marketing or use; and

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

The rights derived from any claim or claims of any patent so extended shall be limited in scope during the period of any extension to the product or method 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 under oath that the regulatory

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

"(A) identify the Federal statute or regulation under which regulatory review occurred;

"(B) state the dates on which the regulatory review period commenced and ended;

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

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

"(E) identify the claim or claims 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 (A) publish the information noticed in the Official Gazette of the Patent and Trademark Office, and (B) issue to the owner of record of the patent a certificate of extension, under seal, stating the fact and length of the extension and identifying the product and the statutory use and the claim or claims 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.

"(c) As used in this section:

"(1) The term 'product or a method for using a product' means any machine, manufacture, composition of matter or any specific method of use thereof for which United States Letters Patent can be granted and includes the following or any specific method of use thereof:

"(A) any new drug, antibiotic drug, new animal drug, device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act;

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

"(C) any pesticide subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act; and

"(D) any chemical substance or mixture subject to regulation under the Toxic Substances Control Act.

"(2) 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.

"(3) The term 'statutory use' means all uses regulated under the statutes identified in sections (c)(4)(A)–(D) for which regulatory review occurred for the product involved.

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

"(A) with respect to a food additive, color additive, new animal drug, veterinary biological product, device, new drug, antibiotic drug, or human biological product, a period commencing on the earliest of the date the patentee, his assignee, or his licensee (i) initiated a major health or environmental effects test on such product or a method for using such product, (ii) claims an exemption for investigation or requests authority to prepare an experimental product with respect to such product or a method for using such product under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of Congress of March 4, 1913, or (iii) submits an application or petition with respect to such product or a method for using such product under such statutes, and ending on the date such application or petition with respect to such product or a method

for using such product is approved or licensed under such statutes or, if objections are filed to such approval or license, ending on the date such objections are resolved and commercial marketing is permitted or, if commercial marketing is initially permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings are finally resolved and commercial marketing is permitted;

"(B) with respect to a pesticide, a period commencing on the earliest of the date the patentee, his assignee, 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;

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

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

"(i) which is subject to a rule requiring testing under section 4(a) of such 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;

"(ii) which is not subject to a testing rule under section 4 of such 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;

"(D) with respect to any other product or method of using a product that has been subjected to Federal premarketing regulatory review, a period commencing on the date when the patentee, his assignee, or his licensee initiates actions pursuant to a Federal statute or regulation to obtain such review prior to the initial commercial marketing in interstate commerce of such product and ending on the date when such review is completed,

except that the regulatory review period shall not be deemed to have commenced until a patent has been granted for the product or the method of use of such product 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 period of patent extension for such product or a method of using such product shall be measured from the effective date of this section.".

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97TH CONGRESS
2D SESSION

H. R. 6444

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.

IN THE HOUSE OF REPRESENTATIVES

MAY 20, 1982

Mr. KASTENMEIER (for himself, Mr. BROOKS, Mr. RAILSBACK, Mr. SAWYER, and Mr. BUTLER) 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.

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 1982".

SEC. 2. (a) Title 35 of the United States Code is amended by adding the following new section immediately after section 154:

"§ 155. Restoration of patent term

"(a)(1) Except as provided in paragraphs (2) and (3), the term of a patent which encompasses within its scope a product subject to a regulatory review period, or a method for using such a product or a method for producing such a product, subject to a regulatory review period shall be extended if—

"(A) the recipient of marketing approval gives notice to the Commissioner in compliance with the provisions of subsection (b)(1);

"(B) the product or method has been subjected to a regulatory review period pursuant to statute or regulation prior to its commercial marketing or use;

"(C) the patent to be extended has not expired prior to notice to the Commissioner under subsection (b)(1); and

"(D) the patent to be extended was issued on or subsequent to the date of enactment of the Patent Term Restoration Act of 1982.

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

"(2)(A) Subject to subparagraph (B), the term of the patent shall be extended by the time equal to the regulatory

review period for such product or method for the period up to ten years after the date of filing of the earliest application for the patent and the time equal to one-half the regulatory review period for the period between ten and twenty years from the filing date of the earliest patent application.

"(B) In no event shall the term of any patent be extended for more than seven years. No extension of a patent may exceed twenty-seven years from the date of filing of the earliest patent application for the patent. If the term that the patent would be extended is less than one year, no extension shall be granted.

"(C) In no event shall more than one patent be extended for the same regulatory review period for the product or method.

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

"(A) the owner of record of such patent is also the owner of record of another patent which encompasses within its scope the same product; and

"(B) such patent on such product has been extended under this section.

"(b)(1) Within ninety days after termination of a regulatory review period, the recipient of marketing approval shall notify the Commissioner under oath that the regulatory

review period has ended. If the recipient of marketing approval is not the owner of record of the patent, the notification shall include the written consent of the owner of record of the patent to the extension. Such notification shall be in writing and shall—

"(A) identify the Federal statute or regulation under which regulatory review occurred;

"(B) state the dates on which the regulatory review period commenced and ended;

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

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

"(E) identify the claim or claims of the patent to which the extension is applicable; the date of filing of the earliest application for the patent; and the length of time of the regulatory review period for which the term of such patent is to be extended; and state that no other patent has been extended for the regulatory review period for the product or method.

"(2) Upon receipt of the notice required by paragraph (1), the Commissioner shall promptly (A) publish the information noticed in the Official Gazette of the Patent and Trademark Office, and (B) issue to the owner of record of the patent a certificate of extension, under seal, stating the fact

and length of the extension and identifying the product and the statutory use and the claim or claims 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.

"(c) As used in this section:

"(1) The term 'product' means any machine, manufacture, composition of matter or any specific method of use thereof for which United States Letters Patent can be granted and includes the following or any specific method of use or of producing thereof:

"(A) Any new drug, antibiotic drug, new animal drug, device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

"(B) Any human or veterinary biological product subject to regulation under section 351 of the Public Health Service Act or under the virus, serum, toxin, and analogous products provisions of the Act of March 4, 1913 (21 U.S.C. 155–158).

"(C) any pesticide subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act.

"(D) any chemical substance or mixture subject to regulation under the Toxic Substances Control Act.

"(2) 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.

"(3) The term 'earliest application for the patent' means the patent application providing the earliest benefit of filing date to the patent and includes patent applications under sections 119 and 120.

"(4) The term 'statutory use' means all uses regulated under the statutes identified in subparagraphs (A) through (F) of paragraph (5) for which regulatory review occurred for the product involved.

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

"(A) with respect to a drug, antibiotic drug, or human biological product, a period commencing on the earliest of the date the recipient of marketing approval (i) initiated a clinical investigation on humans for the specific method for use for which such product is approved or licensed under such statutes, or (ii) submits an application or petition with respect to such product or a method for

using or of producing such product under such statutes, and ending on the date such application or petition with respect to such product or a method for using or of producing such product is approved or licenses under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of March 4, 1913, or, if objections are filed to such approval or license, ending on the date such objections are resolved and commerical marketing is permitted or, if commercial marketing is initially permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings are finally resolved and commercial marketing is permitted;

"(B) With respect to a food additive or color additive, a period commencing on the earliest of the date the recipient of marketing approval (i) claimed an exemption for investigation with respect to such product or a method for using such product under the Federal Food, Drug, and Cosmetic Act, or (ii) submitted a petition for regulation with respect to such product or a method for using such product is approved or licensed under such statute;

"(C) with respect to an animal drug or veterinary biological product, a period commencing on the earlier of the date the recipient of marketing approval (i) initiated a test on the animal for which the use of the product has been approved wherein the test required at least six months to conduct not including any period for analysis or conclusions and the data from which is included in the application or petition with respect to such product or a method for using such product under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of March 4, 1913, or (ii) submitted an application or petition with respect to such product or method under such statutes, and ending on the date such application or petition with respect to such product or a method for using such product is approved or licensed under such statutes;

"(D) with respect to a device, a period commencing on the earlier of the date the recipient of marketing approval (i) submitted a proposed product development protocol with respect to such product or method for using such product under the Federal Food, Drug, and Cosmetic Act, or (ii) submitted an application with respect to such

product or method for using such product under such statute, and ending on the date such application with respect to such product or a method for using such product is approved under such statute;

"(E) with respect to a pesticide, a period commencing on the earliest of the date the recipient of marketing approval (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 pesiticide 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; and

"(F) with respect to a chemical substance or mixture for which notification is required under section 5(a) of the Toxic Substances Control Act—

"(i) which is subject to a rule requiring testing under section 4(a) of such Act, a period commencing on the date the recipient

of marketing approval 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;

"(ii) which is not subject to a testing rule under section 4 of such Act, a period commencing on the earlier of the date the recipient of marketing approval—

"(I) submits a premanufacture notice, or

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

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 such injunction is dissolved or set aside;

except that the regulatory review period shall not l deemed to have commenced until a patent has bee granted for the product or the method of use of suc product subject to the regulatory review period.

"(d)(1) In the event that prior to the date of enactmer of this section a new drug product was approved on a dat more than seven years after the commencement of the regu latory review period and during such regulatory reviev period the patentee was notified that such product's applica tion was not approvable under section 505(b)(1) of the Feder al Food, Drug, and Cosmetic Act and as a result of which th patentee caused a major health or environmental effects tes to be conducted to evaluate carcinogenic potential, then the period of patent extension for such product or the method of use of such product shall be seven years, if the filing required by subsection (b)(1) of this Act is made within ninety days of the date of enactment of this section.

"(2) Notwithstanding subsection (a)(1)(D), in the case of products approved and for which a stay of regulation granting approval pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act was in effect as of January 1, 1981, the period of such patent extensions shall be measured from the date such stay was imposed until such proceedings are finally resolved and commercial marketing permitted, if the filing required by subsection (b)(1) is made within ninety days

of the termination of the regulatory review period or of the date of enactment of this section, whichever is later.".

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

"155. Restoration of patent term.".

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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.

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 1981".

SEC. 2. 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 product, or a method for using a product, subject to a regulatory review period shall be extended by the amount of time equal to the regulatory review period for such product or method if—

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

"(B) the product or method has been subjected to a regulatory review period pursuant to statute or regulation prior to its commercial marketing or use; and

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

The rights derived from any claim or claims of any patent so extended shall be limited in scope during the period of any extension to the product or method 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 under oath that the regulatory

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

"(A) identify the Federal statute or regulation under which regulatory review occurred;

"(B) state the dates on which the regulatory review period commenced and ended;

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

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

"(E) identify the claim or claims 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 (A) publish the information noticed in the Official Gazette of the Patent and Trademark Office, and (B) issue to the owner of record of the patent a certificate of extension, under seal, stating the fact and length of the extension and identifying the product and the statutory use and the claim or claims 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.

"(c) As used in this section:

"(1) The term 'product or a method for using a product' means any machine, manufacture, composition of matter or any specific method of use thereof for which United States Letters Patent can be granted and includes the following or any specific method of use thereof:

"(A) any new drug, antibiotic drug, new animal drug, device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act;

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

"(C) any pesticide subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act; and

"(D) any chemical substance or mixture subject to regulation under the Toxic Substances Control Act.

"(2) 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.

"(3) The term 'statutory use' means all uses regulated under the statutes identified in sections (c)(4)(A)–(D) for which regulatory review occurred for the product involved.

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

"(A) with respect to a food additive, color additive, new animal drug, veterinary biological product, device, new drug, antibiotic drug, or human biological product, a period commencing on the earliest of the date the patentee, his assignee, or his licensee (i) initiated a major health or environmental effects test on such product or a method for using such product, (ii) claims an exemption for investigation or requests authority to prepare an experimental product with respect to such product or a method for using such product under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of Congress of March 4, 1913, or (iii) submits an application or petition with respect to such product or a method for using such product under such statutes, and ending on the date such application or petition with respect to such product or a method

for using such product is approved or licensed under such statutes or, if objections are filed to such approval or license, ending on the date such objections are resolved and commercial marketing is permitted or, if commercial marketing is initially permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings are finally resolved and commercial marketing is permitted;

"(B) with respect to a pesticide, a period commencing on the earliest of the date the patentee, his assignee, 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;

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

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

"(i) which is subject to a rule requiring testing under section 4(a) of such 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;

"(ii) which is not subject to a testing rule under section 4 of such 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;

"(D) with respect to any other product or method of using a product that has been subjected to Federal premarketing regulatory review, a period commencing on the date when the patentee, his assignee, or his licensee initiates actions pursuant to a Federal statute or regulation to obtain such review prior to the initial commercial marketing in interstate commerce of such product and ending on the date when such review is completed,

except that the regulatory review period shall not be deemed to have commenced until a patent has been granted for the product or the method of use of such product 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 period of patent extension for such product or a method of using such product shall be measured from the effective date of this section, except that for products approved and for which a stay of regulation granting approval pursuant to section 409 of the Federal Food, Drug, and Cos-

metic Act was in effect as of January 1, 1981, the period of such patent extensions shall be measured from the date such stay was imposed until such proceedings are finally resolved and commercial marketing permitted provided the filing required by subsection (b)(1) is made within ninety days of the termination of the regulatory review period or the effective date of this section whichever is later.".

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

Attest: WILLIAM F. HILDENBRAND,

Secretary.

Mr. KASTENMEIER. This morning we are fortunate to have present Mr. John Andelin, Assistant Director of the Office of Technology Assessment who will outline for us the highlights of this assessment.

He is accompanied by Mr. Norman Balmer, project director, who is the chief draftsman of the study and Ms. Donna Valtri, assistant project director.

Before calling on our witnesses, I would like to announce that hearings on H.R. 1937 and S. 255 will continue following the August recess. We will be hearing from witnesses with a variety of views on the issue during the course of those hearings.

With this brief explanation out of the way, it is a pleasure to welcome Mr. Andelin and his colleagues.

TESTIMONY OF JOHN ANDELIN, ASSISTANT DIRECTOR, U.S. CONGRESSIONAL OFFICE OF TECHNOLOGY ASSESSMENT, ACCOMPANIED BY NORMAN BALMER, PROJECT DIRECTOR, AND DONNA VALTRI, ASSISTANT PROJECT DIRECTOR

Mr. ANDELIN. Thank you, Mr. Chairman and gentlemen. We appreciate the opportunity to study the impact of extending patent terms for products subject to Federal premarketing and/or premanufactured regulations.

I am pleased to testify today on some of the aspects of this issue which have been raised and reviewed in our study.

Let me underline the chairman's remarks that the study is in the final weeks of the review process and has not been officially approved by our Board and, therefore, the remarks that I make today are not an official position of the Office of Technology Assessment but are based entirely on the study which will be available, we believe, in a few weeks.

Let me also call attention to the material which we provided to you. There are really three pieces that are stapled together. There is my testimony which is approximately eight pages. There is a single page chart at the back of page 8 which is also on the easel for easier viewing and there is another attachment, a single spaced, eight- or nine-page document which is a more detailed summary than the verbal statement.

Mr. KASTENMEIER. Without objection, these three items will be made part of the record.

[The information follows:]

Testimony of Dr. John Andelin
Assistant Director, Office of Technology Assessment
Before the
Subcommittee on Courts, Civil Liberties
and the Administration of Justice
of the
Committee on the Judiciary
U.S. House of Representatives
July 22, 1981

I am John Andelin, Assistant Director for the Office of Technology Assessment's Science, Information and Natural Resources Division. I am accompanied today by Norman L. Balmer, Project Director and Donna L. Valtri, Assistant Project Director for this study of Patent-Term Extension and the Pharmaceutical Industry. Thank you for the opportunity to study the impacts of extending patent terms for products subject to federal premarketing and/or premanufacturing regulations. I am pleased to testify on the many important aspects of this issue which have been raised and reviewed in our study. However, since our project is currently in the final stages of our review process, my comments do not reflect an official position of the Office of Technology Assessment.

Patents were designed to promote innovation by providing the right to exclude others from making, using or selling an invention for 17 years. They enable innnovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.

There are several types of drugs or drug products which may be thought of as innovations; new chemical entities (NCEs), new

formulations, new combinations of active ingredients or new uses for existing drugs. The concept of patent term extension primarily addresses NCE innovation. Research-intensive firms most often produce NCEs.

The relationship between the development process for NCEs and the patent process is illustrated in the figure accompanying my testimony. This figure shows the steps involved in both of these processes and indicates that these steps are taken concurrently. The patent process and the drug development process are, however, independent of each other and each progresses at its own pace. Although the figure accurately depicts the stages that a patented drug will pass through, the duration of each of the stages varies. Therefore, the relationship between the timing of the drug process and the timing of the patent process will also vary.

A patent application is generally filed during the discovery or preclinical stage of development. The latter is the stage at which animal tests for toxicity are undertaken. The next stage of development involves the Food and Drug Administration's (FDA) requirements for safety and efficacy. These tests involve human volunteers and begin with a request for authorization to conduct such tests. This request is termed a notice of claimed investigational exemption for a new drug or IND. There are three phases of clinical testing which then occur, each involving a wider population of volunteers.

Concurrently, the patent is examined by the Patent Office. If the invention is determined to be patentable (e.g., it is novel and not

obvious in view of the state-of-the-art), a patent will be granted.

Back at the FDA, testing is generally still continuing. A New Drug Application or NDA may be filed before all of the safety and efficacy testing is completed but it cannot be approved before these tests are concluded. The drug can be marketed only after receiving NDA approval. By this time, some of the drug's patent term has usually expired.

When a drug enters the market, it generally has a product life characterized by several stages. In the first, sales are growing as the demand for the drug is being developed. In the second phase, sales of the drug are relatively stable. As the drug is replaced by better alternatives or as the condition it treats subsides in the population, sales of the drug decline.

The patent normally expires sometime during the marketing of a drug. At that point, competition may enter. Generic versions of the patented drug can now be manufactured. These products are offered for sale by other research-intensive firms and by production-intensive firms, or firms generally not active in NCE research.

Our study reviewed many aspects of patent term extension within the framework I have outlined above rather than within the specifics of the legislation before this committee. We studied the following areas:

(1) the inequity many see in the reduced patent terms some regulated products receive;

(2) the positions of the various parties in the controversy over patent extension;

(3) measurements of and factors affecting innovation in the

pharmaceutical industry;

(4) the implications of extended patent terms on the various pharmaceutical industry members and consumers;

(5) the relevant portions of patent law;

(6) the mechanisms of patent term extension; and

(7) those aspects of the medical device, pesticide and chemical industries which may indicate some of the implications of patent extensions on innovation in those industries.

My testimony will focus on the implications of extending patents for pharmaceuticals on innovation, industry and society. Let me begin with the subject of pharmaceutical innovation. While patent extension can encourage innovation through the incentives it provides to the patentee, the evidence that is available neither supports nor refutes the position that innovation will increase significantly because of such extensions. There are two major reasons why we cannot be more helpful on this subject. First, there is no single correct method for measuring pharmaceutical innovation, nor is there agreement about the meaning of the various measures suggested. We have found that by most measures explored in this study, innovation does not appear to be increasing. It was beyond the scope of our resources to determine the social implications of a stable or non-increasing rate of innovation.

The second reason why we cannot say more about the effects of patent term extension on innovation is that many factors affect industry decisions to undertake the research and development activities required to produce innovation, and we have not been able to isolate the weight of any individual factor. The factors appear to be interrelated and often, these relationships are quite complex. We have, however, been able to identify many of the individual factors

which have played, or will play a role in the types of pharmaceutical innovation generally conducted by the research-intensive firms. In many cases, we were also able to identify trends in these factors.

Factors Affecting Innovation

Since 1966, average effective patent terms have declined. Some of the factors influencing the length of effective patent terms have changed. This has given rise to the expectation that the decline may be halted in the future.

Profits for research-intensive firms have been stable at levels which are higher than most other manufacturing industries at least since 1956. Research techniques have improved and the competitive pressure for innovation among research-intensive firms has not diminished. Yet there is a widespread belief that the return to research and development investment is declining. Because data are insufficient to measure accurately the return to research investment, we have focused on the underlying factors influencing the returns. The major factors are the costs of R&D activities, the amount invested in R&D, and the revenues and profits of the firms conducting research.

The costs of R&D activities associated with a new chemical entity drug have been increasing rapidly as a result of inflation and more stringent and time-consuming testing requirements. Because the time spent in obtaining FDA approval may be leveling off and new research techniques are being developed, R&D costs should increase more slowly in the future.

Real growth has occurred in expenditures for research and

development. The relationship between revenues and R&D expenditures has remained highly stable over the past 15 years. For the years 1965 through 1978, research expenditures averaged about 8.5 percent of total sales.

Revenues and profits are influenced by the competitive pressures exerted on drugs. The competition may be from other patented drugs, from nondrug therapies, or from generically equivalent drugs that are produced by either research-intensive firms or production-intensive firms. Of the drugs having generic competition, about 80 to 85 percent are sold by research-intensive companies.

Despite the decrease in the average effective patent term that may have allowed generic competition to enter the market earlier, the revenues and profits of research-intensive firms have thus far not been significantly affected by generic competition. But recent governmental actions could result in increased competition from generically equivalent drugs. Most states now have laws that allow or require generic equivalents to be substituted for brand-name drugs specified in prescriptions. The FDA has adopted procedures to facilitate approval of generically equivalent drugs. The Federal government now bases its reimbursements for prescriptions paid for under Medicaid on the lowest wholesale price of generically equivalent drugs. Furthermore the Supreme Court has ruled that laws prohibiting the advertising of drug prices are unconstitutional.

Despite government action to encourage use of generically equivalent drugs, barriers to the acceptance of these products still exist. Physicians, who determine the market for prescription drugs,

tend to write prescriptions for the easily recalled brand-name drugs. Pharmacists fear they will be liable if they fill a prescription for a brand-name product with a generic equivalent that later causes injury. Furthermore, consumers tend to prefer drugs that look exactly the same as the drugs they are accustomed to using.

Thus the effect of generic competition on the revenues and profits of research-intensive firms in the future is uncertain. If generic competition increases significantly, such revenues and profits could decline and R&D expenditures could be reduced. There is a possibility that additional generic competition could encourage research-intensive firms to increase their R&D expenditures in an effort to maintain their market shares through drug innovations.

Implications of Patent Term Extension

I will now address the implications of patent-term extension for pharmaceutical industry members and for consumers. For the research-intensive firm, patent term extension may provide an immediate incentive to undertake R&D through the increased long-term potential for returns to R&D investments. Once extensions begin to run, additional resources wil provide some firms with further incentives.

The bulk of revenues generated by patent-term extension will be obtained by a few firms who have developed financially successful drugs. The increased revenues may serve to perpetuate their dominance in particular research areas, and other firms lacking expertise may possibly be discouraged from entering these areas.

Since the economic incentives provided by patent-term extension

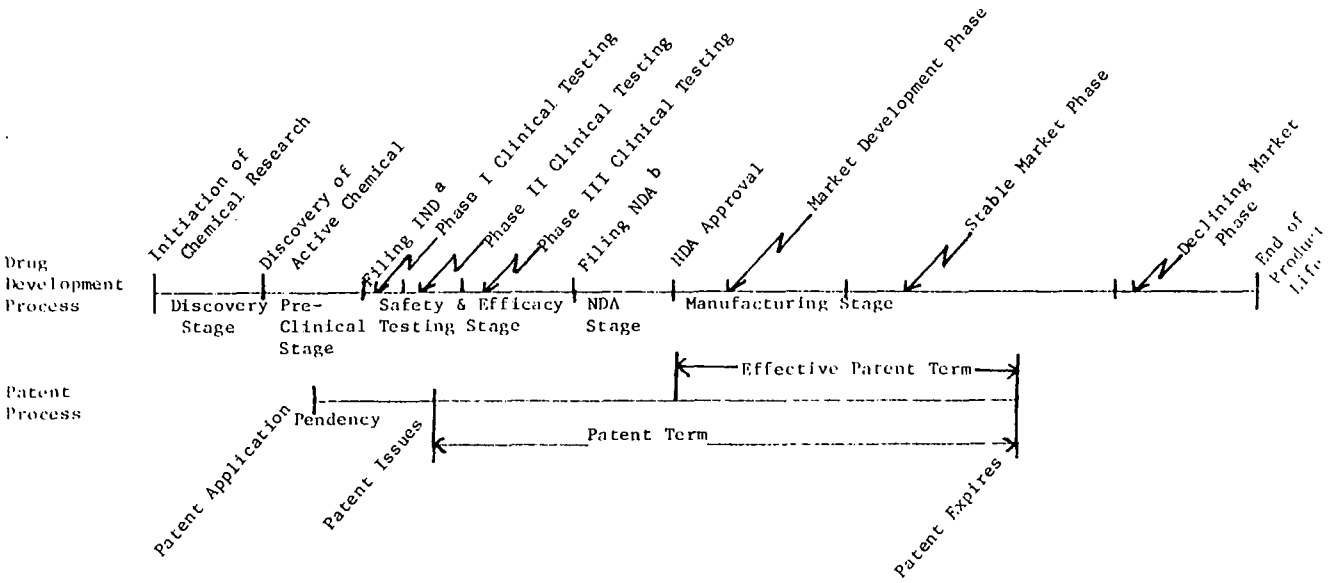
will be greatest for drugs with high income potential, the tendency of firms to direct their research toward drugs with large markets will be reinforced. Some therapeutic areas that are apt to produce economically marginal drugs may receive greater attention as a result of patent-term extension but patent-term extension will not affect research on drugs with small markets.

Patent-term extension poses risks for production-intensive firms. Although they depend on innovative new drugs to expand their product lines, the remaining product lives of drugs coming off patents will determine their long-term revenues. In some cases product lives may be insufficient to justify their entry into the market.

Consumers will benefit if more and better pharmaceuticals are developed. The pharmaceuticals can provide substantial savings over other forms of health care. The cost of drugs for consumers will increase unless patent-term extension results in the introduction of more new drugs which exert a downward price pressure on the prices of existing drugs. It is expected that both the benefits and the additional cost will affect the elderly and the chronically ill more than other segments of society; but patent-term extension will have no effect on either benefits or costs for at least a decade.

I welcome your questions on these or other areas of our study.

The Drug Development Process and the Patent Process



[a]IND: notice of claimed investigational exemption for a new drug.
[b]NDA: new drug application.

SOURCE: Office of Technology Assessment.

ATTACHMENT TO THE TESTIMONY OF DR. JOHN ANDELIN,
ASSISTANT DIRECTOR, OFFICE OF TECHNOLOGY ASSESSMENT
BEFORE THE
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES
AND THE ADMINISTRATION OF JUSTICE
OF THE
COMMITTEE ON THE JUDICIARY
U.S. HOUSE OF REPRESENTATIVES
JULY 22, 1981

PATENT-TERM EXTENSION AND THE PHARMACEUTICAL INDUSTRY

EXECUTIVE SUMMARY

INTRODUCTION

Patents were designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.

Although the patent term in the United States is 17 years, the period in which products are marketed under patent protection (the effective patent term) is usually less than 17 years because patents are obtained before products are ready to be marketed.

Effective patent terms are influenced by many factors, including Federal premarketing and premanufacturing regulations. The products covered by these regulations include pharmaceuticals, medical devices, food additives, color additives, chemicals, and pesticides. These products are subject to different regulations that have had varying impacts on effective patent terms.

The regulations governing the pharmaceutical industry have contributed to a decline in the average effective patent term of prescription drugs. Pharmaceuticals cannot be marketed in the United States until they have been approved by the Food and Drug Administration (FDA). To obtain such approval, drugs must undergo extensive testing to prove they are both safe and effective. While the pharmaceutical awaits approval, its patent term keeps running.

Concern exists that the decline in the average effective patent term of pharmaceuticals may result in diminishing profits, decreased

research and development (R&D) expenditures, and an eventual decline in the introduction of new drugs. Furthermore, to many, it appears inequitable that products aubject to premarketing or premanufacturing requirements are marketed under patent protection for briefer periods than products that are not subject to such regulation.

To address the concerns that have arisen about innovation and equity, legislation has been proposed that would extend the patent terms for products affected by premarketing and premanufacturing regulations.

Although this report briefly describes the equity issue, its focus is on the relationship between patent-term extension and innovation in the prescription drug industry. The effects of patent-term extension on the members of the industry and on consumers are also examined.

The Controversy

Pharmaceutical firms that are heavily involved in basic research (research-intensive firms) support legislation to extend patent terms. These firms claim that the costs of research and development are rising, effective patent terms are declining, and the rates of return to pharmaceutical expenditures are becoming unattractive. They maintain that, under these circumstances, a decline in innovation would not be unlikely and point out that future health care in the United States would suffer if pharmaceutical innovation declines.

Research-intensive firms believe that patent-term extension will provide encouragement for research activities, raise the profitability of drug research for successful innovations, and ultimately result in more innovative products. They contend that the additional drugs will increase pricing competition among different products used for the same or similar ailments and that the consumer will actually save money as a result of patent-term extension.

The firms that derive most of their revenues from nonpatented, generically equivalent drugs (production-intensive firms) believe that patent-term extension might produce a better climate for pharmaceutical innovation and in the long term might provide them with a new supply of drugs which they can market. They contend, however, that they would be economically penalized for each year that the extension prevents them from marketing drugs. They believe that competition will decline as a result of patent-term extension and that the costs of drugs will therefore increase.

Production-intensive firms urge that any legislation for patent-term extension minimize adverse effects on their industry. They are opposed to any legislation that would enable products covered by more than one patent to have effective patent terms that exceed 17 years, and they believe that the duration of the extension for any product should not exceed the actual marketing delay caused by premarketing regulations. They point out that as a result of nonpatent barriers to market acceptance of generically equivalent products, patented products often maintain an exclusive market

position even after their patents expire.

Spokesmen for consumer interest groups believe that patent-term extension will result in higher drug prices without providing better health care. They point out that increased drug costs will fall disproportionately on the elderly and chronically ill (whose incomes tend to be lower than average). They argue that the pharmaceutical industry is extremely profitable and needs no additional incentive to conduct research. These groups are concerned that the legislation proposed to date provides no guarantees that additional revenues derived during patent-term extensions will be invested in R&D activities. Concerns are also expressed that expenditures made for research and development may not be directed toward research areas that provide the greatest benefit to society. Therefore, many consumer spokesmen oppose patent-term extension.

Findings

This study examines the issues raised by the various interest groups. Unfortunately, much of the data needed to differentiate between belief and fact are unavailable or unreliable. The evidence that is available neither supports nor refutes the position that innovation will increase significantly because of patent-term extension. Thus, we have not been able to ascertain the net effects of patent-term extension on pharmaceutical innovation. We have, however, developed findings which should serve to clarify or explain many of the individual factors which have played, or will play, a role in pharmaceutical innovation.

The following is a list of our major findings, which will be discussed in more detail in the later sections.

* The costs of research and development for the average new chemical entity drug have increased.

* Since 1966, average effective patent terms have declined; some factors influencing effective patent terms are, however, changing and there is reason to believe that the decline may be halted in the future.

* Revenues of the pharmaceutical industry have increased steadily and the relationship between revenues and R&D expenditures has remained stable.

* The effects of governmental actions that encourage use of generically equivalent drugs have thus far been minimal on the post-patent revenues of research-intensive firms but could become substantial in the future.

* The prices of drugs whose patents are extended are likely to be higher during the extended period than they would have been if patent protection had ended.

* Competitive pressures on patented drugs from generically

equivalent drugs will be delayed and in some cases prevented by patent-term extension.

* The extension will increase the attractiveness of research for drugs which have large markets but will not increase the economic attractiveness of research on drugs whose potential markets are small.

* The effects of patent-term extension on innovation, the industry, and society will depend in part on the nature of the patent rights during the extension.

Innovation in the Pharmaceutical Industry

Pharmaceutical innovation has resulted primarily from the activities of private industry, most of the expenditures being made by large, multinational companies.

In the pharmaceutical industry a long period exists between the initiation of research and the marketing of new products. Thus the rate of innovation observed today may reflect decisions made 10 or 15 years ago, and decisions made today will affect innovation for the next decade.

The results of the innovative process in the pharmaceutical industry are often measured by the number of new chemical entity (NCE) drugs that are introduced into the market. By this measure, a sharp decline in innovation occurred with the adoption of the 1962 Amendments to the Food, Drug, and Cosmetic Act, which substantially increased the stringency of the drug approval process. The number of NCEs judged by FDA to offer important or modest therapeutic gain has, however, been relatively stable. Although different measures produce different results, by most measures innovation does not appear to be increasing.

Trends in the Factors Affecting Pharmaceutical Innovation

Innovation will not occur unless industry undertakes R&D activities. Many factors that influence R&D decisions appear to favor innovation: the industry continues to enjoy high and stable profits in terms of return to stockholder's equity; research techniques have improved; and competitive pressure for innovation has not diminished.

Nonetheless, there is a widespread belief that the return to R&D investment is declining, and this belief can affect R&D decision making. Because data are insufficient to measure accurately the return to research investment, we have focused on the underlying factors influencing the returns. The major factors are the costs of R&D activities, the amount invested in research and development, and the revenues and profits of the firms conducting research.

The costs of R&D activities associated with a new chemical entity drug have been increasing rapidly as a result of inflation and more stringent and time-consuming testing requirements. Because the time

spent in obtaining FDA approval may be leveling off and new research techniques are being developed, R&D costs should increase more slowly in the future.

Real growth has occurred in expenditures for research and development. The relationship between revenues and R&D expenditures has remained highly stable over the past 15 years. For the years 1965 through 1978, research expenditures averaged about 8.5 percent of total sales.

The revenues and profits are influenced by the competitive pressures exerted on drugs. The competition may be from other patented drugs, from nondrug therapies, or from generically equivalent drugs that are produced by either research-intensive firms or production-intensive firms. Of the drugs having generic competition, about 80 to 85 percent are sold by research-intensive companies.

Despite the decrease in the average effective patent term that may have allowed generic competition to enter the market earlier, the revenues and profits of research-intensive firms have thus far not been significantly affected by generic competition. But recent governmental actions could result in increased competition from generically equivalent drugs. Most states now have laws that allow or require generic equivalents to be substituted for brand-name drugs specified in prescriptions. FDA has adopted procedures to facilitate approval of generically equivalent drugs. The Federal government now bases its reimbursements for prescriptions paid for under Medicaid on the lowest wholesale price of generically equivalent drugs. Furthermore the Supreme Court has ruled that laws prohibiting the advertising of drug prices are unconstitutional.

Despite government action to encourage use of generically equivalent drugs, barriers to the acceptance of these products still exist. Physicians, who determine the market for prescription drugs, tend to write prescriptions for the easily recalled brand-name drugs. Pharmacists fear they will be liable if they fill a prescription for a brand-name product with a generic equivalent that later causes injury. Furthermore, consumers tend to prefer drugs that look exactly the same as the drugs they are accustomed to using.

Thus the effect of generic competition on the revenues and profits of research-intensive firms in the future is uncertain. If generic competition increases significantly, such revenues and profits could decline and R&D expenditures could be reduced. There is a possibility that additional generic competition could encourage research-intensive firms to increase their R&D expenditures in an effort to maintain their market shares through drug innovations.

Implications of Patent-Term Extension for Pharmaceuticals

Patent-term extension can encourage the development of new drugs through the incentives it provides to the patent owner (patentee). But by delaying use of the patented technology by the public, it may also delay some improvements in patented drugs.

Patent-term extension specifically addresses the prime concern of the research-intensive firms: the perceived decline in the rate of return to R&D investments attributed to the reduction in effective patent terms. Whether R&D activities actually increase as a result of longer effective patent terms will, however, depend on decisions made in the private sector.

Since patent-term extension will not provide additional revenues until original patents expire and extensions begin to run, the immediate incentive provided by extension legislation is the potential for obtaining greater returns on R&D investment in the future. Once extensions do begin, revenues for some firms will be greater than they otherwise would have been, thus providing additional incentive for R&D activities.

The price of drugs whose patents are extended will be higher during the extended period than they would have been if patent protection ended. The magnitude of the additional cost to the consumer will be significantly influenced by the extent to which generic competition would have existed had the patent term not been extended.

The bulk of revenues generated by patent-term extension will accrue to a few firms who have developed financially successful drugs. The increased revenues may serve to perpetuate their dominance in particular research areas, and other firms, lacking expertise, may be discouraged from entering these areas.

Since the economic incentives provided by patent-term extension will be greatest for drugs with high income potential, the tendency of firms to direct their research toward drugs with large market potential will be reinforced. Some therapeutic areas that are apt to produce economically marginal drugs may receive greater attention as a result of patent-term extension but patent-term extension will not affect research on drugs with small market potential.

The patent owner and the research-intensive firm will generally benefit from patent-term extension. To the extent that a research-intensive firm relies on revenues from the sale of generically equivalent drugs, its benefits may be reduced.

Patent-term extension poses risks for production-intensive firms. Although they depend on innovative new drugs to expand their product lines, the remaining product lives of drugs coming off patents will detemine their long-term revenues. In some cases product lives may be insufficient to justify their entry into the market.

Consumers will benefit if more and better pharmaceuticals are developed. These pharmaceuticals can provide substantial savings over other forms of health care. The cost of drugs for consumers will be higher than it would otherwise have been unless patent-term extension results in the introduction of more new drugs that exert a downward price pressure on the prices of existing drugs. It is expected that both the benefits and the additional costs will affect the elderly and the chronically ill more than other segments of society; but

patent-term extension will have no effect on either benefits or costs for at least a decade.

The Mechanics of Patent-Term Extension

The effects of patent-term extension can only be fully assessed in terms of specific proposals, because the effects will vary depending on the particular form the extension takes. This report has examined several proposed forms of patent-term extension to determine their possible implications for innovation.

Patent-term extension involves a modification of the present patent system. Therefore, in order to understand extension proposals, one must have a basic understanding of how the patent system works. In brief, a patent is granted for an invention which may be, for instance, a new drug, a new process for making a drug, or a new method for using a drug to treat an illness. A patent provides the right to the patentee to exclude others from making, using, or selling the invention in the United States for 17 years. In return, the patentee discloses his invention. Once the patent expires, anyone is permitted to use the invention.

The invention that is patented is defined by claims which establish the boundaries of the invention, much like a deed establishes the boundaries of a piece of land. A claim for a particular invention may thus include many potential products or processes. When a patentee attempts to enforce a patent, the claim is compared with the product or process against which the enforcement action is directed to determine whether it is included within the definition of the invention contained in the claims.

The effects of patent-term extension on the rights of the patentee and on the ability of others to use the invention will depend in part on whether patent protection is extended for the entire invention defined by the claims or for only a portion of the claimed invention. Effects will also differ depending on whether limitations are placed on the products, processes, and methods for use against which the patent can be enforced.

Numerous proposals which affect patent claims and their enforceability during the extension are examined in this report. Of these proposals, three enable the patentee to maintain an exclusive market position for the drug, while allowing others to use the invention for some purposes during the extension.

1) In the first of these proposals, the extension is provided for only those aspects of the claimed invention that involve the specific chemical contained in the drug approved by FDA and is enforceable only against products, processes, or methods-for-use that must be approved by FDA. Of the three proposals, this one provides the greatest protection to the patentee.

It permits others to use the patented invention for anything except drugs and allows others to make, use, or sell variations

of the patentee's specific chemical for any drug therapy even though the variations may be included within the entire invention defined in the claims. It prohibits use of the patented invention for a drug therapy only if the patentee's specific chemical is used.

2) In the second proposal, the patent rights are extended for the entire invention defined by the claim, but enforcement is limited to the specific therapeutic use approved by FDA. This proposal is broader than the previous one in terms of the active chemicals that are protected, but the patented technology can still be used for other drug therapies.

This proposal permits the development of the patented invention for all uses other than the specific therapy approved by FDA. Under this proposal, enforcement of the patent would be difficult. A competitor could manufacture and sell the identical drug for a different therapy; the competitor's drug might then be prescribed and used for the patentee's therapy. The only remedy available to the patentee would be to sue each of the prescribers or users for patent infringement.

3) In the third proposal, the extension is provided only for those aspects of the claimed invention which involve the specific chemical contained in the drug approved by FDA, and enforcement is limited to the specific therapeutic use approved by FDA. Of the three proposals, this one provides the least protection to the patentee.

This proposal permits others to develop the technology for all uses and allows others to make, use, or sell variations of the patentee's specific chemical for any drug therapy. Furthermore, others can make, use, and sell drugs using the patented technology and the patentee's specific chemical for any drug therapy but the one for which the patentee obtained FDA approval. Enforcement under this proposal is difficult for the same reasons that it is difficult in proposal 2.

Mr. KASTENMEIER. Your basic statement is relatively brief so you may proceed as you wish.

Mr. ANDELIN. Patents were designed to promote innovation by providing the right to exclude others from making, using, or selling an invention for 17 years.

Let me add the original term was 14 years and somewhat over 100 years ago that was modified to 17.

Patents enable innovators to obtain greater profits than could have been obtained if direct competition existed. This helps them in their early years. These profits act as incentives for innovative activities.

Today I wish to look at this incentive for innovation as it applies to the pharmaceutical industry. In particular I will look at it as it applies to one aspect of innovation of the pharmaceutical industry.

There are several kinds of new drugs or drug products that can be innovations: new chemical entities, new formulations, new combinations of active ingredients, and new uses for existing drugs.

Patent term extension would have its greatest impact with regard to innovation of new chemical entities. Therefore, we concentrated our efforts on that and that is what I will discuss today.

Let me make one more comment about some terminology. The industry that produces pharmaceutical drugs is often divided for convenience into firms that depend heavily on research and provide the new chemical entities to the market.

Those are typically called research-intensive firms, sometimes pioneer firms. There may be other terminology but those are the ones we think of as providing us with brand name products and new drugs.

Another sector of the industry which is considerably smaller consists of those firms that at the time of the expiration of the patents covering drugs will enter the market and produce the same drugs. These firms are sometimes called generic companies. In our text we called them production-intensive. We use the words research-intensive and production-intensive to distinguish those types of firms.

Mr. KASTENMEIER. In the case of production-intensive, I think you are saying they themselves do not hold original patents?

Mr. ANDELIN. They could well hold original patents but more likely than not they produce new combinations of active ingredients of drugs that are off patent; or develop new processes to manufacture them. There are many kinds of patents. So they certainly do hold some patents but the profits of the firm and the existence of the firm in the marketplace depend mostly on having a drug that is the same as someone else's. These firms generally do not have to recover the same research and investment costs as do the first entrants.

Mr. KASTENMEIER. So they would either have to wait until the expiration of the 17-year term or be licensed by the original?

Mr. ANDELIN. That is correct. I would like at this point to call attention to the figure that is attached or the one on the board and talk about the relationship between the innovation of new chemical entities and the patent process itself.

I apologize that the chart is complex but that is a reflection of the complexity of the drug approval and patent process and not of

our study. It has basically two lines. The upper one is the drug innovation process, the lower one is the patent process. They are largely independent of each other in the length of time it takes to go through each stage.

That is the reason that the question of patent term extension arises and some of the difficulty of deciding on what length of extension is appropriate if patent term extensions were to be adopted. The drug innovation process starts with an idea, the discovery stage. When something is discovered that has biological activity it gets tested in what is called the preclinical stage, which involves animal toxicity, and can be completed relatively rapidly. Somewhere in that stage is the typical time to apply for a patent.

If the preclinical trials are positive, then the next stage is for the company to apply to the FDA for an IND which is an investigational exemption for a new drug.

It basically says we are ready to start clinical testing. There are three phases of clinical testing, each one involving a larger sample and each designed for different purposes. This is the beginning of safety and efficacy testing with human subjects.

At some point, usually near the end of that testing but it can be anywhere in the process, the company can file an NDA, new drug application, saying we are ready to go to the next step and formally request marketing approval.

Sometime after that they get approval. The steps are typically a few years each. They vary and we can discuss those in detail.

During this time the patent process is running. It is common for the patent to issue somewhere during the clinical testing and most often prior to the new drug application approval.

So the patent has issued but as a result of the FDA regulations the product cannot yet be brought to the market.

Mr. KASTENMEIER. Why is that? The reason I ask the question is because given the problem we are looking at, I would think that since we don't have the first to file system, and as long as the firm has a record of its being the innovator, the creator, the inventor of this chemical compound, why would they apply for a patent that early when indeed if it does issue that will have a less shorter effective patent term than would otherwise be the case if they filed later?

Mr. BALMER. There are basically two reasons. First, you indicated we do not have the first to file system here in the United States. Because of the procedure by which our interference process works, there are definite reasons and definite advantages to have the first application on file.

The individual or that party filing first is given some procedural advantages. The second reason is that if there is a disclosure of that invention or, let's say, a third party discloses it or the innovator himself, there is a 1-year grace period provided here in the United States in which to file a patent application.

Many of these companies are interested in pursuing patents in foreign countries which do have the first to file system and do have an absolute novelty standard which provides no grace period from the time of a disclosure of the invention.

Accordingly, the earlier it is on file, the better for the company.

Mr. KASTENMEIER. Thank you for that answer.

Mr. ANDELIN. Let me pick up at the point the patent issues. At FDA, testing is still generally continuing. The new drug application may have been filed at this point but cannot be approved before the tests are concluded. The drug can be marketed only after receiving the NDA approval.

By this time, with most new chemical entities today some of the drug's patent term has expired. That is, less than 17 years of patent protection remains. The portion of the patent term remaining after marketing approval is obtained is what we term the effective patent term.

I will mention later in the statement that the effective patent term is one of the determining elements that one would like to talk about concerning the interaction of the different components of the industry on innovation.

It is not necessarily the same as the effective market dominance of a given company's position. There are some differences. We will discuss that a little bit. Let me also comment I have just walked you through the FDA approval process with regard to pharmaceuticals but there are certainly many other industries that are affected by similar Federal regulations and have an interest in patent term extension.

If you look again at the chart you can see when the drug enters the market at the NDA approval stage, it has a product life that is characterized by roughly three stages and we have shown them extending beyond the patent term and that is because if they extend less than that the patent term extension has no effect. That is for those drugs where the marketing stage is shorter than the remaining effective patent life the patent term extension has no effect. For those drugs where it is longer there will be an effect. The marketing stage as we show has typically a development phase, a stable phase, and then a declining market at the end. This decline can occur as a result of competition from other drugs, as a result of other therapies, and as a result of, in some cases, the disease or the ailment for which the drug is prescribed having diminished in the population.

The patent normally expires, again for most of the drugs of concern, somewhere during the marketing of the drug. At that stage it is at the end of the line on patent process and that competition may enter with the same drug.

Prior to that there can be competition from other therapies and competition from similar drugs depending on the exact coverage of the patent.

After patent expiration the same drug can be manufactured by others and sold.

The products can be offered for sale by what we call the research-intensive firms. That is other firms with trademarked and patented drugs as their main livelihood may enter the generic market.

In addition, the firms we refer to as the production-intensive firms, also can enter the market at that point. For the research-intensive firms, it becomes a supplement to their income. For the production-intensive firms it becomes the bulk of their income.

Our study reviewed many aspects of patent term extension within the framework I have outlined above rather than within the specifics of the legislation before this committee.

We studied the following areas:

First, we studied the inequity many see in the reduced patent terms some regulated products receive;

Second, the positions of the various parties in the controversy over patent extension;

Third, measurements of and factors affecting innovation in the pharmaceutical industry;

Fourth, the implications of extended patent terms on the various pharmaceutical industry members and consumers;

Fifth, the relevant portions of patent law;

Sixth, the mechanisms of patent-term extension; and

Seventh, those aspects of the medical device, pesticide and chemical industries which may indicate some of the implications of patent extensions on innovation in those industries.

In particular, our emphasis was on Nos. 3, 4, and 5. We also looked with some concern at No. 6, mechanisms of patent term extension. Probably the closest match to the legislation at hand is in that particular section. The rest of my testimony will focus on implications of extending patent terms for pharmaceuticals innovation, industry, and society.

Let me begin with the subject of pharmaceutical innovation. While patent extension can encourage innovation through the incentives it provides to the patentee, the evidence that is available neither supports nor refutes the position that innovation will increase significantly because of such extensions.

There are two major reasons why we cannot be more helpful on this subject: First, there is no single, uncontroverted method for measuring pharmaceutical innovation.

The FDA has a subjective measure which categorizes drugs into those with high therapeutic value, modest change in therapeutic value, not much change in therapeutic value. Do you count the number of drugs, do you allocate by the FDA categories, do you count the number of drugs that come out onto the market, do you count the volume of sales by dollars and patients by cases treated? The measure of innovation is very difficult. There is just not an agreement among the experts about the meaning of various measures suggested.

Mr. RAILSBACK. Could I interrupt you just to ask, did your findings indicate that there had been a substantial dropoff as far as investment in research and development a percentage of, say, sales or revenues of the drug companies? You go back in one place in your statement to 1962, where the procedures become more stringent. You indicated there was a dropoff there. Has R. & D. gone down substantially as far as percentages?

Mr. ANDELIN. On the percentage of R. & D. as a function of revenues the data that we have begins just after 1962. I believe it begins in 1965. This percentage has been remarkably stable at approximately 8½ percent from 1965 through 1978. So that whatever the factors are that affect research and development in a pharmaceutical industry, none of them show an effect other than

the total revenue of the industry in the year in which the R. & D. is done.

Mr. RAILSBACK. Although I gather that some of the other countries and some of the major firms in other countries have had a much larger increase in R. & D. in their respective fields, pharmaceutical fields for instance.

Mr. ANDELIN. I can address part of that question and perhaps my colleagues can amplify or correct. The trend of U.S. pharmaceutical industry in where they do their research is that more and more of it is being done overseas.

Mr. RAILSBACK. Why is that?

Mr. ANDELIN. It is cheaper and they are multinational firms.

Mr. RAILSBACK. Cheaper on labor or what?

Mr. ANDELIN. I will defer to my colleagues.

Ms. VALTRI. Cheaper for several reasons.

Mr. RAILSBACK. The difference in stringency in the regulations and the filings.

Ms. VALTRI. At the earliest stages of research, generally in the United States hospitals, they have boards which approve or reject whether or not an experiment is going to take place. They generally take a long period of time for this approval to be affected. That is not the case generally in Europe. An individual researcher can go ahead with a program without the approval of the boards in general.

Mr. RAILSBACK. As part also of the FDA requirements, isn't length of screening a factor?

Ms. VALTRI. No. This is at the stage before one would really get to the FDA in this country. It is at the research stage.

Mr. ANDELIN. If a drug is to be for sale in this country, it has to go through the same FDA process regardless of where research is conducted. We have with us in fact some specific figures on that. They are in the report, and we can make them available to you whenever you wish.

Mr. RAILSBACK. Thank you.

Mr. ANDELIN. Although I have disclaimed much knowledge about the innovative process and the rate of innovation because of the difficulty of measuring it, it does appear that, by the measures that we used in our study, innovation does not appear to be increasing over the last few decades. That at best is about the same, and by some measurements, such as total new chemical entities approved, there was a dramatic drop in 1962 and it has been constant since then.

We did not attempt to determine the societal implications of a stable or nonincreasing or possibly decreasing rate of innovation. That is, there is a question about the socially desired rate of innovation that is discussed by some in this debate. We found it impossible to shed any light on that discussion.

There is a second reason that we cannot say much about the effect of patent term extension and innovation. The first reason is that it is so hard to measure what you mean by innovation. The second is there are so many factors that affect the innovative process itself.

For example, it depends on many industry decisions, company-by-company decisions, and they are making decisions today about

innovation which may occur a decade or more from now. There are so many factors that affect industry decisions to undertake the research and development that leads to innovation. We have not been able to isolate the weight of any individual factor to the extent necessary to be able to predict the innovative activities that will occur a decade or more from now.

The factors we have identified appear to be closely interrelated, and the relationships themselves are quite complex. We have been able to identify some of these factors, many of them, and I would like to discuss some of these at this point.

These are factors that play a role in the type of pharmaceutical innovation attributed to the research intensive firms. That is, the production of new chemical entities. In some cases we have been able to identify not only what the factors are but the historical trends, and some of the underlying elements of society that might change those trends in the future.

Let me speak about factors affecting innovation at this point. As has been said, we have seen that since 1966 the effective patent terms on average have declined primarily due, I suspect, to the increased time to complete the FDA process. There is some evidence to indicate that the rate of decline or even the decline itself may halt some time in the future, but it has certainly declined over the last 15 years. The profits as measured return on equity, have been stable since 1956, at levels which are higher than most other manufacturing industries.

Accountants and financial analysts have many ways of calculating return on equity. Independent of the approach taken, return on equity has been stable plus or minus 1 percent. By one calculation, 18 percent, plus or minus 1.

Let me distinguish the total profits of a company and a return on R. & D. investment. That is, the innovation we are discussing depends on a research and development input a decade or so or more in advance. So we want to talk about the return to the company of its R. & D. investment rather than the total equity.

Over the last several decades, research techniques continued to improve. The competitive pressure for innovation among research-intensive firms has not diminished at all. There is a widespread belief that the return to research and development investment is declining. There is a belief the research-intensive firms will get less back for the R. & D. they put in today than they used to and that trend has been taking place for some time. Here again the data are very hard to obtain. We find different ways of calculating it with somewhat different results, so we looked at the underlying factors that influence these returns.

Some of the factors are:

The cost to a company to produce a single new drug, total R. & D. expenditures of the industry and the competitive pressures on the revenues and profits of the firms that undertake research. First, the costs of the R. & D. activities associated with a new chemical entity drug have been increasing rapidly as a result of both inflation and more stringent and time-consuming testing requirements. Because the time spent in obtaining FDA approval may be leveling off and because new research techniques are being developed continuously and people are rather pleased with the

research prospects that they see coming on the horizon, the R. & D. costs should increase more slowly in the future. That is, the better research techniques will help fight the inflation and the leveling off of FDA approval process would stop the growth of that influence.

Second, real growth in constant dollars has occurred in the expenditures for research and development. As a percentage of total revenues, R. & D. expenditures have been 8½ percent for 15 years. But in terms of dollars and their worth today, it has gone up. The reason is that the total revenue of the pharmaceutical industry have gone up over that period in constant dollars.

Third, the revenues and profits of these firms are strongly influenced by the competitive pressures that are exerted on drugs. The competition may be from other patented drugs, from nondrug therapies, or from generically equivalent drugs that are produced by either research-intensive firms or production-intensive firms. Of the drugs having generic competition, about 80 to 85 percent are sold by research-intensive companies.

Despite the decrease in the average effective patent term that may have allowed generic competition to enter the market sooner after the first market introduction of a drug, the revenues and profits of research-intensive firms have thus far not been significantly affected by generic competition, let alone by competition from production-intensive firms. This is not necessarily how the future will evolve.

There are factors that are changing and particular recent governmental actions could result in increased competition from generically equivalent drugs. Most States now have laws that allow or require generic equivalents to be substituted for brand-name drugs specified in prescriptions. The FDA has adopted procedures to facilitate approval of generically equivalent drugs. The Federal Government now bases its reimbursements for prescriptions paid for under medicaid on the lowest wholesale price of generically equivalent drugs. Furthermore, the Supreme Court has ruled that laws prohibiting the advertising of drug prices are unconstitutional.

Despite Government action to encourage use of generically equivalent drugs, barriers to the acceptance of these products exist. Physicians, who determine the market for prescription drugs, tend to write prescriptions for the easily recalled brand-name drugs. Pharmacists fear they will be liable if they fill a prescription for a brand-name product with a generic equivalent that later causes injury.

Finally, generic drugs, by a court order at present, are not to look like the patented drug with which they compete. Consumers tend to prefer drugs that look the same as the ones they have been taking. Consumers have some preference to continue on the patented drug even after the patent has expired. Thus the effect of generic competition on the revenues and profits of research-intensive firms in the future is uncertain. If generic competition increases significantly, such revenues and profits could decline.

If the historical ratio of 8½ percent of their revenues going to R. & D. holds, the R. & D. expenditures would similarly decrease. There is another argument, however, that additional generic com-

petition could encourage research-intensive firms to increase their R. & D. expenditures in an effort to maintain their market shares through drug innovations.

That is to bring out their own competition for the drugs that are expiring, leaving a smaller niche for generic competitors.

Let me spend just a minute talking about the implications of patent term extension on pharmaceutical industry members and for consumers. For the research-intensive firm, patent term extension may provide an immediate incentive to undertake R. & D. through the increased long-term potential for returns to R. & D. investments. Once extensions begin to run, additional resources will provide some firms with further incentives.

The bulk of revenues generated by patent term extension will be obtained by a few firms which have developed financially successful drugs. The increased revenues may serve to perpetuate their dominance in particular research areas, and other firms lacking expertise may possibly be discouraged from entering these areas.

Since the economic incentives provided by patent term extension will be greatest for drugs with high income potential, the tendency of firms to direct their research toward drugs with large markets will be reinforced. Some therapeutic areas that are apt to produce economically marginal drugs may receive greater attention as a result of patent term extension but patent term extension will not affect research on drugs with small markets, the orphan drugs.

Patent term extension poses risks for production-intensive firms. Although they depend on innovative new drugs to expand their product lines, the remaining product lives of drugs coming off patents will determine their long-term revenues.

Let me refer you once more to the chart: The remaining product life is the difference between patent expiration and the end of the drug marketing stage. To the extent the patent term is extended, the remaining useful market life of that drug will be shortened. The total opportunity to the generic drug company will be somewhat reduced. They will have fewer years in which to sell their product.

Mr. KASTENMEIER. I am trying to see if I understand you. Did you say if the patent term is extended——

Mr. ANDELIN. That will have no effect on the market life. The time left after the patent expires and the end of the useful life of the drug in the market will be shortened. That is the time in which the production-incentive firms can enter the market. So that the marketing time for production-intensive firms, the time during which they can compete, will be shortened. In some cases if they estimate the remaining market life is too short, they will not enter the market at all. In other cases they will enter later than they once did.

Let me address for a moment how the consumers would feel an impact. First of all, they will benefit if more and better pharmaceuticals are developed. The pharmaceuticals can provide substantial savings over other forms of health care. Today, pharmaceuticals represent about 5 percent of the cost of health care. The cost of drugs for consumers will increase unless patent term extension results in the introduction of more new drugs which exert a downward price pressure on the prices of existing drugs. It does not

mean the price of a given drug will increase during the extension, only that it might not decrease as it would with generic competition.

It is expected that both the benefits and the additional costs will affect the elderly and the chronically ill more than other segments of society; but patent term extension will have no effect on either benefits or costs for at least a decade.

Thank you for the opportunity. We welcome your questions and we will provide a full report to the Congress very soon.

Mr. KASTENMEIER. Thank you, Mr. Andelin. I take it the report will not contain any different or startlingly new information on this subject, than that which you have given us this morning. Is that a fair statement?

Mr. ANDELIN. It certainly is a fair statement. A review procedure is to find where we have done things wrong. We are in the final stages of the review process. If we are convinced we have made mistakes, there may be changes. I can't imagine that. It has been heavily reviewed up to this point, so this should represent the report.

Mr. KASTENMEIER. I appreciate your analysis. Actually, it does not seem to either support or oppose the legislation before us. Is it fair to say it is merely an analysis of the pro's and con's and the factors involved in patent term extension?

Mr. ANDELIN. Yes, sir; I believe, also, some of the information that we described, such as the mechanics of the patent term extension itself, will reflect on various proposals that have been made as to the kind of patent protection that would be provided during the extended term. Again, the Office of Technology Assessment specifically does not take a position for or against the legislation. We try to understand the underlying factors well enough so that we can tell you what the effects will be if you do it and leave the judgment of the social values to the Members.

Mr. KASTENMEIER. One argument can be made—and I don't know whether you have analyzed this or not; I will use a hypothetical—some of what you have said bears this out—that the pharmaceutical houses will insist on making a profit and covering their expenses of research and development notwithstanding terms. Assume that in the 17-year term they would hope to sell 1 million units a year making $1, we will say, a year, a unit for this cover research and development and profit, whatever other factors.

Assuming 17 stable years or an averaging, $17 million, if in fact through regulatory delay they had 8½ years they would have to build in $2 a unit for 8½ years so that they end up recovering $17 million, if you followed my formula. I don't know whether that is correct or not, but there is a tendency to build in the compensation in that way for the shorter term and pass on the cost to the consumer as a result. Is that borne out?

Mr. ANDELIN. We have looked at that issue. The first proposition or assumption you are making is if they could sell it for $2 for the initial market and they knew they had a 17-year patent life they would only sell it for $1. My suspicion is that would not be standard industrial practice. They would, there is some suggestion that the price they can charge depends on the competition and some

financial analysis of how they wish to recover what profits and so on.

Mr. KASTENMEIER. I concede there are many other elements. What I am really suggesting is that there is a tendency in the pricing and marketing of products to compensate, as far as the shorter term, so in this case the research incentive pharmaceutical house does not in fact lose any money on account of the shorter term.

Mr. ANDELIN. First of all, whatever the competition is, there is some discretion on the part of a company to establish some price. Drug sales are more price inelastic, that is, there is less sensitivity to price, than many other commodities, partly because of the third-party payment, and partly because of the actual low percentage of total medical bills that the drugs represent. So, certainly, under the proposition you suggest, some price discretion can exist.

A company that would make a pricing policy of that nature has to take into account that money today is not the same as money later. For example, with patent term extension saving a year at the front end in the FDA review process is probably worth 2 to 5 or even 10 years' worth of revenue at the far end just because money has time value and the firms would rather have it today than in 10 years.

Mr. KASTENMEIER. I know my hypothetical is flawed, but I was trying to suggest whether there is an industry practice to try to recover x number of dollars for research and profit notwithstanding the shorter term.

Mr. ANDELIN. I would expect they would try. I don't know that we have any data to show that the practice exists.

Mr. KASTENMEIER. I have a letter this morning from a boyhood friend of mine in Beaver Dam, Wis., who, although he is self-employed he certainly is not in this field. He wrote and said that he thought this was a good bill because, among other things—I think he was really talking about regulatory delay—his granddaughter has leukemia and was undergoing chemotherapy, which was effective, and the leukemia was in remission. He was aware of the difficulties that particular drug had in clearances and the delays, and he only thanks heaven that it was cleared in time and that he feels there is a sense of urgency about making certain drugs available at an earlier point in time.

Be that as it may, one of the issues is whether this bill be the sole means of addressing what seems to be the problem of regulatory delay. Whether you parenthetically analyzed some form of deregulation or accelerated FDA practices or whatever, might also be useful in giving longer, more effective terms to inventors in the chemical and pharmaceutical fields, it might also help address what would seem to be the problem here. Did I analyze that at all?

Mr. ANDELIN. I would expect patent term extension would have very little direct effect on the approval process itself.

Mr. KASTENMEIER. Of course. What I am saying is, quite apart from the bill Mr. Sawyer and I introduced, might there be other things done such as affecting practices by the FDA among others in accelerating approval of a new chemical, whatever they are, new chemical entities and so forth. Did you analyze that?

Mr. ANDELIN. No, sir, we did not. Let me mention that a new commission to look at the FDA process has just been formed, and there are certainly many studies that have done this. We looked at the patent term extension effect itself, not the FDA process. However, some detailed understanding of the FDA process was necessary to understand the relationship between the two. But obviously one could change the drug approval process to have a change in incentive in a different way than by patent term extension.

Mr. KASTENMEIER. I appreciate that.

One of the things said to us last year was, you should examine whether this is the best or the only way of handling the problem. It is not in the province of this subcommittee to look at whatever the FDA does but to the extent they may be part of the problem, I was curious as to whether you looked at that aspect of it.

Mr. ANDELIN. I think it is fair to say that there are many ways in which innovation can be stimulated. That has been a subject of discussion nationally for some years now. Patent term extension is one of them. It is not the only one.

Mr. KASTENMEIER. I have some other questions but I would like to yield to my colleagues, to the author of the bill, the gentleman from Michigan, Mr. Sawyer.

Mr. SAWYER. Thank you, Mr. Chairman.

To follow up on one of the questions the chairman asked, we have to assume that a drug company will plan to recapture over the life of this patent, the cost of its patent and what it considers to be a reasonable profit and also affected by the competition.

I presume, though, that, if, for example, kind of going along the general example the chairman gave, if they planned to sell, to recover their cost they would have to sell two units at $2 a unit, if it was over 7½ or 8 years, whereas $1 if it was spread over longer. I presume they might not engage in some patent research because they don't feel over the shorter course that they would be able over 7 or 8 years, in light of competition, to recapture the costs. Might not that be true?

Mr. ANDELIN. I am sure that takes place today even on the 17-year period. That is the question of orphan drugs.

Mr. SAWYER. But I assume, though, there may be many instances where it would be an attractive experimentation or investigation of research to get into. If you knew you were going to have 17 years to recapture your cost and profit, it would be more attractive in some instances and it would make attractive some instances that might be unattractive if you knew you only had 7 or 8 years.

Mr. ANDELIN. Sure. There are many corporate elements that go into the decision on which drugs to do what R. & D. on. The market analysis is one of those. If you have a longer term in which to market a drug, some drugs will become economically viable that might not otherwise be.

Mr. SAWYER. So it might have the effect of encouraging R. & D. in some areas that otherwise might not be attractive because of the drastically shorter time for amortization cost?

Mr. ANDELIN. Yes; I think the answer is "yes". I would expect it to be a rather minor effect because the hypothetical drug you are talking about is one that would not be economically viable one way and would cross that threshold and be somewhat profitable the

other way. I would expect most firms would look for other drug possibilities that start out clearly economically viable and profitable and will be even more so with different patent life.

But there are drugs on the line in any given decision point.

Mr. SAWYER. Have pharmaceuticals in general kept pace with costs of other alternative type health cares?

Mr. ANDELIN. The price index for pharmaceuticals has a gone up less rapidly than inflation in general. It had about a 50-percent increase in the last 15 years, whereas most price indices have gone up about 150 percent. So, in terms of real dollars, the drug index implies that the drugs are less expensive today than they once were.

Mr. SAWYER. Apparently pharmaceuticals have not shown the full susceptibility to inflation that the other health cost areas have.

Mr. ANDELIN. I think that is correct.

Mr. SAWYER. Is there any justification that you can see why you would take particular types of articles that are developed in one of these regulated filings, whether it be pesticides or pharmaceuticals or whatever the various field is that are subject to regulation either by Food and Drug or the Department of Agriculture, and giving them a lesser patent effective term than any other kind of newly developed product? Which is, frankly, what is bothering me about this.

Mr. ANDELIN. Yes; the answer is that a change in the patent term by patent term extension is not free, that there are costs and benefits throughout the society. There is a highly different impact on the research-intensive firms than on the production-intensive firms. There would be impact on consumers. I think we tried to outline how you value those impacts.

Mr. SAWYER. Isn't this true in fields other than pharmaceuticals or chemicals in general or other things? The same thing is true in electronics or anything else. There are firms that are heavy in R. & D. and firms that in effect are strictly production firms that don't do any R. & D. to any extent at all.

Take articles on which patents have expired and they are not patentable and make them as production-line items. I don't see where that is unique to the pharmaceutical.

Mr. ANDELIN. Let me comment that there are those industries that are not regulated. Typically, effective patent terms are also reduced for a number of reasons, other than Federal Government premarketing regulations. The 17 years of effective patent term applies, does not apply universally. The interference of the Federal regulatory process, if you will, in the marketing is one reason for a shortened effective patent term.

Mr. SAWYER. What are some of the other reasons?

Mr. BALMER. For example, the product requires development time. There may not be substantial existing support technology and such may be required. For example, the heart pacemaker was invented back in the early 1900's, yet only in the past couple of decades it has come about. There can be other types of governmental regulations; for example, a company which is to build a plant.

Mr. SAWYER. You said aside from Government regulations. What other things? Significant things?

Mr. BALMER. I think one of the primary areas is the development of the required technology, support technology. For example, going back to the example of the heart pacemaker, the concept was in existence in the 1920's.

Mr. SAWYER. Doesn't the use of a pacemaker require some kind of Federal OK?

Mr. BALMER. The point I am trying to bring out is that it required certain technological advances before it could be put into fruition. One of the references that we provide in our report was a study done by Gellman Research Associates for the National Science Foundation. They looked at 500 significant innovations over the period from 1953 to 1973. These products included not only pharmaceuticals, I think there were only about 18 to 20 pharmaceutical-type products—but others they considered significant innovations including aircraft and almost any type of product you might think of. Their findings indicated many of those products in fact required substantial periods of time before they could be marketed, and obviously many of those products are not regulated by Federal regulations.

Mr. LEHMAN. Mr. Balmer, would you amplify on that? You mean you have to build factories frequently in a time period involved in building a factory. There is a time period involved in creating a machine tool which is needed to manufacture the product and that sort of thing, and those are the kinds of economic factors you are talking about?

Mr. BALMER. That is correct, Mr. Lehman. As well, one needs to have a receptive market for a particular product. There are many developmental factors involved.

Mr. BUTLER. I appreciate your testimony. You have given us sort of a survey of the factors. It occurred to me if you increased the term in which a product can be marketed, then the opportunity for profits is increased, and if opportunity for profits is increased you will spend more effort on developing new products. But the other aspect of it is if you have control of the market, as you do when you have a patent, the price to the consumer is not necessarily going to be less but perhaps it is going to be longer because it is not exposed to competition as soon. Can you give me any assurances that this legislation would not result in more cost to the consumer pricewise?

Mr. ANDELIN. We conclude that it will result in some increased cost to the consumers at the time that the patent term extension takes place, which is typically a decade or more from now.

As a result of any patent term extension legislation, the costs will be higher during the patent term extension than they would otherwise have been, all else being equal. But the all else being equal is certainly what Congressman Sawyer was referring to. There may be new drugs on the market as a result of this increased incentive. Therefore, there could be more competition. There could be some social benefits to accrue or to match those increased costs, although increased competition might bring the cost down a bit from what you might expect. So there are competing interests.

I would say if the costs to the consumers don't go up and if the profits of the production-intensive companies don't go down, then

the research-intensive companies won't have any aggregate financial incentive. Now, you have to look at the research-intensive companies individually to realize that many of them say: "We don't care if in the aggregate we don't make more money, we think we can beat our competitors so we will take advantage of this." They can argue their total revenues may decrease even though the individual companies have incentive and the successful ones will be more successful because they have more protection.

Mr. BUTLER. You don't anticipate that, of course, the impact on the production-intensive drug producers is going to be substantial, as you suggest. Are the marginal companies in this area that you anticipate be forced out of business?

Mr. ANDELIN. I can't answer that. The effect on the production-intensive companies will be modified according to the details of any patent term extension that is enacted. What kind of protection is involved in the extension, the full patent or just the chemical or just the use of the drug and so on. There is a range of possibilities that will affect both the research-intensive and production-intensive companies. It will change that balance somewhat.

Mr. BUTLER. I yield back, Mr. Chairman.

Mr. KASTENMEIER. Earlier, when Mr. Balmer explained why it would be necessary for a research-intensive pharmaceutical to make reasonably early patent application, I thought he gave a good analysis of why that is desirable and could not be deferred.

Let me ask you a secondary question. What if in your scheme of things the patent application comes early, but somehow the issuance of the patent is deferred, which in effect will give a longer effective patent term to the pharmaceutical. Is that possible? What militates against some possible changes in that direction?

Mr. BALMER. I believe it is possible. Again, we did not say whether this in fact occurs now or would occur in the future. But there are techniques available within the existing patent laws that enable this. For instance, a company files a first patent application. Then the company learns more information, decides that is relevant to its patent application. It then files a second patent application, which is called a continuation-in-part patent application, which incorporates that new material. Again, it starts the patent process over again from the initial processing examination, on through the Patent Office Procedure.

There are other factors which may occur to that particular patent application as it is progressing through the Patent Office.

There may be a question of whether the claimed invention is patentable. This may require appeals. Those all occur prior to issuance of the patent. Another factor that may come up is that there would be an interference declared with another patent or patent application. That interference proceeding can take a considerable amount of time, particularly if it is for a very significant product. And until that interference proceeding is resolved, the patent will not issue and there will be a 17-year period upon that.

Mr. KASTENMEIER. I take it, except in special circumstances you described, it would not be advantageous for a company, if it had its choice, to have a patent issued later than earlier?

Mr. BALMER. I think the answer would be: even though it would be advantageous from an economic standpoint, to delay issuance, to

enforce that patent the company needs to go to court. If there is evidence and it can be proven that there have been dilatory tactics taken to extend that patent term, that may render that patent unenforceable and have a very negative impact on the company.

Mr. KASTENMEIER. See what the implications are. The question is, in effect, one can extend the patent term or one can provide administrative leave for delay, deferring issuance of the patent so the effective patent term is longer.

Mr. BALMER. One of the mechanisms that we discuss in our report for extending patent terms is to have the 7-year cap, for example, which is in the pending legislation as well as having another cap which relates to the date the first application was filed. So that there would not be any likelihood of a purposeful extension that goes beyond reason.

Mr. KASTENMEIER. I understand. For the study, you obviously consulted a wide variety of companies, and experts, and others in the pharmaceutical industry. I am left with the impression there is a split or there are a couple sides to it. And while this may not be precisely the case, that you identified them as research-intensive and production-intensive companies. Does this split determine what their attitude is to patent term restoration, and could you briefly describe the relative size and economic importance of these two groups?

Mr. ANDELIN. Yes, sir; I think that is a correct description of the industry. The research-intensive firms are in favor of a patent term extension. It is their patent. The production-intensive firms are—I hate to speak for them, but they have much more mixed effects, to the extent there is more drug innovation that opens up more markets for them at all.

But, to the extent they are kept out of any markets, that decreases their potential market niche. I think the most important effect on them is this difference between the time the patent expires and the time the drug market itself runs out. I know production-intensive firms are concerned with the details of the extension. What kind of protection is extended, again, that is the controversy about whether it is just that the chemical or the kind of use or the kind of production procedure that is covered during the extension. In terms of size, the production-intensive firms are much smaller, a few percent of the total drug sales.

Mr. KASTENMEIER. They are relatively small?

Mr. ANDELIN. Yes, sir; the firms themselves are very small.

Mr. KASTENMEIER. Isn't that true in another industry? The gentleman from Michigan mentioned the electronics industry. Several years ago we looked at the question of whether any form of protection could be afforded the semiconductor, computer chip industry, because it does not quite qualify as a form that is copyrightable or patentable. It is a design of circuitry really and it is fairly clear that many of the research-intensive industries who are very small went to great expense to develop these products, of which we are world leaders, on the part of the computer industry. But, we found that in San Jose and other places the industry was so divided between those companies that replicated, in part or in whole, reverse engineered these chips and used them without compensation, including foreign countries such as Japan and European countries,

our own industry was so divided we were not able to proceed with any sort of consensus.

Now, that is not perhaps quite true in this case but there is some sort of analog here that suggests computer industry some of the largest companies were users, not creators, of circuitry. But you say here the users, or the production-intensive companies, are the smaller ones.

Mr. ANDELIN. If I might add to that, that does not mean that the companies that now produce the generic drugs are all small. In fact, most of those drugs are produced by the large firms and sold in competition with other research-intensive firms and are sold through wholesales to some of the production-intensive firms. So most of the production of generic drugs is done by the same companies that we think of as research-intensive, that is, those who invent the new drugs themselves.

After all, once their patent has expired and somebody else is selling it, they can manufacture it rather inexpensively. They sell what they can under their own name and sell others under generic names and/or competitors enter the market to do the same thing.

Mr. KASTENMEIER. You used the term "me-too drug." You received a letter suggesting that increased drug use from longer patent terms could be used to promote so-called me-too drugs. Is that a generic drug?

Mr. ANDELIN. A me-too drug is a drug that would be called new chemical entity. It is very similar, in general, to another existing drug. And it goes through the whole FDA process. It is on the market at the same time as the existing drug. It is for the same ailment. It is usually in the category of drugs that the FDA indicates is not of a major or significant, new, therapeutic value, but it is different. It is a drug whose effect and composition are quite similar to another one but they are sufficiently different that they might be covered by another patent and new marketing promotions. The generic drug is one chemically identical and is sold after a patent drug term expiration.

Mr. KASTENMEIER. In terms of the factors involved, both our bill and that of the Senate I believe have to some extent a retroactive effect. I guess they would affect products currently under review or under review at the time by the FDA, we will say at the time of enactment. Additionally, I think the Senate bill contains some language which would affect at least one particular product quite separately. Do you see any justification or problem with retroactive application of patent law changes in this field?

Mr. ANDELIN. We did not study that issue at this time. Under the equity argument I am not sure I see any difference between retroactive application and prospective application.

In terms of the effect on R. & D. expenditures and innovation, I would guess that one could distinguish between drugs yet to come and those already in the pipeline. You are providing incentive, presumably, to create new innovation but if it is already in the pipeline the incentive won't have such an effect since the innovative process is underway. However, it could enhance the likelihood that the innovative process will be completed. So I suspect one could distinguish. We did not look at that carefully, and there will be less than I just said in the report.

Mr. KASTENMEIER. As you know, there are certain cases perhaps that are unique and tend to be fairly common which regulatory delay and other problems certainly have affected the value of, and which one could, I suppose view as being unfairly treated insofar as in a different time under different circumstances. They might have been promptly cleared or some of those administrative difficulties seemed to be unduly burdensome, but I suspect it would be difficult to distinguish each of these cases.

That might be a separate question. Did you study the comparative law of other nations in regard to climate for innovation with respect to pharmaceuticals?

Mr. ANDELIN. We did look at the difference in law in terms of the patent term, the requirements for obtaining one, the effect on innovation. I believe I am not familiar with that aspect.

Mr. BALMER. I believe that your statement, Mr. Chairman, is fair. We primarily addressed ourselves to what differences in patent law exist between the United States and many foreign countries. Again, we isolated on three particular issues: one, the patent term; two, what is patentable; and three, any provisions they had regarding compulsory licenses. We did not analyze any of those factors specifically in regard to their effect on innovation in those countries.

One of the primary considerations we believe exists is that the United States constitutes such a large world market that it is hard to make a fair analysis with what goes on in France or in another country where those companies are, in fact, perhaps looking toward the United States as a market and are looking toward the United States as a source of their income to compensate for their research efforts.

Mr. KASTENMEIER. One last question. Besides pharmaceuticals and chemicals, did your study suggest there are any other patent areas in which the question of term extension or restoration might be involved?

Mr. ANDELIN. We did not look at that. As I mentioned in my testimony, there are other industries subject to some forms of Federal regulation where their patent terms are undoubtedly effectively less than 17 years. We also mentioned in response to a question that the effective patent term of the 500 major innovations in the last 15 years or so is also less than 17 years.

Mr. KASTENMEIER. The question, of course, is designed to determine whether this is a discrete area which should be separately considered and whether there are no other problems elsewhere in terms of patent extension or restoration.

Mr. ANDELIN. I would suggest a good way to acquire that data is to ask the industry broadly, and those who think they are affected will let you know promptly.

Mr. SAWYER. With respect to there being delays such as one of you suggested, making some kind of machine tools, between the time of the patent and marketing, I presume there are additional delays that would also apply after the approval by a regulatory agency. I can't conceive of a company making a large investment either in advertising or facilitation or whatever, for production until they are sure they have been approved.

Mr. ANDELIN. I think that is correct. One element that is behind that and already accomplished in the sense of going to the market with regard to a drug that has been through the FDA process, is a test of efficacy and safety and in some sense the product liability concerns have pretty much been resolved. With other products that have not been through such a process that is an important early part and that is part of the reason for delay in marketing. Product liability laws are different than they used to be, and corporations are beginning to take that into account.

Mr. SAWYER. As I recall, the bill only affects applications from the date the bill were to become law from the period from that time forward until they went to market. Any time they have been in the pipeline before that is not affected.

Mr. ANDELIN. That is my understanding.

Mr. KASTENMEIER. On behalf of the committee, we wish to thank you, Mr. Andelin and your colleagues for sharing these descriptions of your study with us and your insights into the problem of patent term restoration. As the Chair said before, we will have at least 2 more hearing days in early September on this question, and the leadoff witness, who does not have a particular bias one way or the other, will present an analysis as your office has developed it. We appreciate the value of your views. Thank you.

The Chair would like to announce tomorrow at 10 o'clock we will have two witnesses on the question of jurisdiction of the Federal courts, Supreme Court, and other courts, and then next week we will have 2 hearing days on the question of bail reform, which hopefully will suggest a broad range of jurisdiction. The subcommittee will adjourn until tomorrow morning at 10 o'clock.

[Whereupon, at 12:55 p.m., the subcommittee adjourned to 10 a.m., Thursday, July 23, 1981.]

PATENT TERM RESTORATION ACT OF 1981

WEDNESDAY, SEPTEMBER 30, 1981

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES,
AND THE ADMINISTRATION OF JUSTICE
OF THE COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:10 a.m., in Room 2226, Rayburn House Office Building, Hon. Robert W. Kastenmeier (chairman of the subcommittee) presiding.

Present: Representatives Kastenmeier, Railsback and Butler.

Staff present: Bruce A. Lehman, counsel, Timothy A. Boggs, professional staff member, Thomas E. Mooney, associate counsel, and Audrey K. Marcus, clerk.

Mr. KASTENMEIER. The committee will come to order.

In July, the subcommittee began consideration of legislation relating to patent term restoration and regulatory delay by receiving testimony and studies in the Congressional Office of Technology Assessment.

Today we will begin that portion of the hearings designed to elicit the views of private citizens and associations with an interest in the issue.

This morning we will hear from leading proponents of the legislation and tomorrow we will hear from opponents. Further witnesses will be heard next week.

While no specific dates have been set or selected for future hearings it will undoubtedly be necessary to hear from some additional private parties as well as representatives of the executive branch of Government and these hearing dates will be shortly announced.

With these brief remarks I am pleased to welcome as our first witness this morning Mr. Lewis Engman, president of the Pharmaceutical Manufacturers Association. Mr. Engman, we have your statement.

TESTIMONY OF LEWIS A. ENGMAN, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION

Mr. ENGMAN. Thank you, Mr. Chairman.

As you indicated, I am president of the Pharmaceutical Manufacturers Association, which represents 140 companies that discover, develop, and produce prescription medicines and medical devices.

Our firms account for more than 90 percent of the new chemical entity pharmaceuticals introduced in the United States and a substantial percentage of this country's medical device innovations.

Mr. Chairman, PMA member companies are committed to improving health care by converting new knowledge into better therapy.

For that reason, I appreciate this opportunity to express our support for H.R. 1937, the Patent Term Restoration Act of 1981, which has been introduced by you and others. As you know, similar legislation passed the Senate July 9, 1981.

Nearly 200 years ago, Congress, pursuant to the specific authority set forth in Article I, Section 8 of the Constitution, created our patent system for the purpose of encouraging innovation. It has served this country well.

A patent system, to be successful, must balance several public interests. On the one hand, the public has an interest in the innovation stimulated by promising inventors temporary exclusivity, and in disclosure of the nature of the innovation.

On the other hand, the public has an interest in having many producers competing for its business.

Congress, in 1861, selected 17 years as the period that best balanced these interests. Since 1861, the 17-year patent term has remained unchanged.

No one can prove empirically that 17 years was then, or is now, the perfect patent period. But no one can deny that the patent system, as it has existed for more than 100 years, has contributed enormously to innovation.

What occasions this hearing today and the introduction of this legislation is the fact that the 17-year period that has served so well has been inadvertently, but substantially, eroded for products, such as pharmaceutical products, that must be approved by the Government before they can be marketed.

When a drug firm discovers a promising new chemical compound, the first thing it does before committing itself to the research and development process—which these days costs, on average, about $70 million per new drug entering the market—is to file for a patent.

That patent generally is issued within 2 years and immediately begins to expire. But at the time the patent is issued, the innovating firm is far from sure it will ever have a marketable product.

For that assurance it must await Government marketing approval, an event which may be—and, indeed, generally is—still some 7 to 10 years away.

For pharmaceutical products, therefore, the 17-year patent has become merely a legislative figment.

In reality, a drug patent has an effective life of roughly half that period. As a result, incentives to invest in pharmaceutical research and development have been substantially reduced.

The erosion of effective patent life for pharmaceuticals began about 20 years ago. Since 1960, average patent lives for drugs have been cut nearly in half.

At the same time, inflation-adjusted research investment as a percentage of sales has also been reduced and as research investment in pharmaceuticals has become less attractive, our firms have diversified.

But from the public's point of view, the critical factor is not patent lives or research investments—it is new medicines.

Here, too, the record is disturbing. In 1960, a $3.5 billion industry with effective patent lives averaging 16 years produced 50 new medicines; in 1979, a $20 billion industry with effective patent lives averaging less than 10 years produced only 12 new medicines.

The public has been the loser. The sick—the people with diseases for which medicines have not yet been developed—they have been the real victims of lost patent life.

Mr. Chairman, this unfortunate situation is not the product of congressional design. No one could have anticipated that a testing and approval process which took about 2 years in the early 1960's would take 7 to 10 years by 1980. Reduced patent protection for drugs has evolved by accident, and until recently with little notice.

The bill we are here to discuss today will help correct that problem. By restoring to pharmaceutical patents at least some of the time consumed by the testing and approval process, the bill will help reverse the decline in research incentives.

It will help make investment in drug therapies more competitive with alternative uses of corporate resources.

It will help stimulate discovery and introduction of more and better new medicines.

And it should benefit consumers in two ways—by promoting the development of new drugs that displace far more expensive therapies, such as surgery, and by encouraging the more rapid entry of new drugs that improve upon old medicines and at the same time drive down the prices of those older ones.

One need only look at the savings that have resulted from new drug introductions to appreciate how better therapy and lower cost can arrive in the same package.

Tagamet, Smith Kline's new ulcer drug—if used by all those who would benefit from it—could save some $250 million a year in foregone surgery and physician visits.

Antipsychotic medicines for the control of mental illness have shortened treatment periods and reduced the need for expensive hospitalization.

In 1973, only 35 percent of mental illness patients required inpatient service, down from 77 percent in 1955.

Thanks largely to anti-infective pharmaceuticals, death rates from once dreaded diseases such as tuberculosis and meningitis have declined dramatically since the early fifties.

How tragic it will be if the flow of new cures such as these is unnecessarily restricted in the future.

Mr. Chairman, the remainder of my testimony deals with the details of H.R. 1937 and with the recent report of the Office of Technology Assessment. In an effort to save the committee's time I will not read all this testimony but I will be pleased to discuss these issues with you.

With respect to the OTA report we believe that its findings support enactment of the legislation which you have introduced.

In conclusion, Mr. Chairman, innovation and price competition are not mutually exclusive. They are complementary. The experience with our patent system for over a century has demonstrated that a 17-year patent life provides for optimal innovation and competition for all products in all industries.

For pharmaceutical products, this balance has been significantly disturbed because of requirements imposed by Government regulations.

We believe that it would be in the public interest to restore this balance. That is what your legislation would do, and we support it.

Mr. Chairman, this concludes my prepared testimony. I would be happy to answer the subcommittee's questions.

Mr. KASTENMEIER. Thank you, Mr. Engman. Without objection, your full statement will be received and printed in the record.

[The information follows:]

STATEMENT OF

LEWIS A. ENGMAN

PRESIDENT

PHARMACEUTICAL MANUFACTURERS ASSOCIATION

BEFORE THE

COURTS, CIVIL LIBERTIES, AND

THE ADMINISTRATION OF JUSTICE SUBCOMMITTEE

OF THE

HOUSE COMMITTEE ON THE JUDICIARY

ON

H.R.1937, THE "PATENT TERM RESTORATION ACT OF 1981"

Wednesday, September 30, 1981

My name is Lewis A. Engman. I am President of the Pharmaceutical Manufacturers Association, which represents 140 companies that discover, develop and produce prescription medicines and medical devices. Our firms account for more than 90% of the new chemical entity pharmaceuticals introduced in the United States and a substantial percentage of this country's medical device innovations.

Mr. Chairman, PMA member companies are committed to improving health care by converting new knowledge into better therapy. For that reason, I appreciate this opportunity to express our support for H.R. 1937, the Patent Term Restoration Act of 1981, which has been introduced by you and others. As you know, similar legislation passed the Senate July 9, 1981.

The U.S. Patent System

Nearly two hundred years ago, Congress -- pursuant to the specific authority set forth in Article I, Section 8 of the Constitution -- created our patent system for the purpose of encouraging innovation. It has served this country well.

A patent system, to be successful, must balance several public interests. On the one hand, the public has an interest in the innovation stimulated by

promising inventors temporary exclusivity, and in disclosure of the nature of the innovation. On the other hand, the public has an interest in having many producers competing for its business. Congress, in 1861, selected 17 years as the period that best balanced these interests. Since 1861, the 17-year patent term has remained unchanged.

No one can prove empirically that 17 years was then, or is now, the perfect patent period. But no one can deny that the patent system, as it has existed for more than 100 years, has contributed enormously to innovation.

What occasions this hearing today is the fact that the 17-year period that has served so well has been inadvertently, but substantially, eroded for products, such as pharmaceutical products, that must be approved by the government before they can be marketed.

The Patent System and New Medicines

When a drug firm discovers a promising new chemical compound, the first thing it does before committing itself to the research and development process -- which these days costs, on average, about $70 million per new drug entering the market -- is to file for a patent. That patent generally is issued within two years and immediately begins to expire. But

at the time the patent is issued, the innovating firm is far from sure it will ever have a marketable product. For that assurance it must await government marketing approval, an event which may be -- and indeed generally is -- still some seven to ten years away. (See Exhibit "A") For pharmaceutical products, therefore, the 17-year patent has become merely a legislative figment. In reality, a drug patent has an effective life of roughly half that period. As a result, incentives to invest in pharmaceutical research and development have been substantially reduced.

The erosion of effective patent life for pharmaceuticals began about twenty years ago. Since 1960, average patent lives for drugs have been cut nearly in half (Exhibit "B"). At the same time, inflation-adjusted research investment as a percentage of sales has also been reduced (Exhibit "C") and as research investment in pharmaceuticals has become less attractive, our firms have diversified.

But from the public's point of view, the critical factor is not patent lives or research investments -- it is new medicines. Here, too, the record is disturbing. In 1960, a $3.5 billion industry with effective patent lives averaging 16 years produced 50 new medicines; in 1979, a $20 billion industry with

effective patent lives averaging less than 10 years produced only 12 new medicines.

The public has been the loser. The sick -- the people with diseases for which medicines have not yet been developed -- they have been the real victims of lost patent life.

Mr. Chairman, this unfortunate situation is not the product of Congressional design. No one could have anticipated that a testing and approval process which took about two years in the early 1960's would take seven to ten years by 1980. Reduced patent protection for drugs has evolved by accident, and until recently with little notice.

The bill we are here to discuss today will help correct that problem. By restoring to pharmaceutical patents at least some of the time consumed by the testing and approval process, the bill will help reverse the decline in research incentives. It will help make investment in drug therapies more competitive with alternative uses of corporate resources. It will help stimulate discovery and introduction of more and better new medicines. And it should benefit consumers in two ways -- by promoting the development of new drugs that displace far more expensive therapies, such as surgery, and by encouraging the more rapid entry of

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new drugs that improve upon old medicines and at the same time help drive down the prices of those older ones.

One need only look at the savings that have resulted from new drug introductions to appreciate how better therapy and lower cost can arrive in the same package. Tagamet, SmithKline's new ulcer drug -- if used by all those who would benefit from it -- could save some $250 million a year in foregone surgery and physician visits.[1/] Anti-psychotic medicines for the control of mental illness have shortened treatment periods and reduced the need for expensive hospitalization. In 1973, only 35% of mental illness patients required in-patient service, down from 77% in 1955. Thanks largely to anti-infective pharmaceuticals, death rates from once dread diseases such as tuberculosis and meningitis have declined dramatically since the early fifties. How tragic it will be if the flow of new cures such as these is unnecessarily restricted in the future.

Patent Term Restoration Act of 1981

H.R. 1937 would restore to patent owners up to seven years of the patent life lost due to government premarket approval requirements. Although not

limited to any particular class of products, the bill would have the greatest impact on those products -- such as drugs -- which are subject to the most rigorous and time-consuming regulatory requirements.

Upon application to the Patent and Trademark Office, the owner of a patent subject to one of the regulatory review periods specified in the bill would receive a limited extension of patent term. For a new drug, the extension would generally equal the time from the IND (Investigational New Drug) filing with the Food and Drug Administration to NDA (New Drug Application) approval, up to a maximum of seven years. If the patent had been issued after the IND was filed, the extension term would be measured from patent issuance to NDA approval. For products undergoing regulatory review at the time of the legislation's enactment -- so-called "pipeline" drugs -- the extension would be calculated from the bill's effective date to the time of product approval.

Thus, the bill provides no retroactive benefits for pharmaceuticals already on the market. This approach should allay the fears of those who are concerned about higher prices for existing drugs. And future products will be developed in a new climate of restored incentives for innovation. Indeed those future products may

well owe their very existence to those incentives.

The Need to Improve Incentives for Research & Development

We believe that the public interest is best served when new therapies become available as rapidly as possible, consistent with good scientific practice. For this to happen, incentives to invest in pharmaceutical research and development have to be adequate. Unfortunately, as stated in the recent OTA Report, "A decline in the returns to R&D investment is widely perceived."[2/]

While R&D incentives have been declining, pharmaceutical innovation has suffered. Pharmaceutical innovation is usually measured by the number of new chemical entities (NCEs) introduced. Over the last two decades, the number of NCEs introduced annually has declined. Furthermore, according to the recent OTA study, NCE sales as a percentage of all ethical drug sales have declined from 20% during 1957-1961 to 6.2% during 1972-1976.[3/]

These unfortunate trends are due to several factors:

- Risk: It is estimated that about 10,000 drug candidates are synthesized for every one that actually gets to

market. For every ten drugs that reach the very expensive and time consuming clinical testing (IND) stage, only one is ultimately marketed. 4/

- Cost: In 1962, the average cost of taking a new chemical entity from discovery to market approval was $6.47 million in 1962 dollars, or $16.4 million in 1980 dollars. Today, the cost is up to $70 million.

- Reduced Patent Life: After a company has taken the risk of investing in a new product, paid the high costs of R&D and complied with the lengthy regulatory requirements, the company's new product has a patent life which is only about one-half as long as Congress intended.

Mr. Chairman, the decline in pharmaceutical research and development is a serious problem for society. What can be done to reverse this decline?

One obvious remedy is to reduce the time and cost of getting a new drug to market. Improvement in the approval process should be pursued vigorously.

Last year PMA recommended to FDA several ways to streamline the drug approval process without compromising safety or efficacy.

. . . At the same time, we should be certain that the incentives for innovation are sufficiently attractive. Restoration of patent life would help encourage greater investment in research and development. Greater investment and reinvestment will lead to an increase in the flow of improved medicines.

Mr. Chairman, some critics of this legislation may argue that an effective patent life of 8 or 9 years is plenty long enough and that the best way to save consumers money is to encourage generic competition at the earliest possible stage.

This is a shortsighted view. It ignores the fact that Congress long ago decided that a 17-year period of exclusivity is the proper incentive to stimulate innovation in all fields. It ignores the evidence that investment in drug research has been declining at a disturbing rate under a system of devalued patents. It ignores the fact that this research is vital to our national health. Most fundamentally, it ignores the basic economic fact that competition from new products generates downward pressure on the price of existing

products.

Patent restoration means more incentives for more new products which means more competition. Besides stimulating the discovery of better therapy, patent restoration should exert downward pressure on the prices of new and old products alike.

In the past, significant advances in drug therapy have either treated the previously untreatable or replaced much more expensive but less effective technologies -- anti-infectives rather than death or disability; anti-psychotic medicines rather than mental wards; Tagamet rather than ulcer surgery; Rifampin rather than tuberculosis sanitaria. If patent restoration encourages the quicker introduction of just one of these types of drugs, it will have been worth the effort.

Office of Technology Assessment Report

Mr. Chairman, recently the Congressional Office of Technology Assessment (OTA) published a Report on Patent-Term Extension and the Pharmaceutical Industry. While the OTA Report makes no recommendations, we believe that its findings support enactment of the legislation you have introduced.

R&D. The OTA Report makes the following important findings: "The costs of R&D for the average new chemical entity drug have increased." (page 4) "Since 1966, average effective patent terms have declined...." (page 4) "Patent-term extension will enhance the incentives provided by patents for pharmaceutical research and development." (page 45) "On balance, there is a reasonable likelihood that firms may undertake or increase pharmaceutical R&D activities because of the increased incentives provided by the longer effective patent term." (page 40) Although OTA is unwilling to quantify the effect of patent restoration on innovation, it is the long-standing premise of our patent laws that an effective patent life of 17 years will produce more innovation than an effective life of 10 years.

Generic Firms. The Report also suggests that in the long run, "production-intensive firms" (generic firms) as well as "research-intensive firms" should benefit if innovation increases because there will be more pharmaceutical products to market. The Report makes the very basic point that although "patent-term extension delays their [generic firms'] entry into the market," the generic firms "must rely on research-intensive firms as sources of new products." (page 44)

If new drugs are not developed, no companies will be able to manufacture and sell them.

Consumers. Finally, the Report states that, "Consumers will benefit [from patent restoration] if more and better pharmaceuticals are developed. These pharmaceuticals can provide substantial savings over other forms of health care." (page 7) The Report states that the effect on consumer expenditures for drugs is "unclear" because of the offsetting effects of higher prices for drugs during the restored period and the "downward pressure on the price of existing drugs" from the "increased supply of new medicines." (page 44)

Mr. Chairman, we believe that in the long run, with a full patent term for pharmaceutical products, the real cost of new therapy will not increase. But for consumers, the more important question is whether, absent patent restoration, the new therapy will exist at all.

Conclusion

Mr. Chairman, innovation and price competition are not mutually exclusive. They are complementary. The experience with our patent system for over a century has demonstrated that a 17-year patent life provides for optimal innovation and competition for all products in all industries. For pharmaceutical products,

this balance has been significantly disturbed because of requirements imposed by government regulations.

We believe that it would be in the public interest to restore this balance. That is what your legislation would do, and we support it.

Mr. Chairman, this concludes my prepared testimony. I would be happy to answer the Subcommittee's questions.

FOOTNOTES

1/ Robinson Associates, Inc., "The Impact of Cimetidine on the National Cost of Duodenal Ulcers," (Bryn Mawr, Pa., 1978).

2/ Patent-Term Extension and the Pharmaceutical Industry, Report of the Office of Technology Assessment, OTA-CIT-143, August, 1981, page 36.

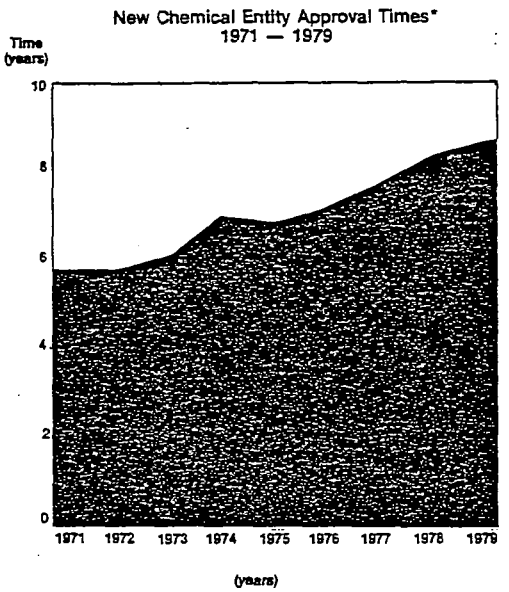
3/ Ibid., page 26.

4/ William M. Wardell, "The History of Drug Discovery, Development and Regulation," in Robert I. Chein, Issues in Pharmaceutical Economics at 10, 11 (1979)

EXHIBIT "A"

The Time Factor in New Drug Development

Even after a new drug has been discovered, it takes 7-10 years to develop it and get it approved for sale.



*Approval Time = time from IND filing to NDA approval by the Food and Drug Administration

Source: Martin M. Eastman, Ph.D., "Components of the Decline in Patent Protection for New Drugs," CEDO, 1980.

EXHIBIT "B"

Declining Patent Protection

These 7-10 years are, in effect, deducted from a drug's patent life. Thus, instea of having 17 years in which to recover its investment like firms in most other industries, the pharmaceutical innovator has only about half that time.

Patent Life Erosion

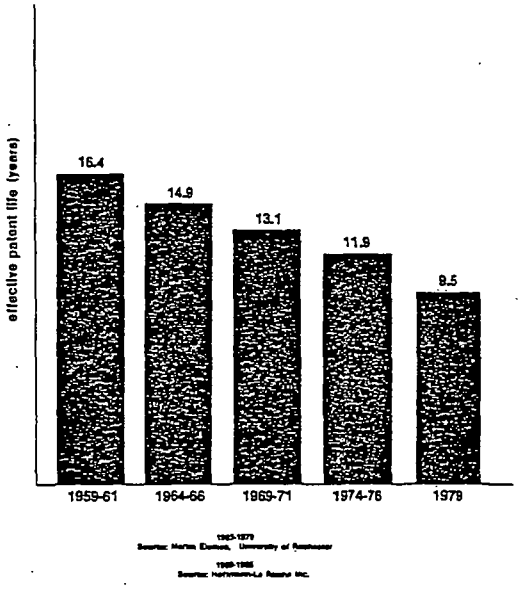
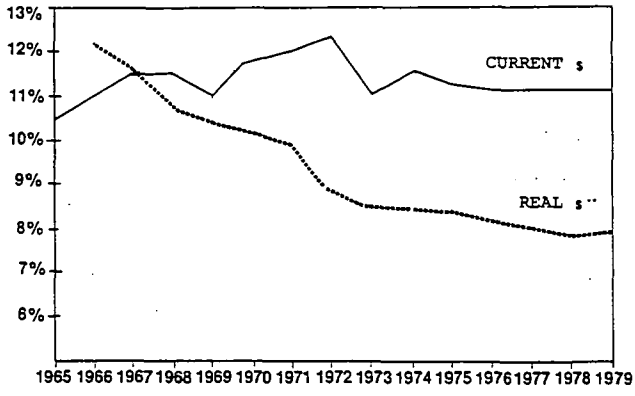


EXHIBIT "C"

Drug research is lagging behind the industry's growth rate.

Although drug companies continue to reinvest a steady 12% of their sales in research, real levels of effort have not kept pace with industry sales growth because research costs have soared in relation to drug prices.

US Pharmaceutical R&D Expenditures as a Percentage of US Pharmaceutical Sales, 1965-1979*



*R&D as a percentage of sales is computed by dividing human and veterinary R&D expenditures in the United States by domestic production, i.e., domestic sales and exports (including subsidiaries abroad), times 100.

** Sales Deflator: Producer Price Index for Ethical Pharmaceuticals, Bureau of Labor Statistics; 1967 = 100.
R&D Deflator: Biomedical R&D deflator used by the National Institutes of Health, Department of Health, Education, and Welfare; 1967 = 100.
Source: *PMA Annual Survey* (various years).

Mr. KASTENMEIER. I compliment you on a good statement. I think your prepared statement does treat some things which we certainly will want to read if not discuss. I was interested in your statement that in 1960 the industry produced 50 new medicines; in 1979, 12 new medicines.

Is that a definitive number that you can identify? Obviously, we are not talking about numbers of patents, we are talking aout new medicines. Is that a discrete number?

Mr. ENGMAN. It is a number which is identified through the approval process at the Food and Drug Administration.

Mr. KASTENMEIER. They only approved 12 new drugs last year?

Mr. ENGMAN. These are the new drugs which were approved by FDA.

Mr. BUTLER. May I interrupt at this point? Is this a reflection on the Food and Drug Administration? How is this relevant? Is it a cost of development of new medicines rather than the term of the patent?

Mr. ENGMAN. Mr. Butler, I think it is a reflection of a number of items, of course. The length of time of the approval process, which has lengthened dramatically at FDA since 1962, has had the effect, as I indicated in my testimony, of reducing the effective patent life and that certainly is a factor.

If we believe in a patent system—in allowing the market incentives to work in a system such as ours—we should be concerned about reducing by one-half the incentives for development of new medicines.

At the same time it is certainly true that the costs of developing a new drug have risen dramatically and now approach in direct and indirect terms some $70 million for each drug.

So I wouldn't want to pin it on any one element.

Mr. KASTENMEIER. Have these delays occasioned by the FDA overall in your view been unreasonable?

Mr. ENGMAN. We believe that those delays are excessive, yes. As a matter of fact, Mr. Chairman, approximately a year ago we took the initiative and through a series of indepth meetings within our industry and among our members and scientists and research people we came up with some specific suggestions for how this process could be shortened.

We have filed those suggestions as petitions with the Food and Drug Administration.

But it is a fact of life. It is also true as science creates more knowledge that the approval process will of necessity take some longer period of time.

Mr. KASTENMEIER. Mr. Engman, I think we were first apprised of the issue when we were looking at the patent policy and other questions last year.

While we do not presume to have solved this particular question last year we were aware of the issue of regulatory delay.

In the meantime, in the last year we have seen a very notable change in Government, a shift in our executive branch away from regulation. Actually, I think even the Congress in 1980 in terms of regulatory flexibility act and a number of other ways moved away from regulation.

Surely this administration and probably the Congress as it is presently constituted even more so is moving toward deregulation. Is it not possible that the effect of this and what you have just talked about will obviate the necessity for patent term restoration legislation because might this problem of regulatory delay on the FDA be otherwise resolved?

Mr. ENGMAN. That is a very good question, Mr. Chairman.

I think it could be a serious one if it were not for the fact that your bill basically handles it in a very ingenious fashion.

First of all, I think we have to look at the movement toward deregulation and the atmosphere that has been created. It has in fact created greater competition once a patent life has expired. For example, the action taken by this administration, a policy Secretary Schweiker announced, with respect to the granting of paper NDA's encourages greater competition from generic products once the patent has expired.

As to whether or not an NDA should be granted to a second manufacturer after the expiration of the patent time—there has been a mixture of economic arguments.

What has happened in the deregulation climate is an encouragement of the more scientific kinds of judgments being made with respect to whether or not there is bio equivalence of the second drug. This policy encourages greater competition so there will be even greater pressures on the research intensive companies.

That is well to the good because this economy, I believe, should thrive on competition, but we have to recognize at the same time we want to encourage innovation and that is what the system is about.

To come back full circle and answer your question, let's assume, for example, that the Food and Drug Administration is successful in reducing approval time. Although the former Director has indicated he didn't think he could cut more than 6 months to a year off the approval time, if we were wrong and it were cut in half, the beauty of the legislation which is before us is that you don't add on any more time to the patent period than what has been lost during the approval period.

If it ultimately takes 3 years to approve a drug, then there is only a 3-year add-on to the patent period instead of a maximum 7. It is not an automatic thing which is just tacked on to the patent of every drug going through the process.

Mr. KASTENMEIER. Theoretically, then, if we abolish the FDA and there is no approval process at all it wouldn't have any effect?

Mr. ENGMAN. That is correct, although I wouldn't want to hold my breath for that and furthermore, I don't think it would be a good thing.

If for no other reason, there would be too many people out there looking for my job.

Mr. KASTENMEIER. I don't think that is going to happen.

But to make your point to the whole sweep of possibilities I say that.

I think it is fair to say the primary opposition to the legislation comes from the generic industry. Indeed, some States have enacted laws requiring substitution of cheaper generic equivalents when available for State-run institutions.

Would the effect of extension of patent term cost any more to these institutions in a direct or indirect sense? Can we tell them that the so-called cost of savings to health care institutions and consumers will not be increased as a result of this legislation?

Mr. ENGMAN. I believe that the effect of this legislation is going to be procompetitive. Let me explain why. First of all, it does not apply to any product now on the market. Any medicine on the market does not have its patent term increased and presumably is subject to the same competitive strictures that everyone faces in this industry.

Second, the theory of the patent law is that by making incentives for developing new medicine the same as for developing a new mousetrap—17 years—you will encourage more new medicines and more new therapies. Presumably some of those therapies would not be developed at all or not as soon with a system with less incentive to do so.

Furthermore, these new drugs that are coming onstream now are basically very, very cost effective kinds of drugs. They replace, as in the case of Tagamet, the need for surgery and hospitalization.

By taking a pill you can eliminate the need in most instances for surgery so the overall impact should be a most effective one from the point of view of our overall health care policy and program.

Beyond that, one would expect as new drugs come on the market that there will be a downward pressure on the prices of existing drugs on the market which may be efficacious today and still might be used by some people for certain illnesses, but would be facing increased competition from even newer therapies.

So, on balance, I believe that this is a procompetitive bill.

Mr. KASTENMEIER. Being procompetitive may or may not be the same thing as a savings to the health care institutions or the consumers. I would not be able to say when the director of a State institution comes to me and says, well, what about this? I cannot merely say the bill provides for more competition.

Mr. RAILSBACK. Will the gentleman please yield?

Mr. KASTENMEIER. Yes.

Mr. RAILSBACK. I think Mr. Engman, however, made a good point when he did refer to Tagamet, which is Smith Kline's ulcer drug, where it would save some $250 million in foregone surgery and physician visits.

Mr. KASTENMEIER. Those are excellent examples, of course, but that assumes that Tagamet and these others would not be on the market except for the Patent Restoration Act.

I don't know cause and effect whether we can actually go that far. I assume a major drug would be developed in any event.

As I observed at the outset, I think the number of new approvals, 12 new medicines—I am not knowledgeable pharmaceutically to know what 12 versus 50 means, other than the numbers. That is, I don't know whether there is another possible explanation but I have to assume that we will, notwithstanding the problems we have had in terms of FDA regulation, continue to produce some of these new medicines.

In any event, I would yield to the gentleman from Illinois. I have some other questions.

Mr. RAILSBACK. Did you want to make a response?

Mr. ENGMAN. I was only going to make one comment and that is when I took my courses in economics, I used the words "competition" and "downward pressure on prices" almost interchangeably so when I was speaking in answer to your question about there being greater competitive factors; it naturally follows that there will also be a greater downward pressure on prices of drugs over and above the savings from new therapies which can replace hospitalization and the other medical costs.

Medicines are roughly 7 or 8 cents of our overall health care dollar and the expensive components, the ones increasing faster than the rate of inflation in our economy, are the hospitalization and other nondrug treatments. So that to the extent we can restore the innovation for developing new medicines we will be helping to create that downward pressure on the overall costs of our health care system.

Mr. KASTENMEIER. I must put in this plug for the pharmaceutical industry. My observation as a layman is there have been produced an incredible number of effective drugs in the past generation and the industry can take credit for it.

I do not see that we are not making progress. It may be that we could do even better. I am not sure. I really have not heard complaints that the pharmaceutical industry is not producing answers.

As a matter of fact, in some respects—genetics or other tangentially related areas—we may be moving so fast as not to be able to fully socially comprehend where we are going. That is perhaps not directly the fault of the pharmaceutical industry.

Mr. ENGMAN. It is true there have been vast advances in science with respect to the development of new therapy and new medicine. It is also true that there are people who contact me who have illnesses which are not treatable at the present time by current medication and who don't share your rosy view of what has been done by the industry.

What it comes down to is why should we in effect have a patent life for drugs which is roughly half that for anything else?

Mr. RAILSBACK. Thank you, Mr. Chairman.

We had a witness from the Office of Technology Assessment. I must say that I have not had a chance to read carefully their report, but I am aware that they seem to hedge their recommendations. In other words, I thought they were going to arrive at one conclusion and then they threw in another factor that they indicated might change the basis of their original recommendation.

Have you had a chance to study their report? And are there any particular areas that you would like to critique of their report?

In other words, did you find it lacking or were there areas where they used erroneous statistics? Or would you prefer not to comment about that?

Mr. ENGMAN. I am always stupid enough to comment about everything. As I indicated in my statement, I do believe the OTA report does support the case for patent restoration.

Obviously, if you sit down and begin to nitpick you can find areas where any individual can think somebody might have said it better or done a better job.

I think the OTA is in a difficult posture because it is a research-oriented agency. But in responding to requests of Members of the House and Senate and having been in the Government at one point myself, I know the pulls and tugs that can go into that process.

If I were just going to pick out one item, the OTA report at one point does recognize that in real terms, in real dollars, if we account for different rates of inflation over the period of time that we have seen erosion of effective patent life, the costs of R. &. D. have escalated faster than drug prices. In effect, you apply two different but valid deflators.

At another place that individual or someone else putting the report together talked of R. & D. expenditures in terms of proportion of sales in real terms.

We believe the more accurate approach would be to use the NIH biomedical R. & D. deflator with respect to R. & D. expenditures and the producer's price index with respect to the prices of products and sales. Applying those factors we see in real terms, I believe, a reduction of R. & D. expenditures which has more or less paralleled the reduction in patent life.

I can point out or question other areas but on balance I think the report is supportive.

Mr. RAILSBACK. Let me interrupt just to point out on page 34 of their report it says, "Real growth has occurred in expenditures of funds for R. & D. In Table 12, the current foreign and domestic dollars spent on R. & D. have been deflated for the years 1965 through 1978, using the NIH biomedical and R. & D. cost deflator."

I am curious if you take out of that equation the foreign dollars spent, would there be a similar result?

Is there any truth to the fact that maybe efforts in foreign countries where the laws are different there may be more expenditure for research and development than where you have a very short patent life?

Mr. ENGMAN. That is certainly true. There has been a trend toward more R. & D. overseas both with respect to investment overall as well as specifically related to pharmaceutical products.

Mr. RAILSBACK. What is the figure for domestic?

Mr. ENGMAN. I don't know whether that could be obtained or not. With respect to those particular numbers used in the OTA report, I would challenge that they were not using the accurate deflators in that particular table.

If you do use those accurate deflators, you would see a reduction from 12.6 percent of sales in 1962 to about 7.9 percent of sales in 1979.

The foreign component I cannot tell you. I can tell you this, however. If we use the R. & D. to sales ratio and if we use an assumption of 1970 being 100, the U.S. research and development expenditures relative to sales have basically remained constant since 1970.

The United Kingdom index has increased from 100 to approximately 170. The Japanese, as you all know from recent articles and the like, are moving very rapidly into this area. This is consistent with National Science Foundation's figures we have showing an overall reduction in U.S. R. & D. and an increase in the R. & D. in Japan and Germany and some other countries.

Mr. RAILSBACK. I guess my question would be you have indicated you are not certain but I think it would be interesting, rather than using table 12 in their book which includes the total domestic and foreign R. & D. to separate the two and show domestic separate from foreign.

On page 35 of their report there is a table 13 in which they indicate a relatively little change in emphasis as far as basic research and product development.

I think I would like to have somebody prepared to address whether they think these statistics support those as accurate.

Mr. ENGMAN. I would say, Mr. Railsback, many of the breakthrough medicines may come through applied R. & D. as opposed to basic R. & D. so there may be a question of the relevance or the distinction between those two items. But we can provide you further information with respect to that.

It is clear from the work which has been done by Mr. Wardell at the University of Rochester that the number of new chemical entities that have been introduced by foreign firms has been increasing significantly with a static or decreasing rate from U.S. firms.

Mr. KASTENMEIER. The gentleman from Virginia.

Mr. BUTLER. As I listened to your testimony it seems to me that the problem is the FDA. If we extend the patent life then this will take the pressure off the FDA and not solve the problem but give up on the bottleneck.

Mr. ENGMAN. I agree with you that part of the problem is the FDA, but we have to recognize that time is a very important factor when you are talking about investments of the magnitude of $70 million for a new drug. A company would prefer to have that product approved sooner than later, even though if it were later there would be a patent extension, because they are losing the capability of reinvesting those funds into other projects, and making a profit on it.

That is part of the system. So the industry will continue to push, encourage and work with the FDA to shorten that approval process, not at the expense of safety and efficacy, but to streamline.

It certainly is clear in this administration and the Congress also, there will be similar pressures so I don't believe you will have the impact of companies saying, all right, now we have our little basket and we will sit back and enjoy it, because they would still be losing in terms of that money having to sit there.

Mr. BUTLER. I tried to follow your discussion with Congressman Railsback. Let me see if I did. This sentence appeared in the testimony from OTA: "In the years 1965–78, research expenditures averaged about 8.5 of total sales and the relationship between revenues and R. & D. expenditures remained highly stable in the past 15 years." You are not challenging that, are you?

Mr. ENGMAN. I am saying that figure may be accurate for what its assumptions provide. But what has happened in this industry is that the inflation factor for R. & D. costs has gone up higher than the inflation factor for the prices of the products being sold.

If you use the pertinent factors applied to each element, you will come out with a decline in real terms in investment in R. & D. vis-a-vis sales.

Mr. BUTLER. I can follow that.

Mr. ENGMAN. That is contained in a chart which we have attached to my statement as Exhibit C.

Mr. BUTLER. So in effect you are telling us—and I think that makes sense that your commitment to research has been pretty much parallel to reduction in the patent life.

Is it necessary to follow from that that an extension of the patent life will reinvigorate your commitment to research expenditures?

Mr. ENGMAN. Yes. The whole system that we operate under is a system of permitting market forces to operate with incentives, and the incentive which is deemed to encourage innovation basically has been the patent system which this committee deals with every year.

What has happened is that we have reduced those incentives inadvertently, through no action of Congress, and by increasing those incentives we are going to have more R. & D. expenditures which will lead to an increase in the rate of new medicines being developed which will provide new therapy more quickly to people in this country.

Mr. BUTLER. That will be reflected—first, I want to say I appreciate the contribution of your industry to the health of the Nation and I don't want to suggest for a moment there may be some other motivation.

Let's assume that the profit motive is the factor. Is the expectation then with extended life the profits in the research intensive firms will be substantially increased?

Mr. ENGMAN. The profit factor and the expectation of profit is one of the key components of what makes our market economy and system operate.

Mr. BUTLER. I am not critical of that.

Mr. ENGMAN. That is part of the system. So my answer to your question would be simply yes. I would caution, however, that expectation of profit may not always be equivalent to what profit is realized.

If you are in a very competitive situation and you have encouraged a lot of research and development and a lot of new products keep coming on the market, as we have seen with respect to the electronics area the profits may not in fact increase. The expectation that profits will increase is what drives the engine.

Mr. BUTLER. Turning once more to the OTA, in the statement of the gentleman before us:

> I will now address the implications of patent term restoration for the pharmaceutical industry members and for consumers. For the research intensive firm patent term extension may provide an immediate incentive to undertake R. & D. through increased long-term potential for R. & D.
>
> Once extensions begin to run, additional resources will provide some firms with further incentive. The bulk of revenues generated by patent term extension will be obtained by a few firms who have developed financially successful drugs. The increased revenues may serve to perpetuate their dominance in particular research areas and other firms lacking expertise may possibly be discouraged from entering these areas.

Would you like to respond to that?

Mr. ENGMAN. I think that we have seen if there is a vigorous climate for innovation that no single firm has the monopoly on

new ideas. We have seen it overnight with development of these new recombinant DNA firms which sprang up from nothing and became Wall Street wonders.

It is a fact of life that the increasing costs of bringing a new drug to market are going to make it increasingly hard for smaller firms to develop drugs as the costs increase.

By the same token, from my experience in enforcing antitrust laws I am not at all convinced all the ideas are going to come from the big firms.

Mr. BUTLER. How many big firms do we have dominating? Based on your antitrust experience are you satisfied there are enough big boys out there to keep it competitive?

Mr. ENGMAN. I know there is a lot of competition and everybody is jockeying for position with respect to recombinant DNA to get a foot in the door. There is a lot of competition.

Mr. BUTLER. Quoting further, "Since the economic incentives provided by patent term extension will be greatest for drugs with high income potential, the tendency of firms to direct their research toward large markets will be reinforced."

[The information follows:]

PATENT-TERM EXTENSION AND THE PHARMACEUTICAL INDUSTRY

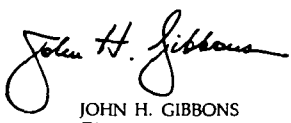
OTA Reports are the principal documentation of formal assessment projects. These projects are approved in advance by the Technology Assessment Board. At the conclusion of a project, the Board has the opportunity to review the report but its release does not necessarily imply endorsement of the results by the Board or its individual members.

CONGRESS OF THE UNITED STATES
Office of Technology Assessment
Washington, D.C. 20510

Foreword

This report examines the relationships between patent-term extension and pharmaceutical innovation. Particular attention is paid to the social implications of patent-term extension. The report was prepared in response to a request from the Chairman of the House Committee on the Judiciary and supporting requests from the Chairman and the Ranking Minority Member of the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce.

The Office of Technology Assessment was assisted by an advisory panel comprised of pharmaceutical industry representatives, consumer interest group spokesmen, medical professionals, lawyers, and others concerned with health care and pharmaceutical innovation. Reviewers from universities, Government, consumer interest groups, industry, and the law provided helpful comments on the draft report. The Office expresses sincere appreciation to all those individuals.



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Executive Summary

INTRODUCTION

Patents were designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.

Although the patent term in the United States is 17 years, the period during the patent term in which products are marketed (the effective patent term) is usually less than 17 years because patents are obtained before products are ready to be marketed.

Effective patent terms are influenced by many factors, including Federal premarketing and premanufacturing regulations. The products covered by these regulations include pharmaceuticals, medical devices, food additives, color additives, chemicals, and pesticides. These products are subject to different regulations that have had varying impacts on effective patent terms.

The regulations governing the pharmaceutical industry have contributed to a decline in the average effective patent term of prescription drugs. Pharmaceuticals cannot be marketed in the United States until they have been approved by the Food and Drug Administration (FDA). To obtain such approval, drugs must undergo extensive testing to prove they are both safe and effective. While the pharmaceutical awaits approval, its patent term keeps running.

Concern exists that the decline in the average effective patent term of pharmaceuticals may result in diminishing profits, decreased research and development (R&D) expenditures, and an eventual decline in the introduction of new drugs. Furthermore, to many, it appears inequitable that products subject to premarketing or premanufacturing requirements are marketed under patent protection for briefer periods than products that are not subject to such regulation.

To address the concerns that have arisen about innovation and equity, legislation has been proposed that would extend the patent terms for products affected by premarketing and premanufacturing regulations.

Although this report briefly describes the equity issue, its focus is on the relationship between patent-term extension and innovation in the prescription drug industry. The effects of patent-term extension on the members of the industry and on consumers are also examined.

THE CONTROVERSY

Pharmaceutical firms that are heavily involved in basic research (research-intensive firms) support legislation to extend patent terms. These firms claim that the costs of R&D are rising, effective patent terms are declining, and the rates of return to pharmaceutical expenditures are becoming unattractive. They maintain that, under these circumstances, a decline in innovation would not be unlikely and point out that future health care in the United States would suffer if pharmaceutical innovation declines.

Research-intensive firms believe that patent-term extension will provide encouragement for research activities, raise the profitability of drug research for successful innovations, and ultimately result in more innovative products. They contend that the additional drugs will increase pricing competition among different

products used for the same or similar ailments and that the consumer will actually save money as a result of patent-term extension.

The firms that derive most of their revenues from nonpatented, generically equivalent drugs (production-intensive firms) believe that patent-term extension will delay their entry into the market and that they will be economically penalized for each year that the extension prevents them from marketing drugs. They also contend that for some drugs, the product life remaining after the extension may be too short to justify their entry into the market. They believe that competition will decline as a result of patent-term extension and that the costs of drugs will therefore increase.

The production-intensive firms contend that many drugs are covered by more than one patent and that the combined patent terms often result in patent protection for the drug in excess of 17 years. They also point out that as a result of nonpatent barriers to market acceptance of generically equivalent products, patented products often maintain an exclusive market position even after their patents expire.

Production-intensive firms believe that some extensions might be equitable in certain situations in which the combined period of protection from all patents on the drug during its marketing is significantly less that 17 years due to excessive regulatory delay. They urge that any legislation for patent-term extension minimize any adverse effects on their industry and facilitate their effective entry into the market upon expiration of the extension. They are opposed to any legislation that would enable products covered by more than one patent to be protected by patents for more than 17 years, and they believe that the duration of the extension for any product should not exceed the actual marketing delay caused by premarketing regulations.

Spokesmen for consumer interest groups believe that patent-term extension will result in higher drug prices without providing better health care. They point out that increased drug costs will fall disproportionately on the elderly and chronically ill (whose incomes tend to be lower than average). They argue that the pharmaceutical industry is extremely profitable and needs no additional incentive to conduct research. These groups are concerned that the legislation proposed to date provides no guarantees that additional revenues derived during patent-term extensions will be invested in R&D activities. Concerns are also expressed that expenditures made for R&D may not be directed toward research areas that provide the greatest benefit to society. Therefore, many consumer spokesmen oppose patent-term extension.

FINDINGS

This study examines the issues raised by the various interest groups. Unfortunately, much of the data needed to differentiate between belief and fact are unavailable or unreliable. The evidence that is available neither supports nor refutes the position that innovation will increase significantly because of patent-term extension. Thus, the net effects of patent-term extension on pharmaceutical innovation cannot be ascertained. However, findings have been developed that should serve to clarify or explain many of the individual factors that have played, or will play, a role in pharmaceutical innovation.

The following is a list of our major findings, which will be discussed in more detail in the later sections.

- The costs of R&D for the average new chemical entity drug have increased.
- Since 1966, average effective patent terms have declined; some factors influencing effective patent terms are, however, changing and there is reason to believe that the decline may be halted in the future.
- Revenues of the pharmaceutical industry have increased steadily and the relationship between revenues and R&D expenditures has remained stable.
- The effects of governmental actions that encourage use of generically equivalent drugs have thus far been minimal on the postpatent revenues of research-intensive firms but could become substantial in the future.

- The prices of drugs whose patents are extended are likely to be higher during the extended period than they would have been if patent protection had ended.
- Competitive pressures on patented drugs from generically equivalent drugs will be delayed and in some cases prevented by patent-term extension.
- The extension will increase the attractiveness of research on drugs that have large markets but will not increase the economic attractiveness of research on drugs whose potential markets are small.
- The effects of patent-term extension on innovation, the industry, and society will depend in part on the nature of the patent rights during the extension.

INNOVATION IN THE PHARMACEUTICAL INDUSTRY

Pharmaceutical innovation has resulted primarily from the activities of private industry, most of the expenditures being made by large, multinational companies.

In the pharmaceutical industry a long period exists between the initiation of research and the marketing of new products. Thus, the rate of innovation observed today may reflect decisions made 10 or 15 years ago, and decisions made today will affect innovation for the next decade.

The results of the innovative process in the pharmaceutical industry are often measured by the number of new chemical entity (NCE) drugs that are introduced into the market. By this measure, a sharp decline in innovation occurred with the adoption of the 1962 amendments to the Food, Drug, and Cosmetic Act, which substantially increased the stringency of the drug approval process. The number of NCEs judged by FDA to offer important or modest therapeutic gain has, however, been relatively stable. Although different measures produce different results, by most measures innovation does not appear to be increasing.

TRENDS IN THE FACTORS AFFECTING PHARMACEUTICAL INNOVATION

Innovation will not occur unless industry undertakes R&D activities. Many factors that influence R&D decisions appear to favor innovation: the industry continues to enjoy high and stable profits in terms of return to stockholder's equity; research techniques have improved; and competitive pressure for innovation has not diminished.

Nonetheless, there is a widespread belief that the return to R&D investment is declining, and this belief can affect R&D decisionmaking. Because data are insufficient to measure accurately the return to research investment, we have focused on the underlying factors influencing the returns. The major factors are the costs of R&D activities, the amount invested in R&D, and the revenues and profits of the firms conducting research.

The costs of R&D activities associated with an NCE drug have been increasing rapidly as a result of inflation and more stringent and time-consuming testing requirements. Because the time spent in obtaining FDA approval may be leveling off and new research techniques are being developed, R&D costs should increase more slowly in the future.

Real growth has occurred in expenditures for R&D. The relationship between revenues and R&D expenditures has remained highly stable over the past 15 years. For the years 1965 through 1978, research expenditures averaged about 8.5 percent of total sales.

The revenues and profits are influenced by the competitive pressures exerted on drugs. The competition may be from other patented drugs,

from nondrug therapies, or from generically equivalent drugs that are produced by either research-intensive firms or production-intensive firms. Of the drugs having generic competition, about 80 to 85 percent are sold by research-intensive companies.

Despite the decrease in the average effective patent term that may have allowed generic competition to enter the market earlier, the revenues and profits of research-intensive firms have thus far not been significantly affected by generic competition. But recent governmental actions could result in increased competition from generically equivalent drugs. Most States now have laws that allow or require generic equivalents to be substituted for brand-name drugs specified in prescriptions. FDA has adopted procedures to facilitate approval of generically equivalent drugs. The Federal Government now bases its reimbursements for prescriptions paid for under medicaid on the lowest wholesale price of generically equivalent drugs. Furthermore the Supreme Court has ruled that laws prohibiting the advertising of drug prices are unconstitutional.

Despite Government action to encourage use of generically equivalent drugs, barriers to the acceptance of these products still exist. Physicians, who determine the market for prescription drugs, tend to write prescriptions for the easily recalled brand-name drugs. Pharmacists fear they will be liable if they fill a prescription for a brand-name product with a generic equivalent that later causes injury. Furthermore, consumers tend to prefer drugs that look exactly the same as the drugs they are accustomed to using.

Thus, the effect of generic competition on the revenues and profits of research-intensive firms in the future is uncertain. If generic competition increases significantly, such revenues and profits could decline and R&D expenditures could be reduced. There is a possibility that additional generic competition could encourage research-intensive firms to increase their R&D expenditures in an effort to maintain their market shares through drug innovations.

IMPLICATIONS OF PATENT-TERM EXTENSION FOR PHARMACEUTICALS

Patent-term extension can encourage the development of new drugs through the incentives it provides to the patent owner (patentee). But by delaying use of the patented technology by the public, it may also delay some improvements in patented drugs.

Patent-term extension specifically addresses the prime concern of the research-intensive firms: the perceived decline in the rate of return to R&D investments attributed to the reduction in effective patent terms. Whether R&D activities actually increase as a result of longer effective patent terms will, however, depend on decisions made in the private sector.

Since patent-term extension will not provide additional revenues until original patents expire and extensions begin to run, the immediate incentive provided by extension legislation is the potential for obtaining greater returns on R&D investment in the future. Once extensions do begin, revenues for some firms will be greater than they otherwise would have been, thus providing additional incentive for R&D activity.

The price of drugs whose patents are extended will be higher during the extended period than they would have been if patent protection ended. The magnitude of the additional cost to the consumer will be significantly influenced by the extent to which generic competition would have existed had the patent term not been extended.

The bulk of revenues generated by patent-term extension will accrue to a few firms who have developed financially successful drugs. The increased revenues may serve to perpetuate their dominance in particular research areas, and other firms, lacking expertise, may be discouraged from entering these areas.

Since the economic incentives provided by patent-term extension will be greatest for drugs with high income potential, the tendency of firms to direct their research toward drugs with large market potential will be reinforced. Some therapeutic areas that are apt to produce economically marginal drugs may receive greater attention as a result of patent-term extension but patent-term extension will not affect research on drugs with small market potential.

The patent owner and the research-intensive firm will generally benefit from patent-term extension. To the extent that a research-intensive firm relies on revenues from the sale of generically equivalent drugs, its benefits may be reduced.

Patent-term extension poses risks for production-intensive firms. Although they depend on innovative new drugs to expand their product lines, the remaining product lives of drugs coming off patents will detemine their long-term revenues. In some cases product lives may be insufficient to justify their entry into the market.

Consumers will benefit if more and better pharmaceuticals are developed. These pharmaceuticals can provide substantial savings over other forms of health care. The cost of drugs for consumers will be higher than it would otherwise have been unless patent-term extension results in the introduction of more new drugs that exert a downward pressure on the prices of existing drugs. It is expected that both the benefits and the additional costs will affect the elderly and the chronically ill more than other segments of society; but patent-term extension will have no effect on either benefits or costs for at least a decade.

THE MECHANICS OF PATENT-TERM EXTENSION

The effects of patent-term extension can only be fully assessed in terms of specific proposals, because the effects will vary depending on the particular form the extension takes. This report has examined several proposed forms of patent-term extension to determine their possible implications for innovation.

Patent-term extension involves a modification of the present patent system. Therefore, in order to understand extension proposals, one must have a basic understanding of how the patent system works. In brief, a patent is granted for an invention which may be, for instance, a new drug, a new process for making a drug, or a new method for using a drug to treat an illness. A patent provides the right to the patentee to exclude others from making, using, or selling the invention in the United States for 17 years. In return, the patentee discloses his invention. Once the patent expires, anyone is permitted to use the invention.

The invention that is patented is defined by claims which establish the boundaries of the invention, much like a deed establishes the boundaries of a piece of land. A claim for a particular invention may thus include many potential products or processes. When a patentee attempts to enforce a patent, the claim is compared with the product or process against which the enforcement action is directed to determine whether it is included within the definition of the invention contained in the claims.

The effects of patent-term extension on the rights of the patentee and on the ability of others to use the invention will depend in part on whether patent protection is extended for the entire invention defined by the claims or for only a portion of the claimed invention. Effects will also differ depending on whether limitations are placed on the products, processes, and methods for use against which the patent can be enforced.

Numerous proposals that affect patent claims and their enforceability during the extension are examined in this report. Of these proposals, three enable the patentee to maintain an exclusive market position for the drug, while

allowing others to use the invention for some purposes during the extension.

1. In the first of these proposals, the extension is provided for only those aspects of the claimed invention that involve the specific chemical contained in the drug approved by FDA and the patent is enforceable only against products, processes, or methods-for-use that must be approved by FDA. Of the three proposals, this one provides the greatest protection to the patentee.

   It permits others to use the patented invention for anything except drugs and allows others to make, use, or sell variations of the patentee's specific chemical for any drug therapy even though the variations may be included within the entire invention defined in the claims. It prohibits use of the patented invention for a drug therapy only if the patentee's specific chemical is used.
2. In the second proposal, the patent rights are extended for the entire invention defined by the claim, but enforcement is limited to the specific therapeutic use approved by FDA. This proposal is broader than the previous one in terms of the active chemicals that are protected, but the patented technology can still be used for other drug therapies.

   This proposal permits the development of the patented invention for all uses other than the specific therapy approved by FDA. Under this proposal, enforcement of the patent would be difficult. A competitor could manufacture and sell the identical drug for a different therapy; the competitor's drug might then be prescribed and used for the patentee's therapy. The only remedy available to the patentee would be to sue each of the prescribers or users for patent infringement.
3. In the third proposal, the extension is provided only for those aspects of the claimed invention which involve the specific chemical contained in the drug approved by FDA, and enforcement is limited to the specific therapeutic use approved by FDA. Of the three proposals, this one provides the least protection to the patentee.

   This proposal permits others to develop the technology for all uses and allows others to make, use, or sell variations of the patentee's specific chemical for any drug therapy. Furthermore, others can make, use, and sell drugs using the patented technology and the patentee's specific chemical for any drug therapy but the one for which the patentee obtained FDA approval. Enforcement under this proposal is difficult for the same reasons that it is difficult in proposal 2.

Chapter 2

The Issue in Brief

INTRODUCTION

The U.S. Constitution vests in Congress the power "to promote the progress of science and the useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries" (art. I, sec. 8). Since 1861, U.S. patent law has specified that these rights shall be secured for a period of 17 years, beginning at the time the patent is granted by the Government. The period during the patent term in which a product is sold (the effective patent term) is, however, usually shorter than 17 years because patents are generally obtained before discoveries are ready to be marketed.

Thus, although all patented inventions receive protection for the same amount of time, the effective patent terms for the inventions vary. The length of an effective patent term depends on the amount of time needed to bring an invention to market; this time is influenced by numerous factors including the availability of capital, the pace of product development, and the ease with which distribution channels can be established.

In recent years, Federal premarketing and premanufacturing regulations have also played a role in determining the effective patent terms for particular products. These products, which include pharmaceuticals, medical devices, food additives, color additives, chemicals, and pesticides, are governed by different regulations that have varying impacts on effective patent terms. Although there are some exceptions, most of these products cannot be marketed until they have been approved by the Federal Government. In some cases, such as pharmaceuticals, this approval is granted only after the product has undergone lengthy clinical testing and extensive review to ensure its safety and efficacy. Since the patent term keeps running during the testing and review period, the effective patent term for the regulated product is reduced.

To remedy this situation, legislation has been proposed that would extend the patent term for products affected by premarketing and premanufacturing regulations. As proposed, these extensions would provide compensation for the period of time spent on testing and review of the product but would not exceed 7 years.

The purposes of the proposed legislation are twofold: to provide equitable protection to products whose marketing is delayed by regulatory requirements and to encourage innovation in industries affected by these requirements.

This study focuses primarily on the implications of patent-term extension for innovation in the prescription drug industry. The subject of equity to the patent owner is discussed only briefly to provide the reader with a background understanding of the issue.

THE PATENT SYSTEM AND PHARMACEUTICAL INNOVATION

Why are changes in the patent system viewed as a mechanism for addressing concerns about pharmaceutical innovation? The answer to this question is rooted in the basic relationship between the patent system and innovation. As used in this report, innovation means the introduction into the market of something new and excludes discoveries that do not reach the market.

According to theory, the primary incentive provided to the patent owner (patentee) by a patent is the ability to prevent for a limited time competitors from selling products of the same

type as the invented product. If the market accepts the product, the patentee can enjoy an exclusive market position, which enables him to charge prices that are higher than those he could have charged if direct competition existed. The potential for obtaining these higher prices can justify the risks and expenses involved in innovative activities.

The patent system has many attributes as a mechanism for promoting innovation. The patent system does not directly involve the Government in research and development (R&D) activities and does not necessitate complex regulatory or oversight activities on the part of Government. Whatever rewards occur derive from the marketplace. Because the patent system has undergone few changes in its 200-year history, a change in patent policy, such as patent-term extension, would probably be regarded as permanent, whereas a new program to provide incentives for innovation might be viewed as a temporary measure and therefore provide little security to the industry.

The use of patents as an incentive for pharmaceutical innovation does, however, have some limitations. Not all inventions can meet the standards established for patentability. Furthermore, although patents are granted for products, process for making products, and methods for using products, product patents can be more readily enforced than the other types of patents and are, therefore, more meaningful. The patent system may provide little or no incentive for the R&D of drugs that would be beneficial to society but that cannot be meaningfully patented. Furthermore, patent incentives alone may be insufficient to encourage the R&D of drugs that have a potentially small market.

In reading this report, the reader is cautioned to remember that the patent system is only one of many mechanisms available to the Government for promoting innovation. Innovation could be encouraged by changes in tax policy, increases in governmental funding of R&D, alterations in the Food and Drug Administration's (FDA) approval procedures, and improvements in the general economic climate. This report does not address these other policy options for promoting innovation, nor compare them with the patent options.

THE LIFECYCLE OF A SUCCESSFUL NCE PHARMACEUTICAL

Before effective patent terms and innovation are examined, it is useful to have a basic understanding of the drug development process. For this reason a description of the lifecycle of a drug from the discovery of a new chemical entity (NCE) to the end of its marketing life is provided. This description is not intended to be representative of all innovative activity within the pharmaceutical industry; rather, it is presented so that the reader will have a framework for understanding later chapters.

Although important pharmaceutical innovations may result from new therapeutic applications of existing chemicals, new processes for making chemicals, or new combinations or formulations of existing chemicals, this study concentrates primarily on innovations resulting from the discovery or synthesis of NCEs. This approach is used for several reasons. Many of the pharmaceutical breakthroughs that have occurred have resulted from NCE research and the development of NCEs generally has required more time and money than other types of innovation and has involved greater risks. Moreover, because FDA testing requirements generally have been more time-consuming for NCEs than for other types of innovation, they have had their greatest impact on the effective patent terms of NCEs. By focusing on NCEs, the most extreme reductions in effective patent terms can be determined, but these effects are not representative of the average effects for all new pharmaceuticals.

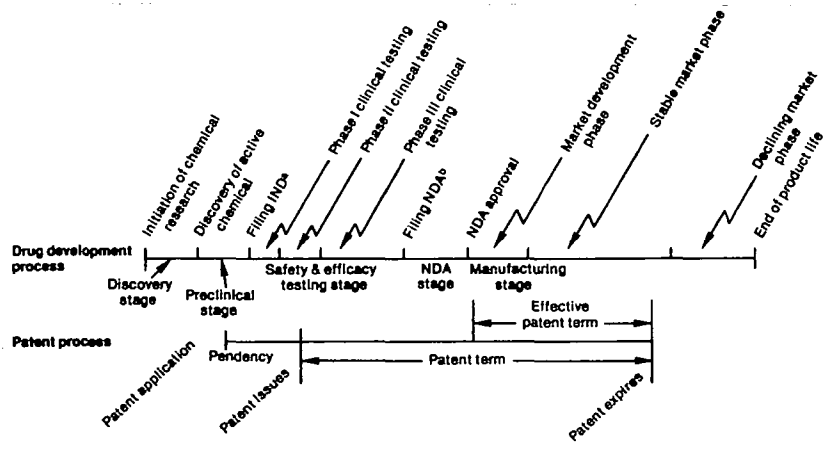
The drug development process for NCEs is time-consuming and expensive and is characterized by a high probability of failure. A decade or more may elapse between the time a chemical having promising biological activity is identified

and the time it is marketed as a new drug. The odds against developing a marketable pharmaceutical are great: on the basis of historic trends, only 1 out of 7,000 to 10,000 newly synthesized chemicals will be found to have promising biological activity.[1] Only 1 out of 10 promising chemicals will survive to marketing.[2] Taking into account the R&D costs of chemicals that fail to reach the market, one investigator has estimated that discovery and development costs per marketed NCE are in the neighborhood of $33 million (1976 dollars).[3] This estimate applies only to NCEs discovered, developed, and marketed by the same firm and includes only direct costs.

[1]William M. Wardell, "The History of Drug Discovery, Development and Regulation," in *Issues in Pharmaceutical Economics*, Robert I. Chien (ed.) (Lexington, Mass.: Lexington Books, 1979).
[2]Ibid.
[3]R. W. Hansen, "The Pharmaceutical Development Process: Estimates of Development Costs and Times and the Effects of Proposed Regulatory Changes," in *Issues in Pharmaceutical Economics*, Robert I. Chien (ed.) (Lexington, Mass.: Lexington Books, 1979).

Knowledge of the relationship between the drug development process and the patent process is essential for an understanding of the issues surrounding patent-term extension. Figure 1 shows the steps involved in both of these processes and indicates that these steps are taken concurrently. The patent process and the drug development process are, however, independent of each other and each progresses at it own pace. Although the figure accurately depicts the stages that a patented drug will pass through, the duration of each of the stages varies. Therefore, the relationship between the timing of the drug process and the timing of the patent process will also vary. A successful NCE must pass through five stages of the drug development process: the discovery phase, the preclinical stage, the safety and efficacy testing stage, the NDA (new drug application) stage, and the marketing stage. In most cases, the NCE will also be subjected to the patent process.

Figure 1.—The Drug Development Process and the Patent Process



[a]IND: notice of claimed investigational exemption for a new drug.
[b]NDA: new drug application.
SOURCE: Office of Technology Assessment.

Drug Development—The Discovery Stage

The discovery stage involves the synthesis or isolation of new chemicals.[4] Initial screening tests are conducted to determine whether the new chemicals possess sufficient biological activity to be worthy of further investigation. This stage may be relatively short if the research is quickly fruitful. On the other hand, many years or even decades may pass before a suitable candidate is discovered.

Drug Development—The Preclinical Stage

Once a promising new chemical is identified, the preclinical stage begins. In this stage, the new chemical is tested in animals to determine its short-term toxicity. Results of these tests are studied carefully for indications that the chemical might not be safe to use in tests on humans. The preclinical stage generally lasts from 1 to 2 years.

Patent Process—The Application

Although the patent process is independent from the drug development process, in many cases a patent application for an NCE will be filed in the U.S. Patent and Trademark Office (Patent Office) when a drug is at the discovery or preclinical stage. Sufficient information exists at this time to prepare a patent application which fully complies with the patent laws. An early filing of a patent application is encouraged by the patent laws of the United States and most foreign countries, since when two or more investigators independently arrive at the same discovery, the investigator who first files a patent application generally has an advantage in obtaining the patent. Also, early filing is encouraged since a disclosure of the invention before the patent application is filed can bar a patent. (For clarification, see ch. 5.)

Several inventions may be made when an NCE is discovered and developed such as the chemical itself, the process for making the chemical, and the method for using the chemical to treat an illness. Separate patent applications could be filed on each of these inventions.

Drug Development—The Safety and Efficacy Testing Stage

The third stage of drug development involves clinical testing and long-term animal toxicity testing. These tests are conducted to satisfy the premarket approval requirements of FDA. These requirements that include the types of tests, the procedures to be used, and the standards to be met, may vary among therapeutic classes (groups of drugs used for similar purposes) and even among drugs for use within a therapeutic class.

The third stage begins when a request for authorization to begin human testing is filed with FDA. The request is termed a notice of claimed investigational exemption for a new drug (IND). Once authorization is received, the first of three clinical testing phases can be initiated. In phase I chemical testing, a small group of volunteers receive dosages of the investigational drug for a short period of time. The primary purpose of the phase I clinical testing is to look for evidence of toxicity or undesirable reactions. Phase I clinical testing can usually be conducted in less than 1 year. Only about one-half of the promising new chemicals identified in the discovery stage survive through phase I clinical testing.

Phase II clinical testing is similar to phase I testing, but more human subjects are used and the investigational drug is administered for a longer period of time. The primary purpose of phase II testing is to ascertain the effectiveness of the investigational drug. Phase II clinical testing may require about 2 years to complete.

Phase III clinical trials are conducted on a large scale; they often involve several hundred human subjects and are conducted for substan-

[4]For a more detailed discussion of the discovery stage, the preclinical stage, the safety and efficacy testing stage, and the NDA stage, see: R. W. Hansen, "Pharmaceutical Development Process," William Wardell, "History of Drug Discovery," and J. R. Virts and J. Fred Weston, "Expectations and the Allocation of Research and Development Resources," in *Drugs and Health*, R. B. Helms (ed.) (Washington D.C.: American Enterprise Institute for Public Policy Research, 1980).

tial periods of time. These tests are designed to determine the efficacy of the investigational drug and to uncover any unanticipated side effects that the drug may have. Generally, phase III clinical trials last about 3 years.

While the phase III trials are underway, long-term animal toxicity studies are also conducted. The purpose of these studies is to determine the effects of prolonged exposure and the effects on subsequent generations. The duration of the studies and the animals used vary widely among therapeutic classes. For drugs that affect the reproduction system or that will be used over long periods of time, the animal toxicity studies will be expensive and of long duration.

Patent Process—Examination and Grant

If the patent application was filed during the discovery or preclinical stage, it is not unlikely that the patent will be issued during the safety and efficacy testing stage. Before a patent can be issued, a patent application is examined by the Patent Office to determine whether the invention is patentable (e.g., novel and not obvious in view of the state-of-the-art). If the invention meets these requirements, a patent is granted (issued) by the Patent Office. The average pendency of a patent application in the Patent Office is about 2 years; however, the pendency is subject to wide variations as will be discussed in chapter 5. If more than one patent application were filed in order to cover several inventions made during the discovery and development of a drug, these applications could issue as patents at different times.

Drug Development—The NDA Stage

Before a drug may be marketed, an NDA must be submitted to and approved by FDA. Frequently, the NDA is filed before phase III clinical tests and long-term animal toxicity tests are completed. However, all the safety and efficacy tests must be completed before FDA will approve an NDA. During the NDA stage, FDA may require additional clinical or animal tests to be conducted. The time required for processing an NDA depends on the completeness of the testing data, the performance of the drug, and the speed with which FDA reviews the data. In 1980, the duration of the NDA phase (for NCEs) varied from about 1 to 7 years and averaged slightly less than 3 years.[5]

The NDA is approved by FDA for a specific drug that will be made by a specific process and used for a specific therapy. If the innovator wishes to change the composition of the drug or its manufacturing process or if he desires to sell the drug for a different therapy, he must file a supplemental NDA and obtain FDA approval for these changes.

Drug Development—The Marketing Stage

By the time the NDA is approved, part of the patent term usually has expired. The remaining patent term may be the only time that the drug has an exclusive market position.

The marketing stage is usually characterized by three periods: the market-development stage, the stable-market stage, and the declining-market stage. In the market-development stage, the demand for the new drug increases. In the stable-market period, the demand for the drug is relatively steady. Later, the market for the drug declines as new and better therapies and drugs are discovered, and eventually the manufacturer takes the drug off the market. Depending on the length of the effective patent term and the product lifecycle, the patent may expire during the market-development stage, the stable-market stage, the declining-market stage, or after the product has been removed from the market. Once the patent has expired, others can manufacture and sell the drug if they have secured premarket approval from FDA. The approval procedure for generically equivalent drugs is discussed in chapter 3.

[5]Department of Health and Human Services, *New Drug Evaluation Project, Briefing Book* (Washington, D.C.: Food and Drug Administration, Bureau of Drugs, 1980).

AN OVERVIEW OF THE PHARMACEUTICAL INDUSTRY

Pharmaceutical innovation has resulted primarily from the activities of private industry. Of the new dugs introduced in the United States between 1960 and 1969, 91 percent were discovered and developed by the industry.[6] Government, nonprofit research organizations, and universities were responsible for the remainder of the new drugs. Because the public relies so heavily on the industry for improvements in drug therapy, efforts to increase innovation must be based on a thorough knowledge of how the industry operates.

Throughout the past four decades, pharmaceutical sales have increased steadily, with the greatest growth occurring in the sales of ethical drugs (products prescribed by health care professionals). The 1978 sales revenues (wholesale) for ethical drugs were approximately $9.5 billion. Total U.S. expenditures for health care were $192 billion of which $15 billion or 7.9 percent were for drugs and medical sundries.[7] Although drug expenditures have increased dramatically over the past decade, they have increased much less rapidly than total health care expenditures.

Since the 1950's, the U.S. pharmaceutical industry has been considered one of the most profitable of all major manufacturing industries. As shown in table 1, the industry's after-tax rate of return on average stockholder's equity has remained stable at a relatively high level and has exceeded the average after-tax rate of return for all manufacturing.[8]

Table 1.—After-Tax Rates of Return on Average Stockholders' Equity 1956-79 (in percentages)

Year	Pharmaceutical industry	All manufacturing	Year	Pharmaceutical industry	All manufacturing
1956	17.6	12.3	1969	18.4	11.5
1957	18.6	11.0	1970	17.6	9.3
1958	17.7	8.6	1971	17.8	9.7
1959	17.8	10.4	1972	18.6	10.6
1960	16.8	9.2	1973	18.9	12.8
1961	16.7	8.8	1974	18.7	14.9
1962	16.8	9.8	1975	17.7	11.6
1963	16.8	10.5	1976	18.0	13.9
1964	18.2	11.6	1977	18.2	14.2
1965	20.3	13.0	1978	18.8	15.0
1966	20.3	13.4	1979	19.3[a]	16.4
1967	18.7	11.7	1980 (1st 3		
1968	18.3	12.1	quarters)	20.8	13.9

[a]Industrial classifications were changed. The percentage of companies reclassified in the drug industry is unknown.

Note: For the purpose of this table, the pharmaceutical industry is defined as corporations primarily engaged in manufacturing biologicals, inorganic and organic medicinal chemicals, pharmaceutical preparations, and grading, grinding, and milling of botanicals.

SOURCE: Quarterly Financial Reports, U.S. Federal Trade Commission.

The Industry Members

In 1979 the Federal Trade Commission staff estimated that the U.S. pharmaceutical industry consisted of 1,300 firms, of which about 750 produced prescription drugs.[9] The prescription drugmakers generally fall into two categories: 1) firms specializing in branded drugs (including patented and generically equivalent drugs), and 2) smaller firms specializing in nonbranded generically equivalent drugs. Throughout this report, firms in the first of these categories are referred to as research-intensive companies and firms in the latter category are referred to as production-intensive companies.

It should be noted that the line between research- and production-intensive firms cannot be easily drawn. Many research-intensive firms produce generically equivalent drugs as well as their own patented branded drugs. Both research- and production-intensive firms manufacture pharmaceuticals for each other, and both may purchase the active chemicals that they use in their products from other firms. In

[6]Federal Trade Commision, "Drug Product Selection," Washington, D.C., 1979 (staff report to FTC).

[7]U.S. Department of Health, Education, and Welfare, *Health United States—1979*, HEW publication No. (PHS) 80-1232 (Hyattsville, Md.: Public Health Services 1980, Office of Health, Research, Statistics, and Technology).

[8]The rates of return shown in table 1 were determined using an accounting procedure that treats R&D expense as current expenditures rather than capital investments. Regardless of the accounting procedure employed, the rate of return for the pharmaceutical industry is higher than that for all manufacturing. For further discussion see: Kenneth Clarkson, *Intangible Capital and Rates of Return* (Washington, D.C.: American Enterprise Institute, 1977), p. 64.

[9]Federal Trade Commission, "Drug Product Selection," op. cit.

some instances production-intensive firms, such as Generics Corp. of America, Biocraft Laboratories, and Philips-Roxane Laboratories, Inc., have engaged in NCE research.

Among the research-intensive firms, the size, type, and scope of research activities vary considerably. Based on these activities, research-intensive firms can be divided into three rough groupings:

1. *The large multinational companies.*—These firms account for the dominant share of pharmaceutical R&D expenditures. About a dozen domestic companies fall into this class, including Eli Lilly, Merck, SmithKline, Upjohn, and Pfizer. Together, the companies account for over one-half of U.S. ethical drug sales and well over two-thirds of the private pharmaceutical research in the United States.
2. *The midsized companies.*—These firms are primarily domestic, have research programs of a much smaller scale, and account for about one-quarter of the U.S. ethical drug sales. Included within this group are A. H. Robins and Richardson Merrell (Merrell National Division was recently purchased by Dow).
3. *The small research companies.*—These firms often conduct research in a limited therapeutic area. Firms, such as Marion Laboratories, that license drug technology and develop drugs for marketing in the United States also fall in this class.

In 1978, 24 firms had U.S. prescription drug sales that exceeded $100 million.[10] Foreign-based firms, such as Roche and Ciba Geigy, accounted for at least 25 percent of the firms in this group. In recent years foreign-based firms have increased their share of the U.S. market, but these efforts by foreign firms are not surprising since the United States represents the largest single market for pharamaceuticals.

In terms of worldwide sales, 10 of the 20 largest multinational pharmaceutical firms are based in the United States. U.S.-based firms and their affiliates account for more than 30 percent of total world sales.[11] Pharmaceutical R&D of U.S.-headquartered firms is, however, increasingly being carried out in other countries, which may have less stringent controls on R&D activities than our own. In 1978, more than $220 million was spent for R&D conducted by U.S. firms in foreign countries.[12]

In contrast with the research-intensive firms, about 600 production-intensive companies derive revenues primarily from the sale of nonpatented products marketed under the generic name of the drug, rather than under a trademarked brand name.[13] Consequently, these companies are often referred to as generic companies. Most of these companies have sales amounting to less than $10 million per year. They usually sell within limited territorial areas and together account for only about 15 to 20 percent of the sales of drugs available from more than one firm.[14] Because these firms generally do not engage in research or heavy drug promotion, the price of their products need not reflect such expenditures. Furthermore, the markup on these products may be lower. Therefore, production-intensive firms frequently sell drugs at prices that are considerably lower than the prices charged by innovator firms. Although some of these firms do engage in R&D activities for the purpose of formulating and compounding existing drugs to improve their activity and benefit to the patient, they generally do not direct their research activities toward finding NCEs.

The sales of U.S. production-intensive firms are generally exclusively domestic. Many production-intensive firms purchase drugs from foreign manufacturers.

In recent years, the market for generic drugs has been increased by some Government actions. For example, many States now allow or require pharmacists to fill prescriptions for

[10]Henry Grabowski and John Vernon, "Government Policy and Innovation in the Pharmaceutical Industry," draft report (Durham, N.C.: Duke University, 1980).

[11]Private communication with Henry Grabowski on July 3, 1981.

[12]Charles River Associates, "The Effects of Patent Term Restoration on the Pharmaceutical Industry," Boston, Mass., May 4, 1981 (report to OTA).

[13]Federal Trade Commission, "Drug Product Selection," op. cit.

[14]Ibid.

brand-named drugs with generically equivalent drugs. Under medicaid, reimbursements to pharmacists are limited to the cost of the lowest priced drug among generic equivalents plus a dispensing fee. The FDA approval procedure for drugs that are generically equivalent to existing drugs has also undergone changes favorable for generic competition. FDA plans to reinstate its "paper NDA" procedure in which published data of reliable safety and efficacy tests will be accepted in lieu of actual tests conducted by the second entrant. Also, in 1970, FDA adopted an abbreviated NDA (ANDA) procedure for certain drugs approved prior to the 1962 amendments to the drug regulation law. Under the ANDA procedure some drugs are able to obtain premarket approval without the submission of safety and efficacy data.

The Market for New Drugs

Industry undertakes R&D in areas that it believes will be profitable. The size of the potential market plays an important role in the selection of these areas. Two factors that influence the market size for any particular new drug are the number of people suffering from the ailment treated by the drug and the advantage the drug provides as compared with other drugs for the same ailment.

For an ailment that is relatively uncommon, the potential market may be so small that any drug, regardless of its therapeutic value, will have little chance of financial success. On the other hand, drugs offering significant or moderate therapeutic advantages to a large number of potential users will generally be financially successful because their advantages will enable the drugs to capture significant market shares. Even drugs that offer little or no therapeutic advantage to most users may be commercially attractive in a large market. Because physicians, rather than consumers generally determine the financial success of a drug, the creation of markets involves a great deal of advertising directed at physicians. On occasion, these marketing strategies can create a large market for a drug that offers only minimal advantages.[15]

Drugs are frequently divided into categories according to the types of ailments they are designed to treat. The market share of different therapeutic categories varies over time, but in 1978, sales of drugs directed at central nervous system disorders were 23.6 percent of total U.S. ethical drug sales; sales of anti-infectives were 15 percent.[16]

Drugs that obtain major shares of the market can meet with extraordinary success. Table 2 shows a ranking of the top eight prescription pharmaceuticals in the United States by sales in 1980. Although the sales figures have not been confirmed, they provide a relative indication of total sales.

The sales figures for the most successful drugs give little indication of average sales. In a study of a group of 119 NCE pharmaceuticals introduced in the United States between 1967 and

[15]Ronald Bond and David Lean, "Sales Promotion, and Product Differentiation in Two Prescription Drug Markets," Washington, D.C., 1977 (staff report to the Federal Trade Commission.)
[16]Charles River Associates, op. cit.

Table 2.—Sales Ranking of the Top U.S. Pharmaceuticals in 1980[a]

Drug (trade name)	Therapy	Manufacturer	U.S. sales (in millions of dollars)
Tagamet	Duodenal ulcers	SmithKline	$250
Valium	Antianxiety	Roche	$230
Inderal	Antiarrhythmic	Am. Home Pdts. (Ayerst)	$200
Motrin	Antiarthritic	Upjohn	$150
Aldomet	Hypertension	SmithKline	$145
Dyazide (dyrenium)	Hypertension	SmithKline	$145
Keflex	Antibiotic	Lilly	$140
Clinoril	Antiarthritic	Merck	$125

[a]By revenues.
SOURCE: *New York Times*, Sunday, May 17, 1981, quoting Oppenheimer and Co.

1976, the sales data (wholesale) were collected for the years during which the drugs were sold. Sales figures for products which were sold for less than 10 years were projected on the basis of historical trends. The top 25 percent of the new drugs had average annual sales of $21.1 million, and the lower 75 percent had average annual sales of $2.3 million.[17] By doubling these figures, one can approximate their value in 1980 dollars.

There are two important points that are not portrayed by the simple sales average. First is the extraordinary range of sales revenues for different drugs. Second is the large percentage of sales, attributable to a small percentage of drugs. According to the study cited in the previous paragraph, 25 percent of the drugs on the market accounted for about 90 percent of sales revenues. These figures suggest that there is a very large difference between the market shares and earning power of the few top drugs and the great majority of drugs. Throughout this study, drugs that have sales of more than $75 million per year will be termed high-income drugs.

Purchasers of Drugs in the United States

In the United States, ethical drugs are purchased by patients, Government agencies, and by pharmacists and hospitals (which resell them to patients). In 1979, 53 percent of manufacturers' sales were made to wholesalers (who distributed mostly to retail pharmacies), 22.5 percent were sold directly to retailers, 14.9 percent to private hospitals, 6.3 percent to Government (including State and local government hospitals), 1.4 percent to other Federal Government agencies, and 1.2 percent directly to physicians.[18]

The users of drugs do not necessarily reflect the population as a whole. People over 65, who are generally on fixed and limited incomes, constitute 11 percent of the population but make 25 percent of all drug purchases.[19] Similarly, persons with chronic diseases such as arthritis, angina, or epilepsy, will have above average health expenditures, but, because of their ailments, may have below-average earnings.

Although third-party payments (Government, philanthropy, industry, and private health insurance) constituted about two-thirds of the payments for personal health care in 1978, only about 16 percent of the payments for drugs and medical sundries in 1979 were covered by insurance or by Government reimbursement programs.[20]

[17]Virts and Weston, op. cit.

[18]Pharmaceutical Manufacturers Association, "20th Annual Survey Report," Washington, D.C., 1980.

[19]The Office of Technology Assessment Workshop on Mar. 24, 1981, American Association of Retired Persons.

[20]Freeland and Schendler, "National Health Expenditures: Short-Term Outlook and Long-Term Projection," *Health Care Financing Review* (winter 1981).

THE ISSUE OF EQUITY

A major argument for patent-term extension is that it is unfair that products subject to premarketing regulations have shorter effective patent terms than products that are unregulated. The point is made by proponents of patent-term extension that industries required to act in a socially beneficial manner should not be penalized for their actions.

On the basis of this argument, it would appear that the patent period should be extended purely as a matter of equity. Undoubtedly if patent-term extension involved no costs to anyone, there would be little disagreement that regulated products deserve extensions. But there are costs and there are disagreements.

Critics of the extension argue that what is equitable for the larger pharmaceutical firms may not be equitable for society. They urge that the issue of patent extension not be decided solely on the basis of equitable treatment to the large manufacturers but also on the basis of the social costs and benefits that will result from the extension.

Although this report focuses on the innovation issue, nonetheless, it is useful to have some understanding of both the nature and extent of any inequities that may exist.

The Nature and Extent of the Inequity

There is concern that industries subject to premarketing regulations are not receiving equitable treatment from the Government. The extent of the inequity is often equated with the extent to which premarketing regulations delay commercialization of the product. However, by issuing a patent, the Government grants the patentee the right to exclude others from making, using, or selling the invention; it does not grant the patentee the right to sell, use, or market the invention himself. Thus, even when a patentee is awaiting premarketing approval, his patent rights are exactly the same as the rights of patentees who are not required to seek premarketing approval.

However, the research-intensive firms do not believe that the inequity derives from their patent rights, but rather from the marketing delays caused by FDA regulations. Estimates of delays caused by FDA are based on the average duration of the FDA approval process. One study found that, on average, NDA approval for a patented NCE was granted 6 to 9 years after an IND had been filed.[21] As seen earlier, however, few products are ready for commercialization at the time an IND is filed. Thus, that portion of the FDA review period that would, even without FDA regulations, be used for testing and development cannot fairly be included in the FDA-induced marketing delay. Although the actual marketing delays attributable to FDA (e.g., through regulatory proceedings, testing procedures, and performance standards) are not precisely known, one can conclude that, in most cases, the delays are less than the 6 to 9 years consumed by the drug approval process.

Whether these delays actually result in an inequity is probably best determined by a comparison of the average effective patent terms for pharmaceuticals and the average for all products.

[21]Charles River Associates, op. cit., p. 3-2.

According to a study of patented NCE drugs receiving NDA aproval, the average effective patent term for drugs approved in 1979 was less than 10 years.[22] Unfortunately, there are no figures for the average effective patent terms for all products, but a rough estimate can be made, based on data on average lag time (the time that elapses between the discovery and marketing of a product). One study showed that the average lag time for 319 significant innovations originating in the United States and introduced between 1953 and 1973, was about 7 years.[23] If it is assumed that in most instances the time between the conception of the invention and the granting of the patent was about 4 years, it can be hypothesized that the average product was not marketed for 3 years of its patent life and that the average effective patent life was, therefore, probably greater than 13 years but less than 17 years. Based on these calculations, the conclusion can be drawn that the average effective patent term for significant innovations in general is probably 3 to 7 years longer than the average term for NCE pharmaceuticals.

This differential in the effective patent terms of pharmaceuticals and other products has led many to believe the extension should be provided, purely as a matter of equity. Others point out that marketing of products is delayed by many types of Government regulations, such as those governing zoning permits or environmental impact statements and that the Government cannot possibly guarantee equitable treatment to all industries at all times.

Because of the time value of money, the revenues generated during an extension that was equal to the actual delay caused by the FDA approval process would not fully compensate firms for the revenues lost during the period that marketing was delayed.[24]

[22]M. Eisman and W. Wardell, "The Decline in Effective Patent Life of New Drugs," *Research Management*, January 1981.

[23]Gellman Research Associates, "Indicators of International Trends in Technological Innovation," Jenkintown, Pa., April 1976 (final report to the National Science Foundation).

[24]Private communication with Henry Grabowski on Mar. 24, 1981.

THE POSITIONS OF THE PARTIES INTERESTED IN PATENT-TERM EXTENSION

Legislation to extend patent terms has been proposed and supported by the research-intensive firms. They argue that the FDA premarket approval procedure for new drugs has inequitably and unintentionally shortened the effective patent lives of pharmaceutical products. These firms further contend that the costs of pharmaceutical R&D have been escalating rapidly, effective patent lives have been declining, and the rates of return to pharmaceutical R&D expenditures are becoming unattractive. They point out that the ratio of R&D funding (deflated by the NIH biomedical deflator index for research costs) to total sales (deflated by the producer price index for ethical pharmaceuticals, Bureau of Labor Statistics) has declined by over 35 percent from 1963 to 1979. They express concern that incentives for R&D are eroding at the very time that advances in science have created the possibility of major improvements in drug therapy. In view of these trends, they contend that the rate of R&D investment will be insufficient for the rapid translation of scientific advances. In such circumstances, they believe that the user of drugs, and not necessarily the pharmaceutical industry, will be the loser.

Some research-intensive firms argue that the present trends have driven many companies away from pharmaceutical R&D and diminished the commitment of others. Many research-intensive companies have shifted R&D expenditures away from self-originated NCEs and towards new delivery systems for existing products because FDA approval can be obtained if companies demonstrate that the potency of the new product is equal to or better than the potency of the existing product. Some of these firms have increased their licensing of NCEs from others and suggest that this increase indicates that basic research is being viewed with increased caution.

It is the thesis of the research-intensive firms that patent-term extension will raise the expected profitability of drug research. It will therefore offset current pressures on decision-makers to reduce the size of their research project portfolio and provide a positive incentive for undertaking research activities. These activities, in turn, would increase the rate of innovation.

The research-intensive companies welcome an analysis of patent-term extension from an overall health-care perspective. They point out that innovative drugs save lives, reduce pain and suffering, and provide substantial health-care savings. Examples cited include an $11 pneumococcal pneumonia vaccine that can prevent a $3,300 treatment of the disease; a 22¢ per day glaucoma drug that saves $590 in surgery costs as well as hospitalization costs; and a rubella vaccine that for $25 million in costs has been estimated to provide a net savings to society of more than $1 billion. They believe that patent-term extension will provide drugs that offer better and less expensive health care, and that it will result in the introduction of more innovative drugs. They contend that the additional drugs will increase the competition among patented drugs and cause a downward price pressure on patented drugs with a resulting savings to the consumer.[25]

The production-intensive firms believe that patent-term extension will delay their entry into the market and that they will be economically penalized for each year that the extension prevents them from marketing a drug. They further contend that the market for some drugs may have declined to such a degree during the extension that their entry into the market will not be economically feasible. They point out that they play an important role in providing low-cost pharmaceuticals to consumers.

The concerns of the production-intensive companies are that patent-term extension will increase the ability of research-intensive firms to

[25]The research-intensive firms' positions have been gathered from private communications from the Pharmaceutical Manufacturers Association, May 1981 and July 1981; private communication from Lewis Sarett, Vice President of Merck and Co., May 1981; testimony of L. Engman, President of the Pharmaceutical Manufacturer's Association before the House Subcommittee on Health and Environment of the Committee on Energy and Commerce, Apr. 1, 1981, and before the Senate Committee on the Judiciary, Apr. 30, 1981.

achieve overall effective patent terms that exceed 17 years if these firms secure more than one patent on a product. They are also concerned that nonpatent barriers to acceptance of their products will prevent them from successfully competing against products whose patents have expired. They believe that a national formulary that listed the generic and therapeutic equivalency of drugs would encourage use of their products. They also believe that if the FDA premarketing requirements for generic equivalents of drugs coming off patent were simplified, more generically equivalent drugs would be marketed. From the point of view of the generic firms, one of the greatest barriers to market acceptance of their products has been court decisions inhibiting their use of the size, shape, and color of drugs whose patents have expired.

The production-intensive firms see the need to provide an equitable, effective patent term to innovator firms in certain situations in which the combined period of protection from all patents on the drug during marketing is significantly less than 17 years due to excessive regulatory delay. They do not believe that it is desirable for the pharmaceutical industry to have longer patent terms than other industries. Nor do they believe that extensions should compensate for time spent on testing that would have been conducted by the innovator firm whether or not FDA premarket regulations existed. Furthermore, production-intensive firms believe that efforts should be directed toward making regulatory proceedings more efficient in order to increase effective patent terms. They believe that any legislation to extend patent terms should not weaken their market position and that such legislation should eliminate the nonpatent barriers that can prevent them from successfully competing against products whose patents have expired.[26]

[26]The production-intensive firms' positions have been gathered from private communications from Kenneth Larson, President of Zenith Laboratories, April 1981, and July 1981; Mr. William Haddad, member of the board of the Generic Pharmaceutical Industry Association, April 1981, June 1981, and July 1981; and Mr. James Flug, counsel for the Generic Pharmaceutical Association, July 1981, and the testimony of Larson and Haddad before the Senate Committee on the Judiciary, Apr. 30, 1981.

Spokesmen for consumer interest groups believe that patent-term extension will result in higher drug prices without providing better health care. They point out that increased drug costs will fall disproportionately on the elderly and the chronically ill (whose incomes tend to be lower than average).

The spokesmen argue that the pharmaceutical industry is extremely profitable and needs no additional incentive to conduct research. These groups are concerned that the legislation proposed to date provides no guarantees that additional revenues derived from patent-term extensions will be invested in R&D activities. There is concern that patent-term extension may encourage less R&D because market exclusivity will be assured for a longer period of time.

Concerns are also expressed by spokesmen that expenditures made for R&D may not be directed toward research areas that provide the greatest benefit to society. A central concern is the degree to which patent-term extension will encourage minor innovations having only nominal therapeutic importance rather than major pharmaceutical advances.

Therefore, many consumer spokesmen oppose patent-term extension.[27]

[27]The consumer interest groups' positions have been gathered from private communication from Fred Wegner, pharmaceutical specialist, National Retired Teachers Association and American Association of Retired Persons, June 1981; and Sidney Wolfe, Director, and Benjamin Gordon, Staff Economist, Public Citizen, Health Research Group, July 1981; the testimony of Wolfe and Gordon before the Senate Committee on the Judiciary, Apr. 30, 1981; and statements by Marcia Greenberger, attorney, Center for Law and Social Policy, during the OTA workshop on patent-term restoration, Mar. 24, 1981.

Chapter 3

Factors Affecting Innovation in the Pharmaceutical Industry

Innovation in the pharmaceutical industry is dependent on many factors including scientific knowledge, profit levels, research and development (R&D) expenditures, and expected returns to research investment. Clearly these factors are interactive and dependent on decisions made in the private sector. Government action can, however, affect these factors and thereby increase or decrease the likelihood that innovation will occur.

In this chapter, trends in both pharmaceutical innovation and the determinants of innovation are examined so that the effects of patent-term extension on innovation may be assessed in chapter 4.

DECISIONMAKING IN THE INDUSTRY

Before examining any of these trends, some characteristics of decisionmaking in the industry will be noted briefly, for, no matter what the actual trends, it is how the trends are perceived in the decisionmaking process that determines R&D activities. If decisionmakers foresee declines in the returns to research investment, they will invest less and innovation levels may decline. The decline, however, would not be noticeable for several years because of the time that elapses between research discoveries and product marketing. Decisions made today, therefore, will affect the supply of drugs over the next 10 to 15 years.

The current decisionmaking environment for pharmaceutical innovation has been compared to the "gamblers ruin" problem, in which investment is made with an uncertain distribution of returns, and the objective of the investor is to win often enough to avoid experiencing severe cash-flow difficulties in the interim. No matter how high the return to investment, a firm that experiences a sufficient number of research failures in a row will not have adequate capital to hold out for the eventual "big win." In an environment of increasingly uncertain returns to pharmaceutical research, only firms with R&D budgets that are large enough to fund several projects at a time can survive the periods of little return and achieve eventual success.[1]

Because of the nature of pharmaceutical research, the characteristics of the decisionmaking process can be very important. One study notes that scientists have less control over research activities than they did in the 1960's and that the decisionmaking process has become more financially oriented.[2]

As a result, research projects undertaken today may receive closer scrutiny than in the past, and assessments of the likelihood of financial and therapeutic success may become more important in corporate decisionmaking. However, the decisionmaker's expectations for different projects may vary, and different firms will perceive the market in different ways.

[1]Thomas R. Stauffer, "Discovery Risk, Profitability Performance, and Survival Risk in a Pharmaceutical Firm," in *Regulation, Economies, and Pharmaceutical Innovation*, Joseph Cooper (ed.) (Washington, D.C.: The American University, 1976), pp. 93-122.

[2]Steven N. Wiggens, "The Pharmaceutical Research and Development Decision Process," *Drugs and Health* (Washington, D.C.: American Enterprise Institute for Public Policy Research, 1980).

TRENDS IN PHARMACEUTICAL INNOVATION

Pharmaceutical innovation is usually measured by the number of new chemical entities (NCEs) introduced. Although this information can be obtained easily, it fails to reflect innovations resulting from new formulations, new combinations of active ingredients, or new uses for existing drugs. Of the 1,916 notices of claimed investigational exemption for a new drug (INDs) pending at the Food and Drug Administration (FDA) on October 1, 1980, only 43.4 percent were for NCEs. Of the 209 candidates judged by FDA to offer important therapeutic gains, 86 were not NCEs. Thus, NCE introductions provide an incomplete measure of innovation and one that gives no weight to differences in therapeutic value.

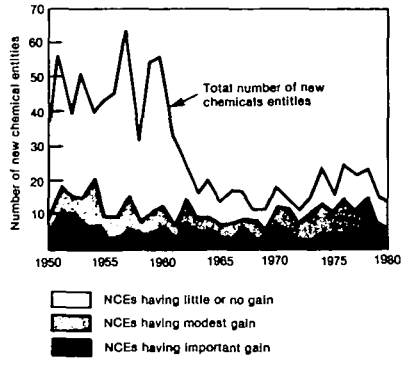
Figure 2 depicts the number of NCEs approved by FDA over the last 30 years, along with FDA's judgments on their therapeutic value. Although the criteria used for assessing the value of the innovations have been subjective and have varied over time, FDA's judgments can provide some perspective on the trends in NCE introductions.

Although the total number of NCEs approved by FDA has dropped significantly since 1950, the number of NCEs approved since 1963 has remained relatively constant. The bulk of the decline in FDA approvals occurred in the early 1960's and involved NCEs considered to offer little or no therapeutic gain. This decline may have been the result of the more stringent FDA drug approval process adopted in 1962. The FDA data indicate that approvals of NCEs offering important or modest therapeutic gain have remained relatively stable.

Trends in innovation have also been measured by NCE sales as a percentage of total ethical drug sales. By this measure, innovation is declining. NCE sales accounted for 20 percent of total sales in 1957 to 1961, 8.6 percent in 1962 to 1966, and 6.2 percent in 1972 to 1976.[3] Actual sales of NCEs have, however, grown since 1962 because total sales have grown.

Thus, interpretations of trends in innovation depend on the measures used and the time period being measured, but, by most measures, innovation does not appear to be increasing.

Figure 2.—Annual Approvals of New Chemical Entities Reflecting FDA's Judgment of Therapeutic Potential



SOURCE: Testimony of J. Richard Crout before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce. April 1, 1981.

[3]Henry Grabowski and John Vernon, "Government Policy and Innovation in the Pharmaceutical Industry," draft report (Durham, N.C.: Duke University, 1980).

THE KNOWLEDGE BASE

New drugs will not be developed unless scientific progress is made. Advances in the understanding of drug therapy and the physiological interactions in the body, along with advances in molecular biology, have opened up important frontiers in pharmaceutical innovation. Technological advances have improved pharmaceutical research techniques for identifying the

types of chemicals that should be synthesized for biological testing, and screening tests have been developed to determine whether a chemical has a good probability of being safe and efficacious.

As the therapy provided by drugs continues to improve, new pharmaceuticals will, however, have to meet tougher standards. Furthermore, as testing procedures become more sophisticated, more drug candidates will be rejected earlier because problems will be detected sooner.

FACTORS AFFECTING RETURNS TO RESEARCH INVESTMENT

The anticipated rate of return is believed to play a major role in the pharmaceutical industry's decisions to invest in innovative activities.

Several studies have indicated that the rates of return to research investment have declined significantly over the last two decades.[4] The assumptions made in these studies about costs, product lives, and profit margins have, however, been questioned.[5] Because of the unavoidable uncertainties involved with assumptions which must be made to project rates of return, this report focuses on the underlying factors affecting returns to research investment.

The major determinants of returns to research investment are the costs involved in R&D activities, the levels of R&D expenditures, and the revenues and profits of the industry. These factors are not only interrelated but are also dependent on other influences. The costs of R&D are controlled by inflation, regulatory actions, and technological advance. R&D expenditures are influenced by current revenues of the firm, by rates of returns, and by the decisionmaker's expectations for the future. Revenues are determined by prices and the quantities sold which, in turn, are determined by market demand, patent protection, and the number and types of competitors.

In the following discussion, the conclusions drawn pertain to the industry as a whole; but the reader is reminded that R&D costs, prices, sales volume, and profits vary among pharmaceutical products. Most companies are dependent on a few high-income drugs for substantial portions of their revenues. Table 3 provides the sales of the three leading products of selected manufacturers as a percentage of the manufacturers total sales. The effect of the determinants on these high-income drugs may be of particular concern to the pharmaceutical industry.

Table 3.—Percentage of Corporate Pharmaceutical Sales Accounted for by Three Leading Products[a]

	1970	1975	1979
Abbot	36	33	28
American Home Products:			
Ayerst	64	74	84
Wyeth	37	44	43
Bristol-Meyers:			
Bristol	69	46	28
Mead-Johnson	40	38	37
Burroughs-Wellcome	NA	56	51
Ciba	47	NA	55
Lederle	48	31	32
Lilly	46	60	43
Merck	35	44	44
Pfizer	52	65	65
Robins	43	45	46
Roche	80	80	70
Searle	45	49	44
Shering	42	48	40
SmithKline	44	42	66
Squibb	28	31	23
Upjohn	47	50	56
Warner-Lambert:			
Warner	53	NA	NA
Parke-Davis	25	27	22

NA = not available.
[a]U.S. sales.

SOURCE: Charles River Associates, Inc., "The Effects of Patent-Term Restoration on the Pharmaceutical Industry," a report to OTA, May 4, 1981.

[4]Charles River Associates, Inc., "The Effects of Patent Term Restoration on the Pharmaceutical Industry," prepared for OTA, May 4, 1981, pp. 4-1 to 4-3.
[5]Ibid.

TRENDS IN REVENUES AND PROFITS

The revenues and profits of the industry have direct bearing on the amount of funds available for R&D activities. As seen in chapter 2, profits in the pharmaceutical industry have been relatively stable. As shown in table 4, the revenues of U.S.-based firms from the sales of ethical pharmaceuticals have grown significantly since 1965, even on a constant-dollar basis. Real growth has occurred in both foreign and domestic sales.

As shown in table 5, the relationship between revenues and R&D expenditures in the U.S. pharmaceutical industry has also been stable. For the years 1965 through 1978, research expenditures ranged between 8.2 and 8.8 percent of total sales. The stability of this relationship suggests that trends in revenues may be a good indicator of trends in R&D expenditures.

Table 4.—Sales of Pharmaceutical Products of U.S. Based Firms 1965-78

Year	Total domestic and foreign sales (millions)	Deflator	Deflated sales (millions)	Real growth in sales (percent)
1965	$ 3,939	103.2	$ 3,817	Base year
1966	4,340	102.6	4,230	10.8%
1967	4,744	100.0	4,744	12.2
1968	5,302	99.0	5,356	12.9
1969	5,837	99.5	5,866	9.5
1970	6,425	99.3	6,470	10.3
1971	7,009	99.0	7,080	9.4
1972	7,739	99.1	7,809	10.3
1973	8,722	99.9	8,731	11.8
1974	9,956	104.2	9,555	9.4
1975	11,554	113.2	10,207	6.8
1976	12,775	120.3	10,619	4.0
1977	13,838	125.4	11,035	3.9
1978	15,978	131.9	12,114	9.8

SOURCE: Derived from Pharmaceutical Manufacturers Association OPA, April 1981, using BLS, producer price deflator for pharmaceuticals

Table 5.—Research and Development Expenditures and Sales Revenues of U.S. Ethical Drug Industry (1965-78)[a]

Year	Domestic sales total	Foreign sales (including exports) total	Domestic R&D current dollars (millions)	Foreign R&D current dollars (millions)	Ratio of R&D to sales in current dollars[b] (percent)
1965	$2,940	$ 999	$ 304.1	$ 24.5	8.3%
1966	3,178	1,162	344.2	30.2	8.6
1967	3,393	1,351	377.9	34.5	8.7
1968	3,808	1,494	410.4	39.1	8.5
1969	4,135	1,702	464.1	41.7	8.7
1970	4,444	1,981	518.6	47.2	8.8
1971	4,796	2,213	576.5	52.3	8.6
1972	5,136	2,603	600.7	66.1	8.6
1973	5,644	3,078	643.8	108.7	8.6
1974	6,273	3,683	726.0	132.5	8.6
1975	7,086	4,468	628.6	144.9	8.4
1976	7,867	4,908	902.9	164.9	8.4
1977	8,434	5,404	984.1	197.7	8.5
1978	9,411	6,567	1,089.2	222.0	8.2

[a]Veterinary-use pharmaceutical research and development is excluded for the years 1965 through 1974.
[b]Global pharmaceutical R&D and sales of U.S. firms.

SOURCES: Henry Grabowski and John Vernon, "Government Policy and Innovation in the Pharmaceutical Industry," draft report, November 1980; and Pharmaceutical Manufacturers Association, "Annual Survey Report—1979-80" (Washington, D.C.: PMA, 1980).

Prices of Drugs Sold

Revenues are determined by the prices and quantities of drugs sold. Pharmaceutical prices have risen very slowly since 1967, but, because the quantity of drugs sold has increased there has been real growth in revenues (see table 4). The Firestone Report of August 1980 indicates that pharmaceutical producers' prices (wholesale) have risen 46.1 percent since 1967. Prices of all industrial producers have risen, on average, 136.5 percent since 1967. Table 6 indicates that producer price indexes for all industries have typically been considerably higher than producer price indexes for pharmaceuticals.

Producer prices vary among therapeutic classes. Table 7 shows the average change in producer prices by therapeutic category. From tables 6 and 7, it can be seen that the average growth in price across all therapeutic classes was 46.1 percent and that the average price change ranged from − 17.8 to + 187.0 percent.

According to a study of price statistics of all NCEs introduced into the United States between 1958 and 1975, prices also vary with the therapeutic value of the drug. Of the NCEs classified as important therapeutic gains, 44 percent had prices that were more than double the prices of the closest competitive products; of the NCEs providing modest, little, or no therapeutic gain, about 10 percent had prices more than double the prices of the closest competitors. Similarly, 30 percent of the former had prices that were less than 120 percent of the closest competitors' prices and about 72 percent of the latter had prices that were less than 120 percent of the closest competitors' prices.[6] This study also indicates that prices for NCEs vary widely: introductory prices ranged from about one-quarter of the price of the closest competitive product to 15 times the price of the closest competitive product.[7]

Table 6.—Producer Price Indexes for Selected Years (1967 = 100)

Year	All industries	Pharmaceutical industry
1949	75.3	117.3
1969	106.0	100.1
1974	153.8	109.3
1975	171.5	116.2
1976	182.4	123.8
1977	195.1	131.7
1978	209.4	138.8
1979	236.5	148.1

SOURCE: *The Firestone Report*, August 1980, p.4.

Table 7.—Average Percentage Change in Producer's Prices by Therapeutic Category, 1969-79

Group	Percent
Contraceptives, oral	+ 187.0
Sedatives	108.6
Antiobesity	81.3
Cough and cold	72.6
Bronchial therapy	66.7
Hormones	63.2
Diabetic therapy	63.0
Antiarthritics	62.3
Antispasmodics	60.7
Cardiovasculars	53.9
Vitamins	46.5
Dermatologicals	41.1
Analgesics	38.0
Diuretics	34.7
Psychotherapeutics	17.5
Anti-infectives	− 1.4
Broad and medium specialists	0.0
Penicillin	− 17.8
Sulfa and antibacterials	+ 24.6
All others	57.1
Total	46.0

SOURCE: *The Firestone Report*, August 1980, p. 2.

The prices and quantities of drugs sold are determined by several factors: market demand, patent protection, and the number and type of competitors. In chapter 2 demand was examined, in this chapter other determinants of revenues are examined.

Product Lives.—Product lives do not necessarily parallel patent lives. Irrespective of the patent, a drug will be prescribed and consumed as long as no other drug or therapy comes along that is better and as long as the disease or condition for which the drug is prescribed continues to be prevalent in the society.

Table 8 lists the 15 top selling drugs in the United States in 1980 and their new drug application (NDA) approval date. The table in-

[6] Duncan W. Reekie, "Price and Quality Competition in Drug Markets: Evidence From the United States and the Netherlands," *Drugs and Health* (Washington, D.C.: American Enterprise Institute for Public Policy Research, 1980), p. 132.

[7] Ibid., p. 134.

Table 8.—Top Selling Drugs by Volume in 1980 and Year of NDA Approval

Drug (trade name)	Year
Valium	1963
Inderal	1967
Dyazide (dyrenium)	1964
Lanoxin	(a)
Tylenol with codeine	(a)
Lasix	1966
Dimetapp	(a)
Motrin	1974
Tagamet	1977
Darvocet-N	1972
Dalmane	(a)
Aldomet	(a)
Ortho Novum	(a)
Actifed	(a)
Keflex	1971

[a]Approval prior to 1963.

SOURCE: *American Druggist*, February 1981, for ranking; FDA, private communication, for NDA approval data for NCE (June 1981).

dicates that 9 of the 15 drugs have product lives of 17 years or more.

Product lives are shortened by competition from other drugs and nondrug therapies, but a widely accepted drug may be able to retain a significant market share when competition emerges.

Since the 1950's, the average product life of drugs has increased. Product lives, however, vary widely depending on the competition within the therapeutic class.

Patent Protection.—Patents protect against competition from other generically equivalent products. (For a discussion of patents, see ch. 5.) Patents do not protect against competition from nonequivalent drugs or nondrug therapies.

Effective patent terms for pharmaceuticals have been declining. The average effective patent life for patented NCEs receiving FDA approval has reportedly declined from 13.6 years for drugs approved in 1966 to 9.5 years for drugs approved in 1979.[8] Three factors have contributed to this decline: an increase in the duration of the clinical and regulatory period required for drug approval; a slight increase in the time between the filing of a patent application and clinical testing; and a decrease in the time between patent application filing and patent issuance. Sixty percent of the decrease in effective patent life has been attributed to the increased testing and regulatory period and 40 percent to the other two factors.

Effective patent lives vary widely among products. Table 9 indicates that the effective patent lives of the drugs with the highest revenues ranged from 11 to 17 years.

Some of the factors influencing effective patent terms are undergoing change. The duration of the FDA regulatory procedure may be stabilizing. The average time between the filing and issuance of a patent application is increasing slightly as a result of a backlog of patent applications in the Patent Office. Thus, there is reason to believe that the decline may not continue in the future. Furthermore FDA is now giving highest priority to the drugs that it believes will provide significant therapeutic advances, hence, these drugs may fare better than the average drug in the future.

Competition and Concentration.—Competition, whether it comes from generically equivalent drugs or nonequivalent drugs, affects both the prices of drugs and the quantities sold. One indication of the degree of competition in an industry is the extent to which sales are concentrated among the leading firms in the industry. The relationship between innovation and concentration is disputed. According to some, high levels of concentration favor innovation since the more highly concentrated the market structure, the greater the ability to obtain higher profits. The higher profits can serve as incentives for innovation and make additional revenues available for R&D.

According to others, concentration can have negative consequences for innovation. In a very competitive market, consumer demands interact with costs of production to determine what drugs firms will produce and what the prices of these drugs will be. In highly concentrated markets, some or much of that power shifts to the producers, and innovation may therefore be determined by corporate needs, rather than consumer needs. The producers may be able to maintain high levels of profitability without innovation. Innovation may also suffer because the factors leading to the more highly concen-

[8]M. Eisman and W. Wardell, "The Decline in Effective Patent Life of New Drugs," *Research Management*, January 1981, p. 18-21.

Table 9.—Effective Patent Lives of 1980 Top Sellers by Revenues

Drug (trade name)	1980 U.S. sales (millions)	Patent approval	NDA approval (date)	Patent expiration	Effective patent (years)
Tagamet	$250	1976	1977	1993	16
Valium	230	1968	1963	1985	17
Inderal	200	1967	1967	1984	17
Motrin	150	1968	1974	1985	11
Aldomet	150	1964	(a)	1981	17
Dyazide (dyrenium)	145	1963	1964	1980	16
Keflex	140	1970	1971	1987	16
Clinoril	125	1972	1978	1989	11

[a]Approved prior to 1963.

SOURCE: For ranking and sales: *New York Times*, Sunday, May 17, 1981, quoting Oppenheimer and Co. For NDA approval date and patent information: private communication from FDA.

trated market can discourage the entry of new firms.

The measurement of concentration has been a subject of controversy. When market shares of firms are calculated as a percentage of total pharmaceutical sales, concentration is relatively low in the pharmaceutical industry. When market shares are measured as a percentage of sales in particular therapeutic categories, concentration in some categories is quite high. When one looks at market shares over time, one finds that the firms in the leadership positions change considerably.[9] Since the shift in market positions is attributed to new product introductions, some economists suggest that this measurement is the one most relevant to innovation.

Competition From Nonequivalent Drugs.—Competition from nonequivalent drugs was somewhat higher between 1972 and 1980 than between 1963 and 1971. Table 10 shows the number of firms receiving NCE approvals and the number of NCEs approved, by FDA category, for those two periods. By aggregating NCE approvals for two 8-year periods, it was found that both the number of firms and the number of NCEs have increased for all but one category of drugs. The table does not explore entries and exits, but considerable turnover has occurred in the firms producing NCE drugs. For example, of the 20 firms producing cardiorenal drugs in the 1972-80 period, 15 had not produced such drugs in the earlier period.

[9]Douglas Cocks, "Product Innovation and the Dynamic Elements of Competition in the Ethical Pharmaceutical Industry," in *Drug Development and Marketing* (Washington, D.C.: American Enterprise Institute, 1975).

Table 10.—Number of Firms Receiving FDA Approval and Number of Drugs Approved, by FDA Drug Category (1963-71 and 1972-80)

	1963-71		1972-80	
FDA division	Firms	NCEs	Firms	NCEs
Cardiorenal	10	13	20	23
Neuropharmacological	20	25	17	23
Metabolism and endocrine	11	14	13	19
Anti-infectives	34	47	36	49
Oncology and radiopharmaceutical	12	24	23	45
Surgical-dental	12	13	13	16

SOURCE: Food and Drug Administration, private communication, June 1981.

Competition From Generically Equivalent Drugs.—After a patent expires, competition may emerge from generically equivalent drugs. Such drugs are manufactured by production-intensive firms who market nonbranded drugs under generic names and by research-intensive firms who market branded drugs either under trade names or under generic names accompanied by firm names. The reputation of research-intensive companies may enable their products to command higher prices than products marketed under generic names alone.

The revenues of branded and nonbranded drugs which either had not been patented or had patents that expired were about $4.4 billion in 1979; some of those drugs, however, did not have competition from generically equivalent drugs. Only about 7 percent of the revenues for branded and nonbranded drugs were earned by production-intensive firms with the remainder earned by the research-intensive firms.[10]

[10]Interview with William Haddad, Generic Pharmaceutical Industry Association, Apr. 21, 1981.

Branded and nonbranded drugs compete among themselves, as well as with the originally patented products. For example, a pharmacist, to avoid a large inventory, may carry only one branded and one nonbranded product. Competitive factors including price influence his choice of products.[11]

The Federal Trade Commission estimated that between 42.1 percent and 74.3 percent of the wholesale price of branded drugs could be saved by the dispensing of nonbranded products instead of more expensive branded drugs.[12]

Counter-Competitive Forces.—An important influence on the level of competitive activity when patents expire is the ease of market entry for generically equivalent products. Barriers to market entry arise from the requirements for FDA approval of generically equivalent products and from nongovernmental factors.

As stated in chapter 2, FDA plans to reinstitute its paper NDA procedure. This practice should significantly lower the barriers to second entrants. However, many firms seeking approval will not be able to provide such data and the FDA requirements for them will continue to discourage entry. FDA has also announced that it plans to consider changing its regulations so that its abbreviated NDA procedure could apply to some post-1962 drugs.[13]

FDA bioavailability tests also can act as barriers to market entry. Bioavailability relates to the absorption of drugs into the body. Tests for bioavailability are required in cases where precise dosage is critical because of narrow margins separating ineffective, effective, and toxic doses. When such tests are required, they may be difficult and time-consuming, and therefore act as disincentives to second entrants.

Nonregulatory barriers to successful market entry also exist. A principal barrier is the third-party aspect of consumer drug selection. The physician, who prescribes a drug for his patient, frequently cannot keep informed about alternative versions of a particular drug and their relative prices, and may prefer branded products because he believes them to be safer. This preference for trademarked brand-name drugs tends to give strong marketing advantages to first-entrant drugs that are therapeutically effective. These advantages can endure over time, and latecomers may need to wage vigorous promotion campaigns or offer improved substitute products to overcome these advantages. With gradually increasing product selection by pharmacists, this timing-of-entry barrier may be weakening.

Pharmacist preference can, however, also act as an entrance barrier. Pharmacists may be reluctant to fill prescriptions for brand-name drugs with generic equivalents because they fear they may be liable if generic equivalents cause injury.

Although pharmacists and physicians play a key role in determining the market for drugs, they are frequently influenced by consumer opinion. Thus, consumer preference also acts as a barrier to entry. Many drugs, have a particular size, shape, and color which are claimed by the innovator firm to be proprietary. A generic product that looks different from the product that the consumer customarily uses may be rejected in favor of a familiar product.

Forces Favoring Competition.—As discussed in chapter 2, actions taken by the Federal and State governments over the past decade have facilitated the development of the low-cost generic market. More than 40 States have repealed laws which prevented pharmacists from substituting generic equivalents for prescribed brand-name drugs. Some of the State substitution laws, such as New York's, require pharmacists to fill prescriptions with the least expensive generic products available according to a State formulary. Other States permit substitutions only when physicians specifically note that substitutions can be made.

The Federal Government's Maximum Allowable Cost (MAC) program, which affects reimbursements to pharmacists under medicaid, also encourages competition. Under the MAC program, the lowest wholesale price of a generically equivalent, multisource drug is identified. The

[11]Federal Trade Commission, "Drug Product Selection," Washington, D.C., 1979 (staff report to FTC).
[12]Ibid.
[13]46 Federal Register 24445, Apr. 30, 1981.

MAC regulations limit the reimbursement to the pharmacist to that lowest identified wholesale price plus a reasonable dispensing fee. Because a growing percentage of all prescriptions are paid by medicaid, MAC is expected to have a significant effect as more drugs fall within the MAC program. Because MAC encourages pharmacists to stock low-priced generic products, pharmacists may be more inclined to use these products when filling prescriptions of nonmedicaid patients.

Several other Federal actions also favor competition: the Government-wide Quality Assurance Program is designed to increase competition among drugs purchased by the Department of Defense, the Veterans Administration, and the Public Health Service; the Model State Prescription Drug Product Substitution Act is designed to assist States in developing laws that encourage the dispensing of generically equivalent drugs; and the FDA list of therapeutically equivalent drug products is designed to provide an authoritative statement regarding generic drug quality. The Supreme Court has also had an impact by voiding, as unconstitutional, laws which prohibited the retail advertising of drugs and drug prices.

The full impact of the repeal of the antisubstitution laws and the Federal Government actions may not yet have been felt. One study reported the market share of 12 selected patented drugs before and after patent expiration for drugstore and hospital markets through 1978. After patent expiration, each of these drugs retained more than a 90-percent share of the drugstore market and more than an 80-percent share of the hospital market. Six of the drugs retained more than a 97-percent share of both markets in 1978. The retail price, in constant dollars, of 4 of the 12 drugs declined; the greatest decline was about 35 percent.[14] It is not clear if price declines were due to generic competition or other factors, such as competition from new patented drugs or the waning of product life.

Trends in Generic Competition.—The trends in generic competition activity levels after patents expire are uncertain. The full impact of recent actions by the Federal and State governments facilitating generic competition has not yet been felt. While these actions have thus far had relatively minimal effects, they could potentially have substantial effects on the revenues and profits of innovator firms. Barriers to subsequent entrants can provide a countervailing force to these Government actions. Over the next few years, as the patent terms end for many high-income drugs, the trends will become more obvious.

[14]Meir Statman, "The Effect of Patent Expiration on the Market Position of Drugs," in *Drugs and Health*, Robert B. Helms (ed.) (Washington, D.C.: American Enterprise Institute for Public Policy Research, 1980), pp. 140-151.

THE COSTS OF RESEARCH AND DEVELOPMENT

Thus far, the factors that influence revenues have been discussed. The returns to R&D investment, however, also depend on R&D costs and expenditures.

The average absolute R&D costs for new chemical entities are difficult to ascertain. Several average R&D cost estimates have been made. One estimate projected the R&D cost for a self-originated NCE (one not licensed from another source) to be $54 million (in 1976 dollars). This calculation included $21 million in opportunity costs of capital (the money that could have been earned by investing in an alternative venture at an 8-percent return for the number of years between the initial investment and the start of sales income) and the costs of failures (7 failures for each success at the clinical stage).[15]

[15]R. W. Hansen, "The Pharmaceutical Development Process: Estimates of Development Costs and Times and the Effects of Proposed Regulatory Changes," in *Issues in Pharmaceutical Economics*, Robert I. Chien (ed.) (Lexington, Mass.: Lexington books, 1980).

Rather than relying on estimates of R&D costs, the factors influencing R&D costs to ascertain trends in R&D costs have been reveiwed in this report. The costs of R&D have increased. Part of the increase is due to inflation; facilities, equipment, and salaries are all subject to inflationary pressures. The Biomedical Research and Development Cost Index of the National Institutes of Health (NIH) has outpaced both the Consumer Price Index and the Bureau of Labor Statistics Producer Price Index for Pharmaceuticals. Many commentators expect such pressures to continue in the future.

Some of the increase in costs has been due to regulatory actions. Testing standards have become more stringent and have required longer amounts of time to conduct. FDA is, however, trying to expedite its approval of new drugs and the duration of the drug approval process may therefore stabilize. Table 11 shows the time required for FDA approval of NCEs between 1976 and 1980. The average time and the median number of years needed to obtain approval dropped in 1980.

Table 11.—Average and Median Number of Years Between IND Filing and NDA Approval for NCEs

Year	Average years	Median years
1976	5.8	5
1977	7.8	7
1978	5.2	5
1979	8.9	9
1980	8.2	7.5

SOURCE: Private communication from FDA, June 1981.

Technological advances have helped to counter the upward trend in R&D costs. By all accounts, the sophistication of pharmaceutical R&D has increased. Some of these advances may provide more efficient (and therefore less costly) ways of conducting research. Although we have no data on this trend, technological advance can be expected to stem some portion of the rising costs in the future.

In an attempt to keep R&D costs down, U.S. firms are committing increasing amounts of research expenditures abroad where regulatory procedures often permit more rapid and less costly drug development.

Expenditures in Research and Development

Real growth has occurred in expenditures of funds for R&D. In table 12, the current foreign and domestic dollars spent on R&D have been deflated for the years 1965 through 1978, using the (NIH) biomedical R&D cost deflator (1967 = 100). R&D expenditures have apparently kept up with and surpassed the rate of inflation for biomedical research. This upward trend may be expected to continue in the near future. Many research-intensive firms have indicated that they are increasing R&D expenditures. For example, Merck & Co. expects to spend $280 million on R&D in 1981, 20 percent more than in 1980.[16]

[16]William Fallwell, "U.S. Drug Companies Held Up Well in Recession," *Chemical and Engineering News*, Mar. 9, 1981, p. 8.

Table 12.—Trends in R&D Expenditures

Year	Total domestic and foreign R&D (millions current dollars)	Deflator	Deflated R&D (millions constant dollars)
1965	329	92.5	356
1966	374	95.8	390
1967	412	100.0	412
1968	449	104.7	429
1969	506	110.4	458
1970	568	117.5	483
1971	629	124.1	507
1972	667	130.3	512
1973	753	136.5	552
1974	859	145.2	592
1975	974	160.7	606
1976	1,068	172.7	618
1977	1,182	186.4	634
1978	1,311	200.3	655

SOURCE: Table 5 and information obtained from the Pharmaceutical Manufacturers Association, April 1981.

Of concern is the allocation of funds between basic research and product development. Declining expenditures on basic research could result in a reduced number of new drug introductions in the future. Industry officials have indicated that a shift from basic research to product development is taking place. Lewis Sarett (1981) of Merck & Co. reported in congressional testimony that a recent survey of U.S. firms by the Organization for Economic Cooperation and Development indicated that pharmaceutical firms are reducing the research share of their R&D budgets. To avoid the risks of research, firms are increasingly licensing technology from other sources and are spending more on development.[17] Nevertheless, preliminary information provided in table 13 suggests relatively little change in emphasis.

Rising costs can also be expected to shift R&D program emphasis among therapeutic classes because some types of drugs can be developed less expensively than others. In periods of rising costs, firms can be expected to emphasize the less costly research areas. Table 14 shows the percentage of R&D expenditures for different therapeutic categories for the years 1975-79. Although some shifts in expenditures are evident, the shifts tend to be more toward areas in which significant therapeutic advances are occurring (e.g., cardiovasculars) than toward areas which involve lower costs (e.g., anti-infectives).

These shifts in expenditures, however, may not indicate any shift in decisions about R&D spending. Expenditures vary depending on where the innovation is in the development process, and these shifts may therefore only reflect normal research progress.

[17]For another example, see: D. Schwartzman, "Innovation in Pharmaceutical Industry;" J. R. Virts and J. Fred Weston, "Expectations and Allocation of R&D Resources;" and Grabowski and Vernon, op. cit.

Table 13.—Relative Funding of Basic and Applied Research in the Pharmaceutical Industry (millions of dollars)

Year	(1) Basic research	(2) Applied R&D	Column 2 as percent of total
1968	60	375	86.2
1969	67	417	86.2
1970	93	474	83.6
1971	77	535	87.4
1972	78	501	87.2
1973	90	605	87.1
1974	107	683	86.5
1975	112	783	87.5
1976	119	883	88.1
1977	131	959	88.0

NOTE: For the purpose of this table, the pharmaceutical industry is defined as corporations primarily engaged in manufacturing biologicals, inorganic and organic medicinal chemicals, pharmaceutical preparations, and grading, grinding, and milling of botanicals.

SOURCE: Derived from National Science Foundation, *National Patterns of Science and Technology Resources 1980*, tables 42 and 45.

Table 14.—Percentage of R&D Funds Spent by Therapeutic Class (1975-79)

Therapeutic class	Percent of total R&D spending[a] 1979	1978	1977	1976	1975
Anti-infectives	18.7	18.3	19.2	19.5	20.1
Central nervous system and sense organs	16.3	16.9	17.0	16.2	18.0
Cardiovasculars	18.6	17.3	15.2	13.2	14.9
Neoplasms, endocrine system, and metabolic diseases	15.3	16.1	15.7	14.7	15.5
Gastrointestinal and genitourinary system	6.3	6.7	6.0	5.8	5.1
Respiratory	4.0	4.4	4.0	4.1	5.5
Biologicals	2.5	3.0	3.1	3.1	3.0
Dermatologicals	2.9	2.8	3.2	2.8	2.8
Vitamins	2.5	2.2	2.5	1.5	1.1
Diagnostic	0.5	0.6	0.8	1.2	1.2
Other human preparations	6.7	5.6	6.3	10.5	6.1
Veterinary preparations	5.3	5.7	6.6	7.2	6.5
Veterinary biologicals	0.4	0.4	0.4	0.2	0.2

[a]In the United States only.

SOURCE: Pharmaceutical Manufacturers Association.

SUMMARY OF FINDINGS

Research-intensive companies are committing increasing amounts of funds toward pharmaceutical R&D, and therefore, the potential exists for major pharmaceutical discoveries. Factors have been highlighted which, based on historical trends, will affect pharmaceutical innova-

tion. Below is a summary of these major trends. Following that is a summary of factors whose effects are uncertain.

Historical Trends That May Discourage Innovation

- The costs of research and development are increasing significantly.
- The price of drugs has generally not kept pace with the increase in R&D costs.
- Effective patent lives have declined, but may be stabilizing.
- A decline in the returns to R&D investment is widely perceived.

Historical Trends That May Contribute to Innovation

- The pharmaceutical industry continues to enjoy high and stable profitability in terms of return to stockholder's equity.
- Recent technological advances have improved research techniques and enhanced the efficiency of research activities. Researchers are no longer totally dependent on the expensive hit-or-miss method for screening new drugs.
- The competitive environment for innovation appears stable for most therapeutic classes, and there is no lessening of competitive pressure for innovation.
- Markets and sales of drugs are growing.

Uncertainties Affecting Innovation in the Future

Historical trends do not reflect recent governmental actions that may affect the postpatent exclusivity of many drugs. These actions include the repeal of antisubstitution laws, adoption of FDA procedures that facilitate approval of generic equivalents of previously approved drugs, adoption of Government reimbursement programs favoring use of low-priced generic equivalents, and court rulings that allow advertising of drug prices.

Although these actions have, thus far, had only minimal effects on the rates of return to R&D investments and on the revenues and profits of research-intensive companies, they could have substantial impact in the future.

If the effects prove to be substantial, firms will probably be unable to maintain their current levels of research. The public, however, will not perceive a decline in innovation for many years. By the time such a decline is noted, the public will face a period of lagging innovation, since new research efforts will not bear fruits for at least a decade.

Chapter 4

The Implications of Patent-Term Extension for Pharmaceuticals

This chapter examines the possible impact of patent-term extension on the numerous factors that affect pharmaceutical innovation. The first portion of the chapter concentrates on whether patent-term extension will result in beneficial pharmaceutical innovation; the second explores the costs associated with patent-term extension and the implications of patent-term extension for the patent owner, the research- and production-intensive firm, and the consumer.

PATENT-TERM EXTENSION AND INNOVATION

A patent provides the right to exclude others from making, using, or selling an invention. The primary incentive provided by this right is the opportunity to derive economic benefits that result from an exclusive market position. By extending the patent term, Congress would extend the period in which these benefits could be derived, and thereby increase the incentives for research and development (R&D) activities.

Whether R&D activities actually increase as a result of these incentives will depend on decisions made in the private sector, and patent terms are but one consideration in these decisions. Patent-term extension will not provide a mechanism for reducing R&D costs, it will not enhance the likelihood of research breakthroughs, and it will not ensure that the results of innovative activity will meet with commercial success. Nor will it stem the trend of domestic companies conducting pharmaceutical R&D overseas.

To the extent that patent-term extension demonstrates Government support for R&D activities, it will provide psychological encouragement to decisionmakers; the effects of such encouragement might, however, be temporary. Since patent-term extension cannot provide firms with additional revenues before the extensions actually begin and the first extensions will not, under the proposed legislation, begin until the 1990's, the immediate incentive provided to the research-intensive firms by patent-term extension is the opportunity to obtain greater returns on R&D investment in the long term. Although an exclusive market position for a drug can exist beyond the expiration of the original patent term, patent-term extension provides a longer and more certain period in which exclusivity can be assured.

Whether firms will actually increase R&D expenditures on the basis of anticipated increases in returns is, however, highly speculative. On the one hand, the increased economic attractiveness of R&D investment could encourage firms to reallocate corporate funds or obtain external funds in order to increase R&D expenditures. On the other hand, the historic stability of the relationship between R&D expenditures and revenues would suggest that R&D expenditures would not increase unless revenues increased.

In the long term, firms obtaining additional revenues in the extended period will have additional funds available for R&D investment. If historic trends prevail, they will spend on average 8 or 9 percent of these additional revenues for R&D. A major portion of the additional revenues will be used for purposes other than R&D. Taxes will need to be paid, production costs allocated, and dividends distributed. The funds may be used for product promotion or diversification. In talking about additional revenues, it should be noted, however, that such revenues will never be able to be quantified since we can never know what revenues would have been generated if the patent term had not been extended.

Despite the fact that revenues generated by the extension cannot be measured, firms with drugs whose patents are extended will probably derive additional revenues since they will have a longer period of exclusivity in which to market their products at premium prices. Therefore, both sales and prices should be greater than they would have been if no extension existed unless the supply of new drugs increases and exerts a downward pressure on prices. After extensions lapse, sales by research-intensive firms may continue to be higher than they would have been had competition entered the market when the original patent expired. In some cases, second entrants may consider the remaining product lives of drugs coming off extended patents insufficient to justify start-up costs and thus may not enter the market. Furthermore, by the time the extensions end, the patented products may be so firmly established in the market that generically equivalent products could not obtain as great a market share as they would have obtained if the extension had not occurred.

Thus, the revenues of research-intensive firms, particularly firms having high-income drugs, should receive a boost from patent-term extension. Nonetheless, pricing pressures are exerted by other patented drugs and nondrug therapies. Whether these pressures will override the research-intensive firms' ability to charge premium prices will depend on circumstances in the relevant therapeutic markets.

The distribution of additional revenues among firms can affect both the level of research activities that will be undertaken and the types of innovation that may result.

The bulk of additional revenues probably will be earned by high-income drugs. The possibility exists that the relatively few firms who develop those drugs will develop more sophisticated research techniques and more extensive research programs than other firms since they will have more funds available for research and development. Their successes may particularly encourage them to undertake additional R&D activities, some of which may be directed at therapeutic areas that go beyond their present expertise. Under these circumstances, innovation would be expected to increase.

On the other hand, other firms may be discouraged from conducting research in the areas pursued by these successful firms which have been able to increase their research dominance in these areas. In such cases some forms of innovation may suffer.

Furthermore, as a result of patent-term extension, specific types of innovation may be delayed. An originator of a drug may have little incentive to improve his product while it is benefiting from patent protection. Second entrants, when they engage in R&D activities, concentrate on manufacturing processes, drug formulations, combinations of active ingredients, or minor, unpatentable modifications of existing drugs. By delaying the entry of firms who engage in such activities, patent-term extension may delay the introduction of this type of innovation.

On balance, there is a reasonable likelihood that firms may undertake or increase pharmaceutical R&D activities because of the increased incentives provided by the longer effective patent term. If this occurs and drugs are developed more rapidly, a downward pressure might be exerted on the price of some drugs and the product lives of some drugs might decrease.

Although R&D expenditures are expected to increase, they will not increase evenly across all therapeutic areas. Since high-income drugs will derive the greatest benefits from patent-term extension, the tendency of firms to direct their research efforts torward developing drugs for large markets will be reinforced.

To the extent that patent-term extension affects the potential rate of return, drugs that might otherwise be economically marginal may become economically attractive. But this will occur only occasionally, particularly if opportunities exist for developing drugs with greater profit potential. For the many marginal drugs that do not have generic competition after their patents expire, patent-term extension will not generate additional revenues.

Patent-term extension could be a significant factor in encouraging certain types of pharmaceutical R&D. In some therapeutic areas, the loss of effective patent term due to the drug ap-

proval process can be great, and research-intensive firms may not initiate R&D activities in these areas. Patent-term extension may reduce or eliminate the discrepancy between the effective patent terms of drugs in these therapeutic areas and drugs in other areas.

Patent-term extension may also encourage second uses for existing drugs. Not infrequently an existing drug is discovered to have a therapeutic use other than the one approved by the Food and Drug Administration (FDA). FDA approval must be secured for the additional use before the drug can be sold for that use. Because of the period of exclusivity provided by the extended patent term, the development of the additional use of the drug may be financially attractive.

The balance between research spending and development spending is not likely to be significantly changed by patent-term extension. Generally, the results of research activities are less certain than the results of development activities, and patent-term extension will not alter the relative levels of uncertainty. However, if additional revenues are generated because of patent-term extension, the firms may be more willing to undertake the risk involved with research activities.

PATENT-TERM EXTENSION AND THE COST OF PHARMACEUTICALS

Drugs whose patents are extended are expected to command higher prices during the extension period than they would have, had their patents been allowed to expire. Despite these higher prices, the drugs may cost less than alternative therapies.

This section, however, does not evaluate the cost-benefit relationship of drug therapies, but is solely concerned with the additional costs of drugs during the extended period. The benefits of innovation that might result from patent-term extension are not taken into account in evaluations of cost. Furthermore this section does not take into account the fact that the prices of drugs with extensions can influence the prices of competitive drugs nor the fact that patent-term extension can affect the prices of drugs after extensions end.

There is a distinction between the additional costs to the consumer due to patent-term extension, and the additional revenues to the innovator firm. First, the additional costs to the consumer due to patent-term extension may not be directly comparable to the additional costs at the wholesale level. The drug is dispensed to the consumer by the pharmacist who assesses a prescription fee or a percentage markup. Nonetheless, substantial price benefits could be gained by the consumer from the purchase of generic drugs. Second, generic competition will have a greater effect on the additional revenues to the innovator firm than on the costs to consumers: when a consumer purchases a low-cost equivalent drug, he saves the difference between the cost of the generically equivalent drug and the cost of the branded drug; but the innovator firm, receives no revenues for the drug he might have sold.

The degree of difference between investment revenues to the innovator firm and increased costs to the consumer cannot be estimated and may vary widely, depending on the portion of the market that would have been captured by generic competition, and whether the innovator firm would have lowered its price in view of the competition. A portion of the revenues derived by the innovator firms can be viewed as the recovery of revenues that would have been generated had the historic postpatent periods of market exclusivity continued to exist.

Projections of the costs of patent-term extension based on historic trends alone overlook some important factors that may influence costs in the future. Some of the determinants of costs are currently undergoing changes, but the magnitude of these changes is not yet known. This

section discusses the uncertainties in the factors determining the costs of patent-term extension and the sensitivity of cost projections to variations in assumptions about the determinants.

Numerous uncertainties limit attempts to predict the increased costs to the public of pharmaceuticals under patent-term extension. The revenues that drugs would have generated without an extension and the revenues they will generate with an extension are not known. The number of drugs that have product lives sufficiently long to extend into the extension period and the average duration of the patent-term extension are not known. Revenues from patented drugs after original patent terms expire depend to some degree on whether competition enters the market. The length of the extension is another unknown factor. There are a number of proposals (discussed in ch. 6) for limiting the duration of the extended patent term.

The general effect of variations in these uncertainties on the costs of patent-term extension can be derived from a sensitivity analysis with three variables: 1) the duration of the average extension; 2) the percentage of drugs, on a sales weighted average, having product lives continuing into the extension; and 3) the percentage by which total sales revenues would have been reduced because of generic competition if patent-term extension did not exist.

The following assumptions have been made to simplify this analysis: the innovator firm charges the same price for drugs during the extension that he charged before the extension; the number of units sold is constant throughout the extension period; the effective patent life for all drugs is 10 years; and the supply of new drugs is continuous, providing the same revenue each year. These assumptions are not intended to reflect actual conditions; the sensitivity analysis is, therefore, not a proper basis for projecting actual costs of patent-term extension to the consumer. However, recognizing this bias, some understanding can be developed from the sensitivity analysis of the effects of the uncertainties on the costs associated with patent-term extension.

For the sensitivity analysis, the values for the duration of the average extension are 3 years, which approximates the average time between the filing of a new drug application for a new chemical entity (NCE) and the FDA approval; 7 years, which approximates the loss of effective patent term now experienced by patented NCEs; and an intermediate value of 5 years. The values for the percentage of drugs, on a sales weighted average, having product lives continuing into the extension are 75 and 100 percent. This variable indirectly reflects the rate of innovation in that as more drugs are developed, product lives are expected to decline. The values for the reduction in total sales revenues that would exist because of generic competition if patent-term extension did not exist are 10, 30, 50, and 70 percent. The 50 and 70 percent values are within the range of the maximum potential wholesale savings projected by the Federal Trade Commission if generic-named products were dispensed instead of more expensive branded drugs.

The results of the sensitivity analysis are provided in table 15. The results are provided per $1,000 of yearly wholesale sales of patented drugs during the original term of the patent. Thus, if it is assumed that: 1) the average extension will be 7 years, 2) 100 percent of the patented drugs will be sold during the extension, and 3) the average total sales revenue would have been 70 percent less without patent-term extension; then the additional cost to consumers of patent-term extension will be $490 per $1,000 of unextended, patented-drug sales or about 140 percent of the cost without patent-term extensions. If the average extension is 3 years, if only 75 percent of patented drugs are sold during the extension, and if the average revenue reduction is 10 percent; then the additional costs would be $22.50 per $1,000 of unextended, patented drug sales, or less than 5 percent of the costs in the preceding example.

Evident from the sensitivity analysis is the fact that the additional cost to consumers due to patent-term extension will be highly dependent

on assumptions made about generic competition. Unless the total sales revenues for the drugs would have been significantly reduced without patent-term extension, the increased revenue to the innovator firms may be relatively insignificant on an aggregate basis.

Table 15.—Sensitivity of the Consumer Cost of Patent-Term Extension to Three Variables[a]

Variable 1: Average extension (years)	3		5		7	
Variable 2: Percentage of drugs that have product lives during the extension period (sales weighted average)	75	100	75	100	75	100
Annual sales revenues of drugs under patent extension (dollars)	225	300	375	500	525	700
Variable 3: Average total sales revenue reduction with competition, percent	Additional cost to consumers[c]					
10	$ 22.5	$ 30	$ 37.5	$ 50	$ 52.5	$ 70
30	67.5	90	112.5	150	157.5	210
50	112.5	150	187.5	250	262.5	350
70	157.5	210	262.5	350	367.5	490

[a]The sensitivity analysis is based on an annual $1,000 worth of wholesale purchases of patented drugs during the original term of the patent. The following assumptions are used in this table: The innovator firm charges the same price for drugs during the extension as before; the number of units sold per year is constant throughout the extension period; the effective patent term for all drugs during the original patent period is 10 years; and the supply of new drugs is continuous, providing the same revenues each year.
[b]It is assumed that $100 worth of new drugs were introduced annually to maintain $1,000 worth of revenues per year of drugs in their original patent term. The amount of sales of drugs during patent extension would be: ($100) × (the sales weighted average) × (the average extension).
[c](Sales of drug under patent extension) × (percentage reduction in revenue).

SOURCE: Office of Technology Assessment.

IMPLICATIONS OF PATENT-TERM EXTENSION FOR SOCIETY

The major groups in society that will be directly affected by patent-term extension are the patentee, the research-intensive firm, the production-intensive firm, and the consumer. Although in most cases the research-intensive firm is the patentee, in some instances the patentee is a separate entity who grants a license to the research-intensive firm to develop and produce the patented drug. In this section we define the consumer as the person for whom the drug is prescribed whether or not payment for the drug is made by a third party (e.g., insurance company or the Government).

The Patentee

Patent-term extension would benefit the patentee by providing a longer effective patent term. If the patentee develops and markets the drug, patent-term extension provides the patentee with the benefits of an exclusive market position during the extension period. If the patentee licenses the patent to another, the patentee can benefit from royalty revenues during the extension period.

Because decisions to develop or market drugs are often based on the length of time remaining in the patent term, the patentee may find that patent-term extension allows him more time to develop a drug or arrange with someone else to develop the drug. In this regard, patent-term extension may be particularly beneficial to universities, medical centers, research foundations, small firms, or foreign companies that may not be able to develop drug candidates in the United States. Therefore, they may arrange for licensees to develop and market the drug candidates. These organizations typically pursue drug candidates only to the preclinical phase; hence the innovator firm is faced with considerable expense and risk should it decide to develop the drug. Finding someone willing to develop the product and working out a licensing arangement frequently requires up to 2 years. Without patent-term extension, the time spent

on licensing activities may reduce the expected patent term to such a degree that the candidate is no longer commercially attractive.

The Research-Intensive Firm

The research-intensive firm may be a patentee, in which case the effects described for the patentee apply. The primary benefit of patent-term extension will be additional revenue obtained due to the exclusive market position during the extension. Although the pharmaceutical industry traditionally has relied on internal funding for R&D activities, patent-term extension could be a favorable factor in securing external funding. This may be of particular advantage to the smaller company.

The costs of patent-term extension to the research-intensive firm are two-fold and appear to be nominal. First, many research-intensive firms market generic and branded-generic drugs. For firms which have not developed new drugs with regularity, these products can be a significant source of income. Patent-term extension may delay the entry of these firms into the generic and branded-generic markets. Second, if patent-term extension increases the rate of innovation, it is possible that the additional competition in innovative drugs could result in some downward pressure on prices and a reduction in the sales of the patented product.

The Production-Intensive Firm

Patent-term extension offers benefits to production-intensive firms only if the rate of innovation is greater than it would have been without patent-term extension and product lives continue beyond the extension period. Production-intensive firms have conflicting interests with respect to patent-term extension. On the one hand, these firms must rely on research-intensive firms as sources of new products. A favorable environment for R&D could benefit them. On the other hand, patent-term extension delays their entry into the market.

The effect of the delay on the production-intensive firm will be particularly acute when the effects of patent-term extension first take hold and the supply of drugs coming off patent protection dwindles. Later, when extended patent terms expire, production-intensive firms may find that the number of drugs with sufficient markets to justify investment has decreased. For those drugs worth marketing, sales potentials will have been reduced, since, in most cases, their remaining product lives will have been shortened. Furthermore, the longer period of exclusive marketing provided by patent-term extension may increase the strength of nonpatent barriers such as brand loyalty and thus reduce the ability of the production-intensive firms to establish their drugs in the market. Thus patent-term extension may have a negative psychological impact on the production-intensive firms.

The Consumer

The consumer will benefit from patent-term extension if more and better drugs are commercialized with patent-term extension than would have been commercialized in its absence. If this happens, the consumer will get better therapy earlier. However, an increase in drug innovation does not necessarily result in improved drug therapies.

An increased supply of new medicines could exert downward pressure on the price of existing drugs. But during the extension, consumers will pay more for most drugs whose patents are extended. Thus, the net effect of patent extension on consumer expenditures is unclear. Furthermore, some groups of consumers, the elderly and chronically ill, will be disproportionately affected, and these groups may be less capable than the population as a whole of bearing the increased costs.

Besides the obvious cost to the consumer of the delayed entry of lower priced generic drugs, patent-term extension may also provide two more subtle costs. The magnitude of these ancillary costs are difficult to ascertain, and they may occur only in isolated cases. First, in some instances, production-intensive firms develop new formulations or compounds which are therapeutically advantageous. These developments may be delayed. Second, to the extent that the

innovator firm is reluctant to market improvements of the patented drug until the patent is about to expire, the consumer will have longer to wait for these improvements.

SUMMARY OF FINDINGS

Patent-term extension will enhance the incentives provided by patents for pharmaceutical research and development. Although patent-term extension lacks a mechanism that would assure increases in R&D activities, the incentives it provides may be sufficient to encourage additional R&D expenditures.

Chief among these incentives are the increased revenues that will occur when extensions begin to run. However, the first extensions will not begin for at least a decade. Thus, in the immediate future, patent-term extension will have no effect on revenues. Although historic trends indicate that R&D expenditures are closely related to revenues, research expenditures could increase before extensions begin if decisionmakers base their funding decisions on anticipated rates of return.

The extension will be most beneficial to firms selling high-income drugs and will therefore encourage research on drugs with potentially large markets. However, it will not increase the economic attractiveness of research on drugs with small markets. More research efforts may be directed toward second uses for existing drugs and towards drugs subject to extensive testing requirements as a result of patent-term extensions.

The bulk of revenues generated by patent-term extension will go to a relatively small number of firms who have a history of success in particular research areas. The successes could increase their dominance in these areas and discourage other firms from conducting similar types of research.

Competition from generically equivalent drugs will be delayed by patent-term extension. In some instances, the remaining product lives on drugs whose patents are expiring may not be sufficient to attract competition from generically equivalent drugs.

The prices of drugs whose patents are extended will be higher during the extension period. The magnitude of the increased costs of these drugs to consumers will depend on the extent to which generic competition would have existed had patent terms not been extended. Generic competition will have a greater effect on the revenues of innovator firms than on consumer costs.

Patent-term extension will benefit the research-intensive firm and the patent owner. However, to the extent that research-intensive firms rely on branded generics for revenues, the benefit will be diminished.

Production-intensive firms have the most to lose as a result of the extension. Although they cannot expand their lines of products if innovation does not occur, patent-term extension will delay their entry into markets and reduce their revenues. In the case of some drugs, production-intensive firms will not enter the market since the remaining product lives after the extensions expire will be insufficient to justify startup costs.

The consumer will benefit if new and better products are developed; however, some drugs will cost more, and the costs will fall disproportionately on the elderly and the chronically ill.

Chapter 5

The Fundamentals of the Patent System

INTRODUCTION

This chapter provides background information on the patent system that will facilitate understanding of the implications of the various proposals for patent-term extension that are discussed in chapter 6.

A patent is the grant by the Government of a right for a limited period of time to exclude others from making, using, or selling an invention.

Patents promote the progress of science and the useful arts in several ways:

- they encourage research since they can provide a mechanism for protecting research results from commercial use by others;
- they encourage the development of products since they can provide an exclusive market position or competitive advantage that enables the patent holder to earn a greater profit and recover his research investment costs;
- they provide a mechanism for the transfer of technology to others who may put the invention to practical use; and
- they enhance the rate at which technology grows by requiring that the invention be promptly disclosed to the public in return for the grant of the patent.

The effectiveness of patents in promoting innovation may vary depending on the other factors influencing the invention and innovation processes. This chapter discusses the patent system in the context of the pharmaceutical industry and examines the role of patents in promoting pharmaceutical innovation. It also provides a brief history of patent law in the United States and examines the practices of those administering and using the patent system.

THE ROLE OF PATENTS IN PHARMACEUTICAL INNOVATION

As stated earlier, once a drug has been discovered, developed, and marketed by a firm, other firms can produce and sell the drug at a price that is considerably lower than that of the innovator since their price need not include the cost of research and development (R&D) or the cost of creating a market. Thus, if there are no restrictions on market entry, later entrants may have a significant competitive advantage.

In view of these facts, research-intensive pharmaceutical firms consider patent protection as a prerequisite to innovation. From the perspective of these firms, patents are valued most highly because they provide a means for restricting the entry of competitors. But patents are also important to pharmaceutical innovation because they allow for the transfer of technology in a valuable form to those capable of putting the technology to practical use.

Historically, a substantial portion of pharmaceutical innovations have been marketed by firms that did not make the original discoveries but instead obtained licenses (i.e., the rights given by patentees to permit others to practice the inventions) to commercialize the inventions. For example, more than one-third of the new chemical entity drugs are commercialized by firms that hold a license for the new technology but do not hold the patent.[1]

The value of a pharmaceutical technology in the business world is significantly influenced by the risk-to-reward ratio and the certainty of the reward. Patents, because of the exclusivity which they provide, may, therefore, be critical factors in corporate decisions to license patents and then complete development of new pharmaceutical technologies.

[1]Private communication from W. Wardell, University of Rochester, July 1, 1981.

A HISTORY OF U.S. PATENT LAW

From the power vested in it by the U.S. Constitution, Congress has enacted the patent law, which establishes the following general principles:

- an invention, to be patentable, must be useful and must be a process, machine, manufacture, or composition of matter (statutory classes);
- a patent can be granted only for an invention that is novel and not obvious (patentability requirements);
- a patent gives the owner the right to exclude others from making, using, or selling the invention in the United States; however, if the invention is made or used by or for the U. S. Government, the patentee cannot prevent the infringement but can only seek reasonable compensation; and
- a patent term shall run for 17 years.

In the Act of 1790, Congress established a 14-year patent term. The selection of the term was somewhat arbitrary and was said to be equivalent to the length of two apprenticeships. The Patent Act of 1836 permitted the Commissioner of Patents, in certain instances, to extend the 14-year term by 7 years. In the Patent Act of 1861, however, Congress repealed the extension provision and established the 17-year patent term, which stands today. From accounts of the history of the Act, it appears that the term of 17 years was a compromise between the House bill, which provided for a 14-year term with a possible extension of 7 years, and the Senate amendment, which provided for a 14-year term with no extension.

Since 1861, numerous bills have been introduced to change the patent term: proposed terms have ranged from 5 years to 34 years (17 years with a possible 17-year extension). The first proposal for changing the 17-year patent term was made in 1881 and authorized the Commissioner of Patents to extend patents for which no reasonable compensation had been received; under this proposal, licensing was compulsory and royalties were limited by law. Most of the other proposals for patent extensions provided for a 17-year term which would be extended for 17 years if the patentee, through no fault of his own, had received an insufficient financial return. The determination of the adequacy of the financial return resided, depending on the specific bill, either with the Commissioner of Patents or with the Court of Claims.

Despite these proposals, patent-term extensions had not received serious congressional attention until the patent-term restoration bills S. 255 and HR. 1937 were introduced in the first session of the 97th Congress.

THE PHARMACEUTICAL PATENT

The cornerstone of the patent system is the patent document. By law, the patent document must provide a teaching of the invention such that others can make and use the invention and contain claims that define the boundary of the invention. To be patentable, the invention defined by these claims can be neither known nor obvious to others.

The portion of the patent application that teaches the invention is commonly termed the specification. The specification serves several functions. First, it describes the invention. Second, it discloses the utility of the invention since patents are only granted for useful inventions. Third, it describes how to make and use the invention since, in part, the purpose of the patent is to secure a disclosure of the invention from the inventor in exchange for the patent right. Fourth, it discloses the best mode of practicing the invention, insofar as it is known to the patent applicant at the time the application is filed. The specification concludes with one or more claims defining the boundary of the patent rights.

The claims serve much the same purpose as a deed to a piece of land. When a patentee at-

tempts to enforce a patent, the claim is compared with the product or process against which the enforcement action is directed to determine whether an infringement exists.

On the other hand, if other parties can show that the claim encompasses subject matter which was known or was obvious prior to the invention, the claim is invalid in its entirety and no part of the claim can be enforced.

Consequently, patent applications frequently contain a plurality of claims that vary in scope. Some claims may be very broad and encompass many possible products or processes. However, the broader the scope of a claim, the greater the likelihood that the claim will encompass subject matter which was known or obvious prior to the invention. Thus as the scope of a claim increases, so does its chances of being declared invalid. Claims of narrower scope may be adequate to protect the particular aspect of an invention that will be commercialized and may be less vulnerable to attacks on validity.

Claims in pharmaceutical patents may be directed to a product, a method for using the product, or a process for making the product. Product claims may be directed to invented chemicals (chemical claims) or to compositions, i.e., mixtures of chemicals. Claims directed at all of these categories could be made for a single pharmaceutical. To illustrate this fact, an example of each type of claim is provided:

- *A chemical claim.*—A compound having the structural formula C_2H_5O- ⬡ $NHC(O)R$ wherein R is $-CH_3$ or $-C_2H_5$.
- *A composition claim.*—A composition useful for treating headaches when administered orally to a human suffering from a headache in a unit dosage form consisting essentially of 5 to 95 weight percent of phenacetin and 5 to 95 weight percent of aspirin.
- *A process claim.*—A process for making phenacetin comprising reacting a compound of the formula C_2H_5O- ⬡ $-NH_2$ with glacial acetic acid at a temperature of 50° to 80° C in the presence of an effective amount of dehydrating catalyst.
- *A method-for-use claim.*—A method for treating headaches comprising orally administering to a human suffering from a headache a therapeutically effective amount of phenacetin.

A headache drug containing 40 weight percent phenacetin and 60 weight percent aspirin is covered by each of these claims. Although these claims might be contained within one patent, it is possible that each of the claims might involve a separate invention and therefore a separate patent. Consider the following hypothetical example:

> Inventor A discovered a group of compounds expressed in the chemical claim (when R is $-CH_3$, the compound is phenacetin). In A's specification a method was disclosed for making the compounds and a use (as antioxidants to preserve rubber).
>
> Later Inventor B discovered an improved process for making the compound invented by A. B received a patent claiming the improved process (represented by the process claim).
>
> Inventor C subsequently discovered that one of the compounds (phenacetin) invented by A was useful in treating headaches and received a patent claiming the method for use (represented by the method-for-use claim).
>
> After C's invention, Inventor D found that the mixture of phenacetin and aspirin provided a better treatment for headaches than phenacetin or aspirin alone. Inventor D could obtain a method-for-use patent (claim not illustrated) and a composition patent (represented by the composition claim) for his discovery.

Each of the four patents can affect what the other patentees can do with their inventions. Table 16 is provided to assist in illustrating the activities which each of the patentees can undertake. It is assumed that the patents to A, B, C, and D were issued, and will therefore expire, in chronological order. While all four patents are

Table 16.—Activities Permitted Before and After Patent Expiration

Activity	Before expiration of any of the patents	After expiration			
		A's patent	A&B's patents	A,B,&C's patents	A,B,C,&D's patents
Make, use, or sell phenacetin	A	anyone	anyone	anyone	anyone
Use B's process to make phenacetin	no one	B	anyone	anyone	anyone
Use phenacetin to treat headaches	no one	C	C	anyone	anyone
Make, use or sell combination of phenacetin and aspirin to treat headaches	no one	no one	no one	D	anyone

SOURCE: Office of Technology Assessment.

in effect, only A can make, use, and sell phenacetin; no one including A, B, C, or D can use B's improved process or C's method-for-use, and no one can make, use, or sell D's composition. B, C, and D cannot practice their inventions since the practice would infringe A's patent on phenacetin, i.e., B, C, and D would be making or selling phenacetin.

When A's patent expires, anyone (including B, C, and D) can make, use, and sell phenacetin. Since B's patent is still in effect, only B can use the improved process, but B cannot use C's method for use nor make, use, or sell D's composition. C, however, can use phenacetin to treat headaches, but he cannot use B's improved process, or make, use, or sell, D's composition. No one, including D, can make, use, or sell D's composition since that would infringe C's patent because phenacetin, albeit in combination with aspirin, would still be used to treat headaches.

When the patents to A and B expire, anyone can practice A's and B's inventions. C's method-for-use patent prevents others from using C's invention and C's patent also prevents use of D's invention. When the patents to A, B, and C expire, D can practice his invention, and exclude all others from practicing his invention. Anyone can practice the inventions of A, B, and C.

Not all types of patents have equal value. Infringements on chemical and composition patents generally are easier to detect than infringements on other types of patents. Infringements on chemical and composition patents occur when manufacturers or distributors make or sell the drugs, and can be readily detected, because neither sales nor distribution can be kept secret. Infringements on process patents take place in relative privacy and may be impossible to discover.

Additionally, a product made abroad using the patented process can be imported into the United States without providing an actionable infringement of the patent. The patentee, however, does have recourse against the infringer through the International Trade Commission but must prove that the importation of the product results in substantial economic harm to a domestic industry and that the process practiced in the foreign country infringes the patent. Proving either of these points can be quite difficult.

The enforcement of method-for-use patents provides unique difficulties. First, the direct infringer is the ultimate user and not the manufacturer. For the manufacturer to be found liable for infringement, the patentee must prove that the manufacturer induced the user to infringe the patent. Second, except in instances in which the drug has no other use, the owner of a method-for-use patent cannot stop the manufacturer from making and selling the drug. For example, if the method-for-use patent were for the discovery that aspirin could be used as a contraceptive, the patentee could not stop existing manufacturers from making and selling aspirin. Because of the vast number of individuals who may use aspirin for its contraceptive activity, and because enforcement of the patent would involve a suit against each user, the enforcement of the patent would not be financially feasible.

Because of their potential for enforcement, chemical and composition patents are generally preferred by the inventor, but method-of-use and process patents could, on occasion, be sufficient to ensure an innovator an exclusive market position.

SECURING A PATENT

The progress from an invention to an issued patent is characterized by three stages: the preliminary evaluation stage, the patent application drafting stage, and the patent examination stage.

Preliminary Evaluation

In the preliminary evaluation stage, the inventor attempts to determine the importance of his invention. For example, once an inventor has discovered a new chemical, he must attempt to discover its utility and determine its potential economic value. The length of the preliminary evaluation stage may range from 1 week to 5 or more years, depending on the perceived importance of the invention and the ability of the inventor to develop the invention to a point that he can sufficiently fulfill the requirements for patenting.

Drafting of the Patent Application

The patent application drafting stage usually takes between 6 months to 2 years, but this stage can vary greatly. During this stage, the breadth of the invention is investigated. For example, is the invention one chemical or a group of related chemicals? The potential patentability of the invention is also considered. Is the invention novel? Is it obvious? The patent application is prepared according to statutory requirements and the legal, regulatory, and procedural requirements of the Patent Office.

If the invention appears to be of economic significance, substantial incentives exist for pursuing the invention diligently and filing a patent application at an early date. The primary incentive is to reduce the potential of losing the patent right to another who has made the same invention. In the United States, if two or more inventors independently discover a patentable invention, a proceeding termed an "interference" is declared to determine which of the inventors was the first to conceive the invention. If, however, the inventor has not diligently pursued the invention, he may be precluded from using his date of conception for determining who was the first to invent. Moreover, procedural advantages are provided to the inventor who files the first patent application. The advantage of an early filing is even more important if foreign patents are sought since almost all foreign countries award the patent to the inventor who files the first patent application. By treaty with many countries, if certain requirements are met, the U.S. filing date serves as the critical filing date for this determination in those countries.

A second incentive for speedy filing of a patent application is to enable the technology to be disclosed to others without the loss of proprietary rights to the invention. In most foreign countries, if the invention is disclosed prior to the filing of a patent application, a patent is barred. In the United States, a 1-year grace period exists in which a patent application can be filed after the invention has been disclosed to the public. This secondary incentive is usually most important in the university environment where pressure is placed on the researcher to publish.

Examination of the Application

Once the third stage is reached, the rate at which the application proceeds is no longer solely dependent on the inventor and his patent attorney but also on the Patent Office.

The patent examination stage is initiated with the filing of a patent application in the Patent Office. The patent application, containing the specifications and claims that the applicant seeks to have patented, is examined by a patent examiner who must determine whether each of the claims defines an invention that is novel and not obvious, and whether the patent application has met other statutory requirements and the regulatory and procedural requirements of the Patent Office. In his examination, the examiner conducts a search of relevant publications and patents. He reports the findings of his examination to the patent applicant. The time between the filing of the patent application and the first report, or "action," from the examiner ranges from 3 to 18 months.

The examiner often finds a publication or patent that brings into question the patentability of one or more claims. Thus, the first action by the examiner may be a rejection of the questionable claims. The applicant is given 3 months (which can be extended by an additional 3 months) to respond to the action. The applicant may modify the claims to overcome the rejection or may show that the rejection was unsound and should be withdrawn.

Approximately 2 months after the applicant responds, the examiner must act on the application and either allow the patent application or issue what is called a final rejection of the questionable claims. The patent applicant then has 3 months to respond: he may delete or amend claims to overcome the rejection; he may argue that the rejection be withdrawn; or he may appeal directly to the Board of Appeals in the Patent Office. If the applicant responds without filing an appeal the examiner can entirely withdraw the rejection or notify the applicant that the rejection, in its entirety or in modified form, still stands. The applicant must thereafter appeal to the Board of Appeals or abandon the patent application.

Because of the heavy workload on the Board of Appeals, 2 years may pass between the filing of an appeal and a resolution of the appeal. If the applicant is unsuccessful at the Board of Appeals, he may then appeal either to the Court of Customs and Patent Appeals or to the District Court of the District of Columbia, in which case the judicial appeal process applies. Another 12 to 18 months may be consumed.

At any point in the examination period, the patent application may be judged allowable. The Patent Office then requires the payment of a fee by the applicant. After this payment has been made, the patent document is printed and issued. A period of 5 to 12 months may elapse between the allowance of the patent and its issuance.

The period between the filing of a patent application and the patent issuance generally ranges from 18 months to 3 or more years. The average patent-pending period is currently a little more than 2 years. In the mid-1970's, it was about 18 months, and in the 1950's, it was well over 3 years.

During the patent examination stage, an applicant may file more than one application. For example, after the initial patent application was filed, the applicant may have discovered additional information regarding the invention and may wish to supplement the original application. To do so, he must file a second patent application containing the information in the first application (old matter) and the supplemental information (new matter). This second application is termed a continuation-in-part application and maintains the benefit of the filing date of the first patent application with respect to the old matter and the filing date of the second patent application with respect to the new matter. The identical patent application may also be refiled (a continuation application), perhaps to obtain a reconsideration by the examiner. If a patent application claims more than one invention, the Patent Office can require that applications be filed for each of the inventions (divisional applications). The divisional applications need only be filed before the first application is abandoned or is issued as a patent. There is no statutory limit on the number of times that an application may be refiled as continuing applications.

While sound reasons exist, in most instances, for a patent applicant to file continuing or divisional applications, there is a potential for abuse. So long as no competitor has entered the market, the delays in the issuance of a patent work to the advantage of the patent applicant since the patent expiration is also delayed.

Interference Proceedings

Interference proceedings are time consuming. Approximately 2.5 percent of all patent applications are involved in interferences, and the figure for important inventions is higher. Interference proceedings can last 20 or more years and most interference proceedings are not completed in less than 4 years. The subject of the interference proceedings might be two or more patent applications or it might be a patent and one or more patent applications.

The time consumed during the interference proceeding will delay the issuance of a patent from an involved patent application and thus delay the expiration of the patent.

These proceedings have, on occasion, lasted so long that pharmaceutical patents have been issued years after FDA premarket approval was obtained.

FOREIGN PATENTS

A U.S. patent provides the right to exclude only in the United States and its territories. Patent rights must be sought in each country in which a patent right is desired.

Although many differences exist between foreign patents and U.S. patents, only three aspects will be discussed: the duration of the patent, the types of inventions that can be patented, and the compulsory licensing of patents.

Duration of the Patent

Virtually all foreign countries have patent terms that begin on the patent application date. The patent term in most industrialized foreign countries is 20 years. The period in which a patentee can exclude others from making, using, or selling his invention is, however, considerably less than 20 years since a portion of the patent term is spent in obtaining the patent. Moreover, in countries in which the grant of a patent can be opposed by the public (opposition procedures), the patent term, may be further eroded. After the patent is granted, however, the patent owner may be able to recover damages for any patent infringement that occurred while the patent application was pending if the infringer knew or could have known of the patent application.

Extensions of patents in foreign countries generally have not been permitted in recent history except to compensate for the patent term lost as a result of war. Some of the British Commonwealth countries do, however, permit extensions (usually up to 5 years) if the patent owner has not been adequately remunerated for his invention. Prior to 1978, Britain had a 16-year patent term that could be extended in cases of inadequate remuneration, but her patent law now conforms with the laws in other European countries: the patent term runs 20 years from the date of the patent application and no extensions are permitted.

Patentable Inventions

The types of inventions that can be patented in foreign countries are in a state of flux. Many countries do not permit chemical claims, and some that allow chemical claims have specifically excluded such claims for pharmaceuticals. Of the approximately 120 countries that have patent systems, nearly one half do not allow claims to pharmaceuticals. Recently, many of the more industrialized countries have begun to permit chemical claims and to permit claims to pharmaceuticals, but the lesser developed countries are not following suit. In some of the lesser developed countries that do permit pharmaceutical patents, the local courts may not find the patent enforceable because it relates to pharmaceuticals. Method-for-use claims for pharmaceuticals are permitted in less than 20 percent of the foreign countries with patent systems. Some countries (Egypt and India) provide shorter patent terms for pharmaceuticals than for other chemicals.

Compulsory Licensing

Most foreign countries (including most industrialized nations) have compulsory licensing laws, which allow members of the public to demand that the patent be licensed for a reasonable royalty. The purposes behind compulsory licensing may be twofold: to provide incentives for putting inventions to practical use, and to encourage industrial development in the country. In most foreign countries a compulsory license can be demanded if the patentee is not "working" the patented invention in the country within a certain time after the issuance of the patent. The term "working" varies in definition

from country to country. In some countries, marketing the patented invention in the country is all that is required. In other countries, the product must be manufactured in the country. In still other countries, an attempt to secure a licensee for the patent is sufficient.

Several countries also require compulsory licensing if the patent owner is not meeting national demand for the product, and several countries require licensing if such licensing is in the public interest.

Chapter 6

The Mechanics of Patent-Term Extension

INTRODUCTION

Throughout this report, patent-term extension has been discussed as a concept, but the specifics of its form have not been reviewed. The effects of patent-term extension will, however, vary depending on the technical details of the extension.

By extending the period in which a patentee may exclude others from making, using, or selling his invention, patent-term extension provides potential rewards to the patentee. However, it also delays use of the innovative technology by others. Thus, to assess the effects of patent-term extension on innovation, one must compare the value of the extended protection for the patentee with the reduced use of the technology by others after the original patent term expires. This comparison can only be made in terms of the type of extension that is granted.

The effects will vary depending on whether the entire patent right is extended or whether the focus of the extension is narrowed to a portion of the invention claimed in the patent. For example, a chemical patent may claim several new chemicals, only one of which is marketed as a drug. If the full patent right were provided during the extension, the patentee could exclude others from making, using, or selling any of the patented chemicals for any purpose. Under this circumstance, those aspects of the patented technology that were not subjected to the Food and Drug Administration's (FDA) premarketing review would have patent protection for more than 17 years. The rights protected during the extension could be modified in a fashion that would still provide meaningful incentives for the patentee but yet allow others to use the patented technology for some purposes during the extension.

As seen in chapter 5, claims can be made for chemicals, compositions of known chemicals, processes, or methods-for-use but not all classes of patents are considered to have equal value. The relative value of each of the classes can be further affected by modifications of the patent rights during the extension. These modifications and their implications on the classes of claims are discussed in the following sections.

Modifications could be directed at the scope of claims during the extension, the products, processes, and uses against which the patent could be enforced during the extension, and the remedies available to the patentee for infringement of the patent during the extension.

Two other aspects of patent-term extension will significantly influence its effects: the duration of the extension, and the obligations of the patentee during the extension.

LIMITATIONS IN SCOPE AND ENFORCEMENT

The most important factors affecting the balance between the degree of protection provided to the patentee and the extent to which the patented technology can be used by others during the extension are those relating to limitations in scope and limitations in enforcement. Although these factors are described separately, they are interactive.

Scope: A patent claim defines the breadth of the invention for which the patent rights are sought. The claim may contain many possible embodiments of the invention, and the full scope of the claim would include all of the embodiments. A limitation in the scope of the claim would result in the claim being narrowed during the extension. For example, a chemical

claim is directed to chemicals A, B, and C in its full scope. If the scope were limited during the extension to only chemical A, the making, using, or selling of chemicals B and C for any purpose would fall outside the narrowed scope of the claim and would not be an infringement.

Enforceability: A patent is enforceable against an infringement of the invention defined by the claim. In the above example, during the original term of the chemical patent, the patentee can enforce the patent against anyone in the United States who makes, uses, or sells any of chemicals A, B, or C, regardless of how the chemical is made or used. During the extension, the enforceability of the claim might be limited by conditions not expressed in the claim. For example, the patentee might only be permitted to enforce the patent against anyone who used or sold the chemical for a particular purpose. Thus, if the enforceability of the claim were limited to chemicals A, B, and C, as used for treating headaches, the claim would not be enforceable against someone who made or sold any of the chemicals for gasoline additives.

Limitations in Scope

If the full scope of the claim could be enforced during the extension, the effects of the extension on the patentee's rights and the availability of the technology for use by others would be those described in chapter 5. If, however, the scope were limited during the extension, the effects would vary depending on the way in which the scope was limited and the type of claim involved.

The scope of claim could be limited in three ways:

- Method S.1—The extension might be provided only for those aspects of the patent claims that involve the specific active chemical approved by FDA.
- Method S.2—The focus of the claim might be narrowed during the extension by restricting the parameters (e.g., temperature range, dosage amount, or type of chemical) recited in the claim to the specific value existing in the FDA approved product, process, or method-for-use.
- Method S.3—The extension might be provided only for the specific chemical (in the case of chemical claims), composition (in the case of composition claims), the specific process (in the case of process claims), or method-for-use (in the case of method-for-use claims) approved by FDA regardless of whether a parameter for each product, process, or method-for-use condition is recited in the claims.

Examples of these methods are provided in the discussion of the various types of claims. These examples are provided to help explain both the concepts involved in these methods and the distinctions between them. As will be seen in the following sections, meaningful patent protection could result if the full scope of the claim is enforceable during the extension or if the scope is restricted, according to method S.1, to the active chemical approved by FDA. Methods S.2 and S.3, however, provide little protection for composition, process, and method-for-use claims.

Chemical Claims: For chemical claims, there is no difference in the amount of protection provided by any of these methods. Since the aspect of the claimed invention involved in the specific FDA approval is a chemical, all of the methods would restrict the claim during the extensions to the specific chemical contained in the FDA approved product.

During the extension any other chemical claimed in the patent could be freely made, used, or sold by others. For example, even a minor modification of the chemical would create a different chemical and take it outside the scope of the extended patent. During the extended period, therefore, the patentee could face direct competition from chemicals covered by his claims during the original patent term. However, the competitor would have to undergo the expense of conducting safety and efficacy tests for FDA approval of the modified chemical. Moreover, the modified chemical would not be chemically and therapeutically equivalent to the existing drug and could not be generically substitututed for the patented drug. The developer of the modified product would, therefore, have to establish a market for the drug.

Because of the nonpatent barriers that supplement the patent protection, these methods provide the patentee with moderate protection.

Although it is possible that the modified chemical might have enhanced therapeutic value, the therapeutic value in most cases would be similar to that of the patented drug. Thus, considerable effort would be spent by competitors to secure FDA approval but few social benefits would accrue. The innovator could attempt to broaden the scope by securing FDA approval (and patent-term extensions) for other chemicals within the original scope of the claim, but, such efforts, while blocking competition, would be costly and would provide few benefits to society.

Composition Claims: For composition claims, the three different methods would have different effects on the amount of protection provided to the patentee and the availability of the technology for use by others.

Assume that a composition claim recites: "A therapeutic composition for treating headaches in humans comprising a unit dosage amount of chemical A or B in an inert carrier" and that the product approved by FDA consists of 0.4 milligrams of chemical A and 3 grams of sodium stearate as a binder.

If method S.1 were used to limit the scope to chemicals approved by FDA, the claim would apply to compositions containing chemical A and any carrier. Thus, the scope of the claim would be limited more by chemical than by composition, and the claim would cover many compositions for which FDA approval was not sought. The scope of the claim would still be broad and the value of the claim to the patentee would be similar to the value of a chemical claim.

If method S.2 were used, to restrict the scope to the specific values for the recited parameters present in the FDA approved composition, the claim would be limited to compositions containing chemical A and sodium stearate. The claim would still cover many compositions for which FDA approval was not sought. The value of the claim would be limited to the patentee since many possible inert carriers exist; by selecting a different, but equivalent carrier, the claim could be avoided. The modifications to avoid infringement would, however, necessitate FDA approval.

If method S.3 were used and claims were restricted to the precise embodiment approved by FDA, the claim would, in our example, be limited to compositions containing 0.4 milligrams of chemical A and 3 grams of sodium stearate. Because the claim covers only one composition it could be easily circumvented.

Process Claims: FDA, in approving a drug, also approves the processes by which it is made. The aspects of the claimed invention involved in the specific FDA approval are, therefore, the process conditions.

For example, the process claim recites: "A process for making chemical A or A^1 by admixing chemical X or X^1 and chemical Y and heating the mixture to between 50° and 80° C in the presence of a dehydrating catalyst." The process used to make chemical A, which was approved by FDA, involves very specific conditions including amounts of reactants and purification procedures.

If extensions were based on method S.1 and the scope of claims were limited to chemicals approved by FDA, in our example the claim would be limited to a process for making chemical A using the specified reactants, a reaction temperature between 50° and 80° C, and any dehydrating catalyst. The process could be used by anyone to make chemical A^1. Many processes for making chemical A other than the one specifically involved in the FDA approval would be covered by the claim.

If method S.2 were used and the scope of claims during the extension were narrowed to the specific values of parameters in the FDA approved invention, the claim would be limited to processes for making chemical A using the specified reactants, a specific temperature, and a specific catalyst. If method S.3 were used, the claim would be limited to the precise process involved in the FDA approval including process limitations not specifically recited in the claim, e.g., the amounts of the reactants and the procedure for purifying chemical A.

Under methods S.2 and S.3, the patent could be easily avoided by minor and insignificant process modifications and the patentee would have disclosed specific process information to the public so that the scope of the claim would be known. Methods S.2 and S.3 would not provide meaningful patent protection.

Method-for-Use Claims: The method used for extending patent terms can have a significant effect on the value of method-for-use claims.

Assume that a method-for-use claim recites: "A method for relieving pain in a human comprising internally administering a therapeutically effective amount of chemical A or B" and that the FDA approval is for orally administering 10 to 20 milligrams of chemical A three times a day to relieve the pain of headaches in adults.

Under method S.1, the claim would be limited to any internal administration of chemical A to relieve pain. The patentee could exercise his rights against another who used or sold chemical A for the treatment of any pain, e.g., arthritis, even though the FDA approval was only for the treatment of headaches.

Under method S.2, the claim would be limited to any oral administration of 10 to 20 milligrams of chemical A to relieve the pain of headaches. Under method S.3, the claim would be limited to the specific use of orally administering 10 to 20 milligrams of chemical A three times a day to relieve the pain of headaches in adults.

Under methods S.2 and S.3, others could use chemical A for relieving the pain of arthritis. Both of these methods present problems of enforcement since doctors could prescribe and consumers use chemical A (produced by another as an arthritis pain reliever) for treating headaches; the only remedy available to the patentee would be to sue each of the infringers individually.

Limitations in Enforcement

If no limitations were placed on enforcement, the patent could be enforced against any product, process, or use that falls within the scope of the claim regardless of the purposes for which it would be used. Thus the public would have no right to use any of the patented technology during the extension. There are, however, methods for limiting enforcement of actions during the extensions:

- Method E.1: During the extension the patent could be enforced only against a pharmaceutical product, process, or use that requires FDA premarketing approval.
- Method E.2: During the extension the patent could be enforced only against one who uses the claimed invention for the same therapy that was specified in the patentee's drug application and for the therapy (termed "specific therapy approved") for which FDA approval was granted.

These methods are illustrated in relation to the following example: the patentee has a chemical claim on chemical A and obtains FDA approval for treating headaches with chemical A.

Under method E.1, the patent could be enforced against anyone making, using, or selling chemical A as a drug, (e.g., sale of the drug for treating high blood pressure would be prohibited) but not against anyone making, using, or selling chemical A for a nondrug use, even though the nondrug use might be regulated. Thus, one could sell the chemical as an herbicide. Method E.1 therefore enables the public to use the patented technology during the extension for other than drug uses. Such use would not result in competition for the innovator's drug.

Under method E.2, the patent could only be enforced against anyone making, using, or selling chemical A for treating headaches. Method E.2 could significantly affect the patentee's incentives but could provide the public with a greater right to use the patented technology during the extension.

From the standpoint of the patentee, method E.2 presents a disadvantage since the patent would be enforceable only when the drug is used for the specific therapy approved. A competitor could obtain FDA approval and manufacture and sell the identical drug for a different therapy; yet the doctor could prescribe or the con-

sumer could use the competitor's drug for the specific therapy approved. As with method-for-use patents discussed in chapter 5, the patentee may not have an effective mechanism to enforce his patent. His only remedy would be to sue each of the prescribers or users for patent infringement.

From the standpoint of promoting pharmaceutical innovation, method E.2 (limiting enforcement to the specific therapy approved) could be beneficial for developing new therapies for existing drugs. A competitor would have an incentive to develop another pharmaceutical use for the drug so that he could market it. The patentee would also have an incentive to develop other pharmaceutical uses so that those uses would be covered during the extension. While some uses developed may provide significant improvements in health care, others may not.

Interaction Between Limitations of Scope and Limitations of Enforcement

By combining scope limitations with enforcement limitations, one can achieve a desirable balance between meaningful patent protection for the patentee and public use of the patented technology during the extension. Three combinations of the methods discussed appear to be most attractive from the standpoint of balancing these sometimes conflicting objectives. Each combination strikes a different balance.

Combination A:

- Limitation in scope: Method S.1—Claims restricted to the chemical approved by FDA.
- Limitation in enforcement: Method E.1—Enforcement only against FDA approved product, process, or method-for-use.

In combination A the scope of the claim would be limited to the chemical approved by FDA, and the patent could be enforced only against products, processes, or methods-for-use which were subject to FDA approval. Of the three combinations, this one would provide the most protection to the patentee.

Combination A would have the following effects:

- the patented technology could be used for all but pharmaceutical purposes;
- others could produce minor variations of the chemical and use the technology for drugs;
- others could not develop the approved chemical for new FDA uses; and
- the patentee could enforce the patent against anyone who marketed an identical drug regardless of the drug therapy for which it was prescribed or used.

Combination B:

- No limitation in scope.
- Limitation in enforcement: Method E.2—Enforcement limited to specific therapy approved.

With combination B, the claim would be interpreted to its full scope; however, the patent could only be enforced against anyone who made, sold, or used the patented product, process, or method-for-use for the specific therapy approved. This combination differs from combination A in that the claim would be broader with respect to the active chemicals covered, but the patented technology could be used for other drug therapies.

Combination B would have the following effects:

- the patented technology could be developed for all uses other than the specific therapy approved by FDA; and
- enforcement would not be practicable against an identical drug developed for a different therapy but prescribed or used for the patentee's therapy.

Combination C:

- Limitation in scope: Method S.1—Claims restricted to chemical approved by FDA.
- Limitation in enforcement: Method E.2—Enforcement limited to specific therapy approved.

Under combination C, the scope of the claim would be linked to the chemical or chemical and use approved by FDA, and the patent could only be enforced against the sale or use of the patented product, process, or method-for-use

for the specific therapy approved. Of the three combinations, this combination would provide the least protection to the patentee.

Combination C would have the following effects:

- others could make, use, and sell minor variations of the chemical for uses identical to the specific therapy approved;
- others could develop the patented technology for all uses other than the specific therapy approved; and
- enforcement would not be practicable against an identical drug developed for a different therapy but prescribed or used for the patentee's therapy.

LIMITATIONS IN REMEDIES

In the original patent term a patentee can secure an injunction against an infringer and obtain damages for the infringement. Proposals have been made to limit the remedies available to the patentee during the extension period. The most restrictive proposal would not permit the patentee to exclude others from making, using, or selling the patented drug but would require him to license the invention for a reasonable fee (compulsory licensing).

If the objective of extending the patent term is to increase the potential for returns to the innovating firm, compulsory licensing would probably not accomplish that objective. The benefits of a reasonable royalty are likely to be less than the benefits received by the patentee through the sales of products. Moreover, the determination of a reasonable royalty can be difficult, expensive, and time-consuming. Burdens would be placed on both the administrators of the law and on the firms contesting the royalty. Most significantly, compulsory licensing would create an uncertainty which would not be resolved until a request for a license was made and granted. For these reasons, compulsory licensing could detract from any incentive for pharmaceutical innovation provided by patent-term extension.

There are, however, intermediate grounds. For example, compulsory licensing could be required only if the firm were not satisfying the needs of the public or if the licensing were essential for national security (e.g., to assure more than one source of supply in the event of a catastrophe). Such intermediate grounds presently exist to protect national interests. Title 28, section 1498 of the U.S. Code, provides that the United States can use or manufacture, or have used and have manufactured for it, a patented invention without the patentee's permission. The patentee however, is entitled to reasonable compensation for such use and manufacture.

THE DURATION OF THE EXTENSION

Several proposals have been made for establishing the duration of the extension.

- the duration could be a period which enables the innovator to obtain adequate remuneration for the invention, and would be decided on a case-by-case basis (proposal D.1);
- the duration could be a predetermined and uniform period (proposal D.2);
- the duration could be the period between the date on which the innovator was prepared to commercialize the invention and the date on which marketing approval was obtained (proposal D.3); or
- the duration could be a period corresponding to at least a part of the time consumed in the regulatory review process (proposal D.4).

Each of these proposals could be modified in such a way that the extension would be terminated if the drug were not being sold by the innovator firm or if the patented technology (e.g., in the instance of a patented process) were no longer being used for the drug.

Proposal D.1: Adequate remuneration.

This method would pose significant administrative problems but because very few new drugs are marketed (between 40 and 100 new drug applications (NDAs) are approved per year), the problems would be small in number. More significantly, the determination of adequate remuneration would be subject to controversy. The extension is most meaningful to the research-intensive companies as it applies to drugs that have been most profitable during the original patent term. Unless the extension included these drugs, the economic benefits from pharmaceutical innovation provided by patent-term extension would be significantly reduced.

Because this method would not provide the public with notice that the patent was being extended until the expiration date of the original patent term was approaching, potential competitors might not initiate steps for manufacturing and marketing the drug until they knew that no extension would be granted. Thus, if the administrative proceedings were lengthy, a de facto extension might result.

Proposal D.2: Predetermined and uniform period.

Extending the patent term for a predetermined period, e.g., 7 years, might result in inequities, with some drugs being protected for more than 17 years. There would be no direct correlation between the regulatory approval time and the patent life. This method, however, would be easy to administer.

Proposal D.3: Marketing delay compensation.

Determining the delay between the time when a firm was ready to market a product and the time the product was approved by FDA would be difficult and the determination would be subject to dispute. Making these determinations would be an administrative burden. Moreover, firms would be encouraged to prematurely proceed with manufacturing plans in order to increase the extension which could be obtained. If the firm timed its manufacturing plans according to the progress of the drug through FDA, the measured delay might be unduly brief.

Proposal D.4: Time consumed in the regulatory review process.

This proposal, which makes the duration of the extension dependent on the time consumed by the regulatory proceedings, overcomes some of the difficulties and inequities of the other three proposals. Because the dates that premarketing approval procedures begin and end are known, this method would not impose a great administrative burden.

Basing the period of extension on the regulatory review period could compensate the patentee for time he would have spent developing and testing the drug even if FDA did not exist. The likelihood of this occurring would depend on when the period eligible for compensation begins. If the objective of patent-term extension is to encourage pharmaceutical innovation, the issue of whether the patentee receives excess compensation may not be of prime importance.

If proposal D.4 were adopted, the innovators might delay the testing needed to secure premarketing approval. But, such dilatory tactics would also delay the marketing and would therefore be disadvantageous to innovators. If, however, the new drug would compete with an existing drug of the innovator firm, dilatory tactics might be used. But such tactics are discouraged by the courts. If a patentee has purposefully delayed steps needed for FDA approval, the court may refuse to enforce the patent, but proving purposeful delay can be quite expensive and time-consuming.

The effects of this proposal would depend on when the period eligible for compensation begins. In general, the earlier in the regulatory process that the clock starts ticking for determining the duration of the extension, the longer and more economically meaningful the patent-term extension will be. There are a number of dates at which the clock could start.

The period could begin on the date that the NDA was filed with FDA. The period between NDA filing and final approval is frequently about 2 to 3 years. This amount of time might be insufficient to provide significant additional incentives for pharmaceutical innovation. A predetermined period of time could, however, be added to the extension. In some instances, adding a predetermined time would more than compensate for time lost in the regulatory review process.

The period eligible for compensation might instead begin on the date that the first clinical trials in the United States were initiated. The time between the initiation of clinical trials and the approval of the NDA for new chemical entities is frequently 5 to 8 years. Beginning the clock at the first clinical trials could result in significantly extended patent terms.

Alternatively, the period eligible for compensation could begin on the date on which the investigational new drug (IND) application is filed with FDA. The filing date of an IND is easy to determine and the filing of an IND is a precondition to the initiation of clinical trials in the United States. The IND could be filed long before clinical trials began.

Another proposal would begin the eligibility period when substantial preclinical animal tests (e.g., tests of longer than 6 months) were started. These tests are frequently initiated prior to the filing of an IND.

Maximum Extension Period

A maximum period of extension has been proposed to eliminate extensions of long duration and to discourage innovator firms from delaying the premarketing approval process to obtain later expiration dates on extensions.

The effects of the extension will depend on the length of the extension. If the maximum period is too short, the potential for incentives for pharmaceutical innovation may be too small to be meaningful. If the maximum period is too long, the social costs of innovation may outweigh its benefits.

The maximum extension could simply be a specific number of years with no qualifications. Proposals have been made, however, that would prevent the extension from going beyond a fixed time from the filing of the first patent application.

This constraint could act as a disincentive for delaying proceedings in the Patent Office. If the date of the filing of the first patent application were selected as the starting point, the patentee would receive no benefit from filing continuation or divisional applications to delay the issuance of the patent application.

OTHER CONSIDERATIONS

There are several other aspects of patent-term extension that must be addressed. Should extensions be granted to marketed drugs that are ordered off the market for further testing? Should patent extensions be granted in cases involving alternative uses of drugs, since alternative uses also must be approved by FDA?

With respect to the first question, extending a patent to compensate for the period when the product is ordered off the market could pose difficulties. If an extension were granted only when a Federal regulatory agency ordered a withdrawal, the innovator firm might be reluctant to voluntarily withdraw the product until such an order was issued. In any event, drugs are withdrawn from the market infrequently.

With respect to the second question, drugs frequently possess efficacy in more than one therapeutic area. The ability to extend the enforceability of the patent to other therapeutic uses that the patentee has developed might promote innovation. If the enforceability of the patent were limited during the extension to the specific therapy approved, the additional extension would not have any effect on the length of the extension for the first use. If the enforceability were not so limited, providing an extension for another therapy would also extend the patent

for the first therapy, and the patentee could therefore increase the effective patent term for the first therapeutic use.

The Number of Patents Extended per Drug

It is possible that more than one patent may provide protection to a drug. The issue dates of the patents may differ, thereby allowing the patent protection provided by a later-issued patent to extend beyond the expiration of the first patent. Patent-term extension could be restricted to only one patent per drug or could apply to each patent covering the drug. Depending on the method used for determining the length of the extension, permitting more than one patent to be extended could result in extensions that expired at different times. If the method for determining the extension corresponded to the effective patent term lost due to premarketing review, no patent could have its term extended beyond 17 years.

The Obligations Incurred by the Patentee

In the normal operation of the patent system, a patent is granted and, in return, the public receives a disclosure of the invention and a description of its best mode. The patentee incurs no further obligations (other than maintenance fees) during the patent term.

Proposals have been made to impose additional obligations on the patentee in return for the extended patent period:

1. after the extension the patentee could be required to provide potential competitors with available data (results from clinical and toxicity testing) needed for securing FDA approval for generically equivalent drugs;
2. after the extension the patentee could be required to relinquish all rights to the trade name;
3. after the extension the patentee could be required to allow others to use the size, color, and shape of the drug that is coming off patent;
4. during the extension maximum prices for the drug could be mandated; and
5. patentees could be required to use a portion of the revenues derived during the extension for research and development.

Appendix

Patent-Term Extension for Other Industries

The Medical Devices Industry

The medical devices industry manufactures products that are used in the diagnosis, treatment, or prevention of diseases or conditions. The benefits of these products reside in their ability to affect the structure or function of the human body through means other than chemical action.[1] The definition includes simple products, such as surgical instruments and orthopedic shoes, and vastly complex products, like cardiac pacemakers and diagnostic equipment. The Food and Drug Administration (FDA) regulates this industry, and only in certain instances is premarket approval required.

The medical devices industry emerged after World War II as a result of technological developments. In the last two decades, the industry has experienced substantial growth in sales: between 1974 and 1980 sales increased by more than 100 percent, with 1980 sales estimated at about $11.5 billion.[2] The industry is comprised of several thousand firms, many of whom are quite small.[3] Several relatively large firms in the industry appear to play a dominant role in the market.[4] According to one source, the larger firms constitute the stable portion of the industry; but the turnover rate for smaller firms is high. This difference does not derive from differences in the types of devices produced. Since a company need not have a large minimum plant size to produce medical devices, it appears that medical devices in general are not characterized by great economies of scale.[5] Thus, entry is not dependent on large amounts of capital.

Sales in the industry are made through a large independent distributor network. Recently, there has been a shift in the character of this network from small local/regional dealers to major national suppliers.[6] Under these circumstances, larger manufacturers have a distinct advantage because they are capable of delivering the quantity a national distributor would require. Insofar as the larger medical-device manufacturer may tend to be a multiproduct concern, its reputation in one line will influence a distributor's decision to carry another of its product lines. Thus, the development of a national distribution network may act as an entry barrier for the smaller medical device company.

For several reasons, the patent system is not as important in this industry as it is in the pharmaceutical industry. First, there are generally many more substitutes available for any one medical device than there are substitutes for drugs. Second, there is a very high turnover in technological achievements in the industry and products are often outmoded before their patents expire. Third, devices are generally simpler to invent around than drugs and the patent, therefore, may provide little protection from imitators. Fourth, premium prices commanded by patented medical devices may not be as great as premium prices in the pharmaceutical industry because some downward price pressure is exerted through an informed and price-conscious market (hospitals, laboratories, and independent distributors, etc.). Thus, while the patent may be viewed by the industry as one of several avenues for the minimization of risk, it is typically not the overriding incentive for innovative activity.

The growth in sales and in the number of firms in the industry seems to indicate a reasonable degree of competition and therefore an environment conducive to innovation. However, insufficient information exists for a reliable evaluation of the industry's competitiveness. First, we have not studied how concentrated any particular device area may be within the industry (e.g., we do not know if one firm or a thousand produces X-ray equipment). Second, regulation of the industry began recently (1976) and its effects may not yet be evident.

FDA began its present scope of regulation of medical devices in 1976 with the passage of the medical device amendments to the Food, Drug, and Cosmetic Act. Prior to 1976, some devices such as soft contact lenses, IUDs, hemostats and others, fell under the purview of FDA because the agency had these devices classified as "drugs." As well, prior to

[1] Health Industry Manufacturers Association, "Summary Report," (Washington, D.C.: HIMA, October 1978), p. 8.

[2] Predicasts, Inc., "Value of Shipment," (SIC code 2831, 3841-43, 3693), 1980.

[3] Health Industry Manufacturers Association, "Summary Report," reported over 1,000 members in 1978 with 72 percent having sales less than $10 million. Thus 280 companies had $7.3 billion of the 1978 $8 billion sales figure.

[4] "Manufacturers of Medical Devices Join the Choruses of Regulatory Critics," *The National Journal* (Sept. 20, 1980), p. 1566, reported more than 5,000 manufacturers in 1980.

[5] Office of Planning and Evaluation, Economics Staff Study 53, Food and Drug Administration (Washington, D.C.: FDA, 1980).

[6] Ibid.

[7] SRI International, "Structure of the U.S. Medical Supply, Equipment and Devices Industry" (Stanford, Calif.: SRI International Printing, 1979).

1976, FDA had postmarket surveillance regulatory powers for devices. That is, FDA could remove a device from the market if it was not safe and had power to ensure that the product's label was not misleading. Thus, while regulation of the industry is not as recent a phenomenon as it might appear, the scope of the regulation has widened considerably since 1976. Currently, the thousands of medical device products are divided among three groups. Class I devices are noncritical items such as bedpans and are subject to generally the same standards of regulation as all devices were prior to 1976, that is postmarket surveillance techniques. Class II devices include items thought to require something more than Class I regulation to ensure safety but not as much control as a premarket approval. Regulation of Class II devices takes the form of setting performance standards. Class III devices (those previously classified as "drugs" as well as others whose use can be similarly dangerous) require premarket approval. The process for obtaining Class III premarket approval is quite similar to that required for drug approval.

Devices can short-cut the regulatory procedures by being judged "substantially equivalent" to pre-1976 devices. In the 4 years since the medical devices amendment was enacted, about 98 percent of premarket notifications were declared "substantially equivalent."[7] Notifications are required 90 days prior to the marketing of a device to ensure that it will not be a member of Class III and require extensive testing.

The full effect of these regulations on the competition and innovation in the industry has not yet been felt. The uncertainty about future regulations may change the weight of the patent as a factor in the innovative process. However, some general tendencies can be noted. The performance standards for Class II devices may dampen innovative activity, as the standards need only be met, not exceeded, to obtain approval.

In addition, FDA has been exploring the concept of voluntary standards for Class II devices. Larger device companies, by virtue of their larger voices, would appear to be able to have their products' standards emerge quickly and effectively as the accepted measure of voluntary standards. To the extent that smaller companies' voluntary standards are different from those of large companies, competition and innovation may become more difficult for smaller device manufacturers.

FDA regulations concerning "substantially equivalent" devices may hold the potential for dampening competition simply by encouraging manufacturers to produce devices that are based on minor changes in old products. However, such products may not be able to obtain patents. If manufacturers claim substantial equivalency at FDA, they may injure their chances to get a patent approved, i.e., an old device may be considered prior art for patent purposes. On the other hand, the issuance of a patent may be considered proof that a device is not substantially equivalent because patents are supposed to be granted for new and unobvious inventions. Thus, the patent may become much less important than it currently is for devices similar to existing products. By the same token, patents may become more important to first entrants with wholly new products.

Two other trends that may affect the industry's competitiveness should be noted. First, while medical devices are more price sensitive than pharmaceuticals, this industry is becoming more subject to price insulation from third-party reimbursement.[8] Compared to most industries, the medical device industry is considered price insensitive, however, hospital cost containment programs often look toward medical devices for areas of savings. Future competition may increasingly be based on other considerations in addition to price and, to the extent that this leads to higher profits, entry may be encouraged. It has been reported that the larger device manufacturers have generally been generating far more cash than they are able to reinvest profitably and thus can be expected gradually to lose their current market shares unless reinvestment alternatives emerge.[9]

In summary, the medical devices industry is likely to continue to be reasonably competitive and innovative in many product lines and patent-term extensions may, therefore, be unnecessary. However, for Class I and II devices, the level of innovation may depend on the balance struck between the attractiveness of obtaining a patent and the desirability of receiving rapid approval for "substantially equivalent devices." In this regard, patent-term extensions could have a limited, but perhaps important, positive effect by shifting the balance toward innovation.

Finally, regulation of this industry is in the early stages. As more devices become available for uses with potentially hazardous side effects, more aggressive regulatory measures may be seen in the future; that is, technological sophistication may lead to a larger portion of devices being classified as Class III (those requiring premarket approval).

[7] "New Device Introductions on the Rise," in *Devices and Diagnostics Letter*, vol. 1, Aug. 12, 1980.

[8] Arthur Young & Co., "A Profile of the Medical Technology Industry and Governmental Policies," draft final report (Washington, D.C.: Arthur Young & Co. Printing, Mar. 31, 1981), pp. IX-7.

[9] Mitch and Martinelli, "An Analysis of Business Performance in the Health Care Industries," *Business Economics*, March 1980.

The Pesticide Industry

Because the pesticide industry and the pharmaceutical industry are subject to similar regulations, the effects of patent-term extension will be similar for the two industries.

Companies selling the most pesticides are often very large and diversified; pesticide sales frequently account for 20 percent or less of company sales.[10] The pesticide industry manufactures herbicides, insecticides, and fungicides, all of which are subject to premarket regulatory approval by the Environmental Protection Agency (EPA). The products are regulated under the Federal Insecticide Fungicide and Rodenticide Act which was amended in 1972 and now requires a demonstration of human safety. As in the pharmaceutical industry, the more stringent requirements have increased the costs and times associated with research and development. The regulatory process in 1975 required about 7 years to complete in contrast with a little less than 3 years in 1960.

The measures of innovation available in the pesticide industry indicate that innovation has, thus far, been virtually unaffected by the increased costs and times required for regulatory approval. Table A-1 below illustrates a steady rate of new pesticide chemicals being registered per year in the United States between 1967 and 1979. It should be noted that fluctuations in pesticide registration are primarily a function of legal and administrative measures at the EPA and are not necessarily a sound measure of innovation in the industry.

Figure A-1 illustrates the growth in research and development (R&D) expenditures in both constant (1967) and current dollars. As can be seen, real growth in R&D expenditures has occurred, with particularly evident spurts taking place after 1975, when one would have expected the effects of the 1972 amendments to be felt.

In table A-2 below, we see similar constant growth in sales (at least for 1970-76).

No measure of the qualitative value of pesticides was available to this study. One can reasonably assume that regulatory requirements for efficacy did not produce a decline in the value of pesticides marketed since 1972.

The research companies appear to be continuing to increase R&D expenditures at the present time, regardless of the trends in patent life. Uncertainty exists as to whether R&D expenditures would increase more rapidly with patent-term extension or whether, without the extension, R&D expenditures would continue to increase if effective patent lives decline.

One important characteristic of the pesticide industry that is dissimilar from the pharmaceutical industry is the role of the Federal Government in pesticide research and development. The Conservation Foundation reports that the Department of Agri-

[10]The Conservation Foundation, "Product Regulation and Chemical Innovation," March 1980, p. II-8.

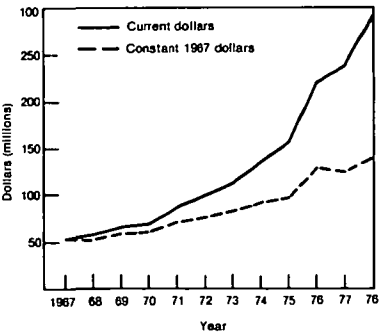
Table A-1.—New Pesticide Chemicals Registered in the United States, 1967-79

Year	Total number[a]
1967	16
1968	16
1969	14
1970	10
1971	4
1972	17
1973	13
1974	21
1975	34
1976	12
1977	4
1978	5
1979	17

[a]Herbicides, insecticides, fungicides, and others.

SOURCES: Organization for Economic Cooperation and Development, "Regulation and Innovation in the Chemical Industry—A Preliminary Assessment of the Impact of Recent Chemicals Legislation," p. 25; and The Conservation Foundation, *Production Regulation and Chemical Innovation*, March 1980, p. III-14.

Figure A-1.—Pesticide R&D Expenditures, Domestic Manufacturers Reporting to NACA, 1967-78



SOURCE: National Agricultural Chemicals Association, Industry Profile Surveys.

Table A-2.—U.S. Pesticide Sales in 1970 Constant Dollars

Year	Total sales (millions of dollars)
1970	$ 70
1971	81
1972	91
1973	91
1974	93
1975	107
1976	118

SOURCE: Organization for Economic Cooperation and Development, "Regulation and Innovation in the Chemical Industry—A Preliminary Assessment of the Impact of the Present Chemical Legislation," p. 29.

culture and the State experiment stations spent $332.6 million on research and implementation of pest control and pest management programs in 1978.[11] Several other Government agencies contribute to pest control research as well. While Government agencies also contribute to pharmaceutical research, the proportion of those funds as a percentage of the total is smaller. In cases where the funds support industry research which, in turn, produces an industry-owned patent, patent-term extension may entail double rewards.

Some of the similarities between the pesticide and pharmaceutical industries are also worth highlighting here in order to provide additional understanding of the possible effects of patent-term extension. First, while some 80 companies actually produce pesticides, another 5,300 are pesticide formulators, or companies involved in the combining and packaging of pesticide products for specific uses. As with the production-intensive pharmaceutical firms, the patented innovations made by formulators will not benefit from extensions of the patent term.

Finally, the pesticide industry has an analogous situation to the "orphan drug" research problem in the pharmaceutical industry. Minor crops do not present enough potential market for a pesticide company to invest in research for that crop. Here patent-term extensions also cannot be expected to induce firms to increase expenditures for minor crop research.

The Chemical Industry

The title of this industry is somewhat misleading; although pharmaceuticals and pesticides are chemicals, they are not meant to be included in this discussion. The chemicals considered here are basic industrial chemicals that are used to make other chemicals or products. Also included are dyes, pigments, paints, plastics, synthetic rubber, and synthetic fibers. The vast majority of the industry's sales are of intermediate goods; that is, they are used to make other products which are then used by consumers.

Chemical products, other than pharmaceuticals, pesticides, food additives, and cosmetics are regulated under the 1976 Toxic Substances Control Act (TSCA), which is administered by EPA. TSCA, in contrast to the laws regulating pharmaceuticals and pesticides, does not require Government approval before a product can be marketed. It requires only that the manufacturer submit a notice to EPA 90 days before he intends to begin manufacture. The notice must contain information about the use of the chemical, the anticipated volume of production, and the expected exposure of workers and others to the chemical, but EPA cannot require manufacturers to submit specific tests with the notice. If the notice does not contain enough information for EPA to evaluate the risks which may be posed by a chemical and if there is reason to believe that the chemical may pose a risk, the agency can delay manufacture of the chemical until adequate information is submitted. If the agency finds that a chemical for which a notice has been submitted will pose an unreasonable risk, it can impose any of a wide variety of restrictions, including a prohibition on manufacturing the chemical.

Because EPA is given only 90 days to review a chemical notice (the 90-day period can be extended up to 180 days), patent-term extension will not be applicable to the great majority of chemical products. Some new chemicals will fall into categories of chemicals which are required to be tested under section 4 of the Act, and for such chemicals a patent extension for the period it takes to conduct the required tests is meaningful. Manufacture of a chemical can also be delayed if the manufacturer submits inadequate information (TSCA sec. 5(e)) or if EPA finds that the chemical will pose an unreasonable risk to health and the environment (TSCA sec. 5(f)). Patent-term extension for chemicals delayed under section 5(e) or 5(f) might reduce the incentives for firms to conduct adequate testing or provide adequate information, since there would be no patent penalty for not doing so. Patent-term extension could be abused by premature filing of a notification without previously conducting adequate testing or withholding pertinent information.

[11] Ibid., p. II-10.

Mr. BUTLER. Would you like to comment on that?

Mr. ENGMAN. It will improve the incentives for investment in all markets. Obviously, there is a concern. Right now the large market would be a cure for various forms of cancer. That would provide a very large market and any company would attempt to direct research in that area and legitimately so.

But this is also true down the scale, and to the extent that you restore the incentives you are going to improve them for research with respect to compounds or therapies that would affect smaller populations because they will become more meaningful than they would otherwise have been. So I think you will see an increase along the whole range.

We don't want to ignore coming up with cures for small population diseases. That is a very important problem.

I have testified before other committees in terms of what we can do to encourage more research in that area. That is a very important area.

We have to keep in mind that there is a large population out there with a particular disease and we can't ignore that side of it either.

I don't view that as necessarily a downside argument.

Mr. BUTLER. Thank you, Mr. Chairman. I yield back. Thank you for your testimony.

Mr. KASTENMEIER. Just a few more questions. Considering there are some certain compelling cases made, maybe several more compelling than others, you have indicated correctly your analysis that the bill provides no retroactive benefits.

Do you think we might consider retroactivity? What factor do you think might be involved in whether in certain isolated cases or generally retroactivity might be included in one form or another in the legislation?

What should guide our thinking?

Mr. ENGMAN. You put me in an interesting position, Mr. Chairman.

Both here and on the Senate side, there has been an attempt to come down with the best way to cut the pie.

If you are looking at the purpose of the patent system from the incentive point of view perhaps the approach taken by the drafters of the legislation makes some sense.

If you are looking at it from some other perspective, obviously you can come up with another approach to it, and we would be willing to look at any of those approaches. I haven't focused on that particularly. If somebody is going to twist my arm and say we would like to give you something else, I am not sure I would walk away from it.

By the same token, we have supported the approach the drafters took. There may be a number of other factors and if you take another approach in trying to rectify certain problems in the past, it might well be legitimate to consider other time frames.

Mr. KASTENMEIER. We have had that problem many years in the past in matters of copyright. That is, whether extension of existing copyright serves any public purpose since it could not possibly provide an incentive to a preexisting property.

We have spoken about the pharmaceutical industry and the Food and Drug Administration but it is also true there are others; generally the chemical industry has similar problems. We may have problems with the Environmental Protection Agency where regulation may play a role where patents are obtained.

I take it you have no position with respect to EPA and the chemical industry insofar as this bill is concerned?

Mr. ENGMAN. No. I think conceptually the problems that the chemical or the agricultural component of that industry face are the same as the problems which we in our industry face. Representatives of those industries have testified before other committees with respect to the impact of this bill on their situations.

Mr. KASTENMEIER. Indeed, and they will before this committee as well. However, to reach the scope of the bill in terms of inclusion or exclusion of other industries, I wondered whether you had any particular view?

Mr. ENGMAN. I would say from a philosophical point of view, I think the same principles apply. If the Government feels it is necessary to step in, as it may often be, to regulate and to assure the public of the safety of a product before it is marketed, then one must look to see what impact there has been on the incentives for innovation in that industry.

From a personal point of view, I would feel the philosophy of the legislation would apply across the board.

Mr. KASTENMEIER. Let me revert to another industry, the processing such as Genentech and Mobil Corporation and others might be involved in, not quite the same area but plausibly could make some case for inclusion.

Do you have any view about that?

Mr. ENGMAN. To be frank with you, Mr. Chairman, I am torn in more than one direction. We don't believe, as we interpret this bill, that it applies to process patents. I understand from discussions with respresentatives of those interested parties such as in the recombinant DNA area, that if the bill is not expanded to cover the process patents, in effect that is an unfortunate situation.

I have also had discussions with our friends in the generic pharmaceutical industry. Incidentally, a number of members of that industry conceptually support the concept of patent restoration since they depend upon new products coming to the market so they can produce them. Their concern is that the addition of coverage for process patents would unduly give the original manufacturers a leg up and be to their disadvantage, since a new process might be discovered which would further extend the bills protection.

There may very well be ways of attempting to meld those two opposite concerns together by providing some kind of limit in specific language, but I think all I can say at this point is that I am alert to both the concerns coming from 180-degree opposite sides of the spectrum and understand each of them.

We would be willing to work with your staff in attempting to address those.

Mr. KASTENMEIER. I thank you for your answer.

My last question, Mr. Engman. Do you support H.R. 1937 it in its present form or are there any changes you would recommend to the committee in the text of the bill?

Mr. ENGMAN. This bill is substantially identical to the bill which passed the Senate and we do support it in its present form, I would hasten to add to the extent there may be questions of interpretation or other specific questions which are raised during these hearings, or else where as far as that goes, we obviously would be willing to consider those.

I think it is the concept and the basic thrust of the bill which is the ingenious part of it. We obviously would want to have that preserved.

I haven't seen any specific language that is better than that. That doesn't mean there might not be improvements in specific areas.

Mr. KASTENMEIER. Your analysis of the Senate-passed bill is that it is substantially the same, it is not different in any notable respect that you care to comment about?

Mr. ENGMAN. Not in any significant respect as far as it affects us.

Mr. KASTENMEIER. I will yield to counsel who has questions from my college from Massachusetts.

Mr. LEHMAN. Congressman Frank was unable to be here so he submitted a series of questions which he has asked me to ask you. I know you have a rather short timeframe because you have to attend an FDA meeting.

Mr. ENGMAN. Let me say, Mr. Lehman, we would be happy in any event to answer any or all of them in writing.

Mr. LEHMAN. We will send them to you in writing but I think he would appreciate having some addressed orally.

What do the proponents, your organization basically, believe would be the normal or reasonable amount of time between patent grants and actual marketing of prescription drugs based on their own integrity and product liability needs and other ordinary commercial steps in the absence of the FDA approval process and what are the components of this period?

In other words, are there other delays other than FDA occasioned delays which make it impossible for you or the companies to commercialize a patent for a period of time and what are they?

Mr. ENGMAN. I think it is not possible to give you a definitive answer to that question, Mr. Lehman. We are in a situation where the control over the development of the drug, the kinds of tests that are run, how the testing is done, the monitoring of that testing, is from day one basically controlled by the Food and Drug Administration. Everything is done within the framework of the regulated industry process. One could as an academic exercise attempt to go backward and do it, but the environment in which one lives is such that it is an imposed kind of situation.

Mr. RAILSBACK. Counsel yield?

Mr. LEHMAN. Yes.

Mr. RAILSBACK. It seems to me Milton Friedman in his book——

Mr. ENGMAN. Free to Choose.

Mr. RAILSBACK. Yes; written with his wife—gets into the whole situation of what it used to be like in the good old days when there wasn't an FDA and it points out as a result a rather large liability occurred when some products were not accurately tested.

He seemed to think that in itself would make a drug manufacturer careful and reluctant to marketing his too early.

He cited some examples where they resulted in deaths of people and caused a company to go bankrupt. I think at one point we did not have a Food and Drug Administration, not too many years ago, probably 30 or 40 years ago.

Mr. ENGMAN. Seventy-five years ago. This is the 75th anniversary.

Mr. LEHMAN. You may want to submit further written responses to that. One thing Mr. Frank was thinking of was comparing you to other industries where a patent may be developed, for example, in the computer industry, and yet the patent may not require any regulatory approval at all yet there is a delay between the granting of the patent and commercialization.

Mr. ENGMAN. Oh, of course. But the OTA report properly points out that we approach up to 7 years in less effective patent life protection than these other—quote—nonregulated industries, so that there is still a significant difference in the kind of regulations which are imposed on health and safety grounds.

Mr. LEHMAN. Mr. Frank's second question is what is the typical delay now between expiration of the relevant patent on a successful job and active entry of the competing product—I think he means the generic product—into the market, and to what extent are these delays attributable to the competing producers themselves, the FDA, or actions by the originating company, such as litigation which might broaden the period of delay of the generic competition?

Mr. ENGMAN. I think that the succeeding witness may also want to address this, and I think he does in his testimony.

This point has been made by some of the opponents of the legislation and they have cited a study by a Dr. Statman that indicates there might be some delay. Even in that study, the author, in spite of his finding, which has been severely criticized by others, still suggests that the patent legislation along the lines of the proposal here makes sense and would be a good thing.

In fact, with the increase of the substitution laws and the like there is significant competition quickly.

Mr. LEHMAN. I think I will ask you one more of Mr. Frank's questions and then we will try to reserve the others, if the chairman will permit, for the other witness.

To the extent that some of the period for approving new drug applications is attributable to inadequacies in the original testing or application, delays by the applicant in responding to FDA requests for further information, or other actions of the patentee himself, what would be the best system of allocating responsibility for that portion of FDA time that is attributable to actions of the patentee himself so appropriate deductions from any extension might be made or should there be any deductions? Should the legislation consider granting FDA some power to assign a certain period of delay to actions on the part of the applicant or would that be something the Patent Office could handle?

Mr. ENGMAN. I think there should be no deductions for two reasons. First of all, we have a competitive situation. Once that filing is made with respect to the patent, that idea is now in the

public domain, which is one of the purposes of the patent law, and you have a lot of other people thinking about whether they can improve upon the idea and come up with another product, so there are great competitive pressures on the company to keep it moving, let alone their own substantial investments up to that time. Beyond that I return to the answer which I gave you in response to his first question. Everything is basically monitored and controlled by the Government, and the web is so tight that I would say to you it is impossible to try to sort out that kind of situation if in fact it happened.

But I don't think you have to be worried about it (*a*) because of the competitive factors I mentioned, and (*b*) if in fact somebody were playing footsie and trying to purposely extend the patent, the other competitors have the ability to go in and challenge that patent or extension thereof, and it is done all the time.

So I think from a realistic point of view, although the question is a good one, it is not possible to separate it out, and, in fact, we have other protections built into the system to protect against it happening.

Mr. KASTENMEIER. Are there other questions? If not, the committee desires to express its appreciation to you for leading off today and doing a fine job. We may need to be in further touch with you not only to respond to Congressman Frank's questions but possibly others.

Mr. ENGMAN. We obviously would be very happy to cooperate. I want again to express my appreciation for the opportunity to appear. I am not so sure that I wouldn't rather stay here than go where I am going next, but I have to go. In any event, I do thank you very much.

Mr. KASTENMEIER. Next the committee would like to greet Dr. Lewis H. Sarett, senior vice president for Science and Technology of Merck and Co., a distinguished scientist in his own right. With Dr. Sarett is patent counsel for Merck and Co., Mr. Rudy Anderson.

TESTIMONY OF LEWIS H. SARETT, SENIOR VICE PRESIDENT FOR SCIENCE AND TECHNOLOGY, MERCK AND CO., INC.; ACCOMPANIED BY RUDY ANDERSON, PATENT COUNSEL

Dr. SARETT. Chairman Kastenmeier and members of the subcommittee, it is a pleasure to be here this morning to testify in support of H.R. 1937. Patent term restoration legislation is supported by the entire pharmaceutical, chemical, and agricultural industries, with the exception of the imitative generic pharmaceutical manufacturers.

The equities of patent restoration cannot be disputed. There is simply no logical reason why products subject to extensive Federal premarket testing and review requirements should have a shorter effective patent term than unregulated products. Yet that is what happens. A new drug marketed in 1979 had about 9.5 years of patent life remaining when it received FDA clearance. If Merck received approval today on its products currently awaiting final FDA approval, the average remaining patent life on those products would be about 7 years.

Although it is not susceptible to empirical proof, there is no doubt in my mind that patent restoration will stimulate pharmaceutical innovation. A company will be more willing to invest in more extensive long-term research.

I have observed, from my participation in all of these, that several questions recur whenever the subject is discussed. Today, I would like to address those questions.

One, is there a need for increased incentives for pharmaceutical research and development? It is only natural that a policymaker would ask whether such an incentive is needed where the pharmaceutical industry is concerned. After all, the pharmaceutical companies are highly profitable; so why should other incentives be necessary? The answer, though multifaceted, is an emphatic yes, the incentive is needed. Let me explain.

First, the rate of new drug development has declined, indicating that increased R. & D. incentives are needed. According to the testimony of the director of FDA's Bureau of Drugs before the House Health and Environment Subcommittee on April 1, 1981, there has been a long-term downward trend over the last two decades in the number of those new drugs that provide the most important therapeutic gains. From 1975 to 1976 there was a 40- to 45-percent decline in the number of new drug compounds referred to as NCE's being studied in humans by U.S. companies and there has been no reversal from that trend since. A sharp decline in such testing can only forebode a decline in the number of new drugs coming on the market.

Another indication of declining R. & D. by U.S. pharmaceutical companies is that in 1964 U.S. firms asked FDA for approval for permission to do research on 70 chemicals developed by their own research. In 1976 only 20 such applications were filed with FDA. Unfortunately, U.S. firms are becoming increasingly dependent on licensing in products from foreign-based firms. We project of the 81 new drugs expected to be approved in the next 5 years, 44 percent will be licensed in from foreign companies.

The second factor is increases in development costs and time. Merck's experience with two nonsteroid anti-inflammatory drugs, Indocin and Clinoril, brought to market 15 years apart, provides a good example of the cost and time increases. We began development work on Indocin in 1961 and were able to market the product 4 years later. Approximately 80 person-years of scientific effort were involved. Our development work on Clinoril began in 1970 and we introduced it 8 years later. A total of 240 person-years went into the development effort. Our costs were more than five times greater than the development costs for Indocin. The effective patent life for Indocin was 16.5 years; for Clinoril, only 10.5 years.

As you would expect, such increases in testing cost and time have had a direct effect on our research efforts. Because our R. & D. budget is not limitless some projects have to be deferred and ultimately even dropped. The predictable results are fewer ongoing projects and a growing backlog of projects waiting to be undertaken. Indeed, in one 5-year period I observed a 10-percent decrease in the number of basic research projects in our laboratories and at the same time our R. & D. expenditures were going up 40 percent.

Another factor is increased competition from generic drugs. At the very time R. & D. costs are increasing, companies such as Merck are also having to confront the realities of shortened effective patent life and increased competition from imitative generic drugs. The decline in effective patent life is illustrated by the tables on page 8 of my testimony.

The argument has been made that brand name drugs retain their market share long after the patent expires, thus rendering patent restoration unnecessary. Current data belie this conclusion. The competition from generic imitations is not a figment of our imaginations, it is very real. Our experience at Merck is that we face almost immediate imitative generic competition here when the U.S. patent expires on one of our products. This competition is from tablets made here in the United States by generic pharmaceutical manufacturers using, as biologically active ingredients, chemicals they import in bulk from Italy and Eastern Europe, countries without effective patent laws.

Forty-nine States and the District of Columbia have enacted generic drug substitution laws. More than half of those laws have been adopted since 1977.

Data from the American Druggist Annual Survey show that the generic substitution laws are having an increasing effect on market share of brand name drugs. The survey measures the pharmacists' discretionary dispensing rate—that is, the percentage of times pharmacists elected to fill a prescription using the brand name drug when State law gave them discretion to choose between the brand name and a generic product. As you can see from the following table, pharmacists are using the brand name drug less and less.

Under these conditions, the legitimate needs of the inventor of a new drug for adequate patent term can only increase.

Let me further illustrate with an example drawn from Merck's own experience. In 1968, Merck began marketing a diuretic, Hydrodiuril. Although Merck did the development work on the drug, the patent was held by another pharmaceutical company and licensed to Merck. We both marketed the product. Our market share for several years was about 78 percent. Because our licensor eventually licensed the patent to a number of generic manufacturers, we began facing generic competition before the patent expired. By 1981, this generic competition had reduced our volume market share to 37 percent. Our licensor had 12 percent with generic products accounting for 51 percent.

It must be remembered that the innovator company also faces competition within the therapeutic market from other patented products throughout the life of the patent. Again, let me illustrate with a Merck example. Early in the market life of Indocin, a major anti-inflammatory advance, this product had about a 63-percent share of the relevant therapeutic market. By 1980, our market share was down to 17 percent, even though the product was still under patent.

It has also been suggested that patent holders are able to extend marketing exclusivity for a product by securing patents on processes for making the active chemical. In reality, process patents are generally ineffective in preventing the marketing of imitations for two reasons. Upon expiration of the product patent the process

disclosed in that patent may be used by anyone. Second, a U.S. process patent is not infringed by the importation of the active ingredient for drug products made here, the usual practice of generic competition as I indicated earlier.

The second question is: How do we know future extra revenues will spur drug research? A legitimate question posed to the proponents of patent restoration involves the issue of investment in research and development today based on anticipated additional future returns. A policymaker naturally wants assurances that patent restoration will in fact increase pharmaceutical research and development.

I am prepared to testify that this legislation will spur pharmaceutical R. & D., although no one can, of course, give you absolute assurances. Both logic and commonsense dictate that restoration of the patent term will in fact increase pharmaceutical R. & D. efforts.

Absent patent restoration, the negative trends I discussed earlier can be expected to cause the major pharmaceutical companies to reduce R. & D. and invest in opportunities with less risks.

Indeed, industry outlays for R. & D. already indicate a loss of incentive. Although in actual dollars the industry consistently spends about 11 percent of its sales on R. & D., the proportion in constant dollars is declining. According to Weston and Virts, when measured in terms of 1967 dollars, the R. & D.-to-sales ratio declined from 10 percent in 1961 to 6.6 percent in 1978.

Restoration of the effective patent life will help counterbalance these trends. As a scientist turned manager, I can attest to the importance of the patent.

The research budget authorized by Merck's board of directors is directly related to the anticipated rewards that will be dependent upon our patent system. We also try to project how many years of patent life will remain on a drug candidate when it finally obtains FDA approval for marketing. Faced with a short, projected effective patent life, management will carefully review other options before committing itself to a massive investment in a drug candidate with a projected long development time.

The importance of an adequate patent term can only be fully appreciated if one understands the nature of the pharmaceutical business and its reliance on research. As a general rule, a company must rely on a few major products it has invented to fund its R. & D. activities in a wide variety of areas.

It takes a long time before the fruits of a research project will reach the market in the form of a new drug. Before a company can undertake an R. & D. project, it must know that the funds will be there 5, 10, 15, even 20 years from now to continue to support that project. Once scientists are hired and laboratories constructed, projects cannot be abandoned and restarted at will depending on the supply of funds. It is for this reason that the patent is so important. An adequate patent life provides assurance to the research company that products going onto the market today and in the immediate future will have a sufficient market life to support long-term research on other projects.

For example, Merck has just recently committed itself to a major new research program in the area of immunology. This represents

a commitment of millions of dollars over the next few years. Our outlay in 1981 alone will be $6.3 million. The program involves 120 scientists, half of whom are new additions to our staff.

If research incentives continue to decline, it is possible that research companies will look for other business opportunities which provide less risk and a greater certainty of success. However, if adequate incentives are restored, I think it is unlikely that pharmaceutical companies will divert their revenues to other areas. It simply is good business sense for a company to direct its efforts into areas with which it is familiar.

The committee should not be misled into believing that H.R. 1937 will immediately generate new sales revenues which can be dedicated to research and development or that it will result in an immediate increase in new drugs. In most cases, increased sales revenue from patent restoration will not be realized for 10 to 15 years. This is so because H.R. 1937 does not apply to drugs which FDA has already approved for a given therapy, even though these products have suffered substantial loss of patent life. Moreover, H.R. 1937 has limited applicability to drugs undergoing FDA required testing or awaiting FDA approval. Such drugs will not receive full patent-term restoration. Under the bill as drafted, the restoration period for these drugs will be measured from the date of enactment of H.R. 1937, regardless of the length of time heretofore spent on testing and FDA approval.

The third question: Won't consumers, particularly the elderly, be hurt by patent restoration? The final question deals with the effect of patent restoration on the consumer, particularly the elderly consumer who is a major pharmaceutical user. We all can accept as fact that since generic imitations need not support costly research and development projects, they can be marketed at a lower cost to pharmacies, which, it should be anticipated, will pass some of the cost savings on to consumers. H.R. 1937 will not have any immediate effect on this generic competition, because any restored patent term will only have future effect. Eventually, however, patent restoration will delay the time when generic imitations will be available to the consumer. The question is whether the benefits of patent restoration outweigh this potential negative effect on consumers. I think the answer is yes.

Patent restoration will provide incentives for research into new drugs which improve and extend the lives of the consumer—heart disease, cancer, stroke, schizophrenia, to name a few.

Health benefits are not, however, the only benefit to the consumer. In many instances, innovative drugs result in significant medical cost savings, cost savings far beyond those from generic competition. Let me illustrate. The average hospitalization cost for a case of pneumococcal pneumonia in an elderly person is approximately $3,300. Our vaccine to prevent this disease, together with the doctor's charge for administration, costs only about $13.50.

The drug cimetidine has produced a precipitous decline in the number of ulcer operations in the United States—from 97,000 in 1977, when the drug was introduced, to 69,000 in 1978 and 81,000 in 1979. Since its introduction, cimetidine is estimated to have saved $65 million in surgical costs alone for duodenal ulcer disease in the United States.

Merck's Timoptic, the breakthrough drug in the treatment of glaucoma, represents both a significant qualitative advance over previous drug therapies and a quantitative cost reduction from the surgery and hospitalization previously necessary in many cases. The cost of treating glaucoma by surgery was $590 per procedure in 1976 and $172 per day of hospitalization in 1977. Merck's per day treatment price for Timoptic to the pharmacist is about 22 cents.

In conclusion, the inventor of a better mousetrap has 17 years of exclusive marketing rights on his invention. Yet the inventor of a drug to prevent blindness or to stop heart attacks receives only 10 years or less of market exclusivity. Government premarket testing and approval requirements have caused this reduction in the patent life for the pharmaceutical product, a result never intended by you in Congress.

I believe I have demonstrated that adequate incentives must exist to offset the negative factors which currently create disincentives to increased pharmaceutical research. The patent restoration legislation offers Congress the opportunity to provide these needed incentives. The evidence shows that the potential societal benefits far exceed any transient future negative effects. Restoration of this important patent incentive will assure that the pharmaceutical industry does not suffer the fate of other industries, such as automobiles and steel, which now must seek government aid in order to compete in the international environment. If H.R. 1937 is enacted, I believe the ultimate beneficiary will be the consumer who wants and needs better health care therapies.

[The complete statement of Dr. Sarett follows:]

STATEMENT OF DR. LEWIS H. SARETT

SENIOR VICE PRESIDENT FOR SCIENCE AND TECHNOLOGY

MERCK & CO., INC.

BEFORE THE

COMMITTEE ON THE JUDICIARY

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES

AND THE ADMINISTRATION OF JUSTICE

U.S. HOUSE OF REPRESENTATIVES

September 30, 1981

88-310 O—82——12

Chairman Kastenmeier and members of the Subcommittee, I am Dr. Lewis H. Sarett, Senior Vice President for Science and Technology of Merck & Co., Inc. It is a pleasure to be here this morning to testify in support of H.R. 1937. Patent term restoration legislation is supported by the entire pharmaceutical, chemical and agricultural industries, with the exception of the imitative generic pharmaceutical manufacturers.

Much has happened since the need for patent term restoration was discussed in your Subcommittee last year by my colleague Dr. P. Roy Vagelos. The Subcommittee's expression of interest in the issue at that time and your subsequent introduction of H.R. 1937 provided much of the impetus for the favorable action by the Senate earlier this year.

Dr. Vagelos, in his testimony last year, gave the Subcommittee a brief introduction to Merck. I will not repeat that today. The important point is that Merck & Co., Inc., is a highly research intensive pharmaceutical company. Merck takes great pride in its history of important medical innovation. The work of my colleagues in the practical synthesis of riboflavin and vitamin B and my own work as the first person to synthesize cortisone are only a few of Merck's accomplishments. Merck's development of new vaccines and its breakthroughs in treatments for high blood pressure, arthritis, glaucoma and in many other areas are among the fruits of our recent R & D efforts.

Merck looks forward to being able to continue this record of achievement. Our 1981 R & D budget is $280 million. It is our

high expectations for the future as well as our concerns that prompt our support for patent restoration legislation. Patent restoration is necessary to enable us to fully pursue the exciting research opportunities that lie just ahead.

The equities of patent restoration cannot be disputed. There is simply no logical reason why products subject to extensive Federal premarket testing and review requirements should have a shorter effective patent term than unregulated products. Yet that is what happens. A new drug marketed in 1979 had about 9.5 years of patent life remaining when it received FDA clearance. If Merck received approval today on its products currently awaiting final FDA approval, the average remaining patent life on those products would be about 7 years.

Quite apart from the equities, however, public policy considerations regarding consumer and societal benefits also favor enactment of the legislation. My testimony will show how new and improved drug therapies offer significant benefits to consumers and substantial savings in cost and lives for society as a whole.

Although it is not susceptible to empirical proof, there is no doubt in my mind that patent restoration will stimulate pharmaceutical innovation. From my experience as a Merck research scientist and research administrator for the past 39 years, I know that effective patent life is an important component in the R & D decision making in our industry. A restoration of this primary research incentive will mean a greater willingness to invest in expensive long-term R & D.

Your hearings last year initiated a still on-going debate about the need for patent restoration legislation. The issue has already been the subject of two Congressional hearings this year as well as an Office of Technology Assessment study. I have observed from my participation in all of these that several questions recur whenever the subject is discussed. Today, I would like to address those questions. They are:

I. Is there a need for increased incentives for pharmaceutical research and development?

II. How do we know future extra revenues will spur drug research?

III. Won't consumers, particularly the elderly, be hurt by patent restoration?

I. Is there a need for increased incentives for pharmaceutical research and development?

Patent term restoration legislation is intended to restore a major R & D incentive for expensive and time-consuming innovation. Thus, it is only natural that a policymaker would ask whether such an incentive is needed where the pharmaceutical industry is concerned. After all, the pharmaceutical companies are highly profitable; so why should other incentives be necessary? The answer, though multi-faceted, is an emphatic yes, the incentive is needed. Let me explain.

A. Decline in rate of new drug development

First, the rate of new drug development has declined, indicating that increased R & D incentives are needed. In 1960, 50 chemically new drugs came onto the market. In 1979, only 12

such drugs were introduced. The efficacy requirement for new drugs enacted in 1962 is partly responsible, and, of course, we would all agree that the reduction of ineffective new drugs benefits society.

Unfortunately, however, there has been a drop in the number of important new drugs as well. According to the testimony of the director of FDA's Bureau of Drugs before the House Health and Environment Subcommittee on April 1, 1981, there has been a long-term downward trend over the last two decades in the number of those new drugs that provide the most important therapeutic gains.

Other data support the conclusion that there is a real decline in U.S. pharmaceutical innovation. Studies conducted at the University of Rochester show that there has been a decline in the number of new drug compounds (referred to as NCEs) being studied in humans by U.S. companies. These studies show that after an initial rise to a high of 84 NCEs in 1964, the number dropped to a plateau of around 50 for the decade between 1965-1974. However, there was a 40-45% decline in NCEs in 1975 to 1976. A preliminary update of this data presented at the March, 1980 meeting of the American Society of Clinical Pharmacology and Therapeutics indicates that this low level of NCE productivity has not changed.

These figures are particularly disturbing because testing in humans is the most important as well as the most time-consuming and costly aspect of new drug development. A sharp decline in such testing can only forebode a decline in the number of new

drugs coming onto the market.

There are other indications that R & D by U.S. pharmaceutical companies is declining. In 1964, U.S. firms asked FDA for permission to do research on 70 chemicals developed by their own research. In 1976, only 20 such applications were filed with FDA. Moreover, U.S. firms are becoming increasingly dependent upon licenses from foreign companies to provide them with research candidates. Merck's projection of new drugs anticipated to be approved in the period 1981-1985 show that 36 of 81 products will have originated outside the U.S. In earlier years licensed pharmaceuticals were of European origin but we are now seeing an influx of Japanese pharmaceutical innovations. This can be attributed to the aggressive policy of the Japanese government in encouraging pharmaceutical innovation.

B. Increases in development costs and time

Increasing development costs and time are another reason why the patent incentive for pharmaceutical R & D needs to be restored. The average development cost for a new drug in 1976 was $54 million, compared to $4 million in 1962. The length of time to bring a new drug to market has also increased, growing from 2 years in 1962 to from 7 to 10 years today. A research company finds it increasingly difficult to justify such outlays for new drugs when they face an effective patent life of less than 10 years.

Merck's experience with two non-steroid anti-inflammatory drugs, "Indocin" and "Clinoril", brought to market 15 years apart provides a good example of the cost and time increases. Both

drugs provided marked therapeutic advantages, with "Indocin" being the original breakthrough in the non-steroidal anti-inflammatory field. Let me preface my remarks by noting that what I will be describing are development, not research, costs and time. The nature of the research process makes it difficult if not impossible to ascribe dollars and time to individual products subsequently developed.

We began development work on "Indocin" in 1961 and were able to market the product 4 years later. Approximately 80 person years of scientific effort were involved. Our development work on "Clinoril" began in 1970, and we introduced it 8 years later. A total of 240 person years went into the development effort. Our costs were more than five times greater than the development costs for "Indocin". The effective patent life for "Indocin" was 16.5 years, for "Clinoril", only 10.5 years.

The major increases in the development time for "Clinoril" were primarily due to increases in toxicology, drug metabolism, and clinical testing. Such tests are much more sophisticated, time-consuming, and exacting than they were even a decade ago. They are necessary to satisfy both ourselves and FDA that the product is useful in treating a disease and that it is safe.

The increased toxicology testing for "Clinoril" included mutagenic studies, carcinogenic studies, and a greater number and type of reproduction studies. For "Clinoril", our laboratory safety assessment and drug metabolism work required approximately 540 research personnel months, compared to 338 for "Indocin".

The clinical testing for "Indocin" consumed 62 research

personnel months compared to 1409 for "Clinoril". These increases reflect much greater emphasis on placebo-controlled clinical trials, more advanced pharmacokinetic studies, and more extensive bioavailability drug interaction studies.

All told, the approval application to FDA for "Clinoril" was more than 11 times lengthier than the submission for "Indocin". For "Clinoril", our NDA contained 122,657 pages, compared to 10,800 pages for the "Indocin" NDA. Once the NDAs were submitted, it took the FDA 12 months to approve "Indocin" and 28 months to approve "Clinoril".

As you would expect, such increases in testing cost and time have had a direct effect on our research efforts. Because our R & D budget is not limitless, some projects have to be deferred and ultimately even dropped. The predictable results are fewer ongoing projects and a growing backlog of projects waiting to be undertaken. Indeed, in one five-year period, I observed a 10% decrease in the number of basic research projects in our laboratories.

The problem of increasing development cost and time is compounded by the risks in pharmaceutical R & D. This risk is substantial. As the OTA study noted, many more chemicals are synthesized than have promising biological activity adequate to qualify for clinical study. And then, after this highly expensive clinical testing, nearly 90% of the new chemical entities never make it through FDA approval. Moreover, successful completion of the FDA screening process is not a guarantee of market success. A recent study by Professor J. Fred

Weston of UCLA and John Virts of Eli Lilly showed that 75% of new drugs could not be expected to recoup the $54 million average R & D cost in 24 years of marketing.

C. Increased competition from generic drugs

At the very time R & D costs are increasing, companies such as Merck are also having to confront the realities of shortened effective patent life and increased competition from imitative generic drugs. The decline in effective patent life is illustrated by the following table of the effective patent life on significant products marketed by Merck in recent years.

Marketed Drugs	Date of NDA Approval	Effective Patent Life
"Diuril"	1958	16.8 years
"Indocin"	1965	16.5
"Edecrin"	1967	16.4
"Sinemet"	1975	15.5
"Flexeril"	1977	8.9
"Clinoril"	1978	10.5
"Mefoxin"	1978	patent application pending*
"Timoptic"	1978	10.6

*Interference proceeding delay

Merck drugs for which FDA approval is still pending also reflect this substantial loss of patent life. The following table illustrates.

Drug	Patent Issued	Effective Patent Life Assuming 12/31/81 FDA Approval
"Blocadren"	1972	8 years
"Midamor"	1967	3 years
"Moduretic"	1973	9 years
"Dolobid"	1972	8 years

The argument has been made that brand name drugs retain their market share long after the patent expires, thus rendering

patent restoration unnecessary. Current data belie this conclusion. The competition from generic imitations is not a figment of our imaginations, it is very real. Our experience at Merck is that we face almost immediate imitative generic competition here when the U.S. patent expires on one of our products. This competition is from tablets made here in the United States by generic pharmaceutical manfacturers using as biologically active ingredients, chemicals they import in bulk from Italy and Eastern Europe, countries without effective patent laws. We anticipate exactly such competition when our patent on "Indocin" expires at the end of this year.

Forty-nine states and the District of Columbia have enacted generic drug substitution laws. More than half of those laws have been adopted since 1977. Nine states require the pharmacist to dispense lower cost generic drugs absent contrary direction by the physician or patient. The rest make generic substitution permissible.

Data from the American Druggist Annual Survey show that the generic substitution laws are having an increasing effect on market share of brand name drugs. The Survey measures the pharmacists' discretionary dispensing rate -- that is, the percentage of times pharmacists elected to fill a prescription using the brand name drug when state law gave them discretion to choose between the brand name and a generic product. As you can see from the following table pharmacists are using the brand name drug less and less.

Brand Name	Patent Expired	Retail Pharmacists' Discretionary Dispensing Rate 1974	1978	1980
Gantrisin	1964	79.4%*	67.9%	55.5%
Erythrocin	1970	40.1*	33.4	31.6
Darvon	1972	80.7	46.3	36.2
Librium	1976	100	49.7	30.2
Lomotil	1976	100	**	43.4
Hygroton	1979	100	100	82

* 1975 data, 1974 data unavailable
** Data unavailable

Under these conditions, the legitimate needs of the inventor of a new drug for adequate patent term can only increase.

Let me further illustrate with an example drawn from Merck's own experience. In 1968, Merck began marketing a diuretic, "Hydrodiuril". Although Merck did the development work on the drug, the patent was held by another pharmaceutical company and licensed to Merck. We both marketed the product. Our market share for several years was about 78%. Because our licensor eventually licensed the patent to a number of generic manufacturers, we began facing generic competition before the patent expired. By 1981, this generic competition had reduced our volume market share to 30%. Our licensor had 12%, with generic products accounting for 51%.

It must be remembered that the innovator company also faces competition within the therapeutic market from other patented products throughout the life of the patent. Again, let me illustrate with a Merck example. Early in the market life of "Indocin", a major anti-inflammatory advance, this product had about a 63% share of the relevant therapeutic market. By 1980, our market share was down to 17%, even though the product was

still under patent.

It has also been suggested that patent holders are able to extend marketing exclusivity for a product by securing patents on processes for making the active chemical. In reality, process patents are generally ineffective in preventing the marketing of imitations for two reasons. Upon expiration of the product patent the process disclosed in that patent may be used by anyone. Second, a U.S. process patent is not infringed by the importation of the active ingredient for drug products made here, the usual practice of generic competition as I indicated earlier. Furthermore, while process patents may stop the use of a specific process, other non-patented manufacturing processes are available to enable a competitor to avoid the patent.

II. How do we know future extra revenues will spur drug research?

A legitimate question posed to the proponents of patent restoration involves the issue of investment in research and development today based on anticipated additional future returns. A policy maker naturally wants assurances that patent restoration will in fact increase pharmaceutical research and development.

I am prepared to testify that this legislation will spur pharmaceutical R & D, although no one can, of course, give you absolute assurances. Both logic and common sense dictate that restoration of the patent term will in fact increase pharmaceutical R & D efforts.

Absent patent restoration, the negative trends I discussed

earlier can be expected to cause the major pharmaceutical companies to reduce R & D and invest in opportunities with less risks. This is simply business common sense. Merck and other research companies must succeed as a business to justify and sustain our scientific commitment. Unfortunately, if the rewards are not sufficient, we cannot continue to justify increased investments in R & D.

Indeed, industry outlays for R & D already indicate a loss of incentive. Although in actual dollars the industry consistently spends about 11% of its sales on R & D, the proportion in constant dollars is declining. According to Weston and Virts, when measured in terms of 1967 dollars, the R & D - to - sales ratio declined from 10% in 1961 to 6.6% in 1978.

Restoration of the effective patent life will help counterbalance these trends. As a scientist turned manager, I can attest to the importance of the patent.

The research budget authorized by Merck's Board of Directors is directly related to the anticipated rewards that will be dependent upon our patent system. An underlying part of Merck's willingness to commit funds to research and development then is the extent to which the fruits of our work can and will be protected by a patent. As soon as our researchers identify a compound and its potential therapeutic utility, our patent lawyers are asked to determine whether the compound will be patentable. If the answer is no, there would be a strong reluctance to proceed with development efforts on the compound. We also try to project how many years of patent life will remain

on a drug candidate when it finally obtains FDA approval for marketing. Faced with a short projected effective patent life, management will carefully review other options before committing itself to a massive investment in a drug candidate with a projected long development time.

It would be naive to suggest that restoration of the patent term is the sole means of encouraging increased pharmaceutical research and development. There are obviously other ways the government can induce companies to invest in R & D. Recent tax incentives and improvements in the efficiency of the regulatory process are two important examples that come to mind.

I assure you, however, that a full patent term is surely the single most important incentive for the pharmaceutical innovator. Tax policies can and do change; and as Dr. Richard Crout of FDA and I agreed when we testified together earlier this year, it is unlikely that the FDA approval process can be shortened by more than a year. The patent system, on the other hand, has historically proven a reliable basis for long-range planning for those of us involved in innovation.

A patent term that is reduced by seven or more years is not an adequate incentive for long-term investment in today's world of ever increasing costs of pharmaceutical R & D.

The importance of an adequate patent term can only be fully appreciated if one understands the nature of the pharmaceutical business and its reliance on research. As a general rule, a company must rely on a few major products it has invented to fund its R & D activities in a wide variety of areas. For example,

53% of Merck's U. S. sales revenue comes from three product families. Out of a total of 52 Merck product families, six products invented by Merck generate 71% of our U. S. sales income. Without an adequate patent term for such future inventions, a company cannot predict with certainty that the continuing income from its future products will be adequate to support its long term research efforts.

It takes a long time before the fruits of a research project will reach the market in the form of a new drug. Before a company can undertake an R & D project, it must know that the funds will be there five, ten, fifteen, even twenty years from now to continue to support that project. Once scientists are hired and laboratories constructed, projects cannot be abandoned and restarted at will depending on the supply of funds. It is for this reason that the patent is so important. An adequate patent life provides assurance to the research company that products going onto the market today and in the immediate future will have a sufficient market life to support long term research on other projects.

For example, Merck has just recently committed itself to a major new research program in the area of immunology. This represents a commitment of millions of dollars over the next few years. Our outlay in 1981 alone will be $6.3 million. The program involves 120 scientists, half of whom are new additions to our staff.

Our experience with our other projects has taught us that it may be years before this project will produce a major commercial

success. Indeed, we spent more than a decade of research on renal pharmacology before we had a major new product. Our diabetes research program has been ongoing for 20 years without a single commercial success.

A full patent term on our new products in the R & D pipeline is important to provide guarantees of future revenues which make it feasible to continue to make the day to day judgments to invest in long-term research projects. Company decision makers must know if they continue to make such investments on a potential product undergoing development, they will be able to rely on a continuous flow of revenues over the long term to support such research. Obviously, today's shrinking patent term on new products discourages companies from investing in new inventions awaiting development as well as new research projects.

If research incentives continue to decline, it is possible that research companies will look for other business opportunities which provide less risk and a greater certainty of success. However, if adequate incentives are restored, I think it is unlikely that pharmaceutical companies will divert their revenues to other areas. It simply is good business sense for a company to direct its efforts into areas with which it is familiar.

This is certainly the case at Merck. Our scientists, our managers, our sales people, and our long-range business and policy planners know the human and animal health industry. As long as the incentives remain adequate, we would prefer to reinvest our revenues into this area.

The Committee should not be misled into believing that H.R.

1937 will immediately generate new sales revenues which can be dedicated to research and development or that it will result in an immediate increase in new drugs. In most cases, increased sales revenue from patent restoration will not be realized for ten to fifteen years. This is so because H.R. 1937 does not apply to drugs which FDA has already approved for a given therapy, even though these products have suffered substantial loss of patent life. Moreover, H.R. 1937 has limited applicability to drugs undergoing FDA required testing or awaiting FDA approval. Such drugs will not receive full patent term restoration. Under the bill as drafted, the restoration period for these drugs will be measured from the date of enactment of H.R. 1937, regardless of the length of time heretofore spent on testing and FDA approval.

III. Won't consumers, particularly the elderly, be hurt by patent restoration?

The final question deals with the effect of patent restoration on the consumer, particularly the elderly consumer who is a major pharmaceutical user. We all can accept as fact that since generic imitations need not support costly research and development projects, they can be marketed at a lower cost to pharmacies, which, it should be anticipated, will pass some of the cost savings on to consumers. H.R. 1937 will not have any immediate effect on this generic competition, because any restored patent term will only have future effect. Eventually, however, patent restoration will delay the time when generic imitations will be available to the consumer. The question is

whether the benefits of patent restoration outweigh this potential negative effect on consumers. I think the answer is that consumers will ultimately gain much more through increased R & D than from the benefits of generic competition during the relatively short time of the extended patent term.

Patent restoration will provide incentives for research into new drugs which improve and extend the lives of the consumer. Heart disease, cancer, stroke, schizophrenia, arthritis, kidney failure and other degenerative diseases of aging are among the unfinished agenda of medical science. There can be no doubt that consumers, particularly the elderly, stand to benefit greatly by research into these areas.

Health benefits are not, however, the only benefit to the consumer. In many instances, innovative drugs result in significant medical cost savings, cost savings far beyond those from generic competition. Although it is difficult to quantify the cost savings from new medicines, let me use a few drugs to illustrate the kind of potential savings which may be achieved.

The average hospitalization cost for a case of pneumococcal pneumonia in an elderly person is approximately $3300. Our vaccine to prevent this disease, together with the doctor's charge for administration, costs only about $13.50.

The drug cimetidine has produced a precipitous decline in the number of ulcer operations in the U.S. -- from 97,000 in 1977, when the drug was introduced, to 69,000 in 1978 and 81,000 in 1979. Since its introduction, cimetidine is estimated to have saved $65 million in surgical costs alone for duodenal ulcer

disease in the U.S.

Abbott Laboratories' sodium valproate, a new medicine to treat epilepsy, has been estimated to save $612 million yearly, quite apart from the number of distressing epileptic convulsions it saves the victims of this disease.

Merck's "Timoptic", the breakthrough drug in the treatment of glaucoma, represents both a significant qualitative advance over previous drug therapies and a quantitative cost reduction from the surgery and hospitalization previously necessary in many cases. The cost of treating glaucoma by surgery was $590 per procedure in 1976 and $172 per day of hospitalization in 1977. Merck's per day treatment price for "Timoptic" to the pharmacist is about 22¢. At a time when hospital costs are escalating, new drugs which shorten or eliminate hospital stays may be one of our most effective cost containment weapons.

New drugs may produce economic savings for the consumer in another way as well, that is by competing with other patented products in the same therapy area. As I mentioned earlier, "Indocin", our anti-inflammatory drug still under patent, has fallen in market share from a high of 63% in 1968 to 17% in 1980. Newer anti-inflammatory drugs have had a significant effect on Merck's market share. Economic studies on the pharmaceutical industry show that competition from other patented drugs within the same therapeutic class is a major factor considered by companies in setting prices.

Conclusion

The inventor of a better mousetrap has 17 years of exclusive marketing rights on his invention. Yet the inventor of a drug to prevent blindness or to stop heart attacks receives only ten years or less of market exclusivity. Government premarket testing and approval requirements have caused this reduction in the patent life for the pharmaceutical product, a result never intended by you in Congress.

The U.S. pharmaceutical industry has the capacity to respond vigorously to the research opportunities that lie just ahead. I believe I have demonstrated that adequate incentives must exist to offset the negative factors which currently create disincentives to increased pharmaceutical research. The patent restoration legislation offers Congress the opportunity to provide these needed incentives. The evidence shows that the potential societal benefits far exceed any transient negative effects. Restoration of this important patent incentive will assure that the pharmaceutical industry does not suffer the fate of other industries, such as automobiles and steel, which now must seek government aid in order to compete in the international environment. If H.R. 1937 is enacted, I believe the ultimate beneficiary will be the consumer who wants and needs better health care therapies.

Mr. KASTENMEIER. Thank you, Dr. Sarett. You indicate that because of lack of prospective patent life some projects ultimately had to be dropped. Do you have any specific examples of research and development projects which your company has dropped because of lack of prospective patent life?

Dr. SARETT. Yes. Three come to mind immediately. One is a project on osteoporosis, which is a gradual deterioration of bone which occurs in the elderly. We would have liked to have financed that project. Cystic fibrosis of the pancreas, a hereditary disease of children, which is ordinarily fatal, is one which we set out to finance and that was squeezed out. Cataracts of the eye, a disease which leads to blindness and is treatable now, generally with surgery, is another example. I'm sure there are many more.

Mr. KASTENMEIER. Are you saying in those three cases you have just mentioned had you a 17-year effective term in terms of marketing a potential drug you would not have canceled those projects?

Dr. SARETT. I think a number of factors would be affirmative and constructive in this situation. Of those factors, certainly the assurance that if after the long and precarious development and risky development career of a product we might get for one of those three diseases it would have an adequate patent term would be an incentive. It isn't all black and white. I can't say we would have done all three of them, but it would have helped in our proposing to management that the expense of embarking on research in those diseases was worth their investment.

Mr. KASTENMEIER. How does Merck or any other pharmaceutical organization price its product in simple terms? What factors go into whether you charge $3 for x number of milligrams or $5? How do you arrive at the price?

Dr. SARETT. Pricing is determined largely by the value to the consumer and that, of course, is determined largely by what is out there already. Competition in a particular field is a very important factor. There are other factors that go into it, but I think that is the dominant thing we look at.

Mr. KASTENMEIER. Does the useful term have anything to do with it? If, for example, you determine that you have 7 years remaining useful life in marketability of this particular new job, is that a factor entering into the equation of pricing?

Dr. SARETT. That certainly is, especially as one comes close to the time when the patent expires, one is aware that the generic companies are planning to introduce a product. Lacking R. & D. expenses, of course, they are able to price it at a lower price.

Mr. BUTLER. Would the gentleman yield?

I would like to follow on that point. If we had shorter terms, we might expect lower drug prices?

Dr. SARETT. Shorter patent terms?

Mr. BUTLER. If the only factor holding the price down is the prospect generics will get into the game——

Dr. SARETT. I am afraid I misled you. Competition comes not only from generics but from other drugs within a particular class. That is to say, to pick some examples, we have Indocin——

Mr. BUTLER. Take Clinoril. What is competing?

Dr. SARETT. Aspirin is competing, for example, and does so very cheaply. I think rheumatologists, for example, would prescribe aspirin first for the patient who came in with aches and pains in his joints. If aspirin didn't do the job, I think he would think of Clinoril or other drugs made by competitors of Merck. Motrin is an example.

Mr. BUTLER. Clinoril was used in your illustration and I think the time will come when I need it. There is nothing, really, that gives you the same service that Clinoril does. I am trying to figure out the factors that would hold that price down because it gets pretty expensive. I would have hoped you would have guessed if you had a 17-year term we wouldn't try to recover our costs in a short period of time and therefore a longer period would mean we would hold the prices down initially. You didn't tell us that and I am really disappointed.

Dr. SARETT. Pricing is a matter of competition, what else is available. It is a matter, also, of some of our pricing being fed back into research and development both in that field for improved therapies, so that the patient with rheumatoid arthritis in 1990 may have a better drug than aspirin or Clinoril.

Mr. KASTENMEIER. I understand your answer to the question is really it is a very complex procedure but that patent term in one form or another is a factor in pricing.

Mr. ANDERSON. I do think Mr. Butler's point is well taken. It certainly is a factor as to how much will be the total return over a full period of patent life as distinguished from how much will be a return over a 10-year patent life.

Mr. KASTENMEIER. Mr. Butler was suggesting a short life might suggest a lower price because, if I understood him, it would have to compete shortly with generics and others.

Mr. ANDERSON. I understood Mr. Butler to say if you were going to have—and I will use the bad term—monopoly over a 10-year period——

Mr. BUTLER. Exclusive patent rights.

Mr. ANDERSON. Yes; but some people will call it a monopoly—that in fact that is the period of time when you get your profits from innovation; and if you have to get them all over a period of 10 years, it may be a higher price than if you have to get them over a period of 17 years. I think it is a factor. As Mr. Kastenmeier says, it is a complex picture but it certainly is a factor.

Mr. BUTLER. Thank you.

Mr. KASTENMEIER. I had assumed the easy answer was it was a factor and that if there were a longer term to amortize research investment, you can place a smaller pricing factor and extend it over a longer period of time. But that is not a simple situation.

Dr. SARETT. Particularly not simple because the competition is unpredictable and it is successful frequently. And in the antibiotic field you may have one that is the most useful hospital antibiotic around today and 2 years from now, whatever its expected patent life, it may be made obsolete by competition.

Mr. KASTENMEIER. Also, as far as making a profit, I would assume, notwithstanding the whole thrust of this, you may have a drug where the effective moneymaking life may be only 8 years.

Even if you have 17 years, and the last 9 years it becomes either obsolete or for other reasons, it tends not to be a moneymaker.

Dr. SARETT. Exactly so. There is one aspect of the impact of H.R. 1937, research and development projects, that I think you bring out here and I would like to elaborate on a little. The distinction has often been made between a me too product and breakthrough product. All of us in research would like to make breakthrough product all the time. We also know it is not possible to plan that well or to be that lucky or that smart. To some extent we have a blend of projects, some as more modest improvements and some as complete breakthroughs.

One of the attractive features of H.R. 1937 is that it encourages the research manager to put more money into breakthroughs than into me too types. The reason it does that, of course, is that breakthrough products have a long market life. At the expiration of the patent patients are still using it. Penicillin is one major landmark. Therefore with patent term restoration the research manager would be encouraged to look for breakthrough because he knows that the patent would extend protection during the market life.

Mr. KASTENMEIER. To suggest one other area, opponents raise the issue or claim that drug companies presently maintain effective patent protection terms for as much as 30 years through aggregating process patents which they term evergreen and they tend to build one patent on another. The result is that it extends the term a considerable length of time.

Mr. Anderson?

Mr. ANDERSON. Mr. Chairman, as Dr. Sarett indicated in his testimony, process patents cannot provide that marketing exclusivity for the pharmaceutical product as alleged in some of the testimony you are hearing. There are two reasons. One, the original patent that covers the chemical compound which is the active ingredient in the pharmaceutical must, under the patent law, provide a very explicit description of the process of making that chemical compound.

At the time that patent on the compound expires, that process is available to anybody to make the product of the patent, so that immediately that product and that process are in the public domain and can be used here in the United States.

The fact of the matter is that such process patents are not relevant to the nature of competition on generic drugs in the United States. What happens in this world is that a patent on the new compound is filed today with a description of the product and a description of the process then known to make the product. Additional patent applications are filed on other processes we might invent. Corresponding patent applications are filed a year later outside the United States and are published shortly thereafter. There are countries—Italy having been one prior to the passage of their patent law—Hungary, Poland, and Czechoslovakia where the scientific community of local manufacturing companies read those patents and develop a manufacturing technique, using our own disclosures, for the manufacture of the active ingredient in their factory in Poland, for example.

There is a market for these chemicals because there are countries such as Brazil and Mexico who have either had no pharmaceutical patents to begin with or have recently vitiated the protection for them. You have tablet manufacturers in those countries who want to buy the chemical compound from Poland, let us say. Thus there is created a market for that chemical that exists over a period of time while our patents are in existence in the United States. Immediately upon the expiration of the U.S. patent a generic manufacturer here may pick up his phone, call his importer in New York, and order, for example, 100 kilos of Indomethacin, the active ingredient of our Indocin from Italy. The chemical goes from Italy to New York, is used as the active ingredient in a pill manufactured in New Jersey; and the generic product is available immediately on expiration.

So it is not U.S. manufacture of the chemical at issue. It is not the question of factories being built here in the United States to synthesize the active ingredient of generic drugs. The compound is available to them on an import basis. Even if a process patent is in our hands, if the process is being used outside the United States, it is almost impossible to prove what process is being used in Poland, for example. Process patents are not infringed by foreign manufacture under our patent law. We do have a right to go to the Tariff Commission, but we can't meet the burden of proof necessary there as to what process is in fact used in some Iron Curtain country.

For these reasons process patents cannot provide you with exclusivity for the product you market.

Mr. KASTENMEIER. Thank you. I would like to yield to my colleagues.

Mr. RAILSBACK. I am curious as to what has caused the enormous increase in costs for research and development of a new drug. I know it has been estimated it is up to something like $70 million per new drug entering the market. Can you give us a breakdown? You said all the new testing requirements. Where does the money go?

Dr. SARETT. The increases have come in from all sides. First of all, the complexity of testing, the number of tests has increased enormously. We do far more indepth testing now than was required, or even possible, 20 years ago.

Mr. RAILSBACK. The private companies are required to do all of those? They are mandated to do all of that testing?

Dr. SARETT. Indeed we are.

Mr. RAILSBACK. At your own expense?

Dr. SARETT. Yes, indeed. It takes about $1 million now to get a drug up to where it is ready to be treated for the first patient or volunteer. We know also, statistically, 9 out of 10 that make it up to that stage where it is ready to go to the first volunteer will disappear, drop out, being inadequate.

Mr. RAILSBACK. So it is $1 million that is not productive?

Dr. SARETT. For every one that makes it, nine of them at $1 million apiece go down the drain. So that is a major factor.

There are hospital expenses associated with clinical testing on a large scale and we know the hospital expenses have escalated enormously. The amount of time that an investment is tied up and is unproductive has increased from, perhaps, 2 to 7 years now. One

has an investment of the order of $30 or $50 million unproductively waiting. That in itself is an expensive procedure. It is all of these factors put together that have escalated the costs.

Mr. RAILSBACK. I think what Lewis Engman was saying is that some of the charts do not really accurately reflect the true deflated expenditures based on realistic criteria.

Dr. SARETT. That is exactly right. The costs for biomedical research before you even get into developing it have risen at 50 percent higher than the Consumer Price Index.

Mr. RAILSBACK. It has been stated by the OTA—and Merck was used as an example—spending of $280 million which reflects an increase of 20 percent in 1980. How do you answer that?

Dr. SARETT. I am sorry, I don't understand the question.

Mr. RAILSBACK. I think the OTA was using Merck & Co. to point out that Merck is actually increasing its expenditures for R. & D. rather than decreasing.

Dr. SARETT. Yes.

Mr. RAILSBACK. How would you respond to that?

Dr. SARETT. We have to increase by the amount of inflation, which may amount to 10 percent. So even if we take 10 percent of the previous year's budget of $240 million, perhaps, you have to add $24 million just to stay even. There are certain areas of basic research which have matured in recent years. Immunology is a good example. The relationship of behavior and mood in man to the chemicals that are in his central nervous system is another area that will show great progress in the next decade. So if Merck wishes to continue to be a leader, it has to invest in these new fields. Those investments, immunology, et cetera, have increased our budgets very specifically and very significantly.

Mr. RAILSBACK. Thank you.

Mr. ANDERSON. If I may, Mr. Chairman, I would like to add one of the other factors that you might expect to be taken into account is that the climate for innovation has improved. Indeed, the fact that you are seriously considering this legislation as a research incentive is something management has recognized in its thinking on investment.

Dr. SARETT. A sign of encouragement.

Mr. RAILSBACK. I am curious. With an expenditure rate of $70 million required to market for a new drug, how can a small firm raise that kind of money? What is happening? Are a lot of the bigger firms either consolidating or buying up these small firms that may have some promising drugs?

Dr. SARETT. The number of new firms—take a period of 20 years from 1960 to 1980 approximately—the number of firms that gave up the effort to survive by pharmaceutical innovation outnumbered the new ones by 4 to 1. So over that period it has been a discouraging time. The small innovative pharmaceutical company is not quite a thing of the past but it may become a vanishing species.

That situation has been tempered wherever a particular new technology came out of a university and it could be developed or exploited for the benefit of the public and the entrepreneurs in that niche. That has happened in recombinant DNA.

Mr. RAILSBACK. That would not include production?

Dr. SARETT. No.

Mr. RAILSBACK. There probably has been an explosion.

Dr. SARETT. I believe there has been an increase in the number of generics; is that correct?

Mr. KASTENMEIER. Actually what the OTA report says is Merck expects to spend $280 million on R. & D. in 1981, this year.

Dr. SARETT. Yes.

Mr. KASTENMEIER. Going into this year, that report is perhaps 1 year old—20 percent more than in 1980—suggesting that more than inflation is involved. Is $280 million a reasonable figure? That is to say, would Merck & Co. do differently under different circumstances? Isn't this enough money to be devoted to research.

Dr. SARETT. When you talk to research, there is no such thing as enough money. We have bottoms up management in our research organization and that means we request that the men at the bench, the chemists, the biologists, suggest a program of what they would like and we will try to finance those which are most promising from many points of view—technical feasibility and general utility for the patients.

In any given year we have to winnow out their total proposals, a great fraction of proposals that don't make it for a variety of reasons but that have merit. With added encouragement we can include a number of those.

Mr. KASTENMEIER. The gentleman from Virginia.

Mr. BUTLER. One question. Going back to the pricing problem, the competition you apparently receive from other manufacturers even during your patent term, I am not sure I understand. Do you license your patent out to other manufacturers to sell under another name?

Dr. SARETT. Not ordinarily.

Mr. BUTLER. Is that done within the industry?

Mr. KASTENMEIER. Not ordinarily The competition comes from their patented product, the result of their research.

Mr. BUTLER. A similar product?

Dr. SARETT. Similar but not identical. It may have advantages, it may have disadvantages. Its spectrum of activity will not be identical. To go back to our anti-inflammatory, aspirin-like drugs are competitive. A drug that might be suitable for you might produce an allergy in me or the other way around, and so that is a kind of competition I was talking about.

Mr. BUTLER. As I understand it, your testimony is, nothing would really be gained by getting this legislation to cover the process patents.

Mr. ANDERSON. I did not mean to imply that. I was trying to respond to the question of whether a process patent can provide marketing exclusivity for a pharmaceutical product of the nature we have been discussing.

This bill's thrust is to restore patent life for products subject to premarketing review. There has been some testimony provided by the recombinant DNA manufacturing group that they have an equity problem of the same nature since FDA has indicated that a product if produced by recombinant DNA must go through the full investigational new drug stage and through the DNA approval process. Their techniques are covered only by process patents. Since they are processes for the making of a product subject to

premarketing regulatory review they should be given some consideration for extension.

Mr. Engman's testimony this morning did indicate there are two sides to this question: one, you certainly should consider that industry's problem seriously because their loss of patent life will be identical to that which we have been discussing. On the other side of the coin is the point Mr. Kastenmeier raised, about a portfolio of patent processes being extended. You have to look for the balance that will be appropriate under those circumstances.

Mr. BUTLER. Thank you. No further questions.

Mr. KASTENMEIER. I just have one question which I should have addressed to the preceding witness, Mr. Engman. You do mention, Dr. Sarett, in the discussion of whether incentives are necessary, that after all, the pharmaceutical companies are highly profitable. Is there any question about that? That is not in contention? However, people feel about the proposal to extend the term is not a question of whether a pharmaceutical company is profitable or not. We can assume they are profitable. Your point is we need not concern ourselves with rescuing a dying industry, but the question is aside from profitable are pharmaceutical companies in the public interest not pursuing because of the limitation of term certain research developments pharmaceutically they might otherwise do if they had the incentive of longer term.

Dr. SARETT. I think the answer to that is emphatically yes. Also I could add although historically many pharmaceutical companies have been highly profitable, that atmosphere is changing dramatically now. There are many factors that are encroaching heavily on profitability of the pharmaceutical industry. I think most of them have been touched on in the testimony this morning but you have to think of the Federal and State drug procurement programs based on price, you have to think of generic prescribing, you have to think of the increased costs that we mentioned.

The fact is that foreign competition which we have not dwelt on this morning is a major factor now. The number of drugs being introduced by United States companies relative to those coming in from abroad is decreasing so I think we have to be very concerned now, profitable historically or not, about the future profitability of the innovative pharmaceutical industry.

Mr. KASTENMEIER. They have the requirements as domestically developed patents, however? They have to clear with the FDA and so forth do they not?

Dr. SARETT. Yes. In its home market they have their own registry actions to deal with but if they choose to market in the United States, then they certainly have to clear that with the FDA.

Mr. KASTENMEIER. So in that respect they have no advantage; they have to clear their own. And I understand by and large they are less difficult than the FDA has proved to be domestically. They must clear that plus American approval through the FDA.

Dr. SARETT. Right. Of course what we are talking about is strengthening the home market. For the small company that is primarily a domestic United States company their environment, of course, is the United States. The company in Germany or Japan has as their primary market their local situation. So there is a difference.

Mr. KASTENMEIER. If we had an organization—I assume there is none—called Foreign Pharmaceutical Manufacturers Association they too would be for this patent restoration bill would they not?

Dr. SARETT. They certainly would, yes.

Mr. KASTENMEIER. On the other hand—and we will hear from them tomorrow—the Generic Pharmaceutical Manufacturers Association does not. By and large do members of the Pharmaceutical Manufacturers Association contrasted to members of the Generic Pharmaceutical Manufacturers Association exclusively—do PMA firms members not manufacture generic drugs?

Dr. SARETT. PMA firms may indeed manufacture generic drugs. Our brand name when the patent expires becomes generic in that sense immediately.

Mr. KASTENMEIER. Do generic pharmaceutical manufacturers ever seek patents on their own brand names?

Dr. SARETT. I don't think patent would cover—you are talking about the generic manufacturers.

Mr. KASTENMEIER. Yes.

Dr. SARETT. Ordinarily they wouldn't have patentable material I wouldn't think.

Mr. KASTENMEIER. I was wondering whether there might be a mix. Essentially they are manufacturing generic drugs but in some cases developing their own.

Mr. ANDERSON. Mr. Kastenmeier, it is conceivable that they could make an invention in a particular formulation, for example, using some particular sugar that presumably gave them an advantage. That could be an invention. I haven't seen any but presumably that kind of invention could be made.

But to bring forth a new chemical entity which is a new active ingredient for a new therapy would never occur.

Mr. KASTENMEIER. That is never done.

Mr. ANDERSON. That never is done by the generic manufacturer.

Mr. KASTENMEIER. The reason I ask is we often have intellectual property, in copyrighting broadcasters who may run some cable, and cross-ownership practices are so complex sometimes it is difficult to follow the interests of some of the people involved. I am trying to see whether here, discreetly, PMA members always differ from generic.

Mr. ANDERSON. I don't know that you can characterize it as PMA members, but the term you normally hear is research intensive industry versus the generic industry. Research intensive is applicable to this country and to others.

Mr. KASTENMEIER. I am trying to determine whether there is any mix in these companies so they could have internally a conflict, a generic division of a large PMA member might in fact, other than parent corporation would like patent registration but as a generic manufacturer subsidiary or division would just as soon not have it, whether there is a difference of interest within some of these companies.

Mr. ANDERSON. There is an internal dialog on the interest. I know of at least one such organization but I assure you the management has reached the conclusion that they are primarily in the business of research for new therapies and the company is in support of the bill, sir.

Dr. SARETT. I think from the point of view of management of a pharmaceutical company, which has both a generic division and an innovative research intensive division, many kinds of rewards that come with innovation are terribly important. I think it is a matter of pride to be able to make a contribution of a significant new drug, a matter of justification of your existence to some extent. I suppose the generic people can say the same thing but it is limited satisfication, it comes with merely lowering the price of something that has already been invented. So the corporate climate it seems to me would favor the innovative side and if there were an internal conflict, such as you suggest, I would agree with Mr. Anderson, it would be resolved in favor of innovation.

Mr. KASTENMEIER. I can well understand that. I am attempting to determine whether there are conflicts or what the composition of the various components in the industry both from the intensive and the generic manufacturers might be.

I thank you both very much for your testimony. It has been very helpful. Dr. Sarett, you have made a tremendous contribution on your own—and also Mr. Anderson.

Tomorrow we will hear Mr. Kenneth Larsen, chairman of the Generic Pharmaceutical Manufacturers Association, accompanied by board members William Haddad and Jacob Schein; and Carolyn Brickey, staff attorney, Public Citizen, Congress Watch, accompanied by Bill Schultz, staff attorney, Public Citizen Litigation Group.

Until tomorrow, the committee stands adjourned.

[Whereupon, at 12:15 p.m., the subcommittee was recessed, to reconvene Thursday, October 1, 1981.]

PATENT TERM RESTORATION ACT OF 1981

THURSDAY, OCTOBER 1, 1981

U.S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES,
AND THE ADMINISTRATION OF JUSTICE
OF THE COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met at 10:40 a.m. in room 2226 of the Rayburn House Office Building, Hon. Robert W. Kastenmeier (chairman of the subcommittee) presiding.

Present: Representatives Kastenmeier, Railsback, and Butler.

Staff present: Bruce A. Lehman, counsel; Timothy A. Boggs, professional staff member; Thomas E. Mooney, associate counsel; and Audrey Marcus, clerk.

Mr. KASTENMEIER. The committee will come to order.

We are convened this morning for the further consideration of H.R. 1937 and S. 255 which relate to patent term restoration. And in connection with this morning's hearing we are very pleased to have, among others, representatives of the Generic Pharmaceutical Industry Association.

They are the chairman, Kenneth Larsen, who is accompanied by William Haddad, a board member, and Jim Flug, counsel.

Mr. Larsen, we are happy to have you. We have your statement and you may continue as you wish.

TESTIMONY OF KENNETH LARSEN, CHAIRMAN, GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION, ACCOMPANIED BY BOARD MEMBER WILLIAM HADDAD, AND COUNSEL, JAMES FLUG, LOBEL, NOVINS & LAMONT

Mr. LARSEN. Thank you very much, Mr. Chairman.

In addition to being chairman of the association, I am president and chief executive officer of Zenith Laboratories. I think to provide you with a little more perspective to my remarks it is well to note that I have been involved in the pharmaceutical industry for about 33 years, the first 30 of which was with a multinational research-oriented pharmaceutical company, and the last 3 with the Zenith Laboratories.

Our association represents manufacturers and those involved in the distribution of generic drugs and, I suppose I should add, in the interest of people who stand to economically benefit from the use of bioequivalent lower-cost generic drugs.

We appreciate your invitation to participate in these hearings, and I would ask, Mr. Chairman, that my entire statement, with the enclosed letter and factsheet, which we will provide, and any other

matters that will be appropriate as this develops—that the record be held open to receive them.

Mr. KASTENMEIER. Without objection we will receive your materials and incorporate them.

[The complete statement follows:]

STATEMENT OF

KENNETH N. LARSEN

CHAIRMAN

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES, AND THE

ADMINISTRATION OF JUCTICE OF THE

UNITED STATES HOUSE OF REPRESENTATIVES

ON

H.R. 1937 THE "PATENT TERM EXTENSION ACT OF 1981"

OCTOBER 1, 1981

88-310 O—82——14

My name is Kenneth N. Larsen. I am Chairman of the Generic Pharmaceutical Industry Association and am President and Chief Executive Officer of Zenith Laboratories. To provide perspective to my remarks, I have been employed in the pharmaceutical industry for thirty three years. The first thirty with a major multinational research oriented pharmaceutical company and the last three with Zenith Laboratories.

The Association represents manufacturers and those involved in the distribution of generic drugs and the interest of the people who stand to economically benefit from the use of bioequivalent generic drugs. We appreciate your invitation to participate in these hearings and present our views on H.R. 1937, the Patent Extension Act.

H.R. 1937 responds to the superficially appealing situation: it seeks to restore years of patent life for drugs and clinical substances allegedly lost because of federal regulations. No one can deny that products in these categories should not be unfairly penalized because of the regulatory process.

However, as the OTA Report clearly states, the record has not established the connection between the proposition and legislation before you.

The first argument for the Bill is one of general equity: Congress having decreed that a seventeen-year patent monopoly is the appropriate incentive to elicit inventions, the Government should not take back a substantial portion of that period through the delay occasioned by regulatory approval. There is a reasonable issue of equity involved, but it should not be pushed too far. Throughout our history, the Nation's inventors have been given a fixed statutory monopoly within which to market their product. They have faced innumerable impediments to full enjoyment of that period, both public and private in origin. The Government has not undertaken an obligation to compensate for such impediments or to offset any delay. This Bill would set a precedent that could open a Pandora's Box of requests from industries who argue that the full enjoyment of the patent term

is hindered by some Government program, policy or law. Accordingly, the specific premises of the legislation and its scope should be clearly established. That is not the cose in the present situation.

The factual premises of the legislation are these: First, that the research and development resources committed by the industry to new drug development are declining because of the diminished return offered by patent terms significantly shorter than the full statutory period. Second, that as a result there has been a decline in the number of significant new drugs developed in recent years. And third, that the declining R&D and declining rate of new inventions are caused by the length of the regulatory process.

It is unclear that the drug companies are inadequately funded to perform the necessary R&D. In 1980, the drug industry earned 20.5 percent on equity, the Nation's fourth most profitable industry -- behind tobacco and energy-related-companies -- and far above the 14.5 percent American average. The drug industry is usually among the two or three most profitable, and there are indications that even more profitable years are ahead, regardless of whether this legislation is enacted. The New York Times recently reported in an article entitled "The Drug Business Sees a Goden Ear Ahead", May 17, 1981, Section 3, p.1, that the industry anticipates enormous profits from the heavy R&D expenditures it has been making and plans to make.

There is also reason to doubt that significant drug discoveries have declined. The FDA has reported that the number significant new drug discoveries has remained consistent ever since the 1950's and regardless of the 1962 amendments. The final OTA analysis of this Bill supports the FDA view and suggests that the "decline in drugs" reflects the extensive marketing during the 1960's of combination drugs and slight variations on basic breakthroughs, and the decline of such proliferation, rather than a substantial drop in the actual number of significant new drug breakthroughs.

The most unsettling ambiguity, however, surrounds the assumption that any decline in new drug development can be traced to the length of the regulatory approval process. For example, a report by the General Accounting Office indicates that the regulatory process is responsible for only some seventeen months of patent life loss.

Further, the stated rationale for patent extension legislation (HR 1937) -- that the federal regulatory process has reduced effective patent life for pharmaceutical products to only 9.5 years -- is not supported by the facts.

The U.S. patent holders of the most frequently prescribed drugs in America, with annual sales of $1,371,000,000, are realizing legal patent protection for an average of 18.5 years.

DRUG PRODUCT	($millions) 1980 SALES*	NDA APPROVAL	PATENT EXPIRATION	YRS.MARKET PROTECTION
Tagamet (Cimetridine)	$233	1977	1993	16
Valium (Diazepam)	220	1963	1985	22
Inderal (Propranolol)	179	1967	1984	17
Aldomet (Methyldopa)	133	1962	1984	22
Keflex (Cephalexin)	131	1971	1987	16
Clinoril (Sulindac)	115	1978	1989	11
Indocin (Indomethacin)	75	1965	1981	16
Naprosyn (Naproxen)	75	1976	1989	13
Aldoril (Methyldopa w/ Hydorchlorothiazide)	58	1962	1981	19
Diabinese (Chlorpropamide)	53	1958	1984	26
Mellaril (Thioridazine)	50	1959	1983	24
Zyloprim (Allopurinal)	49	1966	1986	20

AVERAGE YEARS OF MARKET PROTECTION: 18.5

Total Sales Volume, 1980: $1,371,000,000

*IMS DATA

These years of patent protection have been realized as a result of pyramiding product, process and use patents - without benefit of any extension.

The Generic Pharmaceutical Industry Association depends on the basic research of the major companies and therefore supports the basic rationale and would support a Bill that extends the patent term for the net amount of delay in marketing caused by the FDA process, but apart from FDA requirements, pharmaceutical manufacturers would, by their own admission engage in substantial testing of safety and efficacy to protect themselves against product liability and consumer fraud suits. The increase in our knowledge of potential risks and the increase in sophisticated testing capability has lengthened the time that they would take themselves, just as it has lengthened the time for FDA clearance. The Bill [redacted] contains no mechanism to ensure that the period of the extension is actually limited to the net increase in the time for marketing actually attributable to the FDA regulatory process. The assumption mode[redacted] in the Committee report that the entire "regulatory review period" defined in Subsection (c)(4)(A)-(D) of the Bill equals the net delay in marketing caused by FDA is simply without support in the record. The potential for overreaching is disturbing.

The OTA bipartisan reported concluded after their recent study:

- The available evidence doesn't support the industry's claim that the extension will increase innovation;
- R&D expenditures have not declined significantly but have remained relatively stable at 8.5 percent of total sales since 1965;

- The number of new drug applications has indeed fallen since 1962, but the number of new drugs with "important or modest therapeutic gain" has been stable;
- Post-patent drug profits have suffered little from generic competition;
- Patent extension will raise prices and increase profits for the big drug companies;
- The loss of patent life attributable to FDA activity averages about three and a half years, is often much less and is frequently compensated for by brand characteristics. In any event, many non-drug products lose some of their patent protection because of governmental health, safety, zoning or other requirements.

An editorial in the *American Pharmaceutical Association's* Journal of Pharmaceutical Sciences of July 1981 identified the following modifications in the Bill which we endorse:

- Change the point at which the patent period begins (i.e., "the clock starts to run"); but rather than changing it to the date when the FDA approves the NDA, change it to the date on which the application is submitted to the FDA.
- Exclude "usage" and "process" types of patents from further extending patent life.

- Require full disclosure of the data relating to the safety and effectiveness of the drug as soon as the firm files its NDA with the FDA.

Over and above patent protection the originators brand name products maintain a de facto near monopoly market share beyond the patent life due to extensive promotion and control of color and product configuration.

Further, because of questions created in the minds of professionals and users the penetration of generic drugs has been limited. This is unfortunate, as the perceptions are not based on fact. Generic drugs must satisfy the FDA requirements. Further, generic manufacturers are making technical contributions to the understanding and use of drugs. An example is a recently off patent drug that holds more than $150 million of the market share. Generic companies, in advance of the patent expiration date, formulated the product and in testing found their product to be biosuperior, three times as available as the originator's product. The FDA when presented the data would not approve the generic inequivalent formula. The companies deformulated the product to make it bioequivalent. The FDA advised the generic companies they would not approve the equivalent product as it would mean putting another "poor product" on the market. The originators product continues to hold its market share. Consumers and the government continue to pay the high brand product price.

In addition to these marketing impediments, generic manufacturers also experience the same delays as the research companies. It takes approximately two years for the FDA to review and approve generic product submissions.

The proposed extension provisions and the related factors mean higher cost of drugs to consumers and the government. The cost of patent extension will fall heaviest on you and middle income families, on the nations elderly and chronically ill.

The OTA found the evidence available "neither supports nor refutes the position that innovation will increase significantly". It is clear the Bill means higher drug costs contrasted to on unknown, if any, return in the future.

We recommend the Committee urge the interested parties to meet so these complex and technical matters can be considered and resolved rather than consume the Committee's time. We have attached a letter from GPIA's patent attorney that provides an analysis of the Bill which may interest you.

Just as we should do all we can to encourage the development of vital new drugs, so must we also do all in our power to improve competition and reduce costs. In its present form, we believe this Bill is not in the public interest.

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Northvale, New Jersey 07647

Re: Patent Restoration Bill

Dear Ken:

The purpose of this letter is to summarize our various discussions with respect to the shortcomings of S.255, the pending bill to extend the life of drug patents in circumstances where government regulatory requirements prevent the marketing of a patented product.

Most, if not all, of the criticisms of the legislation set forth in this letter were the subject of my discussions with several patent attorneys representing PMA during a meeting in Washington on April 30, 1981. Their primary response is the "threat" that the major pharmaceutical houses will not invest the time and money required to develop new products if they do not get long term patent protection on those developments. The industry apparently believes that it is entitled to a legal monopoly as an inducement to investment irrespective of whether that investment produces results which meet the normal prerequisites (novelty and unobviousness) to the issuance of a patent.

It seems likely that many of the Congressmen who are supporting this legislation have little or no understanding of patent law and practice and therefore fail to comprehend how much of a "giveaway" is actually involved in the proposed legislation. A few fundamental principles should therefore be noted at the outset of any discussion of this subject. They are:

1. In this country, the seventeen year patent monopoly runs from the date on which the patent issues, not from the date on which a patent application is initially filed. In most other industrialized countries, the patent grant runs for 20 years from the date of filing an application irrespective of how long the patent application remains pending (under examination) by the Patent Office of the particular country involved.

2. In this country, there is a minimum of 2-3 years between the filing date of a patent application and the date on which a patent is actually granted.

3. New matter may not be added to a patent application after the application is filed. However, it is possible to file a new application called a continuation-in-part application in order to add additional disclosure which may not have been known or discovered until after the filing date of the initial patent application. In ongoing research projects, it is common practice to file such continuation-in-part applications. Quite often, when such an application is filed the original application is abandoned since the new (C-I-P) application contains both the original and added disclosure. The net effect of this practice (which is perfectly proper and permissible under the patent law) is that no patent issues for many years and the seventeen year monopoly does not run. This is one of many procedures which is permissible under the patent law which gives a patentee significant control over when a patent actually issues. It would not be difficult to demonstrate that the pharmaceutical companies, like everyone else, regularly take advantage of these procedures.

4. The actual scope of the patent monopoly is determined by the claims which appear at the end of a patent. Under U.S. patent practice, particularly in cases involving chemical and pharmaceutical compounds, it is common practice to obtain claims which are substantially broader than the specific compounds which were actually conceived and reduced to practice prior to the time the patent application was filed. In chemical and pharmaceutical cases, it is not uncommon for the Patent Office to issue a generic claim covering thousands of possible chemical compounds of a generally similar structure based on a disclosure of nothing more than a few specific compounds falling within the genus. In pharmaceutical cases, it if often true that the specific commercially preferred compounds are not discovered

for many years after a patent is actually granted--a naturally occurring factor which shortens the length of the monopoly. Further, a patent claim covering a chemical compound or a large class of compounds would be infringed by whoever makes, uses or sells that compound for any purpose even though the patent only discloses a non-commercial use and someone else later discovers a highly valuable commercial use.

5. It is perfectly permissible under the patent law to obtain a "paper patent", i.e., a patent which describes products or methods which are only ideas which have neven been reduced to practice. It is not an uncommon practice, and as previously noted, many patents in the pharmaceutical field are a combination of a little actual work and a lot of educated speculation.

6. Finally, and perhaps most importantly, the fundamental philosophy underlying the patent law is that a monopoly of limited duration is granted to inventors in exchange for an immediate public disclosure of the invention in the belief that the public will benefit from that disclosure since it will stimulate additional research and, hopefully, further inventions and improvements in the same field by third parties.

With the foregoing as background, some of the key flaws in the Patent Restoration Bill become more apparent. The major flaws are as follows:

(a) The bill, as currently written, would apply to all IND's or NDA's irrespective of when, during the life of a patent application or patent, they were filed. Thus, where a commercial compound is not discovered until several years after a patent is actually granted but is dominated by a generic patent claim, the patentee, by engaging in the clinical research required to obtain an approved NDA can obtain an extension of the life of his patent. Obviously, a primary reason for the shortened patent life, in such an instance, is the failure to have discovered the specific compound at an earlier date. The pharmaceutical companies are already getting a substantial benefit from a patent law which permits them to make generic claims which are broader than the inventions actually reduced to practice. They now seek to extend the life of those broad claims. It is not hard to envision circumstances where the later discovered commercial compound dominated by a broad generic claims will

actually have been discovered and first disclosed to the world by someone other than the patentee, e.g., a university research group. Another probability is that an independent group will discover a new and previously undisclosed use of a patented compound. As previously noted, it is precisely this type of improvement research which the patent law is designed to encourage. The bill would plainly discourage this type of competitive research since the original patent owner of the broad dominant claim could extend the life of his own patent by up to seven years by filing an IND and NDA on someone elses discovery. It can be expected that the original patentee will use the "leverage" which a potential seven year patent extension provides to negotiate for a share in the fruits of the improvement made by the third party--a licensing arrangement which would most likely maintain exclusivity and high prices for an extended time period. One way to eliminate this likely abuse is to limit patent extensions solely to specific products for which an IND has been filed prior to the issue date of a patent.

(b) A variation on the foregoing problem is the situation which may be created by the discovery of a new use or application for a patented product subsequent to its issue date. It is our understanding that under current FDA procedures an NDA is granted for only certain specific treatments or indications. If it is desired to sell the same pharmaceutical compound for a different indication, a new IND and new NDA may be required. A patent extension would apparently be available in such circumstances even though the patent already covers an existing commercial product. Moreover, the patent extension would cover the product of the patent claim and not merely the use of that product for the new indication. Accordingly, the discovery of some minor new indication for an already successful drug product which might ordinarily be considered of insufficient importance to justify clinical research could be used as a vehicle to obtain up to seven years of extended patent protection. As the bill is written, that monopoly extension would apply to all indications and not just the indication which was the subject of the last filed NDA. The evident cure for this potential abuse is to prohibit the application of the extension legislation in circumstances where any approved NDA covering a patented product already exists. This is clearly a fair limitation since the monopoly

which the manufacturer gets on the first commercial product should be more than sufficient to permit recovery of research expenditures.

(c) The bill as presently drafted clearly puts too much blame on government regulation. The vast majority of clinical research now undertaken by pharmaceutical manufacturers would be undertaken even if the FDA were completely shut down since such effort is essential to avoid product liability claims. In this respect, pharmaceutical companies have the same responsibility as other industries to market only safe and effective products. Accordingly, if legislation of this type is to be passed, the maximum extension should be governed by the actual amount of time consumed in meeting government regulations or in awaiting government action which would not otherwise be consumed in bringing a safe and effective product to market. It is hard to believe that the time period involved would be seven years. Rather, it seems more likely that the amount of time lost can be fairly measured by the time between the filing of an NDA (upon the completion of a clinical research program) and the approval of that NDA by the government. Indeed, neither the timing of an IND filing nor the time of the completion of clinical studies and the filing of an NDA is actually controlled by the government. Obviously, a lengthy extension of time is an invitation to delay since there is no penalty in terms of loss of monopoly rights. In that respect, the extension legislation tends to promote delay in the developing and marketing of potentially useful pharmaceuticals until such time as it suits the economic needs of the pharmaceutical manufacturer.

(d) Ordinarily, the issue date of a patent provides third parties with a guaranteed date of expiration. Marketing plans which promote competition can and are made in the light of the expiration date of a patent. As the Bill is currently drafted, the public would receive no notice of an extension of the patent until after an NDA is approved. This is clearly unfair. The bill should provide for the placing of an appropriate notice in the patent file or on the issued patent as soon as an IND is filed.

It is difficult to argue with the proposition that a patentee may be entitled to some relief in those circumstances where he is ready to market a product at the time a patent issues but is prevented from doing so because a filed NDA has not yet been approved by the government. Legislation to correct that specific problem would not be objectionable. It seems unlikely,

however, that such legislation is truly necessary since the patentee can in most (if not all) instances keep his patent application pending in the Patent Office by filing continuation-in-part patent applications until approval is obtained.

It should be equally apparent that where a patent has issued and no IND or NDA has been filed the loss of monopoly time is totally the fault of the patentee. To permit the patentee to obtain an extension of a patent based upon discoveries after the patent issue date (whether his or someone else's) or activities which did not even commence until after the patent issued totally undermines the basic philosophy of the patent system which is designed to give everyone equal access to the development of additional inventions and improvements based upon the information contained in the patent. Limiting the legislation to IND's or more preferably NDA's, on file as of the patent issue date would impose no undue hardship on the pharmaceutical companies since they are not compelled to file patents until the inventions are made. Currently, patent applications are prematurely filed as a means of reserving fields of exploitation and procuring the earliest filing date in the event of a conflict with some third party who independently invents the same subject matter.

The time and expense in bringing products successfully to the marketplace is not unique to pharmaceutical companies. Indeed, many industries face this problem and face the additional problem of immediate competition because patent protection is unavailable or severely limited. The development of good computer software is a prime current example of an industry facing such a problem. In other industries, commercial product life is so short, e.g., the toy industry, that patents are practically useless because the commercial life of the product terminates in the two to three year interval a patent application is pending and pending patent applications give no substantive rights. In other situations involving truly fundamental discoveries, patents have expired before a commercial market was developed. Indeed, in situations involving national security, the government has a right to prevent a patent from even issuing, and the sole remedy is a suit against the government for damages caused by the order and compensation if there has been use by the government.

Clearly, the issuance of a patent does not carry with it any guarantee of commercial success or a commercial monopoly of a minimum length. To the extent that government regulation interferes with commerce, the cure resides in improving government regulation not in undermining the patent system to suit the needs of a particular industry group.

I believe that the foregoing covers most of the major points that have been discussed. Please let me know if you require any clarification or expansion on any of these matters.

Cordially,

AMSTER, ROTHSTEIN & ENGELBERG

Alfred B. Engelberg

ABE:rmp

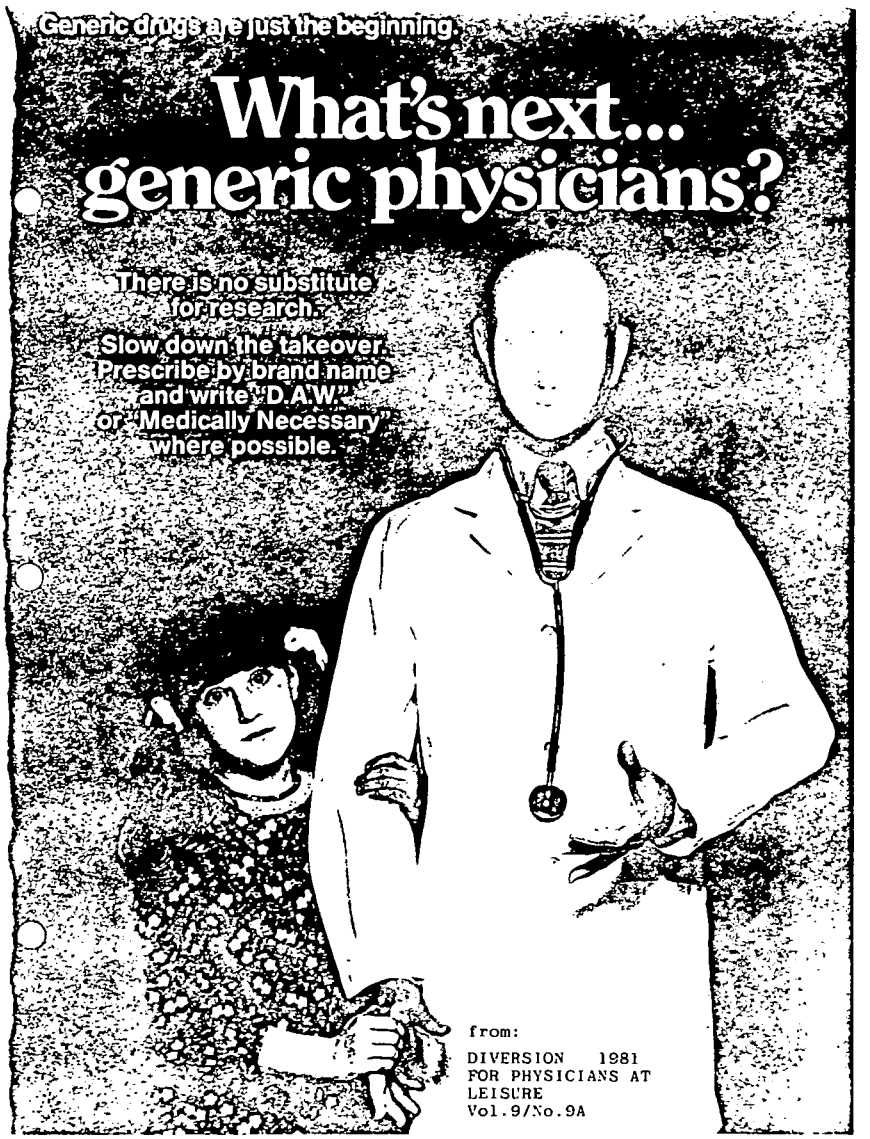
cc: Mr. Haddad
Ms. Fenester

COMPARATIVE GENERIC/BRAND NAME DRUG PRICES

Generic (Brand Name) Drug Products	Generic* Price	Brand* Price	Brand Price Times Greater	Annual** Brand Drug Expenditures (millions)	Equivalent Generic Cost (Col.5 ÷ Col.4) (millions)	Possible Generic Savings (Col.5 - Col.6) (millions)
Dipyridamole (Persantine) 25 mg./1000s	$23.75	$108.34	4.6	$58,937	$12,812	$46,125
Isosorbide Dinitrate (Isordil) 5 mg./100s sublingual	1.46	5.41	3.7	54,102	14,622	39,480
Amitriptyline HCL (Elavil) 25 mg./1000s	17.71	73.53	4.2	29,613	7,051	22,562
Chlordiazepoxide HCL (Librium) 10 mg./500s	5.63	43.65	7.8	27,675	3,548	24,127
Tolbutamide (Orinase) 0.5 gm./1000s	42.67	91.58	2.2	22,637	10,290	12,347
Hydralazine HCL (Apresoline) 25 mg./1000s	11.74	66.07	5.6	22,441	4,007	18,434
Isoxsuprine HCL (Vasodilan) 10 mg./1000s	22.72	137.74	6.1	19,101	3,131	15,970
Meclizine HCL (Antivert) 12.5 mg./1000s	8.73	61.76	7.1	17,173	2,419	14,754

TOTAL POSSIBLE GENERIC SAVINGS: $193,799,000

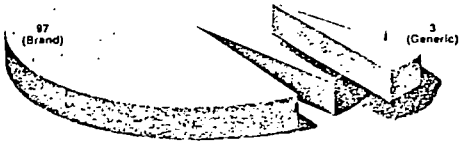
* 1981 Redbook Prices
**1980 IMS Data


Generic drugs are just the beginning.
What's next... generic physicians?
There is no substitute for research.
Slow down the takeover.
Prescribe by brand name and write "D.A.W." or "Medically Necessary" where possible.
from:
DIVERSION 1981
FOR PHYSICIANS AT LEISURE
Vol.9/No.9A

from: DIVERSION - 1981
FOR PHYSICIANS AT
LEISURE
Vol. 8/No. 9A

Drug Therapy June 1981

Is there a generic equivalent for drug research?



Estimated Drug Industry Investment in R&D*

Frankly, the dollars say no.

By the most generous estimates, generic manufacturers contribute barely 3% of the more than one billion dollars spent annually in the laboratories of American drug firms on research and development of new drugs.

For the last quarter of a century, virtually all of the major new drugs that imitators imitate have originated with a handful of research-oriented firms well known to all.

While our national investment in research has been declining steadily for a decade, the American pharmaceutical industry has actually been increasing its commitment, so that it now spends over five times the national average. No other industry dedicates a higher percentage of its profits to research. No industry in America depends less on government subsidies.

In the last two decades, the cost of introducing a significant new drug has risen from roughly $4,000,000 to over $50,000,000, while its effective patent life has eroded from seventeen years to less than ten.

Today, the entire research and development commitment of ALL generic manufacturers combined is not enough to develop one single new drug entity.

When you prescribe generics, you switch profits from the innovators to the imitators... and R&D rarely appears on the imitators' budget sheets. Meanwhile, there are *real* people who may have to suffer and perhaps die needlessly if the incentives to progress are removed. It would be sad to abandon our commitment to the future in the short-sighted search for a bargain.

*Based on 1977 published figures available from National Science Foundation and the Pharmaceutical Manufacturers Association.

ROCHE®

Without the innovators, there could be no imitators

PRIVATE PRACTICE MAY 1978

In 20 years there could be no new drugs to imitate.

A realistic "full disclosure" of the effects of generic prescribing should include—as a major potential side effect—the reduction, if not outright elimination of new drug research in America.

The root of the problem is simple economics...

At current estimates, it takes approximately $60,000,000 and nine years of hard work to bring a single new drug entity to the point where it can be prescribed in clinical practice. Less than one investigational drug in sixty actually reaches the pharmacy, and many that do have limited application and limited acceptance. Yet each must generate a minimum of $7,500,000 in pure profit each year until its patent expires simply to pay for its development costs.

In short, research is expensive and risky.

Few generic manufacturers invest a penny in it. And once it becomes safer and more profitable to imitate than innovate, the firms that have developed practically all the major drugs you prescribe today won't be able to afford research either.

You can preserve the incentive for continuing pharmaceutical research by remembering the originators.

ROCHE®

Without the innovators, there could be no imitators

Generic Pharmaceutical Industry Association

600 Third Avenue, 18th Floor
New York, New York 10016
Telephone (212) 490-8028

GPIA FACT SHEET

PATENT EXTENSION FOR PRESCRIPTION DRUGS

September 1981

SUMMARY HIGHLIGHTS

- The top selling drugs in America are realizing actual legal patent protection for an average of 18.5 years. (See page 2)

- The U.S. pharmaceutical industry is one of the most profitable of all manufacturing industries and "continues to enjoy high and stable profits in terms of return to stockholders' equity."

- "Revenues of the pharmaceutical industry have increased steadily and the relationship between revenues and R&D expenditures has remained stable."

- "Research-intensive companies are committing increasing amounts of funds toward pharmaceutical R&D, and therefore, the potential exists for major pharmaceutical discoveries."

- The Administration is committed to reducing unnecessary regulatory requirements. FDA is already trying to expedite its approval of new drugs and "the duration of the drug approval process may therefore stabilize."

- Patent extension will delay competition and deprive consumers and government purchasers of the savings they can realize with identical, but lower-priced generic drugs.

- The costs of patent extension will fall heaviest on young and middle income families, on the nation's elderly and the chronically ill.

- The benefits of patent extension "will accrue to a few firms" which are already among the most profitable multinational companies in the world.

- The evidence available "neither supports nor refutes the position that innovation will increase significantly because of patent term extension."

NOTE: All quotes are from Patent Term Extension and the Pharmaceutical Industry, Office of Technology Assessment, Congress of the United States. 1981.

Drug Patents Exceed the Statutory Maximum

The stated rationale for patent extension legislation (HR 1937) -- that the federal regulatory process has reduced effective patent life for pharmaceutical products to only 9.5 years -- is not supported by the facts.

The U.S. patent holders of the most frequently prescribed drugs in America, with annual sales of $1,371,000,000, are realizing legal patent protection for an average of 18.5 years

DRUG PRODUCT	1980 SALES* (millions)	NDA APPROVAL	PATENT EXPIRATION	YRS. MARKET PROTECTION
Tagamet (Cimetridine)	$233	1977	1993	16
Valium (Diazepam)	220	1963	1985	22
Inderal (Propranolol)	179	1967	1984	17
** Aldomet (Methyldopa)	133	1962	1984	22
flex (Cephalexin)	131	1971	1987	16
Clinoril (Sulindac)	115	1978	1989	11
Indocin (Indomethacin)	75	1965	1981	16
Naprosyn (Naproxen)	75	1976	1989	13
Aldoril (Methyldopa w/ Hydrochlorothiazide)	58	1962	1981	19
Diabinese (Chlorpropamide)	53	1958	1984	26
Mellaril (Thioridazine)	50	1959	1983	24
Zyloprim (Allopurinal)	49	1966	1986	20

AVERAGE YEARS OF MARKET PROTECTION: 18.5

Total Sales Volume, 1980: $1,371,000,000

* IMS DATA

**Motrin, the 4th ranking drug in America, is licensed by the British patent holder to a U.S. company.

The Pyramiding of Drug Patents

The claim that prescription drugs realize only 9.5 years of patent protection is based on a four-page magazine summary * of an analysis which is seriously flawed in methodology: the authors calculate effective patent life by measuring from the date of the earliest patent issued. Their analysis does not take into account the pyramiding effect of subsequent use, process, or other patents which extend patent terms and prolong monopoly life and premium pricing of prescription drugs.

The authors of this much-quoted article have further understated actual patent life of pharmaceuticals by limiting their analysis to New Chemical Entities (NCEs) and excluding all other drug products. OTA acknowledges this flaw in its report on patent extension.

> "By focusing on NCEs, the most extreme reductions in effective patent terms can be determined, but these effects are not representative of the average effects for all new pharmaceuticals."

It should also be noted that while the four-page magazine article has been cited as the basic -- if not sole -- justification for patent term extension, the full analysis is not yet issued, has not been submitted to the sponsoring agency for review, and is not available for independent verification.

* Research Management, January 1981. "The Decline in Effective Patent Life of New Drugs," a four-page article by Martin M. Eisman & William M. Wardell.

Is Innovation Declining?

Another underlying premise of the pending patent extension legislation -- that pharmaceutical innovation is declining -- is not supported by the findings of the Office of Technology Assessment:

- "Competitive pressure for innovation has not diminished."
- "The relationship between revenues and R&D expenditures has remained highly stable over the past 15 years."
- "Many research intensive firms have indicated that they are increasing R&D expenditures."

Although the number of NCE approvals is an incomplete measurement of innovation, OTA uses this method to determine trends in the industry. Data provided OTA by the Food and Drug Administration shows that the number of NCEs approved in the 8-year period from 1972 to 1980 increased significantly over the number approved in the previous 8-year period:

APPROVED NCEs

	1963 to 1971	1972 to 1980
Totals:	136	175

More importantly, OTA found that "approvals of NCEs offering important or modest therapeutic gain have remained relatively stable."

The Costs and Benefits of Patent Extension

"The price of drugs whose patents are extended will be higher during the extended period than they would have been if patent protection ended." *

"Competitive pressures on patented drugs from generically equivalent drugs will be delayed and in some cases prevented by patent-term extension." *

Since 84% of prescription drug purchases are paid by consumers and not by third-party reimbursement programs, the additional costs of patent extension will fall heaviest on the elderly, the chronically ill, and on young and middle income families.

* OTA Report.

"The bulk of revenues generated by patent-term extension will accrue to a few firms who have developed financially successful drugs." *

The American Association of Retired Persons and the National Retired Teachers Association summarized the cost/benefit relationship of patent extension in a statement submitted to the Senate Judiciary Committee: **

> "We can be sure that additional years of patent protection will result in very real income transfers from elderly consumers to large brand-name manufacturers."

While the Report of the Senate Judiciary Committee made note of the support from AARP/NRTA of "the concept of patent restoration," it failed to cite the Associations' expressed concerns and recommendation:

> "Enactment of patent restoration will likely result in additional increases in the elderly's expenditures for prescription drugs."
>
> "We are concerned about the effect patent restoration would have on competition in the drug industry, particularly price competition, and whether the benefits of patent term restoration are commensurate with the costs such legislation would necessarily entail."
>
> "Finally, our Associations recommend that alternative approaches to further drug research, development and innovation be explored with the aim being to find alternatives to prescription drug prices as a means of financing R&D."

* OTA Report.

** Statement of the National Retired Teachers Association and the American Association of Retired Persons on S.255, the Patent Term Restoration Act of 1981, Submitted to the Committee on the Judiciary, United States Senate, April 30, 1981.

The Case for Patent Extension - Fact or Fiction?

The arguments for patent extension are based, according to OTA, on "a widespread belief" that the return to R&D investment is declining.

OTA, however; finds that there is not sufficient data to prove the accuracy of this widespread belief, and concludes:

> "Many factors that influence R&D decisions appear to favor innovation: the industry continues to enjoy high and stable profits in terms of return to stockholder's equity; research techniques have improved; and competitive pressure for innovation has not diminished."

The "problems" which HR 1937 is supposed to remedy may in fact, therefore, not really exist:

- Drug products, as shown, frequently have effective patent lives in excess of the 17-year statutory maximum.
- "The duration of the FDA regulatory procedures may be stabilizing" according to OTA, and the Agency "is now giving highest priority to the drugs that it believes will provide significant therapeutic advances. . ."
- "Pharmaceutical companies earned the fourth highest return on equity in American industry last year, at 20.5 percent, ranking behind the oil services industry, energy companies and the tobacco industry." *
- "There is a remarkably full research pipeline. Almost every major drug firm is now increasing its research and development spending as a percentage of sales, reflecting a high degree of confidence in the prospects for commercial success of products not yet introduced." **

* The New York Times, "The Drug Business Sees a Golden Era Ahead," May 17, 1981.

** Medical Marketing and Media. "The Drugs in the Eighties: The Growth will be There-Part I," August 1981.

The Generic Drug Industry

Competition from the generic drug industry has significantly reduced the cost of prescription medicine.

The Federal Trade Commission estimated in 1979 that "between 42.1 percent and 74.3 percent of the wholesale price of branded drugs could be saved by the dispensing of nonbranded products instead of more expensive branded drugs." *

For the nation's elderly, who pay 25 percent of the national drug bill, price competition can be a life or death matter. Some 70 to 75 percent of drug misuse among the elderly is due to under-utilization because they cannot afford the medicine that has been prescribed.

Despite the savings that can be realized by the use of identical, but lower-priced generic drugs, 80 to 85 percent of the drugs having generic competition are sold by the large pharmaceutical companies.

Even after patents expire, branded products enjoy what OTA calls "post patent exclusivity," a further extension of market share and monopoly pricing. One study cited by OTA showed that after patents expired, each of 12 major drugs (including Librium and Darvon) retained more than a 90 percent share of the drugstore market and more than an 80 percent share of the hospital market.

Patent extension will provide additional opportunities to extend monopoly pricing periods beyond the 17-year statutory patent term. The members of the GPIA believe that patent extension will delay or preclude the entry of generic drugs into the market, eliminate the competition they provide, and force consumers and government purchasers to pay higher prices for prescription drugs.

* OTA Report.

Mr. LARSEN. Thank you very much.

Rather than read my entire statement, in the interest of conserving time and perhaps leaving time for questioning, I would like to just talk a little bit about the bill as I see it.

On the surface, it would appear to be reasonable—and that was my first personal conclusion and that was the conclusion generally of our association.

Then, on closer examination of the bill, we began to see some things that caused some doubt—caused some doubt about the matter of equity, the matter of reasonableness, and the basis of justification in fact.

If you were to take a look either at the exhibit to the left, which is difficult to read, or on page 5 of my statement, you will see some reason for having these doubts.

The rationale for the patent extension legislation is that the Federal regulatory process has reduced effective patent life for pharmaceutical products to only 9.5 years.

We don't believe that is supported by fact. If you take a look at page 5 you will find that the U.S. patent holders of the most frequently prescribed drugs in America, with annual sales of $1.3 billion, are realizing legal patent protection for an average of 18.5 years. You can pick the drugs, you can identify them, and you can see the value of these drugs in the marketplace.

The events that lead to the extension of these years have to do with the pyramiding of patents on product, on use, and, in some situations, on process.

Now, the OTA, in examining the only report that was available, found that the understatement of actual patent life for pharmaceuticals was because there was a limit in the analysis to new chemical entities, and it excluded all other drug products. OTA acknowledged the flaw in the report on patent extension by focusing on new chemical entities, the most extreme reductions in effect of patent terms can be determined. But these effects are not determinative of the average effects for all new pharmaceuticals. If you were to look at new chemical entities, there were a total of 136 from 1963 to 1971 and for the same number of years, 1972 to 1980, we are talking about 175.

More importantly, OTA found that approvals of new chemical entities offering important or modest therapeutic gains have remained relatively stable as the figures support.

I found it interesting, because I have a lot of respect for the American Pharmaceutical Association, to find, in an editorial in the July 1981 issue of the Journal of Pharmaceutical Sciences, that they stated the following concerning the bill, that they basically endorsed the concept of the bill, as I personally do because I feel it is only just and right that companies or individuals that invest in basic research deserve a return on that investment. But the points that they made, which we certainly endorse are:

To change the point at which the patent period begins, where "the clock starts to run," and if we do this, and we start with the day of the NDA application, we remove much of the area of gray and we get right at the rudiments of where the delays may take place within the FDA.

They have further stated to exclude usage and process types of patents from further extending patent life.

The third point they made was to require full disclosure of the data relating to the safety and effectiveness of the drug as soon as the firm files its NDA with the FDA.

Now, I think the people at the American Pharmaceutical Association are well qualified to make judgments in this area, and they sit kind of in a seat of authority; they are fully knowledgeable, and I think that their conclusions must have a great deal of weight as this matter is concerned.

Over and above the patent protection, the originators' brand name products maintain a de facto near-monopoly market share beyond the patent life due to extensive promotion and control of color and product configuration.

Further, because of questions created in the minds of professionals and users, the penetration of generic drugs has been limited, and it varies from State to State. This is unfortunate as the perceptions are not based on fact.

Generic drugs must satisfy the FDA's requirements. Further, generic manufacturers are making technical contributions to the understanding and use of drugs. There are several drugs that I could cite for you as examples where knowledge has unfolded as tne results of the efforts of generic companies, but just one is a recently off-patent product that holds more than $150 million market share.

Generic companies, as they normally would do in advance of patent expiration date, formulated the product and in testing found their product, without using any unusual means in the formulating of it, to be a biosuperior product, generally three times as available as the originator's product. The FDA when presented the data would not approve the generic inequivalent formula. The companies deformulated the product to make it bioequivalent. The FDA advised the generic companies they would not approve the equivalent product as it would mean putting another, quote, "poor product," end quote, on the market. The originator's product continues to dominate and hold its market share. In fact, it has grown in the last 2 years. Consumers and the Government continue to pay the high brand-product price. Generally, brand products are insensitive to generic competition.

You know, one of the things I thought when I was with a major company and I looked at generic companies—and I had a different perspective at that time—was, "Boy, those are the guys that really compete with us." And as I moved over to the generic side of the industry I found something unusual. And some of the testimony I offered before a hearing that Representatives Gore and Marks held earlier was that the competition that we created doesn't really have much effect on the brand-product pricing. And Bill Haddad will give you some more information on this as we go.

But the generic companies compete very vigorously with each other, and there is a rapid price decline in the price of products as generic companies, after the first, second, and third enter—each one tends to erode the price, making the price at a lower cost to the consumer and a lower cost to the Government.

In addition to these marketing impediments, generic manufacturers also experience the same delays as the research companies. It takes approximately 2 years for the FDA to review and approve generic product submissions. From my own company's experience, they have generally gone beyond 2 years, and we had to experience the same thing a major company does, request a change in standards, the redoing of a biostudy, which means resubmission and another 180 days of consideration. So we, too, have a time delay.

The proposed extension provisions and the related factors mean higher cost of drugs to consumers and the Government. The cost of patent extension will fall heaviest on you and middle-income families, on the Nation's elderly and chronically ill. Twenty-five percent of the cost of drugs is carried by the elderly. They are the ones that will carry a substantial portion of the costs that would be created by extension.

The OTA found the evidence available neither supports nor refutes the position that innovation will increase significantly. It is clear the bill means higher drug costs contrasted to an unknown, if any, return in the future.

We recommend the committee urge the interested parties to meet so these complex and technical matters can be considered and resolved rather than consume the committee's time.

I might say that our association initiated such meetings and they have not—have not—been able to carry forth with those.

We have attached a letter from GPIA's patent attorney that provides an analysis of the bill which I think should interest you because it looks at the patent situation as it is, and I encourage you to read it. Those of you who are attorneys will certainly understand it well.

Just as we should do all we can to encourage the development of vital new drugs, so must we also do all in our power to improve competition and reduce costs.

Certainly that isn't an objective of today. Yesterday morning I heard, concerning the State of Illinois, they were concerned with what was going to happen to funding. One of the opportunities is to expand the use of generic drugs.

In its present form we believe this bill is not in the best public interest. That isn't to say that we do not agree with the tenet of providing a return for research and innovation, but it has to be on a basis that also serves the interests of the consumer.

I thank you, Mr. Chairman.

Mr. KASTENMEIER. Thank you, Mr. Larsen.

I have some general questions.

First of all, the letter you have attached to your statement, the seven-page letter, would you identify him in terms of who he represents?

Mr. LARSEN. Mr. Engelberg, who wrote the letter, is a member of the firm of Amster, Rothstein & Engelberg. He has represented the GPIA in this matter. He has participated in the meetings that I alluded to between our association and the Pharmaceutical Manufacturers Association. He met with their patent counsel. And he happens to also represent our firm, Zenith, in some matters but not in all broad legal matters. He represents it mainly in the issues of product identification—size, color, shape.

Mr. KASTENMEIER. In your concluding remarks you recomend that the committee urge interested parties to meet so the complex and technical matters can be considered and resolved.

Would you identify what interested parties there are. I assume you are talking basically about the Pharmaceutical Manufacturers Association or members thereof. What other interested parties might there be?

Mr. LARSEN. I think as far as I am concerned those are the two prime members. I am sure there are other parties that have interests in the bill. I know the consumers have had interest. But I think for the technical resolutions it is going to have to require—at least my idea—the two principal parties to sit down and look at this thing, members of the PMA and ourselves, because that is where the basic conflicts in presentations exist.

Mr. KASTENMEIER. One of the several points you make is that you, too—that is to say, generic manufacturers—have trouble with the Food and Drug Administration. And you spent a few minutes of your testimony and a page of your brief statement referring to difficulties you two have had. I take it you regard that as an element in the general complex problem which is being addressed by the proposal before this committee.

Mr. LARSEN. I think there are many people that recognize it as a problem. The FDA, we know, is looking at the problem. We know there is another House committee that is examining the problem. We know in a preceding term the Waxman committee took a look at it, the GAO has looked at it. I think it is a commonly recognized problem, that if we can do something about expediting the flow of products through the FDA, part of the arguments disappear.

One of the things that has happened just this past year that has helped generic companies and helped reduce the cost of drugs, even though its full effect has not been felt because of the limited amount of approvals, has to do with post-1962 drugs and the sequence of getting through the NDA paper process.

We have two sections over in the FDA—making it simplistic—and that is the abbreviated new drug section under Dr. Siff, and Dr. Siff's area of responsibility is primarily related to pre-1962 drugs, and the other is the new drugs under Dr. Finkel.

Drugs in the new drug section cover the whole gauntlet of things from brandnew chemical entities that offer superior advantages in the way of health care, and then there are the generics. And they have a prioritization system in which I suppose the top on the priority is the brandnew chemical entity that offers the greatest return and benefit to health care, and category 5 happens to be generic. So, therefore, if more new chemical entities come in, you never get out of category 5 because something else moves in in front of you.

I believe the simplest and easiest way to resolve that is to say, "OK, generic drugs which are proven in the marketplace and for which substantial information exists as to their safety and efficacy should be transferred over into the other section to simplify the review, get away from the presentation of this paper."

And it would do another thing that would be a great benefit to the research-oriented companies—it would not dilute the efforts of the new drug staff to reconsidering the old, reinventing the wheel,

the reexamination, and all the disciplines that that means, of each submission of a generic drug as though it were a new drug, because that is the process that takes place. Bill is pointing out something to me.

Mr. HADDAD. May I reference something. I am William F. Haddad, a member of the board of directors of the GPIA.

On page 4 of the report that you instructed the OTA to prepare for you, in recommendation No. 3 they make a conclusion which I think would be helpful to you today, and in answer to some of the questions that were raised yesterday. And it says, "There is reason to believe that the FDA decline may be halted in the future."

That is somewhat borne out by the GAO study, but the GAO, in fairness, concludes that there is much more that can be done under Vice President Bush and others in eliminating regulations.

Mr. RAILSBACK. Where are you reading?

Mr. HADDAD. Finding No. 3 which begins, "Since 1966, average effective patent terms have declined. Some factors influencing effective patent terms are, however, changing, and there is reason to believe that the decline * * *"

Mr. RAILSBACK. I see it.

Mr. HADDAD. That can be borne out, but GAO indicates a great deal more can be done. We personally believe they can do more and might eliminate the entire question from consideration.

Mr. KASTENMEIER. In terms of what I take you are leading to—and this is a general question, not a specific one—you spoke of diverting examinations to certain sections and the like.

Does the general trend toward deregulation and the present climate—I must say it started at least in the last Congress and presumes to be abetted by this administration as well as this Congress—is that in any particular sense likely to meet the problem of term or the problem that you confronted that you referred to in terms of the FDA, or series of problems?

Mr. LARSEN. I think there is an amount of "wait and see" involved, but we have optimism that the position taken by the administration in all of these studies may finally come to fruition that will simplify this review process particularly on generic-type drugs. And I think if you simplify the process on generic-type drugs you free up the talents of people in the FDA to concentrate more on the complete new chemical entities, the vital things.

We know—and I know members of MPA companies have the same knowledge—that there has been drafted within the Food and Drug Administration procedural matters that would affect this. And we have been hearing for some time that they would be coming out—and this goes back to the prior administration period—but as yet they have not surfaced, as to the process of hearings and so forth, so we don't get into the same holdup as occurred with post-1962 drugs. I suppose the simplest way would be to pass legislation to effect the transfer and get rid of all this discussion and hearings and so forth. That, to me, would probably prove to be quicker and simpler than having it come out in the Federal Register, and then wait a year and a half while hearings and everything else take place—a personal opinion.

Mr. KASTENMEIER. I have several other questions, and then I am going to yield to my colleagues who I'm sure also have questions. I'd like to at least mention what the questions are.

I'd like you to discuss when I return to you whether you have any reservations about the OTA study or comments about it. Assuming some legislation emerges, what changes would you recommend, since you indicated at first examination that which is attempted to be achieved by the legislation appears to be reasonable, even though on further examination it may not be, in your view.

And also if we have timid-like further discussion of the term that you impute on page 5, the leadoff discussion of how these drugs can average 18.5 years. I think that should be fleshed out a little bit in terms of an explanation.

But I am going to defer those so my colleagues can have some questions.

The gentleman from Illinois.

Mr. RAILSBACK. Thank you, Mr. Chairman.

What is the investment in testing and marketing a generic drug? We have heard the figure bandied about that it's $70 million for research and development of a new drug. I am just curious as to what are your costs in developing and marketing a generic drug—or before the marketing, really, the testing cycle.

Mr. LARSEN. I understand where your question is coming from. First of all, the $70 million in my judgment is an overstated figure because I think with any drug it may vary from something much less than that, and possibly up to $70 million, because the same situation exists in generic drugs.

I am thinking of a drug now in particular where we invested to date, all of our internal costs—we invested $60,000 in a biostudy, had it at the FDA for approximately a year and a half—and we weren't the only company—and the ground rules changed and the requirements changed for the drug in light of some new facts and the like, and now we are in the process of doing another biostudy which will cost $70,000.

So I suppose the overall cost of that drug before we get it to market—because we have to produce demonstration lots that we have to hold during the 180 or 360 days or 2-year process which you essentially lose because your dating begins to lapse as you go—but we are talking from $200,000 to $500,000, would be my guess.

Mr. HADDAD. Could I intervene, Mr. Railsback?

Mr. RAILSBACK. OK.

Mr. HADDAD. You used the word "bandied about."

Mr. RAILSBACK. Yes.

Mr. HADDAD. I would like to bring that up. I was very fortunate to be part of the OTA panel, and the author of that study was present and I will repeat to you verbatim, very quickly, the conversation that ensued about how that $70 million was arrived at. And it is on tape and could be provided to this committee.

I said, "Was it a random survey?"

He said, "No."

I said, "How did you get your information?"

He said, "From companies that are willing to participate."

I said, "Did you get all the information from all of the companies?"

He said, "No."

I said, "Is that information available to us or OTA or to some university for verification?"

He said, "No."

I said, "How are we able to verify it?"

He said, "You cannot because they are confidential figures"—and I can understand that.

Further, he said his figure was not $70 million, it was $54 million escalated by inflation to the $70 million figure.

Mr. RAILSBACK. The $54 million was an earlier year's figure?

Mr. HADDAD. Yes, and accurately escalated at $70 million, but there are other studies that indicate the numbers may be much less than that.

Mr. RAILSBACK. What do you think it costs them?

Mr. HADDAD. Truthfully?

Mr. RAILSBACK. Yes. What do you think it costs them?

Mr. HADDAD. What you do is average out your losses with your successes, which every business must do, and every business must make a profit. That is the bottom line. I honestly don't know the answer, I have no way of getting it, but you can find it out if you want to find it out. You pick the research-intensive companies, you pick the random drugs, you get the figures, you get the worksheets.

I'll tell you what I found out—under subpena, in executive session in the city of New York—sworn testimony of detailmen before me, under oath, with penalty of going to jail, testified in executive session in the State of New York that they were required to charge up their marketing and detail expenses, including trips to the Superbowl and other such advantages, to account for R. & D.

Is it true? I do not know. They testified to that under oath. We achieved our objective in the executive session. It was not that objective.

So you have the ability. I urge you to try to find it out. It will be very difficult and very expensive and they will not cooperate.

So I do not know your answer. I apologize.

Mr. RAILSBACK. In respect to the generic drug industry, are there occasional writeoffs and losses in your industry for drugs that you want to market that don't get off the ground? And what is your figure on that? Do you have any statistical percentages?

Mr. LARSEN. I think that is kind of hard for me to identify. I can only speak to you of one company in that regard.

Mr. RAILSBACK. Your losses, I take it, would naturally and understandably be much less because you are dealing with drugs——

Mr. LARSEN. Yes, we are dealing with drugs that are much less in cost, we are dealing with a selling price that is substantially less, and everything is scaled down. But I think as you look at the companies, they experience the same kinds of problems another company does. We do a biostudy and we find out something very unusual. The particular product that I referenced as an example—my particular company ended up doing three biostudies to satisfy themselves that we knew what we were talking about. We disclosed the information to the FDA well up in front—and this is over a year ago, more than a year and a half ago—and we are still discussing and developing information, and in this case we are going so far as to looking at the clinical picture and even talking to

people outside the United States on the drug. And yet, we have made these investments and we don't see any opportunity for return on that drug at this time.

To be specific, I don't know what our ratio would be compared to the majors. I don't know that they can even tell you that.

Mr. HADDAD. But add to your list one other factor, Mr. Railsback. Like the Japanese, we invest in plant and advanced tooling. We are so advanced that the major generic companies come to us to make their product for them.

You were not answered, Mr. Chairman, on a very vital question. Eighty to eighty five percent of all generics made in America are made by PMA firms and sold under the name of branded generics at a price that New York estimated at approximately four times the generic price that we charge. We invest in plant, land, equipment, and staff.

Mr. RAILSBACK. Wait a minute. Let me interrupt and see if I understand.

What you are saying is that the PMA companies are really producing 80 percent of generic drugs.

Mr. HADDAD. Yes. Lilly very much so.

Mr. RAILSBACK. And you are adding to that that even though they are producing these so-called generic drugs, they are charging four times what the true generic companies, the nonproduction companies—I'm sorry, the nonresearch companies—charge?

Mr. HADDAD. Let's use the OTA term, which may or may not be accurate, the production-intensive firms.

Mr. RAILSBACK. So the production-intensive firms charge substantially less for their generic production of drugs than the research intensive?

Mr. LARSEN. I can cite you an example.

Mr. RAILSBACK. But is that right?

Mr. HADDAD. Yes.

Mr. LARSEN. Yes. As an example, there is a drug called dipyridamole. And this was presented to Gore's and Marks' hearing. The originator's product was priced in 1977 at $95.40 using the Red Book average wholesaler's price, which is a standardized index that we might look at.

In 1978 that price was $99.75. In 1979, the generic companies came in. The first generic company that came in, the price was $44.50 selling to the same market that the other product was. Interestingly enough, that year the originator's product went up to $105.25 average wholesaler as compared to $99 it was before in the face of competition.

Mr. RAILSBACK. Using a brand name or generic?

Mr. LARSEN. Using a brand name, yes. And then at the time of that hearing, which was last spring, the generic price was $18.95 from the $44.50, and the originator's average wholesaler price was $108, 5.7 times greater.

Mr. RAILSBACK. No, but what I was trying to find out was whether their generic name products are sold at a much higher rate than the production-intensive firms are selling them for?

Mr. LARSEN. I guess, in my judgment.

Mr. RAILSBACK. You are still talking about brand name?

Mr. KASTENMEIER. I hate to interrupt but we only have several minutes left to vote, and this interesting colloquy can proceed after that. We will recess for 10 minutes and ask the witnesses to excuse me.

[Whereupon, a short recess was taken.]

Mr. KASTENMEIER. The committee will come to order.

When we recessed, Mr. Railsback was in the process of asking some questions of Mr. Larsen and the panel.

Would you like to conclude?

Mr. RAILSBACK. Yes, thanks, Mr. Chairman.

The point, I guess, that I was trying to elicit was an example of the 4-to-1 ratio that you mentioned that I thought was relative to the cost of generic drugs being sold by research-intensive companies compared to the price of generic drugs being sold by production-intensive companies.

Now, did I understand that it is your allegation that the research-intensive companies are actually selling them for about four times higher than the production-intensive companies?

Mr. LARSEN. I guess it's not an allegation. I think if you take a look at the Red Book price as the average wholesaler price and then compare that to generics, you get this kind of comparison.

That is not to say there might not be some brand product out there that falls somewhere in between.

Mr. RAILSBACK. Yes. I think we are not on the same wavelength, and I apologize if I am misstating you. I am not talking about the originator brand price.

Mr. LARSEN. I understand.

Mr. RAILSBACK. I am talking about, say, Lilly or, say, Searle producing a generic drug. And is your allegation that their sales prices average about four times the price of generic drugs being sold by the production-intensive companies? I am not talking about the brand name.

Mr. LARSEN. I understand your question. I am just looking for the right words.

Mr. RAILSBACK. Yes, because that seems very high to me if that is true.

Mr. LARSEN. Set aside antibiotics.

Mr. RAILSBACK. Yes.

Mr. LARSEN. Because this is a different world, and anything I would say about things in a general way and then try to relate it to antibiotics could be flawed in many ways.

Mr. RAILSBACK. Yes.

Mr. LARSEN. The first brand product will maintain the higher price for some time.

Mr. RAILSBACK. I understand that.

Mr. LARSEN. There may be some erosion, but minimal.

Mr. RAILSBACK. Yes.

Mr. LARSEN. As generic companies come in there are two kinds, the branded generics or the commodity generics or whatever you want to call our section of the industry.

Mr. RAILSBACK. Let's call it production-intensive.

Mr. LARSEN. All right, production-intensive versus the research-intensive brand companies. Chances are that you would find the

brand generic product less than what the originator's product is. Basically you have to buy into the market. You have to establish it.

Mr. RAILSBACK. We understand it.

Mr. LARSEN. And then our price would be less than that.

Mr. RAILSBACK. All right. By how much?

Mr. LARSEN. I will have to develop some statistics for you and I will supply that for the record.

Mr. RAILSBACK. In other words, both the chairman and I were under the impression that at one point you were saying it was a 4-to-1 ratio.

Mr. LARSEN. That's a share of the market.

Mr. HADDAD. Let me clarify this.

Mr. RAILSBACK. I think I have you all fouled up.

Mr. HADDAD. No, Mr. Railsback, you asked a very pertinent question and I will answer it with fact, even though my friends in the PMA may laugh. Under subpena I embarrassed several witnesses but the record of which I will provide if I can get their permission.

First, I refer to page 6 of your report, that of the drugs having generic competition, about 80 to 85 percent are sold by research-intensive companies.

Mr. RAILSBACK. I thought the point made by Mr. Larsen was it was 80 percent——

Mr. HADDAD. Eighty to 85 percent, you never know. We visited two plants. These two factories had a contract to make their own generics under their own respected names. They also made branded generics, Mr. Kastenmeier and Mr. Railsback, very reliable, respectable firms belonging to the PMA—some of whom have been mentioned today. They came down the same production line; they had the same inspection procedure; they went through the same FDA clearance; they met good manufacturing practices. One was sold for $1 and one was sold for approximately $4. That is in the record. I will ask New York State to make that record available to you.

Mr. RAILSBACK. Let me interrupt all of you for just a minute, and that is to say I think you have to be careful making a general statement that there is a 4-to-1 difference in the sales price by production-intensive companies as compared to research-intensive of generic products. In other words, that was the statement the chairman thought you made and I thought you made it, but when I asked you for an example, you gave an example giving a branded name——

Mr. HADDAD. It is called branded generics.

Mr. RAILSBACK. No——

Mr. HADDAD. There is a three-tier level. There is the innovator company that spends a lot of time and money to develop drugs that help save lives. They go off patent and become subject to competition. When they become subject to competition, for a while they stick to their trade name because of the peculiar method in which drugs are distributed—and it is spelled out in the OTA report. Doctors write the prescription and consumers pay the price.

When consumers were benefitted by laws on substitution, the States required lower priced generic drugs, they created something

called branded generics, which are lower than their own trade name which they continue to sell and dominate in the market.

Below that is a generic that may be made by a Zenith or a Darby or somebody else. There is a three-tier system.

What the Congress has failed to investigate and what the HHS has failed to investigate is the Red Book pricing. Frequently, under oath, we were told, "We have given you six for five in order to maintain the Red Book price," by a trade name company. I won't get into that; it is too complicated. There is a three-tier system. I will provide you personally with that information for the record, Mr. Railsback, and we will compute what an average difference is, which New York State does, which refuses to use the Red Book price.

Mr. RAILSBACK. Mr. Chairman, I think I have used up my time. I have some more questions, too.

Mr. LARSEN. I would just like to supplement from my experience. One of the difficulties in answering your question forthrightly—and Bill touched on it—having spent time in one of the major companies and having been involved in the programing and systems work on all the myriad levels of sales, is that a concentration might be made to put out a package, "If you buy all these antibiotics the terms are this," or, "the terms are 180 days," and when you begin to examine that it is very difficult to identify each individual company. But we will try to give you by product the originator, other branded products, and generic products in comparison on a standardized basis as best we can.

Mr. RAILSBACK. And when you are talking about other branded products, you are talking about generic drugs being sold by research-intensive companies under another name.

Mr. HADDAD. Yes.

Mr. LARSEN. The Lederle tetracycline. They trade on their respectability. They are good companies.

Mr. RAILSBACK. I understand.

Mr. KASTENMEIER. I would conclude that in providing the committee with the information you may want to allude to reports made from other sources—I don't know if you'd have access to this material. We understand the three-tier system. It would not be difficult to understand that the off-patent brand-named drug of a company would bring more, possibly because of the name of that company or another company which was in fact a research-intensive company, than a similar product or the same product no longer covered by patent by a production-intensive company such as Zenith.

But the relationship among the several types—you mentioned three types—in terms of whether there are ratios that could indeed be produced would be of interest to us.

Mr. HADDAD. The governors today are much more interested in that than the Congress is because the responsibility has shifted to the States.

Mr. KASTENMEIER. Let the chair say that Mr. Haddad has a brief statement. But before we yield to Mr. Haddad for his statement, which we might have called upon him to make at an earlier point, I'd like to yield to the gentleman from Virginia. He is quite patient in waiting for his opportunity.

Mr. BUTLER. Thank you, Mr. Chairman, and I apologize for not coming back as quickly as I had planned. We are solving a lot of major problems today on the Hill. So if my questions have been covered, you can respond in that fashion and I'll go back and read the record.

Just out of curiosity, do generic manufacturers in the United States produce the actual ingredients for their products or do they import them from abroad?

Mr. LARSEN. I would say in a broad way that most of the materials that go into generic drugs are from overseas. There are some notable exceptions where some of the generic companies that are members of this association, and particularly on antibiotic drugs, manufacture the bulk as well as the finished dosage form.

Mr. HADDAD. And the same question would be answered in the same way by the PMA.

Mr. BUTLER. You mean they would be able to tell us what the generic manufacturers do?

[Laughter.]

Mr. HADDAD. They would tell you what their members do.

Mr. LARSEN. I think you'd find the product and processes are patented here in this country. And probably, as was stated to you yesterday, countries outside the United States begin to develop and produce the product. Therefore, as a generic company, whether you are a PMA company—and I can say this because generic product development was part of my responsibility in a major company as well as now in this company—you have to turn outside the country to get your initial material. And generally speaking, by the time that you are ready to bring the product to market, there is no source within the States other than the innovator who developed the product, so therefore you continue to reach out, PMA company or production generic company, to sources outside the United States.

I do know that as of today a company is being formed that intends to begin to produce chemicals within this country taking advantage of some of that know-how as the process patents expire. Hopefully they will be competitive and keep it on shore as opposed to off shore.

Mr. BUTLER. Opponents of the patent restoration point to savings to consumers from breakthrough drugs, and they mention several of them—timoptic, I think, was one we talked about yesterday where cost savings are estimated at $612 million a year.

Now, how do the actual savings from generics compare to these costs and savings?

Mr. LARSEN. Well, I think we have an exhibit that may partially answer that question and I think for greater detail—because your question relates somewhat to Mr. Railsback's bill, do you want to speak to that?

Mr. HADDAD. I'd like to supply that for the record because I don't recognize the drug, but if I understood the question yesterday, it was that when librium goes off the market and valium comes on the market, the effectiveness of valium greatly exceeds the effectiveness of librium and therefore the patient in the long run saves money. I don't know if that is the question you are asking me, Mr. Butler.

Mr. BUTLER. Not exactly. I guess what I really want to identify is savings from your presence in the manufacturing world.

Mr. HADDAD. When a drug goes off patent there are tremendous savings. The trade name company, because of its great expenditures and justifiable expenditures on detailing and advertising and the control of the drug magazines, continues to sell at a high price. We sell at a lower price. When generic companies become competitive, the price drops only after patent life is legally ended and competition is permitted.

Mr. BUTLER. All right. Well, now, this is a little bit off it and I know you have gone into price while I wasn't here, and I will try not to trespass on the same ground, but basically what you are saying is the generics are selling—the same product——

Mr. HADDAD. Identical.

Mr. BUTLER. Sir?

Mr. HADDAD. Identical.

Mr. BUTLER. Identical?

Mr. HADDAD. Identical.

Mr. BUTLER [continuing]. The identical product at anywhere from one-fourth to 100 percent of the price that the originators are——

Mr. HADDAD. Yes.

Mr. BUTLER. If that is true, why haven't you captured a larger part of the market?

Mr. HADDAD. Because for 17 years—let me tell you what happened. I have a 14-month-old daughter. She was taken to the emergency ward the other night.

Mr. BUTLER. Well, I hope she's all right, but really it is taking so much time.

Mr. HADDAD. She's all right, thank God. I will do it quickly because I am sure you are the sort who will understand quickly. She was given an antibiotic which cost $35. We could have bought it generically for $5. We paid $35 for it because it was written on a prescription where it's called—it's called the Haddad law in New York. At the bottom of the prescription, if you sign it on the right, they can substitute a generic from a list approved by the FDA. If you sign on the left you must pay the higher price.

And the generic companies, despite what they told you yesterday—and please excuse me abusing your patience—they put out ads like this because in many cases the doctor has to put "DAW," dispense as written. I had to pay $35 instead of $5 and I paid it because I thought my daughter's life was in danger. And there is no difference, because every single batch in the United States, Mr. Kastenmeier, is tested.

If that answers your question, you can understand why I'm an angry young man—or old man.

Mr. LARSEN. Stanford Research ran a study and they say when the first production-intensive commodity product comes into the market you can expect that product to be roughly 20 percent down. We know that as a second one comes in there is great erosion. And this kind of relationship exists. We will try and gain feedback from the Stanford study that can give you this comparison.

Mr. HADDAD. Your own study says between 47 and 74, which is too big a spread. They quote an FDA study which says it is between 47 and 74, which is too big a spread.

Mr. LARSEN. Just on the product I cited, and just the Government business alone on that product, were there to be the introduction of generic competition, I bet you the Government would save 40 percent of what they are spending now.

Mr. KASTENMEIER. Would the gentleman from Virginia yield?

Mr. BUTLER. Certainly.

Mr. KASTENMEIER. I want to make sure I understand his question. I thought the gentleman from Virginia was asking a question comparing the savings in dollars that the pharmaceutical industry, the innovators, testified to in general terms as compared to hospitalization and other things which would eventuate——

Mr. RAILSBACK. Surgery.

Mr. KASTENMEIER. In some cases surgery—if the drug had not been developed by them—asking you to compare that savings, which is maybe oranges and apples, with the savings that you are suggesting, compared to what it would have cost the average person for a drug off patent.

Mr. HADDAD. The Congress intelligently protected the innovator in America with the patent law, that if you discover something you need to recapture your cost and an enormous profit because you have a 9-to-1 failure. And they do that. The company that came before you yesterday is the most research-intensive firm in America. They made a half-million dollars profit last year because of their ability. And they have stopped. Tagamet is an example. A friend of mine couldn't live and work because he didn't have Tagamet. I think it's Lederle or SKF. But they will make their profit back. They are protected by patent law.

All we are asking you to do is to find out whether the patent law has been cut in half by the Kefauver amendment of 1962. That is all we are asking you to do, nothing more.

Mr. BUTLER. Mr. Chairman, you correctly interpreted my question.

Mr. LARSEN. I don't think that question can be answered directly because you're talking about a whole new chemical entity or compounds that treat a new entity of disease or does it better, and certainly and obviously we support the concept that a person needs to be rewarded for this.

The question of whether or not all the added provisions within the bill are necessary. My own personal view is: Let's put a cap on the thing. Let's fix a cap and state, "OK, this is the guaranteed period of protection, and that guaranteed period of protection begins with the point you submit the NDA, and the date begins from that point." And I suggest it begin at that point because then it puts an onus on two parties that are involved. It puts an onus on the person making the submission that it is complete at the time because they will have made a substantial investment before that date and there will be no reason then for them to want to see it delayed or otherwise. And it puts a compulsion therefore to make sure it is complete.

Many times applications go to the FDA, whether they be a generic company or a major company, and a request comes back, "Please supply more information"—we can get into the merits of that—"Please supply more information," but that is reality.

And I think the other thing is that the FDA should be held accountable. And if there is an extension of the period of time and a review process to see how effectively the FDA is doing the job, they cannot—if they are going to be held accountable for operating within a span of time, we accomplish two elements. We make sure the drug is going to be presented in its most perfect form for a review, and we are saying, "FDA, you are accountable for time."

And I think part of the problem we need to address ourselves to is the responsible management of the FDA as a function in getting the job done. And I think that is what Dr. Hayes has said, and I think that is what Dr. Hayes is getting at.

Mr. BUTLER. I will give it back, Mr. Chairman.

Mr. KASTENMEIER. Mr. Haddad has a brief statement to make.

Mr. HADDAD. I will shorten it the best I can. We don't get an audience very often. I'd like to read from your own report, page 12, Mr. Railsback. It starts:

> In reading this OTA report, the reader is cautioned to remember that the patent system is only one of the many mechanisms available to the Government for promoting innovation. Innovation could be encouraged by changes in tax policy, increases in funding of R. & D., changes in the Food and Drug Administration approval procedures, and changes in the general economic climate.

The third witness here today, Mr. Schein, was going to address himself to that, but he wanted to point out the recent Reagan administration has given a 25-percent investment tax credit for research, and that research extends to staff as well as expenditures. So they have a 25-percent investment tax credit under the new law which was not calculated at the time of your bill.

Briefly, I want to make these brief points and then I'll skip through my testimony as quick as I can.

PMA's pious observations about competition are fictitious illusions. That campaign continues. It says generics are not as safe as trade names. That (indicating) is an unspecified ad that appears in trade journals.

Second, the two studies on which this legislation is based are built on termite-ridden foundations. One I have already explained.

Third, this legislation is a king pin of a well-organized, well-orchestrated, and a continued successful effort to finally eliminate the entrepreneur from the generic business under the mistaken notion that the President was elected to eliminate small business.

Ironically, President Reagan is our best supporter, our champion. His California program was among the best in the nation. Along with him are the Republican Governors of Michigan, and I don't know if he is a Republican or Democrat in Illinois, Senator Long and Senator Laxalt.

And then I'll read you my statement quickly because I think it's the heart of the matter, Mr. Railsback.

I am a member of the board of directors of the Generic Pharmaceutical Industry Association. I began my interest in the high cost of prescription medicine with the late Senator Estes Kefauver, and in the long years between then and now I have worked closely with Senators Long, Nelson, and Kennedy. As a director of a legislative committee in New York, as I explained, I conducted an intensive investigation of pricing practices of the pharmaceutical industry. A series of stories I wrote for the New York Herald Tribune contrib-

uted to an out-of-court settlement of $200 million—$200 million—of a cartel complaint on tetracycline, then the most widely sold and used antibiotic in the world. American companies had conspired with foreign counterparts to prohibit the sale of generic tetracycline. And I have also been an Inspector General to halt cheating in companies, and also Inspector General of the Peace Corps.

I relate this history today because the clock seems to have reversed itself and turned back to the first days when we began this difficult battle against the giants of the pharmaceutical industry who remain resistant to the efforts of the Congress and various administrations and the public to control their inclination to confuse the public about the facts of our profession. I have just witnessed the entire Senate of the United States bamboozled by an argument that cannot stand the light of day. These are not easy words for a businessman who has worked for the Senate to relate in public hearing, but they are the truth.

My close and long friends in the U.S. Senate—and here in the House—have told me that logic was against my point of view that, in fact, patent life had been reduced from 17 to 9½ years by bureaucratic ineptitude, and it should be restored to inspire expenditures on research. I agreed. But then when I asked them for the source of their information, I was presented with a four-page synopsis of an unpublished report from an institute which, to use the kindest words possible, has long been identified as a spokesperson for the major pharmaceutical firms, a fact we uncovered when they argued in New York State that generics approved by the FDA were not as safe, effective, or efficient as those same drugs produced by the trade name manufacturers.

You have, on page 30 of your report, a footnote of a synopsis of an unpublished study which goes to the heart of the study.

Mr. KASTENMEIER. When you say "your report"——

Mr. HADDAD. I beg your pardon. I understood you ordered the OTA report.

Mr. KASTENMEIER. You are talking about the OTA report?

Mr. HADDAD. Yes. It is a footnote on the bottom of page 30 and it explains the information they used came from an unpublished study.

In the last months we have unsuccessfully sought for an independent resolution of this admitted conflict between their view and ours.

The argument of the other side goes this way: The Kefauver-Harris amendments of 1962—adopted after the thalidomide crisis—required drug companies to prove that their products were not only safe but effective. The majors contend that this process has cost them half their patent life and reduced their ability to spend moneys on research.

I am submitting for the record an article from the New York Times entitled, "The Drug Business Sees a Golden Era Ahead."

THE NEW YORK TIMES, SUNDAY, MAY 17, 1981

The Drug Business Sees A Golden Era Ahead

Hit on a Tagamet, and the money rolls in. New funds are pouring into research. Do science and Reagan spell an end to 'drug lag'?

BY THOMAS C. HAYES

THE Warner-Lambert Company, a major pharmaceutical concern, earned a respectable 13.3 percent on shareholder investment last year, just a shade below the national average for manufacturers of all stripes. But in the exceptionally profitable pharmaceutical industry, it was an also-ran.

Warner-Lambert and its fellow also-rans now have a chance to recoup. With the expectation of increasing demand for a host of new drugs for an aging population, with early signals that the Reagan Administration will relax regulatory requirements, and with such dramatic advances as interferon research in the biological sciences, the drug industry may be on the brink of even greater profitability.

"These factors will make the 1980's a golden age of drug research," Ronald M. Nordmann, senior drug analyst at Oppenheimer & Company, said. "You will see more interesting new drugs in the 1980's than any decade within memory."

This is the industry of the Big Breakthrough, where the introduction of one successful product can literally make a faltering company whole or pay for an expensive research program many times over. No one knows this better than the SmithKline Corporation, whose stock has multiplied eightfold since 1975, the year before its ulcer remedy, Tagamet, was introduced. Profits from Tagamet, which last year passed Valium as the world's largest-selling prescribed drug, have helped catapult SmithKline into the big-spending race to create new cures.

The drug manufacturers, in addition to seeking speedier Government testing, are already lobbying for extension of drug patents to hold on longer to exclusive rights on best-selling drugs. And virtually all of them are planning higher outlays for research.

In the 70's, companies like Warner-Lambert suffered by comparison because they were slow to commit funds to aggressive research. "We have not had the most productive history in developing new compounds," Donald E. O'Neill, president of Warner's Parke-Davis pharmaceutical division, acknowledged in an interview.

This year, though, reflecting an outlook that has become close to gospel across the pharmaceutical business, Warner allocated about $80 million of its overall $120 million research budget to Parke-Davis. The 20 percent increase is typical of big and small companies alike. Warner, meanwhile, is hoping to strike it rich with Lopid, a hypertension drug awaiting approval from the Food and Drug Administration. A success with Lopid would bring in large amounts of cash that could further support research.

Best-selling drugs like Tagamet can tally $5 billion in sales in 10 years on an investment of roughly $40 million. Such discoveries can transform a dull, frustrated company into the envy of its peers.

"The name of the game continues to be getting the big product to come along and have an important effect on sales and earnings," Neil P. Sweig, health care analyst with Shearson Loeb Rhoades Inc., said.

Companies are using advances in molecular biology and computer science to concentrate their research on drugs that have a wide potential application. Before, research was more of a hit-or-miss screening of unproven compounds. Today, the biggest efforts are being mounted for drugs to treat heart disease, hypertension or high blood pressure, arthritis and the varieties of aches and pains associated with advancing age.

Restrictions by the F.D.A. have continually narrowed the number of new drugs approved each year. Under the Reagan Administration, a general move toward deregulation is expected. No one, however, is predicting a return to the days before 1963 when drug manufacturers had only to establish that a new drug was safe before it was approved for general use by physicians. Since then, manufacturers have also had to prove that their new drugs actually worked. From a high-water mark of 65 new drug introductions in 1959, the figure dropped to 12 last year. Top researchers in the major drug companies, like Merck & Company, Pfizer Inc. and Eli Lilly & Company, and industry analysts are reluctant to say how much they expect the so-called drug lag to abate. Most believe it will.

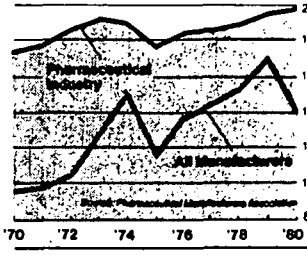
"People have seen the importance of new products and their specific, positive effect on human health," said Dr. P.

Continued

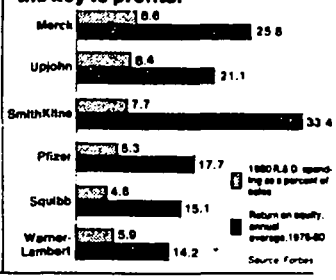
A Prescription for Profit

Profitability has consistently been good.

Return on equity, in percent



Research is considered the key to profits.



The Top Sellers

Ranked by 1980 sales in the United States

Drug	Manufacturer	Disease or Function	Introduced	Sales (Millions)
Tagamet	SmithKline	Peptic ulcers	1977	$250
Valium	Hoffmann-LaRoche	Muscle relaxant, tranquilizer	1966	$230
Inderal	Am. Home Products	Heart disease, hypertension	1967	$200
Motrin	Upjohn	Arthritis	1974	$150
Aldomet	Merck	Hypertension	1963	$150
Dyazide	SmithKline	Hypertension	1965	$145
Keflex	Eli Lilly	Oral antibiotic	1971	$140
Clinoril	Merck	Arthritis	1978	$125

Source: Oppenheimer & Company

Roy Vagelos, a physician who heads Merck & Company's research arm, Merck Sharp & Dohme Research Laboratories. "It's also fair to say there will be a significant increase in new drugs because of what has happened in science," he added.

THE drug companies were once tight-lipped about the secret compounds still submerged in a battery of animal and patient tests mandated by the F.D.A. Today, by contrast, they are more eager to discuss the potential of the drugs. The bidding on Wall Street for pharmaceutical shares is closely tied to the promise of drugs in the pipeline.

"Stocks move on the basis of significant new products," John P. Curran, a specialist in pharmaceutical economics at Wood Gundy, said. "A stock will explode on news of big prescriptions after a new drug is introduced."

Merck created a stir on April 1 when it announced that a new drug, Timolol, reduced deaths among 188 patients who had suffered recent heart attacks by 39 percent. The company's shares jumped 4¾, to 68¾, that day, and subsequently reached 86⅝, closing Friday at 83, up 2⅜.

Another Merck offering, Heptavax-B, "has the potential to eradicate hepatitis B virus infections, which is uncurable and untreatable, much like measles has been eradicated," Dr. Vagelos said. Both drugs have completed pre-market tests. Merck hopes to manufacture them for sale next year if the F.D.A. approves the drugs.

Merck, with headquarters in Rahway, N.J., is spending $280 million on research this year, the most of any American pharmaceutical manufacturer. It was the most profitable, earning $415.4 million, with a hefty 13.3 percent profit margin and 22.3 percent return on equity.

"Merck has always been the premiere research house in the United States," Mr. Nordmann of Oppenheimer said. "But it went through a very dry period, from 1968 to 1975. It now appears they are back on stream with an overabundance of new products that are about to be introduced."

Although Merck might have appeared dormant, it did not cut back on research, according to Dr. Vagelos. "Many of the drugs that are breaking the surface now were in the pipeline during that time," he said.

It's true that a company never knows when research will be successful. "But, as these biological processes are elucidated better and better," said Martha H. Fameci of Arthur D. Little Inc., a consulting concern, "it will allow companies to be more technologically and philosophically sophisticated."

The first signs are already apparent, research executives say. "The main impact of the new biology is making itself felt now at earlier stages of investigation for new compounds," Dr. Barry M. Bloom, head of research at Pfizer, said.

As an illustration, Dr. Bloom said Pfizer researchers were able to use gene-splicing methods to quickly identify a drug that appears to sharply reduce deterioration of the nervous sytem suffered by people with severe cases of diabetes.

It took Pfizer three years to identify the compound and another two years for preliminary tests in humans. "I wouldn't want to guess how long it would have taken by random, nonrational searching," Dr. Bloom said. The drug, Sorbinil, was patented in December 1978. Pfizer must complete another study of the drug's effect on dozens of patients before it can apply for F.D.A. approval.

At the end of 1980, it took a drug manufacturer an average of 33 months to obtain approval from the F.D.A. to begin selling a new drug. Pfizer, for instance, has been waiting since March 1978, for approval of Feldene, a once-a-day treatment for arthritis. The drug has been a success in several European countries. Analysts who follow Pfizer expect that Feldene's worldwide sales could eventually top $200 million a year after it is approved in this country.

THE F.D.A. is a unit of the Department of Health and Human Services. It has come under fire from drug manufacturers, who contend that the agency too often drags its feet before completing its review of a new drug application. But the long and expensive path to marketing a drug cuts both ways. Companies with F.D.A. approval to sell a drug have a strong edge over competitors seeking to sell a copy or a slight variation of their innovative drug.

Critics of the pharmaceutical research companies say that keeps drug prices artificially high and unjustly inflates profits. In response to those pressures, the Reagan Administration last month opened the door for the F.D.A. to allow so-called "me-too" manufacturers to cite published tests of the pioneering research companies in compiling their applications, rather than being forced to replicate the costly experiments on their own.

Still, Richard S. Schweiker, the new Secretary of Health and Human Services, is expected to trim the so-called drug lag at the F.D.A. The new head of the F.D.A., Dr. Arthur Hull Hayes Jr., a physician from Pennsylvania, was chosen by Mr. Schweiker. Members of the Reagan Administration are well-acquainted with the drug manufacturers' laments. Mr. Schweiker was an active author of legislation to ease drug regulations when he was a Republican Senator from Pennsylvania.

"The appointment of Schweiker is a big plus for the drug industry," Mr. Nordmann of Oppenheimer, said. "His goal is to eradicate the drug lag. It will cut down on the time and expense of getting a new drug on the market."

Vice President Bush was a director of Eli Lilly from 1977 to 1979. And Donald H. Rumsfeld, Secretary of Defense in the Ford Administration, is now president and chief executive of the G.D. Searle Company. The F.D.A. has blocked Searle's introduction of a putatively profitable, noncaloric sweetener called Aspartame, since 1974, requiring more tests on possible harmful side effects.

In addition to more expeditious drug reviews, drug manufacturers are seeking extension of patent laws that would guarantee them certain years of exclusive manufacturing and marketing rights for the drugs they develop in their laboratories.

According to the Pharmaceutical Manufacturers Association, the 12 drugs approved in 1980 averaged 10 years in research and F.D.A. review before they could be sold. That left seven years of exclusive sales rights. After that, competing manufacturers will be free to study the research and sell copies of the original drug.

Dr. Sidney Wolfe, a physician who heads the health care unit of Public Citizen, a consumerist lobbying group in Washington, contends that Americans have paid too high a price for prescription drugs. The United States is one of the few countries in which the government does not control the price of drugs.

"It's an industry that is rolling in money," Dr. Wolfe said. He also attacked efforts by pharmaceutical companies to convince Congress to extend drug patents. The manufacturers argue that they are increasingly less able to recoup their research costs, because of the dwindling patent life.

"It's outrageous," Dr. Wolfe countered. "The best-selling drugs have hit as much as $5 billion in sales before the patents come off. Their research is not terribly creative anyway. Most drugs are copies of what is already available. They offer little therapeutic advantage."

In brief, the debate is over how much profit is enough for drug manufacturers, given the risks they assume. They do not publish profit markups on the drugs they sell. But Dr. Wolfe contends that it is not unusual for pioneering drugs to sell at wholesale for seven times the price of generic copies.

"That should give you an idea of the fraction of the wholesale price that is represented by actual cost, including research and development," he said. Drug executives argue that the threat of lawsuits hangs

over each of their products, despite what could be an experience of thousands of prescriptions without damaging side effects.

The Pharmaceutical Manufacturers Association, adding the average expense of research gone awry on laboratory failures, puts the average cost of marketing new drugs at $70 million. The risks of unforeseen side effects and related vulnerabilities to law suits add to a drug company's expenses. Last year, for instance, SmithKline pulled a new antihypertension drug from the market after reports of liver disorders and some deaths. It has been hit by 30 law suits. The drug, Selacryn, was licensed from a French manufacturer.

Despite such vagaries, pharmaceutical companies earned the fourth-highest return on equity in American industry last year, at 20.5 percent, ranking behind the oil services industry, energy companies and the tobacco industry.

Breakthrough drugs contribute most of the profits. Four out of five drugs available never cross the threshold of sales of $20 million a year, according to the Arthur D. Little firm. In some cases, the huge investments and long seed time necessary to execute a successful research program have caused some companies to back away from drugs, according to Richard L. Hughes, a health-care specialist with Little.

"One group says that even if you bring out a wonder drug in 10 years, it may not equal what you could get by simply investing in the money market at 15 percent and waiting 10 years," he said. "Risk and return has become a very important factor."

In the main, however, drug company executives are going with the scientists, putting more money into research today with the hope that more new drugs and bigger profits will blossom at some distant tomorrow.

"All it takes is one hit every three to five years, and you can sustain all the risk," Mr. Sweig, the Shearson analyst, said. ■

NO. 2: VALIUM

Valium is no longer the runaway leader among prescription drugs, but the tranquilizer and muscle-relaxant still is among the world's most widely dispensed druggist potions.

Valium rang up about $350 million in sales around the world last year for its creator, Hoffman-La Roche Inc. That trailed the $625 million for Tagamet, the five-year-old ulcer treatment from the SmithKline Corporation.

From a peak of more than 60 million in 1976, Valium prescriptions dipped below 33 million last year. Physicians have been disturbed by patient abuse of the drug, especially when combined with alcohol. Some heavy users also have suffered addiction. The company maintains that Valium's safety under proper dosage has never been in dispute.

A further dip in sales is expected after 1985, when Valium's patent expires. "Valium is being looked at enviously by a number of people," Irwin Lerner, president and chief executive of Hoffman-LaRoche, said in an interview at the company's American headquarters, in Nutley, N.J. The company, which posted $2.5 billion in worldwide sales last year, is based in Basel, Switzerland.

Still, Hoffman-LaRoche has had a huge and steady stream of profits from Valium since its introduction in 1963. It helped bankroll the company's strong position among the small army of companies searching for new drugs, including a cancer cure from an interferon compound. Roche poured $350 million into research last year, the most of any drug company in the world.

"The profits from Valium are footing the bill for our work in interferon," Mr. Lerner said. "We think we have more exciting leads than at any other time in our history."

Some Big Bets Coming to Market

Product	Company	Purpose	Potential Market* (Millions)
Timolol	Merck	Reduces risk of second heart attack	$500 to $1,000
Auranofin	SmithKline	Oral dosage of gold for rheumatoid arthritis	$250
Feldene	Pfizer	Treatment of arthritis	$200
Human insulin	Eli Lilly	Treatment of diabetes; first big product from genetic engineering	$200
Capoten	Squibb	Treatment of hypertension	$200
Inocor	Sterling	Expected to replace digitalis in treating congestive heart failure	$200

* Potential annual sales, worldwide, at peak of use. Source: Shearson Loeb Rhoades Inc.

Mr. HADDAD. The other is a financial report from Wall Street which I will identify for you in a moment. It is from a major Wall Street house.

[Mr. Haddad's complete document and statement follows:]

Statement by William F. Haddad
Board Member
Generic Pharmaceutical Industry Association
October 1, 1981
Patent Extension Legislation

Gentlemen.

My name is William F. Haddad. I am a Member of the Board of Directors of the Generic Pharmaceutical Industry Association. I began my interest in the high cost of prescription medicine with the late Senator Estes Kefauver and in the long years between then and now I have worked closely with Senators Long, Nelson and Kennedy. As Director of a legislative committee in New York, I conducted an intensive investigation of pricing practices of the pharmaceutical industry. A series of stories I wrote for the New York Herald Tribune contributed to an out-of-court settlement of a cartel complaint on tetracycline, then the most widely sold and used anti-biotic in the world. American companies had conspired with foreign counterparts to prohibit the sale of generic tetrocycline.

I relate this history today because the clock seems to have reversed itself and turned back to the first days when we began this difficult battle against the giants of the pharmaceutical industry who remain resistent to the efforts of the Congress and various Administrations and the public to control their inclination to confuse the public about the facts of our profession. I have just witnessed the entire Senate of the United States bamboozeled by an argument that can not stand the light of day. These are not easy words for a businessman who has worked for the Senate to relate in public, but they are the truth. My close and long friends in the U.S. Senate --- and here in the House ---

Haddad --- two

have told me that logic was against my point of view that, if in fact, patent life had been reduced from 17 to nine and a half years by bureaucratic ineptitude, it should be restored to inspire expenditures on research. I agreed. But then when I asked them for the source of their information, I was presented with a four page synopsis of an unpublished report from an institute which, to use the kindest words possible, has long been identified as a spokesperson for the major pharmaceutical firms, a fact we uncovered when they argued in New York State that generics approved by the FDA were not as safe, effective or efficient as those same drugs produced by the trade name manufacturers.

In the last months we have unsuccessful sought for an independent resolution of this conflict between their view and ours.

The argument of the other side goes this way: The Kefauver-Harris amendments of 1962 --- adopted after the thalidimide crisis --- required drug companies to prove that their products were not only safe, but effective. The majors contend that this process has cost them half their patent life.

We argued that if this was correct, it should be restored. But we said the Congress must first establish what was the average patent life in 1962 (somewhat less than 17 years according to the OTA report before you) and to establish what legal patent life was today . This is easily computed, when you have access to the data, by determining what the legal life was of the major drugs now on the market. When

Haddad --- three

you have that information, you know precisely the answer to the question before the House: has patent life been reduced by the Kefauver-Harris amendments, and, if so, by what amount of time.

By a happenstance, GPIA was able to obtain data on the principle drugs now on the market and we determined that the average patent life of the major drugs was over 18 years. Over 18 years. Not the nine and a half years that my friends in Congress have repeated to me.

Gentlemen, the crux of the question is simply this: are we correct or is the PMA accurate? And how do you arrive at the answer? By a theoretic study on hypothesis, or the actual marketplace figures? If we could assemble the data, we would have presented a larger list than the one before you today. We do not have access that data. You do. OTA does. GAO does. FDA does. HHS does. But not GPIA. Nor PMA.

How is it possible then, to have patents over 17 years? Here you have opened the pandora's box, one on which the industry has sat for years. You can pyramid patents and keep competition off the market for up to 30 years. It has been done. It is being done. That's what this Congress --- in my humble opinion --- should investigate.

I know that good friends --- honest men --- capable representatives of the consumer --- men and women who want to cut taxes and reduce bureaucracy --- have signed on this legislation in the honest belief that patent life has been cut in half. It has not, gentlemen, it has not.

Haddad --- four

There are patent loopholes just as there are tax loopholes for the experienced to use. They have been consistenly used to keep generics off the market.

OTA said that 15 to 19 multinational companies --- already among the most profitable in the world --- consistently the most profitable in the world --- will benefit from this legislation. They have advised you that there is no way to assure that the new profits will go into research. And they state that the so-called drug lag has leveled off and the FDA has told you that for significant breakthroughs, there is no significant time lost. The GAO has indicated that it takes less than two years of bureaucratic approval time once the evidence is presented. And President Reagan and HHS has promised to reduce that time --- which, incidently, is precisely what it takes for us to have a generic win FDA approval.

The legislation before you is loosely drafted. We were told in the Senate that it was not before a subcommittee and that the committee itself would correct the legislative defects. We were told that the full committee would not act until after the OTA finalized its inquiry. And then we were told it would be debated on the floor of the Congress. None of that happened. Now we are told that the House will rectify the defects we cited in the legislation. How do you determine, for example, who is to blame for the delay between the IND and the NDA? What if a company does not submit a complete report and it is sent back for perfection? Under this law, all that time is restored, up to seven years.

Haddad --- five

On the other side of the ledger, we are told by OTA that it will be the consumer, the elderly, the poor and the government who will pay the price of the longer periods of patent life. And they will have no guarantee that the longer periods of profit will result in increased research.

And then we are confronted by the Wall Street stories which speak of great drug breakthroughs in the months and years ahead. They predict that the industry is at the door of a new golden age, a story far different than you hear in the Congress when the wealthiest companies in the world cry poormouth to you and plead for increased revenues. We do not begrudge them their profits, nor do we begrudge them their success, but, in this case, we merely argue that new legislation must be based on proven fact which is available, not academic theory from suspect sources.

I thank you for your time and patience. I would welcome any questions you may have to ask.

# # # # # # #

The Morgan Stanley REPORT

Wall Street report

The Drugs in the Eighties: The Growth Will Be There — Part 1

by James L L Tullis

Investors desire certainty, to the extent it can be defined. Yet seldom in recent history have the capital markets reflected as high a degree of uncertainty as they do today. For example, currently the cost of debt capital is both very high and subject to extreme short-term volatility. Moreover, whereas market participants increasingly anticipate recession and disinflation in 1981, economic activity and interest rates continue to be far higher than general expectations.

In this environment, an industry which offers relatively high predictability and which is intrinsically capable of adjusting to a broad range of potential economic scenarios will attract investors. This is particularly true if the fundamental outlook for the business is improving.

STRONG RELATIVE PROFIT PROSPECTS, IMPROVING FUNDAMENTALS

The drug industry's earnings outlook is excellent, both near and longer term, particularly in relation to expected trends in domestic corporate profits. In the 1981 to 1986 period, we expect net income of both ethical and consumer-sensitive pharmaceutical firms to expand more rapidly than in 1975 to 1980. (However, the pickup will be more pronounced in the ethical segment, which is more sensitive to trends in the prescription drug business.)

Specifically, we estimate profits in the ethical drug sector will rise about 12 percent in 1981, while earnings in the consumer-sensitive category expand 5 percent if Warner Lambert with its large write-offs is included or 10 to 11 percent excluding Warner-Lambert. By contrast, corporate profits are now forecast to rise 3 to 4 percent this year. On an operating basis, the industry's performance should be even more impressive than these earnings projections indicate, because our estimates include the impact of the severe currency-related penalties which all of the heavily multinational drug firms are incurring this year as a result of the dollar's continuing strength. (We think currency factors will reduce drug profits overall by 5 to 10 percent this year.)

In 1982, industry earnings growth should be especially strong. Our preliminary forecasts, as detailed in Table 1, call for profit gains of close to 20 percent in both the ethical and consumer sensitive segments next year. Such increases would outpace the 10 percent advance forecast for profits in general, even in the rapid recovery stage of an economic expansion.

In 1983 to 1986, we anticipate earnings growth in the ethical drug sector will average about 15 to 16 percent per year, which represents a significant premium above the 7 to 8 percent gains projected for corporate profits.

Consumer-sensitive firms should also post net income advances exceeding those of the S&P 400 in that interval, although the expected earnings expansion (12 to 14 per cent per annum) will be less rapid than that in the ethical category.

Based on these projections, drug stocks should retain considerable appeal well into the next economic expansion. In addition, the group's investment attractiveness should be enhanced by a number of other factors:

- The liquidity of the pharmaceutical industry remains very high, with almost all firms retaining substantial cash positions which exceed short-term debt and in most cases total borrowings. As a result, three benefits accrue. (1) high short term interest rates generally help earnings as interest income more than offsets interest expenses (2) dividends can be increased faster than profits expand (as was the case in 1979 and 1980) and (3) companies have funds to repurchase stock in the open market aiding per share earnings comparisons (more than half of the drug firms currently have active stock repurchase programs).
- The drug industry, which has demonstrated its general ability to cope with inflation by raising prices and controlling costs, should also be a significant beneficiary of disinflation. Pharmaceutical firms would begin to feel the impact of diminishing cost increments before the rate of price hikes slowed, thus, margins would improve early on. Importantly, our five year earnings forecasts for the

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Table 1. Healthcare Industry: Current Earnings Estimates

Industry Segment	Price 5/26	Div. Rate Per Share Cur.	12/81	Yield Cur.	12/81	Earnings Per Share 1979A	1980	1981E	1982E	P/E Ratio 1980	1981E	1982E	EPS Next Quarter 1980	1981E	Ending
Hospital Supply															
ABT	56.00	1.44	1.44	2.57	2.57	2.97	3.46	4.05	4.75	16.18	13.83	11.79	0.85	1.00	JUN
AHS	46.00	1.08	1.08	2.35	2.35	2.78	3.03	3.55	4.20	15.18	12.96	10.95	0.76	0.81	JUN
BAX	56.00	0.76	0.76	1.36	1.36	3.02	3.40	3.87	4.63	16.47	14.47	12.10	0.87	0.94	JUN
BDX	47.00	1.00	1.17	2.13	2.49	3.01	3.14	3.55	4.00	14.97	13.24	11.75	0.80	0.88	JUN
MDT	40.00	0.48	0.60	1.20	1.50	2.52	2.80	3.50	4.25	14.29	11.43	9.41	0.80	0.80	APR
Consumer Sensitive															
AHP	34.00	1.80	2.02	5.29	5.94	2.51	2.84	3.20	3.63	11.97	10.63	9.37	0.64	0.71	JUN
BMY	53.00	1.84	1.84	3.47	3.47	3.50	4.08	4.55	5.15	12.99	11.65	10.29	0.97	1.06	JUN
JNJ	106.00	2.30	2.60	2.17	2.45	5.76	6.50	7.35	8.70	16.31	14.42	12.18	1.63	1.86	JUN
MNP	31.00	1.52	1.65	4.90	5.32	3.40	3.52	3.70	4.11	8.81	8.38	7.54	0.56	0.70	JUN
STY	22.00	0.92	1.03	4.18	4.68	1.85	2.04	2.20	2.45	10.78	10.00	8.98	0.42	0.43	JUN
WLA	23.00	1.32	1.35	5.74	5.87	1.55	2.41	0.52	2.50	9.54	44.23	9.20	0.69	0.58	JUN
Ethical Drugs															
LLY	62.00	2.30	2.70	3.71	4.35	4.43	4.52	5.17	6.35	13.72	11.99	9.76	0.98	1.05	JUN
MRK	91.00	2.60	3.00	2.86	3.30	5.06	5.54	6.20	7.40	16.43	14.68	12.30	1.47	1.57	JUN
PFE	48.00	1.60	1.65	3.33	3.44	3.26	3.48	3.70	4.60	13.79	12.97	10.43	0.79	0.79	JUN
SGP	37.00	1.60	1.73	4.32	4.68	4.12	4.45	4.60	5.25	8.31	8.04	7.05	1.20	1.22	JUN
SRL	31.00	0.52	0.52	1.68	1.68	1.68	1.85	2.25	2.65	16.76	13.78	11.70	0.46	0.49	JUN
SKI	83.00	1.92	2.30	2.31	2.77	3.78	4.65	5.70	6.75	17.85	14.56	12.30	1.04	1.27	JUN
SQB	36.00	1.20	1.25	3.33	3.47	2.71	2.65	2.70	2.95	13.58	13.33	12.20	0.50	0.47	JUN
SYN	58.00	1.30	1.60	2.24	2.76	3.77	4.28	5.45	6.35	13.55	10.64	9.13	1.03	1.35	APR
UPJ	63.00	2.00	2.25	3.17	3.57	5.03	5.71	6.25	7.07	11.03	10.08	8.91	1.53	1.60	JUN

E = Morgan Stanley Research Estimate

industry would not be significantly changed if the underlying inflation rate dropped to 6 percent from the 8 to 9 percent level forecast.

• Political and governmental trends, still an important element in the industry's outlook, have become more favorable. Under Reagan Administration directives to reduce federal red tape, the pace of new-drug approvals should accelerate. Also, the probable attempt to cut down the extremely large existing backlog of pending new-chemical entity applications (as shown in Table 2) could result in a significant short-term spurt in the number of products coming to market. In addition, chances have increased that Congress will eventually pass legislation to extend the duration of patent protection for pharmaceuticals, providing long-needed relief for the industry.

• *There is a remarkably full research pipeline. Almost* every major drug firm is now increasing its research and development spending as a percentage of sales, reflecting a high degree of confidence in the prospects for commercial success of products not yet introduced.

• *Although drug stocks have performed well for the* past three years, the shares of almost all pharmaceutical companies are inexpensive by historical standards (Figure 1). Since 1946, the multiple premium accorded to the drug companies relative to the S&P 400 averaged about 70 percent, in a range of 20 to 150 percent (excluding one brief period in the early 1950s when the group commanded no premium and two longer intervals in the late 1940s and early 1970s when the stocks sold at price/earnings ratios more than 200 percent above that of the composite). Currently, drug shares are valued about 33 percent and 24 percent above the multiples of the S&P 400 based on estimated 1981 and 1982 earnings, respectively. At the same time, the ratio of the industry's profit growth rate to that of the composite is near peak levels.

WHY ARE DRUG FIRMS DOING WELL?

The current strong and improving fundamental position of the drug industry is best appreciated in the context of past experience. Between 1945 and 1974, *pharmaceutical company sales and profits grew, on average,* at an annual rate of 10 percent. Earnings gains followed a relatively predictable cycle, expanding as much as 20 percent a year during economic advances and only about 2 percent during economic contractions. From 1975 to 1977, *the industry went through a sustained three-year* period of laggard (less than 10 percent per annum) profit expansion at a time when many other sectors were

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Table 2. New Chemical Entity NDAs Awaiting FDA Approval in the United States

Industry Segment	Estimated New Chemical Entity NDAS Currently Before FDA	R&D Spending 1979	1980	1981E
			($ Millions)	
Consumer Sensitive				
American Home Products	4	$ 90.0	$102.0	$116
Bristol-Myers	4	103.0	128.0	150-155
Johnson & Johnson	3	192.7	232.8	280
Morton-Norwich*	2	19.2	21.8	24
Sterling	0	48.9	58.1	68
Warner-Lambert	1	94.0	103.0	116
Ethical Drugs				
Eli Lilly	3	177.0	200.7	230-235
Merck	5	188.1	233.9	280.0
Pfizer	5	138.0	160.0	190.0
Schering-Plough	4	75.0	90.0	110.0
Searle	2	59.5	71.3	90.0
SmithKline	0	103.0	136.0	170.0
Squibb (Capoten just approved)	0	69.0	77.0	90.0
Syntex*	1	42.0	54.0	66.0
Upjohn	6	129.3	147.3	160.0

*Fiscal 1979, 1980, and 1981, respectively.
Morgan Stanley Research Estimates

registering extremely robust increases. There were several reasons for the relatively disappointing performance of drug firms:

(1) Inflation had accelerated, but pharmaceuticals manufacturers, following a 30-year record of stable pricing policies overall, were loath to increase prices aggressively. At the time, Senator EDWARD KENNEDY was holding regular hearings on industry practices before a liberal, Democratic Congress, presumably hostile to drug company profits.

(2) Unit volume growth was poor (3 to 4 percent a year domestically versus a historical trend of 7 to 8 percent), as only a handful of new products was introduced and as side-effect concerns pared consumption of certain leading products (such as oral contraceptives, tranquilizers, antibiotics, and some analgesics like *Darvon*).

(3) An initial attack on drug prices by many foreign governments hurt foreign earnings just as the sustained three-year strengthening of the United States dollar caused large penalties on the translation of overseas profits into dollars. Drug industry net income still expanded from 1975 to 1977 – but at less compelling rates than in many prior years and less rapidly overall than earnings of the S&P 400.

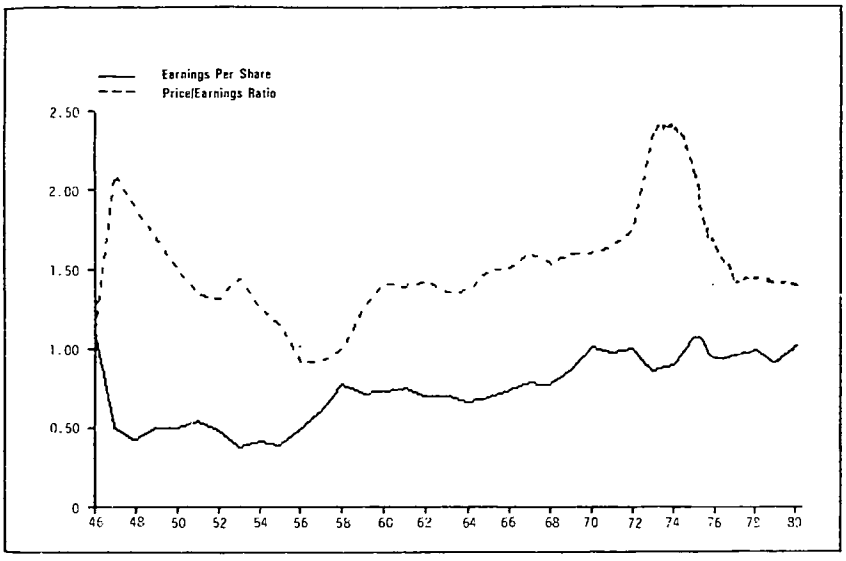
From 1978 to 1980, the industry's vitality improved for several reasons. Drug firms gradually became more willing to increase prices. By 1980, the annual rise in realizations reached 8 to 9 percent, a level since surpassed. Domestically, governmental agencies, which pay for only a very small portion of all drug purchases, and consumers showed no sign of resistance. Senator Kennedy's hearings ended quietly. Unit volume gains were helped (a bit) by new-product introductions. Also, the dollar weakened and currency impacts became positive rather than negative. Foreign governments learned that drugs represent but a small portion of healthcare costs and are economically efficient; thus, officials gradually began to allow price increases. Tight cost controls put into effect in 1976 and 1977 started to exert a favorable impact on margins. Profit momentum improved, with the industry registering double-digit gains of 19 percent, 15 percent, and 11 percent in 1978, 1979, and 1980, respectively. Table 3 shows trends in pretax profits in the 1975 to 1980 period and our estimates for 1981 and 1982.

The gains forecast for this year and next are surprisingly strong, especially when one considers that currency trends will probably have a more adverse impact on profits in 1981 than in any prior year while the economic outlook has weakened, with at least a mild recession now expected in the second half of the current year. In the following sections, we will discuss the assumptions used in developing our earnings model.

DOMESTIC MARKET OUTLOOK 1981–1982

We project that overall prescription dollar volume in the domestic market will expand rapidly (up 15 to 17 percent) in 1981 and as fast (or perhaps a bit faster) in 1982.

Figure 1. Standard & Poor's Drug Index Relative to 400 Industrials



Source: Morgan Stanley Research

The potential for further acceleration in 1982 derives from the possibility that the Food and Drug Administration (FDA) will "unjam" the large backlog of new drugs awaiting domestic marketing approval. The primary element in the strong sales growth forecast for 1981 and 1982 (compared with historical 10 percent per annum trendline increases) is higher drug prices. We estimate realizations will rise at a double-digit (10 to 12 percent) rate in 1981 – faster than in any prior year – and 9 to 10 percent in 1982. Our projections for next year assume a slightly slower pace of price boosts, as the Morgan Stanley economic forecast indicates inflation should moderate by then. However, if inflation remains high, we think the rate of drug price expansion will also stay high.

It is important that investors recognize that drug unit demand is not sensitive to price. In many businesses (e.g., autos, soft drinks, and restaurants), the price increases needed to maintain margins during a period of high inflation eventually lead to reduced consumption. However, demand for prescription drugs is uniquely price insensitive because (1) the cost/benefit equation is extremely favorable; (2) the patient has less to do with the purchase decision than his doctor, who is not paying the bill; and (3) the average patient spends only about $40 to $45 per year on prescription drugs – a remarkably small absolute amount. Reflecting these elements, surveys show that consumers have remarkably little awareness of or concern about drug prices. Also, federal and state government purchases represent a very small (10 percent at most) portion of drug volume, and government (in this country) has no real control over drug pricing.

We forecast unit volume will increase 4 to 5 percent this year, a slightly higher gain than in the past five or six years, but still below the long-term trend. In 1982, we expect unit volume expansion to accelerate to 6 to 7 percent, primarily because of better economic conditions but also because of an increased flow of new products to market. If the FDA can straighten out its approval processes and actually begin to catch up on long overdue approvals, unit volume growth next year might exceed 7 percent. It seems clear that the number of new-drug approvals granted in 1982 will be higher than the 12 of

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Table 3. Healthcare Industry: Pretax Earnings (1975-1982)

($ Millions)

Health Industry Segment	Amount								Year-to-Year % Change						
	1975	1976	1977	1978	1979	1980[a]	1981E	1982E	1976	1977	1978	1979	1980[a]	1981E	1982E
Hospital Supply															
Abbott	102.40	118.00	183.40	233.70	282.60	337.66	391.11	451.27	34.77	32.90	27.43	20.92	19.48	15.83	15.38
Amer. Hosp. Supply	97.70	117.70	134.40	147.90	155.00	187.00	222.00	266.00	20.47	14.19	10.04	4.80	20.65	18.72	19.82
Baxter Travenol	55.60	84.50	108.10	119.10	145.00	164.00	192.00	231.00	51.98	27.93	10.18	21.75	13.10	17.07	20.31
Becton, Dickinson*	62.20	75.90	84.40	91.20	102.00	100.00[c]	110.00	126.00	22.03	11.20	10.43	9.44	−1.96[b]	10.00	14.55
Medtronic**	25.10	23.60	27.80	39.90	53.17	64.80	80.91	102.00	−5.98	17.80	43.53	33.26	21.87	24.86	26.07
Total	343.00	439.70	538.10	631.80	737.77	853.46	996.02	1176.27	28.19	22.38	17.38	16.80	15.68	16.70	18.30
Consumer Sensitive															
Amer. Home Prds.	496.50	544.40	596.40	682.30	751.00	852.00	980.00	1075.00	9.65	9.55	14.40	10.07	13.45	12.68	11.76
Bristol-Myers	257.80	288.70	329.00	375.70	421.00	490.00	546.00	615.00	11.99	13.96	14.19	12.06	16.39	11.43	12.64
Johnson & Johnson	318.80	361.50	432.20	514.20	590.00	675.00	774.00	912.00	13.39	19.56	18.97	14.74	14.41	14.67	17.83
Morton-Norwich***	33.90	7.50	54.60	62.10	76.80	72.96	77.87	87.29	−77.88	628.00	13.74	23.67	−5.00[b]	6.73	12.10
Sterling	145.80	153.50	163.40	183.80	200.00	222.00	235.00	262.00	5.28	6.45	12.48	8.87	11.00	5.86	11.49
Warner Lambert	289.00	296.00	341.00	362.00	231.00	330.00	125.00	364.00	2.42	15.20	6.16	−36.19	42.86	−62.12	191.20
Total	1543.80	1651.60	1916.60	2180.10	2269.80	2641.96	2717.87	3315.29	7.12	16.05	13.75	4.11	16.40	2.87[f]	21.98[f]
Ethical Drugs															
Eli Lilly	301.50	346.10	394.50	482.50	558.00	590.00	670.00	808.00	14.79	13.98	22.31	15.65	5.73[b]	13.56	20.60
Merck	378.30	416.40	453.50	501.90	606.00	655.00	717.00	853.00	10.07	8.91	12.00	19.31	8.09[b]	9.47	19.00
Pfizer	211.90	237.90	263.60	319.80	363.00	409.00	448.00	557.00	12.27	10.80	21.13	13.69	12.67	9.54	24.33
Schering Plough	210.50	234.40	241.60	272.70	307.00	326.00	338.00	388.00	11.35	3.07	12.87	12.58	6.19[b]	3.68	14.79
Searle	93.50	89.60	106.10	121.60	114.00	138.00	167.00	202.00	−4.17	18.42	14.61	10.20	2.99	21.01	20.96
SmithKline	94.20	107.10	134.30	261.30	354.00	446.00	546.00	652.00	13.69	25.40	94.56	35.48	25.99	22.42	19.41
Squibb	134.90	147.40	154.70	150.50	149.00	159.00	171.00	196.00	9.27	4.95	−2.71	−1.00	6.71	7.55	14.62
Syntex	48.90	49.30	46.50	62.90	75.00	89.00	116.00	138.00	0.82	−5.68	35.27	19.24	18.67	30.34	18.97
Upjohn	120.20	128.30	147.60	202.00	204.00	230.00	249.00	291.00	6.74	15.04	36.86	0.99	12.75	8.26	16.86
Total	1593.90	1756.50	1942.40	2380.70	2750.00	3042.00	3422.00	4085.00	10.20	10.58	22.56	15.51	10.62	12.49	19.37
Health Industry Total	3478.70	3847.80	4397.10	5194.60	5757.57	6537.42	7135.89	8576.56	10.61	14.28	18.14	10.84	13.54	9.15	20.19

*Fiscal years ended September 30
**Fiscal years ended April 30
***Fiscal years ended June 30
[a]Results shown are after the effect of change to LIFO accounting by five firms in 1980. Before the effect of these accounting changes, pretax profits and rates of increase of the segments and total industry were: Hospital Supply, $867.76 million, up 17.62%; Consumer Sensitive, $2,653.66 million up 16.93%; Ethical Drugs $3,126.80 million, up 13.3%; and the entire Total $6,648.22 million, up 15.47%.
[b]After the effect of switching to LIFO accounting, which reduced reported 1980 results. Had LIFO accounting been used in both years, pretax earnings growth rates would have been respectively: 10.23% (Morton Norwich), 12.06% (Becton, Dickinson), 11.68% (Eli Lilly), 13.76% (Merck), and 11.79% (Schering Plough).
[c]Warner Lambert is accruing $134.3 million of one-time charges in 1981. Excluding the effect of these write-offs, the Consumer Sensitive segment's rate of increase in pretax earnings would be 13.59% and 16.84% in 1981 and 1982, respectively.
[f] – Morgan Stanley Research Estimates

1980). Most observers consider 15 to 20 per year a realistic target, in view of history and the current backlog on file.

Both new FDA Commissioner HAYES and Secretary of Health and Human Services SCHWEIKER are on record supporting a much faster pace of drug approvals. Congressmen GORE and SCHEUER, noted liberal Democrats, recently sponsored legislation aimed at accelerating the pace of new-drug clearances. Congress is now holding hearings on the proposals (we recently attended one and were impressed by how rapidly the message of the 1980 elections has sunk in). We anticipate that the legislators will actually help, not hinder, SCHWEIKER and HAYES in spurring the FDA bureaucracy into action.

Also, there is a remarkably large backlog of drugs now awaiting approval. As Table 2 shows, the leading United States drug firms now have some 40 completed new-drug applications (NDAs) for completely new chemical entities on file pending Government action (plus many more NDA submissions for combination products, new dosage forms, or additional claims). Foreign drug manufacturers who sell here probably have another 20 to 30, at least. We think it is possible that to clear up this backlog, the FDA will speed up the review of completed NDA submissions. If this occurs, it is conceivable that the number of approvals could spurt to 25 or more in 1982 and 1983, which would stimulate unit volume growth in the United States market.

Table 4. New Chemical Entity NDAs with Very Large Commercial Potential Now Awaiting United States Approval

Company	Drug	Field of Therapy	Why Unique	Estimated U.S. Sales ($ Millions) 1982	1985
Johnson & Johnson	*Ketoconazole*	Fungal Disease	Superior efficacy	$60	$150
Lilly	*Opren*	Arthritis	Once-a-day dosage No G-I side effects May induce remission	50	150
Lilly	*Moxalactam*	Antibiotics	Superior efficacy	60	150
Marion	*Cardizem*	Cardiovascular	Superior efficacy	75	100
Merck	*Blocadren*	Cardiovascular	Same as other beta blockers, but may also be labeled as protective against heart attacks	30	125
Merck	*Moduretic*	Cardiovascular	Comparable efficacy but less toxicity	30	100
Merck	*Ivermectin*	Anthelmintic (animal use only)	Superior efficacy	40	100
Pfizer	*Procardia*	Cardiovascular	Superior efficacy	40	125
Pfizer	*Feldene*	Arthritis	Once-a-day dosage	90	150
Pfizer	*Cefobid*	Antibiotic	Superior efficacy	30	100
Searle	*Verapamil*	Cardiovascular	Superior efficacy	45	125
Upjohn	*Xanax*	Psychopharmaceutical	Possible dual claim for anxiety and depression	25	100

Morgan Stanley Research Estimates

Assessing the NDAs now on file, certain drugs have especially promising prospects. In our opinion, the applications for products with the greatest relative commercial potential and impact on earnings are those of Johnson & Johnson, Eli Lilly, Merck, Pfizer, and Searle. This evaluation is an important factor in our purchase recommendations on the last four issues. As highlighted in **Table 4**, the specific drugs with the most exciting commercial prospects are Pfizer's *Procardia, Feldene*, and *Cefobid*, which together could generate more than $100 million in incremental sales for the company domestically next year (and more overseas); Merck's *Blocadren, Moduretic, Ivermectin*, and *Tocainide*, which have a similar or greater composite potential; Lilly's *Opren* and *Moxalactam*, which are expected to add at least $100 million in sales in the United States (and more overseas); Johnson & Johnson's *Ketoconazole*, a breakthrough improvement in fungal disease treatment with long-term commercial potential in the $100 million or greater range; and Searle's *Verapamil*, which we forecast will be the most heavily used calcium antagonist by 1984 or 1985. The calcium antagonists are the next major wave of cardiovascular treatment agents and, in our opinion, will represent a domestic market of $250 million or more (and worldwide volume of $1 billion) by 1985.

We also expect the domestic volume gains forecast for 1981 and 1982 to be accompanied by margin expansion. Profitability of drug sales in the United States is improving currently (and should continue to do so for the next several quarters) because higher prices are more than offsetting inflationary cost pressures. The gross margin is gradually increasing, and SG&A costs should only rise about 11 to 12 percent this year and next (i.e., less rapidly than revenues). In summary, we forecast domestic pretax profits will grow about 20 percent in 1981 and 21 to 25 percent in 1982. Since the composite (i.e., domestic plus foreign) profit gains projected for the industry are considerably lower (12 percent) in 1981 and somewhat smaller (19 percent) in 1982, it is clear that we anticipate international earnings will expand much more slowly than those from domestic sources and also less rapidly than the historical 15 percent per annum trend.

Part 2 of this report will appear in the September *MMSM*. Included will be discussion of the years 1981 to 1982 – the international market outlook, who will register the strongest gains, which firms could provide profit surprises – along with analysis of the longer-term outlook.

Mr. HADDAD. We argued that if this was correct, it should be restored. But we said the Congress must first establish what was the average patent life in 1962—somewhat less than 17 years according to the OTA report before you—and that quote is on page 17. We urge you to establish what the legal patent life was when competition was prohibited in 1962, and then we ask you to please take the drugs that are now on the market and simply and statistically determine how long they have been on the market without competition. If we are wrong, Mr. Larsen and myself will support the PMA legislation. But you do not have that fact before you and we are not able to gather that fact. What we did show you on major drugs was 18.5 years.

Gentlemen, the crux of the question is simply this: Are we correct or is the PMA accurate? And how do you arrive at the answer? By a theoretic study on hypothesis, or the actual marketplace figures? If we could assemble the data, we would have presented a larger list than the one before you today. We do not have access to that data. You do. OTA can. GAO can. FDA can. HHS can.

How is it possible, then, to have patents over 17 years? Here you have opened the Pandora's Box, one on which the industry has sat for years. They can pyramid patents and keep competition off the market for up to 30 years. It has been done. It is being done.

I know that good friends—honest men—capable representatives of the consumer—men and women who want to cut taxes and reduce bureaucracy—have signed onto this legislation in the honest belief that patent life has been cut in half. And, Mr. Chairman, when I knocked on the doors of a number of Congressmen they said it can't be bad legislation if you put your name to it.

Mr. RAILSBACK. Really?

Mr. HADDAD. Really.

Mr. KASTENMEIER. That wasn't my good friend Railsback.

Mr. HADDAD. No, these were liberal Democrats.

It has not, gentlemen, it has not. There are patent loopholes just as there are tax loopholes for the experienced to use. They have been consistently used to keep generics off the market.

OTA said that 15 to 19 multinational companies—already among the most profitable in the world—consistently the most profitable in the world—will benefit from this legislation. They have advised you that there is no way to assure that the new profits will go into research. And they state that the so-called drug lag has leveled off and the FDA has told you that for significant breakthroughs there is no significant time lost—that for significant breakthroughs, there is no significant time lost.

The GAO has indicated that it takes less than 2 years of bureaucratic approval time once the evidence is presented. And President Reagan and HHS has promised to reduce that time—we urge that process—and Vice President Bush and his committee tried to do that.

The legislation before you is loosely drafted. It was, I must say in open hearing, drafted by the PMA. We were told in the Senate that it was not before a subcommittee and that the committee itself would correct the legislative defects. We were told that the full committee would not act until after the OTA finalized its inquiry.

Two days before your report was published and after a draft was widely submitted, Senator Weicker's fillibuster was interrupted, and this was passed by voice vote. We want you to determine if you can who is to blame for the delay between the IND period when the testing is done and the NDA period.

And you asked this question yesterday: What if a company does not submit a complete report and it's sent back for perfection? Under the law, all that time is restored, up to 7 years. If my company were expending research funds and a patent was filed and it did not conflict legally with what I was doing, I'd have cut off research and go on to more profitable business, thus limiting, not expanding, competition. That is a hard, cold fact of business life. The reason we can survive in a competitive society is because we watch the bottom line.

On the other side of the ledger, we are told by OTA that it will be the consumer, the elderly, the poor, and the government who will pay the price of the longer periods of patent life. And they will have no guarantee that the longer periods of profit will result in increased research.

And then we are confronted by the Wall Street stories which speak of great drug breakthroughs in the months and years ahead. They predict that the industry is at the door of a new golden age—and it is—a story far different than you hear in the Congress when the wealthiest companies in the world cry poormouth to you and plead for Chrysler-like subsidies.

Again, thank you for your patience.

Mr. KASTENMEIER. I might say to you, Mr. Haddad, about the legislation before us, lest there be any misconception about it, I made it quite clear that I introduced this at the request of the industry, not as a personal statement by me nor as drafted by me. I had no part in drafting the legislation before us, H.R. 1937. I agreed to introduce it because last year we had a patent bill concerning the issue of patent restoration. The bill was already quite complex and I think only part of it was realized in terms of being passed. Those who were seeking patent restoration were agreeable that the issue be deferred until this Congress at my request. In consideration of that I agreed in good faith to entertain the subject fully at this session of Congress, and even to that end to introduce the bill to assure anybody who might be otherwise concerned that the matter would be considered.

Mr. HADDAD. Can I quote you, please?

Mr. KASTENMEIER. It is a matter of public record, Mr. Haddad. It is ridiculous to ask me if it can be quoted.

Mr. HADDAD. I have run into that difficulty because of the nature of your interest in this subject in the past, and it has proved very difficult for me to make any inroads.

Mr. KASTENMEIER. I have only one question I wanted to ask Mr. Larsen, and I'm afraid it is not an easy question. But much of the testimony tends to devolve upon the questions of what are the practical terms of coverage. Because in your statement and the reference to use patents and process patents and other types of development to try to pyramid the term, the effective term of coverage, there appears to be a question. And you have noted that a number of patents have effective terms for much longer, in fact,

than 17 years, in answer to the question of the proposition that a patent's effective term may be 9.5 years or something.

If it is possible for you in simple terms for the benefit of this committee to do so, I would like you to treat that question more fully of how it is that the effective term of patents is longer than an average of 9.5 years, even than 17 years.

Mr. LARSEN. From a legal standpoint and an examination of the patent system, again I would urge you to read Mr. Engelberg's letter, which we have given you a copy of, because I think in many ways it will help explain parts of the question that you have.

I don't think there is any due order that says as to when the patent will be filed, what is the character of the application, whether it's specific, whether it's general, when did the work begin on the drug, did it begin as a specific entity or did it begin as a broad class of compounds. But there is a relationship there.

And a product patent can be filed at a given point in time and will issue normally 2 or 3 years after that unless something else is put in.

A process patent may be filed. There may be a series of process patents.

Process patents are only good, I suppose, if they can be controlled, and are only good if the economics of the subsequent processes outmode the earlier ones so that it is not economical to use the earlier disclosures.

The use patent has to do with the method of use per se. And on any one of these drugs, the interrelationship may change or may be different. The one may relate to process, and I realize that as one looks at process one has to ask themselves the question: How well can a patentholder control that product through process control? Some of these are very difficult—let's say the material comes in from overseas. Others are very explicit and easy because the product itself has a trace chemical in it, has a chemical entity in it that discloses that the patentholder's product has been used. I can think of some instances of that.

We asked this very question that you asked when I saw this data. We asked a man who has spent many, many years of his life and who is now retired from one of the major companies to do some examination of this for us and take and give us a scenario on the process patent life and the use patent life, and he came forward and gave us information on a few of these products.

For us to research the whole list in its entirety is difficult for our organization.

We can go back and give you the information that we developed on three or four of the products. I don't have it with me. I have it in my file and I will be glad to do so, using these as specific examples.

Mr. KASTENMEIER. It might be useful to do this: The fact sheet included with your statement includes Diabinese and Zyloprim as entities remaining under patent protection until 1984 and 1986, respectively. However, the committee is informed that these drugs are already on the market in generic versions. That is what we are told. If this is so, I assume it must be because you are referring to the process patent rather than the product patent, and the generic

houses may be producing these chemicals under old processes. I don't know what other explanation there might be.

Mr. LARSEN. I can speak to Diabinese, chlorpropamide. My company received approval of that drug just a month ago. Other generic companies had received approval of the drug 1 month, 2 months, or maybe 1 year ago. The product has been marketed by some generic companies—I am thinking of particular generic companies—that have ignored the issue of patents and have ignored the issue of FDA. I don't like to associate my point of view or our organization's point of view with that action because we don't condone it, we have no part of it, and we have no interest in that.

But on Diabinese, I referred the issue of whether or not that product was sufficiently covered by patent to our patent counsel and got a lengthy letter back that said in essence, "Ken, it's too thoroughly covered. You can't do it. You are going to have to sit and wait until 1984."

Other members of our organization, I understand, from their own patent counsel have gotten similar advice.

I think if you find the drug sold in the marketplace by somebody that is being unscrupulous and unmindful of what the law is or finding ways to circumvent it, the holder of the patent has to vigorously pursue their rights, and I would defend that pursuit of their rights. The ownership of the particular company I am responsible for changed about 3½ years ago and I came into its management 3 years ago on October 15. The first issue presented to me was, "Let's get out of this business of running against patents and let's clean things up." And I think most of the generic companies that exist today operate on that philosophy.

I can find out for you, and if Mr. Schein were here he would be in a better position to tell you because his business is concentrated in the distribution side of the business, whether or not what you say is so, and he could probably, if it is so, identify the company that manufactures it.

But I think as a general statement that the members of our organization do not want to violate patents and will not violate patents.

Mr. KASTENMEIER. You are talking about patents other than a product patent?

Mr. LARSEN. I am talking about product or process. We may interrogate them intensively to see whether there is an opportunity, but I think everybody should do that and then make a decision. But in the case of Diabinese or chlorpropamide—now, Zyloprim or allopurinal is another long-life one, and that gets down to the same sort of thing of whether there is an overlapping patent that holds it. You can get a royalty license on it and the economics of the licensing just doesn't sit well, although there are companies that have gone the licensing route, generic companies.

Mr. KASTENMEIER. If you go beyond the product patent to the so-called process or use patents, which I gather are involved in these projections of availability or effective length of patent, you are really talking about another dimension.

Mr. LARSEN. Yes.

Mr. KASTENMEIER. Because those patents do not have the same direct effect in forbidding people to somehow get engaged in

coming up with, let's say, a generic drug. Because they could use an old process; they could in other ways circumvent anything other than the product patent itself.

Mr. LARSEN. In my experience—and I am getting to be less and less of a technical person although that is where my beginning was in the industry—I don't think that that is really a case in fact. I cannot think of an example at this point of a situation where a product is being produced without having given—I can think of one company that has given due notice to the holder of the patent that they do not believe their patent is valid after having asked for a license and being granted a license to produce and sell the product. I think this is rightfully determined in the courts, and that is an issue of one's view of a patent.

It happens with the big companies. I could cite you one I am aware of right now that is outside of this country where a major company has come to an associate company of the one that I am with overseas and has asked for the rights to use their process and information on a given product, and they have referred it to me to discuss here on site, and two major companies are contesting presently. And this is a normal part of the process—testing whether or not the original patentholder's patent process is valid. I think if you look at the antibiotic Amoxycillin, it has been manufactured all over the world. And they have manufactured that while the patent was in place. And major companies said, "Look that isn't valid, and we are going to do it." And Amoxycillin is a good example, and the major companies led the way into that, and there were two on-shore manufacturers of generics who decided, "We, too, will produce."

Ampicillin is another matter. I think that patent was substantially substantiated.

One of the things we can do with this exhibit, if you like, is we can identify as best we can with the limitation of our resources and supply to you the extent to which the product patent applies to this extended dating time and process and use.

Mr. KASTENMEIER. Yes; that would be helpful.

Mr. LARSEN. OK, we'll do it.

Mr. KASTENMEIER. I think what I'd like to do also for the committee—I think the other side should probably comment on that, too.

Mr. FLUG. I should point out, Mr. Chairman, that this chart or a similar chart has now been in existence and out in public for probably close to 6 months. So whatever information you received that contradicts it is probably as much information as there is to contradict it, and we'll be glad to take a look at what there is.

Mr. KASTENMEIER. In conclusion, then, as I understand it, the two affirmative suggestions that you have are that, one, the principal parties to the problem might get together, that would be useful, and you might consider, consumers as a third party as well as the generics and the PMA as a proper party.

And, second, if one looks for a possible change in the patent law, it might be to commence from the time of application for approval for the period of 17 years, other than that which is proposed in the bill.

Mr. LARSEN. I think that is one of the suggestions made by the American Pharmaceutical Association which we would endorse. There are other considerations. And, Jim, you might quickly run over those points we have raised.

Mr. FLUG. Just to make sure that the answer to all three of your questions is on the record: Your first question was the opinion on the OTA report. I think both witnesses have pointed out that we find much of great help to the position the association has taken in the OTA report, and specifically the fact that the only evidence of a patent decline is this one report which is based only on NCE's, new chemical entities, which OTA itself says are not representative of all pharmaceuticals and only on first patents, therefore raising the whole issue that you have raised of which patent is the relevant patent to determine patent life. So that the absence of further information in the OTA report we find basically reflective of the absence of basic information for the justification of the whole bill.

Second, the OTA report, as did your witnesses yesterday, I think, provides evidence for two very important points that go to the heart of the bill.

One is the point Mr. Railsback and Mr. Butler made, which is the point: How much of this delay between patent and marketing would go on even in the absence of the FDA, because the nature of the equity point is to compensate for the excessive time taken by the approval process?

A witness yesterday in his prepared statement said, "We need to satisfy not only FDA but ourselves." And the question is how do you divide that time between FDA and between "ourselves"? I think when that question was asked you did not get a straight answer. It was, "Everything is FDA." We know that is not so, and the committee has to separate that out.

The witness also said that even as to a patented drug they never know when competition from a different patented drug is going to come on. And I think that goes to the heart of the theory of the bill that somehow the increased patent life is going to accelerate an evasion. And that is because they can't make projections that far out. They have to make much closer-in projections. Things that happen that far out cannot be used to make substantial changes.

So both in the OTA report and the testimony yesterday we find substantial support for the questions we have raised about the bill.

As to the changes in the bill, these are things again based on our basic problems with the bills. If there were to be a bill and you satisfied yourself on all these factual issues we don't think are satisfied, we think you need to look at the starting point for calculating the regulatory review period.

Mr. Ingman testified yesterday it begins at the IND request, and that is not the way the bill is drafted or the way the Senate thought it was. They came out with a totally different interpretation of the bill. We think the IND would be too early.

Second, separate out the time from the FDA and other time, and separate the time at the end of the patent when again, because of the same regulatory delays, the product is prevented.

Third, the regulatory delay caused by the applicant's own errors or omissions.

Fourth, have the applicant put FDA and everyone on notice of its intention to invoke this extension process so everybody knows in a sense and they are on their best behavior that some sort of clock is running and the specific breadth of the requested extension so everybody knows what you're dealing with in terms of the nature of the extension.

Next, the need to condition any extension on a patentee's contention to make the extension the exclusive remedy. The pyramiding is a self-help remedy. There are others that have been applied. If you are going to provide an extension, that has to be the exclusive one, so that that competition can then come into the market. One of those that we haven't mentioned and that is very important is the effort to use barriers to the use of the same size, shape, and color, or to keep the generic out of effective competition.

There is nothing in the bill that opens the extension process up to any public review or competitor review so that people can insert into the process varying opinions on what the length and breadth of the extension should be.

Next, the need to determine whether the extension process, if you decide to go ahead with it, is actually producing the results you foresaw for it, that is, whether meaningful innovation is resulting as a result of the extension process and whether the increased patent protection is being balanced by that finality of patent protection and the immediate competition.

Next, steps to accelerate the approval of the generic competitors at the FDA.

Other steps to eliminate the self-help remedies to the extent those are being abused, even for those who are not using the extension process.

And, finally, to the extent that there is a retroactive element—it was said here yesterday there is not a retroactive element—there is a retroactive element here in the sense that drugs that have already had a major part of their R. & D. expenditures and decisions made will benefit from this legislation in its present form.

So, those are just examples of the kinds of things that need to be addressed either in negotiations between the parties or by the subcommittee before it really decides whether this is a viable legislative option compared to all the other ways of assisting in innovation.

Mr. HADDAD. With your indulgence, our membership has asked or advised that there are other methodologies for stimulating innovation, such as tax regulation, tax relief on the kinds of drugs you are worried about, where there is no market, that that become the priority for the Government where it is not feasible for private industry to do it, and what the OTA refers to and does not explain as the other alternatives to this particular legislation.

Mr. LARSEN. I guess what we would like to do is thank you for the opportunity, and if you don't have any more questions——

Mr. KASTENMEIER. We probably do have some other questions but we can put them to you, I think, by letter because some of our members are not here.

At least one question was asked yesterday that seemed to reflect a concern for the effect on generics and others at the end of the term. The question was—and I think it probably should have been

asked of you and of the preceding witnesses—how generics are affected by FDA clearances themselves in terms of delay, what marketing or other special problems they have coming into the market, and whether they sometimes confront litigation from others in terms of frustrating their generic use of the product.

As I say, if you have anything to say on that score that you haven't already said, I will give you an opportunity to say it now.

Mr. LARSEN. I think that much of that might be in my statement, but I think just in synopsis, yes, there are a lot of problems of getting to the market. I think the greatest example of that is the post-1962 drug and the paper NDA process. Our association became an intervenor in the case and supported the FDA's side. I personally think the length of time that that change was hidden within the FDA and was not brought forth interferred with the opportunity to reduce the price of drugs, because it precluded competition, competition from branded generic companies, or competition from production-oriented companies.

I think one of the things that we are faced with today, and I think the Government is faced with, is the matter of the commonality of color. Generally speaking, the originator takes action if we duplicate color. I have great concerns and doubt as to whether or not that serves the public interest, because in effect this extends some patent rights, it extends some market control, it precludes competition.

My mother takes a yellow capsule and a white pill and so forth. These are problems.

There is a member of our organization—and this was drawn to Dr. Hayes' attention—who was producing the drug for some time, lost in the contest of color, changed the color, let's say from orange to yellow. Shortly thereafter he received a customer complaint that said, "The yellow one isn't as effective as the orange one." The next complaint came via the FDA. The FDA came in and examined it and found that the drug was everything it should be.

So, here we have the psychologic effect and a secondary effect of control. I think the matter of color, in terms of public safety, should expire along with the patent. It would be a terrible, terrible thing to find for a drug where there were six manufacturers and that drug was available in three different dosage sizes—to have them out there in different colors—the confusion and risk there would be.

We are faced with the same problems that anybody is who submits drugs to the FDA. I think the FDA tries to act in a responsible kind of way but we all find the time goes on longer than what we want. We want to bring the drug to the market. I think there is an adequate body of people investigating this, and, hopefully, some good will come of all those investigations.

Mr. KASTENMEIER. Thank you, Mr. Larsen, and your colleagues for your appearance here today. We will take your recommendations under consideration.

The chair will announce that that concludes the hearings today. The succeeding witnesses representing Public Citizen, Congress Watch have kindly agreed to appear on a subsequent day due to the lateness of the hour and the interruptions occasioned by votes. We will try to reschedule them at an early date.

Until we do schedule our next hearing on this matter, the committee will stand adjourned.

[Whereupon, at 12:45 p.m., the hearing was adjourned.]

PATENT TERM RESTORATION ACT OF 1981

WEDNESDAY, OCTOBER 7, 1981

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES,
AND THE ADMINISTRATION OF JUSTICE
OF THE COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to call, at 10:25 a.m., in room 2226, Rayburn House Office Building, Hon. Robert W. Kastenmeier (chairman of the subcommittee) presiding.

Present: Representatives Kastenmeier, Sawyer, and Railsback.

Staff present: Bruce A. Lehman, counsel; Timothy A. Boggs, professional staff member; Thomas E. Mooney, associate counsel; and Audrey Marcus, clerk.

Mr. KASTENMEIER. The committee will come to order.

This is the fourth day of hearings for the subcommittee on the subject of patent term restoration, H.R. 1937 and similar Senate bill, S. 255. We have heard from the Office of Technology Assessment, from principal proponents and principal opponents of the legislation. This morning we are pleased to have two other areas represented on the question of agricultural chemicals, the question of research foundation licensing.

Certainly.

Mr. RAILSBACK. There are a number of editorials that have been made available to me that I have no knowledge of, including one from the New York Times, relating to our hearings and this subject. I wonder if I could have them made a part of the record, maybe not the printed record, but have them included in our record.

Mr. KASTENMEIER. Without objection those editorials will be received. I see no reason why we cannot peruse them and those that are relevant can in fact be made part of the record. We can exercise discretion in making these part of the record.

[The editorials follow:]

SATURDAY, MAY 23, 1981

The New York Times

Founded in 1851

ADOLPH S. OCHS, Publisher 1896-1935
ARTHUR HAYS SULZBERGER, Publisher 1935-1961
ORVIL E. DRYFOOS, Publisher 1961-1963

The Half-Life Patents

For reasons long since forgotten, Congress a century ago chose to set 17 years as the appropriate period for patent protection. To encourage bright minds and investors, any invention was promised exclusivity in the market for that length of time. But in recent years, without anyone intending it, Federal health and safety regulations have eroded the effective life of many patents. For some products, the exclusive marketing period has shrunk to less than 10 years. The system discriminates unfairly against some of the most important research-oriented industries.

Consider the case of new drugs. When a pharmaceutical company uncovers a promising compound, it generally files for a patent immediately and usually gets it within two years. But before the compound can be marketed, it must pass stringent tests of safety and effectiveness. The regulatory review, required to protect the public, can itself take seven or more of those patented years. So the average effective patent life for drugs dropped from 17 years in 1969 to 9.5 years in 1979. The meaningful patent life for pesticides is now down to 12 years.

This discrimination is clearly accidental. Perhaps the best of several remedies is embodied in legislation just approved by the Senate Judiciary Committee and awaiting hearings in the House. It would simply extend the patent term for each product to compensate for time lost in clearing regulatory hurdles, up to a maximum of seven years.

Some argue the change would stimulate more research, lower costs, assist small business, help universities and promote exports. Others fear higher product prices in the protected industries without any significant benefit.

But that debate seems beside the point. The central issue is fairness and uniformity. If 17 years is to be the appropriate life for a patent, then a patent should be meaningful for 17 years. And if there is reason to distinguish between one industry and another, that should be done directly, not by inadvertence. It would seem to make no sense to protect a toy for 17 years but an important drug or agricultural chemical for only half that time. What Government grants at the patent office should not be taken away by its regulatory arms.

WEDNESDAY, MAY 20, 1981

The Washington Post

AN INDEPENDENT NEWSPAPER

Patently Fair

THE DRUG industry is said to be at the brink of a new age of medical breakthroughs. It now hopes to strengthen its chances for solid returns on its research investments through a bill reported yesterday by the Senate Judiciary Committee. The bill would assure the drug companies and other industries subject to regulatory review that the protection afforded by patent laws is not seriously eroded by the often lengthy period of testing and review required before marketing is allowed. This is a reasonable assurance to require, and the Senate should approve the measure.

For reasons we assume have nothing to do with the locust cycle, patent law deems 17 years the appropriate period for protecting inventors from copycats. Since 1972, when requirements for more rigorous testing of drugs were added to the law, the time required for such preliminaries has stretched from seven to 10 years. As a result, by the time a drug is ready for market almost half the patent life has elapsed.

Since drugs are very expensive to develop, the industry argues that the effective curtailment of patent life discourages new research. Against the arguments of consumer advocates that longer patent lives will increase drug prices by delaying competition, the companies respond that encouraging more research will increase competition and thus lower prices; that drugs, however priced, are far and away the cheapest form of medical treatment and that longer patent protection may discourage high initial price markups now needed for quickly recouping costs.

There are merits on both sides of the price argument. The drug companies, moreover, with their enormous and durable profitability, do not make anyone's list of neediest cases. But there are stronger arguments in favor of patent life assurance. One is simple fairness. If 17 years is the right period for protecting the exclusive rights of inventors, there is no reason why those subject to federal regulation should be denied it solely by reason of that regulation.

There is also the strong desirability of reducing unwarranted pressure on the regulatory process. You don't have to be in favor of mindless bureaucratic delay to recognize the tremendous importance of thorough testing of drugs before they are widely peddled as the latest miracle cure. Some risk may be unavoidable, but no one can want to increase the chances of producing deformed infants.

Stronger regulation not only has reduced that posaibility, but it may also have had other beneficial side effects. The higher cost of introducing new drugs, it is said, diverted companies from trial and error research and from the marketing of slightly better products into the basic biological research that is now promising to produce real cures for ailments ranging from asthma to heart disease and cancer.

There are probably ways that the FDA could further speed up clearance of major drug discoveries without jeopardizing the testing process. But assuring drug companies of a substantial period of patent protection is a reasonable and fair way to avoid having the desire for such protection translate into an unhealthy pressure on the review process.

THURSDAY, MAY 28, 1981

THE WALL STREET JOURNAL.
Published since 1889 by
DOW JONES & COMPANY, INC.

Long Life to Patents

The words "patent law" can hardly be said to possess a life-or-death ring. Not compared to words like penicillin or Salk vaccine. Yet the recent impact of the patent law on the drug industry could well be inhibiting those very kinds of discoveries.

Patents are a bribe: If you invest your time and money on risky endeavors, society will reward your success by granting you a temporary monopoly. U.S. patent laws confer a monopoly for 17 years during which the inventor can, presumably, earn a rate of return that makes the investment worthwhile. Society gets a reward too, of course; it gets an invention it might not otherwise have had.

This bribe is crucial to the drug industry. It's very costly, very time-consuming and very risky to develop a new drug. Currently, the process takes about 10 years, costs $70 million and has a failure rate of 90%. The promise of patent protection kept things humming until, in 1962, the thalidomide tragedy convinced everybody that new drugs needed more rigorous testing. This, in turn, meant more time elapsed before drugs could be brought to market.

Thus, the length of time between patenting a drug and getting FDA approval gradually ballooned from about one year, pre-1962, to over seven years now. In other words, drugs making their debut today have less than a 10 year monopoly life—not 17.

The telescoping of effective patent life has reduced rates of return to drug research and development. Industry studies show that over the past two decades, rates have been sliced in half. Since new products need anywhere from 12 to 19 years to generate R&D returns above 8%, the current life span of less than 10 years looks especially grim. After all, prudent financial management could earn a bigger bang-for-the-buck by buying government long bonds. As it is, drug companies have been diversifying into businesses like cosmetics and salad dressings where returns are nearer to market.

Falling rates of return have, quite naturally, translated into falling R&D. The ratio of R&D to sales has declined from 13 in 1962 to 8 in 1979. Moreover, this decline is mirrored in the decline in the number of new drugs: In 1960, the $3.5 billion drug industry brought forth 50 new drugs; in 1980, a $22 billion industry produced only 12 new medicines.

Other than the obvious implications of this drying-up of R&D, we might note one particular ill-effect—the impact of health care costs. Drugs are amazingly cost-effective. Consider two examples. Tagamet, an anti-ulcer drug, saves millions of dollars in surgical costs a year and the advent of a new class of heart drugs, calcium blockers, *(due out any minute)* might totally eliminate coronary bypass surgery.

There is a simple way to help restore R&D incentive to the drug industry: guarantee the full 17-year protection by starting the patent clock ticking *after* FDA approval, not before. Companies need an assured time horizon to make investment decisions and they should, in the present cost climate, be able to count on a full 17 years. Such a guarantee would reduce uncertainty over expected returns and cash flows, and, we hope, create the incentive to cure our hay fever.

Both the House and the Senate have bills to restore 17-year patent protection to the drug industry. We know that congressional action on patent law reform will not excite the network news into prime-time coverage. But that doesn't make it unimportant and there is every reason to believe, as even the sternest free market economists do, that society's return on this kind of bribe is well worth the payment.

Chicago Tribune

FOUNDED June 10, 1847

STANTON R. COOK *Publisher*
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JOHN McCUTCHEON *Editorial Page Editor*

19 Section 1 Friday, May 1, 1981

Where the patent laws don't work

Patents are intended to give investors and creators of a new product 17 years of exclusivity to reap a return on their investment and make a profit from their discovery before it can be copied freely by others. But for developers of new medical drugs, it hasn't been working out that way.

Today, the process of getting a new medication approved by the Food and Drug Administration (FDA) has become so complex that, on the average, almost half of the patent life of a drug now expires before the product can be put on the market. In some instances, a manufacturer has only three or four years left to sell a new medication before the patent runs out and it can be copied by competitors.

With less chance to earn back their initial investment — it cost an average of $70 million to develop a new drug in 1979 compared to $8 million in 1962 — pharmaceutical companies are less motivated to invest in research and drug development and increasingly inclined to shift to non-drug products. Drug companies introduced an average of 53 new medications per year between 1959 and 1962, but only an average of 18 per year between 1977 and 1979.

So Congress is considering new legislation that would stop the clock from running on the patent life of any product that must be reviewed and approved by a government agency before it can be put on the market. The bill would add to the remaining life of the patent the time elapsed between the initial application for classification as an "investigational new drug" and final FDA approval — up to a maximum of seven years. If passed, the new law would also help companies developing new chemical products, although government approval time is not quite as lengthy for these substances.

Some objections have been raised to the proposed legislation because it would lengthen the time until a drug could be copied by the developer's competitors and marketed as a generic product, presumably at a lower price. But in the long run, we all stand to benefit much more from the discovery and availability of new medications. It is far less expensive to treat patients with drugs than with surgery or long hospitalization, which may be the only alternatives. And one of the most effective ways to cut health care costs is to develop new medications. Enormous savings, for example, could be made if we had more effective drugs for heart disease, cancer, genetic disorders, respiratory diseases, and a long list of other ailments for which better treatment is urgently needed.

On the average, scientists now screen more than 10,000 possibilities for every one new medication that is eventually approved by the FDA and put on the market. The proposed legislation would provide some inducement to pharmaceutical companies to continue risking their time and money on such long shots.

EDITORIAL The Augusta Chronicle May 11, 1981

When patent laws don't work

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With less chance to earn back their initial investment — it cost an average of $70 million to develop a new drug in 1979 compared to $6 million in 1962 — pharmaceutical companies are less motivated to invest in research and drug development and increasingly inclined to shift to non-drug products. Drug companies introduced an average of 53 new medications per year between 1959 and 1962, but only an average of 18 per year between 1977 and 1979.

So Congress is considering new legislation that would stop the clock from running on the patent life of any product that must be reviewed and approved by a government agency before it can be put on the market. The bill would add to the remaining life of the patent the time elapsed between the initial application for classification as an "investigational new drug" and final FDA approval — up to a maximum of seven years. If passed, the new law would also help companies developing new chemical products, although government approval time is not quite as lengthy for these substances.

Some objections have been raised to the proposed legislation because it would lengthen the time until a drug could be copied by the developer's competitors and marketed as a generic product, presumably at a lower price. But in the long run, we all stand to benefit much more from the discovery and availability of new medications. It is far less expensive to treat patients with drugs than with surgery or long hospitalization, which may be the only alternatives. And one of the most effective ways to cut health care costs is to develop new medications. Enormous savings, for example, could be made if we had more effective drugs for heart disease, cancer, genetic disorders, respiratory diseases, and a long list of other ailments for which better treatment is urgently needed.

On the average, scientists now screen more than 10,000 possibilities for every one new medication that is eventually approved by the FDA and put on the market. The proposed legislation would provide some inducement to pharmaceutical companies to continue risking their time and money on such long shots.

EDITORIAL

Madison, Wisconsin The Capital Times April 28, 1981

A prickly patent problem

DEVELOPING new drugs is expensive, time-consuming and risky. It takes an estimated $70 million and seven to 12 years from the time a company begins testing a product and the federal government approves it for marketing.

As the regulatory process stretches out, the clock continues to tick away on a drug's patent life — the 17-year period in which a manufacturer has exclusive rights to produce a compound. By the time most new drugs are marketed today, their patent life has been cut by more than half — to about eight years.

THE RESULT has been that fewer and fewer new drugs are introduced — 59 in 1959, for example, compared to 15 in 1979 — and less and less money is invested in drug research. Some companies have even fled pharmaceuticals altogether, to seek more lucrative rewards in cosmetics manufacturing.

If you follow the line of some conservatives, the solution is to cast off whole layers of the testing and approval process. We don't buy that. Requirements for testing a drug's safety and effectiveness were developed, after all, in response to some genuine abuses of consumer trust — as well as in reaction to horror stories like the Thalidomide episode.

A MORE reasonable alternative is now before Congress in the form of legislation sponsored by Wisconsin's Robert Kastenmeier in the House, Maryland's Charles Mathias in the Senate, and a bipartisan list of almost 30 others. The measure would require that the 17-year patent life begin only after the Food and Drug Adminstration has approved a drug — or that a fixed number of years be added to patent life to make up for time lost to regulation.

Critics of this legislation charge that it simply buttresses the patent as a legal monopoly that keeps others out of the market. Not necessarily. The Kastenmeier-Mathias reform would restore incentives for investment in research on new drugs — a likely spur to more intense price competition benefiting the consumer. Consumers are also the ultimate beneficiaries of pharmaceutical innovations.

The patent-reform legislation is a sensible way to deal with some of the unintended minuses of regulation without throwing out the pluses.

April 7, 1981

Our Opinions

Profits and Patent Life

Under federal law, the holder of a patent on a new product has 17 years of exclusive manufacturing and sales rights before his idea becomes fair game for everyone.

In recent years, however, the time required to test a new product and prove that it meets government standards has eroded the effective patent life substantially.

The problem is particularly acute for manufacturers of drugs and medicines, agricultural and industrial chemicals, medical equipment — any product that must undergo extensive testing to meet strict health or safety standards. New drugs now take seven to 10 years to make it through the Food and Drug Administration's approval process. Twenty years ago, the average was less than a year.

The Pharmaceutical Manufacturers Association contends the erosion of patent life has caused a decline in the number of new drugs introduced in recent years. Clearly, it has been a factor, and both consumers and the industry stand to suffer.

A bill, which has bipartisan support, has been introduced in the U.S. Senate to permit extension of patent life by the amount of required testing and evaluation time. In other words, the manufacturer's 17 years of commercial exclusivity would begin on the day of government clearance, not the day the patent is granted.

The manufacturers note that the reduced patent life discourages companies from making the huge investments necessary to develop new drugs, causing some to turn, instead, to less complicated goods like toothpaste and deodorant.

A change in the law now, the bill's backers argue, would pay off in a decade or so, when more new medicines would reach the market. Opponents say that giving manufacturers a longer monopoly could drive prices up, a hardship for senior citizens, who are the biggest consumers of pharmaceutical products.

Surely, the opposite would be true. The increased competition that would accompany the enhanced profit opportunity would control prices adequately — and give doctors and their patients more drugs to choose from.

The proposed extension of patent life is a simple recognition of changing times. It offers an incentive to both business and medical research, and should be enacted without delay.

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THE HOME NEWS New Brunswick, NJ April 25, 1981

Editorials

Patent law discourages drug research

A provision of the federal patent law has become a major problem for the pharmaceutical research industry and it has negative implications for the public at large.

Legislation before Congress would relieve the inequity by extending protection under new patents beyond the current 17 years.

The rationale was explained to a congressional committee recently by Lewis A. Engman, president of the Pharmaceutical Manufacturers Association.

Engman said the bill to extend patent life would stimulate development of new medicines and reduce the future cost of medical care.

The problem lies in the fact that when a company develops a new medicine or compound, it must file immediately for a patent. But the following testing and approval process can consume up to ten years so that by the time a new product gets to the market, 50 percent or more of its patent protection time has already been used up.

Engman said that condition stunts the expansion of pharmaceutical research and consequentiy retards new discoveries in the field.

The proposal before Congress would not eliminate thorough and cautious approval procedures for new products, but would provide that protected time up to seven years which is lost between the issuance of the patent and the marketing of the product would be restored.

The spokesman for the research industry told the congressional committee that "fundamental fairness is being denied holders of patented products that have to undergo lengthy approval processes prior to marketing. Congress' intent, that all inventions be accorded equal and adequate protection, is being thwarted."

Engman added that consumers meanwhile are being deprived of therapy development because of what he called this "statutory accident."

He said that the net effect of what amounts to a severely shortened patent life is a reduction of investment incentives.

Engman declared that pharmaceutical patents "are a public policy issue in the truest sense, for it is the public which now is paying for surgery and more expensive therapies that could be supplanted by potential new discoveries resulting from research."

Life enhancing research is an area in which the country cannot afford delays caused by a statutory accident. The inequity should be corrected.

Editorial

Cincinnati, Ohio CINCINNATI ENQUIRER April 18, 1981

PATENTS

Congress weighs additional time for drug creators

THE AMERICAN pharmaceutical industry, one of the most imaginative and creative in the world, has turned to Congress in the hope of correcting a growing injustice.

As matters now stand, the creator of a new drug is given a patent that enities it to be the drug's exclusive manufacturer for 17 years. The problem arises when the time-consuming licensing procedure — including extensive tests by the Food and Drug Administration (FDA) — significantly reduces that span of time. Twenty years ago, the real life of a pharameutical patent had been reduced to just over 16 years; by 1971 it was down to 13 years, and by 1979 down to 9½ years.

The idea of granting exclusive rights to the laboratory that discovers a medically useful drug, of course, is to provide it an opportunity to recover a reasonable share of the costs of development — which frequently run into millions of dollars.

Only days ago, *Enquirer* readers learned that the drug Timolol, originally developed for high blood pressure and later was found to be useful in treating glaucoma, is now believed capable of preventing second heart attacks. The original patent on Timolol was granted in 1972, and it probably will be later in 1981 before it is accepted as a drug for heart-attack victims. By that time, however, its patent will have less than eight years to run.

When the life of a pharmaceutical patent is reduced, its holder faces the necessity of recovering development costs in a much shorter period of time. That adds appreciably to the drug's retail costs. A further result is discouraging the kind of research that has been responsible for new pharmaceutical breakthroughs in the past.

House and Senate committees are conducting hearings this month on legislation to restore to each patent's life the time devoted to regulatory review.

The nation's sound health — to say nothing of elemental justice — points to the legislation's early approval.

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Relief needed

The pharmaceutical industry that brought us a stead stream of miracle drugs over the last few decades has been unjustly hampered in recent years by a federal roadblock which today entails a delay of seven to 10 years to win approval of a new drug discovery for marketing.

Although some consumer organizations spearheaded by the Naderites applaud this delay, it is expensive from both a medical and economic standpoint. The drug companies must spend millions of dollars, ultimately passed on to consumers, to win their Food and Drug Administration approval and the long delay denies patients access to new healing powers.

The immediate problem is that pharmaceutical companies, which are only able to patent their discoveries for 17 years, spend about half that time winning FDA approval. This discourages them from new drug research.

Part of the problem can be cured by congressional passage of a bill which would extend to the patent times all thos years spent in dealing with the FDA bureaucracy.

A hearing is set this Thursday before the Senate Judiciary Committee and we encourage Alabama Sens. Howell Heflin and Jeremiah Denton to support the pharmaceutical industry.

Wednesday, April 29, 1981

Pasadena, CA STAR NEWS March 10, 1981

Patent laws inhibit medical advances

Encouraging research and innovation in any industry is largely a matter of providing sufficient incentives.

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Consequently, by the time enterprising pharmaceutical houses actually begin selling most of their new products, the effective life of their patents has shrunk by almost half.

The predictable result has been a steady decline during the last decade or so in the amount of money, time and effort pharmaceutical companies are willing to invest in research on new drugs. As rewards for innovation have diminished, so has innovation itself.

That lag is too long and must be remedied if sick people are to have the benefits of modern science — but some lag is necessary so that we can be sure the benefits are there and truly outweigh any possible side effects.

The obvious remedy would seem to be an amendment to the patent law compensating drug companies for at least some of the years they lose to the FDA review process.

Not surprisingly, the pharmaceutical industry is suggesting just that in the form of legislation that would extend patent life to ensure a full 17 years of protection once a new drug had been approved for market by the Food and Drug Administration.

That strikes the Star-News as eminently fair. Moreover, if the American public is to continue enjoying the benefits of new and better pharmaceutical products, a change in existing patent law is also essential.

Tallahassee, Fla. DEMOCRAT March 2, 1981

Red tape cuts patent life

In the last two decades the number of new drugs being tested and developed in the pharmaceutical industry has declined. Major drug firms say it is because they are seldom able to recover their research investments through subsequent drug sales.

The Pharmaceutical Manufacturers Association says that the inability to profit from the development of a new product, and return a share of that profit to still more research, is because much of the patent life of a new product is lost before it is ever marketed.

In an effort to encourage innovation and reward inventors for disclosing their inventions, Congress established a 17-year patent life on new products. Theoretically, an inventor's product can be sold for 17 years before competitors can copy the brand-name item and enter the marketplace.

But patent life is actually diminished because patents must be applied for so early in the developmental stages that the patent life begins running long before the item is approved by the Food and Drug Administration for commercial sale.

Government regulation, evaluation, testing and clearance processes take so many years that pharmaceutical houses say their discoveries actually enjoy a patent life of about 9.9 years.

And once the patent life expires, the inventors must compete with other drug manufacturers, including those that market generic drugs. Florida and several other states permit the cheaper generic drugs to be substituted unless a doctor specifically prescribes a brand-name drug.

Pharmaceutical houses want Congress to extend the patent life so that they will have more time to recuperate financially from the extensive research efforts that precede most important medical discoveries.

But the welfare of the consumer must also be considered and critics argue that a longer patent life will simply constitute a legal monopoly and give the investor 17 years of exclusive marketing rights and the ability to set prices without fear of being undersold. They say restoring the lost years of patent life might even retard the introduction of new drugs because the firm, once assured of extended protection, might choose to sit on its discovery.

Perhaps the best way to assure pharmaceutical houses have time to recoup their costs and encourage continued research would be to reduce the number of years it takes to get a product on the market. The average of seven years it is now taking for a product to clear the Food and Drug Administration and meet the myriad of other government regulations is astonishing.

Government review procedures should be improved and shortened so that products can be rejected or accepted as safe for public consumption in far less time.

Kerrville, Texas TIMES March 5, 1981

The Patent Laws

EDITORIAL

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Ahoskie, N.C. NEWS HERALD March 9, 1981

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San Diego, CA San Diego Union February 24, 1981

Too Long to Wait

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Sacramento, CA Sacramento Bee March 1, 1981

Longer Life For Drug Patents

One of the anomalies of the nation's patent laws is that, while Congress has provided 17 years of patent protection for the makers and inventors of new products and devices, the government's own clearance procedures often reduce the benefits of such protection by several years — in some instances to little more than half the period provided by law. The most common categories of such products are drugs, pesticides and other chemicals which, because of extensive review procedures under the regulations of the Food and Drug Administration, the Environmental Protection Agency or other government agencies, sometimes cannot be marketed until six or seven years of the 17-year patent period have already expired. That obviously is a disincentive to research and development of new products.

There is now legislation in the Senate that would change all that. With the strong backing of the Pharmaceutical Manufacturers Association (PMA), Sen. Charles McC. Mathias of Maryland and a group of other senators are sponsoring a bill, S 255, that would, in effect, extend the life of a product's patent for the length of time it takes for it to clear the government's review process and reach the market. The PMA claims that "investment of funds in research and development of products such as drugs and chemicals requiring lengthy government approval is discouraged by shortened patent lives. A decline in new drug introductions has paralleled the decline in patent life and must be reversed to bring about a new encouragement of technological innovation in the United States."

That may be an overstatement — the decline in new drug introductions unquestionably stems from a variety of causes — yet the argument still has merit: obviously the shorter the effective life of a patent, the less incentive there is for innovation and development. There has been considerable pressure from drug manufacturers in recent years for the government to speed up its review procedures and thus get new products on the market more quickly. In some respects, such streamlining may make sense, but it also involves serious hazards in a field where the damage resulting from casual review of the safety of new products has been extensive.

The Mathias approach makes much more sense. The review process should be careful and deliberate, yet there is no reason why inventors and manufacturers ought to pay the price in reduced patent protection or why the process as a whole should unnecessarily discourage the invention of new drugs. If there is any economic virtue in a shorter patent period, it should be established through careful study and deliberation, not through the accidents of a review process designed to protect the health and safety of the nation.

Wapakoneta, Ohio NEWS March 23, 1981

Patent laws need changing

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Brooklyn, NY BULLETIN March 9, 1981

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Fresno, California Bee March 10, 1981

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March 2, 1981
Hot Springs National Park, Arkansas

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El Dorado, Arkansas News-Times March 3, 1981

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Camden, Arkansas NEWS March 3, 1981

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Magnolia, Arkansas BANNER NEWS March 3, 1981

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The obvious remedy would seem to be an amendment to the patent law compensating drug companies for at least some of the years they lose to the FDA review process.

Not surprisingly, the pharmaceutical industry is suggesting just that in the form of legislation that would extend patent life to ensure a full 17 years of protection once a new drug had been approved for market by the Food and Drug Administration.

That strikes us as eminently fair. Moreover, if the American public is to continue enjoying the benefits of new and better pharmaceutical products, a change in existing patent law is also essential.

Pixley, California ENTERPRISE March 4, 1981

-Patent laws need changing

Encouraging research and innovation in any industry is largely a matter of providing sufficient incentives. That is why adequate patent laws are indispensable to the development of improved products. Patents permit innovative entrepreneurs to reap just rewards by protecting their exclusive right to market a new product for a set number of years.

The patent life for drugs is fixed in federal law at 17 years, long enough to guarantee the kind of financial return that rewards entrepreneurs and benefits the public by encouraging more and more research.

But in recent years, this cycle of reward and progess has been increasingly threatened. Partly as a result of a stricter Food and Drug Administration law passed in 1962, the regulatory lag between development of a new drug and its ultimate approval for market by the FDA has stretched to an average of nearly eight years.

Consequently, by the time enterprising pharmaceutical houses actually begin selling most of their new products, the effective life of their patents has shrunk by almost half.

The predictable result has been a steady decline during the last decade or so in the amount of money, time and effort pharmaceutical companies are willing to invest in research on new drugs. As rewards for innovation have diminished, so has innovation itself.

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Long Beach, CA Press Telegram March 12, 1981

Editorials

Patent laws are unfair to drug manufacturers

Manufacturers of prescription drugs have a special problem that is caused by the federal government, and which the federal government should solve.

After a company develops a drug and obtains a patent, the drug still cannot be sold until it has cleared the painstaking review procedures of the Food and Drug Administration. Six or seven years may elapse before the drug is on the market. But the patent life starts to run out from the day the patent is issued.

Manufacturers of pesticides and other chemical products have a similar problem. The 17-year patent period begins years before the Environmental Protection agency or other federal regulators allow the product to be sold.

That's not fair. If the patent period is too long, it should be shortened. But it should not be shortened indirectly by federal regulators.

The pharmaceutical industry argues that, in addition to being unfair, the present practice discourages the development of new drugs. In at least some cases, the argument is believable.

To solve the problem, Sen. Charles McC. Mathias of Maryland has introduced a bill that would extend the life of a patent by the time it takes for the product to clear the federal regulatory process.

Probably the process can and should be speeded in many cases. But speed is not always consistent with safety, and the Food and Drug Administration is generally right to proceed cautiously in approving new medications.

The Mathias bill would relieve the pressure for haste in government review, and thus insure that health and safety remain the primary concerns. At the same time, the bill would provide protection for manufacturers, who shouldn't be penalized because their products must be carefully and exhaustively evaluated for safety and usefulness.

American Medical
NEWS

The life of patents

One of the hidden costs of modern medicine is the life of patents — or rather, the unhealthy life of patents.

You can get an economic argument by taking either side of the proposition that patent protection raises the costs of drugs.

An unduly protective patent law allows the originator of a drug to hold prices high while enjoying a monopoly. A lack of patent protection wipes out the incentive for venturing capital and research to develop a new drug. Those are the classical arguments; take your choice.

THE RISE OF government regulation, however, has introduced a disquieting new factor into the patent-law equation. It boils down to this: A 17-year clock starts ticking the moment a pharmaceutical firm receives an American patent for a new drug. It may be years, however, before all the regulatory hurdles are cleared and the drug can be marketed.

The result is that patent lives shrink, producing what economists call the "free rider effect." The innovator takes the risk, while competitors get a free ride in the form of a developed product all can sell at the end of a shortened patent life.

The end result is inevitable. No innovator can afford for long to give his competition a free ride. He stops taking risks; he reduces his research investment.

THIS TROUBLESOME matter was discussed not long ago by Lewis A. Engman, president of the Pharmaceutical Manufacturers Assn., before a pharmaceutical conference at Lincolnshire, Ill.

"When one points this out," said Engman, "the frequent response is: 'Well, you're making plenty of money, what's your complaint? If we give you back the rest of your patent life, you'll just make more.'

"That's possible. But if the industry makes more, it will be because it has responded by doing what the patent was intended to promote — innovation in the public interest."

The pharmaceutical industry is actually two industries, Engman said: a research industry and a pill industry.

"Every pharmaceutical company is in the pill industry," he said. "Fewer and fewer today are in the research industry.

"Declining patent lives have made research less appealing. Discovery costs have risen while recovery time has declined. So in real terms, companies have been cutting back investment in research and development in relation to sales."

THE FOOD AND DRUG Administration is reviewing ways to simplify drug-approval procedures. PMA has submitted petitions to FDA suggesting specific changes.

Many economic analysts believe the U.S. patent law has stood the test of time, and should be retained. Either markedly shortening or lengthening the period of patent protection would cause severe economic dislocations.

Our economy does not need an artificially shortened patent life, brought on by overregulation of some new products.

The life of drug patents, like the lives of the patients the products are designed to serve, should be satisfying, both in length and in health.

EDITORIAL

EDITORIAL THE COMMERCIAL APPEAL September 3, 1981

Patent Medicine

ALTHOUGH THE Reagan administration is working to inject price competition into health care, one piece of legislation appears to do just the opposite. Congress has been asked to restore the 17-year life of patents for medicines and medical devices.

By definition a patent is a monopoly granted by the government. The purpose isn't to foster competition among prices and products but just the opposite. It is protection of patent holders to let them recoup their expenses over time and at a fair profit.

IS EXTENDING that privilege any sort of prescription for containing health-care costs? In this case, at least, all is not as it seems.

EDITORIAL

The country has come a long way from the old patent-medicine days, when drumbeaters made every claim they could in order to make the sale. Today drugs must undergo extensive tests to show their safety and effectiveness. Those tests, however, have cut into both time and profit for U.S. pharmaceutical firms. Last year, for instance, the average patent life remaining when a new drug is marketed was 7 years and 5 months. The return on investment has declined, as well, from 15 per cent a decade ago to around 12 per cent.

The companies' trade arm, the Pharmaceutical Manufacturers Association, admits this percentage still is slightly higher than that of most industries. Yet, the association says, profits are needed for research and development.

It has a point. A recent study by the U.S. Office of Technological Assessment found that passage of the Patent Restoration Act could lead to higher drug costs; those costs, however, would tend to be offset by the development of new and more effective drugs by an industry with a history of plowing back its profits instead of investing in unrelated fields.

Even some with good reason to resist haven't opposed the patent law change. The American Association of Retired Persons, an organization of older citizens — the group which consumes the largest percentage of the nation's prescription drugs — acknowledges the potential rewards as well as the risks, including possible price gouging. But in a nation where prescription drug therapy takes only 8 cents of every health-care dollar (in 1960, it took almost 14 cents), and where new breakthroughs promise to reduce hospitalization time and doctors' fees, the benefits could be substantial.

THERE IS A danger, however, only indirectly related to patent life.

When physicians prescribe trendy, newer drugs instead of reliable, older medicines that would do just as well and cost substantially less, patients and their pocketbooks suffer. Sometimes the public purse does, too, when government-sponsored insurance coverage picks up the "fair price" of a prescription.

There are some drugs for which there is no substitute: Tagamet, for one, the ulcer prescription that's the nation's biggest seller, which retails for about 26 cents a tablet. Its price tag is mild, however, compared to those of the newer antibiotics, which can cost more than $1 per capsule and which can run $100 and above for a 100-pill prescription.

Anyone under the weather isn't going to quibble about a few cents if it cures what ails. But don't patients have to swallow enough without a druggist bill that makes them sick?

PATENT EDITORIAL

SEATTLE TIMES JULY 30, 1981

Patent-restoration bill incentive for drug firms

SINCE 1962 a simple equation that adds up to a thriving drug-research industry has become increasingly distorted. The incentives that have produced innovations are minimized because pharmaceutical manufacturers, in effect, have only half a patent life on their products. If the trend continues, the public loses, too.

Drug manufacturers are given a 17-year patent on new products. But before the drug reaches the marketplace, it must undergo extended testing to prove not only that it is safe, but — since 1962 — also that it is effective.

Consequently, it takes eight or nine years before a new drug can be sold to the public — that's the half of the patent life that is lost. The companies then have eight or nine years to earn back the money they've spent developing and testing the drug and to support research into new drugs.

Many companies have not been able to do that profitably and have diversified to keep their profits up. The biggest single moneymaker for the Squibb Corp., long synonymous with vitamins, is Bubbleyum chewing gum. Other companies have turned to the production of household cleaners and cosmetics. Such diversity may please stockholders, but it does not encourage the manufacturers to invest an average of $70 million in the development of a new drug.

Legislation now before Congress (House Bill 1937 and Senate Bill 255) would restore some, if not all, of the lost patent life. Companies could retain exclusive rights to their innovations for an additional seven years (maximum) to offset the time it takes to do the testing.

The major argument against the measure, which has wide support, is that longer patent terms would raise the cost of the drugs to consumers. The bills do not affect existing patents, however; it would be many years before costs to consumers could be accurately calculated.

Even if costs rise, however, that has to be weighed against the need to encourage companies to continue researching and developing drugs, and to maintain a brisk pace in bringing the innovations into the marketplace.

AMERICAN-STATESMAN AUSTIN, TEXAS JULY 16, 1981

EDITORIAL

Patent law

A proposal pending in the Congress to change the patent law is so sound that it is a wonder it was not acted on long ago.

Under the current patent law, an inventor holds exclusive rights to the invention for 17 years. But in the cases of pharmaceuticals and other products subject to the federal approval process, the testing and evaluation procedures eat up much of the "effective patent life" of the product.

The drug industry says that in its case, that about halves the 17 years specified in the law.

The effect is said to be a decline in the number of new drugs entering the market, in expenditures on research, and a shift to trying to extend the marketable life of existing drugs.

The proposed Patent Term Restoration Act would effectively extend the patent term of products subject to the federal approval process by the time used up in regulatory review, if that does not exceed seven years.

Congress should put its stamp of approval on the this patently useful measure.

EDITORIAL

KANSAS CITY STAR JULY 13, 1981

Short life of drug patents

Partly to reward inventors and partly to help firms recover their investments in research and development of new products, the government grants patents that run for 17 years.

Congress is now considering a bill to extend that patent life span. Strong arguments in favor of the change rise from the situation in the drug industry where the effective patent life is now somewhat less than 10 years. A massive increase in regulations related to testing, checking and cross-checking during the development of a new medicine before the Food and Drug Administration permits marketing of the substance has occurred in the past two decades. As much as seven years may lapse between the time the patent is issued and the date the drug can be sold. The proposed Patent Restoration Act directs that a regulatory review period be calculated for each product and the patent be extended for that period, not to exceed seven years.

Research is expensive. The industry estimates it costs an average of $70 million to research and develop a new drug. As profit-making enterprises, firms make decisions to invest their capital where the return is best. The number of new drugs introduced since the early 1960s has dropped dramatically from 53 to 18 in the late 1970s, partly, the industry says, because firms have cut back on the proportion of money put into research. The benefit of medicines that treat painful and debilitating diseases is obvious. And some contend that higher prices of protected drugs, an argument against extension of the patent law, would be offset by the introduction of more and better substances with the competition forcing prices down.

Some elements of the debate cannot be settled. Whether drug companies are already making too much money depends on the yardstick and whose figures are used. If you get relief from a new drug when you're sick, you would agree consumers benefit from broadened, even if expensive, research efforts. Otherwise, you might not.

But fairness is the major issue. Allowing a 17-year patent on a toy but one for 10 years, for all practical purposes, on a medicine is discriminatory. The protections of the regulatory process are needed to make sure drugs are as safe as the best minds and advanced technology can make them.

MARYVILLE TIMES TENNESSEE JULY 3, 1981

Our opinion

180 Patent change could boost medicine

A bill which has been approved unanimously by the Senate Judiciary Committee and is pending in a House subcommittee would extend the term during which a manufacturer is permitted to hold the patent on a new drug. And it could revive the lagging U. S. pharmaceutical industry to the ultimate benefit of American medical patients.

Supporters of the bill contend that the measure will spur innovation and increase the number of useful drugs reaching the market.

The change would extend the patent term of products subject to the federal approval process by the length of time consumed by regulatory review, up to a maximum of seven years.

Under the present 45-year-old patent law, an inventor of a product or process holds exclusive rights to the invention for 17 years only. However, in the drug industry, the federally mandated testing and evaluation period eats up much of the effective patent life of the product.

Because of the extended regulatory procedures, the period of effective protection for marketed drugs declined by almost seven years between 1960 and 1978 and there are indications the downward trend will continue. In other words, the length of time in which a new drug can be marketed with the protection of a patent is now about one-half of the 17-year period specified by the act.

The decline in the effective patent life of new drugs has had several negative effects on the U. S. drug industry:

- The number of new drugs entering the American market has fallen dramatically during the past 20 years, so the United States is now lagging behind major European pharmaceutical-producing countries.
- There has been a reduction in expenditures on research by drug firms as a "real" percentage of sales.
- The emphasis of drug research has been shifted from the development of new products to efforts to extend the marketable life of existing drugs, and from long-term to short-term development work.

Besides an increase in new drugs reaching the market, other positive results which supporters of the patent term restoration action say would result are:

- A downward pressure on drug prices, resulting from increased competition among companies.
- A boost for smaller, research-based pharmaceutial firms which face longer Federal Drug Administration approval periods and a "brand name loyalty" barrier in the marketplace.
- More product competition, but less emphasis on marketing competition.

A successful new drug is really a money maker. But for each success there are numerous failures and usually the bigger the success, the more that has been spent on research. If half of the patent life is used up by the time the drug is approved for sale, the manufacturer will be less likely to gamble on more expensive long-term research and if it does gamble and succeed it will have to charge more in order to recover its cost.

We feel this type of extension could be beneficial to the consumer in the form of more and better new drugs as well as a competitive factor which should reduce cost.

CINCINNATI POST CINCINNATI, OHIO June 24, 1981

Patent remedy

For nearly two centuries, the U.S. patent system has been promoting "the progress of science and useful arts" by giving holders of patents 17 years of protection for their discoveries.

Lately, however, the system has been working against innovation in certain fields, particularly drugs and chemicals, which by their nature must undergo thorough government testing to prove their safety and effectiveness before they can be marketed.

For medicines, the process now takes about seven to 10 years. The result is that the effective patent life of a new compound can be much shorter than the 17 years guaranteed by law.

The drug companies claim that since drug law amendments in 1962 lengthened approval procedures, a decline in new drug introductions has paralleled the decline in patent life. We think they have a case.

For example, of 12 new drugs or chemical entities approved by the Food and Drug Administration in 1980, the average patent life remaining was only seven years, five months. One drug patented back in 1961 had no patent protection left.

Congress may do something about this problem in this session. A "Patent Term Restoration Act" has been introduced in both houses which directs a "regulatory review" period be calculated for each product subject to such review, whether a drug or anything else, and that an equal period be added to the product's patent life, but not to exceed seven years.

We agree with numerous critics that there's room for improvement in the FDA's lengthy and supercautious testing of new drugs. But that's another matter. The patent expansion bill would help ensure that neither the drug industry nor the public is unnecessarily penalized in the meantime.

SAINT LOUIS POST - DISPATCH SATURDAY, JUNE 20, 1981

Patently Fair To Drug Companies

A bill now under consideration in the U.S. Senate would give drug companies and other manufacturers of substances that come under regulatory review fuller use of patent protection. A patent gives the company or person obtaining it protection from duplicative competition for 17 years. For drugs and other such substances, however, much of the patent time is consumed in valid safety and efficacy review. The bill would restore up to seven years of patent life to a drug once it is through the review process.

In 1980 only 12 new drugs were approved; their average remaining patent life was 7 years, 5 months. The drug companies make a fairly persuasive case that the time devoted to regulatory review sharply curtails the patent's financial incentive for research and development. Since 1972 amendments to the drug law increased testing requirements — and hence lengthened the time between a drug's development and when it goes on sale — the introduction of new drugs on the market has steadily declined.

The opposition to the patent restoration proposal is largely economic. Some say that drug companies will keep prices high and that it will take longer for lower-priced generic drugs to be marketed. These arguments are not without some merit. But restoring patent life could spur more research and the development of drugs. And companies may spread the cost of recovering R&D money over the longer period, holding down the price to the consumer. Finally, there is the matter of equity. Patent laws provide 17 years' protection. Why should drug producers be denied that?

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Restore Drug Patent Protection

It takes an average of seven years to win Food and Drug Administration approval of a new patented drug due to increased safety standards, more sophisticated testing techniques and other demands that have been added to the process through the years.

Under the present arrangement, there is no provision in the patent process to offset the long bureaucratic delay in approving marketing of new drugs. Companies which pay an average cost of $20 million to introduce a new drug simply lose seven years of the life of their patent. This means that the average effective life of a new patented drug actually is only 10 years, rather than the 17 allowed under law and enjoyed by other industries not subject to the long delays of the FDA.

As a matter of equity, it is difficult to defend the apparent unfair treatment of drug companies. They are entitled to the full benefit of a 17-year patent just like a company in any other field. Taking away an average of seven years from a patent life is no small matter when one considers how costly it is to develop a new drug and the many risks involved in bringing new products to the market. A great many of them don't make it commercially even after a drug company has obtained the patent and gone through the long process to gain FDA approval.

The shortened patent term is affecting research and development and introduction of new drugs in this country.

The record shows that in the early 1960s, before long delays were imposed, the average effective life of an approved patented drug was 16 years. As a result, a U.S. pharmaceutical industry with sales of $2.6 billion was able to produce 53 new drugs a year.

When amendments to the federal drug law altered the approval process, the delays mounted until the average effective life of a patented drug fell to only 10 years. The result was that a drug industry whose sales had grown to $16 billion a year was able to produce only 18 drugs a year in the 1977-79 period.

More importantly, undue delays in producing new remedies could shorten or endanger the lives of countless persons. While safety is paramount, needless red tape that hinders the production of life-saving drugs is unconscionable.

The Patent Restoration Act, which has received unanimous approval of the Senate Judiciary Committee, would extend a drug patent by the amount of time equal to the length of the regulatory review period required to gain approval for marketing.

Drug companies would still be required to go through what appears to be a too-lengthy review process; but at least it would give them the full patent life to which they are entitled. Since the government is the problem, the least Congress should do is to remove the heavy penalty that the long FDA delays have imposed. Congress should pass the Patent Restoration Act.

Arkansas Gazette. WEDNESDAY, JUNE 17, 1981

Patent Life of Drugs Decreasing in Years, New PMA Study Says

By BILL LEWIS
Of the Gazette Staff

New drugs must be patented when invented. The testing period follows — often eating up years of the patent's 17-year life.

The Pharmaceutical Manufacturers Association prepared a report recently on the 12 drugs that were approved for use by the federal Food and Drug Administration in 1980. The patent dates ranged from 1961 to 1975, and the amount of time remaining of patent protection after FDA approval ranged from 11 years and 10 months down to zero. The average patent life remaining for all 12 drugs was seven years and five months.

The patent life of new drugs has been decreasing steadily in recent years. For the period of 1959 to 1961, patent life was 16.4 years. Changes in drug laws requiring more stringent testing were enacted in 1962, and patent life dropped to 14.9 in 1964-66, to 13.1 in 1969-71, to 11.9 in 1974-76 and 9.5 in 1979. It has fallen another two years since then.

Senator Charles Mathias (Rep., Md.) and 21 other senators of both parties introduced earlier this year Senate Bill 255, the Patent Term Restoration Act of 1981, which would restore the patent life of those products, including drugs, that must be approved by the government before they can be marketed.

Lewis A. Engman, president of the PMA, which represents 149 pharmaceutical houses that account for more than 90 per cent of the new pharmaceuticals introduced in the United States, testified before the Senate Judiciary Committee in April that the erosion of patent time for products that must be approved by the government was an inadvertent penalty.

"Because the patent clock starts before the testing and government review process, and ticks throughout, the effective patent life for regulated products unintentionally has been reduced — and for no products more than for pharmaceutical products," Engman said.

Patents are sought immediately on promising new drugs, and generally they are issued within two years. The 17-year period then begins.

"But at the time of the patent's issuance," Engman said, "the innovating firm is far from sure it will ever have a marketable product; for that assurance it must await final market approval, an event which may be — and indeed generally is — still some seven to 10 years away." Thus, he said, the 17-year patent protection "has come to be no more than a legislative figment," for the effective life is less than half that.

Engman said the cost of developing a new drug now averages $70 million. That cost, coupled with the risk involved and the reduced patent protection period, substantially has reduced the incentives to invest in pharmaceutical research and development.

In 1960, when the patent life for pharmaceuticals began its decline, the pharmaceutical industry, then a $3.5 billion empire, produced 50 new medicines. Last year, the industry had grown to $22 billion but produced only 12 new medicines.

"The public is the loser," Engman said. "The sick, the people with diseases for which medicines have not yet been developed, have been the real victims of lost patent life."

The situation is of no one's design, Engman said. "No one could have anticipated that the testing and approval process that took two years in the early 1960s would take seven to 10 years by 1980."

Opposition to the bill has come only from one of Ralph Nader's consumer groups, which has called the move to restore lost patent life "a rip-off for the consumer who will get nothing out of it." It also contends that drug companies already are making lots of money and don't need investment incentives, and that restoration of patent time simply would enable drug manufacturers to charge higher prices.

The manufacturers counter these arguments with some of their own.

"In the long term," says the PMA, "full patent lives ensure both better drugs and lower prices. Drugs for which consumers pay a premium under the current system of half-patent lives would be, in the more innovative climate full patents would produce, only the second or third best products available and [would] sell at the barest of margins. Conversely, the products for which consumers might be paying premiums today under a system of full patents are products which do not yet exist because of half patents."

The PMA concedes that its members are making money and are not on anybody's "neediest cases" list. But they argue that the truest measure of incentive is the direction of capital flow and that for several years, the industry has been reducing real investment in drug research and putting increasing emphasis on other lines of business.

To the charge that longer patents means higher prices, the industry said that that inferred that patents confer power to set prices. "A patent confers the exclusive right to exploit a novel technology," the PMA said. "A patent does not, and cannot, confer the right to set the price of that technology. Price is set by the market; price reflects production costs, size of patient population, the degree to which a product reflects an advance over its competition and, most important, the rate at which other innovators come forward with competitive or superior products." No amount of patent protection, they add, will support a product's price or profitibility once something better comes along.

The FDA is under increasing pressure to shorten the length of time needed for testing new drugs — a procedure that probably is subject to reduction only in the area of administrative handling within the FDA itself. The stringent testing requirements were enacted to safeguard against a repetition in this country of the thalidomide disaster in Europe, when a tranquilizer that had been inadequately tested produced severely deformed infants whose mothers had been given the drug while pregnant with them.

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Editorials Wed., June 17, 1981

Extending Patents

THERE ARE ABOUT 40 pharmaceutical manufacturers in this country, many of them in the Bay Area, and they are doing better than $16 billion a year. They are rich and profitable but they are not as technologically innovative as they once were. They are introducing fewer new drugs each year because research that produces new drugs is on the decline. They say they don't get enough benefit out of the life of their patents to pay the way of more intensive product development.

In 1959, the American drug establishment introduced 65 newly patented drugs; last year, only 12. Obviously this trend is adversely affecting the general public through the loss, i. e., the non-appearance, of uninvented drugs that might benefit health, cure disease and save lives.

THE WAY TO TURN this around, the companies are telling Congress, is to give the innovator of a new drug the same 17 years' protection for the exclusive life of his patent that the inventor of a newly manufactured widget gets. Once granted a patent, an ordinary product can go right into production. Not so with drugs and chemicals that must undergo the process of review and approval by a government agency. This is ever lengthening.

Of the 12 new drugs introduced in U. S. pharmacies last year, five had been patented as long ago as the 1960s, the other seven in the first half of the 1970s. Result: the average patent life remaining when at last the drugs went to market was seven and a half years. Ten years had been chewed up in regulatory review.

THE DRUG COMPANIES are not seeking to avoid review and testing; they want a law that would add back onto the term of the patent the time lost in testing and approving the new product. Seventeen years' market protection is their demand, and we think it's fair and justified. The Senate Judiciary Committee has agreed to this unanimously.

Why doesn't the House Judiciary Committee do the same? Apparently because of organized consumer objections that patent extension is a rip-off with nothing in it for them, that the drug companies are already making lots of money (true) but don't need more investment incentives (clearly untrue), and that with long-life patents the companies will charge higher prices longer. Also true, but as the 17-year patent incentive brings more new drugs onto the market, product competition will prove once again to consumer advocates what they seem to overlook: that intensive research and innovation are the real price regulator — for drugs as for any other product.

MEMPHIS PRESS-SCIMITAR EDITORIAL JUNE 16, 1981

Patent Remedy

For nearly two centuries, the U.S. patent system has been promoting "the progress of science and useful arts" by giving holders of patents 17 years of protection for their discoveries.

Lately, however, the system has been working against innovation in certain fields, particularly drugs and chemicals, which by their nature must undergo thorough government testing to prove their safety and effectiveness before they can be marketed.

For medicines, the process now takes about seven to 10 years. The result is that the effective patent life of a new compound can be much shorter than the 17 years guaranteed by law.

The drug companies claim that since drug law amendments in 1962 lengthened approval procedures, a decline in new drug introductions has paralleled the decline in patent life. We think they have a case.

For example, of 12 new drugs or chemical entities approved by the Food and Drug Administration in 1980, the average patent life remaining was only seven years, five months. One drug patented back in 1961 had no patent protection left, meaning that anybody could begin copying it.

This is not good, especially when the drug industry is reportedly on the brink of major new medical breakthroughs. Fortunately, Congress may do something about it this session.

A "Patent Term Restoration Act" has been introduced in both houses. It directs that a "regulatory review" period be calculated for each product subject to such review, whether a drug or anything else, and that an equal period be added to the product's patent life, but not to exceed seven years.

We agree with numerous critics that there's room for improvement in the FDA's lengthy and supercautious testing of new drugs. But that's another matter. The patent expansion bill would help ensure that neither the drug industry nor the public is unnecessarily penalized in the meantime.

Topeka Capital-Journal Topeka, Kansas June 14, 1981

Half a patent

Drug manufacturers have come up with a number of effective pain relievers over the years. Now they'd like Congress to deliver a pain reliever to them, in the form of changes in the patent laws.

The pharmaceutical industry contends that the patent clock should be stopped during the lengthy review process required by the Food and Drug Administration. In many cases, the drug makers claim, the 17-year patent life is almost half gone by the time new drugs are cleared for sale to the public.

No one is saying FDA review should be abandoned, only that the time it takes shouldn't count against the life of a patent. The bill that would correct this unequal treatment under the patent law has passed the Senate Judiciary Committee, where Kansas' Sen. Bob Dole was a co-sponsor. Senate approval is expected, and hearings are scheduled in House committee.

Drug makers say that because their products are available to consumers for only about half of the life of the patent, the number of new drugs marketed each year is steadily declining. Some warn that the industry is nearing the point where research and development will become so costly that companies will move their operations to foreign countries, where the patent-to-pharmacy-shelf time is much less.

And, the delays are depriving the patients of the cheapest form of effective health care (medicines), drug makers add.

The other side of the argument is that restoring the full 17-year patent life to new drugs only would delay the time when other makers could manufacture and market the medicine as a generic item, theoretically lowering its cost. Opponents also contend that drug research would slow down, since companies would have more time to exclusive sales of specific drugs, and not feel so pressed to come up with other new medicines.

Those are reasonable arguments, but fairness is a compelling factor in the drug makers' favor. There is no good reason why the inventor of, say, a solar energy device, should have 17 years' exclusivity to his invention and a drug company should have only 9½ years (on the average) to its invention.

And it seems more reasonable to conclude that drug research and development would increase if companies know they'd be able to get full marketing benefits from their investment. It likely would motivate them to invest more in research and development. That's just good business sense.

If someone earns a patent, he shouldn't have to settle for half a patent.

The Courier-Journal

BARRY BINGHAM JR. *Editor and Publisher* — ROBERT T. BARNARD *Opinion Page Editor*

Associate Editors

JOHN HART JAMES EDDLEMAN BERT EMKE

HUGH HAYNIE, *Cartoonist*

SUNDAY, JUNE 7, 1981 FOUNDED 1826.

Drug-law change is needed to stimulate vital research

PATIENTS facing staggering bills for prescription drugs may look coolly on the current effort to extend the period in which pharmaceutical companies are protected against lower-cost competition. But the industry makes a good case, both in basic fairness and in the interest of consumers, for passage of this legislation.

The problem arose as an unintended offshoot of the 1962 congressional decision, in the wake of the Thalidomide birth-defects tragedy, to require more testing before new drugs could be marketed. Such testing shortens the life of drug patents; in a few cases, the entire 17-year period of patent protection has expired before the manufacturer has been allowed to market a drug.

A lab technician checks the pulse of a volunteer in a drug-testing program.

What this means is reduced incentive to invest heavily in research. One reason fewer new drugs are being introduced is because companies with insufficient remaining patent protection may not be able to recoup their investments. Once the patent lapses, other companies that spent nothing on research can make and sell the same drug at much lower cost.

The cost of developing a new drug now averages about $70 million, up from $6 million when Congress passed the 1962 legislation. And the manufacturers note that they produced 50 new drugs in 1960 but only 12 in 1980. At a time when the industry believes profound breakthroughs to be imminent, it's clearly in the public interest to encourage more research, not less.

One useful step, of course, would be to streamline the regulatory process. The Food and Drug Administration has reduced some of the time required for animal and human testing of new drugs. But the industry recognizes that this approach has limits. So it wants Congress to extend the 17-year period of patent protection to restore at least part of the time lost to protracted reviews. (Such an extension also should reduce industry pressures for unwise shortcuts in testing.) The proposal has

continued.....

been approved by the Senate Judiciary Committee, but a companion House committee hasn't scheduled hearings.

An example of why the industry wants this bill is the Merck drug, Timoptic, patented in 1972. During subsequent animal testing, one of its spinoffs was found to be a treatment for glaucoma. Glaucoma is a frequent cause of blindness, especially in the elderly.

Merck then started four years of human tests in late 1974. When it sought to market the drug, the Food and Drug Administration put the product on a "fast track." As the first new anti-glaucoma drug in 70 years, it seemed a medical breakthrough.

But though Merck then won final approval in only eight months, that left only 10¼ years of the 17-year patent period to recapture its research investment, pay for the "dry holes" in this and other research, and make a profit for stockholders. And Merck did better than most. The 12 drugs approved in 1980 by the FDA had an average remaining patent life of seven years and five months. That's about half what it was in 1960.

The proposed legislation would add as many years to a patent as were lost in regulatory review, but in no case more than seven years. It has strong Senate backing: Kentucky's Huddleston and Indiana's Lugar are among its 27 sponsors. But its 30 House sponsors (including Louisville's Representative Mazzoli) so far have failed to persuade the House Judiciary Committee to hold hearings. If not started soon, it will be too late for action in 1981.

This measure makes sense, not only in fairness to an industry unduly penalized by regulatory delays but in the interest of citizens whose very lives may hinge on research now unwisely discouraged. Drug costs might rise, though the industry says increased research actually would heighten competition and reduce prices in the marketplace. But they'll still be a bargain compared to other forms of medical treatment — and especially compared to sickness or death.

Friday, June 5, 1981

The Albuquerque Tribune
A Scripps-Howard Newspaper
WILLIAM TANNER, Editor
Norman Bell, Managing Editor
Jack McElroy, City Editor John Parker, Editorial Page Editor
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Remedy patent system ills

For nearly two centuries, the U.S. patent system has been promoting "the progress of science and useful arts" by giving holders of patents 17 years of protection for their discoveries.

Lately, however, the system has been working against innovation in certain fields, particularly drugs and chemicals, which by their nature must undergo thorough government testing to prove their safety and effectiveness before they can be marketed.

The drug companies claim that since drug law amendments in 1962 lengthened approval procedures, a decline in new drug introductions has paralleled the decline in patent life.

We think they have a case.

For example, of 12 new drugs or chemical entities approved by the Food and Drug Administration in 1980, the average patent life remaining was only seven years, five months. One drug patented back in 1961 had no patent protection left, meaning that anybody could begin copying it.

This is not good, especially when the drug industry is reportedly on the brink of major new medical breakthroughs.

Fortunately, Congress may do something about it this session.

A "Patent Term Restoration Act" has been introduced in both houses. It directs that a "regulatory review" period be calculated for each product subject to such review, whether a drug or anything else, and that an equal period be added to the product's patent life, but not to exceed seven years.

We agree with numerous critics that there's room for improvement in the FDA's lengthy and supercautious testing of new drugs. But that's another matter. The patent expansion bill would help ensure that neither the drug industry nor the public is unnecessarily penalized in the meantime.

Birmingham Post-Herald

ANGUS McEACHRAN
Editor

W. H. METZ
Vice President

Wednesday, June 3, 1981

Patent remedy

The U.S. patent system is intended to provide inventors of new products and processes with 17 years of control over their discoveries so they can recover their costs and make a reasonable profit.

For nearly two centuries, the system has worked well. But lately the necessity of governmental testing before many products may be marketed, particularly drugs and chemicals, has worked against innovation.

For medicines, the testing process now takes about seven to 10 years. Since patents must be applied for when the discovery is made, the effective patent life of a new compound is often much shorter than 17 years.

The drug companies claim that since drug law amendments in 1962 lengthened approval procedures, a decline in new drug introductions has paralleled the decline in patent life. We think they have a case.

For example, of 12 new drugs or chemical entities approved by the Food and Drug Administration in 1980, the average patent life remaining was only seven years, five months — far too short to recover costs at reasonable prices. One drug patented back in 1961 had no patent protection left, meaning that anybody could begin copying it.

This is not good, especially when the drug industry is reportedly on the brink of major new medical breakthroughs. Fortunately, Congress has a chance to do something about the problem with the "Patent Term Restoration Act.

This measure would direct that a "regulatory review" period be calculated for each product subject to such governmental testing, whether a drug or anything else, and that an equal period be added to the product's patent life, up to seven years.

We agree with numerous critics that there's room for major improvement in the FDA's lengthy and supercautious testing of new drugs. But that's another matter. The patent expansion bill would help ensure that neither the drug industry nor the public is unnecessarily penalized in the meantime.

Monday, June 1, 1981 THE EVANSVILLE PRESS

The Evansville Press
A Scripps-Howard Newspaper
William W. Sorrels, editor

Tom Tuley, managing editor
Tom Ryder, metro editor
Dale McConnaughay, editorial page editor

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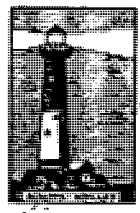

The Pittsburgh Press

A Scripps-Howard Newspaper

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Give Light and the People Will Find Their Own Way

Sunday, May 31, 1981

Patent Remedy

For almost two centuries the U.S. patent system has been promoting "the progress of science and useful arts" by giving holders of patents 17 years of protection for their discoveries.

Lately, however, the system has been working against innovation in certain fields, particularly drugs and chemicals, which by their nature must undergo thorough government testing to prove their safety and effectiveness before they can be marketed.

For medicines, the process now takes about seven to 10 years. The result is that the effective patent life of a new compound can be much shorter than the 17 years guaranteed by law.

The drug companies contend that since drug-law amendments in 1962 lengthened approval procedures a decline in new drugs has paralleled the decline in patent life. They have a case.

For example, of 13 new drugs or chemical entities approved by the Food and Drug Administration last year the average patent life remaining was less than 7½ years.

This cannot serve the interest of the public health or welfare, for it discourages the kind of pharmaceutical research that leads to better medicines.

★ ★ ★

Fortunately, Congress may do something about it this session. A "Patent Term Restoration Act" has been introduced in both houses.

This would direct that a "regulatory review" period be calculated for each product subject to such review — whether a drug or anything else — and that an equivalent period then be added to the product's patent life, up to a maximum of seven years.

This would help ensure that neither the drug industry nor the public would be needlessly penalized.

The Knoxville News-Sentinel

A Scripps-Howard Newspaper
Established Dec. 23, 1886

RALPH L. MILLETT JR., Editor — ROGER A. DALEY, Business Manager

"Give Light and the People Will Find Their Own Way"

Sunday, May 31, 1981

A Remedy for Patents

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"Give light and the people will find their own way."

Rocky Mountain News

A Scripps-Howard Newspaper

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William W. Fletcher, Business Manager

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May 30, 1981

SATURDAY Editorials/

Healthy, wise and equitable

THE drug industry can help keep Americans healthy and itself stay wealthy if Congress is wise.

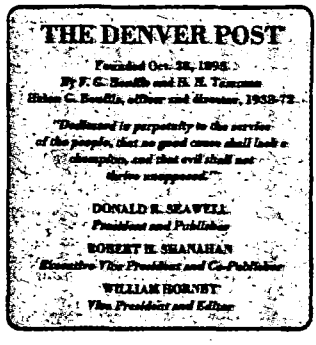
The industry has a problem. When a firm comes up with a new idea for a drug to treat some disease or the other and perhaps save lives, it takes out a patent. But by the time the government is through testing the drug to make sure it does what it's supposed to do, a goodly amount of the patent life may have been eaten up. That means the company, with only limited protection but a huge investment in the drug, may not make much money off it.

There's a bill in Congress to correct this. Under the legislation, the number of years the government spends examining a drug before allowing it on the market will be added back to the patent life. Patents last for 17 years. Today, if the government takes 10 years, say, to look at a drug, a firm will have just seven years of protection. Under the legislation, it would have the full 17 years.

The legislation strikes us as equitable. Why should the drug industry endure patent handicaps that don't afflict other industries?

But beyond that, the legislation would be in the public interest. Many drug firms these days produce more than just drugs. They have found deodorants a profitable item, for instance. If the profit disappears from developing new drugs, some drug firms may decide to concentrate on deodorants instead. The losers would be sick people looking to get well.

Consumer groups have argued that the legislation would make drugs more expensive during the years of extended protection, and that is obviously true. But the higher costs are preferable to having the industry disengage from its aggressive search for new and better drugs.



May 30, 1981

Patently obvious

LAST YEAR Duphar Labs won approval by the Food and Drug Administration to market a drug called Yutopar, useful in preventing miscarriages. Since U.S. patent law provides 17 years of exclusive manufacturing rights for inventors, the company should have been able to look forward to a profitable return after 12 years of developing and testing the drug.

But, as it happens, Duphar Labs will have exclusive rights to Yutopar for barely five years. After that time any competitor, unhampered by research and testing costs, will be free to copy the formula.

The reason is that drug companies find it prudent to take out their patents *before* they begin the lengthy testing necessary to get new drugs approved for sale. Thus, the 12 years Duphar spent ensuring that the drug was safe and effective left it with less than a third of the useful patent life remaining.

The FDA, aware of the "regulatory lag" controversy, has streamlined its procedures to clear most new drugs in about two years, rather than the former three. But that's only after the companies have completed their own complex tests, many of which simply can't be rushed.

We're not suggesting clutching at the crying towel for drug manufacturers. But if it's unprofitable to invent new drugs, then the progress of public health will face a sharp setback. Thus, we welcome Secretary of Health and Human Services Richard Schweiker's support for drug patent law reform proposed in a bill introduced by Sen. Charles Mathias, R-Md.

Basically, the proposed reform extends patent protections to new drugs by the amount of time consumed during the regulatory review process, provided the period does not exceed seven years. In the Duphar case, such a reform would have restored its useful patent life to 12 years. The seven-year limit is a livable political compromise.

The only real criticism of the proposal has come from consumer groups. They note that it may delay the time when new drugs can be produced as "generic" drugs by manufacturers who can market them more cheaply since they are unburdened by research and development costs. The reality is that a drug first has to be invented before it can be produced either under a brand name or generically.

The present burden of regulatory lag is merely killing the goose that lays the egg of research and development in the drug industry. The need for reform seems, well, patently obvious.

OKLAHOMA CITY TIMES

TIMES Editorials

44 ••• Thursday, May 28, 1981

Patent life needs a lift

GIVEN the present anti-business climate prevailing among much of the populace, it may be hard to work up much sympathy for drug and chemical companies in the dilemma they face under current patent laws.

But the public should take notice and put pressure on Congress to provide some relief from the regulatory burden that now stifles incentives for research and development. It would be in the public's interest to remove the barriers to a continuing flow of new and improved medical therapies.

The vehicle for doing so is the proposed Patent Term Restoration Act, embodied in S.R. 255 and H.R. 1937. The Senate Judiciary Committee has looked favorably upon it, but the bill faces a tougher run in the House Judiciary Committee. Oklahoma's Rep. Mike Synar is a member of that committee.

The basic patent law gives all holders of patents 17 years of protection for their discoveries. The object is to encourage research and development of new products.

By their nature, though, products like drugs and chemicals require a lengthy review process by the federal government to demonstrate their safety and effectiveness before they can be marketed. That means they are kept out of the commercial market and, thus, are denied part of their congressionally guaranteed 17 years of patented life protection.

The bill would restore the patent life consumed during this review and approval process. It would require that a "regulatory review" period be calculcated for eacb product and that an equal amount of time be restored to that product's patent, for a period not to exceed seven years.

Several good arguments can be marshaled for this change. One is simple fairness, treating all patent holders alike by giving them sufficient time to recoup their research and development costs in the commercial market. It takes seven to 10 years to get a new medicine through the federal Food and Drug Administration's approval procedures, so that its effective patent life is less than 10 years. The average is 7.5 years. For chemicals, the patent life has been reduced to 12 years.

That discourages investment in research and development and, consequently, inhibits technological innovation. From 1963 to 1975, the percentage of medicine and drug patents worldwide that originated in the United States declined from 66 percent to 54 percent.

Particularly hard hit are small businesses, the most innovative segment of the economy and the most dependable source of new jobs. They are the ones most in need of patent protection in order to attract investment capital. Also affected are university research programs, which invent new compounds but, because of the lengthy review process, find they have only a few years of royalty-bearing life in their patents.

Passage of the bill would help the pharmaceutical and chemical manufacturers, but society would be the real winner because of the medical advances and the possibility of lower prices resulting from increased competition that would come from greater research activity.

Mr. KASTENMEIER. The Chair is pleased to hear from Jack Early, president of the National Agricultural Chemicals Association. He is accompanied by Dr. Dale E. Wolf, chairman of the board of that association.

Gentlemen, you are both welcome.

TESTIMONY OF JACK D. EARLY, PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, ACCOMPANIED BY DALE E. WOLF, CHAIRMAN OF THE BOARD

Mr. EARLY. Thank you, Mr. Chairman. We appreciate the opportunity to be here, and you have identified us. I am Jack Early, president of the National Agricultural Chemicals Association, and as you indicated, with me today is Dr. Dale Wolf, of DuPont Co., and he also serves as the chairman of the board of the National Agricultural Chemicals Association.

Mr. Chairman, the National Agricultural Chemicals Association represents the crop-protection-chemicals industry. The member companies of the association produce virtually all of the crop-protection chemicals used in the United States for agricultural purposes—both the technical-grade chemicals and the end-use crop-protectant chemicals formulated from these basic chemicals.

We have submitted to the committee a much longer written report, testimony. With your permission I would like to give you a digest of that this morning and give the highlights in the interest of time.

Mr. KASTENMEIER. Without objection your statement in its entirety together with other materials attached to it will be received and made part of the record.

[The material referred to follows:]

STATEMENT OF

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

I am Jack Early, President of the National Agricultural Chemicals Association (NACA). I am accompanied by Dr. Dale E. Wolf, Vice President, Biochemicals Department of E.I. du Pont de Nemours & Company, and Chairman of the Board of NACA.

The National Agricultural Chemicals Association represents the crop protectant (pesticide) chemicals industry. The member companies of the Association produce virtually all of the pesticide chemicals used in the United States for agricultural purposes -- both the technical grade chemicals and the end-use crop protectants formulated from these basic chemicals. We use the word "pesticides" to include various kinds of agricultural chemicals, such as insecticides, fungicides, bactericides, and herbicides, or, in other words, those chemicals used to protect crops from destruction by various insect, disease, and weed pests.

Mr. Chairman, we appreciate this opportunity to contribute NACA's views and indicate our support for H.R. 1937. We believe the Patent Term Restoration Act will help to maintain the incentive needed for pesticide research and development. It will restore to pesticide patent holders a portion of their patent rights which are lost as a result of the federal registration process. Importantly, patent restoration is not a broad or automatic extension of patent rights. It doesn't give companies any unusual or unfair advantage. It does not require additional Government bureaucracy. It will stimulate innovation by returning the full extent of the patent

protection which was given by the Congress as incentive for full development of inventions, and further research.

Congress intended that a seventeen-year patent be awarded to promote the development of new technology, thereby encouraging the early disclosure of an invention while affording protection for the inventor. Since the adoption of the patent incentive system in 1790, there have been tremendous changes in scientific knowledge in general and in the field of agriculture specifically -- and developments should continue to be encouraged.

Pesticide chemicals require extensive scientific evaluation of potential toxic effects to assure public health and safety to the consumer, worker, and the environment. As a result, there has been an ever-increasing period of review for pesticides. Regulatory review is certainly proper for the protection of our citizens. However, the regulatory review process has caused an unforeseen erosion of the patent system. A recent study over a six-year period, conducted by our industry, has determined that the average time for registering a pesticide is five to seven years from initiation of a major health test until first registration of a label. During that time, the patent term continues to run on those pesticides for which a patent has issued. By the time that a company has obtained its registration and enters the market, a significant portion of the patent term has been lost. An inequity has been created, and clearly the time has come when the incentives of the patent system need to be restored.

During the past forty years, the agricultural pesticide industry, through chemical and field research, has been very creative and innovative. For example, the invention of pre-emergence herbicides has created a technical revolution in the production of corn, soybeans, cotton, and many other grain crops throughout the world. Yield increases resulting from weed control with these chemicals can range from as little as ten percent to as much as fifty percent or more, depending on the weed intensity in the production area. A high percentage of the U.S.-grown corn and soybeans is treated with pre-emergence herbicides for weed control. This technology is utilized on almost 150 million acres of cropland. If the value to the farmer is calculated (yield, quality, dockage discounts, mechanical efficiency, etc.), the total dollar improvement to the U.S. farm economy from this one concept would be in excess of $5 billion per year ($35/acre x 150M ac.).

Continued innovation, however, must be supported by adequate return of investment in research and development from sales of patented products. On an average, it now takes over eight years and some $20 to $25 million to bring a new product from discovery through registration. Normally, the construction of new and unique chemical plants to produce the technical grade chemical is also required, at a cost of an additional $40 to $70 million.

We would like to stress the point that in our industry, there must be value to the farmer in order for a new pesticide product to gain acceptance. A patent holder is not at liberty

to indiscriminately price his patented product. He must deal with today's farmers who are sophisticated, highly cost-conscious business people. Many manage numerous cash crops on thousands of acres of farmland often valued in the millions. Many rely upon their own computers to reach cost-effective decisions. Like any other business person, the farmer must realize a profit on his investment.

When it comes to pesticides, the farmer is looking for two things: (1) a product that will control his specific insect, weed, or disease problem; and (2) one that will provide him with a return of $3 to $4 for every dollar invested. If a particular pesticide product falls short of either goal, he will choose competitive chemicals or non-chemical methods to control pests. Rarely, if ever, is a farmer limited to the choice of a single control option.

In short, pesticide manufacturers cannot price their products so high that the benefit to growers is ultimately erased by forcing the growers to sell at non-competitive prices in the marketplace.

The competitive pricing which occurs in the agricultural chemical industry is illustrated by Table 649 of Agricultural Statistics, 1980, published by the U.S. Department of Agriculture (copy attached as Appendix A) which shows that since 1967, the price of agricultural chemicals has increased only 50 percent, while the prices of other farm necessities, such as seed and fertilizer, have increased 187 percent and 96 percent, respectively.

Recently Congress authorized the Office of Technology Assessment to review the effect of patent term restoration on several industries. Although the major thrust of that report, titled "Patent Term Extension and the Pharmaceutical Industry," dealt with pharmaceuticals, there was a small segment of the report that dealt with the pesticide industry. On balance, we believe that the Report supports the case for patent term restoration. In some instances, however, the Report's assessment of the pesticide industry is based upon statements which are erroneous and tends to misrepresent the situation regarding the development of agricultural chemicals.

For example, the OTA Report states that federal research assistance, through the U.S. Department of Agriculture, is available to our industry. We wish to point out that the $322.6 million cited for pest research is spent essentially on service to farmers and the public, not the chemical industry. The extent to which Federal money is spent and by what agencies in the public interest is shown in a USDA response to the President's Environmental Message of August 2, 1979. The chemicals being evaluated by USDA are already patented by the industry and provided to the agency for their programs. Most of the patented compounds evaluated by the USDA were not further developed and were never registered. What government research does for the industry in this instance is to provide information on new patented products regarding any deficiencies or other perceived difficulties. In other words, the USDA identifies which patented products should not move forward in

development and subsequent registration. The government does not provide research information that companies can use to generate and patent a new compound. The excellent research done by Federal and state agencies, which results in new discoveries that are extremely useful, is published by the agency and becomes public information. Consequently, such information does not generate any private patent rights.

The technical grade pesticide -- the product that is in issue here -- is the chemical which is processed into formulated retail products for application to specific crops under specified environmental conditions. Each use of a given chemical must be separately registered with the Environmental Protection Agency (EPA), and extensive test data must be submitted to the agency to demonstrate its safety to man, animals, and the environment. A single pesticide chemical may have a wide variety of crop or pest uses when formulated, and each use requires review and approval by the EPA, based in part on test data specific to that use.

For the record, we would like the Subcommittee to note that historically, safety requirements for pesticides were first introduced in 1958 under the Miller Amendment to the Federal Food, Drug, and Cosmetic Act and required that tolerances be established for residues in food for human consumption. In concert with this requirement, our industry members had to obtain appropriate toxicological data by conducting animal studies to determine a "no-effect" level on

which a safe maximum residue limit could be established, in conjunction with an acceptable daily intake.

However, the Federal Environmental Pesticide Control Act of 1972 (FEPCA) and its 1978 amendments dramatically increased the time and cost of developing new chemical products for agriculture, as we have already indicated. Pre-market review for both pesticides and pharmaceuticals is now similar. The time from discovery of pesticidal properties of a compound to full commercial registration increased on an average from fifty-eight months in 1967 to ninety-two months in 1979, and is still increasing.

To assist the Subcommittee in developing an even greater appreciation of the problem, we have included a diagram and explanation (see Appendix B) depicting the chronological development of a herbicide from initial synthesis and discovery of biological activity to the first commercial sales.

Because the process is rather complex, we have included with the diagram an explanation of the scientific and regulatory steps which must occur between discovery of a new pesticide and its entry into the marketplace. Rather than take the Subcommittee's time now to review the chronology outlined in the diagram, we would encourage you and members of your staffs to study it carefully at your convenience. However, at a glance, you can see why many years of a new product's patent life are absorbed during the federal regulatory process. The six-year period of regulatory testing and review disallows earlier market development and delays the time when the

consumer can benefit from the product. It then takes many years after first commercial use to reach the full market penetration and total product utilization that result in maximum sales benefits. These years of market development use up an additional part of the patent life. As a consequence of the regulatory process, the last several years of patent protection that is available for non-regulated products -- a time of maximum sales -- have been cut off for regulated products.

If the company has an extremely unique and innovative product concept, it has only the remaining time of the patent life to develop market strategy, develop environmental compliance procedures, recoup the invested capital and regain all other costs and expenditures, and generate sufficient return to continue in the business. In contrast, with a simple non-regulatory controlled patented product, the patentee may enjoy the fruits of his patent from the first day the patent is issued.

Again, NACA believes that the OTA Report may leave the Subcommittee with an erroneous impression regarding the effect of regulating delays on innovation. The OTA assertion on page 73 "...that innovation has, thus far, been virtually unaffected by the increased costs and time required for regulatory approval" is misleading. Innovation is always directly affected when experimental programs are too expensive to conduct, or will take an unreasonable amount of time. The tables and figures in the OTA Report fail to take into account

other factors, such as the lure of a new market which prompts companies to expend large amounts of capital into a new venture; or the inability of a regulatory agency to spell out the guidelines for requirements to obtain approval of a registration application. Moreover, the statistics relied upon by OTA were derived as a result of business decisions during the early years when EPA review was not as time consuming and complex. We can anticipate that ever-increasing costs of R&D attributable to the review process will have an adverse effect upon future agrichemical innovation. At that point, we will see a reversal in the growth rate and market sales picture.

Our conclusion is supported by the report issued by the Conservation Foundation and utilized as a source by the OTA, which states that the time delay in bringing a product to the market is likely to be a more important factor in innovation decision than direct costs.

Further to this point, we direct the Subcommittee's attention to Appendix C which sets forth the results of an NACA survey of 47 research intensive companies within the Association on questions relating to the impact of patents and government regulation upon their research and development. Thirty-five companies responded and nearly all indicated that a favorable patent position was a critical factor in determining whether to invest in new product development. The survey also indicated that availability of patent protection is a highly important element in long-range research planning and funding. Respondents reported that the uncertainties, cost, and delay

caused by government regulations have forced a reduction in research efforts. These companies favored restoring to patent owners the term of patent protection set by Congress. We can conclude that without fully adequate patent protection, our member companies cannot continue to undertake the time-consuming research involved in discovering and developing new pesticide products and still compete with other companies who can copy their successes without the heavy cost of research and development.

The unchecked erosion of patent protection can only serve to discourage continued innovation. When protection is devalued, much of the incentive to invest long-term high-risk capital in innovative pesticide research goes with it. This is, perhaps, best illustrated by Appendix D which shows the trend of increasing research and development costs, yet a decreasing number of agricultural pesticides being registered. We note that the OTA Report includes Table A-1 (page 73) to show a steady rate of new pesticide chemicals being registered in the U.S. from 1967 to 1979. We would like to point out that the table does not make the distinction between agricultural and non-agricultural pesticides, which is reflected in Appendix D, and therefore the OTA report inaccurately depicts the trend of new registrations.

The accomplishments of American agriculture comprise one of the most gratifying success stories in the annals of world history. Food production has increased in this country by 200-fold since the turn of the century. Today only three

percent of the U.S. population feeds us and much of the rest of the world. In 1980, exports of agricultural products contributed almost $40 billion to our balance of payments.

Let me remind the Subcommittee that throughout the world, losses of food to pests are enormous. Estimates of loss (U.S. Department of Agriculture, Agricultural Research Service, Handbook No. 291) have ranged as high as forty-five percent of production in countries where pesticides are not readily available. Even when pesticides are readily available, insects, disease, and weeds are major contributors to the destruction of food and fiber. Agricultural pesticides significantly reduce but do not eliminate pest losses. The use of pesticides not only increases the quantity of our food, but also improves its quality, reduces disease to humans, increases the farmer's profits, reduces labor costs, and improves his cash flow. These achievements are due in large measure to the agricultural chemicals industry's long-term commitment to innovation.

Nobel Prize winner, Dr. Norman E. Borlaug (who received the Nobel Prize for Peace for his outstanding contribution to alleviation of world hunger through the development of improved wheat varieties), warns that food production must double by the year 2030 to feed a world population of eight billion. "We can't feed the world with old technology. And we can't feed it without insecticides, fungicides, herbicides, and good machinery," says Borlaug.

Obviously, doubling food production -- the need identified by Dr. Borlaug -- will require sustained incentive and innovation on a scale never before seen in worldwide agriculture. The U.S. pesticide industry, to remain a dynamic contributor to development of such new technology, must be encouraged. H.R. 1937 will stem patent devaluation and will spur pesticide innovation for the benefit of the American way of life.

The innovative organizations in our industry regard the patent system as a prime motivator for undertaking costly programs in the high-risk area of new pesticide research and development. Thus, we are understandably concerned whenever these important incentives, provided by that system, are eroded.

There is an obvious need to reconcile the patent system with the federal regulatory process. H.R. 1937 will effectively meet this need.

Thank you.

APPENDIX A

Table 649.—Prices paid by farmers: Index numbers, by groups of commodities, United States, 1965–1979[1]
(*1967 = 100*)

Year	Family living indexes							Production indexes					
	Family living (all commodities)	Food	Clothing	Housing	Autos and auto supplies	Medical and health care[2]	Education, recreation, and other[3]	Production (all commodities)	Feed	Feeder livestock	Seed	Fertilizer	Agricultural chemicals
1965	92	92	92	92	97	92	92	92	97	90	109	109	92
1966	96	100	94	96	98	96	93	96	101	96	98	103	96
1967	100	100	100	100	100	100	100	100	100	100	100	100	100
1968	104	108	106	104	105	106	108	100	94	104	104	94	101
1969	109	109	112	107	109	115	116	104	96	117	103	97	103
1970	114	114	114	109	112	120	115	106	101	122	112	88	98
1971	118	116	114	115	120	128	120	113	103	125	134	91	100
1972	123	129	119	116	124	134	124	115	108	148	136	94	108
1973	132	149	121	121	126	137	127	146	160	192	157	122	128
1974	151	168	134	149	153	149	138	186	194	163	215	187	119
1975	168	178	151	168	172	167	157	186	187	134	206	217	160
1976	174	189	161	178	194	184	168	191	181	144	241	195	174
1977	181	(3)	(3)	(3)	(3)	(3)	(3)	209	188	155	251	181	157
1978	194	(3)	(3)	(3)	(3)	(3)	(3)	217	193	221	273	193	143
1979	215	(3)	(3)	(3)	(3)	(3)	(3)	242	224	292	286	196	150

Year	Production indexes—Continued							Prices paid (total commodities)	Interest	Taxes	Wage rates[4]	Production, interest, taxes, and wage rates	Commodities, interest, taxes, and wage rates
	Fuels and energy	Farm and motor supplies	Autos and trucks	Tractors and self-propelled machinery	Other machinery	Building and fencing	Farm services and cash rent[5]						
1965	88	88	88	92	88	97	.....	92	79	87	88	94	94
1966	88	89	94	96	94	98	.....	96	80	94	93	98	96
1967	100	100	100	100	100	100	.....	100	100	100	100	100	100
1968	101	102	107	104	104	106	.....	103	112	110	106	103	103
1969	103	104	112	111	110	113	.....	106	125	120	119	107	106
1970	104	108	120	116	116	119	.....	110	134	129	124	113	112
1971	107	111	121	122	122	121	113	115	143	136	134	117	116
1972	108	114	127	128	126	131	123	122	154	143	142	125	125
1973	116	130	135	137	134	147	136	142	164	154	156	149	144
1974	139	147	151	151	150	161	158	161	175	164	173	169	164
1975	177	168	171	166	167	174	178	177	203	186	193	188	185
1976	187	184	212	217	201	216	214	187	209	173	210	198	191
1977	203	198	234	238	215	229	232	196	239	194	228	205	203
1978	212	171	246	259	228	245	265	212	400	215	242	237	219
1979	276	189	275	288	248	273	305	241	501	238	265	281	250

[1] Index values for 1968 through 1973 were revised and published in May 1976 using 1971–73 weights. Indexes were recalculated and several new indexes introduced. Revised monthly indexes for January 1968–April 1975 are available upon request.
[2] Based on Consumer Price Indexes of Bureau of Labor Statistics.
[3] Beginning 1977, based on Consumer Price Indexes of Bureau of Labor Statistics.
[4] Discontinued.
[5] New index; values for years prior to 1971 are not available.
[6] Simple average of seasonally adjusted quarterly indexes.

Economics, Statistics, and Cooperatives Service—Crop Reporting Board.

(Excerpt from AGRICULTURAL STATISTICS 1980, U.S. Department of Agriculture.)

APPENDIX B

Chronology of Pesticide Development

The following explanation of scientific and regulatory steps indicates the time frame required to bring a potential pesticide candidate from synthesis to commercial sale (diagram attached).

Point I identifies the time of synthesis. Point II shows the time for bioevaluation. As will be related below, after the initial bioevaluation (II), and if biological activity is of sufficient interest, patent actions may be initiated at Point III. Bioevaluation screening tests are designed to reveal activity of a compound. It could have commercial potential as a herbicide, plant growth regulator, fungicide, insecticide, etc., any of which activity may be useful in solving a problem in agriculture.

When the kind and degree of biological activity of a compound is sufficient to suggest commercial utility, a broader and more intensive testing program is carried out, usually followed by limited, small-scale outdoor field tests. Obviously, these require a full growing season; i.e., one crop year. If results of the first year studies are promising, small field tests across wide geographic ranges are carried out during the second growing season. If results from this broader testing still appear favorable, a decision is made to continue toward commercialization of the compound.

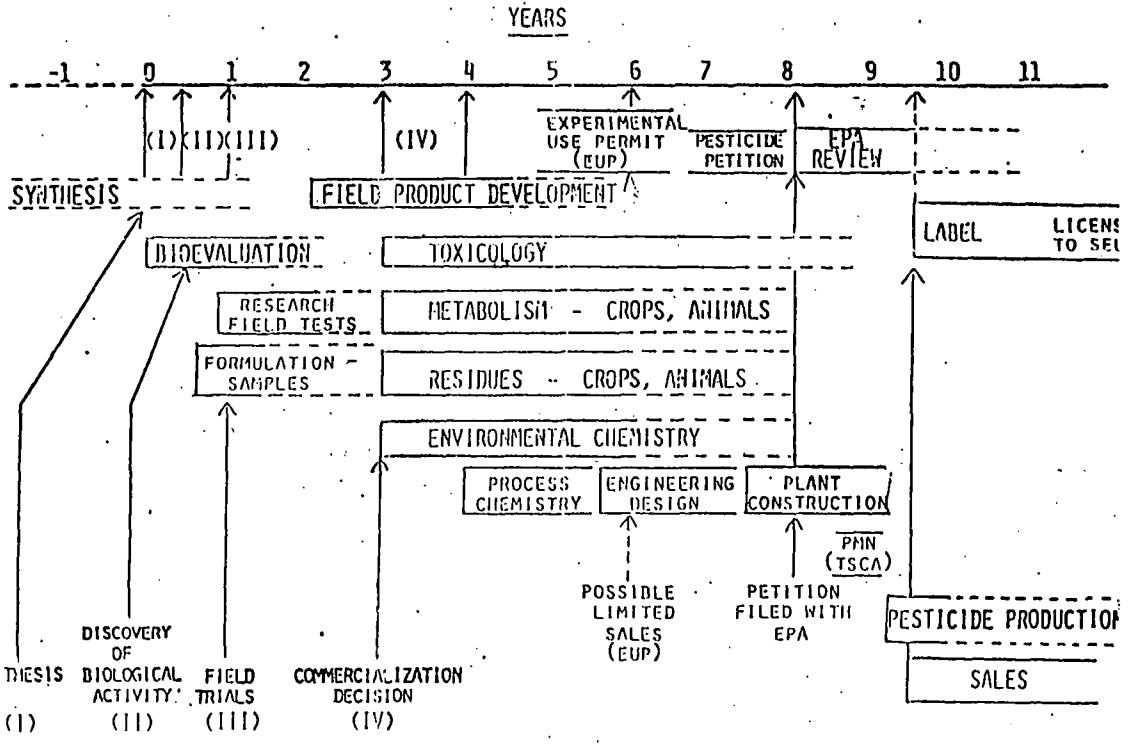
At that time, indicated by Point IV, a very lengthy and expanded research and development effort is launched. This includes generation of technical data which ultimately are used to support the registration of that commercial candidate chemical (IV). General kinds of information are depicted in rectangles. The longest run of time is five years minimum, a period now dictated by the toxicology testing requirement. The latter is a test series in prescribed sequence

to define dose-response levels for the chemical in laboratory animals. After the feeding phase of a chronic study (1.5 - 2.5 years), about one year is required to complete full examinations of all animals and to prepare the final report. Therefore, the toxicology sequence requires about five years elapsed time for completion. And the trend now is for an even longer time.

All of the other kinds of information identified in the rectangles of the diagram can be obtained within that five years. However, this is the minimum accelerated time for a well-resourced organization. The small developer cannot afford to take a risk of that magnitude. At commercial decision time (start of Point IV), toxicology, metabolism, and environmental chemistry studies are initiated. The extended field studies and other major programs are started at the onset of the next growing season. Ancillary programs such as formulation, process chemistry, process/environmental are started as resources become available. The steps leading to a manufacturing plant are carried out in that five-year period encompassing the toxicology sequence. Final manufacturing plant construction, start-up, and actual production will normally coincide with the EPA review time of 1.5 years. Ideally, sufficient inventory of the proposed new product can be prepared to meet first year market sales by the time the label is granted by EPA, provided, of course, that pre-manufacturing notice (PMN) requirements for the manufacturing process have been satisfied under the Toxic Substances Control Act. The new candidate pesticide cannot be sold until a conditional or full registration is granted and an acceptable label has been approved by EPA.

Patent activities normally commence whenever significant biological activity of a given compound is projected to have commercial utility in agriculture (III). This initiation of patent action can follow observations in greenhouse studies and a patent covering the compound and/or use of this compound may issue within 2-3 years after the initiating action. As is apparent from the diagram, this can result in loss of five or more years in the 17-year patent life.

PESTICIDE DEVELOPMENT CHRONOLOGY
FROM DISCOVERY TO SALES



APPENDIX C

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

PATENT QUESTIONNAIRE

TOTAL NUMBER OF RESPONSES: 35	Yes	No	No Answer
1. Do you have a research program which includes the synthesis of novel compounds and the screening of the compounds for utility as pesticides?	29	6	
2. Is a favorable patent position a mandatory element in making the decision to commit capital to new products ("new products" includes new uses of compounds)?	22	13	
Always		7	
Generally		6	
3. If your company commits research funds primarily with the aim of developing a superior product or to fulfill a gap in consumer need, is a secondary aim to develop patented procedures?	32	1	
Did not understand question.			1
If the word "procedures" means processes for manufacture, the answer is	1		

Brief Statement if answer is "no":
"We are primarily interested in R & D efforts toward establishing product position."

Statement with a "yes" answer:
"We consider patented chemicals and procedures to be automatic in our research, i.e. we don't debate if we should try - we expect it".

4. If research expenditures constitute a commitment of capital for your company:
   A. To what extent are patent considerations weighed in long-range research planning and funding?
      Always 28
      Generally 6
      Seldom 1
   B. If patent protection is sought on "basic" products being developed, do you also consider expanded patent positions to enlarge the parameters of research (i.e., cost reducing process patents, novel formulations)? 35

5. How important is a favorable patent position at the following stages in a research program?

	Essential	Major Importance	Slight Importance
A. Early Idea	7	14	13
B. Bench Development	11	18	6
C. Pilot Plant	19	14	1
D. Plant Design	23	11	

Note: One responded only to question "B"

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

PATENT QUESTIONNAIRE

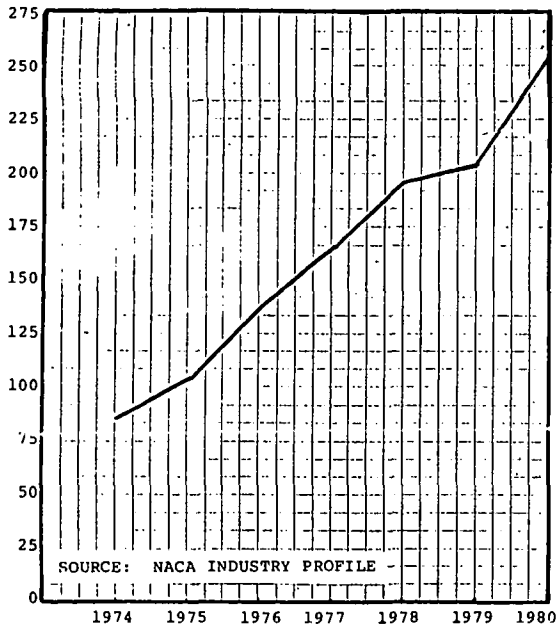
	Yes	No	No Answer
6. Do you consider foreign patent protection when committing capital for:			
A. New Products	33	2	
B. New Processes	33	2	
7. Does the discovery of the existence of third party patents tend to direct research into areas which:			
A. Are chemically related, but patently distinct?	33	2	
B. Entirely chemically unrelated?	19	14	2*
*no relevance to third party patents			
8. Do you know of instances where your patents have spurred competitors to further research?	30	5	
9. Do you know of specific instances where the existence of government regulations has reduced research efforts in a specific area?	33	2	
10. If the answer to question 9 is yes, is the reduced effort substantially the result of regulations causing long delays to obtain product registration?	29*	4	2
*Comments "but also give much weight to the uncertainty of getting product registration". "but also due to expanded test requirements".			
11. If the answer to question 10 is yes, do you favor a patent term for a new agricultural product to commence at time of product registration for a stated period of time, rather than the present term of 17 years from time of patent issuance?	29	3	3*
*Comment: Extend patent life by number of years needed to get registration.			
12. If the answer to question 11 is yes, but there is the possibility of providing the first opening to compulsory licensing after the following number of years, how would you answer?			
All blanks accounted for			
Five Years	1	16	18
Ten Years	8	14	13
Fifteen Years	23	3	9
	32	33	40

Explanation for 32 Yes replies to only 29 Yes answers in question 11:

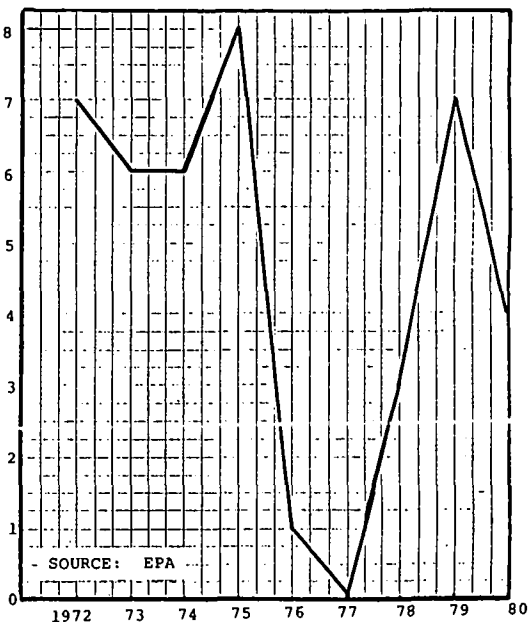
2 Yes answers checked both 10 and 15 years
1 No answer checked 5 and 10 years as Yes
1 Yes answer checked No for 5, 10 and 15 years

APPENDIX D

R&D COSTS OF NEW PRODUCTS IN MILLIONS OF DOLLARS (TOTAL PER CALENDAR YEAR)



NUMBER OF NEW AGRICULTURAL CHEMICALS REGISTERED ANNUALLY*



*First registrations for products containing new active ingredients never before registered and available on the market to agricultural producers for use on either food, feed, fiber crops and tobacco but excluding uses on ornamental crops, forests, and rangeland.

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FOR IMMEDIATE RELEASE

LACK OF PATENT PROTECTION BLUNTS PESTICIDE INNOVATION, NACA SAYS

WASHINGTON, D. C., October 7, 1981--Development of needed new crop protection chemicals will be jeopardized unless Congress reconciles the patent system with the federal pesticide regulatory process, a leading spokesman for the industry warned today.

"The agricultural chemicals industry cannot continue to undertake the massive research necessary for new pesticides without adequate patent protection," Dr. Jack D. Early, President of the National Agricultural Chemicals Association testified before the House Judiciary Subcommittee on Courts, Civil Liberties and the Administration of Justice.

Dr. Early, accompanied by NACA Board Chairman Dr. Dale E. Wolf, Vice President, Biochemicals Department, E. I. du Pont de Nemours & Company, told the panel that patent holders lose five to seven years from their 17-year patents as a result of present registration requirements for new pesticides.

This unchecked erosion not only places patent holders at an unfair advantage in recouping investment costs, he said, but serves as a discentive for the continued investment of long-term, high-risk capital in innovative pesticide research.

The NACA executive testified in support of the Patent Term Restoration Act (H.R. 1937), which would restore the portion of patent time lost during the regulatory review process.

Meeting future food demands, expected to double over the next 50 years, will require "sustained incentive and innovation on a scale never before seen in worldwide agriculture," Dr. Early said. "H.R. 1937 will stem patent devaluation and help spur pesticide innovation."

NACA is a non-profit, Washington-based trade association whose 107 members make or formulate virtually all the crop protection pesticides used in the U. S. and a large percentage used abroad.

Mr. EARLY. Mr. Chairman, we appreciate this opportunity to contribute NACA's views and indicate our support for H.R. 1937. We believe the Patent Term Restoration Act will help to maintain the incentive needed for crop protection chemicals research and development. It will restore to crop protection chemicals patent holders a portion of their patent rights which are lost as a result of the Federal registration process.

Crop protection chemicals require extensive scientific evaluation of potential toxic effects to assure public health and safety to the consumer, worker, and the environment. As a result, there has been an ever-increasing period of review for these chemicals. Regulatory review is certainly proper for the protection of our citizens. However, the regulatory review process has caused an unforeseen erosion of the patent life on new and innovative agrichemical products. In turn, this erosion is becoming a disincentive to the future research and development of new agricultural chemicals and their uses.

A recent study conducted by our industry has determined that the average time for registering a crop protection chemical is 5 to 7 years from initiation of a major health test until first registration of a label. More specifically, the time from discovery of pesticidal properties of a compound to full commercial registration increased on an average from 58 months in 1967 to 92 months in 1979, and is still increasing.

To assist the subcommittee, we have included a diagram and explanation in appendix B depicting the chronological development including the scientific and regulatory steps involved with a herbicide from initial synthesis and discovery of biological activity to the first commercial sales.

We would encourage you and members of your staffs to study this description carefully at your convenience. At a glance, you can see why many years of a new product's patent life are absorbed during the Federal regulatory process. The period of regulatory testing and review disallows earlier market development and delays the time when the consumer can benefit from the product. It then takes many years after first commercial use to research the full market penetration and total product utilization that result in maximum sales benefits. These years of market development use

up an additional part of the patent life. As a consequence of the regulatory process, the last several years of patent protection that is available for nonregulated products—a time of maximum sales—have been cut off for regulated products.

Recently Congress authorized the Office of Technology Assessment to review the effect of patent term restoration on pharmaceuticals, but a small segment of the report dealt with the agricultural chemical industry. On balance, we believe that the report supports the case for patent term restoration. In some instances, however, the report is not completely accurate, and we would refer the subcommittee to our written statement for specific references to those passages with which we take issue.

The innovative organizations—the research-intensive companies—in our industry regard the patent system as a prime motivator for undertaking costly programs in the high-risk area of new agricultural chemical research and development. Thirty-five out of forty-seven companies responded to a recent NACA survey within the association on questions relating to the impact of patents and government regulation upon their research and development. Nearly all indicated that a favorable patent position was a critical factor in determining whether to invest in new product development.

On an average, it now takes over 8 years and some $20 million to $25 million to bring a new product from discovery through registration. Normally, the construction of new and unique chemical plants to produce the technical-grade chemical is also required, at a cost of an additional $40 million to $70 million.

The NACA survey also indicated that availability of patent protection is a highly important element in long-range research planning and funding. Respondents reported that the uncertainties, cost, and delay caused by Government regulations have forced a reduction in research efforts. Appendix D of our written statement shows the trend of increasing research and development costs, yet a decreasing number of agricultural chemicals being registered. We can only conclude that without fully adequate patent protection, our member companies cannot continue to undertake the time-consuming research involved in discovering and developing new crop-protection products and still compete with other companies who can copy their successes without the heavy cost of research and development.

Our conclusion is supported by the report issued by the Conservation Foundation and utilized as a source by the OTA, which states that the time delay in bringing a product to the market is likely to be a more important factor in innovation decision than direct costs.

We would like to stress the point that in our industry, there must be a value to the farmer in order for a new agricultural chemical to gain acceptance. A patent holder is not at liberty to indiscriminately price his patented product. He must deal with today's farmers who are sophisticated, highly cost-conscious business people.

When it comes to agricultural chemicals, the farmer is looking for two things: (1) a product that will control his specific insect, weed, or disease problem; and (2) one that will provide him with a

return of $3 to $4 for every dollar invested. If a particular agricultural chemical falls short of either goal, he will choose competitive chemicals or nonchemical methods to control pests. Rarely, if ever, is a farmer limited to the choice of a single control option.

In short, agricultural chemical manufacturers cannot price their products so high that the benefit to growers is ultimately erased by forcing the growers to sell at noncompetitive prices in the marketplace.

The competitive pricing which occurs in the agricultural chemical industry is illustrated by table 649 of "Agricultural Statistics," 1980, published by the U.S. Department of Agriculture, copy attached as appendix A, which shows that since 1967, the price of agricultural chemicals has increased only 50 percent, while the prices of other farm necessities have increased as much as 187 percent.

During the past 40 years, the agricultural pesticide industry, in at least one significant instance, has created a technical revolution in the production of corn, soybeans, cotton, and many other grain crops throughout the world through the invention of preemergence herbicides. If the value to the farmer is calculated from this one concept, the total dollar improvement to the U.S. farm economy would be in excess of $5 billion per year.

The accomplishments of American agriculture comprise one of the most gratifying success stories in the annals of world history. Food production has increased in this country by two hundred fold since the turn of the century. Today, only 3 percent of the U.S. population feeds America and much of the rest of the world. In 1980, exports of agricultural products contributed almost $40 billion to our balance of payments.

Crop-protection chemicals continue to play a major role in combating losses of food and fiber to insects, disease, and weeds. The use of agricultural chemicals not only increases the quantity of our food, but also improves its quality, reduces disease to humans, increases the farmer's profits, reduces labor costs, and improves his cash flow. These achievements are due in large measure to the agricultural chemicals industry's long-term commitment to innovation in agriculture.

The U.S. agricultural chemical industry, to remain a dynamic contributor to development of such new technology, must be encouraged. H.R. 1937 will stem patent devaluation and will spur crop-protection-chemical innovation for the benefit of all Americans.

We thank you for the opportunity, Mr. Chairman. Dr. Wolf and I will be delighted to respond to any questions the committee may have.

Mr. KASTENMEIER. Thank you, Dr. Early.

Do you support H.R. 1937 in its present form, or do you have any recommendations for modification?

Mr. EARLY. We support it in its present form, Mr. Chairman.

Mr. KASTENMEIER. Let me ask a couple of general questions about the industry.

You said you represent agricultural chemicals in terms of pesticides. You do not represent the nonagricultural pesticide industry?

Mr. EARLY. That is correct, Mr. Chairman.

Mr. KASTENMEIER. Is there a substantial nonagricultural pesticide industry that would have a separate view from yours?

Mr. EARLY. There is a substantial industry outside the agricultural pesticide area represented through the Chemical Specialties Manufacturers Association here in town. We share a lot of common members within our organization. I have no reason to believe they would not support our position on this. I have not discussed it.

Mr. KASTENMEIER. You do not believe they would have a different point of view.

Mr. EARLY. They rely on innovation as much as we do.

Mr. WOLF. A research-intensive company like Du Pont belongs to both the National Agricultural Chemicals Association and the Chemical Specialties Manufacturers Association, and based upon my past association and knowledge of the CSMA, I think they would agree with NACA on this issue.

Mr. KASTENMEIER. Even if you may not have followed the preceding hearings, you know of your own knowledge I am sure that in the pharmaceutical field there are those research-intensive pharmaceutical companies and then there are the so-called production-intensive or generic part of the industry. They do not share the same view about the need for this legislation. Is there any comparable segment of your industry or the companion industry which might have a view different than yours?

Mr. EARLY. We do have a comparable situation. We refer to them in our industry as "me too" manufacturers, those who pick up at the end of the patent life. So we have a similar situation. I should point out the National Agricultural Chemical Association does represent not only the basic manufacturers of those in research and development innovation, but I would guess some 65 percent of our membership are those people that are not directly involved in the discovery and innovation of new products but would be formulating, and some would be what we would call "me too" manufacturers in this area. But I think they recognize without the innovation going on in the industry and the proper rewards being given to those willing to invest that money that the industry would not survive and the farmers would not have their product. So while they may have concerns, I think they recognize the innovator must be rewarded for his investments and time.

Mr. WOLF. Mr. Chairman, most all of their products come from the innovation of the basic manufacturers, and they do not get those products until they are discovered by someone like ourselves.

Mr. KASTENMEIER. But chances are they would still express the reservations that the generic pharmaceutical industry expresses. Would you not think so?

Mr. EARLY. I am not sure they would. We have not heard anybody in our industry saying "We object to this patent term restoration."

Mr. WOLF. "Me too" manufactures, which comprise approximately 65 percent of the NACA membership, have expressed support for patent term restoration legislation.

Mr. KASTENMEIER. As far as Federal regulatory activity goes, is the EPA the exclusive Federal agency that superintends development of new chemicals in your industry?

Mr. EARLY. Yes; they are. They are responsible for reviewing the whole registration process.

Mr. KASTENMEIER. I assume that from time to time you have concerns about delay and so forth. Could you briefly comment on the Environmental Protection Agency and its relationship to your industry with reference to approvals and regulatory treatment. Is it acceptable? Have you had an antagonistic history with the Agency?

Mr. EARLY. our industry relationship with EPA has not been antagonistic. However, there have been, and will continue to be, occasions when the industry will differ with EPA on a given issue. This, of course, is not unusual. We have had a long experience with EPA which stems back to 1970 when the Agency assumed responsibility for pesticide regulation. Moreover, with the adoption of FIFRA amendments in 1972 and 1978, our dealings with EPA intensified as we were required to perform new extensive health and environmental effects tests which, for the most part, were justifiable. What has developed over the years, as previously indicated, has been an ever-increasing period of time devoted to EPA pesticide review and registration. We are optimistic that this review process can be reduced. Further, we are constantly working with EPA to accomplish that goal. Certain things can be done to reduce the present time frame of 8 years in order to bring a new product from discovery through registration. For example, we constantly have these debates with our scientists and their scientists as to what is a valid study. Hopefully we can reduce that time. Time is such a critical factor. I think our relationships have been good. We think they are very good at the present time. We have a new administration which we are working with and we are encouraged that they are looking at the registration process very carefully inasmuch as it makes sense to look at the regulatory agencies from time to time to insure that they function properly. We are encouraged that we will see some improvement in that process.

Mr. KASTENMEIER. Before I yield to my colleagues I want to pursue the chart that you have included with your materials. It is called "Pesticide Development Chronology from Discovery to Sales." You have "Thesis" at the zero point and then you have "Pesticide Production and Sales" at the 9½-year mark. Going back it appears that at the 8-year mark, more or less, maybe a little after the 8-year mark, there is a petition filed with EPA. Then you have from that period until the 9½-year mark, "EPA Review." This means EPA has about 18 months' activity with reference to this development?

Mr. EARLY. That is not uncommon for 18 months to be required to review a new chemical pesticide, not uncommon at all. Some have taken longer. Dr. Wolf's company has had experience along that line.

Mr. KASTENMEIER. At the 8-year point is that the first time you come in contact with EPA in this process?

Mr. EARLY. Not usually. Industry representatives, primarily scientists, will engage in a constant dialog with EPA officials so as to determine what environmental and health studies are required and how these studies should be performed. Normally the first time official contact would be had with the Agency would be when one

would apply for an experimental use permit, which would be about year 6.

Mr. KASTENMEIER. It says EUP. What is that?

Mr. EARLY. Experimental use permit. With the filing of an experimental use permit, most companies have completed the vast majority of health and safety studies required by EPA and are prepared to proceed toward pesticide registration. Many companies forego filing for an EUP and apply for registration based upon the health and safety data generated under EPA direction. An EUP would allow them to do a limited amount of research on the farms with contractors, et cetera, to see if the product will really do what the registrant says it will do. He gathers some additional information also on residues and crops and animals, et cetera. So it is a controlled investigational process that the registrant goes through in that couple of years there.

Mr. KASTENMEIER. One of the things we do not see on this chart I do think the Pharmaceutical Manufacturers' Association has, is an indication of when the patents are filed, when the patent is pending and when it is likely to be granted as a corollary to this developmental statement.

Mr. EARLY. There is a brief explanation on the pages which precede the Pesticide Development Chronology. Rather than having you go through that now, Mr. Chairman, I believe if you look at the chart between 0 and 1 year. When you are in the first year, you usually have a strong indication that a product has biological activity of some kind. So you would probably file for a patent during the first year.

Mr. WOLF. It is our experience that when you find biological activity in a new compound you would file a patent. This would normally occur approximately 6 months to 1½ years after synthesis.

Mr. EARLY. Given the present patent system, it would probably take 2 years before a patent would issue once application is made, so that on average your patent would not begin to run until year 3. This will vary, of course.

Mr. KASTENMEIER. Unlike the situation suggested by the pharmaceutical industry, it does not appear that EPA or EPA review is the delaying factor in commercialization in sales or production. Indeed, your first contact with the EPA is to get the experimental use permit at year 6 and then to have review after year 8. So in terms of the delay from year 3 they are a factor, but maybe only incidental.

Mr. EARLY. That is not really correct. Prior to the filing of an EUP, companies engage in elaborate and costly testing in order to generate the necessary information required by EPA to obtain an experimental use permit. Toxicology, metabolism, and residue studies are the type of tests conducted in order to obtain an EUP. These studies can extend for everal years, as indicated on the chart. That is going on as a requirement in order to get an experimental use permit.

Mr. KASTENMEIER. I yield to my colleague from Michigan.

Mr. SAWYER. You said you file for a patent as soon as you observe biological activity. I do not know what you mean.

Mr. WOLF. We test any new chemical to determine whether it has any effect on insects, diseases, weeds, or other effects. But if you notice in the greenhouse some outstanding biological activity, either it controls one of those or it does not. If it does control it you would say I have found a new discovery, a chemical that will do something that maybe nothing else will do or do it better. At that point you would file a patent.

Mr. KASTENMEIER. At this point I yield to the gentleman from Illinois, Mr. Railsback.

Mr. RAILSBACK. Thank you very much. I am curious about the relationship, if any, of the fertilizer manufacturers with the so-called pesticide manufacturers. For instance I know some people that are involved with a firm called Liquid Grow in Iowa that I think engage primarily in the production of liquid fertilizer. Is there any correlation or do you speak for them or would they have the same problem?

Mr. EARLY. We do not represent the fertilizer industry at all. That is represented through another group. We are strictly what we call the crop-protection-chemical area or pesticide.

Mr. RAILSBACK. Are you familiar with their situation? Would it be similar as far as regulatory clearance and review?

Mr. WOLF. They do not have the same EPA clearance requirements as we do. As soon as a fertilizer company can determine that its product is effective, it can register the product through the appropriate State agency and sell it. You do not need a Federal clearance.

Mr. RAILSBACK. You indicate in your statement that the Government research is really not very helpful from the standpoint of patentability of new innovative chemical pesticides. You also indicate that one of the reasons for that is when the Government research does reveal something that may be very useful, it goes public with it. I am just curious, this is a question that may not be exactly relevant to the area, but I am curious. We have had a lot of questions surrounding that substance referred to which was used in Vietnam called agent orange. Was that a patented chemical herbicide, or was it something that came from the Government?

Mr. EARLY. Agent orange is a combination of two herbicides, 2,4-D plus 2,4,5-T. I am not aware that either of those were on patent.

Mr. WOLF. The original patent was controlled by a company called American Chemical Paint Co. as a matter of fact. On the 2,4,5-T part, I do not know that it was patented.

Mr. RAILSBACK. Is it now no longer under patent?

Mr. EARLY. No.

Mr. RAILSBACK. How do you feel about chemical patent applications that may be in the pipeline that would not be extended under this legislation? Do you have any feelings about that?

Mr. WOLF. In its present form, the bill is designed to create additional incentives for future research and development, which we heartily support. Some believe, however, that innovation can receive an additional boost if the proposed legislation was made retroactive to some degree. But again, we are comfortable with the committee's present focus upon future innovation.

Mr. RAILSBACK. To follow on one of the questions the chairman asked, I am curious too about what happens when patent life does

expire in your industry. Is there a substantial drop when you have the "me-tooers" come in, a substantial drop in prices?

Mr. WOLF. A drop in price for agriculture chemicals results when a competing product which can perform in similar fashion enters the marketplace. The patent on the original agrichemical product may or may not have run out when this competing product comes in. There are a few examples where the price did drop at the end of a patent period. This usually results from overseas imports where, because of a lack of patent law or effective patent law enforcement, those products have been made before our patent runs out in the United States.

Mr. RAILSBACK. Are the "me-tooers" formally research-intensive companies? In other words, the majors that pick up the expired——

Mr. WOLF. In very rare cases.

Mr. RAILSBACK. The majors will then produce the substance. Will they call it a different generic name or what?

Mr. WOLF. They will call it a different trademark name, but there are very few cases that I can cite to you where major companies have come into the "me too" business. Frankly you cannot support the research you are doing on a product at that stage in its lifetime, normally.

Mr. RAILSBACK. You say normally, the majors do not come in——

Mr. WOLF. Normally they do not.

Mr. RAILSBACK. Who does then come in, just small companies?

Mr. WOLF. A great number of overseas imports come from countries like Hungary and Israel where the product is made while the patent is valid here.

Mr. RAILSBACK. Do they have to go through any clearance with EPA?

Mr. WOLF. Yes, they do have to, but EPA, as the FIFRA law is written they can use data which has been supplied by our industry.

Mr. KASTENMEIER. The gentleman from Michigan.

Mr. SAWYER. Do you feel that a process patent ought to be covered?

Mr. WOLF. In the field of agricultural chemicals I think process chemical patents are of little value. Usually that does not help at all in extending the patent life of the product, since by the time the patent runs out you have disclosed to the public, via that patent, the process information so that a competitor could pick that up anyway. I would say, unlike some areas such as the basic chemical industry, process patents are not all that valuable in the case of agricultural chemicals at present. Process patents will be highly important in some newer fields, such as the production of old pharmaceuticals, agrichemicals, and industrial chemicals by new biological methods.

Mr. SAWYER. We have heard the argument raised that if you get additional uses, you can really extend the patent beyond the intention of this bill.

Mr. EARLY. That is not correct, Mr. Sawyer. Under the terms of the bill, the period of patent extension for pesticides is limited to the initial registration with EPA. Thus, there is no possibility of receiving additional patent term extensions based upon additional EPA use registrations.

Mr. KASTENMEIER. In that regard—and this proceeds from earlier questions we have had from the pharmaceutical industry—how difficult or how easy is it to copy agricultural chemicals when they go off patent? That is to say one of these small competitors. Is it difficult or is it rather easy for them to do so?

Mr. WOLF. It would vary by chemicals. Some chemicals are easy to make. And there are some of those that could be easily copied. Others which are very complicated or require a specific raw material, it would be more difficult, but there are very few of the latter kind in the agrichemical business. They are easy to copy as a general rule.

Mr. KASTENMEIER. I think that was the testimony in the pharmaceutical industry, although I note you refer to plant construction, which suggests that it may be more costly to get into the production of a given chemical than it might otherwise be unless a comparable pharmaceutical investment took place.

Mr. WOLF. Generally agrichemicals, the portion that comes from the cost of manufacturing is higher than the cost for those similar pharmaceutical products.

Mr. KASTENMEIER. With reference to foreign competition or foreign sales, does Federal regulatory delay restrict your ability to sell in these markets abroad, and if it does or does not, what safeguards or what hurdles do other nations have with reference to American herbicides?

Mr. WOLF. You are talking about shipping U.S. products abroad?

Mr. KASTENMEIER. Yes.

Mr. EARLY. We have a notification process whereby we must notify the Environmental Protection Agency if we are shipping abroad a material that is not registered for use in the United States. There is also a notification process that goes from EPA through the State Department that notifies all friendly countries around the world whenever the Agency makes a decision on whether a product should be banned or suspended or canceled or restricted in some form. So there is a notification process that goes out. Beyond that every country, almost every country certainly in the Western World and increasingly more in the Third World—are establishing their own registration process. For example, if Dr. Wolf wants to sell a herbicide in Germany he must go through their registration process in Germany in order to sell the product in Germany which is similar to what we have in this country. He must go through that whole process.

Mr. WOLF. Perhaps worldwide there are some countries that you can obtain registration several years earlier for a particular item than you could in the United States. In many of these countries, such as West Germany, Japan, and France, it is just as difficult and takes just as long as it does in the United States.

Mr. KASTENMEIER. In these first countries you mentioned, the ones that are easier, in that respect the U.S. regulatory process for delay does not necessarily affect your ability to market products in those countries?

Mr. WOLF. Not necessarily, but more so every year, Congressman, because there are more countries around the world that pay attention to what the United States does in the registration area.

Mr. RAILSBACK. Mr. Chairman, can I ask a question?

In those countries where you do have a similar length of regulatory review process, is there patent life extension?

Mr. WOLF. One is able to obtain a patent life extension in the United Kingdom, for example. While I cannot speak for every country, I know there are others which provide for some sort of patent compensation for time lost in the regulatory review process.

Mr. RAILSBACK. We are led to believe that in some countries as far as drug patents they were easier to come by and that regulatory review process was not as long.

Mr. WOLF. I am sure that is true.

Mr. EARLY. I think generally that is true for our industry. If you look at all the countries around the world you would have to say the review process and the requirements for registration in the United States would take longer on the average than most countries around the world. I think you would agree with that.

Mr. WOLF. No question.

Mr. KASTENMEIER. If there are no further questions, the subcommittee thanks you both for your very able presentation this morning. We appreciate it.

Mr. WOLF. May I take 1 minute to comment on the real need for patent term restoration. It comes down to what is today a real problem of increasing productivity in the United States in farming. One of the ways you are going to get that and get farming to be less energy intensive is to encourage new innovation. Those of you who come from farming areas are aware this is a pretty tough year for profit in agriculture even though crop yields are good. If you look ahead with the job we have to do and the amount of energy that is used on farms, one of the things we must do in my opinion being an ex-farmer is find more ways that the farmer can do his job with less money and keep the cost of food down. We have to produce more food, and we have to produce it at less than the rest of the world is doing.

Mr. KASTENMEIER. I appreciate those comments. I believe in American agriculture. We are today taking up the farm bill as a matter of fact in terms of what programs we will have for various commodities. That is all part of the question of how we can enable American agriculture to succeed. We appreciate your testimony. Thank you.

Mr. KASTENMEIER. The Chair now would like to call an old friend, director of licensing at Wisconsin Alumni Research Foundation, Mr. Marvin Woerpel, who came in from Madison today. We appreciate this testimony because it deals with the practices of the nonprofit organization in terms of questions of patent application. Mr. Woerpel, we are pleased to have you.

TESTIMONY OF MARVIN WOERPEL, DIRECTOR OF LICENSING, WISCONSIN ALUMNI RESEARCH FOUNDATION

Mr. WOERPEL. Thank you, Mr. Chairman. I appreciate and thank you and the other committee members and staff as well for the opportunity to appear before it to present testimony relevant to H.R. 1937, the Patent Term Restoration Act. I hope, in the few minutes available, to acquaint you with the important and considerable impact which this legislation, when passed, can have on the

university community in general, and upon the University of Wisconsin in particular.

First, may I briefly qualify myself. I am now the director of licensing for the Wisconsin Alumni Research Foundation [WARF] and have been such for 20 years, following nearly 10 years of service as the assistant director of licensing. I am a member of the Licensing Executive Society, an international organization committed to the profession of technology transfer, and currently serve on the board of trustees United States/Canada segment of that organization.

For the benefit of committee members and staff not so well acquainted with our foundation as you are, Mr. Chairman, WARF is a corporation which exists for the purpose of supporting research at the University of Wisconsin in two ways. These are: First, to provide a channel through which discoveries made at the university can be transferred to the industrial sector; and second, to grant moneys received for the use of such discoveries to the university to support new research.

WARF is fully set apart from the university but exists solely for the benefit of the University of Wisconsin. The university inventors are not obligated to take inventions to WARF, but do so on a voluntary basis. In turn, WARF's grants are to the university, not back to individuals. WARF has operated in this manner since 1925.

Through the unique combination of the strong life-science research which has long characterized the University of Wisconsin, Madison, and the effective use of the patent system which works so well for chemical inventions, WARF's contribution to the American people has been greatest in foods and pharmaceuticals. Its role in bringing Steenbock's vitamin D to the U.S. milk supply in the thirties, followed by improved iodine retention in table salt as taught by Professor Hart, is widely recognized. These were followed by Professor Link's discovery of the anticoagulent warfarin, which came to mean death to rodents but life to humans.

I take time to mention these because, of course, it is this class of invention which today is most affected by the necessary but time-consuming regulation by Federal agencies. You have already received extensive testimony from the affected industries which will document and support the substantial public benefit which can accrue from this legislation. Let me assure you that the universities will also be beneficiaries of patent term restoration.

Because warfarin continues to make a major contribution to the control of rodents even though the patents expired long ago, I thought it might provide an interesting and relevant case history. Our files show that the patent application was filed on April 2, 1945, and the patent issued on September 16, 1947. Licensing efforts with the established marketers of rodenticides failed to generate any licenses. WARF itself undertook to obtain the necessary permits from the USDA to facilitate field testing by pest control operators. Please recall that these were the good old days fondly remembered by those who today must register such a compound with the EPA.

The permit was first discussed on June 1, 1949, with USDA representatives and permission to market on an experimental basis was granted September 1949. I might contrast that to the 6 years

on the chart that was just shown you by Dr. Early. By June 29, 1950, the tests were finished and registration completed.

Licenses were granted on December 1, 1950, and WARF royalty income in 1950 amounted to $248,394 and averaged $300,000 per year until patent expiration in 1964.

The regulatory delay of only 1 year—trivial by today's standards—can be presumed to have cost the University of Wisconsin $300,000 in lost revenues. The time required before EPA today would probably exceed 2 years and the loss to the university proportionately increased.

These dollar amounts achieve greater significance in terms of WARF's annual royalty income which in the same period totaled only about $600,000 per year. Hence the lost revenue would have formed a substantial portion of the WARF annual grant to the University of Wisconsin in support of research.

When discoveries are made at the University of Wisconsin the information is promptly published by means of theses, scientific papers, seminars, and technical programs. Patentability requirements are not permitted to impede this flow of information. The U.S. patent laws provide, however, that prior publication prohibits the granting of patent protection if the publication of an invention occurs more than 1 year prior to the filing of a patent application. Thus WARF must make its invention evaluations and file patent applications promptly to preserve rights, yet the better understanding of the invention and its probable worth is usually developed as the result of later studies. During that rather time-consuming process the viable patent term inexorably diminishes.

While an invention may be considered to be complete by a university scientist, his industrial counterpart will consider the project to have only been begun. True public benefit from the invention cannot accrue until the safety and efficacy of the product is established through expensive and time-consuming tests. The task of convincing the market or the market-serving delivery systems of the merit of the invention also remains to be accomplished which, too, requires a major investment. Little wonder that only the best of university output reaches the outside world.

It is our task at WARF to cross this interface. This has become increasingly difficult during my career, which spans the period during which the Federal regulation of foods, pharmaceuticals, pesticides, and other agricultural chemicals has become more expensive and time-consuming, and the time for the licensee to recoup its investment has grown proportionately shorter.

As do all new product-related enterprises, WARF must invest in 10 or more inventions to average 1 that will produce revenue. To lose a large proportion of the patent term to regulatory delay on the successful ones simply reduces either our ability to license new inventions or adversely affects WARF's grant for additional research at the university.

Mr. KASTENMEIER. I must regretfully interfere with the concluding remarks to announce we do have a vote in progress and in order for Mr. Railsback and myself to make that vote we are going to have to leave right now. With your indulgence we will recess the committee hearing for about 10 minutes, and we will return to you as soon as we can get back.

The committee is therefore recessed for 10 minutes.

[Recess.]

Mr. KASTENMEIER. The committee will come to order.

The committee will try to move along in anticipation that there might be subsequent votes and interruptions. Mr. Woerpel, we interrupted you. Will you be good enough to continue.

Mr. WOERPEL. As you may imagine, there are many colleges and universities which own patents and aspire to augment their budgets with patent-related income. There is a Society of University Patent Administrators [SUPA], the membership of which represents about 100 such institutions. Although not authorized to do so, I know that I speak for all of them in presenting my support for H.R. 1937.

University inventions are filed early resulting in early patent dates, yet suffer long development times which have become even longer due to Federal regulation. H.R. 1937 will redress this to a major extent. Please work for its passage in the House of Representatives.

If H.R. 1937 is passed, it will be because you and your colleagues consider it to be in the interest of the public. That being the case, may I ask why should its benefit be limited to inventions approved after its enactment? WARF and many other owners of existing patents have suffered the shortening of the life of currently productive patents. We recommend, therefore, that the bill be modified to provide its benefits to those products which have completed the regulatory review but whose patents have not expired.

Three of WARF's 25 commercially used patents were substantially delayed by the regulatory process, but are now in the marketplace and producing income which will be applied to further university research efforts. We also own patents or patent applications on 19 other inventions which must, before they can provide public benefit, pass Federal regulatory review.

To summarize: U.S. universities do $5 billion of research annually with funds supplied by the public through Government agencies. The resulting discoveries and/or technology developed will accrue to the benefit of the public only when industry adopts them and finishes the complex task of readying them for commercial use. Federal regulations slow this process, make it more expensive, but worst of all, increase its uncertainty.

As a result, those of us charged with the responsibility for the transfer are successful with only those inventions for which the perceived risk is least.

Passage of H.R. 1937 will change this balance favorably toward more inventions being accepted for development by industry. This will benefit the public, the industry, and the university sources of the new product.

I too will be happy to answer any questions that you may have of me.

Mr. KASTENMEIER. Thank you, Mr. Woerpel. I would like to first yield to my colleague from Michigan. I have several questions, but I will defer them until he has had an opportunity.

Mr. SAWYER. I am pleased to hear your testimony. I also might comment the University of Wisconsin—over the years of practicing law in Michigan I had a lot of clients—I am not sure they are the

only university that are heavily into patents, but they are the ones whose names come up in my experience far more often than others.

I do not think I have any questions, Mr. Chairman.

Mr. KASTENMEIER. Mr. Woerpel, I do have a question. You ask why it should not be retroactive. Indeed, this is a question which has been raised in some particular situations. The Senate raised this and treated it in terms of individual cases where the equity seemed to indicate that the company ought to be made whole in this connection. But generally I think you are aware that—and it is so argued—that we legislate prospectively, particularly in the field of intellectual property, where what we presume to do is offer it as an inducement to innovation rather than as a windfall for past discoveries that cannot any longer be affected, at least in terms of inducing those discoveries. That is one of the primary facts here. We also have the problem of whether other competing parts of industry would be deprived of an earlier access to invention, in pharmaceuticals, whether generic or otherwise. It is not merely an awarding of an additional term without some other effect on competitors.

I would like to ask you whether—and you very descriptively suggested difficulties that are caused by delay, not even solely in the current regulatory system but in the past, for new drugs and chemicals—but that suggests the question, would not a better response to the problem be to eliminate the delays through regulatory reform than to amend the patent laws?

Mr. WOERPEL. I think part of the answer to that question lies in the table that you were looking at when Dr. Early was here this morning, and you were looking at that period that began in 6 years rather than in the last 18 months of that period. It seems to me that the efforts to reduce regulatory delay will have their greatest effect on that most visible part of what the agency is doing. The invisible part, the part you were not even aware of apparently—or at least it was pointed out this morning—is that pre-NDA or prenew pesticide, whatever that is called—I have forgotten—but there is a lot of work that goes on between the representatives of a company and the regulatory agency to decide on what test protocol should be used; in fact even the extent of testing that may be required in different geographical areas. All of that is part of the regulatory process even though it does not appear officially in response to the new drug application. I believe that even though that is shortened quite a bit—I mentioned we have three inventions that are currently in the mill—these all happen to be pharmaceuticals—from NDA, which is the official application for the new drug, registration period until application was approved was 14 months, 15 months, and 11½ months respectively, all of which are reasonably short and good. We would be happy to just get those periods added back into our patent life. However, the real work began in the case of one of those 3 years earlier, one 9 years, and another one 10 years before the issuance of the new drug application.

So I would be selfish enough to want to have both the Patent Term Restoration Act and the shortening of the regulatory process as well.

Mr. KASTENMEIER. For the moment, looking at the regulatory process, is the complaint the amount of time, or is it the delays, or is it what is required? That is, what degree of safety or whatever the regulatory agency, whether it is EPA or FDA insists on. Is it the time element itself or is it the barriers, the difficulties presented by virtue of what they believe necessary to insure safety and efficacy?

Mr. WOERPEL. I am really not in the best position to answer that question. I think that the people in industry will know that, whereas I can only surmise. I would remind you that when we take technology from the university into the industrial sphere we are taking what we call a bare bones patent. We have little technology to carry along with it. We at WARF do not represent the inventor except in this one legal sense. So when we take the technology out we are talking to people who have to take lots of risks. They do not even have a good sense of how good our technology is in the first place. They do not understand it as well as if they had done the work themselves. But what we sense when we try to transfer at this point with that underdeveloped technology is a great reticence to take the risks that will involve both time and particularly dollars to take this invention all the way through that process. But which aspect of that looms the larger in their minds I do not think we would be able to tell. It probably differs case by case.

Mr. KASTENMEIER. We have heard testimony that American innovation in the drug field has declined at least in the raw numbers of new drugs that are being developed or are on the market. Frankly I do not think we are qualified to make a judgment as to the meaning or existence of that decline. Do you from your perspective believe that genuine innovation is declining in America and needs added incentive such as this bill?

Mr. WOERPEL. My visceral reaction is I do believe that. Whether I could document it adequately for your satisfaction I doubt. I think again looking at that element of innovation that arises at the universities I think university researchers are going to continue to research if they can be granted enough funds to do the work. They do not do the work in the first place for the production of a product. They do it for the creation of knowledge, and this matter of having an invention that is patentable and useful is really secondary, a very important benefit to the university and society, but as far as the individual researcher not his primary motivation, therefore I do not think that research is diminished in quantity or quality at our university or perhaps at any of the others during this period where we overall as a country, seem to be slipping, but it does not seem to be in the university sector.

Mr. KASTENMEIER. Are you also saying, Mr. Woerpel, that the university or other similar institutions have less to gain by adoption of this bill than the pharmaceutical companies?

Mr. WOERPEL. Proportionately I think so. For example, at Wisconsin, WARF's annual grant amounts to 5 percent of the research budget. Even if we were able to let us assume double our income as a result of this legislation—which I am sure would not be the case—it would not have a proportionately great influence on the university's research budget.

Mr. KASTENMEIER. My last question is on H.R. 1937. You suggested one possibility, that is retroactivity. Are there any other changes or areas that we ought to consider in connection with this bill other than what the bill presently provides?

Mr. WOERPEL. Mr. Sawyer asked the question earlier whether process claims should be included. There are times in our experience where an old compound—old in the sense that it is no longer patentable under the U.S. rules—has been studied and a new use found. It is possible to patent for use in the United States, but many times new synthesis that is particularly expeditious and efficient could provide a means for controlling the compound and be perhaps the only patent that would be available at that point. In that case I think it would be perfectly reasonable to extend the term of that patent for any regulatory delay that had been experienced, as well as the product package. We do not have as many of this kind of inventions, and do not have as much experience with it.

Mr. KASTENMEIER. I think you may be the first person to suggest that. I do not think the Pharmaceutical Manufacturers Association suggested that, but that is of interest that you think use patents might also be subject to extended protection.

What about process patents?

Mr. WOERPEL. I would have included those. The process of the manufacturer would be one of the claims that would be involved.

Mr. KASTENMEIER. What about other industries such as Mobil Oil Co. for example? It is essentially a processing manufacturer in some of these fields. It might include its products and it might also be included?

Mr. WOERPEL. I think this becomes philosophical. It is the intent of the legislation and it seems to me it is important legislation because I truly believe it will increase the amount of R. & D., the numbers of inventions will be increased that will be looked at and taken farther along the process to see whether they are in fact marketable. If that happens, the public will be well served by new and more products to choose from, and to the extent that the intent of the legislation is to provide that, it seems to me there should be no limit on the technology or the limit of the form of the patent coverage that legitimizes that.

Mr. KASTENMEIER. Thank you very much, Mr. Woerpel, for your help here today. I suspect indeed you do speak not only for the University of Wisconsin Research Foundation, but probably the general thrust of your ideas would be concurred in by the other 100 institutions. In any event we appreciate your testimony, and this will conclude today's hearings on patent term restoration. We have yet to receive testimony from the administration, from at least one consumer organization. Until we can set those dates firmly this will conclude at least today's hearing, and we will announce further hearings in the next few days.

Until that time the committee stands adjourned.

[Whereupon, at 11:30 a.m., the subcommittee adjourned, to reconvene at the call of the Chair.]

PATENT TERM RESTORATION ACT OF 1981

THURSDAY, NOVEMBER 5, 1981

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES
AND THE ADMINISTRATION OF JUSTICE
OF THE COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to call, at 10:15 a.m., in room 2226, Rayburn House Office Building, Hon. Robert W. Kastenmeier (chairman of the subcommittee) presiding.

Present: Representatives Kastenmeier, Sawyer, and Butler.

Also present: Bruce A. Lehman, counsel; Timothy A. Boggs, professional staff member; Thomas E. Mooney, associate counsel; and Audrey Marcus, clerk.

Mr. KASTENMEIER. The committee will come to order.

We are convening this morning for the continuation of our hearings on patent term restoration, H.R. 1937 and S. 255.

This morning, we are very pleased to have as witnesses the Commissioner of the Food and Drug Administration, Hon. Arthur Hull Hayes, and also representing the Environmental Protection Agency, Mr. Edwin H. Clark II, who is the Acting Assistant Administrator for Pesticides and Toxic Substances.

We are pleased to have you both.

Dr. Hayes, I would call on first, who is, I think, accompanied by two of his associates, and then we will defer questioning until Mr. Clark has also testified, since, to a very great extent, questions and colloquy, deal in some respects with both agencies. That will afford us an opportunity to get comparative comments.

Therefore, I am very pleased to greet and have you proceed first, Dr. Arthur Hull Hayes.

TESTIMONY OF ARTHUR HULL HAYES, JR., M.D., COMMISSIONER OF FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY THOMAS SCARLETT, CHIEF COUNSEL, OFFICE OF GENERAL COUNSEL, FOOD AND DRUG DIVISION, AND J. RICHARD CROUT, M.D., DIRECTOR, BUREAU OF DRUGS; AND EDWIN H. CLARK II, ACTING ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

Dr. HAYES. Mr. Chairman, I am pleased to be here today and discuss the drug approval process with you and other members of the subcommittee.

As a clinical pharmacologist with professional experience in new drug investigations, I had great interest in the drug approval proc-

ess long before becoming Commissioner. I view the issue of patent life and pharmaceutical innovation as a very important one, and I wholeheartedly agree that there is a need for a careful examination of the issue.

The Department already has expressed support for patent life extension legislation, now pending in the Congress, as a means of preserving innovative pharmaceutical research. New drugs generally require extensive and expensive development and testing before they can be marketed. In an industry where high development costs and risk of failure are standard and small potential markets are not uncommon, it is important to preserve incentives for investment and innovation.

We are working to reduce the premarket approval process time by revising the new drug regulations and through the efforts of a 21-member task force—for the review and improvement of the drug approval process—which I recently appointed. We have received many suggestions for improvement and are looking forward to receiving the recommendations of the Commission on the Federal Drug Approval Process sponsored by Members of Congress, James H. Scheuer and Albert Gore, Jr.

Regardless of the outcome of these efforts, our premarket approval system must continue to be thorough enough to assure the safety and efficacy of new drugs, even if that means living with a process that takes longer than we would ideally prefer. We cannot encourage innovation at the expense of safety.

Let me explain briefly how the regulatory process for new drugs works, to give you some sense of the time and effort involved. Most new chemicals that are going to become drugs are initially identified by the drug industry through a process of studying thousands of new molecules for biological activity. Compounds that appear promising are then examined more carefully in animals for their potentially useful effects, and short-term toxicity tests are also conducted.

At this point, a compound that shows medical promise, appears reasonably nontoxic in animals, and has sufficient marketing potential is ready for early evaluation in humans. By this time the manufacturer has usually applied for a patent on the new compound, and perhaps 1 to 3 years have gone by since its initial synthesis.

At this point, the proposed new drug encounters the drug regulatory system. Prior to testing the new drug in humans, the manufacturer must file with FDA an investigational new drug [IND] notice.

One intent of this regulatory review is to protect the safety of persons who participate in drug research and to assure their rights, particularly that they have given their voluntary and informed consent.

A secondary intent of this review is to assure the scientific quality of studies conducted in humans so that meaningful data are obtained.

After obtaining an IND, the manufacturer is free to proceed with research on the new drug, providing he keeps the FDA informed of new studies, reports progress, and alerts the FDA and the clinical

investigators immediately if unforeseen serious side effects or injuries occur.

Parallel with these clinical studies, the manufacturer conducts more extensive toxicological studies in animals to evaluate the potential for adverse effects on reproduction or the developing fetus and the potential for carcinogenicity. Simultaneously, the manufacturer develops the final dosage form—for example, tablet or capsule—and evaluates its absorption by the body. He also scales up the production process and develops control procedures to assure the manufacturing quality of the final product.

The length of the investigational phase, from submission of an IND to submission of a new drug application [NDA] is highly variable from drug to drug. The period depends upon the amount of information needed for the particular drug, the scientific and technical problems encountered in the research studies, and the priority given to the drug by the manufacturer in his overall product development program.

When the investigational phase is completed, the manufacturer gathers together the results of all studies and submits them to FDA in a new drug application. This application is reviewed in detail by a team of reviewers, including a physician, a toxicologist, a chemist, a biopharmaceutics expert, and a statistician.

The purpose of FDA review of an NDA is to determine whether the drug meets the statutory standards for marketing, namely the standards for safety, effectiveness, labeling, and manufacturing. The statute provides a limit of 180 days for this review. However, most NDAs are not approved after the first review cycle because of deficiencies in one or more of these areas. Eventually about 85 percent of the NDAs submitted by major drug firms are approved but usually this is after a second or third review cycle. The overall time from submission of an NDA to its approval may vary from 6 months to several years. For new molecular entities, which are the most difficult and controversial applications, the total time has averaged 2 to 3 years over the past decade; in 1980, it was 2 years.

The adequate and well-controlled trials requirement in the 1962 Drug amendments has literally revolutionized the number and quality of clinical trials on drugs. Such trials were uncommon in the 1960s but today are the standard approval to evaluating the merits, or lack thereof, of new therapies in general. Over the past 20 years, this process has resulted in an enormous improvement in our knowledge about new drugs.

The result is that the huge numbers of questionable combination drugs and the overblown claims that once encumbered three-fourths of the products in the prescription marketplace are gone. Instead, we now have new drugs that have been scientifically studied and which really work; they have been tested carefully and are accurately labeled. While reasonable persons may disagree today on the merits of individual regulatory requirements or on particular drug decisions, no one who has seen the sweep of drug development over the past 30 years can help but be impressed by the quality of the modern-day drug development enterprise.

A number of trends which affect and are affected by our regulatory review should be taken into account in determining the effect of patent life on innovation. One trend is the rising estimated cost

of drug development. We at the FDA are in no position to judge the accuracy of the various estimates which have been given. Clearly, some of this increase is due to inflation and higher interest rates; further, these estimates include the cost of unsuccessful products and of the capitalizing of research expenditures. Nevertheless, it is self-evident that the extensive scientific information supporting a new drug today makes the cost of development far greater than it once was.

An additional trend has been an increase in the time required to develop a new drug. During the late 1960s and early 1970s the average time from the submission of an IND to the submission of an NDA was about 3 years. Today, however, it has risen to 5 years. Coupled with the average time of 2 years for NDA review, this means that the average new molecular entity entering the market today has been under development for 7 years, plus the 1 to 3 years that occurred before the IND was submitted. FDA does not have data to estimate the impact of those times on effective patent life.

I would also emphasize that the last few decades have seen an extensive evolution in science and medicine and this has increased enormously the complexity of drug development. New drug development in the future is going to be an even more technically complex and expensive process. When considering the adequacy of incentives for innovation, we need to recognize this long-term trend.

Another need to be recognized is that involving a group of drugs that has perhaps suffered more than any other in the drug development process. Known as "Orphan Drugs" or drugs having low commercial interest, their unavailability has been a public issue for several years. FDA has chaired the Interagency Task Force on Significant Drugs of Limited Commercial Value, which in its report of June 29, 1979, presented a number of options for dealing with the problem. We are now cooperating with the Commission on Drugs for Rare Diseases sponsored by the Pharmaceutical Manufacturers Association. While progress is being made, any steps taken to encourage innovation would hopefully be of value in alleviating this problem.

In summary, Mr. Chairman, an extensive amount of information is required to support the approval of a new drug for marketing. But requiring such information does take time and money. The average time from the synthesis of a new molecular entity to its approval for marketing as a drug is on the order of 8 to 10 years. The average time for development of innovative dosage forms and minor chemical variants—for example, salts or esters—of already established entities is probably somewhat less.

These long, development times have led to safer and better products, but they also may adversely affect innovation by cutting into the patent lives of drugs. For this reason, the Department has supported the principle of patent life extensions as a matter of equity to drug manufacturers and as an incentive for innovation.

I emphasize that these times are not the time for approval by FDA. The actual review and approval or disapproval of an application takes only a portion of this time. The bulk of this time is taken up by the research and development process in industry.

Mr. Chairman, this ends my formal statement. My colleagues and I will be pleased to answer any questions the subcommittee may have.

Mr. KASTENMEIER. Thank you, Dr. Hayes, for a concise and appropriate statement. We will have some questions and we appreciate your comments.

At this point, I would call on Mr. Clark.

Mr. CLARK. Good morning, Mr. Chairman. I am Edwin H. Clark II, Acting Assistant Administrator for Pesticides and Toxic Substances of the U.S. Environmental Protection Agency. My office has responsibility for implementing the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA] and the Toxic Substances Control Act [TSCA]. I welcome the opportunity to appear before you today to discuss the premarket review and clearance activities under these statutes.

In your letter of invitation, you requested that we discuss the procedures used by EPA for approving chemical products for marketing, to aid your consideration of the Patent Term Restoration Act of 1981. I am happy to comply with your request and, instead of offering any comments on the proposed legislation, I will discuss our activities under TSCA, FIFRA, and the Federal Food, Drug, and Cosmetic Act [FFDCA]. In doing so, I will relate these procedures to the time, expense and testing requirements they place upon the applicants.

Before describing the individual programs, I would like to make two general observations regarding them. The first is that the fundamental regulatory approaches of the two programs are very different. Under the pesticide program EPA must approve and register any pesticide before it can be used in the United States. Under TSCA, the Agency does not have this responsibility; but is given a limited period in which to review proposed new chemicals in order to determine whether any action should be undertaken to limit their use.

The second observation is that the basic decision rules in both programs are the same—they are both "balancing acts" which require a comparison between the risks that may be associated with a chemical's use and the benefits that those uses will provide.

Under section 5 of the Toxic Substances Control Act [TSCA] any person intending to manufacture or import a new chemical substance for commercial purposes in the United States must submit a notice to the Environmental Protection Agency [EPA] at least 90 days before beginning manufacture or import. This is called the Premanufacture Notice [PMN]. A new chemical substance is one not included on EPA's inventory of existing substances compiled under section 8 of TSCA. Chemicals already regulated under another Federal statute—for instance, pesticides, drugs, food additives, et cetera—are exempted from this notification requirement and from any other regulatory activity under TSCA.

Each PMN must include the name of the chemical, its chemical identity and molecular structure, proposed categories of use, an estimate of the amount to be manufactured, the byproducts resulting from the manufacture, processing, and disposal of the chemical, and any test data in the manufacturer's possession or under its control.

EPA has an initial 90 days to review a PMN to determine whether the new chemical substance may present an unreasonable risk to human health or the environment. The review period may be extended an additional 90 days for good cause. If the Agency determines that there may be an unreasonable risk associated with a new chemical, it can require the manufacturer to conduct testing or supply other information, and in the interim can limit the amount of the chemical produced or impose controls. The Agency can impose permanent restrictions if there are sufficient data to demonstrate that the chemical will pose an unreasonable risk. If EPA does not take action within the review period, manufacture or import may begin immediately.

Prior to the passage of TSCA, somewhere around 1,000 new chemicals were estimated to be introduced annually into interstate commerce. Since the new chemical program began in July 1979, the number of PMNs received has been climbing up to that number. Nearly 1,000 premanufacture notices have thus far been submitted under section 5. Thirty-two notices were received during the last 6 months of 1979; 356 through 1980; and 600 have been received thus far in 1981. We estimate that we will receive 800 notices in fiscal year 1982 and 1,000 notices in fiscal year 1983. To date, we have proposed three orders—pertaining to nine chemicals—to develop additional data and in every case the manufacturer has decided not to produce the chemical rather than conduct the required testing.

The Agency has no authority to require testing of new chemicals unless it finds that they may provide an unreasonable risk or it has already promulgated a rule under section 4 of TSCA requiring testing of the particular chemical class to which the new chemical belongs. The Agency currently has only one proposed testing rule which pertains to a class of chemicals. However, companies do frequently test their new chemicals voluntarily, particularly for acute effects. Testing for chronic effects is much less common. Any such test data available must be submitted with the PMN.

Additionally, the Organization for Economic Cooperation and Development [OECD] is developing a minimum premarketing set of data [MPD] which currently includes 14 test protocol and would provide information for the evaluation of new chemical substances. In January 1981, EPA published the OECD MPD as voluntary testing guidance under section 5 of TSCA. Elements of the OECD MPD can be selected depending on the nature of the substance to be tested.

It has never been contemplated and would not be scientifically sound to apply all elements of the MPD to every substance. The Federal Register notice included estimated costs of each test in the MPD. It is important to note that these are only cost estimates of tests which are not binding. The figures do provide an indication of the range of costs and testing which industry might choose to undertake, particularly if they are considering export to other OECD member States, where such testing becomes a requirement. EPA estimates show testing costs of the OECD MPD ranging from $50 to $13,000 per test.

Premanufacture notices are reviewed in EPA's Office of Toxic Substances. The review process is divided into two parts. The pur-

pose of the initial review, which lasts approximately 45 days, is to screen out chemicals which do not present a risk, and to identify those substances which should be considered for further agency action. Each notice is reviewed by a team of scientists and other staff which may include a chemist, engineer, economist, human health scientist, environmental scientist or exposure evaluator, as appropriate.

Notices are also briefly reviewed by standing committees composed of senior technical staff, which evaluate process chemistry, health and environmental hazard potential, and human exposure and environmental release. At the end of initial review, the team managers review all the data developed and recommend appropriate agency action.

New chemicals which are identified as potential risks by the initial review team enter a second stage of the process, the detailed review. Here, EPA's goal is to more accurately estimate the risk and to consider nonrisk factors—for example, costs or benefits to society—in determining whether agency action is required. A second team of reviewers, having special expertise in the specific issues of concern, evaluate what further steps, if any, should be taken.

Throughout the review process the agency uses the premanufacture notice as one basis for performing its risk assessments and unreasonable risk judgments, but not as the exclusive source of information for such decisions. As time permits, EPA attempts to obtain additional information from the manufacturer, and uses literature searches, contractor support, consultations with scientific and engineering experts to supplement and verify information provided in the original PMN.

EPA necessarily receives large amounts of information involving trade secrets or other kinds of confidential or proprietary information in the PMN and other TSCA programs. The agency takes the responsibility to protect this information very seriously. We have published procedures in the TSCA Confidential Business Information Security Manual which all employees must follow, and are committed to take appropriate disciplinary action against any person who willfully discloses confidential business information.

In comparison to the process of reviewing PMN's under TSCA, EPA must conduct a more comprehensive regulatory review of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA]. This is because FIFRA requires that a pesticide be registered or licensed by the Federal Government before it can be marketed in the United States. Pesticide registration is based on a determination by EPA that the pesticide "when used in accordance with widespread and commonly recognized practice * * * will not generally cause unreasonable adverse effects on the environmen.t"

Unreasonable adverse effects are defined by the act as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide". In other words, as under TSCA, the agency makes its pesticide registration decisions through a risk/benefit balancing process.

Specifically, FIFRA defines a "pesticide" as any substance used for "preventing, destroying, repelling, or mitigating" any pest, except internal parasites or diseases.

Most of these substances are synthetic organic pesticides, of which the United States produces 1½ billion pounds each year, but they also include a wide range of other chemical types and even biological materials. These active ingredients are produced by about 30 basic producers, and are then formulated by more than 3,300 firms into approximately 35,000 end-use products.

In order to determine whether a pesticide meets the statutory standard of "no unreasonable adverse effects," EPA must review scientific data which characterize the effects and potential risks of the pesticide. FIFRA requires that applicants bear the burden of proof, and thus, submit or cite whatever scientific data are necessary to support registration.

On the basis of these data the product is evaluated along with the product label which specifies how the pesticide should be used to insure that risks are reasonable. Once the product successfully completes product evaluation and labeling, it is registered. Special precautions may be placed on the registered labels, some protective apparatus may be prescribed in the use directions, or limits may be put on certain hazardous ingredients. The pesticide label summarizes EPA's restrictions on how and when the chemical can be used.

The other law relevant to EPA's pesticide regulatory program is the Federal Food, Drug, and Cosmetic Act [FFDCA] which requires that tolerances—or exemptions—be established for all pesticides used on food or feed crops. A tolerance is the maximum residue level of a pesticide that can legally remain in or on a particular commodity shipped in interstate commerce. EPA establishes tolerances, generally at the request of applicants for registration, at levels which both protect the public health and reflect good agricultural practices.

The agency reviews approximately 20,000 applications for registration or modifications each year. These applications range from requests for minor label changes to requests for initial registration of new pesticide chemicals.

For the last 3 years, EPA has approved, on the average, 20 applications per year to register products containing new pesticide chemicals. The number of new pesticide chemicals involved—as opposed to products containing them—has been approximately 15. In fiscal year 1981, the agency rejected 69 applications for products containing new chemicals. In such cases, the applicant generally needs to supply additional information concerning the product, which may require that additional testing be conducted.

For the simplest registration requests, the work involved for both applicant and the agency is relatively small and is more administrative than scientific. For new chemicals, however, registration is a larger undertaking which can involve, for the pesticide producer, several million dollars and approximately 4 years of laboratory and field testing. We have estimated that the total cost of developing and bringing a major new pesticide to market is $50 to $70 million, of which $2 to $2.5 million, or 3 to 5 percent, is required to satisfy EPA's data requirements.

In some cases the applicant may also need to conduct large-scale experimental programs prior to applying for registration. These must be approved by EPA, and FIFRA has established a 120-day period for the agency to complete its review of the EUP applications. While the range for completion of review has been from 1 day to 501 days, the average processing time within EPA has been 70 days. If the applicant also applies for a temporary tolerance under FFDCA, the application may take, on average, 2 or 3 months longer to review.

The completion of review by EPA may result in an approval; a rejection because of insufficient data; or a denial of the proposed experimental use because it would result in unreasonable adverse effects. Experiments permitted under an experimental use permit may take several years to complete.

Generally, the applicant for registration of a new pesticide must submit testing results on the new product. These tests seek information on the product's physical and chemical properties; potential human health effects; fate when released into the open environment and effects on wildlife; and residues which may remain on food or feed.

For most of these tests the agency has proposed guidelines, as required by FIFRA, which specify the minimum tests necessary to support registration. The guidelines do not require absolutely specific protocols to be followed, but provide instruction on required testing, acceptable test methods, standards for acceptable testing, and information required in test reports. Under some guidelines, the applicant must meet each test requirement, while others are tiered testing schemes, which require additional testing only if the first tier tests indicate effects at a level of concern. Applicants may rely on the guidelines to determine specifically what data will be required.

If a new chemical is intended for use on a food or feed crop, the applicant must provide information not only to support the product registration under FIFRA but also to establish a tolerance or exemption under the FFDCA for use of the pesticide on a particular crop.

For food uses—and other nonfood uses with significant human exposure—the human health hazard data requirements are much greater than for uses with little human exposure potential. Long-term oncogenicity and reproduction studies, among others, may be required in addition to short-term or acute toxicity tests. Further, the applicant must also develop data on residues as well as analytical methodology to reliably detect those residues. Accurate characterization of residues can be a complex and lengthy process, and may require repeated review by the agency and additional data development by the applicant.

A pesticide producer may make use of another producer's data to support registration of a new product. The owner of the data is entitled to unreasonable compensation for the use of the data if they were submitted in support of a registration after December 31, 1969. All such data are compensable for a 15-year period.

The data submitted to support a new chemical application are reviewed by agency scientists to characterize and evaluate effects expected to result from use of the pesticide. Evaluation criteria

may vary in specifics but, in general, the criteria focus on the adequacy of the experimental design, the conduct of the experiment and its conformance with good laboratory practices, and the reliability and adequacy of the conclusions reached.

If the data submitted follow the guidelines carefully and indicate that there is no substantial risk to human health and the environment, the agency generally finds that they are sufficient to support registration. However, when these data pose important, unresolved questions bearing on potential health or environmental hazards, additional testing and evaluation may be necessary. Particularly for new chemicals proposed for food use, both the data development burden and the review time may be greater than for those with nonfood use. In many cases, a pesticide producer may apply for a nonfood use registration first. When registration is granted for this first use, the producer may begin marketing the product and continue to develop data for additional use requests.

Any or all of these factors—the completeness of the data base, the proposed use, and issues that come up during the agency's review of the chemical—may affect the registration of a new pesticide. Ordinarily, barring problems with data or test results, the entire review process, from receipt of application to final registration, may range from 6 months to 2 years. Significant gaps in the data base or substantial evidence of health or environmental hazards may increase the time necessary to achieve registration by several years.

Recognizing that the pesticide-producing industry makes a substantial investment in developing data, FIFRA does provide for the protection of this investment. The agency is very careful to protect confidential business information and has adopted procedures similar to those under TSCA to this end.

In addition, data developed and submitted in support of a new pesticide registered after 1978 are accorded exclusive use protection, under which, for 10 years, the data may not be used by any subsequent producer to support registration of a new product without permission of the data owner. All other data submitted to the agency in support of a registration may be used by subsequent producers without prior permission of the data owner.

This concludes my prepared statement. I would be happy to respond to your questions.

Mr. KASTENMEIER. Thank you, Mr. Clark.

In a nutshell, you heard Dr. Hayes say that the average time in the FDA up to approval of marketing may be 8 to 10 years. Such is not true with respect to the various chemicals and products that you review; is that correct?

Mr. CLARK. Under TSCA, where we review most of the chemicals, that is not true. The time period is much shorter. We only will look at a new chemical for a maximum of 135 days or so.

Under the Pesticides Act, industry tells us that it can take 5 to 7 years to get a pesticide registered, yes.

Mr. KASTENMEIER. A long time but somewhat less?

Mr. CLARK. Still a long time but a little bit less than Food and Drug I believe; yes.

Mr. KASTENMEIER. I note Dr. Hayes concludes in his statement that the Department has supported the principle of patent life

extension. I did not hear you say anything about that. Apparently the agency has no position on this.

Mr. CLARK. In my previous testimony before the Senate the agency supported the principle of patent life extension; yes. It has given support to the proposed bill.

Mr. KASTENMEIER. But you did not state that this morning.

Mr. CLARK. I did not state that this morning; no.

Mr. KASTENMEIER. Dr. Hayes, obviously the Department speaks for the FDA in terms of the policy matter and you generally support the bill and speak for the Department?

Dr. HAYES. Secretary Schweiker is on record for supporting the principle of patent life extension; yes, sir.

Mr. KASTENMEIER. Dr. Hayes, one of the issues raised in both the Senate and the House bills that the gentleman from Michigan and I offered, compensate patentholders for a period of delay beginning when patency has initiated a major environmental test of the product.

In the earlier formulation of the bill that wasn't necessarily the case. However it has been pointed out FDA and UPA do not formally become involved until much later on when the stress of new drug notice is filed, in other words to permit tests in humans.

In the case of the EPA, it first becomes involved in the granting of an experimental use permit.

In your view, Dr. Hayes, should regulatory delay be considered simply from the time the agencies are examining the data submitted or should it include the entire testing period even though that period is under private control?

Dr. HAYES. Are you speaking of review of data by FDA at the time of the IND, that is, when we review the toxicologic and other data prior to the first clinical study? Or, are you speaking of the final review of all data including the human data for approval of the drug for marketing?

Mr. KASTENMEIER. I am speaking of the point at which the notice is filed with you for experimentation on humans, the IND.

Dr. HAYES. The IND.

Mr. KASTENMEIER. Is that the proper period to start or an earlier period when the company initiates a health and environmental effects test.

Dr. HAYES. I really do not have the data and I do not know how, from a scientific standpoint or regulatory one, I could judge how far one could or should go back before the IND because we really are not involved and I really have no way to know how long it takes a company to develop a particular drug. There are many ways that companies will develop a drug to the point that they feel that they wish to ask the FDA's permission through the IND process, to test it in man. This involves everything including what we call structure activity relationship synthesis—something looks good there, might be similar and you play with the molecules; massive screening programs; and a large share serendipity, very often, with astute observers.

It varies for different sorts of drugs. An established class of drugs obviously can be developed at that stage more quickly than when you are looking for a breakthrough, that is, an entirely new sort of drug.

From the standpoint of FDA I have no way to know how far back before the filing of the IND—that is, the first interface with the FDA—one might go.

Mr. KASTENMEIER. Of course that is not my question, Dr. Hayes. The point at which you are involved is when the notice is filed?

Dr. HAYES. That is correct.

Mr. KASTENMEIER. My question to you is, in terms of reflecting administration support, or departmental support for the principle of patent life extension, we have to determine from what period, right? From that period for which your agency assumes some regulatory responsibility, or also for a preceding period. I am not asking you how far back that preceding period is, but I am asking you whether any of that period also should be included for purposes of patent extension.

Dr. HAYES. I do not think I have any data upon which to make such a judgment, Mr. Chairman.

Mr. KASTENMEIER. It has nothing to do with data, Dr. Hayes. It has absolutely nothing to do with data.

Dr. HAYES. It has to do with data as far as FDA is concerned, and I really do not feel I am in a position to support patent restoration for a time that I really do not understand. I do not know how that differs from development of other products for example.

Mr. KASTENMEIER. That is the most forthcoming answer I can get.

Can you explain what if any clearance procedures FDA presently has for the so-called generic drugs that are placed on the market?

Dr. HAYES. Yes. It depends upon the time that the drug relates to in terms of the innovative compound. For certain compounds originally marketed before 1962, the regulatory requirements are considerably less than for an innovative drug, the reason being we do not feel that duplicative testing or retesting, if you will, is necessary.

There can be exceptions. Clearly, there are certain aspects of chemistry, manufacturing, bio-availability and so forth that are important. For generic compounds that mimic, or are generic versions of innovative drugs marketed since 1962, there is a different policy. They are treated as requiring full new drug application.

Mr. KASTENMEIER. One of the reasons I ask this, there has been a suggestion there is a quid pro quo for patent term restoration which would be the removal of some of the barriers confronted by generic drugs in the approval process. Do you think that is a reasonable view?

Dr. HAYES. I think it is, Mr. Chairman, and as you are perhaps aware, last spring when Secretary Schweiker removed the stay on the so-called paper NDA policy that referred to post-1962 drugs, or generic copies thereof. In fact, that was just a balance or a total program, if you will, of bringing innovative drugs as well as generic drugs to the market more quickly.

Mr. KASTENMEIER. So there is a possibility of continuing that process?

Dr. HAYES. Yes, sir.

Mr. KASTENMEIER. If I might ask this question of you both. Dr. Hayes, what in your view is the most reasonable expectation of time that could be saved by streamlining the review process

without requesting help? Do you think any of these reviews might produce a streamlining of the review process?

Dr. HAYES. I am rather certain they will. The review process now can be as long as 2 or 3 years depending upon recycling, and need for additional data. I think there are certain requirements, planning, general techniques, and the like, that can streamline it. It is still a very small fraction of the total development time, but I think that some improvements can be made there.

Mr. KASTENMEIER. This committee isn't particularly knowledgeable about the Federal drug approval process, sponsored by some of our colleagues on the Commerce Committee. That, I take it, is looking toward streamlining the review process in part?

Dr. HAYES. In part it is looking at the review and approval process as well as the development process and how that relates to the science and the regulations.

Mr. KASTENMEIER. I will yield to my colleagues after one other question.

Do either of you have a view as to whether legislation is supplied only prospectively or might it capture drugs and pesticides currently in the approval process or already approved but still under patent?

Do you have any feeling?

Dr. HAYES. I do not feel I have any basis for having an opinion, sir.

Mr. CLARK. Nor do I.

Mr. KASTENMEIER. I yield to the gentleman from Michigan, Mr. Sawyer.

Mr. SAWYER. Have you been reading these articles in the Washington Post about drugs that are being administered with all kinds of disastrous effects?

Dr. HAYES. Yes, I have been reading the articles in the Post and will be testifying before another committee on that subject tomorrow.

I do not believe everything I read in the Post; I do not minimize it.

Mr. SAWYER. Those drugs apparently don't have to be approved by FDA; is that right?

Dr. HAYES. That is not true, sir. There are no drugs exempt from the law. That is a misconception and I think perhaps there is some inaccurate reporting or interpretation thereof. There are no drugs that are exempt from the law either by statute or obviously by what would be an illegal regulation.

Mr. SAWYER. I got that impression from the articles and I was curious.

I thought I would ask you the question as long as you are here.

Dr. HAYES. There are questions, and the reasons for the hearings I believe on both sides of the Congress are to determine whether in fact the system is working, how well it is working, how does the reporting system work for adverse effects and the like, but I assure you no new drugs are exempt from the law.

Mr. SAWYER. Two questions have been raised by people who have talked to me about the pending bill. One is whether or not it should include processing practices. It includes processing and use practices.

Dr. HAYES. I have no information to refer to that.

Chemical processes are not in my competence and I cannot speak to it.

Mr. SAWYER. Do you have a view on retroactive effects? I understand there was a bill that would affect pending applications only from the date of the passage of the act.

There is some talk about going back to the date of filing, where an application had been pending for 3 years. Have you any view on that?

Dr. HAYES. I really do not because I think a lot would depend upon how retroactive or at what stage in fact the extension began, what your point of departure was, and I am afraid I do not really have an opinion.

Mr. SAWYER. Thank you, Mr. Chairman.

Mr. KASTENMEIER. The gentleman from Virginia.

Mr. BUTLER. I have no questions, Mr. Chairman.

Mr. KASTENMEIER. In conclusion, gentlemen, I would like to ask Dr. Hayes if he is familiar with the bill before the committee and whether you approve of it in its present form, or if you have any other recommendations with respect to it, recognizing the fact that the Department has supported the principles.

Dr. HAYES. I have read the bill, but I have not analyzed it and was told that you were not seeking, today, an analysis of the bill. I am sure that the Department would be very happy to provide an analysis and how they feel about the details or if they would have any recommendations for additions or deletions or other changes, but I am not prepared to suggest that at this point.

Mr. KASTENMEIER. I appreciate that.

Formally, I will request you, or in consultation with the Department, itself, to review the bill in terms of whether it is acceptable in its present form or whether you have recommendations for changes in the language of the bill.

Dr. HAYES. I would be very glad to.

Mr. KASTENMEIER. Also if EPA would do the same thing.

Mr. Clark. We would be happy to.

[The above information may be obtained from the files of the Subcommittee on Courts, Civil Liberties and the Administration of Justice.]

Mr. KASTENMEIER. Obviously that which has brought about complaint goes to the very considerable delays, and you yourself, Dr. Hayes, have talked about the average time from synthesis after new molecular entity, from approval to marketing, 8 to 10 years.

Can you give us a ball park figure of what—and granted all the rest of what you have said; namely, protection of health is an overriding consideration and that for other reasons the process has gotten longer, but looking at the process for purposes of streamlining, what might we expect from the 8 to 10 years?

How substantially might that be reduced?

Dr. HAYES. The review time, which is only 1 to 3 years of that, could be streamlined by perhaps some months. I think the much more fundamental question, Mr. Chairman, is not the streamlining of the intra-agency review time—it always is going to take a finite amount of time to review data—but the more fundamental question relates to that which precedes the review and approval, or

disapproval, and that is the testing that is involved. I refer to both the animal toxicology as well as the clinical studies conducted, of course, in man.

To significantly reduce that time, which is 5, 6, or 7 years preceding the final review at the NDA, it involves asking what do we have to know about a drug in 1981 to determine that it is safe and effective. There is no question that we feel—the scientific community, certainly, the American public and those of us at the FDA—that we need to know more than we did let us say 20 years ago when the drug amendments were passed in 1962.

Science has come a long way. When I first began, the methods of investigating certain drugs for cardiac arrhythmias at that time would not stand now. We have too many better ways of monitoring what happens, the long-term effects.

In terms of toxicology, a few decades ago we didn't have tests for long-term carcinogenicity or mutagenicity, effects on the fetus and the like. Now we do, and we expect that when one is able to learn something, as science and technology moves forward, we will avail ourselves of it, that we will not live in a past age. Therefore, to make significant cuts in that test time will mean a fundamental look and some very fundamental decisions about how much information do we need for all drugs or for certain kinds of drugs to say, with some degree of certainty—and that, again, is a judgmental call—"This drug is safe, this drug is effective and it can now go on the market."

When one talks about large incremental increases in 8- to 10-years, one is not talking about streamlining, involving some months. That is a desirable goal to be sure but not a large percentage of the total time. If one wants an incremental decrease of some magnitude in the 8 to 10 years, one is talking very fundamental science, very fundamental judgment based upon that science and very fundamental expectations by the people.

Mr. KASTENMEIER. The expectations on the part of the public will remain high, I assume.

Dr. HAYES. If anything, Mr. Chairman, I think they will increase. Just as I think scientific capability, and therefore the expectations of what science and clinical medicine tells us in testing drugs, will increase.

Mr. KASTENMEIER. The length of time required in this country to bring a drug to the market, has this led to American companies going overseas and doing testing overseas, with the idea it would be less expensive and less time consuming, in an effort to shortcut some of this 8- to 10-year period by overseas investigation and processing?

Dr. HAYES. Testing overseas does not necessarily cut the time. It is the same sort of studies. The science in most of the countries where drug testing is done is no different than here.

Mr. KASTENMEIER. They have to come to you in any event?

Dr. HAYES. That is correct.

I think there are reasons, Mr. Chairman, why drug companies in my view have on many occasions done drug testing in one location rather than another, and I think these have nothing to do very often with science or the regulatory postures of any particular country involved, but rather with what the dollar is doing today, or

whether there are investigators for a particular drug, or appropriate patient population to study that drug all the more quickly.

I think there are a host of factors, but ultimately for approval in this country, the safety and the efficacy must be demonstrated by the criteria that are used in the United States.

If a study can be done less expensively or more quickly for other reasons—economic reasons, patient reasons, investigator-availability reasons, facility availability, then they may be done overseas. In like manner, there are studies done in this country, the data from which are taken to support drug approval in other countries.

Mr. KASTENMEIER. Do you have any reason to believe that extension of the patent term in the case of pharmaceuticals would generally mean an increase in cost of drugs across-the-board as far as patients or consumers are concerned?

Dr. HAYES. I am afraid I am not an economist who can pass on what will be the ultimate result. I think it comes to questions that I am not prepared to answer because I have not the data or the background, such as what would it do to innovation and creativity, would there be more drugs coming along, would there be more competition because there would be more drugs for the same disease or symptoms and therefore there would be competition?

I think it is fair and obvious to say it is a very complex issue, and what in fact would happen down the road in terms of ultimate cost of a particular drug or drugs in general to patients in this country, I would hesitate to predict.

Mr. KASTENMEIER. Do my colleagues have additional questions?

If not, on behalf of the committee I want to thank you both, Dr. Hayes, Commissioner of FDA, and Mr. Clark for representing his agency. You have both been very helpful and we appreciate your comments.

The Chair will announce this does conclude today's hearing, and that we will have 2 additional days. One will involve witnesses who will speak to the possible amendments to the bill, relating to among other things, process patent and retroactivity.

And another day will be devoted to the Commissioner of Patents and at least one other witness who was scheduled to testify at an earlier period but was not able to.

November 12 and November 18 we plan to hear these people.

Until that time, the committee stands adjourned.

[Whereupon, at 1 p.m., the subcommittee was adjourned.]

PATENT TERM RESTORATION ACT OF 1981

THURSDAY, NOVEMBER 12, 1981

U. S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES
AND THE ADMINISTRATION OF JUSTICE,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met at 10:05 a.m. in room 2226, Rayburn House Office Building; Hon. Robert W. Kastenmeier (chairman of the subcommittee) presiding.

Present: Representatives Kastenmeier, Railsback, and Sawyer.

Staff present: Bruce A. Lehman, counsel; Thomas E. Mooney, associate counsel; Timothy A. Boggs, professional staff member; and Audrey Marcus, clerk.

Mr. KASTENMEIER. The committee will come to order.

This morning we are very pleased to continue our hearings on the subject of patent term restoration, represented by H.R. 1937 and S. 255.

This morning we are very pleased to have two groups of witnesses, the Congress Watch, Public Citizen, represented by staff attorney Carolyn Brickey, and also by staff attorney William Schultz.

Also we have the Honorable Gerald Mossinghoff, who is U.S. Commissioner of Patents and Trademarks.

Commissioner Mossinghoff has graciously agreed to proceed second to accommodate the other witnesses, who incidentally were previously scheduled but because of conflicts in floor activity agreed to testify at a later date. We appreciate the Commissioner's ceding to our first two witnesses, Ms. Brickey and Mr. Schultz.

We are very pleased to have you here this morning. We have your statement. You may proceed any way you wish.

TESTIMONY OF CAROLYN BRICKEY, STAFF ATTORNEY, CONGRESS WATCH, PUBLIC CITIZEN, AND BILL SCHULTZ, STAFF ATTORNEY, LITIGATION GROUP, PUBLIC CITIZEN

Ms. BRICKEY. Mr. Chairman and members of the subcommittee, thank you for this opportunity to express our views on H.R. 1937, the Patent Restoration Act of 1981.

Congress Watch is the lobbying arm of Public Citizen, Inc., a consumer organization with more than 70,000 member contributors. With me is Bill Schultz, an attorney with Public Citizen's litigation group.

I would like to summarize my testimony, Mr. Chairman, and then have the full text inserted in the record.

Mr. KASTENMEIER. Without objection, your statement will be received in the record. You may summarize as you wish.

Ms. BRICKEY. Two years ago, Mr. Chairman, we worked closely with a number of groups and individuals who wanted to revamp the provisions of the Food, Drug, and Cosmetic Act pertaining to pharmaceuticals. Among the most hard-fought issues of that effort were the barriers to the production of generic drugs, access to safety and efficacy test data and restrictions on the size, shape, and color of drugs.

Ultimately that legislation did not pass the House, but those same issues must be raised in connection with H.R. 1937. Even using the magic ruler of the business community—cost-benefit analysis—costs to the consumer and benefits to the drug industry do not balance in the patent extension equation. The Office of Technology report is helpful, however, in setting out the costs and benefits of the proposal.

We have learned from the report, Mr. Chairman, that the profits of the drug industry are high and stable. We learned that research and development has experienced real growth in the past few years and that trend is expected to continue.

We have also learned that a number of drug companies, such as Merck, Schering, and Pfizer, plan to increase their research and development budgets next year by 20 percent or more.

A number of experts in the field have also indicated that the best incentive for innovation is competition, and the OTA report indicates that the environment for competition is also very stable. There is no mechanism in the bill to insure where these profits derived from H.R. 1937 will go.

The industry says that it needs greater incentives, which means higher prices. It also says that by adding new drugs to the marketplace that these new drugs will bring prices down. But it can't have it both ways. Either prices are going to be higher or they are going to be lower.

Mr. KASTENMEIER. I'm sorry. You said you can't have it both ways? Prices are either going to be higher or lower?

Ms. BRICKEY. That's right. In the OTA report it is very clearly stated that higher prices are going to result from the passage of this bill. Yet the drug companies say that because there will be more drugs that that competition may force prices down. But that will not mean incentives to the companies to do research and development. It is either going to be one way or the other, as far as we can tell.

We don't believe that the industry has met its burden by showing that innovation will result from the passage of this bill. The report indicates that the evidence that is available neither supports nor refutes the contention of the industry.

The next issue raised by supporters of the bill is fairness. In other words, it is inequitable to continue with the current patent situation and the patents ought to be extended. However, we think that you can't examine the impact upon the drug industry in a vacuum. You also have to examine the impact that these changes would have on consumers. We know the industry is highly profitable and it is expected to continue to be so, and we don't need a bailout for the drug industry.

We also know from the report, from other sources, that higher prices most likely will follow. The chronically ill and the elderly are the least able to sustain this burden. At this point in time there is an important need to keep health costs down, to promote competition in the health industry.

There is no evidence at this point that new drugs would be created that are now considered economically marginal; that is, drugs that would not be created unless this legislation were passed.

If, however, these assumptions were accepted, one, that it is inequitable to continue the current situation, and two, that innovation would increase, assumptions that we do not accept, we believe that there are two glaring inequities in the bill. The first is that drugs already in the regulatory pipeline would be included by this bill, and we think that those drugs should clearly be excluded because the incentive to create and develop these drugs is already there and we don't need new incentive for those drugs.

The second inequity in the bill is that the extension time that could be compensated for is much too broad. We believe that the time included in the extension should be limited to the time of the complete filing of the new drug application.

Now there are other important public health issues that are raised by this legislation. In fact, more troubling questions are raised than answered in the legislation.

The first is that we believe abbreviated new drug applications, which now are only extended to pre-1962 drugs, should be extended to post-1962 drugs so that generic products can get on the market more quickly and efficiently than they are now.

An FTC report in 1977 indicated that savings from generic drugs could range from 42 to 74 percent of the wholesale price of drugs. So we need to encourage these generic drugs to encourage competition to provide low prices.

Another problem is that the trade name keeps or allows the proprietary drug company to keep control, or substantial control, of the marketing of the drug even after the patent has expired.

There is a chart in our testimony which shows which percentage of the market these drugs control even after the patent expires, and I have some additional figures which I will submit for the record to indicate that in 1980 prescriptions written and prescriptions dispensed for these drugs are very, very similar in numbers.

A third inequity in the bill I would like to see addressed is restrictions on size, shape, and color of drugs. We believe that for the generic markets it is very important that these drugs should be put on the market or allowed to go on the market with the same size, shape, and color, because it is very important to elderly patients and to those individuals who take a large number of drugs and need to rely on physical characteristics to identify the drug.

In summary, Mr. Chairman, we believe that this bill will only result in higher prices. We know that that is a certainty in the bill. The benefits that have been touted as a result of the bill are speculative. They have not been supported by the OTA report or by other available evidence and we would urge the committee to look at the basic foundation for the bill before deciding to act on it and then to look at these other issues we've raised, such as the impact

on the generic industry and methods of redressing those inequities in any legislation that is passed.

We would be happy to answer any questions that you have.

[The complete statements of Ms. Brickey and Mr. Schultz follow:]

STATEMENT OF

CAROLYN BRICKEY, CONGRESS WATCH

AND

BILL SCHULTZ, LITIGATION GROUP

Mr. Chairman and members of the Subcommittee:

Thank you for this opportunity to express our views on H.R. 1937, the Patent Restoration Act of 1981. Congress Watch is the lobbying arm of Public Citizen, Inc., a consumer organization with more than 70,000 contributors. With me is Bill Shultz, an attorney with Public Citizen's Litigation Group.

Two years ago, Mr. Chairman, we worked closely with a number of groups and individuals who wanted to revamp the provisions of the Food, Drug and Cosmetic Act pertaining to pharmaceuticals. Among the most hard-fought issues of that effort were the barriers to the production of generic drugs--access to safety and efficacy test data and restrictions on the size, shape and color of drugs.

Ultimately that legislation did not pass the House, but those same issues must be raised in connection with H.R. 1937. Even using the magic ruler of the business community--cost-benefit analysis--costs to the consumer and benefits to the drug industry do not balance in the patent extension equation. The Office of Technology Report[1/] is helpful, however, in setting out the costs and benefits of the proposal.

The drug industry is highly profitable and stable without any likelihood of serious financial difficulty in the foreseeable future. The amount of funding for research and development hovers steadily between 8 and 9 percent of total sales, and the portion of the R & D funds devoted to research alone is also stable.

1/ Cited hereafter as "Report."

The passage of H.R. 1937 would result in higher prices, which is the so-called incentive of patent extension. There is some suggestion that patent extension might create more drugs with a resulting competition to lower drug prices, but no evidence has been presented to support this contention.

It is logical and sound public policy for the proponents of a change in the law to bear the burden of 1) establishing that there is a problem and 2) showing that their proposal will solve the problem. Supporters of patent extension have met neither burden.

The drug industry contends that there is a decline in the research and development of drugs, and therefore, a decline in innovation. The OTA report contradicts both of these assertions as mentioned above. The basis for the decline in innovation, according to the industry, is the decrease in the number of New Chemical Entities (NCEs). However, the number of NCEs of high or moderately high therapeutic value has remained constant since the 1950's.

Based upon more than two decades of R & D of important NCEs, it is reasonable to conclude that this constant number of drugs will continue to be produced. It would be inequitable to allow the drug industry to charge higher prices for this group of drugs which will be developed without the passage of this legislation. The inequity would be even greater for those drugs already in the regulatory pipeline. Since these drugs have obviously already been developed, any retroactive application of H.R. 1937 would merely be an economic windfall for the drug industry.

It appears, however, that the industry is asserting that there is a second class of more marginal drugs that companies would research and develop if the additional resources were available to do so. If that is the

case, this argument should be supported by facts and figures. Yet no evidence has been presented to show that this class of drugs exists or would be developed if H.R. 1937 became law. The Report verifies that this burden has not been met by patent extension supporters by stating, "The evidence that is available neither supports nor refutes the position that innovation will increase significantly because of patent-term extension." (p. 4)

The drug industry argues that it is unfair that in some cases patent life does not constitute a full 17 years. They point to the existence of regulatory procedures as the ultimate culprits of marketing delay. Yet, supporters of patent extension fail to acknowledge that a significant portion of the delay time is due to their own testing which would be required whether FDA approval were necessary or not. Their proposal incorporates all of the time involved in the pre-marketing stage regardless of the cause for the delay. Proponents also ignore the fact that a number of top-selling drugs result from "pyramided" patents which extend patent life beyond 17 years.

It is widely acknowledged that higher prices would fall disproportionately on the elderly and chronically ill, two groups in society least able to handle the additional economic burden. The Report indicates that these increased profits would go to a few firms that have established their dominance in certain research fields. Also acknowledged is the fact that the competitive pressure of generic competition would be delayed or perhaps prevented where the product life of a drug is too short to justify a second entry after the patent expires. If this bill becomes law, a greater inequity to the public will result than the current so-called inequity to the economic health of the drug industry.

The industry's discussion of patent extension ignores a number of important existing barriers to the marketing of generic alternatives. These barriers include brand name usage, restrictions on size, shape and color of drugs and the FDA approval process for generics.

Even after a number of years off patent, the brand name manufacturer has a strong hold on the marketing of many drugs. Drug companies expend great sums of money to inculcate the brand name in the minds of practicing physicians, thus extending the monopoly period far beyond the life of the patent. A recent report from the FTC Bureau of Economics concluded that the unlimited life of a brand name extracts unreasonably high social costs because it discourages competition.[2/] The report recommended that brand names, like patents, be given a limited life. We believe that a sensible approach would be to require that the patent life and brand name end at the same time.

Restrictions upon the physical characteristics of drugs produces a similar barrier to market acceptance. Chronic users of a particular medication expect that the appearance will be uniform. Even more important is the fact that individuals who take a number of medications depend upon the

Drug (Generic Name)--Type[3/]	Years Off Patent (By 1979)	Share of Market in 1979 (% of Retail Rx's Filled)
Darvon (propoxyphene) --Painkiller	7 years	90%
Librium (chlordiazepoxide) --Tranquilizer	3 years	90%
Apresoline (hydralazine) --Antihypertensive	13 years	86%
Gantrisin (sulfisoxazole) --Antibiotic	15 years	95%

2/ FTC, Bureau of Economics: Staff Report on Sales, Promotion and Product Differentiation in Two Prescription Drug Markets, p. 80, February 1977.

3/ National Prescription Audit, IMS, Inc., 1979

description to insure that the right pill is being taken in the correct dosage.

Government regulation assists the trade-name companies in extending their monopoly beyond the period protected by the patent laws. Once the patent has expired, a competitor should be free to market the product with minimal government interference. In particular, there is no need to require generic drug companies to submit animal and human tests to show that their products are safe and effective. Those tests simply consume unnecessary resources and impede the ability of the generic companies to compete.

With respect to drugs first sold prior to 1962, the Food and Drug Administration (FDA) has recognized that further testing of generics is unnecessary, and the Agency allows the generic company to file an abbreviated new drug application (ANDA). The ANDA is abbreviated by not requiring studies of safety and effectiveness for drugs which have already been tested and have been on the market a long time. Such testing is the major and most expensive element of the new drug application.

The FDA, however, has not yet extended the ANDA system to drugs first marketed in 1962. In this category are many big selling drugs which are off patent or are about to come off patent. There is no good reason why the policy used for pre-1962 drugs should not be applied to post-1962 drugs. Small businesses and consumers are being injured by this unnecessary and unjustifiable delay, and although we believe that the FDA now has the authority and is now required to adopt an ANDA system for drugs which have already been proven to be safe and effective, we urge that any legislation which concerns the economics of the drug industry contain a provision explicity requiring the FDA to adopt an ANDA system for all drugs which are

off patent. There is simply no justification for requiring generic companies to delay marketing their products until the FDA has evaluated studies on safety and effectiveness, where the FDA has already approved an identical product which differs in name only. Whatever the appropriate patent term is, it seems to us that once the drug, or any product, comes off patent, it should be available for immediate competition without any interference by the federal government.

It is ironic to us that proponents of the bill have claimed that this legislative proposal will help small businesses which have lost some patent protection as a result of delays by Federal agencies.4/ With respect to drug marketing, it is the small drug companies that suffer from the monopoly power of the larger, trade-name companies. Extending the period of patent protection will extend that monopoly, and hurt the small generic companies. In order to promote competition, help small business and reduce drug prices, serious consideration should be given to a compulsory licensing law. Compulsory licensing would require the pioneer drug company to license a competitor at fixed and reasonable royalty. The royalty fee is paid to the innovator firm, and acts as an incentive to invest in research. A limit on the royalty protects the public from excessive profits. The law could also provide for a short period, perhaps 3 years of marketing, during which the pioneer firm would not be required to license the product.

The only known result of the passage of a patent extension bill is higher drug prices. It would be unwise and unfair to create higher prices at a time when the government and private insurance companies need to find

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4/ See Exhibit 1, pg. 8 for additional information on generic drug prices vs. brand name drug prices.

ways to keep health costs down. It would be especially inequitable to impose these costs on the elderly and chronically ill for those drugs which will be developed as part of the overall marketing of new drugs.

No evidence has been presented to show that a number of drugs now considered marginal economically will be researched and developed as a result of this extension. The Report indicates that R & D for orphan drugs will not be affected by this legislation since only decisions governing those drugs with wide marketability might be affected.

There is no guarantee where increased revenues might go. Additional revenues could be spent on increased dividends, product diversification, buying other companies, and advertising of current products. Furthermore, there is no guarantee that any additional R & D would be directed toward the research necessary to find "breakthrough" drugs or drugs of high therapeutic value.

Any legislation passed by this body to extend the patent life of drugs should also provide for the removal of brand name and physical characteristics restrictions, Abbreviated New Drug Application Procedures for post-1962 drugs and compulsory licensing. The bill should limit extension to the first patent filed for each drug, and curtail the amount of time in the process to which can be included in the extension, perhaps to the date of NDA filing. Drugs already in the regulatory pipeline should be excluded from the bill.

SALES DATA FOR FOUR OFF-PATENT DRUGS

Drug	Manufacturer	Years Off-Patent as of 1979[1]	Market Share in 1979	# Rx Filled in 1979[2]	Retail Sales 1979[2]	Cost of Brand Name Drug[4]	Cost of Cheapest Generic Version[4]	Price Ratio
Darvon (propxyphene)	Lilly	7	90%	22,400,000[3]	-	$41.70[5]	$ 6.80[5] (Spencer-Mead)	6.1
Librium (chlordiazepoxide)	Roche	3	90%	8,200,000	$57,700,000	$87.63[6]	$ 5.50[6] (Interstate)	15.9
Apresoline (hydralazine)	Ciba	13	86%	2,900,000	$23,200,000	$98.48[7]	$11.65[7] (Henry Schein)	8.5
Gantrisin (sulfisoxazole)	Roche	15	95%	2,900,000	$15,900,000	$52.78[8]	$14.95[8] (Wolins-Pharmacal)	3.5

1 Merek Index, ninth ed., 1976.

2 National Prescription Audit, IMS America, 1979.

3 All Darvon products.

4 1981 Redbook.

5 Wholesale price per 500 65 mg.

6 Wholesale price per 500 25 mg.

7 Wholesale price per 1000 50 mg.

8 Wholesale price per 1000 500 mg.

Mr. KASTENMEIER. Thank you very much for that brief but certainly to the point testimony.

The question of higher or lower prices—and that concerns the committee—that presumes not necessarily a quantum higher price for each product, but a price being sustained for a longer period of time which would be higher than the lower price generic might be at that point in time. Is that what you mean by higher price?

Ms. BRICKEY. Well, it is not clear exactly how that would operate in the marketplace. Certainly it would be logical that higher prices could be charged for a longer period of time. There is no way to know at this point whether even higher prices would be charged initially to recoup the research and development costs early in the market life of the drug.

Mr. KASTENMEIER. How does Public Citizen feel about just the single concept, just looking at it isolated from all other factors, of an effective 17-year term for protection for pharmaceuticals as well as other inventions?

Ms. BRICKEY. You mean the way that the law is now?

Mr. KASTENMEIER. Yes. That is to say, if pharmaceuticals have effectively 17 years to market the product as contemplated by the patent laws originally for any creation, do you feel that they should not have 17 years protection for the product?

Ms. BRICKEY. Well, Mr. Chairman, I guess we are not prepared to either praise or criticize the way that the patent law works currently. I believe that we feel that the current law should be left in place unless some reason is shown why the law should be changed, and we don't believe that that case has yet been made in this legislation.

Mr. SCHULTZ. May I add something to that answer?

Mr. KASTENMEIER. Of course.

Mr. SCHULTZ. This to me is really the fundamental question. I don't think the case has been proven that the bill would create an incentive for innovation. The real argument that is being advanced is one of fairness. The patent laws contemplated 17 years; other inventors get 17 years. Why shouldn't the drug companies?

There are really two answers we have to this. The first one is you shouldn't just look at the patent question. You should look at the market in a broader sense. And if you do that, we think that we see that the drug companies get a monopoly for much longer than the patent life, and that's unusual. Because of the way drugs are advertised, because of the importance of the trade name, because there are so few doctors, and a variety of reasons, the monopoly ends up extending well beyond the patent term, and that may well compensate for the loss in patent life and it may mean an effective longer term.

Mr. KASTENMEIER. But if there are some unfair competition questions attending that which you've raised, shouldn't that be dealt with directly rather than through patent term life?

Mr. SCHULTZ. I guess what we are saying, and this is just the first half of my answer, there are a lot of unevennesses in the world and we object to correcting this one without correcting some of the others simultaneously.

For example, it might be logical if you are going to have this increase in the patent life of drugs too at the same time have what

we call an ANDA policy for generic drugs, which would mean that once the patent expires the competitor has a right to go on the market, and so on.

Now let's put that aside and just analytically look at this question of the 17 years. Let's assume that the drug companies are on the same basis as everybody else and all we are really interested in is fairness and the 17-year patent life. If you look at the time it takes from the time testing is first started for a drug until the approval, that is often said to be about a 10-year period, and the theory of the bill is that to the extent the company has to wait to market its drug because of Government regulation, that time ought to be restored. Now, out of that 10-year period approximately the last 2 years is the time it takes the FDA to review the new drug application and approve it. For those 2 years there is the strongest argument for restoring the time to the patent. But you have to separate that from the previous 8 years, which is the time it takes to test the drug, to decide what it works for, to decide whether it works, to decide whether it is worth marketing and so on.

To us that is time that is comparable to the time an inventor might spend after he initially gets the idea for his product, the time he might spend developing it and getting ready to manufacture it, and the inventor does not get that time restored, and we don't believe the drug companies should have those 8 years of testing restored.

Mr. KASTENMEIER. Then it is your position, I take it, namely, that extension of term is not unthinkable but it is a question of when it starts and what other elements are associated with it, the generics and other competitive factors, so that you might be willing to consider an extension of term.

Ms. BRICKEY. Our position would be that we don't believe the case has been made for extension. But if you do accept the argument that it is fair to restore this time that is involved in the regulatory period, then we believe it should be limited to the time when the NDA, a complete NDA, is filed with the FDA, because that's the time that you are talking about restoring from the regulatory process.

Mr. KASTENMEIER. As you know, and I don't want to argue the point, if we look at it hypothetically we could assume that there was a point in time many, many years ago in which one could devise a chemical compound which would be useful for your health and virtually without restraint put it on the market and then enjoy somewhat near 17 years of protection.

In the interim, however, we have decided as a matter of protecting the public, and for other purposes, that certain testing and approval of applications have to be part of the permission to market drugs. That has apparently come out of the 17 years. So it does not seem unreasonable that since the public is being served by the approval process that we contemplate what we might do, and to a point it has been shrinking; that is, the marketability period. As I understand it, Commissioner Mossinghoff will testify that effective life today is 9.5 years as opposed to the theoretical potential of 17 years. To the extent that that represents a problem, and it apparently does not represent a problem—witnesses largely have concluded it does not represent a problem—in terms of do the drug

companies need to be bailed out or they are not making profits, I think that is not really the question. They concede that. That's not the question. Their position, I take it, is that nonetheless what is currently required and what will be required in the future for investments in effective new drugs will be so substantial from their forecasts as to require a longer term than the shrinking term that they are now given in terms of protection.

I don't know what your comment is.

Mr. SCHULTZ. As you know, we simply don't think that case has been made, especially if you look at the effective monopoly life, which is the relevant question, not the patent term. But if we go back to the beginning of your question, you said there was a time when a company could discover a drug and with minimal regulation go ahead and put it on the market. That may be true, but even then the company would spend considerable time testing the drug, identifying what it was useful for, identifying whether it was effective, and that time was always counted against the patent if the company wanted to file the patent at the time of the discovery of the drug. This bill would give the companies an advantage they have never had.

Mr. KASTENMEIER. Well, I thank the witnesses, and I yield to the gentleman from Illinois.

Mr. RAILSBACK. Thank you, Mr. Chairman.

I want to thank the witnesses also and indicate I think your point about the abbreviated new drug application certainly merits study. In other words, I think that raises a very useful point with which I am inclined to agree, that if we do extend the patent life, then maybe we ought to shorten the procedure for the generic companies to be able to market.

Let me ask you this. You cite some examples, and Darvon is one of the examples where Spencer-Mead is the lowest cost producer of the generic drug, and then you list, I think, about three other examples. What kind of companies are they that are producing the generic drugs? For instance, is Spencer-Mead a large drug firm? And what about the other three? Are they so-called research intensive firms? Are they just producer or generic type firms only?

Ms. BRICKEY. Well, since this is the lowest price generic it could be that these are producer-type companies, but I can't answer that for sure.

Mr. RAILSBACK. The reason I ask, we've had testimony some time ago that something like, I think it was, 80 percent of generic drugs are actually produced by large companies, and I think they are called research-intensive companies, and if that is true, then I find it extremely difficult, given the disparity or the gap between the generic price and the brand name price, why the generic companies haven't done a better job in their marketing and advertising. I mean, it just doesn't make sense if you've got one drug that costs seven times what the generic drug costs. And these are being manufactured by large firms that are the research-intensive firms. I don't understand it. In other words, it has got to be lousy, lousy advertising.

Mr. SCHULTZ. I think it shows the marketplace is not working for drugs, and we think that one of the main reasons is the strong identification with the trade name. In other words, the doctors

prescribe by trade name. I think the generic companies try very hard in advertising, but it is hard to educate the doctors to other names.

Mr. KASTENMEIER. What bothers me is that with generic companies at least 80 percent of the production is by the large research intensive companies. Maybe we are persuaded that out of equity there should be some kind of patent life extension. I do think you make a good point though about trying to shorten the procedure. Do you think we are the subcommittee that can do that? I have some doubts about that.

Mr. RAILSBACK. Yes, I have some doubts about that, too. I strongly favor doing as you suggest. What is your feeling about that? What would be the proper committee to do that?

Ms. BRICKEY. Well, I suppose the jurisdiction over that issue by itself would be Energy and Commerce. But I believe they would also be in favor of taking that kind of action. Since this bill does address economic incentives for the drug industry, which is a very important issue, that issue should be incorporated also.

Mr. RAILSBACK. Thank you, Mr. Chairman. That's all I have.

Mr. KASTENMEIER. The gentleman from Virginia.

Mr. SAWYER. Thank you, Mr. Chairman.

I appreciate your contribution also.

Turning to another subject, since we've got you here, the big boys in the cable television industry have gotten together and offered us a proposal for a revision of the cable television legislation, and there is nobody participating in the negotiations representing the so-called consumer. Are we going to have the benefit of your wisdom with reference to that legislation?

Ms. BRICKEY. We do have an attorney working on that issue, and I will certainly tell him to get in touch with your office.

Mr. SAWYER. Well, tell him to get in touch with my chairman. We would appreciate that.

Ms. BRICKEY. We will be glad to do that.

Mr. SAWYER. Turning to the subject before us, on page 4 of your testimony, I have the impression that what you are saying, "We believe that a sensible approach would be to require that the patent life and brand name end at the same time," means right of a trademark would be eliminated when a drug product comes off patent.

Ms. BRICKEY. Yes.

Mr. SAWYER. Is this an across-the-board recommendation? Or is this limited to the rights of trademark in all industries? Or just pharmaceuticals?

Ms. BRICKEY. Just going to the drugs.

Mr. SAWYER. How do you make that judgment? That is a sweeping contention. How do you justify that?

Ms. BRICKEY. We believe it is a far different situation when you are dealing with, the kind of markets you're dealing with with drugs. You are dealing with a physician-controlled market, as it were. The physician determines what drug will be prescribed, and he is most accustomed to using this brand name to determine that drug will be prescribed. In the marketplace, if you are looking at a Ford Escort or whatever, it is a much more open situation in which the consumer is looking at all these cars or whatever the product

may be and evaluating which one they want to use. In this case really the doctor is determining what product will be used and not the consumer.

Mr. SAWYER. Well, the basic function of the trademark is to indicate the origin or the manufacturer of a product. That's considered helpful to the consumer.

Ms. BRICKEY. We believe you can still indicate the origin of the product. For instance, if the company that developed and produced the drug is Squibb, you can put that on the container of the drug when it is dispensed to the patient, or you could even put a mark on the pill or capsule itself, if that would be helpful in identifying the origin of the drug. It is not necessary though that you retain the name Librium or whatever.

Mr. SCHULTZ. One possibility would be, if we adopted this, the drug could be sold as Lilly's Darvon so that it would be identified with the manufacturer, but then another company could sell it as Henry Schein's Darvon.

It is a unique situation here. The doctor chooses the product and the consumer pays for it.

Mr. SAWYER. I can see the virtue in that. I am having difficulty in my own mind saying why should we single out the pharmaceutical industry for this.

Mr. SCHULTZ. I guess what concerns us is when you look at the figures of the length of time the monopoly is retained after the patent expires, it appeared to us that something wasn't working in the market and something ought to be done, and this is our suggestion. Maybe there are other suggestions as well. But what is clear to us is that the marketplace is not working.

Mr. SAWYER. It is clear that the marketplace is not working because low-priced generics are not selling at all.

Mr. SCHULTZ. That's right. The monopoly is retained long after the patent expires.

Mr. SAWYER. Thank you. I yield back to the chairman.

Mr. KASTENMEIER. Well, the committee thanks you both for your testimony this morning, and furthermore, if you develop any further insights on this question, or ideas, we would be very pleased to hear from you.

Mr. RAILSBACK. Can I add one thing, Mr. Chairman?

Mr. KASTENMEIER. Yes.

Mr. RAILSBACK. I think that if action is taken by our subcommittee, and say we do decide to recommend some kind of an extension, then I would hope that we would explore their one suggestion and maybe even have the subcommittee send a letter to the proper committee recommending that they may very well want to take action in light of what we are doing. Because I think they make a good point on that abbreviated application.

Mr. KASTENMEIER. I think that is a matter before Henry Waxman's subcommittee, Commerce Committee. I have had some discussions with him, but we have not explored that. But taking the gentleman's advice, I will explore that with him.

It has also been brought to my attention that Secretary Schweiker has modified certain rules with respect to generics to make it somewhat easier for them.

But in any event, we appreciate your testimony on that question. That is one reason we will keep the door open to you for any subsequent developments.

We thank both of you very much.

Ms. BRICKEY. Thank you very much, Mr. Chairman.

Mr. KASTENMEIER. Now I am pleased to greet the Commissioner of Patents and Trademarks, the Honorable Gerald Mossinghoff. We are very pleased to meet him and wish him the best in his new term. We know he has many, many problems. We hope this committee is able, with him, to cope with some of them effectively in the next several years.

In any event, we are very pleased this morning to greet the Commissioner on this question of patent-term extension, and I would like to recognize the gentleman from Illinois.

Mr. RAILSBACK. Mr. Chairman, as you know, I had occasion, with Mr. Mooney, about 1 year ago to go down to the Patent Office and visit and actually examine many of the different departments in a very cursory manner. But even I as kind of a layman was very much distressed at the backlogs that we became aware of, the lack of good data processing, the lack of information retrieval, and it prompted me, as you know, to try to get the Patent Office separated out from the Department of Commerce, because I really believe that the Department of Commerce was not paying adequate attention to the Patent Office and was clearly not providing enough resources or even requesting enough resources. And I am very pleased that the new Commissioner, I think, is very much aware of the problem.

I think he has embarked upon some modernization that should be very beneficial. And I would only hope that he would continue that and that maybe we can upgrade the Patent Office so that our country, which is supposed to be the number one innovative and creative country in the world from a technological standpoint, that we can maybe help our inventors in that kind of effort.

But I do applaud what the new Commissioner is doing and I join with you in welcoming him.

Mr. KASTENMEIER. There is no doubt that Commissioner Mossinghoff faces a very great challenge. There is no question about that.

Commissioner Mossinghoff.

TESTIMONY OF GERALD J. MOSSINGHOFF, COMMISSIONER OF PATENTS AND TRADEMARKS

Mr. MOSSINGHOFF. Thank you very much, Mr. Chairman.

Let me say that this is my first appearance before the subcommittee and I am delighted to be here today. I welcome this opportunity to testify on patent-term extension and also welcome the opportunity to establish and reinforce close working relationships with the subcommittee on the plans that Secretary Baldrige and Deputy Secretary Wright and I have for modernizing the Patent and Trademark Office.

Clearly your support of our efforts is absolutely critical to us and we look forward to working with you in the years ahead.

Having been honored with the appointment as Commissioner last spring by President Reagan, I returned to the Patent and Trade-

mark Office where I began my Federal career 24 years ago as a patent examiner. Since my return, it has been my privilege to work with Secretary Baldrige and Deputy Secretary Wright on plans to improve the Patent Office, but it wouldn't be appropriate today to go into some of those.

Congressman Railsback did include in the Congressional Record the other day a speech that I had given to the American Patent Law Association. We do have a lot of efforts underway to address just the problem that Congressman Railsback mentions.

To remedy some of the problems, we have developed a comprehensive plan of action. Secretary Baldrige and Deputy Secretary Wright are committed to reverse, during this administration, the present trend of the growing backlog of patent and trademark applications and to lay the foundation for a fully automated Patent and Trademark Office in the years ahead.

If I may digress another time, the committee included very appropriately last year in Public Law 96-517 a requirement on the Patent and Trademark Office to conduct a 2-year study on automation. The report is due to you in December of 1982, and I am pleased to report that the first draft of that study, which I think is a very comprehensive and complete job, has already been published and has been made available widely to industry and bar groups to look at. I think that may be something of a record. We are 13 months ahead of time in publishing the first draft of the automation study, and I think it demonstrates the emphasis that we are going to put on that aspect of long-term improvements within the office.

Mr. KASTENMEIER. Will you recall for me, the legislation provided for a final draft, however, to be presented to the Congress by December 1982? Is that correct?

Mr. MOSSINGHOFF. That is right. December 12, 1982, we must submit a final draft. But it was our view that we would tend to get more help from industry, inventors, patent groups, and people interested in trademarks if we provided a fairly definitive statement now and give them a fairly long time to respond, give us their wisdom, so that we can incorporate their judgment in the report that we finally submit to you.

We have held one major hearing, an all-day hearing last July, and we contemplate holding another hearing early next spring to sharpen for Congress that report on automation.

Mr. KASTENMEIER. Is it likely that the final report will be made available before December 1982?

Mr. MOSSINGHOFF. We are hopeful it will be.

Mr. KASTENMEIER. I see.

Mr. MOSSINGHOFF. The plans for the Office itself are complemented by the new reexamination procedures which went into effect this past July. Those procedures, for which this subcommittee can take a large part of the credit, provide a simple and efficient administrative mechanism to test the validity of issued patents. Our patent system is greatly improved, in our view, by raising the confidence of patent owners and others in patent validity without their having to resort to protracted and costly patent litigation.

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I might say that since July we have about 100 cases that we are now reexamining or have received for reexamination. Roughly a third of those are apparently involved in litigation where the litigation has been suspended and the parties are back before the Office for reexamination. We have ordered reexamination or we have reached decisions on 60 cases and ordered reexamination of 54 of those 60 cases. So the system seems to be working well and we are working very hard to carry out the procedures in an expedited way as the law you passed requires for us. And we, the industry, and the bar appreciate the implementation of that reexamination.

Judicial consistency in the patent area is another much needed improvement of the patent system. Again, this subcommittee deserves credit for its efforts which led to the Judiciary Committee's favorably reporting H.R. 4482. We support this bill as well as its companion in the Senate which would establish a single Federal appellate court to hear patent cases from district courts and the various administrative boards of the Patent and Trademark Office. Providing a single authoritative tribunal to handle patent cases nationwide, in our view, will greatly contribute to a single standard of invention patentability which will be understandable to industry and inventors alike.

We are also in need of a Federal patent policy which applies uniformly to all Government agencies and to all of their contractors. The two bills, H.R. 4564, and the Senate counterpart, S. 1657, would establish such a policy—which this administration supports. A uniform Federal patent policy would encourage industry to invest in inventions resulting from Federal sponsorship, thereby fostering the promotion of private sector capital formation, job creation and productivity.

Just as a uniform Federal patent policy would contribute to the improvement of our patent system, so also would a uniform approach to the effective length of patent terms. The inequity to certain sectors of our industry, whose inventions are denied a full patent term due to Federal premarketing approval requirements, has been widely recognized. This administration also recognizes the need for remedial action to increase innovation. Therefore, it strongly supports enactment of the Patent Term Restoration Act of 1981.

This legislation would add a new section 155 to title 35 of the United States Code to provide for an extension of the patent term for patented products, or patented methods for using products, that are subject to regulatory review pursuant to Federal statutes and regulations before they are permitted to be introduced for commercial use.

The first subsection of section 155 would authorize an extension equal to the regulatory review period up to a maximum of 7 years. To obtain this extension, the patent owner would have to notify the Commissioner of Patents and Trademarks that the patented product or method had successfully completed premarket testing and regulatory review.

Subsection (b) would specify the information which the notice to the Commissioner must contain, including the length of the regulatory review period. Upon receipt of such notice, the Commissioner

would be required to publish it promptly in the Official Gazette and to issue to the patent owner a certificate of extension.

Our support of the bill is based on the premise that the patent system will provide a healthy stimulant for investment in research and development only if its incentives are not unfairly curtailed. Given the progressive increase in the loss of commercial exclusivity caused by federally mandated testing and regulatory review requirements, we can no longer ignore the fact that certain sectors of our industry are denied the full benefits which the patent system was intended to provide.

Inventions in agricultural chemical technology, and even more so in the pharmaceutical field, depend heavily on patent protection. Development of such inventions is extremely costly, yet their imitation is often simple and inexpensive. Not only do many other inventions need a far greater outlay of capital to duplicate, but they also may have a shorter life before being overtaken by the advance of technology.

Pharmaceutical and agricultural chemical inventions, on the other hand, are generally commercially attractive long after the expiration of the patent term. This is evidenced by the large interest the production intensive sector of industry displays in exploiting those inventions. This interest is a healthy one and competition on the open market should be encouraged. However, to the extent that a shortened effective patent term lessens the incentives of industry to continue making large commitments toward research and development, we should move to insure that these incentives are restored.

Effective patent protection is a necessary prerequisite to pharmaceutical and chemical research, given the enormous costs and risks involved. Enactment of this bill would go a long way toward making that protection effective again.

If we are to reverse our declining rate of innovation, we cannot afford to make our patent system progressively less attractive to important sectors of research intensive industry. The patent system is by no means the only incentive which encourages large amounts of financial commitments to research and development. But it certainly ranks high among other alternatives in providing the opportunity for rewards to those whose labors have proved successful. Enactment of the Patent Term Restoration Act would redress an inequity by restoring to patentees a part of their patent term which has been eroded by Federal premarket regulatory review. Given the proposition that the patent term is a form of compensation to the inventor for having fully disclosed his invention to the public, one inventor should not be treated differently from another. The Federal Government should not induce full public disclosure of an invention through a patent grant of 17 years and then reduce the effective life of the patent through premarket regulatory review procedures.

Opponents of this proposed legislation have argued that the problem which the bill would alleviate has not been demonstrated. They have pointed to high profit margins of industries which would benefit from this bill and have concluded that, as a consequence, there is no problem. I would suggest that the patent system not be misused as an economic regulator of U.S. industry. To establish

different effective patent terms depending on the potential economic success of a particular sector of technology is not an approach I would recommend. And to fail to stem the erosion of effective patent terms due to Government regulation is just as unfair. Accordingly, there is a demonstrated problem: Certain sectors of our industry dealing with technologies which are subject to premarket regulatory review are not receiving the full benefit of the patent system to which they are entitled by virtue of having disclosed their inventions to the public.

Mr. Chairman, I think everyone cites the OTA study, which was a balanced study by any measure. If I may at this point, I was struck by several conclusions that were reached in the OTA study. They reached four conclusions which I would fully support.

On page 40 of the study, they indicated, and I am quoting this, that "On balance, there is reasonable likelihood that firms may undertake or increase pharmaceutical R. & D. activities because of the increased incentives provided by the longer effective of patent term. If this occurs and drugs are developed more rapidly, a downward pressure might be exerted on the price of some drugs and the product lives of some other drugs might decrease."

The second conclusion was, "To the extent that patent term extension affects the potential rate of return, drugs that might otherwise be economically marginal may become economically attractive."

Third, they conclude that, "Patent term extension could be a significant factor in encouraging certain types of pharmaceutical R. & D."

And finally, they conclude that, "Patent term extension may also encourage second uses for existing drugs."

It seems to me that this study was balanced almost in the extreme; it was really an on-the-one-hand and on-the-other-hand kind of study. But I believe those four conclusions would be sufficient to support enactment of the legislation.

Concern has been expressed that the proposed legislation would further increase the noncompetitive period of exclusivity. Such concerns assume that the period of patent exclusivity is normally noncompetitive. But in general, patented products in the market are not completely free from competition. They often compete with other similar patented or unpatented products in the same field of application and are not instant financial successes solely on the basis of having been patented. They are, however, protected from slavish imitations and that protection should be continued to be effective for the full patent term—17 years.

Opponents of the Patent Term Restoration Act speculate that its enactment would not guarantee the expenditure of greater resources into research and development. Proponents of the bill, on the other hand, note that significantly shortening the patent term, while not the sole reason, has had an adverse effect on research and development investments. I cannot categorically state, and I don't believe anyone else can, that patent term extension will significantly increase innovation. I do stress, however, that throughout the many years of its existence, our patent system has encouraged innovation through the incentives it provides. It is a logical conclusion that as these incentives are diminished, if they

are, so is the encouragement which the patent system might otherwise provide.

Proponents and opponents of this bill have significantly different opinions regarding the actual effective patent life presently accorded to pharmaceuticals. Studies have been cited to show that the effective life of a pharmaceutical patent is about 9.5 years. I believe that is supported by the OTA data. Others refute this claim by stating that the real average life is somewhere around 18.5 years. Those who assert that the average life of a pharmaceutical patent is greater than 9.5 years do so on the basis that the effective patent life has been calculated by measuring only the date of the earliest patent issued. They maintain that by obtaining later patents on the same technology, the patentee increases the effective patent life of the product, thereby maintaining an unwarranted market advantage. This practice has been labeled "the evergreening of patents."

It is claimed that patentees can prolong their protection by obtaining process and use patents after they have been granted a patent on the product itself. While it is certainly possible to obtain additional patents in an area of technology, one should be clear exactly on what basis those patents are obtained and what kind of protection they afford. First, any patent issued must be patentably distinct from all other patents, which is to say it must contain a different invention. If someone first obtains a product patent and later discovers another unexpected and patentable process for this product, he is entitled to protection of his invention. This is not an extension of the original patent or merely an obvious variation of the original invention; it is a separate and distinct invention capable of being patented in its own right.

The same applies to a new discovery of a process for the manufacture of the originally patented product. If such a process is a separately patentable invention, it is entitled to protection. In such a case, the patentee of the original product has not extended the patent term of his product, he has made new inventive contributions to the technology. He is therefore entitled to protection in turn for having publicly disclosed his new invention.

However, what does a patent on a new use for a product or on a new process for making a product convey to the patentee? Regulatory review aside, if the original patent on the product has expired, the public is free to manufacture that product for all the uses for which the product was originally intended, as well as for any other use, except for the newly patented one. If a patent for a process of manufacture was also obtained, this particular new manufacture is protected, although the public is free to make the product in any other manner, including the original manner. As a consequence, the product itself does not enjoy continued and evergreening patent protection.

Lastly, it must be recognized that practical enforcement of use patents and of process patents is difficult. In the case of a protected use, unauthorized substitution is very hard to police. Patents which cover processes for manufacture are equally difficult to enforce. As a consequence, I find the allegations of patent pyramids difficult to accept and would tend to favor the view that full protection of a

particular product on the market depends upon the product patent itself and upon its effective patent term.

While we, of course, welcome the streamlining of premarket regulatory review procedures, I do not think that they can be compressed sufficiently to provide adequate relief for patentees whose effective patent terms are eroded and at the same time be fully satisfactory to safeguard health, safety, and the protection of the environment. And I believe that is the testimony of the other more expert Government witnesses in the area of drug clearances.

There is no reason, however, why both objectives cannot be met. Adequate regulatory review is a matter of necessity. At the same time, it is equally important that pharmaceutical and agricultural chemical industries be afforded the same protection and benefits of the patent system as are available to inventors in other technologies.

Few, if any, other technologies depend for their development upon the lively interaction of scientists and researchers. Publication is often an important factor toward academic and other recognition. Mutual awareness of research results avoids duplication of effort and fosters continuous technological improvements. However, statutory bars against the patentability of published inventions can only be avoided through the prompt filing of patent applications. Foreign filing requirements for obtaining patent protection abroad also dictate that applications be filed promptly. Delaying the beginning of the patent term by postponing the filing of a patent application is therefore an unacceptable solution.

Another possibility would be to delay issuance of the patent until completion of the regulatory review procedure. Although appearing attractive at first because of its administrative simplicity, this option is also objectionable, in our view. Delayed publication of the technology would contribute to wasteful duplication of research and development. Efforts by competitors to develop improved products and methods in nonregulated fields could also be adversely affected, as the patent may well be broader than the product for which regulatory review is sought. Lastly, this solution does not address the problem of regulatory review commencing after the actual issue of the patent.

As noted in previous testimony, still other alternatives to redress the problem have been considered and for various reasons were not found to be satisfactory solutions. The administration, therefore, continues to support enactment of the Patent Term Restoration Act as a fair remedy to correct the inequity of shortened effective patent terms caused by Federal premarket regulatory review procedures.

As far as the scope of the bill is concerned, section 155(c)(4)(D) would extend the possibility of patent term extension to any product which cannot be marketed without the authorization of a Federal regulatory agency. We have little, if any, evidence that such open-ended relief is needed at this time. As a consequence, we do not support this omnibus provision. Other suggestions for improvements in the bill have been detailed to you, Mr. Chairman, in a recent letter from the General Counsel of the Department of Commerce.

In closing, I would stress that enactment of the bill will not impose undue costs or burdens on the Patent and Trademark Office. The mechanics of applying for and receiving a restoration of the patent term are administratively simple. We do believe, however, that present section 155(b)(2) should be amended to authorize us to question whether a patent owner has met all of the conditions for receiving an extension. The section now requires the Commissioner automatically to issue an extension even where conceivably the request contains an obvious and significant discrepancy.

Mr. Chairman, that completes my prepared testimony. I would be pleased to respond to any questions you may have.

[The complete statement of Mr. Mossinghoff follows:]

STATEMENT OF GERALD J. MOSSINGHOFF
COMMISSIONER OF PATENTS AND TRADEMARKS

BEFORE THE

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES
AND THE ADMINISTRATION OF JUSTICE
OF THE
COMMITTEE ON THE JUDICIARY
U.S. HOUSE OF REPRESENTATIVES

ON H.R. 1937
"PATENT TERM RESTORATION ACT OF 1981"

NOVEMBER 12, 1981

Mr. Chairman and Members of the Subcommittee:

I welcome this opportunity to testify on the subject of patent term extension, and to place this concept within the context of our efforts to improve the U.S. patent system.

Having been honored with the appointment as Commissioner last spring, I returned to the Patent and Trademark Office where I began my career in Federal Service as an examiner 24 years ago. Since my return, it has been my privilege to work with Secretary Baldrige and Deputy Secretary Wright on the improvement of the U.S. patent system, which in recent years has come under increasing criticism. We are all familiar with the many current articles decrying the state of the patent system generally and that of the Patent and Trademark Office in particular.

To remedy these problems, we have developed a comprehensive plan of action. Both Secretary Baldrige and Deputy Secretary Wright are committed to reverse, during this Administration, the present trend of the growing backlog of patent and trademark applications and to lower pendency of these applications to respectable levels. A further goal is to lay the foundation for a fully automated Patent and Trademark Office.

The plans for the Office itself are complemented by the new reexamination procedures which went into effect this past July. Those procedures, for which this Subcommittee can take a large part of credit, provide a simple and efficient administrative mechanism to test the validity of issued patents. Our patent system is greatly improved by raising the confidence of patent owners and others in patent validity without their having to resort to protracted litigation in every case.

Judicial consistency in the patent area is another much needed improvement of the patent system. Again, this Subcommittee deserves credit for its efforts which led to the Judiciary Committee's favorably reporting H.R. 4482. We support this bill, as well as its companion S. 1700, which would establish a single Federal appellate court to hear patent cases from district courts and the various administrative boards of the Patent and Trademark Office. Providing a single authoritative tribunal to handle patent cases nationwide will greatly contribute to a single standard of patentability understandable to inventors and business executives.

We are also in need of a Federal patent policy which applies uniformly to all government agencies and to all of their contractors. H.R. 4564 and S. 1657 would establish such a policy, which the Administration supports. A uniform Federal patent policy would encourage industry to invest in inventions resulting from Federal sponsorship, thereby fostering the promotion of private sector capital formation, job creation and productivity.

Just as a uniform Federal patent policy would contribute to the improvement of our patent system, so also would a uniform approach to the effective length of patent terms. The inequity to certain sectors of our industry, whose inventions are denied a full patent term due to Federal premarketing approval requirements has been widely recognized. This Administration also recognizes the need for remedial action to increase innovation. Therefore, it strongly supports enactment of the Patent Term Restoration Act of 1981.

This legislation would add a new section 155 to title 35 of the United States Code to provide for an extension of the patent term for patented products, or patented methods for using products, that are subject to regulatory review pursuant to Federal statutes and regulations before they are permitted to be introduced for commercial use.

Section 155(a) would authorize an extension equal to the regulatory review period up to a maximum of seven years. To obtain this extension, the patent owner would have to notify the Commissioner of Patents and Trademarks that the patented product or method had successfully completed premarket testing and regulatory review.

Section 155(b) would specify the information which the notice to the Commissioner must contain, including the length of the regulatory review period. Upon receipt of such notice, the Commissioner would be required to publish promptly the information contained in the notice and to issue to the patent owner a certificate of extension. Section 155(c) would define certain terms used in the bill.

Our support of the bill is based on the premise that the patent system will provide a healthy stimulant for investment in research and development only if its incentives are not unfairly curtailed. Given the progressive increase in the loss of commercial exclusivity caused by Federally mandated testing and regulatory review requirements, we can no longer ignore the fact that certain sectors of our industry are denied the full benefits which the patent system was intended to provide.

Inventions in agricultural chemical technology, and even more so in the pharmaceutical field, depend heavily on patent protection. Development of such inventions is extremely costly, yet their imitation is often simple and inexpensive. Not only do many other inventions need a far greater outlay of capital to duplicate, but they also may have a shorter life before being overtaken by the advance of technology. Pharmaceutical and agricultural chemical inventions, on the other hand, are generally commercially attractive long after the expiration of the patent term. This is evidenced by the large interest the production intensive sector of industry displays in exploiting those inventions. This interest is a healthy one and competition on the open market should be encouraged. However, to the extent that a shortened effective patent term lessens the incentives of industry to continue making large commitments toward research and development, we should move to ensure that these incentives are restored. Effective patent protection is a necessary prerequisite to pharmaceutical and chemical research, given the enormous costs and risks involved. Enactment of this bill would go a long way toward making that protection effective again.

If we are to reverse our declining rate of innovation, we cannot afford to make our patent system progressively less attractive to important sectors of research intensive industry. The patent system is by no means the only incentive which encourages large amounts of financial commitments to research and development. But it certainly ranks highly among other alternatives in providing the opportunity for rewards to those whose labors have proved successful. Enactment of the Patent Term Restoration Act would redress an inequity by restoring to patentees a part of their

patent term which has been eroded by Federal premarket regulatory review. Given the proposition that the patent term is a form of compensation to the inventor for having fully disclosed his invention to the public, one inventor should not be treated differently from another. The Federal government should not induce full public disclosure of an invention through a patent grant of seventeen years, and then reduce the effective life of the patent through premarket regulatory review procedures.

Opponents of this proposed legislation have argued that the problem which the bill would alleviate has not been demonstrated. They have pointed to high profit margins of industries which would benefit from this bill and have concluded that, as a consequence, there is no problem. I would suggest that the patent system not be misused as an economic regulator of U.S. industry. To establish different effective patent terms depending on the potential economic success of a particular sector of technology is not an approach I would recommend. And to fail to stem the erosion of effective patent terms due to Government regulations is just as unfair. Accordingly, there is a demonstrated problem: certain sectors of our industry, dealing with technologies which are subject to premarket regulatory review, are not receiving the full benefit of the patent system to which they are entitled by virtue of having disclosed their inventions to the public.

Concern has also been expressed that the proposed legislation would further increase the noncompetitive period of exclusivity. Such concerns assume that the period of patent exclusivity is necessarily noncompetitive. But in general, patented products in the market are not completely free from competition. They often compete with other similar patented or unpatented products in the same field of application and are not instant financial successes solely on the basis of having been patented. They are, however, protected from slavish imitations and that protection should be continued for an effectively full patent term.

Opponents of the Patent Term Restoration Act speculate that its enactment would not guarantee the expenditure of greater resources into research and development. Proponents of the bill, on the other hand, note that significant shortening of the patent term, while not the sole reason, has had an adverse effect on research and development investments. I cannot categorically state that patent term extension will significantly increase innovation. I do stress, however, that throughout the many years of its existence, our patent system has encouraged innovation through the incentives it provides. It is a logical deduction that as these incentives are diminished, so is the encouragement which the patent system might otherwise have provided.

Proponents and opponents of this bill have significantly different opinions regarding the actual effective patent life presently accorded to pharmaceuticals. Studies have been cited to show that the effective life of a pharmaceutical patent is about 9.5 years. Others refute this claim by stating that the real average lies somewhere around 18.5 years. Those who assert that the average life of a pharmaceutical patent is greater than 9.5 years, do so on the basis that the effective patent life has been calculated by measuring only the date of the earliest patent issued. They maintain that by obtaining later patents on the same technology, the patentee increases the effective patent life of the product, thereby maintaining an unwarranted market advantage. This practice has been labeled "pyramiding" or "the evergreening of patents".

It is claimed that patentees can prolong their protection by obtaining process and use patents after having been granted a patent on the product itself. While it is certainly possible to obtain additional patents, one should be clear exactly on what basis those patents are obtained and what kind of protection they afford. First, any patent issued must be patentably distinct from any other patent, which is to say, it must contain a different invention. If someone first obtains a product patent and later discovers another unexpected and patentable process for the use of

this product, he is entitled to protection of his invention. This is not an extension of the original patent or a merely obvious variation of the original invention; it is a separate and distinct invention, capable of being patented in its own right.

The same applies to a new discovery of a process for the manufacture of the originally patented product. If such a process is a separately patentable invention it is entitled to protection. In such a case, the patentee of the original product has not extended the patent term of his product, he has made new inventive contributions to the technology. He is therefore entitled to protection in turn for having publicly disclosed his invention.

However, what does a patent on a new use for a product or on a new process of making a product convey to the patentee? Regulatory review aside, if the original patent on the product has expired, the public is free to manufacture that product for all the uses for which the product was originally intended, as well as for any other use, except for the newly patented one. If a patent for a process of manufacture was also obtained, this particular new manufacture is protected, although the public is free to make the product in any other manner. As a consequence, the product itself does not enjoy continued and evergreening patent protection.

Lastly, it must be recognized that practical enforcement of use patents, and of process patents, is difficult. In the case of a protected use, unauthorized substitution is very hard to police. Patents which cover processes for manufacture are equally difficult to enforce. As a consequence, I find the allegations of patent pyramids difficult to accept, and would tend to favor the view that full protection of a particular product on the market depends upon the product patent itself and upon its effective patent term.

While I would welcome the streamlining of premarket regulatory review procedures, I do not think that they can be compressed sufficiently to provide adequate relief for patentees whose effective patent terms are eroded, and at the same time be fully satisfactory to safeguard health, safety and the protection of the environment. There is no reason, however, why both objectives cannot be met. Adequate regulatory review is a matter of necessity. At the same time, it is equally important that pharmaceutical and agricultural chemical industries be afforded the same protection and benefits of the patent system as are available to innovators in other technologies.

Few, if any, other technologies depend for their development upon the lively interaction of scientists and researchers. Publication is often an important factor toward academic and other recognition. Mutual awareness of research results avoids duplication of effort and fosters continuous technological improvements. However, statutory bars against the patentability of published inventions can only be avoided through the prompt filing of patent applications. Foreign filing requirements for obtaining patent protection abroad also dictate that applications be filed promptly. Delaying the beginning of the patent term by postponing the filing of a patent application is therefore an unacceptable solution.

Another possibility would be to delay issuance of the patent until completion of the regulatory review procedure. Although appearing attractive at first because of its administrative simplicity, this option is also objectionable. Delayed publication of the technology involved would contribute to wasteful duplication of research and development. Efforts by competitors to develop improved products and methods in nonregulated fields could also be adversely affected, as the patent may well be broader than the product for which regulatory review is sought. Lastly, this solution does not address the problem of regulatory review commencing after the actual issue of the patent.

As noted in previous testimony, still other alternatives to redress the problem have been considered and for various reasons were also found not to be satisfactory solutions. The Administration, therefore, continues to support enactment of the Patent Term Restoration Act of 1981, as a fair remedy to correct the inequity of shortened effective patent terms caused by Federal premarket regulatory review procedures.

As far as the scope of the bill is concerned, section 155(c)(4)(D) would extend the possibility of patent term extension to any product which cannot be marketed without the authorization of a Federal regulatory agency. We have little, if any, evidence that such open ended relief is needed. As a consequence, we do not support this "omnibus" provision. Other suggestions for improvements in the bill have been detailed to you, Mr. Chairman, in a recent letter from the General Counsel of the Department of Commerce.

In closing I would stress that enactment of the bill will not impose undue costs or burdens on the Patent and Trademark Office. The mechanics of applying for and receiving a restoration of the patent term are administratively simple. We do believe, however, that present section 155(b)(2) should be amended to authorize us to question whether a patent owner has met all of the conditions for receiving an extension. The section now requires the Commissioner automatically to issue an extension even where, conceivably, the request contains an obvious and significant discrepancy.

# # # #

Mr. KASTENMEIER. Thank you, Commissioner Mossinghoff.

As I understand it, your testimony is that you support the bill pending before the committee, save only the two sections you've mentioned in your closing comments.

Mr. MOSSINGHOFF. Yes. One being substantive and the other really being procedural.

Mr. KASTENMEIER. How did you plan to go about questioning whether a patent owner has met all the conditions for receiving an extension?

Mr. MOSSINGHOFF. Well, it would essentially be a formal determination. We would not spend time—we wouldn't look behind what had been done or into what had been done. But if something contains an obvious question that comes out of the work that is provided to us, I think the Commissioner should have the authority to request clarification to determine, for example, when the time started or when the clearance was obtained. You obtain it either through an inquiry to a sister agency that did the regulatory review or to the person requesting the restoration.

Mr. KASTENMEIER. Your other change, you refer to such open-ended relief, whether such open-ended relief is needed. In that respect, are you referring to other products and chemicals and pharmaceuticals which might be subject to some form of regulatory process?

Mr. MOSSINGHOFF. Yes. What I have specific reference to is on page 5. The key phrase in the bill is the term "regulatory review period." Beginning on page 5 of the bill, that phrase is defined in four different ways in paragraphs (A), (B), (C), and (D). The substantive part of the bill refers to the bill encompassing and extending the amount of time for a patent which has been subject to a regulatory review period, and paragraph (A) on page 5 keys into the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, or the act of Congress of March 4, 1913; (B) refers specifically to the Federal Insecticide, Fungicide, and Rodenticide Act; and (C) refers to the Toxic Substances Control Act; (D) then refers in a rather broad way "with respect to any other product or method of using a product that has been subjected to Federal premarketing regulatory review," and conceivably that would include such things as environmental impact statements under the National Environmental Policy Act or OSHA regulations, and I just don't think that the case has been made to extend the coverage beyond the three specific acts.

If the case can be made, I think our position would be the same as on the other three acts. But I think the burden is on those who would try to broaden it to make a case that NEPA or OSHA or whatever should be included. I don't think a factual case has been made.

Mr. KASTENMEIER. I can see that point. I must say that to date we have not had any testimony that there are other specific areas that do need this protection other than the (A), (B), and (C). So I think your comments are well made. There has been no evidence to that effect.

In terms of regulatory delay, let me ask you this. Do you think that the time in which—let's say a pharmaceutical product can be marketed after FDA approval. That point in time to the point at

which patent expires is equivalent to any other invention which has been, one, invented, two, filed, and three, approved by the Patent Office. At that point do you think they are equivalent in terms of marketing?

Mr. MOSSINGHOFF. Based on my experience both in private practice and the government, it usually doesn't take anywhere near that time with other, even complicated, inventions to fabricate, build, and acquire the financing. The corporate decision to proceed doesn't take anywhere near the amount of time that it does to get FDA clearances. There is always some delay, surely. If you have an invention, there is always delay from the time that you know enough about it to file a patent application and acquire a patent to the time you are actually able to put it in the store and have your salesman sell it. There is always a delay. But that delay is nowhere near what these periods of time are in the FDA.

I would say, at the outside, in most areas I believe it would be a year or two between the time that corporate decision is made to proceed and the time an invention can be sold or devices incorporated in the invention. Clearly in the electronics business, the heavy machinery business, I think that's true.

Mr. KASTENMEIER. I yield to the gentleman from Illinois.

Mr. RAILSBACK. Yes. May I ask, are there many examples of pyramiding, as far as you know? I know you said it is very difficult to enforce. I understand that. Say you have a new product. Just the simple fact that your 17-year life is about to expire and then are you permitted to file for a so-called process patent, the manufacturing process, is that done very often or not?

Mr. MOSSINGHOFF. I really don't know how often that is done. I am not that familiar with the chemical industry, as a practical matter. It is certainly possible after a product has been on the market for a long time to invent a new process for making the product and patent that process and obtain a valid patent on the process. The fact is, after the product patent expires, whoever wants to make that product can use all other unpatented, including the original, ways of making it.

Mr. KASTENMEIER. That is what I am asking. In other words, I take it that we are assuming that this is not permitted except where there is a new process.

Mr. MOSSINGHOFF. A new method and an unobvious method that has to satisfy all the requirements for patentability in its own right; and once the product patent expires, that product can be made by a generic company using the old process.

I read the testimony of Genentech before the Senate on the Senate counterpart of this bill, and their company, which specializes in new ways of producing existing drugs, dramatic new ways. It seems to me that's not an evergreening of the patent; that's just a very significant invention which somehow deserves to be patented.

Mr. RAILSBACK. So what you are saying is really once the product life protection expires there is nothing to prevent a generic company from either using the old process or, for that matter, developing it for all of the uses that the original patentee listed and used.

Mr. MOSSINGHOFF. That's right.

Mr. RAILSBACK. OK. Thank you.

Mr. KASTENMEIER. The gentleman from Virginia.

Mr. SAWYER. Thank you, Mr. Chairman.

You have in your suggestion that section 155(b)(2) should be amended to authorize us to question whether a patent owner has met all the conditions for receiving an extension. Do you have language you want to suggest to us for that?

Mr. MOSSINGHOFF. Yes, sir. We included language in a letter to the subcommittee that the Deputy General Counsel of the Department of Commerce sent up on July 27.

Mr. SAWYER. Thank you very much. Mr. Chairman, are we going to get a copy of that?

Mr. KASTENMEIER. Yes.

Mr. SAWYER. No further questions.

Mr. KASTENMEIER. On behalf of the committee we thank you, Commissioner Mossinghoff, for your presentation before the committee today and compliment you on your testimony.

Mr. MOSSINGHOFF. Thank you very much.

Mr. KASTENMEIER. That concludes our witnesses today. We will have two more witnesses on Wednesday, November 18. Until that time the subcommittee stands adjourned.

[Whereupon, at 11:18 a.m. the hearing was adjourned.]

PATENT TERM RESTORATION ACT OF 1981

WEDNESDAY, NOVEMBER 18, 1981

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES
AND THE ADMINISTRATION OF JUSTICE,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to call, at 10:08 a.m., in room 2226, Rayburn House Office Building, Hon. Robert W. Kastenmeier (chairman of the subcommittee) presiding.

Present: Representatives Kastenmeier, Railsback, Sawyer, and Butler.

Also present: Bruce A. Lehman, counsel; Timothy A. Boggs, professional staff member; Thomas E. Mooney, associate counsel; and Audrey Marcus, clerk.

Mr. KASTENMEIER. The committee will come to order.

We are again in hearing this morning on patent term restoration, represented by bills H.R. 1937 and S. 255.

This morning, we will consider principal amendments to the bill, among other items, and I am pleased to be with my colleague on the rostrum this morning, Congressman Bob McClory, of Illinois.

Our first witness this morning is an old friend and indeed our former colleague of this body. He is the distinguished Senator from Iowa, Hon. Charles Grassley. We are very pleased to greet Senator Grassley over on our side, and indeed we will be very interested in what Senator Grassley has to say.

TESTIMONY OF HON. CHARLES E. GRASSLEY, A SENATOR IN THE CONGRESS FROM THE STATE OF IOWA

Senator GRASSLEY. Thank you, Mr. Chairman, and members of the subcommittee, former colleagues of mine. It is gracious of you to allow me to bring to your attention a necessary clarification of H.R. 1937, the patent term restoration bill.

I have an Iowa constituent whom I sincerely feel would be jeopardized by the bill as it presently stands. Her name is Mary Collins, president, Impro, Inc., of Waukon, Iowa.

As a member of the Senate, I cosponsored similar language as S. 255. When the Senate held a hearing on April 30, 1981, I raised the question of the trigger provisions, but the answers did not address this present situation.

Since that time, it has been brought to my attention that there are provisions within these bills that need amending. That is why I am here today, to insure that my constituent and others like her do not lose a timely opportunity to express their views and obtain equity. I will be happy to answer any questions you may have.

We, as legislators, have been partially responsible for the problem this legislation addresses. And so I support the concept that it is equitable to restore to those inventors their time lost from patent life due to the agency regulatory review process.

On the Senate side, we perceived this problem as an anomaly. Nowhere in our report or hearing, however, was the express concern I bring before you today addressed: That H.R. 1937 does not cover those patentholders who lose additional patent life due to invalid agency tests or bias and who have to secure their license by court decree or administrative order.

Concern has only been expressed in the past by witnesses and legislators about premarket testing, regulatory review requirements, or lengthy review processes. Objections are discussed in section (4)(A)(iii), but nowhere is it stated that if an agency is found at fault will there be compensated time given in addition to the 7-year cap both bills provide. This time usually runs an extra 3-5 years.

We, in the Senate, discussed our intention not to promote dilatory actions for prospective users of this legislation, but again did not cover those in the pipeline. During your recent hearings, based on a request to my Republican colleagues to raise this issue—which they graciously did—agency officials gave a nonanswer to questions about retroactivity.

Your counsel, on behalf of Representative Frank, asked them about delays between patent grants and marketing caused by litigation, but the witness-answer by the Pharmaceutical Manufacturers Association was also nonresponsive. They only addressed significant competition, and that they were not aware of other delays. So, I feel it is essential I raise this issue again.

With regard to the effective date of this bill, only Merck testified in our Senate hearing that their products in the FDA pipeline would have less than 8 years of patent life left when this bill is passed. I would like to briefly explain the situation as I see it and as it affects my constituent to show you where the damage occurs to her and those in her class.

In 1965, Impro filed an FDA application, which was turned over to USDA for jurisdiction.

USDA issued a temporary license and then revoked it pending further testing.

USDA conducted a test in 1966 which is now the subject of judicial review that charges they violated their own protocols and deliberately sabotaged the tests.

During the years from 1967-80, this firm complied with all agency regulatory review processes and obtained information that clearly established the invalidity of the tests.

In the meantime, the patent for their product was issued in 1968.

Former Representative Gross of Iowa, my predecessor in the House, and Representative Charlie Rose, on whose subcommittee I sat in 1978, both helped with this problem.

In 1981, the firm filed in court to get the test declared invalid and obtain their license. It is expected another 3 to 5 years will pass before a decision is rendered.

These actions have now taken 13 years off their patent life.

So, you can see, the 7-year cap and effective date do not address those in the pipeline under the situation described here.

My constituent has fought an uphill battle with the regulators. Subsequent events have proven her correct. The issue here is that she, and others like her fighting for their legal rights, should be covered by this bill and given sufficient time to market their products when a decision comes down in their favor.

I strongly support my constituent's request that some form of amendment and clarifying language in the report and bill clearly states: If a patentholder is to receive back that period of time lost due to agency review, it will include time lost due to invalid tests and litigation arising from agency fault. I submit several solutions for your consideration:

One, add language to section 155 about "objections", after the words "approval or license"; or to the validity of a test, with respect to the product or method for using the product, conducted by or under contract or other arrangement for the regulatory review agency * * *."

Later continue in the next paragraph, after "such objections"; or on the basis of an invalid test, conducted by or under contract or other arrangement for the regulatory review agency", ending on the date such proceedings "or such controversy regarding the test" are finally resolved * * *."

Two, grant an exception to the 7-year cap and allow for specific language that says: "except that such additional time shall be granted to include that period of time lost from patent life due to agency fault." [Court decree in the affirmative implied.]

Three, on the Senate side, we adopted the Searle amendment—section 155(c)(4)(D). If that language is adopted here, I request an amendment be added after their words "January 1, 1981". They would be: "or for products for which judicial review is pending" and after the words "stay was imposed", add, "or such judicial review is completed * * *."

Four, also, clarifying language must be inserted in the committee report that this issue has been raised and the bill covers or does not cover it.

To make these changes would provide equity for my constituent and all those in her class as they struggle to market their inventions for the benefit of mankind. My staff is available to sit down with yours and work out what is best for all concerned.

I would also like to have submitted for the record a statement I put in the Congressional Record October 7, 1981, a statement I made on the Senate floor on this issue.

That is the end of my statement.

[The complete statement of Senator Grassley follows:]

[The statement in the Congressional Record dated October 7, 1981, follows:]

STATEMENT BY HON. CHARLES E. GRASSLEY, A SENATOR FROM IOWA

Mr. Chairman, thank you for your gracious consent to allow me to bring to your attention a necessary clarification of H.R. 1937, the Patent Term Restoration Bill. I have an Iowa constituent whom I sincerely feel would be jepardized by the bill as it presently stands. Her name is Mary Collins, President, Impro, Inc., of Waukon, Iowa. I co-sponsored this bill as S. 255. When the Senate held a hearing on April 30, 1981, I raised the question of the "trigger" provisions, but the answers did not

address this present situation.[1] Since that time, it has been brought to my attention that there are provisions within these bills that need amending. That is why I am here today, to ensure that my constituent and others like her do not lose a timely opportunity to express their views and obtain equity. I would like to submit this testimony for the record, along with a copy of remarks I made for the Congressional Record. I'll be happy to answer any questions you may have.

We, as legislators, have been partially responsible for the problem this legislation addresses. And so, I support the concept that it is equitable to restore to those inventors their time lost from patentlife due to the agency regulatory review process. On the Senate side, we perceived this problem as an "anomaly." [2] Nowhere in our report or hearing, however, was the express concern I bring before you today addressed: That H.R. 1937 does not cover those patentholders who lose additional patentlife due to invalid agency tests or bias and who have to secure their license by court decree or Administrative Order.

Concern has only been expressed in the past by witnesses and legislators about "premarket testing", regulatory review requirements, or "lengthy review processes." "Objections" are discussed in Section (4)(A)(iii) but nowhere is it stated that if an agency is found at fault will there be compensated time given in addition to the seven-year cap both bills provide. This time usually runs an extra 3-5 years.

We discussed our intention not to promote "dilatory actions" for prospective users of this legislation, but again did not cover those in the pipeline. During your recent hearings, based on a request to my Republican colleagues to raise this issue (which they graciously did), agency officials gave a non-answer to questions about retroactivity. Your counsel, on behalf of Rep. Frank, asked them about delays between patent grants and marketing caused by litigation but the witness answer by the Pharmaceutical Manufacturers Association was also non-responsive. They only addressed "significant competition", and that they were not aware of "other delays." So, I feel it is essential I raise this issue again.

With regard to the effective date of this bill, only Merch testified in our Senate hearing that their products in the FDA pipeline would have less than 8 years of patentlife left when this bill is passed.[3] I would like to briefly explain the situation as I see it and then let my constituent explain the fine points herself to show you where the damage occurs to here and those in her class.

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USDA issued a temporary license and then revoked it pending further testing.

USDA conducted a test in 1966 which is now the subject of judicial review that charges they violated their own protocols and deliberately sabotaged the tests.

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In 1981, the firm filed in court to get the test declared invalid and obtain their license. It is expected another 3-5 years will pass before a decision is rendered in their favor.

These actions have now taken 13 years off their patentlife. So, you can see, the seven-year cap and effective date do not address those in the pipeline under the situation described here. This lady speaks the truth and subsequent events have proven her right. The issue here is that she, and others like her fighting for their legal rights should be covereed by this bill and given sufficient time to market their products once a decision comes down in their favor.

I strongly support my constituent's request that some form of amendment and clarifying language in the report and bill clearly states: If a patentholder is to receive back that period of time lost due to agency review, it will include time lost due to invalid tests and litigation arising from agency fault. I submit several solutions for your consideration:

1. Add language to Section 155 about "objections", after the words "approval or license"; or to the validity of a test, with respect to the product or method for using the product, conducted by or under contract or other arrangement for the regulatory review agency . . . " Later continue in the next paragraph, after "such objec-

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[1] Senate Hearing Record, S. 255, "The Patent Term Restoration Act," J-97-21, April 30, 1981, pages 20, 250-261.

[2] Senate Report 97-138, "The Patent Term Restoration Act of 1981," June 16, 1981, page 2.

[3] "Senate Hearing Record," ibid., page 59.

tions"; or on the basis of an invalid test, conducted by or under contract or other arrangement for the regulatory review agency," ending on the date such proceedings "or such controversy regarding the test" are finally resolved . . . ."

2. Grant an exception to the 7-year cap and allow for specific language that says; "except that such additional time shall be granted to include that period of time lost from patentlife due to agency fault. (court decreed in the affirmative implied).

3. On the Senate side, we adopted the Searle Amendment (Section 155(c)(4)(D). If that language is adopted here, I request an amendment by added after their words "January 1, 1981," They would be: "or for products for which judicial review is pending" and after the words "stay was imposed", add, "or such judicial review is completed. . . . "

4. Also, clarifying language must be inserted in the Committee Report that this issue has been raised and the bill covers or does not cover it.

To make these changes would provide equity for my constituent and all those in her class as they struggle to market their inventions for the benefit of Mankind. My counsel is available to sit down with yours and work out what is best for all concerned.

Thank you.

[From the Congressional Record, Oct. 7, 1981]

S. 255. The Patent Term Restoration Act (H.R. 1937)

Mr. Grassley. Mr. President, it has been brought to my attention that S. 255, the Patent Term Restoration Act (H.R. 1937), is presently being considered in the House of Representatives. A clarification is needed to help those patentholders subjected to invalid tests and litigation outside the normal regulatory review period covered in this legislation.

This class of patentholders would not receive the same equity as those who obtain their licenses in the normal course of business. Rather, they lose additional patentlife due to the exercise of their administrative/legal rights. I raise a preliminary question about this issue of "trigger provisions"/time extension at our Senate hearing on April 30, 1981, but not feel it was adequately answered.

In the course of applying for licenses, the regulatory agencies require patentholders to provide proof of efficacy and safety. They require patentholders to test their products and they also conduct their own agency research. Many times agencies contract out to private researchers because they lack in-house specialization or equipment. In the process, they remain fully aware of the time limitations placed on the patents of their applicant licensees.

Businesses normally try to obtain licenses at the beginning of their patent-life period, allowing for a full 17-year marketing cycle.

Since most applications are filed during the patent pending stage in the normal regulatory review period, only a few years of patent life are used. The right to patent usually comes along at the same time the license is approved. This is a normal and prudent business practice. However, when one has to exercise their administrative/legal rights due to agency fault, then most of the patent life is consumed as the licensees seek equity.

I strongly recommend that clarifying language with regard to such invalid agency tests from patentholders exercising their lawful administrative and legal right be included in this legislation. That language, which I am now presenting to the Judiciary Committee of the Hosue of Representatives, Subcommittee on Courts and Civil Liberties is to correct this gap.

A second problem is how to grant time equity for those applicants who came into the regulatory review period pipeline many years ago and are still engaged in the lawful exercise of their administrative/legal rights. If this legislation passes in its present form, they would only have a year or two of redress and no normal marketing period. This is not in conformity with the intent of this legislation.

I propose the effective date of this section be amended to add language allowing for an exception "that such additional time shall be granted to include that period of time lost from patent life due to agency fault." I feel these minor changes in S. 255—H.R. 1937—would restore equity to this class of patentholders I feel are not presently convered. I will work with the final stages of this legislation to insure it is amended properly or clarified to my satisfaction.

I bring this to your attention because there have been numerous challenges to agency testing procedures through the years. They have had to be initiated by regulated licensees who sincerely felt and could prove the agency was at fault in denying them a license or conducting a test. I personally know of an Iowa firm

which is involved with such a problem with invalid agency tests and are now losing most of their patent life as they pursue their lawful administrative/legal rights. I feel such people should be compensated and that this action would not be a windfall, but equity.

Mr. KASTENMEIER. Thank you, Senator Grassley, for a very able and concise statement. Indeed, your statement in its entirety, together with the four suggestions for statutory language and the statement you made with respect to this question on the Senate floor, will be received as a part of the record.

I have just one or two questions.

How would one determine agency fault? Would one have to litigate that, or how would you determine when the agency is at fault?

Senator GRASSLEY. That is a subject of litigation now, and I would presume that, as far as I am concerned, it could still be the subject of litigation. It would not preclude, but I don't have any suggestions, that it ought to be statutory, but I would be satisfied, and I think it would cover the instance I cover if the courts made that determination.

Mr. KASTENMEIER. In other words, that might be litigated, and if agency fault were held applicable, among other remedies would be the extension of terms?

Senator GRASSLEY. That is the way I see it at this point. Now, that may be a little more narrow than it ought to be, but I am suggesting to you a narrow instance, one that we forgot about, but I don't think I ought to impress upon you that it ought to preclude whatever your research would indicate to be the broadening of it, because I think sometimes we can be too narrow in our approach. But I think this would satisfy the problem that my constituent has and that presumably out of 220 million people there is somebody else in the country who would have the same problem; but I don't know of any.

Mr. KASTENMEIER. As far as you know, at the present time, only Impro, Inc., an Iowa corporation, has this problem, but indeed it may be common to others as well.

Senator GRASSLEY. There are others in litigation, but we haven't been able to get the figures from the agency yet.

Mr. KASTENMEIER. The gentleman from Michigan, Mr. Sawyer.

Mr. SAWYER. I have no questions.

Mr. KASTENMEIER. The gentleman from Virginia.

Mr. BUTLER. What is the product of Impro?

Senator GRASSLEY. It is a product used for fighting diseases to keep resistance down, resistance of animals. Basically, it is veterinarian.

Mr. BUTLER. I have no further questions.

Mr. KASTENMEIER. In that case, we thank you for your appearance today and urge you to come over more often. We appreciate your appearance.

Senator GRASSLEY. Mr. Chairman, could I confirm with you, will there be a technical session of staff to work on amendments between now and consideration by the committee?

Mr. KASTENMEIER. I assume various amendments to the bill—and there are amendments to the bills being proposed—at the point of markup, will be offered by one or more members on the subcom-

mittee. There are seven of us: The Chair's assumption is that in one form or another they will be considered.

Senator GRASSLEY. Is my testimony sufficient for consideration of that, or would you like to have my staff around to work with your staff on this language, so that I know it will be considered?

Mr. KASTENMEIER. It would be useful if your staff would be willing to put the four points on page 3 of your testimony into amendment form. It approximates that now, as a matter of fact. It is very close to that presently, but I think for our purposes if you would do that so it may be considered at the appropriate time during markup, it would be useful.

Next, the Chair would like to call Mr. John Robson. With our second witness is our distinguished colleague and senior member of the Judiciary Committee, our friend, Bob McClory, of Illinois.

STATEMENT OF ROBERT McCLORY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. MCCLORY. Mr. Chairman, I have come here this morning to introduce a very distinguished witness appearing before your committee today.

John Robson is former General Counsel of the Department of Transportation in our Federal Government. He was Chairman of the Civil Aeronautics Board in the Ford administration and in that capacity he promoted the deregulation of the airlines which contributed so much toward consumers' benefit.

He is executive vice president of G. D. Searle, and works with our former colleague there, who is president of the company, John Rumsfeld. He has a special interest in this legislation, which Mr. Robson will explain. He is a very able lawyer, and I know that he will be able to delineate the problems which G. D. Searle has and suggest an amendment or amendments which can contribute to equity and fairness in connection with the development of this important patent legislation.

Mr. KASTENMEIER. We thank our colleague for that introduction of our witness.

Mr. Robson, you are most welcome, and we would be pleased to hear your testimony.

TESTIMONY OF JOHN E. ROBSON, EXECUTIVE VICE PRESIDENT, G. D. SEARLE & CO., ACCOMPANIED BY DR. FRANK STURTEVANT, DIRECTOR, OFFICE OF SCIENTIFIC AFFAIRS

Mr. ROBSON. As Representative McClory said, my name is John Robson. I am the executive vice president of G. D. Searle & Co. With me is Dr. Frank Sturtevant, who is director of Searle's office of scientific affairs.

We appreciate the opportunity to appear before the committee in support of H.R. 1937. You have already heard a great deal of testimony concerning this legislation. Searle joins with the many others who have appeared before your committee in support of H.R. 1937.

Our purpose today is to discuss an amendment the Senate made when it passed this legislation. The amendment was proposed by Senator Heflin and unanimously adopted. It was the only amendment to the original bill adopted by the Senate, and it applies to a

small class. The amendment would apply to aspartame, the low-calorie sweetener developed by Searle.

Let me take a moment to describe aspartame. It is a food additive, not a drug. It is a combination of two amino acids which are the constituents of protein. The two amino acids which comprise aspartame occur naturally in more than half of all foods. Independently, they are not sweet, but when coupled, they produce an intensely sweet taste—about 200 times sweeter than sugar. So small quantities of aspartame produce a sweetness equal to sugar at a fraction of the calories. And, because aspartame is made up of two naturally occurring amino acids, it is metabolized by the body in the same way as proteins are when consumed in meat or milk.

If you have questions on the scientific aspects of aspartame, Dr. Sturtevant would be happy to answer them later.

When aspartame was finally approved by the FDA in July of this year, it became the only sweetener to be approved by the Food and Drug Administration [FDA] in the last 25 years and one of only three sweeteners to come on the market since the turn of the century.

The committee is aware of the FDA's position on the two artificial sweeteners—cyclamates and saccharin. The FDA has removed cyclamates from the market. And, as you know, an act of Congress has deferred FDA's proposed actions to remove saccharin from the market or severely limit its use.

For millions of people who are diabetic or for whom obesity is a life-threatening disorder, the availability of a low-calorie or nonsugar sweetener is critical. And millions of diet and health-conscious people consider such a product essential for a balanced, healthy diet. For these groups the FDA's concerns about artificial sweeteners have posed a serious dilemma. Aspartame is one answer to this dilemma. Unfortunately, because of 8 years in the regulatory morass, aspartame has not reached the people who could have benefited from its availability.

Mr. Chairman, members of the subcommittee, I have in recent years served as chairman of a Federal regulatory agency. I am well aware that there are delays and mishandled cases in a regulatory system. However, I submit to you that the FDA's handling of aspartame—finally approved for marketing in July of this year—is an unparalleled instance of unnecessary regulatory delay and ineptitude which has worked an egregious injustice to Searle.

Briefly recounted, the tortuous regulatory history of aspartame is as follows:

On January 19, 1970, Searle was issued a use patent on aspartame as a sweetener. The necessary toxicity and other scientific studies were then conducted over the next 3 years. In February 1973, Searle submitted to the FDA an application for approval of aspartame. After a year and one-half of review, in July of 1974, the FDA approved Searle's aspartame food additive petition. Up to this point, even though 4½ years of patent life had expired, the regulatory treatment given aspartame was normal, the same given most other food additives submitted at the time.

Then things changed.

In August 1974, two private individuals objected to FDA's authorization to market aspartame—as they were entitled to do

under FDA regulations—and requested that FDA stay its permission. The Agency, however, rejected this request because, in FDA's words, the objectors "* * * did not indicate that there is any new reliable evidence that aspartame is unsafe."

The law provided that the objectors could request an administrative evidentiary hearing on their objections. Searle was prepared to participate in such a proceeding. However, 6 months following its approval of aspartame, in January 1975, FDA proposed that a totally new procedure, a Public Board of Inquiry [PBOI] be utilized if the objectors would waive their rights to an evidentiary hearing. The Public Board of Inquiry procedure had never been used before. No regulations or procedures had been developed or adopted. According to FDA, the PBOI was designed to provide a prompt, professional resolution of scientific issues. Searle voluntarily withheld marketing of aspartame on the assurance that the inquiry and resolution of the issues raised by the objectors would be expeditious.

Another 6 months passed without any tangible progress on the administrative front and with Searle still withholding aspartame from the market.

In July 1975, a middle-level FDA official suggested in a congressional hearing that there were inaccuracies in certain Searle animal research studies. This testimony sparked an FDA investigation.

Six months later, on December 5, 1975, the FDA Commissioner, without giving Searle an opportunity for a hearing, ordered a stay imposed on the Agency's 1½-year-old approval of aspartame. The stay was based on FDA's assertion of a need to verify certain aspartame scientific data submitted by Searle to FDA.

Mr. KASTENMEIER. I am sorry to interrupt you. However, there is a vote on the House floor for which this subcommittee is responsible. I shall have to recess the committee for about 15 minutes. We will be back at that time and will be very pleased to hear the balance of your statement. For the period of 15 minutes the subcommittee is recessed.

[Recess for Members to vote.]

Mr. KASTENMEIER. The subcommittee will be in order. When the subcommittee recessed, we were in the process of hearing Mr. Robson's testimony.

Mr. Robson, if you will be good enough to continue.

Mr. ROBSON. I shall pick up right where I left off, Mr. Chairman.

The stay was based on FDA's assertion of a need to verify certain aspartame scientific data submitted by Searle to FDA. FDA also refused to convene the PBOI or any other form of hearing, despite the fact that Searle was willing to proceed to a public administrative proceeding that could have resolved the issues raised by the objectors.

However, not until April 1977—17 months after FDA's stay was imposed—did a team of FDA officials actually come to Searle to examine the research records.

Finally, in July 1977, at FDA's insistence, Searle agreed that, to break the logjam, the authenticity of the data should be further reviewed by an independent organization of academic scientists recommended by FDA. To our knowledge, this review, like the

PBOI procedure, was an entirely novel step in the food additive regulatory process.

In August 1977, Universities Associated for Research and Education in Pathology [UAREP] a group of distinguished academic scientists, was commissioned to conduct this unique review of Searle's data. This review, submitted by UAREP to FDA in December 1978, confirmed the authenticity of the Searle aspartame data. FDA indicated its agreement with the UAREP findings.

Now, believing that no legitimate barrier remained to its marketing of aspartame, in April 1979, Searle requested that FDA remove the stay FDA had imposed in 1975. Searle pointed out that the sole basis for the stay—questions concerning the authenticity of data—had been removed by the UAREP report and by the FDA's own review. Although he conceded that fact, FDA Commissioner Kennedy nonetheless refused to lift the stay, emphasizing the imminence of the Public Board of Inquiry hearing on the old objections, and stating in his letter to Searle of April 10, 1979, that he was advised that the hearing would be "* * * convened this summer." However, it was not until January 1980—nearly 9 months later—that the PBOI actually convened. The PBOI hearing concluded on February 1, 1980.

Five years after FDA had imposed its stay, nearly 2 years after UAREP had authenticated the aspartame data, and 8 months after the PBOI hearing concluded—FDA released the report of the Public Board of Inquiry. The Board's report concluded that marketing of aspartame should be delayed until an additional study was done.

Ten months later, in July of this year, 1981, the FDA Commissioner disagreed with the Board on the need for additional scientific studies, removed the stay and permitted the marketing of aspartame to begin in October 1981.

Seven years passed from the date of FDA's original approval of aspartame in 1974 to the lifting of the stay in 1981. Not a grain of aspartame was marketed to the U.S. consumer during that period. The aspartame approval process spanned the tenure of seven FDA Commissioners. Today, 5 years and 1 month of the original 17-year patent life remain—about 33 percent.

I don't propose to discuss here the scientific issues concerning aspartame. The aspartame data has been examined and the product approved for use by the health regulatory authorities of France, Canada, Switzerland, Belgium, Luxembourg, Brazil, Mexico, the Philippines, the Food Additive Committee of the World Health Organization, and the FDA.

FDA Commissioner Hayes, in his decision last July, noted that "few compounds have withstood such detailed testing and repeated, close scrutiny * * *." The health regulatory agency of Canada stated that, "The data on the safety of aspartame are the most comprehensive ever received by the health protection branch in support of a food additive." To this, I can add nothing.

What I do want to emphasize is the unique and wholly unorthodox handling of aspartame by the FDA and the repeated and protracted regulatory delays that have stolen a substantial portion of aspartame's patent life and worked a real injustice.

Aspartame became the FDA proving ground for a novel, untested procedure—the Public Board of Inquiry—for which there were no regulations or guidelines except as FDA prescribed them as they went along.

Sixteen months elapsed after questions about the authenticity of data were raised by FDA personnel before the FDA commenced an on-site investigation—December 1975 to April 1977.

Sixteen months were consumed by the FDA's insistence that the aspartame data be submitted for verification to an independent organization of academic scientists—July 1977 to December 1978.

Thirteen months elapsed—December 1978 to January 1980—after all data had been verified before the Public Board of Inquiry was convened.

Eighteen months elapsed between the conclusion of the PBOI hearing and the FDA's decision.

Despite the fact that FDA had in 1974 decided that the objections raised by the two individuals were not sufficient to justify a stay, FDA refused for 30 months to lift the stay once the questions about the authenticity of data were resolved—April 1979 to October 1981.

I am aware that some delays do occur in the regulatory process. But the delays of this type—especially when a perishable commodity like patent life is in the balance—go beyond the bounds of reason or excuse.

The regulatory zigging and zagging in this case was unique. First the approval. Then a decision by FDA not to stay when objections were made by third parties. Then a Public Board of Inquiry for which there was no precedent or procedure. Then a decision to stay its previous approval. Then outside verification of data. Then the persistent refusal of FDA to lift its stay, although the basis for the stay had been removed. Then—8 years later—approval once again.

The amendment to H.R. 1937 in the form passed by the Senate provides some redress for the set of actions which we believe a dispassionate observer would conclude represent a flagrant regulatory miscarriage.

Your committee has jurisdiction over the appropriate form of remedy. This is not a wrong that can be redressed by litigation or monetary awards against the Government. The right to benefit from one's invention is inherent in the patent law. That is what has been lost in this unique case. Neither the FDA nor the courts can do anything about that. This statutory provision is the appropriate remedy. It is properly a part of H.R. 1937, which deals with the issue of de facto patent life in the area of pharmaceuticals and food additives.

It is important for the committee to note what this provision we are discussing today does and what it does not do. The provision applies to a very limited class. Indeed, to our knowledge, it does not apply to any other product.

The provision does not attempt to reach back and restore to the patent life from its granting in 1970 or to cover the normal regulatory review period that began in February 1973 and ended in July 1974, when the FDA initially approved aspartame.

The provision does not attempt to reach back and restore to the patent life the 1½ years that elapsed between July 1974 and December 1975, when Searle withheld marketing on FDA assurances

of prompt resolution of the issues raised by the two objecting individuals.

The provision, in the case of aspartame, restores to the patent life only the 5½ years that elapsed during the unprecedented stay FDA imposed on the marketing of aspartame in December 1975, after the product had been approved, and which FDA did not remove until October 1981.

This amendment would put aspartame back in essentially the same position in terms of patent life as all other approved food additives that went through the FDA regulatory review process back in 1973 and 1974.

There is, I believe, a further purpose that recommends this provision. Research remains to be done on additional uses and new processes for manufacturing aspartame. For example, means to prolong aspartame's shelf life can expand its use in low calorie beverages and other liquid food products. Also, aspartame at present cannot be subjected to intense heat over a prolonged period of time, precluding its use in any product that requires baking or heat processing.

As I mentioned above, only about 5 years remain on the aspartame patent. The incentives to continue and expand future research and development on aspartame, perhaps making it usable for the public in many different new applications, will be positively influenced if this provision is enacted.

Research investment is risky. The value of that investment is dramatically affected by the regulatory process. It would seem useful, then, in the rarer instances when egregious examples of regulatory mishandling occur, that they be remedied. There is a value in stating to those who contemplate increased research investments that when things get horribly off the track, that they can be fixed. Such action adds to the confidence of innovators that the atmosphere in the area in which they must operate is one of fairness and equity.

In summary, then, we urge your approval of H.R. 1937 in the form passed by the Senate.

We again wish to express our appreciation for letting us appear.

We will be happy to answer any questions you might have.

["Aspartame: A Brief Chronology" follows:]

ASPARTAME: A BRIEF CHRONOLOGY

	February, 1973	Searle submits petition to the FDA for use of aspartame as food additive.
	July, 1974	The FDA approves aspartame for use in dry-based foods and beverages.
18 months delay	December, 1975	The FDA Commissioner stays approval of aspartame pending validation of certain Searle research studies; Board of Inquiry held in abeyance.
17 months delay	July, 1977	The FDA completes validation of three Searle studies. UAREP now permitted to proceed with validation of remaining toxicity studies.
13 months delay	December, 1978	UAREP validation of remaining 12 Searle studies is submitted to the FDA.
	April, 1979	Searle asks the FDA to lift stay on aspartame's approval.
		The FDA Commissioner confirms that Searle studies have been authenticated by UAREP but denies Searle's request to lift the stay; he determines that Board of Inquiry on original objections must be conducted first.
8 months delay	January 30, 1980	Public Board of Inquiry convened.
	October 1, 1980	Public Board of Inquiry submits report and its decision on aspartame to the FDA Commissioner.
10 months delay	July 15, 1981	The FDA Commissioner makes final ruling on aspartame.

Total delay: 5½ years.

ASPARTAME: A CHRONOLOGY

December, 1965	Aspartame sweetening properties are discovered by G. D. Searle & Co. scientist, James M. Schlatter.
March, 1966	Searle begins two years of extensive research to learn properties and commercial possibilities of aspartame.
June, 1969	Searle begins safety testing to submit data for FDA review of aspartame.
February, 1973	Searle submits petition to FDA for use of aspartame as food additive.
July, 1974	FDA approves aspartame for use in dry-based foods and beverages.
August, 1974	Dr. John Olney and attorney James Turner file objections to FDA's approval of aspartame.
December, 1974	FDA proposes a Public Board of Inquiry as procedure for resolving questions raised by objectors.
December, 1975	FDA Commissioner stays approval of aspartame pending validation of certain Searle research studies; Board of Inquiry held in abeyance.
September, 1976	FDA recommends that Universities Associated for Research and Education in Pathology (UAREP) review 15 aspartame toxicity studies. Searle agrees.
April, 1977	FDA decides it will review three of the 15 studies to speed up validation process.
July, 1977	FDA completes validation of three Searle studies. UAREP now permitted to proceed with validation of remaining toxicity studies.
December, 1978	UAREP validation of remaining 12 Searle studies is submitted to FDA.

ASPARTAME: A CHRONOLOGY

April, 1979	Searle asks FDA to lift stay on aspartame's approval.
	FDA Commissioner confirms that Searle studies have been authenticated by UAREP but denies Searle's request to lift stay; he determines that Board of Inquiry on original objections must be conducted first.
June, 1979	FDA announces intention to convene Public Board of Inquiry on aspartame.
August, 1979	France approves use of aspartame as a sweetener in tablet form.
August, 1979	Three-member Board of Inquiry named.
September, 1979	Canadian Health Protection Branch issues Information Letter recommending approval of aspartame.
January 15, 1980	FDA announces date for PBOI hearing.
January 30, 1980	Public Board of Inquiry convened.
February, 1980	Belgium and Luxembourg approve use of aspartame as a sweetener in tablet form.
August 29, 1980	Philippines approves use of aspartame as a sweetener in both tablet and powder form.
September 29, 1980	Brazil approves use of aspartame as a sweetener in both tablet and powder form.
October 1, 1980	Public Board of Inquiry submits report and its decision on APM to FDA Commissioner.
December 16, 1980	Searle is notified that the Joint Expert Committee on Food Additives (JEC/FA) of the FAO-WHO are recommending aspartame for human use at an acceptable daily intake of 40/mg/kg of body weight.
December 19, 1980	Searle submits its report of Exceptions to the Decision of the Public Board of Inquiry.
January 26, 1981	Searle submits its Response to Exceptions to the Decision of the Public Board of Inquiry.
July 15, 1981	FDA Commissioner makes final ruling on aspartame.

Mr. KASTENMEIER. The gentleman from Illinois, Mr. Railsback.

Mr. RAILSBACK. Thank you, Mr. Chairman. I want to welcome a very good friend that I almost forgot was going to be here this morning.

Let me ask you this: You mentioned, I think in your statement, that we are dealing with a use patent rather than a product patent?

Mr. ROBSON. That is correct.

Mr. RAILSBACK. Why is that?

Mr. ROBSON. The patent that was granted to Searle, Mr. Railsback, does not cover the combination of the two amino acids I talked about earlier. It covers only the use of those constituents as a sweetener.

Mr. RAILSBACK. As I understand your statement, you are really concerned about, after the approval has been granted——

Mr. ROBSON. That is correct. During only the period of the stay which was imposed by FDA.

Mr. RAILSBACK. Was your amendment offered on the Senate floor by Senator Heflin?

Mr. ROBSON. I believe that is the procedure under which it was handled; yes, sir.

Mr. RAILSBACK. I am curious, why was it at that stage, or was there consideration by the Senate earlier in committee?

Mr. ROBSON. I am not sure of the answer to that, but I can provide it to the committee.

[The information follows:]

HEFLIN AMENDMENT

G. D. Searle representatives approached a number of Members and key staff of the Senate Committee on the Judiciary during the panel's consideration of the Patent Restoration Act to explain the aspartame situation and seek assistance. Many Members were sympathetic to Searle's concern and an amendment was drafted. However, we are informed that the Committee leadership decided to report the Patent legislation without any amendments in order to avoid a series of debilitating motions that were readied by an opponent of the Restoration Act. Committee leaders notified Searle representatives that they were unable to consider the aspartame amendment under the circumstances, but expressed support for a floor amendment.

Senator Heflin agreed to offer the amendment on the floor when the Patent bill was up for debate and vote. It passed without objection, even from those Senators who did not favor the Patent bill.

I trust this explains the circumstances surrounding the Heflin amendment to your satisfaction.

JOHN E. ROBSON.

Mr. RAILSBACK. I think that is all.

Mr. KASTENMEIER. The gentleman from Michigan.

Mr. SAWYER. I have no questions, Mr. Chairman.

Mr. RAILSBACK. Mr. Chairman, if I could, I have one other question: Do you have any idea what cost you have incurred during this period from about 1975?

Mr. ROBSON. Our estimate, Mr. Railsback, is that Searle invested around $80 million over the period of the development of aspartame.

Mr. KASTENMEIER. Is aspartame unique in this connection? Is there any patent for a product approved by FDA other than that in the Senate bill?

Mr. ROBSON. We sought to find out if there were others. FDA advised us they knew of none. We are not aware of any, though I can't guarantee to the committee there aren't any.

Mr. KASTENMEIER. Thank you, Mr. Robson, for your appearance this morning.

Mr. ROBSON. Thank you, Mr. Chairman.

Mr. KASTENMEIER. The House is in the midst of another vote. I will, therefore, recess the committee for 10 minutes, at which time we will hear from Mr. Richard Leazer. Until that time, the committee stands in recess.

[Recess for Members to vote.]

Mr. KASTENMEIER. The subcommittee will be in order.

The Chair takes pleasure in recognizing Mr. Richard Leazer. The Chair has known Mr. Leazer for some time and is glad to have him testify on a problem which currently his company and perhaps others are confronted with.

TESTIMONY OF RICHARD LEAZER, PRESIDENT, OHIO MEDICAL ANESTHETICS, INC.

Mr. LEAZER. Mr. Chairman and members of the subcommittee, my name is Richard Leazer. I am president of Ohio Medical Anesthetics, and I am grateful to have this opportunity to present my comments on the issue of Patent Term Restoration.

For the past 18 years I have been involved with the health care industry and for the last 15 years I have been with Ohio Medical, the health care division of Airco, Inc. Airco is a producer of a diversified line of industrial and medical products.

I am responsible for the marketing of my division's two inhalation agents—Ethrane and Forane—and for the development of future anesthetic contributions Ohio Medical hopes to provide through its research and development program. Currently our annual sales total approximately $40 million.

Ohio Medical Anesthetics traditionally has been an innovator as evidenced by the fact that our firm pioneered the first use of nitrous oxide as an analgesic or painkiller. Since then, we have continued to introduce new developments in anesthesia technology.

Ohio Medical Anesthetic products are life-sustaining agents which are used in hospital surgical procedures, offering the physician and patient rapid induction of anesthesia, excellent patient-recovery characteristics, the safety of compatibility with other surgical products, lower metabolism and minimal effect on cardiac stability. In simple terms these products put the patient to sleep while surgery is carried out.

Although we have just two patented products, we are continually seeking to improve the anesthetic products offered the surgical community. As a small business, our research budget is less than $1 million and with such constraints we must make judicious use of every research dollar. We are trying gradually to increase our research and within the past few years we achieved the magic milestone for us of budgeting a million dollars of R. & D.

Our research funds, like that of other small research-oriented firms, depend upon the returns realized from a limited number of products. Ohio Medical Anesthetics does not have the benefit of dozens of patented products in the FDA review system. We are

relying upon our two marketed products to recover our costs and a reasonable rate of return over a normal patent life in order to fund additional research activities.

It is specifically because of our dependence upon the benefits of the U.S. patent system that we support H.R. 1937, which is designed to provide incentive for further research through restoration of the effective patent life lost during regulatory review.

Ohio Medical's Anesthetics, as inhalation agents, must undergo a governmental regulatory review before marketing that assures physician and patient alike the safety and effectiveness they deserve. The Government—in this case the Food and Drug Administration—must be assured that these life-sustaining products will not adversely affect the vital signs of the patient during surgery.

These regulatory review periods often can be lengthy. Long regulatory review periods result in shorter effective patent lives for our products and directly affect our ability to plan and provide the funds for future research.

One of our anesthetics is known and marketed as Forane and is a very significant inhalation agent that is of tremendous benefit in surgical procedures.

Ohio Medical's research department first discovered this product in 1965 and, over the course of the next 4 years, we undertook the extensive animal toxicity studies that were prerequisites for filing our IND in 1969. In other words, we devoted 4 years of time and money to develop and test this product before the Government regulatory process began.

In December of 1969, we filed our notice of claimed investigational exemption—IND—with the U.S. Food and Drug Administration but did not receive our new drug approval—NDA—from the FDA until December of 1979, 10 years later.

The major cause of this delay was a claim by one doctor, based upon one study, that Forane was a possible carcinogen.

As a direct result of this single doctor's claim, the Food and Drug Administration, in 1975, withheld its then-imminent approval for the marketing of Forane and established a program of mandatory testing of all anesthetic gases for carcinogenicity.

Now, 6 years later, the Government has repudiated that doctor's claim. Let me read to you, please, from the Federal Register of August 28, 1981, in which the Food and Drug Administration says of that doctor's study:

> * * * FDA has concluded that the study is deficient, and that reliance upon its results as a basis for recommending further testing is unwarranted.

Thus, we were held up by the FDA from obtaining approval for our product on the basis of charges made by one individual that have been proved to be totally unfounded and the Government itself so concedes.

We respectfully submit that it is grossly unfair that we be penalized for this unreasonable delay by the Federal Government.

One would expect that, having received our patent in 1970, we would have the benefits of it for 17 years—until 1987. Instead, because of the extraordinary delay in getting NDA approval, our benefit extends only from 1979 to 1987, a period of just 8 years.

To make matters worse, we had dedicated a significant portion of a plant facility in Cleveland, Ohio, to the manufacture of Forane.

But when the FDA kept delaying our new drug approval year after year, we no longer could keep that portion of our plant standing unused, so we put the entire facility to use in manufacturing a different product. That meant that when we finally did get our manufacturing approval for Forane, we had to produce it in a new plant elsewhere.

My point here is that inordinate Government delay forced us to change our business plan. It was not until May 26 of this year that we received final governmental approval for our Forane manufacturing facility, so, as a practical matter, we are talking about 6½ years of remaining patent coverage, rather than 17.

It makes no sense to us, in logic or in equity, that someone who, without a cent of research, invents a better shoehorn, as an example, should receive 17 years of exclusive coverage under his patent, while someone else who spends millions of dollars in research to develop a life-sustaining anesthetic gets only 6½ years of coverage. This result seems to us to be all wrong in terms of the relative importance of human needs.

Ohio Medical Anesthetics supports the concept of the Patent Term Restoration Act of 1981. However, it is our position that the benefits of the legislation should apply to all unexpired patents, whether or not the regulatory review period has been completed prior to the effective date of the legislation.

Extending existing unexpired patents by the amount of the regulatory review period is necessary to allow firms, especially relatively small businesses such as Ohio Medical Anesthetics, time to recoup their investment, make a reasonable profit and have moneys available for future research and development.

We respectfully submit that it should be a matter of some priority for Congress to encourage relatively small health-care companies like ourselves to continue to invest funds to seek new and improved medical products. To promote competition, and to allow the smaller firms to engage in that competition, we need the equitable relief I have suggested here today.

Let me now discuss specifically why the proposed legislation does not assist Ohio Medical.

H.R. 1937 contains the following purpose clause:

> 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.

On the Senate side, the report of S. 255 states that the purpose of the bill involves:

> Restoring to the term of the patent the time lost in complying with the Government's premarket testing and review requirements, up to a maximum of 7 years.

If the legislation really did what those statements of purpose say it would do, we would be content.

But it does not.

Keeping in mind our particular situation—patent granted in 1970; exemption for investigation applied for in 1969 and NDA granted in 1979, you would expect that Ohio Medical would receive a 7-year extension.

As we read the bill, though, we would receive no extension whatsoever. Why?

For two reasons: First, our regulatory review period has ended, and since section 155(b)(1) requires the giving of notice to the Patent Commissioner within 90 days of the termination of the regulatory review period, that time already has passed and thus no relief would be available to us.

A possible solution to this particular problem would be to require notice within 90 days after the termination of the regulatory review period or the effective date of the act, whichever date is the later.

But even if that technical correction is made, the second reason that we gain no relief is because of the very last sentence of the bill which states:

> In the event the regulatory review period has commenced prior to the effective date of this section, then the period of patent extension for such product or a method of using such product shall be measured from the effective date of this section.

Since our regulatory review period commenced in 1969 and has already ended, we would receive no relief. If the FDA had delayed another 10 years, until 1989, then and only then presumably would we have received a 7-year extension.

We request that the subcommittee correct this inequity.

We believe an instructive analogy to what we are seeking here today can be found in your treatment of then-existing copyrights under the Copyright Act of 1976.

In the 1976 copyright law, you lengthened the terms of existing copyright holders. Existing copyrights were extended to endure for a term of 75 years from the date the copyright was originally secured.

In explaining the need for longer copyright terms, your committee report emphasized, among other factors, the importance of assuring an author "the fair economic benefits from his work." It went on to point out that "the arguments in favor of lengthening the duration of copyright apply to subsisting as well as future copyrights."

The 1976 Copyright Act reflected the committee's view, we believe, that equity and evenhandedness required that a new policy on copyright duration be applied not merely to future but to existing copyright holders.

We submit that these same concerns for equity and evenhandedness equally require patent term extensions for holders of existing patents, whether or not regulatory review has been completed at the time legislation becomes effective. Both copyrights and patents confer exclusivity which limits the ability of others to exploit another's creative activity. Both are intended to promote and reward that creative activity.

If you agree with this analysis, then one is led to the logical conclusion that this legislation should be amended to apply to all products covered by unexpired patents and subject to regulatory review.

If, however, for policy reasons your committee cannot accept the principle of granting relief to all such products covered by unexpired patents, we respectfully submit that, at the very least, you should afford relief to those products that have completed regulatory review prior to the effective date of the legislation and have

spent more than a reasonable period of time undergoing such review.

Certainly products that have spent an inordinately long period of time in regulatory review, as is the case with Forane, which we described to you today, should receive the benefits of H.R. 1937.

If we can be of assistance to the committee in developing legislative language to achieve the results we have suggested here, we would be delighted to do so.

We deeply appreciate having this opportunity to set forth our views and only hope that our comments will further your goal of granting fair and equitable treatment to patent holders.

Mr. KASTENMEIER. I want to compliment you on your statement, Mr. Leazer. In fact, the analogy to the copyright law is one which was argued in the past, and I think it is germane.

I have just a brief question. There is a vote on which I must rush to. Does your situation differ from that of the Searle Corp., as presented by Mr. Robson?

Mr. LEAZER. To a moderate extent in that I believe their product received FDA approval and our product had reached the approvable stage and at that point the approval was withheld for an extended period of time.

Mr. KASTENMEIER. What is the position of the various trade associations, many of whom have, in fact, testified on the bill, with respect to your amendment?

Mr. LEAZER. I am not fully clear on that issue. I believe their focus has been primarily on the basic philosophy that the extended regulatory review period has deterred the incentive we should have for furthering research. I have not discussed this individually with any associations.

Mr. KASTENMEIER. So far as you know, they do not either oppose or specifically support your amendment?

Mr. LEAZER. That is correct.

Mr. KASTENMEIER. I want to thank you for your testimony today, and we will make sure the other members are aware of it.

Before proceeding with our next witness, the subcommittee will again have to recess for a period of 10 or 15 minutes.

[Recess for Members to vote.]

Mr. KASTENMEIER. The subcommittee will be in order. I expect to be joined shortly by one or more of my colleagues.

In the meantime, I would like to call the next witness, who happens to be Mr. Michael Koleda, president of the National Council on Synthetic Fuels Production. We are very pleased to greet you, Mr. Koleda. Would you identify your colleague?

TESTIMONY OF MICHAEL S. KOLEDA, PRESIDENT, NATIONAL COUNCIL ON SYNTHETIC FUELS PRODUCTION, ACCOMPANIED BY MICHAEL GILMAN, ASSOCIATE PATENT COUNSEL, OFFICE OF PATENT COUNSEL, MOBIL OIL CORP.

Mr. KOLEDA. My colleague, Mr. Chairman, is Michael Gilman, associate patent counsel with Mobil Oil Corp.

Mr. KASTENMEIER. You may proceed, Mr. Koleda.

Mr. KOLEDA. Mr. Chairman, my name is Michael Koleda. I am president of the National Council on Synthetic Fuels Production, a

trade association of companies active in the development of U.S. synthetic fuels industry.

Mr. Gilman is accompanying me and will be happy to answer questions with me at the end of the testimony.

You have my written statement, Mr. Chairman. In the interest of time, I need not repeat it in its entirety, and I would ask only that it be entered into the record and that I be permitted to summarize my comments here.

Mr. KASTENMEIER. Your statement will be received and made part of the record.

Mr. KOLEDA. Thank you, Mr. Chairman.

The National Council on Synthetic Fuels Production supports the intent of H.R. 1937, that is, to assure that the developers of patents enjoy the full 17-year period term granted by U.S. law.

This period of exclusivity is the backbone of the U.S. patent system. There is ample evidence of the need for H.R. 1937 as a remedy, not nonpatent-related Federal regulatory delays that effectively deny patent holders the full term of patent developed through intensive capital investment and hard work.

We in the synthetic fuels industry, Mr. Chairman, do not argue that the Federal regulations for the protection of health and the environment are not needed. We only ask that when the implementation of these regulations delays the entry into commerce of a patented invention, the term of the patent not be diminished.

The council feels, however, that for considerations based essentially on inequity, H.R. 1937 would be importantly improved by extending to process patent the benefits of patent term restoration now given in this bill to products or methods of using a product.

It is of the utmost importance to member companies of the council that the remedial scope of H.R. 1937 cover process patents which often provide the only feasible route for obtaining patent exclusivity in synthetic fuels research and development. This is because much synthetic fuels research is directed toward devising new and improved processes for making known and therefore unpatentable products. While synthetic gas methanol, other alcohols or gasolines, are not patentable products, the new processes for creating them are and should, therefore, be protected by the Patent Term Restoration Act.

The spur to innovation is the reward of a patent system. This is true for processes as well as for machines, products and methods of their use. Federal regulatory delays can effectively decrease the term after process patent just as clearly as they can affect the terms of patents or properties or methods of use.

The capital necessary to develop new technologies for the synthetic fuels industry and the intensity of research that industry could well diminish without the full reward of the 17 years mandated by the patent laws. Amending the Patent Term Restoration Act to include process patents can help prevent this.

Finally, Mr. Chairman, the national synthetic fuels effort is designed not necessarily to produce new products, but really to provide the spur to the private sector to develop new processes for producing liquid and gaseous fuels from domestic shale, coal, other domestic energy sources.

The energy security of the country is very much at the center of this national effort.

We in the synthetic fuels industry know of no good reason not to include process patents within the purview of H.R. 1937. We believe very strongly that equity considerations argue convincingly for including process patents within the terms of the act and would urge the committee to act upon this recommendation in its consideration of the bill.

[Mr. Koleda's prepared statement follows:]

TESTIMONY OF MICHAEL S. KOLEDA, PRESIDENT, NATIONAL COUNCIL ON SYNTHETIC FUELS PRODUCTION

The National Council on Synthetic Fuels Production welcomes the opportunity to submit its views on H.R. 1937, the Patent Term Restoration Act of 1981.

The NCSFP is a non-profit association of more than 60 corporations involved in the emerging synthetic fuels industry. The Council represents synthetic fuels producers, architect and engineering firms, equipment manufacturers, research and development organizations, and the financial community. The interests of the Council's members embrace all synthetic fuels—gas and liquids from coal, oil shale, tars and biomass. The Council's aim is to provide an organization through which its members can address issues affecting the industry and can present to government officials and members of Congress the views of the synthetic fuels industry.

Many of our members have committed and/or are presently expending substantial amounts of capital for the research, development and implementation of various processes for the production of gasoline and other conventional—and therefore largely unpatentable products—by previously unknown—and therefore patentable—processes. Most of these processes, being fundamentally new, require substantial amounts of capital for their full development and implementation. For example, it has been estimated that the first commercial implementation of the H-coal liquefaction process (developed by Dynaelectron Corporation) will cost about two (2) to three (3) billion dollars for a 50,000 barrels per day plant. In this effort the memebers of the Council have relied on the protection of the U.S. patent system to retain the exclusive position in their respective technological fields, thereby ensuring adequate return on the capital expended on research and development.

Many scientists familiar with the research and development (R and D) process and with the constraints of the U.S. patent law have expressed an understanding of the limits imposed by the patent law on the types of patentable inventions resulting from our member companies' R and D. Mr. Marvin Woerpel, Director of Licensing at the Wisconsin Alumni Research Foundation, recently testified before this Subcommittee that in many cases a process for making a product (or synthesis of a product) is the only invention that is patentable under the U.S. patent law. In such cases, Mr. Woerpel stated, it would be perfectly reasonable to extend the term of that patent by the amount of time that regulatory delays caused any diminution of the patent term. Accordingly, Mr. Woerpel would include process patents in this bill.

The term of patent exclusivity of every United States patent is seventeen years (35 U.S.C. 154). However, the theoretical seventeen year term is in many practical cases foreshortened because the patentee must comply with federal regulations which, in effect, deprive him of a portion of the initial term of his patent during which he must carry out the requisite tests and otherwise satisfy the requirements of federal statutes. The patent life of such inventions is therefore often less than the seventeen years mandated by Congress for all patents.

H.R. 1937 seeks to resolve an apparent conflict between two opposing public policies affecting the U.S. patent system. On the one hand, the U.S. patent laws entitle a patent holder to a seventeen year period of exclusivity during which the patentee is entitled to the use of the U.S. court system to preclude anyone from using, making or selling the patented invention. On the other hand, various necessary health and environment-oriented laws enacted by Congress in recent years force the patentee to comply with a number of regulatory requirements before his patented invention may be commercialized. Compliance with such laws and regulations may take from four to nine years or longer. At least a portion of the time of the compliance period takes place during the time of the patent exclusivity, thereby foreshortening the patent term. H.R. 1937 would restore to the patentee the full seventeen (17) year period by adding to the end of the patent term the time lost, up to seven (7) years, in complying with the federal regulatory requirements.

However, the full seventeen year period of patent exclusivity would be restored to some, but not all, patents whose life may have been foreshortened by the necessity of complying with federal regulations. Although this legislation relates to almost all of such adversely-affected patents, it excludes process patents. H.R. 1937 relates only to patented products (defined in the bill as ". . . any machine, manufacture, composition of matter . . ."—section 155(c)(1)) and to methods for using a product (defined in the bill as ". . . any specific method of use . . ." of any machine, manufacture or composition of matter—section 155(c)(1)). The bill therefore excludes patented processes for making a product—the area of the patent protection most significant to our members.

As mentioned above, most of the processes developed by our member companies for the production of synthetic fuels are heretofore unknown methods of production which are novel and therefore usually patentable. Obtaining patent protection on such processes assures the patentees of the period of exclusivity in the patented area. This area of exclusivity, however, cannot be extended to most of the products of such processes, because the products (e.g., gasoline, liquefied petroleum gas) are know and therefore usually unpatentable. Accordingly, our member companies must rely almost exclusively on the process patent protection to retain their proprietary position in a given area of research.

However, merely obtaining a patent for a given process does not assure the patent owner of the right to commercially exploit the process. The patentee must meet a number of health and safety-oriented federal regulations before the process can be commericallly exploited. For example, the preparation and approval of an Environmental Impact Statement (EIS) for a grass roots plant incorporating patented technology may take from four (4) years up to nine (9) years. At least a portion of the EIS preparation/approval process takes place during the term of the patent. Because the patented process cannot be commerically exploited until the regulatory requirements are satisfied, the term of the patent is in effect less than the seventeen years mandated by 35 U.S.C. 154.

If passed, H.R. 1937 would be an expression of the Congress' desire to restore to the patentee the full seventeen (17) year period of patent exclusivity. However, the Council is concerned that the bill does not apply to process patents. The same inequity which is perceived in delaying the commercial exploitation of pharaceutical and agricultural products because of federal regulations also exists in the case of process patents which are subject to federal regulations. A patented process must satisfy the requirements of several federal statutes, some of them also impacting patented products, before a facility incorporating the patented process can be built. Such federal statutes include, for example, National Environmental Policy Act, Clean Air Act, Clean Water Act, Toxic Substances Control Act (TSCA) and Federal Food, Drug and Cosmetics Act. For example, Section 2603 of the Toxic Substances Control Act (15 U.S.C. 2603) provides that the Environmental Protection Agency (EPA) may require testing of any chemical substance, the manufacture, distribution in commerce, processing, use or disposal of which, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, of if there are insufficient data and experience upon which the effects of any of the aforementioned activities on health or the environment can be determined. The required methodologies which may be prescribed by the EPA in developing the test data include epidemiological studies, serial or hierarchical tests, in vitro tests and whole animal tests. This and other sections of the TSCA apply equally to patented products and processes in the pharmaceutical area, as they do to patented products and processes in other areas of chemical industry, including synthetic fuels. In other words, the same kind of test data, causing similar delays in the commercialization of the patented subject matter, may be encountered in the case of synthetic fuels as it is in the case of pharmaceuticals and agricultural chemicals. A synthetic fuel, while it may be identical or nearly identical to traditional fuels, may be required by the EPA to undergo at least some, and perhaps all, of the aforementioned tests. These tests could delay the commercialization of such synthetic fuels processes, as the commercialization of patented pharmaceutical and agricultural chemicals is presently delayed by the necessity of meeting the FDA requirements.

The delay encountered by Paraho Development Corporation in commercializing its patented oil shale technology is an example of delays due to environmental regulations encounted by process patent holders. Paraho obtained a number of patents (e.g., 4,042,485; 4,066,529; 4,116,779 and 4,145,191) on the methods of processing oil shale into gasoline and other conventional hydrocarbon products. On May 11, 1972 Paraho, through its wholly-owned subsidiary, Development Engineering, Inc. (DEI), obtained a lease from the U.S. Government for the mining and processing on a pilot plant scale of up to 400,000 tons of oil shale on the government-owned land near Rifle, Colorado. The facility is called the Anvil Point Oil Shale Development

Project and its purpose is the demonstration of the commercial feasibility of the Paraho's patented processes.[1]

On June 27, 1974, two years after the date of the initial lease, Paraho requested a Governmental approval for the contruction of a larger retort at the Anvil Points facility, and for the mining and processing therein of eleven million (11,000,000) tons of oil shale. On November 4, 1975, the U.S. Energy Research and Development Administration (ERDA) advised Paraho that, pursuant to the provisions of the National Environmental Policy Act (NEPA), an Environmental Impact Statement (EIS) must be prepared by Paraho and approved by ERDA before permission could be given by ERDA to mine and process the additional oil shale at the Anvil Points facility. A draft version of the EIS was completed and submitted to ERDA in January 1977. During the period of January 1977 to March 1980, four revisions of the draft EIS were prepared and submitted to the Department of Energy (DOE), successor of ERDA, for review. The DOE projects mid-January 1982 as the target date for completing the review of the EIS. If this target date is met, Paraho will have experienced a delay of six (6) years and 2 months in its attempt to commercialize patented oil shale technology. In the meantime, Paraho has already experienced a delay of a little over six (6) years because of the necessity of complying with the provisions of the National Environmental Policy Act.

Section 101, Title 35, United States Code, defines the following statutory classes of patentable inventions: 1. process; 2. machine; 3. manufacture; or 4. composition of matter.

The term "Process" is defined in Section 100, Title 35, United States Code, as "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material". Therefore, the term "new use"[2] of a known process, machine, manufacture, composition of matter, or material is a sub-species of the generic term "process" as defined in the U.S. patent law.

Of the aforementioned four main statutory classes of inventions, H.R. 1937 covers three main classes (namely machine, manufacture or composition of matter) and a portion of the fourth class (namely only these processes which are directed to new uses of previously known machines, manufactures, or compositions of matter). The need for dividing the fourth main class of the statutorily-defined classes of inventions into its composite parts and including only one small portion thereof within the provisions of the bill is not apparent from the text of the bill. Such need is also not apparent from our study of the legislative history accompanying S. 255, a similar bill which was passed by the Senate earlier this year.

The U.S. patent system has always granted patents on inventions directed to processes for making products. At the same time, similar, and in some cases identical, federal regulations adversely affect products and processes. Thus, we believe that as a matter of equity the proposed restoration of patent terms diminished by federal regulation is fair and justified not only for the pharmaceutical and agricultural chemicals industry, but for any other industry affected in the same manner by federal regulations. The key concept of the act is "restoration". When Congress passed 35 U.S.C. 154, it determined that every patent should have the term of seventeen years. When the term of some patents is decreased as a consequence of the regulations protecting our health and environment, the term of all of such patents should be restored to the seventeen year term.

The exclusion of process patents, which have historically been part of the U.S. Patent system since its inception, is not based on any legal, logical or philosophical precepts. United States process patents do not cover the product made by such process. Therefore, the inclusion of process patents in this legislation would not enlarge the rights of product patentees beyond the scope of rights granted to them by this legislation, so long as the restoration of patent term for all patents is granted only if the patentee is precluded from commerical exploitation of his patented invention by federal regulator requirements.

Some opponents of an amendment adding patented processes to H.R. 1937 argue that, although theoretically the principle of patent term restoration might apply to

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[1] In addition to the aforementioned patents, the processes used at the Anvil Points Facility are also covered by the following patents: 3,401,922; 3.432,348; 3,561,927; 3,581,611; 3,685,356; 3,736,247; 3,777,940; 3,849,061; 3,884,621; 4,002,421; and 4,029,220.

[2] Until 1952 it was not certain whether a newly-discovered use of an old product was patentable when phrased in the process claim terminology. The adoption of a new definition of the term "process" in Section 100, Title 35, United States Code, quoted above, made it explicitly clear that the new use of a known process, or product can be patented in terms of the process claim language, provided that it satisfies other requirements for patentability which apply to all statutory classes of inventions. See P. J. Federico, "Commentary on the New Patent Act", 35 U.S.C.A. 1, 16-17 (1954).

patented processes, practical application of the principle may be difficult to administer because of a possible lack of a nexus between the governmental regulatory review of any given project and the patented process or processes used therein. Accordingly, it is argued, any governmental review of the project, no matter how incidental it may be to the patented process, may be used by the patentee to extend the effective process patent life.

We believe that it is possible to devise a specific language entending the principle of the bill to patented processes which, at the same time, would condition a process patent term extension on the showing, by the patentee, that the governmental review of the project is directly and necessarily related to the patented process. The requirement of the nexus between the review and the patented process could be strengthened and made even more explicit by appropriate rules promulgated after the bill is passed. In the few cases where the explicit language of the bill and of the rules may leave some doubt as to the existance of the necessary nexus, the final determination could be made by the Commissioner of Patents and Trademarks. In this connection, we welcome and endorse the Commissioner's suggestion, expressed during his recent testimony before this Subcommittee, for a greater discretionary authority in granting the extensions of the patent term. We believe that such greater discretionary authority would enable the Commissioner to grant the extension where the delay has a direct impact on the patented process, and deny it where the delay is merely incidental to the patented process.

It is of utmost importance to the member companies of our organization that the remedial scope of this important legislation cover process patents, whose commercial exploitation is impeded or delayed by compliance with the federal regulations. The loss of a portion of the patent term due to compliance with such requirements, and without fault of the patentee, is just as applicable to process patents as it is to machine, product and method of use patents. In the nationally vital area of synthetic fuels research, process patent protection is often the only feasible route of obtaining exclusivity in a given area of research. This is because the very nature of this research results only in new and improved processes for making known—and therefore unpatentable—products. The thrust of our research and development in these areas is to find new—and therefore patentable means of making known products, such as gasoline.

The spur to innovation is the reward of the patent system. This is true for processes as well as machines, products and methods of their use. Whenever federal regulatory review delays commercial exploitation of patented inventions, the rewards afforded by the patent system are diminished, regardless of the type of patent (product, process or machine) involved. Without the full reward of the seventeen years mandated by Congress, the capital committed to the development of the infant synthetic fuels industry and the intensity of research in that industry is likely to diminish, as apparently has been the case in the pharmaceutical and agricultural chemicals industry. It appears to be a matter of national priority, both for economic and self-defense reasons, to provide every conceivable legal and financial opportunity for the infant synthetic fuels industry to rapidly develop into a major economic force of the United States industrial base.

For the reasons discussed above, the National Council on Synthetic Fuels Production urges the Subcommittee to amend H.R. 1937 in order to include patented processes, thereby treating all patentees fairly and equally.

Mr. KOLEDA. I thank you very much for this opportunity. Mr. Gilman and I would be happy to try to answer any questions that you might have.

Mr. KASTENMEIER. As I read page 4 of your statement, it appears to involve a delay in construction of a factory due to the need to file an environmental impact statement. Are you suggesting that we extend all of a company's process patents whenever construction of a plant facility meets delay?

Mr. KOLEDA. I think the question here, if I understand it, Mr. Chairman, what we are getting to is whether the delay that is incurred on getting a patentable process into commerce is directly related to the patented process in question, and I am not prepared to say at this time—I think it is a complicated question—whether that delay is directly related to that process or not.

Our position in principle is that if, to the extent the delay can be traced to the process, itself, then the process' full 17-year term ought to be restored to the extent that it is under H.R. 1937 now. So on the specific question, if I understand it, of an environmental statement for the entire complex, would that delay, applied to all of the patent processes involved, I would like to ask Mr. Gilman to comment on it, but I think our feeling is in principle as I said to the extent that it can be directly tied. In some cases it won't be.

Mr. GILMAN. I think the key word in Mr. Koleda's answer is to the question was "directly related." In our view it is the delay in commercialization of a patented process which is directly and necessarily related to the Government regulatory review delay and yet the patent term restoration should apply. If it is not directly related, it should not apply.

Mr. KASTENMEIER. Do those companies dealing with process patents have a trade association of their own?

Mr. KOLEDA. The National Council on Synthetic Fuels Production is a trade association of about 60 companies that will be active in the development of synthetic fuels.

Mr. KASTENMEIER. All would have an interest in process patents?

Mr. KOLEDA. Those that would be producing synthetic fuels would have a great interest in the patented processes for producing these fuels; yes.

Mr. KASTENMEIER. Looking beyond the area of synthetic fuels and fuel production, are there other industries, as far as you know, that would have an immediate interest in process patent protection or term extension under this bill?

Mr. GILMAN. The chemical industry in general deals—if one excludes the pharmaceutical and pesticide areas of the chemical industry, as has been done in some of the reports that this committee has considered—the chemical industry as a whole and the oil industry as being technologically a part of the chemical industry, have a great interest in the process amendment simply because, for the most part, inventions made in that industry are process-related rather than product-related.

Mr. KASTENMEIER. This is a question that is obvious. It is to try to determine the impact of such an amendment, the effect of such an amendment in terms of industries or of types of operations.

Would there be symbiotically, those who would be adversely affected by the extension, who would oppose extension of the term, relating to process patents?

Mr. KOLEDA. I don't know, Mr. Chairman, of any resistance to what we are talking about here, the extension to processes. I have not heard of it. I think what the feeling of our member-companies would be with respect to this is that the idea of H.R. 1937 is correct, but that there seems to be no argument in equity that we can discern that organization for including only part, a subsection of patents and not all patents. I don't know who might oppose that.

Mr. KASTENMEIER. What regulatory agencies would occasion delay, most commonly, with respect to process patents?

Mr. KOLEDA. With respect to the symbiotic fuels industry with which I am most familiar, Mr. Chairman, I would expect the Environmental Protection Agency would be a key agency in this regard.

Mr. KASTENMEIER. Can you think of any others?

Mr. GILMAN. Whichever agencies are involved beyond the Environmental Protection Agency, in protecting our environment. These are the areas of Government regulatory review with which we deal. Most of the potential regulatory problems we have and foresee revolve around TSCA—Toxic Substances Control Act. The Clean Air Act and Clean Water Act, whichever agencies administer those acts, would be the ones we would deal with.

Mr. KASTENMEIER. I am informed the Generic Pharmaceutical Association specifically testified in opposition to process patent extension. I don't recall the reasons they gave, but apparently they did testify against that, as well as against the bill in its present form and certain other amendments.

Do you have any—most of this, I take it, is prospective, since the National Synthetic Fuels Corporation is newly extant; that this is not so much a matter of experience in delay as that which can be forecast reasonably; is that correct?

Mr. KOLEDA. That is substantially correct, Mr. Chairman—in some sense, unfortunately—but we are looking ahead with this industry. This is a new industry, albeit an extremely large and complicated one, and I think based on the history of large complicated projects, not just in the energy industry, but certainly in the energy industry, we can anticipate numerous opportunities for delay, some of which, as we have indicated, will directly affect these processes.

Mr. GILMAN. Mr. Chairman, there is provided in the written submitted statement an example of a specific delay that has been in effect, which is illustrative of the kinds of delays that can be reasonably anticipated in the light of what has happened in the past.

Mr. KASTENMEIER. I appreciate your calling that to my attention.

I might parenthetically add that the full Committee on the Judiciary is presently looking at a regulatory reform act which, incidentally, will involve these regulatory agencies. Not that it in and of itself mitigates the necessity for this legislation, but it does bear on it to some extent. Prospectively that will have some impact in coping with Federal regulatory activity.

I want to thank you both, Mr. Gilman and Mr. Koleda, for your testimony this morning. It has been very helpful.

Mr. KOLEDA. Thank you, Mr. Chairman. We appreciate the opportunity to appear.

Mr. KASTENMEIER. The subcommittee again is going to have to recess because of a vote on the House floor. We have one more witness who has been very, very patient indeed, and he is Mr. Stephan Lawton, the Washington counsel for Genentech.

I regret the delay, but I hope you will be patient at least one more time.

The committee stands in recess for 10 minutes.

[Recess for Members to vote.]

Mr. KASTENMEIER. The subcommittee will come to order.

The Chair is very pleased to greet Stephan E. Lawton, who is the Washington counsel for Genentech, Inc.

Mr. Lawton, you may proceed as you wish.

TESTIMONY OF STEPHAN E. LAWTON, ESQUIRE, WASHINGTON COUNSEL, GENENTECH, INC.

Mr. LAWTON. As your staff said, this is the bitter end, and I will attempt to be brief.

I have prepared and a copy is before you, a longer statement, which I would simply request be inserted in the record, and I have prepared a summary of that statement, which I think is also before you, and I will attempt to summarize the summary in the interest of time.

My name is Stephan Lawton.

Mr. KASTENMEIER. Without objection, your statement will be received. I take it it might be more useful to present for purposes of the record your longer statement and also your oral statement.

Mr. LAWTON. I represent Genentech, which is a California-based company that was founded 5 years ago in the belief that genetic engineering technology could quickly be made to produce practical benefits primarily in the pharmaceutical field and in other fields, such as the agricultural field. Today, the fruits of our research have produced at least three products that are presently undergoing human clinical trials. Those products being human insulin, human growth hormone, will essentially cure dwarfism in this country, and, of course, human interferon.

All of these products are being made by Genentech, by genetically engineered microorganisms.

They are presently undergoing clinical trials in major medical centers across this country.

Our thesis, Mr. Chairman, is straightforward. This bill is, in our judgment, a procompetitive bill because it fosters innovation. Innovation in our judgment arises most frequently in the small entrepreneurial company context. It is our view that patent term restoration will make patent protection more meaningful and therefore the formation of small innovative companies that can grow up under the shelter of patent protection only enhances competition, both by increasing the number of market entrants and by the downward pressure the new products, such as those I have described.

New products of innovation exert on the prices of older products. Obviously the patent term restoration legislation that is before your committee immediately follows from these precepts and from the commonsense notion that what government gives with the right hand, it ought not to take away with the left.

We have spent several million dollars on research and development, and, of course, the level of these expenditures is increasing as Genentech grows. We have been in existence, as I have stated, for 5 years, but, owing to the recognized and understandable necessity of obtaining regulatory approval—principally, of course, approval of new drug applications by the Food and Drug Administration—we have yet to sell one ounce of our products to end-users.

The promise of patent protection originally induced private risk capital investment which will sustain us during these dry years until we get to market. And also by licensing a portion of our technology to others, we can earn the revenue needed for our day-to-day operations on an expanded front until our first products can be sold directly.

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To the extent, therefore, that the patent reward is made more meaningful by restoring the full-term envisioned by earlier Congresses, the opportunities for startup and innovative companies like Genentech to continue to fund lifegiving research will be enhanced.

Mr. Chairman, for reasons which are by no means entirely clear to us, the legislation before you makes no provision for restoring the term of patents on new processes for making old substances. Although a limited number of new substances have already been produced by gene-splicing techniques, by far the greatest effort of recombinant DNA-oriented companies to date have been expended in creating practical means for the industrial production of substances that are old in the sense that they are already made in the body.

Until Genentech devised a process for biosynthetic production of human insulin, that substance, although of course, well known and old, had never been made available in quantities suitable for the treatment of diabetics across the United States. Until Genentech devised a method for the biosynthetic production of human interferon, that substance, although old in nature, was available for the treatment of cancer patients only in low purity, minute quantities and at a price that effectively put it beyond the reach of people who may ultimately need it.

Until Genentech devised a method for the biosynthetic production of human growth hormone, that substance, again, although old and, again, of course, of known composition, was unavailable across the United States to the majority of children suffering from dwarfism because of critical limitations in raw material sources.

I might add those raw material sources are essentially the cadavers of people from which human growth hormone is extracted during autopsy. We will have the ability to make human growth hormone as well as, of course, the other substances that I mentioned.

The present position of the Food and Drug Administration—and I must tell you it is a position with which we have no quarrel whatsoever—is that an old substance, even one which has been approved for treatment when gotten from more conventional sources, is treated as a new drug when made by genetically engineered microorganisms, and thus a substance like the three that I have described will be required to go through the new drug approval process by the Food and Drug Administration, even though comparable products made by—made in a different way—have already been approved by the Food and Drug Administration.

Under the legislation, if the product that the Food and Drug Administration therefore regards as a new drug is, in fact, old and hence cannot be encompassed within the scope of the patent as the new Section 155(a)(1) would require, then the provisions of the proposed bill would not be available to restore the patent term lost through the new drug regulatory review period that the Food and Drug Administration will impose.

Mr. Chairman, you asked the previous witness who wanted what is, in our judgment, a much broader amendment, and we have no comment on that; you asked the previous witness if there were opposition to an amendment of this kind, and I do recall sitting in

hearings on the Senate side in which there was opposition to an extension of a process patent amendment by representatives of the generic pharmaceutical industry.

I believe that their position was that somehow if our amendment were adopted, that this would prohibit the generic companies from being able to provide generic equivalent of the product once the product patent had expired.

We believe very strongly that this concern is misplaced and that their interpretation of the relationship between the patent laws and the Food and Drug Act is not a correct one.

The patent laws require that at least one method of making a product be disclosed in the original patent application, and that is, I believe, section 112 of title 35 of the United States Code.

As a result, if the process is patentable, if the original process will be patented at about the same time as the product, itself, is patented—and, of course, if a process is not patentable, it would become available immediately. Thus, both the product, such as in our case a drug, and the original method or process of making it, will become available to the public at about the same time that the product patent expires.

We therefore would quarrel as a legal matter with the assertion that approving our amendment, which would involve new processes, would in any way retard the generic drug companies from being able to take to market an old product, although, of course, they would have to use the old process of making it.

Mr. Chairman, we have had discussions with your staff with respect to this matter. I would say, and I hope not gratuitously, that I worked on the Hill for 8 years, and I knew very well the history of this committee and the legal precision that this committee demands before an amendment to a major piece of legislation is adopted.

I appreciate very much the courtesy that you and your staff have shown us, and we stand ready to provide any assistance to you and to the other members of the committee and to the staff in helping develop such an amendment.

In summary, I would only say that what we want is coverage of process patents if, as a result of the process, old products are required to undergo premarket approval—in most instances a new drug application by the Food and Drug Administration.

I thank you very much, Mr. Chairman, for your time and your courtesy.

[Mr. Lawton's prepared statements follow:]

SUMMARY STATEMENT OF STEPHAN E. LAWTON, ON BEHALF OF GENENTECH, INC.

Mr. Chairman and members of the Committee, my name is Stephan Lawton. I am an attorney in private practice and serve as Washington counsel for Genentech, Inc., a small California company founded just five years ago in the belief that genetic engineering technology could quickly be made to produce practical benefits in the pharmaceutical and other fields. Today, three products of our research are already undergoing the human clinical testing that is required before marketing approval can be obtained: human insulin, human growth hormone and interferon, all made by genetically engineered microorganisms.

Nothing in Genentech's experience has been more instructuve with regard to the vital role patents play in our free enterprise system than the opportunity we have had to look at the world from the vantage point of the samll, start-up company. When, under the umbrella of patent protection, a small company can compete on the strength of its innovative capability with larger, older and more entrenched concerns, the patent system operates to best purpose, as an essentially procompetitive mechanism.

We strongly endorse H.R. 1937 -- introduced by Chairman Kastenmeier; the ranking minority member, Mr. Railsback; and the vast majority of members of the Subcommittee -- as should every small company whose competitive edge lies in its innovative capabilities and whose activities must undergo regulatory review before the onset of commercialization.

Our thesis is straightforward. Innovation is important. It arises most frequently in the small, entrepreneurial company context. Patent term restoration will make patent protection more meaningful. The formation of small, innovative companies that can grow up under the shelter of patent protection only enhances competition, by increasing the number of market entrants and by the downward pressure the new products of innovation exert on the prices of older products. The patent term restoration legislation before this Committee immediately follows from these precepts, and from the common sense notion that what government gives with the right hand, it ought not to take away with the left.

Genentech has spent millions of dollars on research and development, and the level of those expenditures is increasing as the company grows. We have been in existence for more than five years but, owing to the recognized and understandable necessity of obtaining regulatory approvals, we have yet to sell an ounce of product to end-users. The promise of patent protection induced private risk capital investment which will sustain the company in these dry years. By licensing a portion of our technology to others, we can also earn the revenue needed for operations on an expanded front until our first products can be sold directly. To the extent the patent reward is made more meaningful, as by restoring the full term envisioned by earlier Congresses, the opportunities for start-up companies like

Genentech to continue to fund life-giving research will be enhanced.

The genius of the legislation before this Committee lies in its simplicity, flexibility and automatic adaptation to a host of different circumstances. However, for reasons not clear to us, H.R. 1937 makes no provision for restoring the term of patents on new processes for making old substances. Although a limited number of new substances have already been produced by gene splicing techniques, by far the greatest efforts to date have been expended in creating practical means for the industrial production of substances that are old in the sense that they are already made in the body. Until Genentech devised a process for biosynthetic production of human insulin that substance, though old and of known composition, had never been available in quantities suitable for the treatment of diabetics. Until Genentech devised a method for the biosynthetic production of human interferon that substance, though old in nature, was available for the treatment of cancer patients only in low purity, minute quantities and at a price that effectively put it beyond reach of the people who might need it. Until Genentech devised a method for the biosynthetic production of human growth hormone, that substance, though old and of known composition, was unavailable to the great majority of children suffering from dwarfism because of critical limitations in raw material sources.

The present position of the Food and Drug Administration --

a position with what we have no quarrel -- is that an old substance, even one approved for treatment when gotten from conventional sources, will be treated as a "new drug" when made by genetically engineered microorganisms. If the product that FDA regards as a "new drug" is in fact old and hence cannot be encompassed within the scope of the patent, as required by new section 155(a)(1) of Title V of the U.S. Code, as proposed by H.R. 1937, then the provisions of the new law will not be available to restore patent term lost through the "new drug" regulatory review period that FDA will impose.

We recommend that H.R. 1937 be amended to provide for the restoration of patent term where "old" products are subjected to regulatory review because manufactured by a new and patentable process. We believe that this can be accomplished by a relatively minor clarifying amendment and will be pleased to provide any assistance to the Committee and its staff in developing such an amendment.

As far as we can tell, the only opposition to the amendment is from groups that believe that authorizing patent restoration for a so-called process patent for a product subject to regulatory review would preclude generic pharmaceutical companies from marketing generic equivalents of the product once the patent on the product itself has expired. We believe this concern to be misplaced. The patent laws require that at least one method

of making a product be disclosed in a patent application. As a result, if the process is patentable, the original process will be patented at about the same time as is the product. (If the process is not patentable, it becomes available immediately.) Thus, both the product, such as a drug, and the original method of making it will become available to the public at about the time the product patent expires.

Mr. Chairman, this concludes our statement. We appreciate the opportunity to present testimony to you today on this important issue and will be pleased to respond to any questions you may have.

Genentech, Inc.

STATEMENT OF

STEPHAN E. LAWTON

WASHINGTON COUNSEL

GENENTECH, INC.

BEFORE THE

COMMITTEE ON THE JUDICIARY

UNITED STATES HOUSE OF REPRESENTATIVES

ON

H. R. 1937

THE PATENT TERM RESTORATION ACT OF 1981

Wednesday, November 18, 1981

Mr. Chairman and members of the Committee, my name is Stephan Lawton. I am the Washington counsel for Genentech, Inc., a small California company founded just five years ago in the belief, not then widely shared, that genetic engineering technology could quickly be made to produce practical benefits in the pharmaceutical and other fields. Today, three products of our researchers are already undergoing the human clinical testing that is required before marketing approval can be obtained: human insulin, human growth hormone and interferon, all made by genetically engineered microorganisms.

Although just a tiny company, Genentech thought enough of the importance of patents to its future to appear before the Supreme Court in its recent consideration of the question whether patents would be available for the new microorganisms our technology produces.[1/] We appeared then in the role of amicus curiae, or "friend of the Court". We appear today as a "friend of the Congress" to again emphasize the importance of patents and of a strengthened patent incentive to the small, high technology company. When, under the umbrella of patent protection, a small company can compete on the strength of its innovative capability with larger, older and more entrenched concerns, the patent system operates to best purpose, as an essentially procompetitive mechanism.

Nothing in Genentech's experience has been more instructive with regard to the vital role patents play in our free enterprise system than the opportunity we have had to look at the world from the vantage point of the small, start-up

company. Although surrounded by trees that cast great shade, Genentech is seeking its own place in the sun, and we expect that the availability of meaningful patent protection will help us do it.

We strongly endorse H.R. 1937, the Patent Term Restoration Act of 1981, as should every small company whose competitive edge lies in its innovative capabilities and whose activities must undergo regulatory review before the onset of commercialization.

Our thesis is straightforward. Innovation is important. It arises most frequently in the small, entrepreneurial company context.[2/] Patent term restoration will make patent protection more meaningful. More meaningful patent protection will permit small companies to flourish, and grow, where otherwise they might not. Conditions that encourage the growth of startup companies also encourage investment in them, and therefore investment in innovation. The formation of small, innovative companies that can grow up under the shelter of patent protection only enhances competition, by increasing the number of market entrants and by the downward pressure the new products of innovation exert on the prices of older products. The genius of the patent term restoration legislation before this Committee immediately follows from these precepts, and from the commonsense notion that what government gives with the right hand, it ought not to take away with the left.

Venture Capital and the High Technology Start-up Company

It is not surprising that most innovation arises at the level of the individual entrepreneur and in the small company context. One who would start any new enterprise needs a good idea because, at the outset, that is the only asset he or she has. The idea should be a new one, otherwise the start-up company will be unable to differentiate itself from established companies in the marketplace. But the new company whose principal asset is a good idea is also the company least likely to secure access to conventional financing. Most bankers don't lend on dreams. The availability of risk capital is accordingly an essential ingredient in formation of the new, innovation-intensive concern. The circumstances of Genentech's own formation are illustrative, and underline the importance of both venture capital as a source for science funding, and patent rights as an inducement for investment.

Genentech was formed in 1976. In that same year, one Nobel laureate unequivocally characterized predictions that human peptide hormones could be made in bacteria, using syntetic genes, as belonging "more in the field of science fiction than science".[3/] That same year, scientists at the City of Hope National Medical Center in Duarte, California were rebuffed when they sought federal funding for just such a project. The project lacked scientific merit, they were told, and could not in any event be completed within the three years for which funding had been

sought. Genentech, with venture capital funding, made the money available in exchange for patent rights if the project succeeded. The privately funded project was completed not in three years, but rather in nine months. And in testimony before a committee of the Congress, another Nobel laureate hailed the Genentech-funded achievement as "astonishing".[4/] In similar testimony, the president of the National Academy of Sciences called it a "scientific triumph of the first order".[5/] The promise of patent protection induced private risk capital investment that established the credibility of the new technology, leading to all that has followed.

The Relationship of Patents to Capital Access

The availability of meaningful proprietary protection is a significant, if not indispensable, criterion for selection of new venture investments.[6/] Investors are risk-takers, but absent the availability of meaningful protection for the product of innovation, the risk of investment in innovation is too great to bear. What farmer will invest in seed if the law permits others to take his crops? A new company is a fragile thing, and patents are part of its survival kit. And patents which provide the full term of protection intended by earlier Congresses become an important inducement to risk investment in research. This is particularly so where the products of that research can be sold, and the risk reward realized, only after long years of regulatory review.

Patent Term Restoration and the Small Company

We have spent millions of dollars on research and development at Genentech, and the level of those expenditures is increasing as the company grows.[7/] We have been in existence for more than five years but, owing to the recognized and understandable necessity of obtaining regulatory approvals, we have yet to sell an ounce of product to end-users. The promise of patent protection lets us raise capital to sustain the company in these dry years. By licensing a portion of that technology ot others, we can also earn the revenue needed for operations on an expanded front until our first products can be sold directly. The available levels of both types of funding are, naturally, influenced by perceptions of the ultimate worth of our proprietary position. To the extent the patent reward is made more meaningful, as by restoring the full term envisioned by earlier Congresses, the opportunities for start-up companies like Genentech to continue to fund life-giving research will be enhanced.

Patents and Competition

We believe that patent term restoration will enhance competition, not diminish it.

Every opponent of patenting chooses the pejorative term "monopoly" as the cornerstone of his or her argument. The argument from "monopoly" overlooks a fundamental precept of

the patent system. Rather than taking away from the public something it earlier enjoyed, patents produce to the public understanding, and ultimately to its own enjoyment, something the public might otherwise never had had, or had only after long years. The only "monopoly" the patentee gets is a monopoly over his or her own creation, and then for only a limited term. Those who endure the risk of innovation ought to receive in full measure the reward for success.

H.R. 1937 will not not extend the patent for any product for which regulatory approval has been given in the past, and therefore will not influence its price in the future. And we believe enactment will lead to lower prices for the products of the future by increasing competition in two ways.

1. Competition between products. When the courts look at a monopolization charge, they first define the relevant market. They look not at monopolization of any single product, but instead at the whole constellation of different products that compete with one another because they exhibit what the judges call cross-elasticity of demand. In this philosophy, cellophane competes with wax paper, plastic wrap with both, and aluminum foil with all three. The new products of innovation, when they are better, exert downward pressure on the prices of the different but cross-elastic products that predate them. Legislation that enhances the climate for new product innovation enhances the climate for this most meaningful form of competition.

2. Competition between companies. Competition is also a function of the number of companies operating within a given field. The fewer the entrants, the less occasion there is for competition. And yet many studies have shown that since 1962 the number of firms engaged in the manufacture and distribution of pharmaceutical products has markedly declined. Some have predicted that the tendency toward market concentration will continue as a result, among other things, of the costs imposed by the regulatory environment and the inability of small companies to maintain the research and development efforts required to provide new patents.[8/] But the new revolution in biotechnology offers ground for optimism. Genentech was only the first of the dozens of new firms that have formed around this technology, all seeking a formula for survival and growth in research and in the development of a proprietary position. Restoring the full term of patents can help these new market entrants to sustain themselves. Capital is more easily raised when research and regulatory costs can be recouped from marketing revenues over the full term of an issued patent. Where the remaining patent term has not been foreshortened by regulatory delays, economics will more often justify the small company's defense of its patent (and its market) in expensive litigation brought to "break the patent", oftentimes by breaking the patent owner. And to the extent the full measure of patent protection is made available through restoration of term, start-up companies can get greater

value from licenses they grant to meet interim cash needs. In every respect, the restoration of the full term of patent protection can be expected to enhance competition.

Patent Term Restoration: An Ideal Adjustment of Regulatory Mechanisms

The genius of the legislation before this Committee lies in its simplicity, flexibility and automatic adaptation to a host of different circumstances. The useful life of a patent is restored in every different case only as the period of regulatory review in that case requires. The more a new product departs from past practice, the longer will be its review period, the longer will be its patent term restoration, and the more will the patent reward be assured for those who take the greatest risk in departing from the tried and true. But we do not believe passage of the legislation before this Committee will in any way encourage regulatory delay. The greatest incentive will remain for eliminating delays in new drug approvals: the need to get safe and effective drugs to people who are sick.

I should add that in the case of each of the new products of our research now undergoing clinical testing, our experience with the Food and Drug Administration has been encouraging. We have found that Agency both professional in its attention to its important mission and receptive to the potential of our new technology. FDA's attitude to the present time has been both forthcoming and cooperative. It is quite possible that regulatory clearance will come before any basic patent issues to Genentech. 9/

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Our concern is accordingly not one of focus on products now in testing, but rather on the future conditions under which our young company and others like it will seek their full maturity.

The Need for Patent Term Restoration Relating to Processes

H.R. 1937 makes no provision for restoring the term of patents on new processes for making old substances. Although a limited number of new substances have already been produced by gene splicing techniques, by far the greatest efforts to date have been expended in creating practical means for the industrial production of substances that are old in the sense that they are already made in the body. Until Genentech devised a process for biosynthetic production of human insulin that substance, though old and of known composition, had never been available in quantities suitable for the treatment of diabetics.[10] Until Genentech devised a method for the biosynthetic production of human interferon that substance, though old in nature, was available for the treatment of cancer patients only in low purity, minute quantities and at a price that effectively put it beyond reach of the people who might need it. Until Genentech devised a method for the biosynthetic production of human growth hormone, that substance, though old and of known composition, was unavailable to the great majority of children suffering from dwarfism because of critical limitations in raw material sources.[11] One can anticipate that a great number of additional materials, until now unavailable or in short supply, will become available

through the development of other such methods, if the full patent incentive for such developmental work can be restored.

The present position of the Food and Drug Administration is that an old substance, even one hitherto approved for treatment when gotten from conventional sources, will be treated as a "new drug" when made by genetically engineered microorganisms. If the product that FDA regards as a "new drug" is in fact old and hence cannot be encompassed within the scope of the patent, as required by Section 155(a)(1) of H.R. 1937, then the Act will not be available to restore patent term lost through the "new drug" regulatory review period that FDA will impose.

The genetic engineering example is only one of many that might be imagined. Frequently, occasion will arise for protracted regulatory review before an invention of great value can be commercially practiced, even where the invention relates not to a new thing, or a new method of using a thing, but rather to the first practical method of making that thing. Innovation in the science of making "old" things in better and more economic ways should be encouraged to the same extent the bill in its present form would encourage the making of new things. Most particularly should this be done when regulatory agencies bid fair to treat products that are "old" in the patent sense as "new products" for purpose of regulatory review.

We believe H.R. 1937 should be amended to provide for the restoration of patent term where "old" products are subjected to regulatory review because manufactured by a new and patentable process. We believe that this can be accomplished by a minor clarifying amendment and will be pleased to provide any assistance to the Committee and its staff in developing such an amendment.

Mr. Chairman, this concludes our statement. We appreciate the opportunity to present testimony to you today on this important issue and will be pleased to respond to any questions you may have.

FOOTNOTES

1. Diamond v. Chakrabarty, _____ US _____, 65 L. Ed. 2d 144 (1980).

2. Jewkes, Sawyers and Stillerman, The Sources of Invention, St. Martins Press (1958).

3. "The Position of Applied Research in Nonindustrial Laboratories", an address by Sir Ernst Chain, May 1976, in Biotechnological Applications of Proteins and Enzymes, Zvi Bohak and Nathan Sharon, eds., Academic Press, N.Y. (1977), at 15. Sir Chain holds the Nobel Prize for Physiology and Medicine.

4. Hearings on Regulation of Recombinant DNA Research before the House Subcommittee on Science, Technology and Space, 95th Congress 1st Sess. 55 (1977). (Testimony of Paul Berg). In 1980 Dr. Berg was awarded the Nobel Prize for Chemistry.

5. Testimony of Phillip Handler, id at 27.

6. Address by Thomas J. Perkins, President, National Venture Capital Association, before the San Francisco Bay Area Council Outlook Conference, January 13, 1981. The Supreme Court's confirmation of patents on genetically engineered microorganisms preceded the October 14, 1980 public offering of Genentech stock by several months. The October 14, 1980 banner of the San Francisco Examiner declared "Genentech Jolts Wall Street", a reaction that suggests the investing public agrees with Mr. Perkins.

7. Five years ago Genentech had one employee. Today it employs 230 and is seeking more.

8. F.H. McKim, "Will Your Company Survive the Economics of the '80s?" in Pharmaceutical Executive 1, 50-55 (April 1981).

9. Examination of related patent applications was suspended pending resolution of the threshold question addressed by the Supreme Court in Chakrabarty, supra n. 1.

10. Previously, only animal insulin was available to diabetics.

11. Until recently, human growth hormone could be extracted only from human remains.

Mr. KASTENMEIER. Thank you, Mr. Lawton.

I understand you do not have precise statutory language to offer as an amendment at this time.

Mr. LAWTON. We certainly intend to, Mr. Chairman, and we intend to only in consultation with this committee.

Mr. KASTENMEIER. I wonder if you would amplify the similarities or differences between Genentech and the Synthetic Fuels Council, which also seeks extension of process patents, but not precisely in the same way or with respect to the same regulatory agencies as yours.

Mr. LAWTON. Let me say, first of all, we take no position either in favor of or in opposition to the amendment that I understood was being requested by the previous witness.

Mr. KASTENMEIER. Is it not the case that an amendment that you would prepare for your principal, would be undoubtedly different than that which they would prepare?

Mr. LAWTON. It would be more limited, Mr. Chairman. It would apply only in the case in which, as a result of a new process—in our case, the recombinant DNA process—would require an old product to undergo premarket approval. So that it would apply only to instances in which premarket approval is required, and it would, of course, apply only in instances that by virtue of the fact that we have a new process, that new process requires the product to go through premarket approval. The way the bill is drafted, we are not covered under that situation.

Mr. KASTENMEIER. Would it apply to toxic substances, among other things, as well as pharmaceutical compounds?

Mr. LAWTON. If I remember the toxic substances legislation correctly, there are some instances in which they are required to undergo regulatory review. If they were required to go through regulatory review because of the process by which the toxic substances were made, and if the toxic substance was an old product, then, yes, sir, it would apply.

Mr. KASTENMEIER. On the surface it would seem that what you have conceptually in the way of an amendment is, in fact, quite limited in terms of the application or effect.

Mr. LAWTON. We believe it is, and, of course, we would argue very strongly that there is an equitable argument here, that if a product patent would be extended because it has to go through regulatory review, then in the instance in which we described, a process patent should likewise be extended.

Mr. KASTENMEIER. Mr. Lawton, apart from Genentech, are there other companies such as Genentech which are engaged in genetic engineering technology and which presumably would produce products broadly in the same field?

Mr. LAWTON. Yes, indeed, there are, Mr. Chairman. They are our competitors. We were the first company to go public. We went public 18 months ago. Since that time, at least one other company, CETUS, also located in California, has gone public, and, of course, the literature is full of what may well be by now hundreds of recombinant DNA companies which exist in one form or another. There are very few public companies.

Mr. KASTENMEIER. I have no further questions. You have given excellent testimony. I would suggest you work out some language for the committee when we are engaged in the markup.

That concludes our testimony for today, and we appreciate your appearance.

Mr. LAWTON. Thank you, Mr. Chairman.

Mr. KASTENMEIER. I appreciate your being as patient as you were to wait to be the last witness on a rather difficult morning in terms of interruptions.

Accordingly, the subcommittee will stand adjourned.

[Whereupon, at 1:08 p.m. the subcommittee adjourned, to reconvene subject to the call of the Chair.]

APPENDIXES

APPENDIX 1—ADDITIONAL STATEMENTS

A. American Petroleum Institute

B. Joseph DeGrandi, Chairman, Section of Patent, Trademark and Copyright Law, American Bar Association

C. Thomas D. Kiley, Vice President and General Counsel, Genetech, Inc.

D. Donald K. Lourie, President and Chief Executive Officer, Lescarden Limited

E. National Agricultural Chemicals Association

F. National Retired Teachers Association and the American Association of Retired Persons

G. Albert C. Zettlemoyer, American Chemical Society

Statement by the

American Petroleum Institute

on the

Patent Term Restoration Bill (H.R.1937)

Subcommittee on Courts, Civil Liberties

and the Administration of Justice

U.S. House Committee on the Judiciary

September 30, 1981

The American Petroleum Institute (API) appreciates the opportunity to present its views on the Patent Term Restoration Bill of 1981, currently being considered by the Subcommittee. The API is a trade association composed of more than 320 member companies and over 8,000 individual members engaged in every aspect of the petroleum industry, including the exploration, production, transportation, refining and marketing of petroleum products. API members have historically led the world in the advancement of petroleum technology. The API, therefore, has a strong interest in the Patent Term Restoration Bill.

The Patent Term Restoration Bill of 1981, if passed, would restore the term of the patent grant for the period of time, not exceeding seven years, that nonpatent regulatory requirements prevent the marketing of the patented product or a method for using a product. While API supports the principle of restoring the seventeen year period of exclusivity to patent owners, it is believed the legislation should not be limited only to product and method of use patents, but should be extended to all patents.

As an example of the need for an extension of the bill to cover all patents, in the case of synthetic fuels, patent protection is often limited to the processes for making a product because the product itself and the method of its use are conventional. At the same time, commercial implementation of patented processes is subjected to nonpatent regulatory delays similar to those experienced by owners of product patents and methods for using products.

To apply the principle of patent restoration to all patents whose commercialization may be delayed because of federal regulatory requirements, API would recommend amendments to the Patent Term Restoration Bill (H.R.1937) as shown in the attachment (additions are underlined; deletions are in brackets).

In essence, these amendments substitute the words "patented subject matter" for the words "a product or a method for using a product" throughout the bill. In addition, the term "patented subject matter" is now defined in terms of the definition of the statuatory classes of invention set forth in the presently existing patent statute, 35 U.S.C. 101 (see page 4, lines 1-4 of the attachment). Similarly, the term "commercialization" is also defined in the amended bill in terms of a patent statute (35 U.S.C. 102(b)) which has been widely and thoroughly interpreted by a number of district courts and courts of appeals.

Some of the other minor recommended amendments shown in the attachment include the following:

Page 2, line 18 - clarifies the fact that multiple extension of patent term may be obtained as long as the sum total of all extensions does not exceed 7 years;

Page 4, lines 15-17 - patented processes, using patented or unpatented products or by-products, which may be subject to the Toxic Substances Control Act regulations are added to a non-limiting list of examples illustrating the definition of the term "patented subject matter";

Page 4, line 19 - the term "major health or environmental effects test" is explicitly defined as the test which is required by federal law or regulation; and

Page 7, line 7-19 - this section is amended to explicitly state that the bill is not effective retroactively to the portions of regulatory delays prior to the time of the effective date of the Act.

With these recommended amendments, API supports the adoption of the Patent Term Restoration Bill.

97th CONGRESS

1ST SESSION

H.R. 1937

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] commercialization of [a] patented [product] subject matter.

IN THE HOUSE OF REPRESENTATIVES

February 18, 1981

Mr. Kastenmeier (for himself and Mr. Sawyer) 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 a patent grant for the period of time that nonpatent regulatory requirements prevent the [marketing] commercialization of [a] patented [product] subject matter.

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 1981."

SECTION 1. 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] The term of a patent which encompasses within its scope [a product, or a method for using a product, subject] patented subject matter, the commercialization of which is delayed due to a regulatory review period, shall be extended by the amount of time equal to the regulatory review period [for such product or method] 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 [product or method] patented subject matter has been [subjected to a] affected by regulatory review for such a regulatory review period pursuant to statute or regulation prior to its [commercial marketing or use] commercialization; and

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

The rights derived from any claim or claims of any patent so extended shall be limited in scope during the period of any extension to the [product or method] patented subject matter affected by [subject to the] regulatory review [period] and to the statutory use, if any, for which regulatory review was required.

"(2) In no event shall the term of any patent be extended for a total of 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 under oath that the regulatory review period has ended. Such notification shall be in writing and shall:

"(A) identify the Federal statute or regulation under which regulatory review occurred;

"(B) state the dates on which the regulatory review period commenced and ended;

"(C) identify the [product] patented subject matter and the statutory use [for which] thereof, if any, affected by the required regulatory review [was required];

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

"(E) identify the claim or claims 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 (A) publish the information noticed in the Official Gazette of the Patent and Trademark Office, and (B) issue to the owner of record of the patent a certificate of extension, under seal, stating the fact and length of the extension and identifying the [product] patented subject matter and the statutory use, if any, and the claim or claims 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.

"(c) As used in this section:

"(1) The term ['product or a method for using a product'] 'patented subject matter' means [any machine, manufacture, composition of matter or any specific method of use thereof for which United States Letters Patent can be granted and includes the following

or any specific method of use thereof] all subject matter set forth in 35 U.S.C. 101, and in the case of a patented process also shall mean any product or by-product produced thereby and in the case of a patented machine, manufacture or composition of matter also shall mean any specific method of use thereof. The term shall include without limitation:

"(A) any new drug, antibiotic drug, new animal drug, device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act;

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

"(C) any pesticide subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act; and

"(D) any chemical substance or mixture subject to regulation under the Toxic Substances Control Act.

"(E) any process which produces a patented or unpatented product or by-product, the use, processing or disposal of which is subject to the Toxic Substances Control Act."

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

"(3) The term 'statutory use' means all uses regulated under the statutes identified in sections [(c)(4) (A)-(D)] (c)(1) (A)-(E) for which regulatory review occurred for the product involved.

"(4) The term 'commercialization' means 'in public use or on sale in this country' as set forth in 35 U.S.C. 102(b).

"(5) The term 'regulatory review period' means -

"(A) with respect to a food additive, color additive, new animal drug, veterinary biological product, device, new drug, antibiotic drug, or human biological product, a period commencing on the earliest of the date the patentee, his assignee, or his licensee (i) initiated a major health or environmental effects test on such product or a method for using such product, (ii) claims an exemption for investigation or requests authority to prepare an experimental product with respect to such product or a method for using such product under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of Congress of March 4, 1913, or (iii) submits an application or petition with respect to such product or a method for using such product under such statutes, and ending on the date such application or petition with respect to such product or a method for using such product is approved or licensed under such statutes or, if objections are filed to such approval or license, ending on the date such objections are resolved and [commercial marketing] commercialization is permitted or, if [commercial marketing] commercialization is initially permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings are finally resolved and [commercial marketing] commercialization is permitted;

"(B) with respect to a pesticide, a period commencing on the earliest of the date the patentee, his assignee, 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;

"(C) with respect to a chemical substance or mixture for which notification is required under section 5(a) of the Toxic Substances Control Act -

"(i) which is subject to a rule requiring testing under section 4(a) of such 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;

"(ii) which is not subject to a testing rule under section 4 of such 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;

"(D) with respect to any other [product or method of using a product that has been subjected to] patented subject matter, the commercialization of which has been delayed due to Federal [premarketing] regulatory review, a period commencing on the date when the patentee, his assignee, or his licensee initiates actions pursuant to a Federal statute or regulation to obtain such review [prior to the initial commercial marketing in interstate commerce of such product] and ending on the date when such review is completed, except that the regulatory review period shall not be deemed to have commenced until a patent has been granted [for the product or the method of use of such product 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 period of patent extension [for such product or a method of using such product] shall [be measured from] not include any portion of the regulatory review period prior to the effective date of this section.".

AMERICAN BAR ASSOCIATION

SECTION OF PATENT TRADEMARK AND COPYRIGHT LAW 1981-1982

1155 EAST 60TH ST., CHICAGO, ILLINOIS 60637 TELEPHONE (312) 947-4000

September 30, 1981

Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts,
Civil Liberties and the
Administration of Justice
United States House of Representatives
2232 Rayburn House Office Building
Washington, D.C. 20515

Dear Representative Kastenmeier:

I have been informed that the Subcommittee on Courts, Civil Liberties and the Administration of Justice will hold hearings on H.R. 1937, the "Patent Term Restoration Act of 1981", on September 30 and October 1 and 7, 1981.

For inclusion in the printed hearing record we submit the enclosed statement of the Section of Patent, Trademark and Copyright Law, supporting enactment of H.R. 1937. These views are being submitted only on behalf of the Section of Patent, Trademark and Copyright Law and should not be construed as representing the position of the ABA.

If you, the members of your Committee, or your Committee staff have any questions regarding the position of the Section of Patent, Trademark and Copyright Law, please let me know.

Sincerely,

Joseph A. DeGrandi

Joseph A. DeGrandi
Chairman

JAD:rrd
Enclosure
cc: Honorable Peter W. Rodino, Jr., Chairman, Committee on the Judiciary
Honorable Jack Brooks
Honorable Don Edwards
Honorable John Conyers, Jr.
Honorable John F. Seiberling
Honorable George E. Danielson
Honorable Romano L. Mazzoli
Honorable William J. Hughes
Honorable Sam B. Hall, Jr.

cc: Honorable Michael L. Synar
Honorable Patricia Schroeder
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Honorable Dan R. Glickman
Honorable Harold Washington
Honorable Barney Frank
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STATEMENT OF

JOSEPH A. DeGRANDI, CHAIRMAN

SECTION OF PATENT, TRADEMARK AND COPYRIGHT LAW

AMERICAN BAR ASSOCIATION

submitted to the

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES AND THE ADMINISTRATION OF JUSTICE

of the

COMMITTEE ON THE JUDICIARY

U.S. HOUSE OF REPRESENTATIVES

concerning

H.R. 1937

PATENT TERM RESTORATION ACT OF 1981

September 30, 1981

Statement to the

Subcommittee on Courts, Civil Liberties and the Administration of Justice

of the

Committee on the Judiciary

U.S. House of Representatives

September 30, 1981

I am Joseph A. DeGrandi, Chairman of the Section of Patent, Trademark and Copyright Law of the American Bar Association. My statement on H.R. 1937, the "Patent Term Restoration Act of 1981", is being presented solely on behalf of the Section of Patent, Trademark and Copyright Law and does not represent the position of the American Bar Association itself. To date, the Section's views on this specific bill have not been submitted to -- and therefore have neither been approved nor disapproved by -- the House of Delegates or Board of Governors of the ABA.

For several years now, both the Congress and the Section of Patent, Trademark and Copyright Law have been concerned about the decreasing term of effective patent life for products that may not lawfully be sold within the United States until after they have undergone pre-marketing federal agency review. The types of products most directly affected are (i) chemical substances and pesticides which are subject to review by the Environmental Protection Agency under either the Toxic Substances Control

Act or the Federal Insecticide, Fungicide, and Rodenticide Act, and (ii) human and veterinary drugs and biological products, medical devices and food and color additives which are subject to review by the Food and Drug Administration under, inter alia, the Federal Food, Drug and Cosmetic Act.

Of necessity, the regulatory review process for these products requires substantial safety and/or efficacy testing. Advances in scientific instrumentation and testing techniques over the past two decades coupled with increased regulatory requirements have resulted in the substantial dilution for these products of the 17-year patent grant contemplated by Congress. New pesticides now have, on average, 12 years of patent life remaining when marketing commences and newly approved drugs, on average, have but 9.5 years of patent term.

This dimunition of patent term because of EPA and FDA requirements was hardly contemplated by the Congress in 1836 when the first patent statute was codified -- we then had neither an EPA nor an FDA. Nor was the impact on patent term considered when Congress enacted the statutes administered by these federal agencies.

During the 95th Congress, several measures were introduced to remedy the impropriety of depriving the innovator -- through no fault of his own -- of the ability to profit from the commercial exploitation of an invention through the full 17-year life of the patent. Among the

bills introduced in the 95th Congress were H.R. 8891, introduced by Congressman Rogers; H.R. 11447, introduced by Congressman Symms; and S. 2040, introduced jointly by Senators Javits and Williams.

At its 1978 Annual Meeting, the Section of Patent, Trademark and Copyright Law passed a resolution favoring in principle -- but without endorsing any specific legislation -- the granting of an extended patent term where marketing has been delayed by governmental agency requirements. The resolution approved at the 1978 Annual Meeting provided as follows:

> RESOLVED, that the Section of Patent, Trademark and Copyright Law favors in principle granting to a patent owner an extended patent term when the ability to commercially exploit a patented invention has been delayed, during the term and through no fault of the patent owner, by governmental authorities, statutes or regulations.

I should note that the Section's decision at that time not to support specific legislation was based upon the coupling in S. 2040, for example, of patent term restoration with compulsory licensing at some time during the term of the patent. It has been the longstanding position of the Section of Patent, Trademark and Copyright Law to oppose the principle of compulsory licensing as being contrary to the basic purpose of the patent system.

During the 96th Congress, patent restoration legislation was again introduced in the Senate. S. 2892 was introduced late in the second session and time did not allow for full consideration of this measure. Nonetheless, at the 1980

Annual Meeting of the Section of Patent, Trademark and Copyright Law, the following resolution was adopted which specifically supported passage of S. 2892 or similar legislation:

> RESOLVED, that the Section of Patent, Trademark and Copyright Law favors in principle granting to a patent owner an extended patent term when the ability to exploit commercially a patented invention has been delayed, during the term and through no fault of the patent owner, by governmental authorities, statutes or regulations; and specifically the Section of Patent, Trademark and Copyright Law favors enactment of S. 2892 (Bayh) 96th Congress, entitled The Patent Term Restoration Act of 1980, or similar legislation.

That resolution of support by the Section of Patent, Trademark and Copyright Law clearly encompasses S. 255, which was passed by the Senate on July 9, 1981, and its companion bill in the House of Representatives, H.R. 1937.

Over the years, studies of the American patent system generally have concluded that it has performed well its Constitutional mandate "to promote the progress of science . . . by securing for limited times to . . . inventors the exclusive right to their . . . discoveries." U.S. Const. art. I, Section 8, cl. 8.

Indeed, the Subcommittee on Patent and Information Policy of the federal Advisory Committee on Industrial Innovation suggested in its September 1979 final report that the patent system's "significant contribution to the economic development of our country . . . is so well accepted . . . that we tend to take it for granted." However, the Subcommittee's report also noted a decline in innovation in the United States and recommended a number of legislative initiatives to address the problem, including several in the patent area.

Recent evidence strongly suggests that the patent system's failure to compensate for the federal pre-marketing review requirements imposed on certain products and devices has discouraged America's innovative talents. As Senator Mathias noted in his January 27, 1981 remarks introducing S. 255, the average number of new drugs introduced annually in the United States has declined by approximately two-thirds over the past 20 years.

It is our understanding, moreover, that the annual growth rate for pharmaceutical R & D in the U.S. was about 11% from 1973 to 1979. At the same time, the corresponding growth rates for competitors from the United Kingdom, West Germany and Japan were approximately twice that number. As a result, between 1963 and 1975 U.S. patents for new drugs obtained by foreign-based companies increased from 34% to 46%. American pharmaceutical companies' share of the international market declined from 34% in 1955 to 13% in 1975 and at least one study also predicts that by 1985, U.S. companies' share of our own domestic pharmaceutical market will decline by 12%.

This decline in our technological preeminence, as regrettable as it may be, is quite understandable when we realize it currently takes 7 to 10 years and some $70 million of capital (as opposed to the 2 years and $6 million it required in 1962) to bring a new medicine from the laboratory to the marketplace. Instead of increased patent incentives to compensate for such increased risks and costs,

during the same period the effective patent life of a new drug has decreased to an average of 9.5 years. Moreover, as EPA's own studies have concluded, the commercial patent life for new pesticides has been reduced to an average of just 12 years because of pre-marketing federal agency procedures.

It is not our purpose today to lay blame for these conditions at the feet of governmental regulators. Instead, we submit that the patent system itself must be adjusted to provide adequate flexibility to accommodate national health and safety concerns, while continuing to serve its fundamental purpose of encouraging domestic research and development efforts through the incentive of 17-year commercial exclusivity.

The federal government's ability to assure the safety of new products is left fully intact under H.R. 1937. At the same time, this bill manages to provide a simple but effective remedy for many American innovators -- both small and large businesses alike -- who have seen their patent protections severely diluted by the pre-marketing federal agency review process.

We commend the sponsors of S. 255 and H.R. 1937 for their well-reasoned and balanced approach to this issue. Specifically, we consider it wholly appropriate to limit the patent restoration provisions to products or devices which successfully pass the agency review process. We also consider the addition of Section 155(c)(4)(D) to be an important improvement. Under this provision, all products subject to

federal pre-marketing review or notification requirements will receive the same equitable treatment as those categories of products and devices expressly identified in the legislation.

Moreover, the Section of Patent, Trademark and Copyright Law supports the limited application of this legislation only to the specific purpose or use involved in the regulatory approval and not to the entire range of products that might result from the original patent grant. The Section also concurs in the use of a maximum 7-year patent extension period since this should provide adequate time for pre-marketing testing without encouraging a patentee to engage in dilatory behavior.

The Patent Term Restoration Act of 1981 is also commendable for its use of objectively identifiable criteria to define the applicable "regulatory review period". Pursuant to proposed Section 155(c)(4), the review period automatically terminates either on the date the agency involved in the review process formally grants marketing approval to the patent-holder or upon expiration of the statutorily-defined period for agency action.

Likewise, the procedures for exercising the right to a patent term restoration are extremely workable. All the patent-holder need do is to give notice to the Patent and Trademark Office that the product has successfully completed regulatory review. Upon timely filing of this notice by the patent-holder within 90 days of completion of the review process, the Commissioner of Patents and Trademarks

will publish this information in the Official Gazette and, thereafter, will issue a certificate extending the patent life and will record the certificate in the official file of the patent.

In summation, we think the record is quite clear that domestic research and development efforts and, in turn, the American public at-large, have been adversely impacted by the problem which H.R. 1937 seeks to redress. Our country simply can no longer tolerate the continued growth in the importation of foreign manufactured goods, nor must we suffer the consequences of this drain on our economy when we have at hand a means of encouraging domestic R & D. Indeed, the federal Advisory Committee on Industrial Innovation has endorsed legislation in the nature of H.R. 1937.

The enactment late last year of Public Law 96-517 -- in particular, its patent reexamination provisions -- should substantially improve the quality and reliability of U.S. patents and reduce the amount and scope of patent litigation. On behalf of the Section of Patent, Trademark and Copyright Law of the American Bar Association, I urge the Congress to take the next step by passing H.R. 1937 and restoring to the life of a patent the amount of time required for government testing of a new product.

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September 18, 1981

BY MESSENGER

Bruce A. Leyman, Esquire
Chief Counsel
Subcommittee on Courts, Civil
Liberties, and the Administration
of Justice
2137 Rayburn House Office Building
Washington, D.C.

Dear Mr. Leyman:

We represent Genentech, Inc., a publicly-owned company based in San Francisco, engaged in research and the manufacture of pharmaceutical and other products using the recombinant DNA, or genetic engineering, process. We understand that the Subcommittee on Courts, Civil Liberties and the Administration of Justice has scheduled hearings on patent restoration legislation and respectfully request that Genentech be afforded the opportunity to present oral testimony during these hearings on October 7, 1981.

Enclosed herewith is a copy of testimony presented during Senate hearings by Thomas D. Kiley, Vice President and General Counsel of Genentech. As the testimony indicates, Genentech strongly favors enactment of patent restoration legislation, but believes that the bill should be amended to restore the term of patents on new processes for making old substances. The present position of the Food and Drug Administration (with which we do not quarrel) is that an old substance, even one hitherto approved for treatment when gotten from conventional sources, will be treated as a "new drug" when made by genetically engineered microorganisms. Under the Senate version of the proposed legislation, the "process" patent for making these substances would not be extended even though the product is subject to a new drug application and thus regulatory review, by FDA.

Pierson, Ball & Dowd

Bruce A. Leyman, Esquire
September 18, 1981
Page Two

It seems obvious that one of the principal purposes for the proposed legislation is to restore patent protection to all new pharmaceutical development; thus we believe that new methods of making pharmaceutical products (assuming they are patentable and that the methods themselves require regulation as new drugs) should be covered by the bill. Otherwise stated, innovation in the science of making "old" things in better and more economic ways should be encouraged to the same extent the bill in its present form would encourage the making of new things. We strongly believe that an amendment to cover "process" patents under the above circumstances will enhance competition. It will encourage the formation of small, innovative companies such as Genentech by allowing them to grow up under the protection of the shelter of patent protection.

I shall call your office later in the day to seek to schedule Genentech's testimony and to try to arrange an appointment with you to discuss Genentech's concerns. I full recognize the constraints on your time (for eight years I served as Chief Counsel of the Health Subcommittee when it was chaired by Congressman Rogers of Florida) and will be as brief as possible.

Thanks very much in advance for your interest and I look forward to speaking with you soon.

Very truly yours,

PIERSON, BALL & DOWD

Stephan E. Lawton /kam

SEL:kam
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STATEMENT OF

THOMAS D. KILEY

VICE PRESIDENT AND GENERAL COUNSEL

GENENTECH, INC.

BEFORE THE

COMMITTEE ON THE JUDICIARY

UNITED STATES SENATE

ON

PATENT TERM RESTORATION

Thursday, April 30, 1981

Mr. Chairman, my name is Tom Kiley. I am the chief legal officer of Genentech, Inc., a small California company founded just five years ago in the belief, not then widely shared, that genetic engineering technology could quickly be made to produce practical benefits in the pharmaceutical and other fields. Today, three products of our researches are already undergoing the human clinical testing that is required before marketing approval can be obtained: human insulin, human growth hormone and interferon, all made by genetically engineered microorganisms.

Although just a tiny company, Genentech thought enough of the importance of patents to its future to appear before the Supreme Court in its recent consideration of the question whether patents would be available for the new microorganisms our technology produces.[1] We appeared then in the role of amicus curiae, or "friend of the Court". We appear today as a "friend of the Congress" to again emphasize the importance of patents and of a strengthened patent incentive to the small, high technology company. When, under the umbrella of patent protection, a small company can compete on the strength of its innovative capability with larger, older and more entrenched concerns, the patent system operates to best purpose, as an essentially procompetitive mechanism.

I am no greybeard of the drug industry, nor any expert in it. For sixteen years, my experience has had to do with patents, first as an examiner of patents, then in a

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multi-national corporation, then for ten years in the patent trial courts, and more recently in the small company context of Genentech. Nothing in my experience has been more instructive with regard to the vital role patents play in our free enterprise system than the opportunity I have had to look at the world from the vantage point of the small, start-up company. Although surrounded by trees that cast great shade, we at Genentech are seeking our own place in the sun, and we expect that the availability of meaningful patent protection will help us do it.

We strongly endorse S.255, the Patent Term Restoration Act of 1981, as should every small company whose competitive edge lies in its innovative capabilities and whose activities must undergo regulatory review before the onset of commercialization.

My thesis is straightforward. Innovation is important. It arises most frequently in the small, entrepreneurial company context.[2] Patent term restoration will make patent protection more meaningful. More meaningful patent protection will permit small companies to flourish, and grow, where otherwise they might not. Conditions that encourage the growth of start-up companies also encourage investment in them, and therefore investment in innovation. The formation of small, innovative companies that can grow up under the shelter of patent protection only enhances competition, by increasing the number of market entrants and by the downward pressure the new products of innovation exert on the prices of older products.

The genius of the patent term restoration legislation before this Committee immediately follows from these precepts, and from the commonsense notion that what government gives with the right hand, it ought not to take away with the left.

Venture Capital and the High Technology Start-up Company

It is not surprising that most innovation arises at the level of the individual entrepreneur and in the small company context. One who would start any new enterprise needs a good idea because, at the outset, that is the only asset he has. The idea should be a new one, otherwise the start-up company will be unable to differentiate itself from established companies in the marketplace. But the new company whose principal asset is a good idea is also the company least likely to secure access to conventional financing. Most bankers don't lend on dreams. The availability of risk capital is accordingly an essential ingredient in formation of the new, innovation-intensive concern. The circumstances of Genentech's own formation are illustrative, and underline the importance of both venture capital as a source for science funding, and patent rights as an inducement for investment.

Genentech was formed in 1976. In that same year, one Nobel laureate unequivocally characterized predictions that human peptide hormones could be made in bacteria, using synthetic genes, as belonging "more in the field of science fiction than science".[3] That same year, scientists at the City of Hope National Medical Center in Duarte, California were rebuffed