S. HRG. 98-578

THE PATENT TERM RESTORATION ACT OF 1983

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
PATENTS, COPYRIGHTS AND TRADEMARKS

OF THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

NINETY-EIGHTH CONGRESS

FIRST SESSION

ON

S. 1306

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

JUNE 22, JULY 19, AND AUGUST 2, 1983

Serial No. J-98-46

Printed for the use of the Committee on the Judiciary

U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON : 1984

25-841 O

COMMITTEE ON THE JUDICIARY

STROM THURMOND, South Carolina, *Chairman*

CHARLES McC. MATHIAS, Jr., Maryland
PAUL LAXALT, Nevada
ORRIN G. HATCH, Utah
ROBERT DOLE, Kansas
ALAN K. SIMPSON, Wyoming
JOHN P. EAST, North Carolina
CHARLES E. GRASSLEY, Iowa
JEREMIAH DENTON, Alabama
ARLEN SPECTER, Pennsylvania

JOSEPH R. BIDEN, Jr., Delaware
EDWARD M. KENNEDY, Massachusetts
ROBERT C. BYRD, West Virginia
HOWARD M. METZENBAUM, Ohio
DENNIS DeCONCINI, Arizona
PATRICK J. LEAHY, Vermont
MAX BAUCUS, Montana
HOWELL HEFLIN, Alabama

VINTON DEVANE LIDE, *Chief Counsel and Staff Director*
DEBORAH K. OWEN, *General Counsel*
SHIRLEY J. FANNING, *Chief Clerk*
MARK H. GITENSTEIN, *Minority Chief Counsel*

SUBCOMMITTEE ON PATENTS, COPYRIGHTS AND TRADEMARKS

CHARLES McC. MATHIAS, Jr., Maryland, *Chairman*

PAUL LAXALT, Nevada
ORRIN G. HATCH, Utah
ROBERT DOLE, Kansas

HOWARD M. METZENBAUM, Ohio
PATRICK J. LEAHY, Vermont
DENNIS DeCONCINI, Arizona

RALPH OMAN, *Chief Counsel*
STEVEN J. METALITZ, *Staff Director*

CONTENTS

APPENDIX

CORRESPONDENCE

ADDITIONAL STATEMENTS FOR THE RECORD

THE PATENT TERM RESTORATION ACT OF 1983

WEDNESDAY, JUNE 22, 1983

U.S. SENATE,
SUBCOMMITTEE ON PATENTS,
COPYRIGHTS AND TRADEMARKS,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:45 a.m., in room SD-226, Dirksen Senate Office Building, Senator Charles McC. Mathias, Jr. (chairman of the subcommittee), presiding.

Also present: Senators Metzenbaum, DeConcini, and Grassley.

Staff present: Ralph Oman, chief counsel, Charlie Borden, professional staff member, Pam Batstone, chief clerk, Subcommittee on Patents, Copyrights and Trademarks; and Wes Howard, counsel to Senator Metzenbaum.

OPENING STATEMENT OF SENATOR CHARLES McC. MATHIAS, JR.

Senator MATHIAS. The subcommittee will come to order.

The Patents, Copyrights and Trademarks Subcommittee will hear testimony on the Patent Term Restoration Act of 1983, which is a bill that I introduced 2 years ago and again this year in May. The purpose is to correct an inequity in the patent system by extending the life of the patent up to a maximum of 7 years to compensate for time lost while a newly patented product clears the tests that are imposed by the Government.

The pharmaceutical drug and the agricultural chemical industries are particularly affected by this regulatory predicament. Over the past 20 years, as the premarket testing required for products in these fields has become more sophisticated and more time consuming, the inventors of the products have been left with less and less of the normal 17-year protection which is provided for patentable products.

And this has, in effect, been a deterioration of patent life and it has undermined the basic rationale of the patent system, which is that the promise of some reward spurs greater effort and spurs taking greater risks in the development of new and creative products.

[A copy of S. 1306, introduced by Senator Mathias, follows:]

II

98TH CONGRESS
1ST SESSION

S. 1306

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 SENATE OF THE UNITED STATES

MAY 17 (legislative day, MAY 16), 1983

Mr. MATHIAS (for himself, Mr. BAKER, Mr. THURMOND, Mr. BIDEN, Mr. PERCY, Mr. DOLE, Mr. LAXALT, Mr. HATCH Mr. DECONCINI, Mr. BAUCUS, Mr. HEFLIN, Mr. DENTON, and Mr. GRASSLEY) introduced the following bill; which was read twice and 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 1983".

SEC. 2. (a) Section 155 of title 35 of the United States Code is amended by—

(1) striking out "Notwithstanding" and inserting in lieu thereof "(d) Notwithstanding"; and

(2) striking out

"§ 155. Patent term extension"

and inserting in lieu thereof the following:

"§ 155. Restoration of patent term

"(a)(1) Except as provided in paragraphs (3) and (4), the term of a patent which encompasses within its scope a product subject to regulatory review, or a method for using or a method for producing such a product, shall be extended from the original expiration date of the patent by the amount of time equal to the regulatory review period 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 has been subjected to regulatory review pursuant to statute before 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).

"(2) The rights derived from any claim of any patent extended under paragraraph (1) shall be limited—

"(A) in the case of any patent, to the scope of such claim which relates to the product subject to regulatory review; and

"(B) in the case of a patent which encompasses within its scope a product—

"(i) which is subject to regulatory review under the Federal Food, Drug, and Cosmetic Act, to the uses of the product which may be regulated by the chapter of such Act under which the regulatory review occurred; or

"(ii) which is subject to regulatory review under any other statute, to the uses of the product which may be regulated by the statute under which the regulatory review occurred.

"(3) In no event shall the term of any patent be extended for more than seven years nor shall more than one patent be extended for the same regulatory review period for the product.

"(4) The term of a patent which encompsses 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 products; and

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

"(b)(1) To obtain an extension of the term of a patent under subsection (a), the owner of record of the patent shall

notify the Commissioner, within ninety days after the termination of the regulatory review period for the product to which the patent relates, that the regulatory review period has ended. Such notification shall be in writing, under oath, and shall—

"(A) identify the Federal statue under which regulatory review occurred or, if the regulatory review occurred under the Federal Food, Drug, and Cosmetic Act, the chapter of the Act under which the review occurred;

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

(C) identify the product for which regulatory review was required;

"(D) state that the requirements of the statute under which the regulatory review referred to in subsection (a)(1)(B) occurred have been satisfied and commercial marketing or use of the product is not prohibited;

"(E) identify the patent and any claim thereof to which the extensionis applicable and the length of time of the regulatory review period for which the term of such patent is to be extended; and

"(F) state that no other patent has been extended for the regulatory review period for the product.

"(2) Upon receipt of the notice required by paragraph (1), the Commissioner shall promptly publish in the Official Gazette of the Patent and Trademark Office the information contained in such notice. Unless the requirements of this section have not been met, the Commissioner shall issue to the owner of record of the patent a certificate of extension, under seal—

"(A) stating the fact and length of the extension;

"(B) identifying the product and the statute under which regulatory review occurred; and

"(C) specifying any claim to which such extension is applicable.

Such certificate shall be recorded in the official file of the patent so extended and shall be considered as part of the original patent.

"(c) As used in this section—

"(1) the term 'product' means any machine, manufacture, or composition of matter for which a patent may be obtained, and includes the following:

"(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. 151–158);

"(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 'regulatory review period' means—

"(A) with respect to a product which is 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) initiates a major health or environmental effects test on such product, the data from which are submitted in an application or petition with respect to such product

under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of Congress of March 4, 1913;

"(ii) claims an exemption for investigation or requests authority to prepare an experimental product with respect to such product under such statutes; or

(iii) submits an application or petition with respect to such product under such statutes,

and ending on the date such application or petition with respect to 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 product which is 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 are 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 for such pesticide 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 under section 3 of such Act, either conditionally or fully; and

"(C) with respect to a product which is 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 notifica-

tion period for such chemical substance or mixture, or if an order or injunction is issued under subsection (e) or (f) of section 5 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 chemical substance or mixture, the data from which are included in the premanufacture notice for such substance or mixture,

and ending on the expiration of the premanufacture notification period for such substance or if an order or injunction is issued under subsection (e) or (f) of section 5 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 be deemed to have commenced until a patent has been

granted for the product which is subject to regulatory review, for the method for using such product, or for the method for producing such product. In the event the regulatory review period has commenced prior to the date of enactment of this section, then the period of patent extension shall be measured from such date of enactment.".

(b) The analysis for chapter 14 of title 35, United States Code, is amended by amending the item relating to section 155 to read as follows:

"155. Restoration of patent term.".

O

25-841 O - 84 -- 2

Senator MATHIAS. I want to welcome all of our witnesses today. I regret that I have to remind you of the 5-minute limit for the oral summary. The record will remain open for 2 weeks for additional submissions. I will ask the members of the committee to forward any written questions that they may have no later than Monday so that witnesses will have ample time to respond for the record.

Before calling on the first witness, let me turn to the ranking minority member, Senator Metzenbaum.

OPENING STATEMENT OF SENATOR HOWARD M. METZENBAUM

Senator METZENBAUM. Mr. Chairman, I am looking forward to working with you in connection with this particular piece of legislation and I do want to suggest at the outset that I am informed that there are a number of witnesses who wanted to be heard and will not be able to be heard, and I would like to urge upon you some consideration as to the possibility of having an additional day of hearings so that those who have an interest in this very important subject will have an opportunity to state their case.

Now, I do not know the names of who they are, but my staff tells me that there are some who speak for very representative organizations and they will not be able to be heard on the schedule today. Now, it may be possible, if the hearing moves rapidly enough, to still put them in before the hearing concludes today even though they are not on the list. But I would think that we ought to at least make that effort.

As we begin our hearings on the patent term extension bill, we look at a measure which would give extra monopoly profits to a handful of highly successful companies. The hope is that somehow, if we give them more profits, the extra profits will trickle down to the public in the form of new drugs and related products.

I do not think there is any secret about the fact that, sure, we all want new drugs; we want new answers. There are challenging problems that exist and we would like to have the answers. So in the past we have provided some special tax arrangements for R&D—a 25-percent tax credit for R&D—with the thought that with all that extra money, we would solve some of the world's most challenging problems in the field of illness.

Our experience, however, has taught us that innovation does not come about by reason of monopoly profits and the mere availability of the money does not solve the problem. The best spur to innovation in our free enterprise system is the fact of competition—the opportunity that if you have the new drug that provides the answer, there will be people buying it and there is a profit involved, and that is well and good.

But if there is one thing we have learned over the past few years, and I would say since January of 1981, it is that trickle-down theories of public benefits do not work. As the Vice President of the United States has said, "Voodoo economics work to benefit only those at the top." This is as true in the context of drug innovation as it is in the economy as a whole.

Now, I look forward to hearing from our witnesses representing consumers, senior citizens, labor and other groups as to whether they expect to reap the trickle-down benefits.

The drug companies claim that they are being treated unfairly. They believe that the Government's attempt to make sure that drug products are safe and effective eats away at the life of the drug patents, and that is the issue before us.

They claim that, as a corollary, the shortened patent life has taken away their incentive to create new and innovative life-saving products. Mr. Chairman, I am afraid that the rhetoric is good, but that it is not supported by the facts because those facts will not stand up to even a cursory analysis.

First of all, it is clear that no products have a full 17-year marketing period. The first thing an inventor does is file a patent application, then he or she goes out to plan his or her marketing and do his or her tests. The fact that the Government participates in this process in the drug industry does not make the industry deserving of special treatment.

Any responsible firm would do tests to make sure that its products are safe and effective. Let us assume you have a new patented airplane or patented car parts. Most firms are not here seeking extra monopoly profits. Let us assume you had any new kind of patented product; you would have to test it.

If this bill were to pass, I would expect that others would be here saying, "We want an extension while we do our testing." And as I pointed out before, the mere fact that the Government is involved in that testing process is no reason to change the rules of the game.

I remember when we in this committee had a bill to provide an exemption for the soft drink bottlers, and sure as shooting, within a few months the beer distributors were in for the same kind of exemption.

If we have an exemption for the drug industry, we will have an exemption for all—everybody else will be here asking for the same kind of extension. As a matter of fact, much of the delay in the Government's approval of new drugs is the fault of the drug companies themselves.

One former official of a major drug company was recently quoted in the Wall Street Journal as saying that "the industry has to take a good deal of the rap for drug lag because many drug applications are incompetent, poorly done, and do not prove anything."

We have seen the results of such shoddy work in the tragedies of Thalidomide and DES. Why should we provide monopoly profits as a reward for incompetence?

Further, Mr. Chairman, all the evidence and informed predictions show that R&D in the drug industry is not on the decrease; it is actually on the increase. The National Science Foundation concluded that one of the major causes of this increase is the presence of both foreign and domestic competition.

Once again, we see that competition, not monopoly, is the answer. The result of this R&D in the future will be the new drugs we need, just as past R&D has so successfully rewarded both the public and the drug companies.

The pharmaceutical makers claim that fewer and fewer drugs are being approved. As we will see, that is hogwash. The rate of drug approvals has gone up, not down, in recent years. The drug companies themselves predict that their market will triple in 10

years, to a total of $217 billion in annual sales worldwide. Is that not a fantastic spur to innovate in and of itself?

Finally, Mr. Chairman, what the drug companies want appears to be the most risky and indirect means to improve the public health that I can imagine. Think of it: The hope of this bill is that up to 7 years of added monopoly profits for already successful firms will be the best way to create new drug products.

Mr. Chairman, even the study most favorable to the industry by Dr. Grabowski, our witness today, predicts that as much as three-quarters of the extra profits will not go to new R&D. I expect it will go mostly toward advertising and other actions that enable the drug companies to maintain their monopoly even after the patents have expired.

The Office of Technology Assessment, which is to be applauded for its fine and balanced analysis of this issue, spoke to this very question. The OTA concluded that even if some of the extra profit goes into R&D, it will mostly be aimed at the big-ticket drug products which are not necessarily the ones that are most needed.

And it will have the further effect of entrenching the handful of huge, multinational firms that dominate the industry. All of these supposed benefits will be paid for by senior citizens and the chronically ill; that is, those who are least able to support those monopoly profits.

Mr. Chairman, if we do need more incentives, there must be better ways to provide them. For example, why is the tax credit that I mentioned earlier that we gave for R&D in 1981 not sufficient to spur innovation? How much more do you have to do in order to get this hoped for innovation?

I would guess that we maybe went overboard. Maybe if we are looking at this, there ought to be an amendment to take away the 25-percent R&D tax incentive in consideration for giving the extension. I am not prepared to support that, but it seems to me that you have to, at some point in Government, call a halt to just giving more and more and more to those who have special interests and taking away from those who do not have the same effective lobbying groups around here.

Mr. Chairman, I believe strongly in the patent system. It has worked well. It is important that we hold these hearings so that the Senate will fully understand the harm that this legislation would cause.

Thank you, Mr. Chairman, and I repeat that I hope you will give some consideration to whether or not an additional day of hearings is indeed needed.

Senator MATHIAS. Thank you, Senator Metzenbaum. I think we all share a desire to have a complete record here and I think I can assure you that the record will be complete.

Senator METZENBAUM. Thank you. The chairman has always been fair and I know he will continue to be.

Senator MATHIAS. Senator Grassley, do you have any statement?

Senator GRASSLEY. Mr. Chairman, thank you very much. I was a cosponsor of this bill last Congress and am supportive of it this year. I am interested in a particular aspect of the bill which I will address later during questioning.

Senator MATHIAS. Well, we are happy to have you.

Senator GRASSLEY. Thank you.
Senator MATHIAS. Senator DeConcini?

OPENING STATEMENT OF SENATOR DENNIS DeCONCINI

Senator DECONCINI. Thank you, Mr. Chairman.

Mr. Chairman, I am a cosponsor of S. 1306, the Patent Term Restoration Act, because it accomplishes three worthy goals, in my judgment. First, it will restore the intent of the patent law to protect, for a set period of time, the rights of a creator of the fruits of his labor.

Second, it will reward and encourage technological innovation. Third, it will probably result in innovative, better, less expensive medicines.

Throughout the years, our patent system has encouraged innovation through the incentive that it provides with patent protection. Patent term restoration will help restore research incentive by protecting the rights of the inventor.

It costs an average of $87 million to discover and develop a new drug today. This development cost must be recovered during the patent life of the new drug, since after its patent expires a new drug faces competition from imitator products whose manufacturers have no development costs to recover.

When a researcher uncovers a promising new invention, he files for a patent, obviously. The patent usually is granted within 2 years and the 17-year patent term commences to run. But for medicines, it is a little different. It takes 7 to 10 years for a patent holder to guide a new medicine through the Food and Drug Administration approval procedures. Effective patent life is therefore about 7 to 10 years, about half of what the patent law intended.

These years consumed in the approval process are, in effect, deducted from the drug's patent life. Instead of having 17 years in which to recover its investment, like firms in virtually all other industries, patent life is cut substantially, almost in half.

Now, there has been a question raised about what is known as the new drug application date, and I am sure we will hear testimony concerning that, and I welcome this line of argument to see whether or not there is a possible adjustment in the date.

However, new prescription medicines have in recent years been entering the market with less than half the patent protection afforded other types of inventions. The reason: Patents on new medicines are granted and begin to expire long before the FDA approves them for sale.

Medicines approved during 1981 lost an average of 10.2 years of their 17-year statutory patent lives before their first sale. Lost patent life is unfair to inventors who discover new medicines, but it also has grave implications for the American consumer.

Lost patent life reduces incentives to invent new drugs and do more research, retards the rate of medicine innovation, erodes the U.S. competitive position in an important high technology area, and raises the cost of medical care at a time when medical costs are a national problem.

Since patent lives have declined, real levels of pharmaceutical research have dropped, the rate of new drug approvals has remained

static, and a large percentage of the new drugs that are approved each year are being discovered not by American firms, but by foreign firms.

The Patent Restoration Act will reverse these harmful trends by restoring a portion of the patent life lost during the governmental approval process. The act would put medical research back on a competitive footing.

I think we have to look at the problem, Mr. Chairman, in an equitable manner. I do not believe that the drug firms and the inventors of new drugs should be given some extra special privilege here that any other inventor is not. But, certainly, they do not stand in equity now with other patents that are filed, and therefore are in a very disadvantageous position.

So, I am hopeful that we will hear both sides of this issue. We can resolve a fair and equitable date to give some relief so we can encourage the continued innovation and research in this area. Thank you, Mr. Chairman.

Senator MATHIAS. Thank you, Senator DeConcini.

Our first witness is the acting Deputy Secretary of Commerce, Gerald J. Mossinghoff, who is wearing two hats, also being the Commissioner of Patents. So he is a familiar figure in this committee and we are glad to welcome him here this morning.

STATEMENT OF GERALD J. MOSSINGHOFF, ACTING DEPUTY SECRETARY OF COMMERCE, U.S. DEPARTMENT OF COMMERCE, WASHINGTON, D.C.

Mr. MOSSINGHOFF. Thank you, Mr. Chairman. Mr. Chairman and members of the committee, I welcome this opportunity to testify on the subject of patent term extension which, in our view, would improve our patent system by providing 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, we strongly support enactment of S. 1306, the Patent Term Restoration Act of 1983.

Mr. Chairman, I will skip to page 2. You have described what the legislation would do. 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, estimated to be over $80 million in the pharmaceutical area, and perhaps $40 million in the agricultural chemical area. 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 or generic drug sector of industry displays in exploiting those inventions after the patents expire.

This interest is a healthy one and competition in the open market should clearly 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.

The patent system is by no means the only incentive which encourages large amounts of financial commitments to research and development. As Senator Metzenbaum mentioned, the 25-percent R&D tax credit applies, and this administration is recommending that that tax credit, which was due to expire on December 31, 1985, be extended for 3 years until 1988 across the board to support all research and experimentation.

But the patent system 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 will redress an inequity by restoring to the 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, in our view. The Federal Government should not induce full disclosure of an invention through a patent grant of 17 years and then reduce the effective life of the patent through premarket regulatory review.

Mr. Chairman, a year ago we asked the National Productivity Advisory Committee to consider patent term extension. That committee was established by the President in 1981 to recommend concrete steps that the Government could take to achieve higher levels of national productivity and economic growth.

The committee, whose 34 members include business, labor, and academic leaders—a totally bipartisan committee—unanimously adopted a recommendation to enhance the incentives for R&D in the agricultural chemical and pharmaceutical fields through patent-term restoration.

During the last Congress, opponents of this type of legislation argued that the problem which such a bill would alleviate has not been demonstrated. They have pointed to the high profit margins that exist in the pharmaceutical industry.

I would suggest and urge that it would be clearly unfair to establish a different patent term depending on the economic success of a particular sector of our technology. And to fail to stem the erosion of effective patent term 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, and among the most innovative of our industries, 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 of 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 their having been patented. They are, however, protected from slavish imitations, and that protection should be continued, in our opinion, for an effectively full-patent term.

Opponents of the Patent Term Restoration Act have previously speculated that its enactment would not guarantee the expenditure of greater resources for research and development.

Here, again, I would cite from the Office of Technology Assessment study which, as Senator Metzenbaum pointed out, took a very thorough look at this issue. The OTA study has been criticized both by opponents and proponents, but OTA concluded that, on balance, if patent term restoration is enacted, there is a reasonable likelihood that firms may undertake or increase pharmaceutical research and development activities because of the increased incentives provided by the longer effective patent term.

If this occurs and drugs are developed more rapidly, downward pressure might be exerted on the price of some drugs and the product lives of some drugs might decrease.

Second, it was OTA's conclusion that, to the extent that patent term extension affects the potential rate of return, drugs that might otherwise be economically marginal may become economically attractive.

Finally, patent term extension could be a significant factor in encouraging certain types of pharmaceutical research and development.

Senator MATHIAS. Mr. Secretary, this court aspires to do equal justice to rich and poor alike. The red light has now shone on you, and if we are going to enforce discipline on the other witnesses, I have got to lower the boom on you, so if you can close——

Mr. MOSSINGHOFF. Mr. Chairman, that concludes my prepared statement. [Laughter.]

Senator MATHIAS. You can always tell a pro. [Laughter.]

Some of the witnesses who will appear this morning, and some perhaps who will appear at a later session, have an obvious economic interest in this bill either to be for it or against it. The companies that do research and develop drugs would like to see the bill passed; they have an economic interest in that.

The generic drug companies who oppose it have an economic interest in opposing it. But we have a third class of witnesses who seem to oppose the bill without any economic interest, and I, pending their statement and pending what they have to say, have to conclude that they are not fully supportive of the patent system.

Now, you have spent a lot of your life in administering the patent system. What do you see, philosophically, is the benefit to the American people of having a patent system, not confined to

drugs, but what are patents all about? Why did the founders of this country include a provision for patents in the Constitution?

Mr. MOSSINGHOFF. Well, Mr. Chairman, that was one of the more interesting debates that went on during the writing of the Constitution. Thomas Jefferson, who himself was a prolific inventor, was the foremost proponent of establishing exclusivity.

Actually, some of the debate was, similar to what we might hear today on patent term extension. Why should we give people monopoly rights?

Senator MATHIAS. You used the word "exclusivity." Senator Metzenbaum in his opening statement called it monopoly. Now, is there a difference?

Mr. MOSSINGHOFF. Well, I think exclusivity is quite different from monopoly. I think to have classic monopoly power, you have to be able to tie up a reasonable portion of the market, and I do not know of inventions that have tied up an area of the market without having competition.

Indeed, as new drugs are brought on, they create competition; those new drugs create competition for drugs already on the market. So I think there is a clear difference between monopoly power and exclusivity, which is what the Constitution guarantees to inventors.

The patent system itself, I think, is what made this country what it is. I think the history of the United States is literally recorded in the patents that are on file in the U.S. Patent and Trademark Office.

There was a feeling, I guess, coming out of the Great Depression era that maybe the patent system had been fine for the original part of our history but was no longer serving the public.

In part, that prompted President Johnson to establish a high-level commission on the patent system in the early 1960's. That commission and every study, including President Carter's Domestic Policy Review, confirmed that the patent system is absolutely the finest way to encourage people in a free market economy to invest their time and talent and money in innovation and innovative activities.

The worldwide trend has not been to question the patent system, but to determine how to make it work better and more efficiently from an administrative point of view. For example, in the world, patent systems are being established now where there were none before, and China is a classic example, where they are going to establish a patent system.

So I would hope that opponents of this particular legislation would not view the exclusivity of the patent grant provided under the Constitution as a form of monopoly, because it clearly is not in modern technology.

Senator MATHIAS. Well, let me be very specific. What do you see as the interest of the American consumer in the patent system? Is the patent system for the benefit of the producer or for the benefit of the consumer, or for both?

Mr. MOSSINGHOFF. I think for both, but I would say primarily for the benefit of the consumer. You and I and everyone else, as consumers, have new products and things that make our lives better from every point of view—not just a materialistic point of view, but

from every point of view—because the patent system has stimulated people to invest their time and talent in innovation.

Senator MATHIAS. Now, one idea that has been discussed in the past year or so is to do what this bill would do not by legislation—and I think we all would like to be relieved of any additional acts of Congress, whenever that is possible; the last thing we need is more laws—but to do what this bill would do by administrative action rather than by legislative action.

Now, is that a possibility? How would you view that?

Mr. MOSSINGHOFF. Well, we could not, by administrative action, extend the life of any patent already granted. We could, I am convinced, by administrative action legally delay the grant of a patent to accommodate a reasonable standard. We would have to do this under a full rulemaking under the Administrative Procedures Act, and I do address that in my prepared statement.

To the extent that such an administrative action would delay the disclosure of new technology either in the pharmaceutical area or the chemical agricultural area, I would personally oppose it. I think that it is very important for this new technology to be disclosed so that other duplicative work is not done.

Senator MATHIAS. That would proliferate the work of that well-known inventor "pat pending."

Mr. MOSSINGHOFF. That is exactly right. You would have pat pending for a given period of time.

Senator MATHIAS. For years.

Mr. MOSSINGHOFF. It could be. We now have regulations which permit the delay of an application. A classic example is where we have a patent application that is ready to be issued as a patent, but we know of an earlier application that would otherwise knock it out.

In such a case, we will suspend the prosecution of the later-filed application until the earlier-filed application is issued so that we can then reject the later-filed application.

Senator MATHIAS. What complications would that alternative produce?

Mr. MOSSINGHOFF. Well, if it were designed so that it would not delay the disclosure of new technology, I think it could be legally done. We would have to look at it very carefully from a policy point of view.

If I may, Mr. Chairman, why do we not accept that question and go back and see what would be involved from an administrative point of view?

Senator MATHIAS. We would appreciate your further advice on that.

Senator Metzenbaum?

Senator METZENBAUM. Mr. Mossinghoff, you say that the bill is necessary in order to provide equity to drug companies, and that the companies do not get their full 17 years and somehow that is inequitable.

Did Congress really intend that the patent should be operative from the standpoint of marketing for a full 17 years?

Mr. MOSSINGHOFF. Well, they clearly intended that under normal circumstances there would be a 17-year period of exclusivity. A

patent clearly does not guarantee the right of anyone to market anything; it is really a right to exclude others.

But I would say yes, I think the thrust of the 17 years, which was enacted a century ago, is that there be that period of exclusivity.

Senator METZENBAUM. You know, I am sure—and if you do not, we will now tell you—that Congressman Orestes Cleveland of New Jersey, in 1871, at the time the patent law was amended, said the following:

> It is within the experience of many members of this House, and it is within the experience of thousands of poor inventors in the country who have been assisted by the liberality of our patent laws, that it takes them half, three-fourths, nearly the whole time their patent has to run during the first term, before they can succeed in perfecting the operations necessary under it, and in getting the article into the market or disposing of their patent.

Now, really, I think this is just a continuation of the discussion that went on 112 years ago, because Congressman Cleveland at that time went on to note that it often takes 12 years before an inventor is able to succeed "in establishing his article and demonstrating its value and inducing capitalists to take hold of it."

What an interesting fact of life that now, 112 years later, we are discussing the very same issue, I guess, so we can induce capitalists to take hold of it in 1983. It seems to me that it is not a new issue. When Congress passed the law, they obviously knew that there would be delays, and that is the reason they went out as far as 17 years.

Now we are here to make it go to 24 years, and I just have difficulty in following what has happened to cause us to think that this legislation is so necessary at this moment in what it will contribute to the commonweal.

Mr. MOSSINGHOFF. Well, let me comment on that. I think, obviously, the situation now in terms of being able to move products into the marketplace is quite different from what it was 112 years ago.

My experience—and my particular area in private practice and in government practice is primarily the electronics area—is that it takes nothing like the 10 years or so that it takes to get a drug approved through FDA or to get an agricultural chemical approved by EPA to move an electronic invention or a mechanical invention.

Indeed, the clients that we had when I was in private practice looked at several criteria before they decided to spend the resources to apply for a patent. A principal criterion was whether the product was ready to go on the market.

So, with respect to electronic equipment and with respect to simple mechanical devices—vending machines, things of that nature—usually, they were on the market before the patent issued. Everyone has seen "pat pending." Every time you see the words "pat pending," that means that a product is on the market prior to the patent even being issued by the Patent and Trademark Office.

I think a clear, demonstrable exception to the general rule that inventions are ready to be exploited about the time that we issue the patent on them is in the areas highlighted in the bill, namely, agricultural chemicals and pesticides and drugs.

Senator METZENBAUM. Well, in the OTA study, did they not indicate that if it is assumed that in most instances the time between the conception of the invention and the granting of the patent is 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?

Mr. MOSSINGHOFF. Yes; I remember that conclusion.

Senator METZENBAUM. So there is some delay with respect to all products. When they had the catalytic converters for automobiles and when they had some of the other products that were made for automobiles, such as hydramatics and fluid drive and that type of thing, in many of those instances the patents were first applied for and then they continued experimenting before they ever started to market them in automobiles.

So, there may be a difference in degree and time, number of months or years, but the facts are that in almost every instance the time between filing of the patent application and the time of marketing—there is a delay while further exploration is made as to its marketability as well as its effectiveness. Is that not the case?

Mr. MOSSINGHOFF. I do not know what data the OTA used. Indeed, conceptually, it would be difficult to envision how a study might be done.

I do not think I could agree, Senator, that in almost every case the patent issues before the product is marketed, because it seems to me that almost every product you pick up has "patent pending" on it. That means that the product is on the market and the application is still pending in the Patent and Trademark Office.

Senator METZENBAUM. Yes.

Mr. MOSSINGHOFF. Now, one of the things we are trying to do is speed up that process.

Senator METZENBAUM. You thought the OTA report was worth quoting in some parts. It must be worth quoting in this part, would you not think?

How about this part here? I was rather impressed with this language, which I think may have either been just before or just after the language you quoted:

> 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 insure 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.

Now, that is pretty strong language coming from a Government agency, and certainly does not support the position of the Commissioner of Patents here before this committee this morning.

Mr. MOSSINGHOFF. I do not believe that patent term extension will guarantee that there will be breakthroughs. I do not in any way have that view. I think that there is a demonstrable period of time that these particular drugs and agricultural chemicals are delayed beyond what most other inventions are.

I agree with you that you can find examples on either side.

Senator METZENBAUM. Is there not something you can do about that from an operating standpoint? Is it not possible for you to expedite the process?

Mr. MOSSINGHOFF. Well, to expedite the patent examining process, from my point of view, would merely exacerbate the problem for the drug industry. That would merely mean that the patent would issue sooner and they would lose more of their life.

On the issue of whether the FDA process could be expedited, I do not pretend to be an expert in that field at all, but I believe the consensus is that they might be able to wring out 1 year, perhaps, of the 10-year period of time, but certainly no more than that. And this administration is not recommending that we in any way cut back on the amount of scrutiny that is given a new drug by FDA, or the amount of scrutiny given a new chemical by the Environmental Protection Agency.

Senator METZENBAUM. I just have one more question. You made a statement that the patent system has made this country what it is. Now, I have no fault to find with the patent system, as such; I respect it and support it.

But I have a little difficulty in accepting the breadth of that statement because I thought that the free enterprise system made the country what it is. I thought the right of people to compete freely made the country what it is, and I did not know that the right of some people to be protected with their innovations or their inventions or their research really made this country what it is.

It was sort of a novel approach that I am wondering if you just jumped into since you became the Commissioner of Patents and if you really do not think it was the right of people to compete freely, subject to the protection of the patent laws, that has made our country what it is.

Mr. MOSSINGHOFF. Well, Senator, I agree with you on the free enterprise system and I think that the patent system is an indispensable part of the free enterprise system.

Senator METZENBAUM. OK, I will buy that.

Mr. MOSSINGHOFF. It is the key that makes the innovative part of the free enterprise system work. People are given the right freely to choose to do research and development and to invest their time and energy and creativity in research and development, precisely because they can then enter the free enterprise system and reap a reward.

It happens all too seldom that they get the reward. There are an awful lot of people who invest that time and energy and do not quite make it. But I really believe the patent system is indispensable to the free enterprise system.

Senator METZENBAUM. I am not arguing whether it is indispensable. I think it is an integral part of it. I am not prepared to abrogate it, nor do I suggest in any way terminating it. I do think that it is not quite the factor that you would make it to be in having made our country as great as it is.

Senator MATHIAS. Thank you, Senator Metzenbaum.

Let me violate the first rule of courtroom procedure and ask a question that I do not know the answer to. For what purpose did Orestes Cleveland arise and deliver his eloquent remarks?

Senator METZENBAUM. Well, my dad was there, but I was not. [Laughter.]

Senator MATHIAS. I thought you remembered it well. [Laughter.]

Senator METZENBAUM. But when he stood up, I thought he delivered his remarks very well. He was a very distinguished fellow, and more than that I cannot tell you.

Senator MATHIAS. I suspect he was complaining that the patent term was being abridged by bureaucratic procedures—I do not know that.

Senator METZENBAUM. Well, what we will do is I will get the Congressional Globe, 2856, April 20, 1870, and check it out, and also find out what his attire was on that day because I think that is relevant as well.

Senator MATHIAS. I do not know, but I can just conclude from the tone of his remarks that he would have supported this bill.

Senator METZENBAUM. No, I do not think so. [Laughter.]

Oh, no.

Senator MATHIAS. Senator DeConcini?

Senator METZENBAUM. He would be coming up from the grave to oppose it. [Laughter.]

Senator DECONCINI. Mr. Secretary, we are faced with a question of whether or not there can be a real distinction with pharmaceutical-related R&D and other electronic or mechanical innovation.

Do you know of any medicines or drugs that are marketed patent pending? Does that ever occur, or has that ever occurred, to your knowledge?

Mr. MOSSINGHOFF. I believe it has, Senator, but I have no specific answer in mind.

Senator DECONCINI. It is not a common thing, is it?

Mr. MOSSINGHOFF. No, it is not.

Senator DECONCINI. And it is common to have other innovations and inventions that have filed for patent to be marketed patent pending?

Mr. MOSSINGHOFF. That is right. I believe that what I might provide for the record, and I reviewed it preparing for this hearing, is that of all the drugs, instead of trying to create a sample—I think samples tend to be chosen by whatever side of the argument you are on—but taking all the so-called new drug application approvals in 1980 and 1981, I think all of those suffered some degradation of their patent term.

Indeed, the average life of those drugs—and that is a 2-year sample and you could take any other years—the average patent time left after they received their approval was something like 7 years.

That seems to me to be a fair approach; instead of taking a sample, because I think either side can choose their sample, taking all the drugs in any period of time and see what happens.

Senator DECONCINI. I think that information would be helpful to us.

Also, if I understand the chairman's question, you are going to provide some analysis of what the alternatives are administratively within the Patent Office to address the patent restoration issue, is that correct?

Mr. MOSSINGHOFF. Yes, Senator.

Senator DECONCINI. I think that would be very helpful to us, also.

Mr. MOSSINGHOFF. I would want to make sure that our Solicitor and the General Counsel of the Department of Commerce took a hard a look at what we could do legally.

Senator DECONCINI. Under the bill, S. 1306, there is a cap of 7 years on the length of time a patent can be restored. Where did the 7 years come from? We realize testimony will show average-lost patent life for medicines is upward of 10 years in 1981.

But why 7 years' restored patent life? Why not 5, why not 8? Do you know how this came about?

Mr. MOSSINGHOFF. It was obviously an arbitrary decision. I think that it is based on the fact that at least for the 2 years I have looked at, the average patent term has been reduced by 10 years.

I think there is a general feeling—it is certainly my personal feeling—that not all of that 10 years should be returned. As Senator Metzenbaum said, "There is obviously some testing that would be done whether there was a Food and Drug Administration or not."

Senator DECONCINI. And that is true with other applications, obviously. Do you have any average time of what it does take for a patent to be issued?

Mr. MOSSINGHOFF. For a patent to be issued, it takes now about 28 months.

Senator DECONCINI. Twenty-eight months.

Mr. MOSSINGHOFF. And we are determined to get that down to about 18 months, and we are well on our way to achieving that.

Senator DECONCINI. And how long has it been historically? Do you know what the longest period of time has been?

Mr. MOSSINGHOFF. The longest period, I believe, was around 4 years.

Senator DECONCINI. And that is for nonmedicines?

Mr. MOSSINGHOFF. That is the average time of pendency.

Senator DECONCINI. So that includes medicines?

Mr. MOSSINGHOFF. It would include those in the mix.

Senator DECONCINI. And the 28 months now would also include the 10 years that was the average in 1981 for medicine?

Mr. MOSSINGHOFF. Well, this is the time it is pending in the Patent and Trademark Office.

Senator DECONCINI. Yes.

Mr. MOSSINGHOFF. The 10 years is——

Senator DECONCINI. That is separate because it is from the FDA?

Mr. MOSSINGHOFF. The FDA people.

Senator DECONCINI. So you do not count the FDA period of time of approval in your patent approval time?

Mr. MOSSINGHOFF. No, we do not.

Senator DECONCINI. So your average 28-month period is just talking about what it takes to file a patent and get it approved?

Mr. MOSSINGHOFF. To file a patent application and for us to examine it and go to a final decision.

Senator DECONCINI. So Senator Metzenbaum is correct, then, that any invention takes a period of approval time, and certainly the people that enacted patent legislation were aware of the existence of approval requirements. I do not think anybody will doubt that.

Do you know of any consideration given at any time to a longer patent life for medical inventions? Was there ever any consideration given to that, to your knowledge?

Mr. MOSSINGHOFF. In terms of the 17 years?

Senator DECONCINI. Yes, a longer patent life because medicines may take longer to test.

Mr. MOSSINGHOFF. No, I do not believe so. The 17 years was designed way back when there was a general period of apprenticeship. Now, we are talking about colonial times. The general period of apprenticeship was 7 years, and so the first Congress decided that the patent would run for two periods of apprenticeship and be renewable for a third. So it was 14 years and renewable for another 7.

When they finally came to center in on a specific number, as I am told, the House opted for 14 years and the Senate opted for 21 years. And as sometimes happens on Capitol Hill, they compromised and came out with 17.

Senator DECONCINI. Going back to the 7-year cap, you do not feel adamant as to how many years it should be. Your testimony, from what I gather, is based on the equity argument that some relief should be given and what it is is up to us to decide.

Mr. MOSSINGHOFF. That is right. There should be a fair return, but I could not make the case for 7 years over 8 years over 6 years.

Senator DECONCINI. Thank you very much, Mr. Secretary. Thank you, Mr. Chairman.

Senator MATHIAS. Thank you.

Senator Grassley, do you have questions?

Senator GRASSLEY. Yes. Thank you, Mr. Chairman.

Last Congress I raised an issue about a patent holder, who happens to also be a constituent of mine, who was subject to a false test by a Federal agency. She was denied a license a long time ago and 16 years' use of her patent was lost as a result of that denial.

Now, since that time a Federal district court has issued an injunction against the Agency, the Department of Agriculture, stating that their conduct constituted arbitrary and capricious action and an abuse of discretion.

Can you tell me if this bill covers that situation, and if not, could you suggest legislative language which would remedy it.

Mr. MOSSINGHOFF. I do recall the general case but I do not know whether the product was kept off the market because of the acts that are specifically mentioned in S. 1306.

Last year when the earlier bill of last Congress was pending, S. 255, it referred specifically to the five acts that are mentioned in this bill.

It also talked about any other regulatory holdback in premarket clearance, and the administration testified against that. We thought that a good case had been made in these specific cases where there is a clear problem that needs to be solved. But we did not recommend that the coverage be extended to all forms of regulation.

It was simply viewed by us that, one, the case had not been made in other areas. Two, it was simply too broad. We did not know if we were talking about OSHA or the National Environmental Policy Act or the hundreds of other regulations.

So, unless the product was kept off the market because of one of these acts, I do not believe this legislation would apply to it.

Senator GRASSLEY. Thank you. Does this case merit coverage?

Mr. MOSSINGHOFF. I honestly do not know enough to answer that question, Senator.

Senator GRASSLEY. OK. I think what we need, though, is to find that out the answer to that question because this is one example of a person not having use of their patent because of regulatory delay. There was a restriction in interstate commerce so that what sales could be made had to be made in intrastate commerce.

Today, with the way interstate commerce has evolved, that is very difficult. Surely, there was a chilling effect by a Government agency on that product and the person was hurt.

It seems to me like it is an example of the type of problem that the bill hopes to solve. So what I would ask you to do, then, is see if we can answer that question.

If that question is answered in the positive, then I would hope to have some language worked out to overcome that problem because, you know, this is just one example of financial injury suffered at the hands of a regulatory agency. A court has gone so far as to say in a very clear way that this loss was because of arbitrary and capricious action by an agency.

It would seem to me like that is exactly what we are trying to get at here, or one of the things we are trying to get at.

Mr. MOSSINGHOFF. It is, indeed. Let me take a look at that and we will work with your staff, Senator, to get the facts. In general, each year several private relief bills are proposed which would extend the lives of patents because someone was not able to get something on the market.

We oppose those, generally. We think the patent system is kind of a fail-safe system itself; the people who enter it take the chance that for one reason or another, they may not be able to achieve the full 17 years.

We think the drug industry and the agricultural chemical industry are kind of a classic exception to that. In your case, though, it may warrant another exception, particularly if there was Federal action involved. So we will take a look at that.

Senator GRASSLEY. Well, let me speak just a little more generally. This could be just one example of this type of abuse, there have got to be other examples as well. As a result, it seems to me to be something we ought to address through a general statute, as opposed to just righting one wrong of one constituent, I would look at it in the larger context, as well.

Mr. MOSSINGHOFF. Fine.

Senator GRASSLEY. Thank you. Thank you, Mr. Chairman.

Senator MATHIAS. Thank you, Senator Grassley. Thank you very much, Mr. Secretary.

Mr. MOSSINGHOFF. Thank you, Mr. Chairman.

[The following material was subsequently received for the record:]

STATEMENT OF GERALD J. MOSSINGHOFF
ACTING DEPUTY SECRETARY OF COMMERCE

Mr. Chairman and Members of the Subcommittee:

I welcome this opportunity to testify on the subject of patent term extension, which would improve our patent system by providing 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 1983.

This legislation would expand section 155 of title 35 of the United States Code to provide for an extension of the patent term for patented products, or patented methods for using or producing products, that are subject to regulatory review pursuant to Federal statutes 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 regulatory review of the product had been successfully completed and that commercial marketing or use of the product was not prohibited.

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. Thereafter, if all requirements have been met, he would issue to the patent owner a certificate of extension.

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 or generic drug 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.
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 will 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.

During the last Congress, opponents of this type of legislation argued that the problem which such a bill would alleviate has not been demonstrated. They have pointed to high profit margins of industries which would benefit from this type of legislation and have concluded that, as a consequence, there is no problem. I would suggest that it would be clearly unfair to establish different patent terms depending on the potential economic success of a particular sector of technology. 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 have previously speculated that its enactment would not guarantee the expenditure of greater resources for research and development. Proponents of the bill, on the other hand, noted 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. As these incentives are diminished, so is the encouragement which the patent system might otherwise have provided.

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 necessary. 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.

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 has serious drawbacks. Delayed publication of the information supporting the patent could 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.

The Administration, therefore, strongly supports enactment of remedial legislation generally, and encourages passage of the Patent Term Restoration Act of 1983 in particular, as a fair remedy to correct the inequity of shortened effective patent terms caused by Federal premarket regulatory review procedures. To this end, I would be pleased to offer the assistance of the Department of Commerce in any fashion you may deem appropriate.

In closing I would stress that enactment of S. 1306 will not impose undue costs or burdens on the Patent and Trademark Office because the mechanics of applying for and receiving a restoration of the patent term are administratively simple.

RESPONSES TO QUESTIONS OF SENATORS MATHIAS AND DECONCINI

Chairman Mathias asked whether the legislative solution proposed by S. 1306 could instead be achieved administratively. The procedure outlined below could be instituted under the authority of 35 U.S.C. 6(a), after compliance with the full rulemaking requirements of the Administrative Procedure Act. At this time, however, the Administration has not considered whether such an alternative would be appropriate. Consequently, the following outline is presented strictly in reply to the Chairman's question.

* * * * *

A. The patent application is examined and processed in the normal manner until payment of the issue fee.

B. Along with the issue fee, the applicant could file a petition requesting deferral of the issuance of the patent until the Federal premarket regulatory review has been completed.

C. The petition would include:

(1) the date on which the Federal premarket regulatory review began, or is expected to begin, and its anticipated termination date, if known;

(2) authorization to open the complete application file to inspection by the general public;

(3) a request that the contents of the application be published;

(4) an agreement to notify the Patent and Trademark Office (PTO) within one month of the termination date of Federal premarket regulatory review and an agreement to file an equivalent disclaimer of the term of the patent if the one month notice is not provided;

(5) a fee which would cover the cost of processing the petition, of publishing the application, and costs incurred by the deferred publication of the patent; and

(6) an acknowledgment that the PTO may reopen prosecution of the application at any time during the deferral period, if issues of patentability should arise.

D. Upon receipt of such petition, the PTO would:

(1) notify the applicant that issuance of the patent was being deferred for a period not to exceed seven years;

(2) publish the contents of the application; and

(3) open the application to inspection by the general public.

E. After being notified by the applicant that the Federal premarket regulatory review had been completed, or after seven years from date of the notice of deferral mentioned in paragraph D(1), whichever is earlier, the PTO would issue the patent.

* * * * *

It should be noted that this procedure would delay issuance of all of the subject matter disclosed and claimed in the patent application, including that which may not be subject to Federal premarket regulatory review. The applicant could request that the Federally nonregulated subject matter be carved out and made the subject of a separate application. This application could then issue as a patent, leaving the Federally regulated subject matter pending in the original application. However, this action may threaten the patentability of the pending application because it could be rejected over the earlier issued patent on the ground of double patenting. In cases where the PTO has authority to require division of the subject matter in an application, (35 U.S.C. 121), the inventions to be divided into separate applications must be independent and distinct from each other. Such a requirement is usually made during the initial stage of examination of the application and does not expose the applicant to the threat of a double patenting rejection. By the time the application is ready for issue, the examination process would most likely have limited the subject matter to one patentable invention and consequently the invention subject to Federal premarket regulatory review would not patentably differ from other subject matter contained in the application. Division of that application by the applicant himself could, therefore, severely prejudice his rights in the later application. Because of these considerations, the limitations provided for in section 155(a)(2) of S. 1306 can not adequately be reflected in the administrative extension procedure.

In response to Senator DeConcini's question of whether medicines are ever marketed before having been patented, the following list is provided which shows all therapeutic new chemical entities approved by the Food and Drug Administration during 1980 and 1981, as well as their patent issue dates. During this two-year period only one therapeutic NCE received FDA approval before the relevant patent issued thereon.

EFFECTIVE PATENT LIFE FOR NEW DRUG APPROVALS
1980-1981

Product Brand Name	Generic Name	Manufacturer	FDA Date of NDA Approval	Patent Issue Date	Effective Patent Life (Years)
ASENDIN	amoxapine	Lederle	9-22-80	8-1-72	8.86
CALDEROL	calcifediol	Upjohn	8-5-80	9-3-74	11.08
CINOBAC	cinoxacin	Lilly	6-13-80	6-13-72	9.00
LUDIOMIL	maprotiline HCl	Ciba-Geigy	12-1-80	8-27-68	4.74
MECLAN	meclocycline	Ortho	5-30-80	5-16-61	0.00
MECLOMEN	meclofenamate Na	Warner/Lambert Park Davis	6-25-80	4-11-67	3.79
SISEPTIN	sisomicin SO_4	Schering	10-29-80	9-23-75	11.90
VANSIL	oxamniquine	Pfizer	7-23-80	6-28-74	10.93
VIROPTIC	trifluridine	Burroughs-Wellcome	4-10-80	8-17-65	2.35
YUTOPAR	ritodrine HCl	Merrell-National	8-24-80	11-12-68	5.22
ZOMAX	zomepirac Na	McNeil	10-28-80	8-14-73	9.79
BUPRENEX	buprenorphine	Norwich-Eaton	12-29-81	3-18-69	4.22
CAPOTEN	captropril	Squibb	4-6-81	8-8-78	14.34
CARAFATE	sucralfate	Marion	10-30-81	3-11-69	4.36
CLAFORAN	cefotaxime Na	Hoechst-Roussel	3-11-81	5-1-79	15.14
DESYREL	trazodone	Mead Johnson	12-24-81	4-30-68	3.48
EMCYT	estramustine	Roche	12-24-81	1-17-67	2.07
FANSIDER	sulfadoxine & pyrimethamine	Roche	10-28-81	5-3-66	1.51
ISOPTIN	verapamil	Knoll	8-12-81	7-19-66	1.93
LOPID	gemfibrozil	Warner/Lambert	12-21-81	7-4-72	7.53
MEZLIN	mezlocillin	Miles	9-21-81	8-10-76	11.88
MIDAMOR	amiloride HCl	Merck	10-5-81	4-11-67	2.52
MOXAM	moxalactam disodium	Lilly	10-6-81	2-6-79	14.34
NASALIDE	flunisolide	Syntex	9-24-81	3-24-64	0.00
NIZORAL	ketoconazole	Janssen	6-12-81	6-15-82	17.00
PAXIPAM	halazepam	Schering	9-24-81	2-25-69	4.42
PIPRACIL	piperacillin	Lederle	12-29-81	9-5-78	13.68
PROCARDIA	nifedipine	Pfizer	12-31-81	12-23-69	4.98
PROSTIN VR PEDIATRIC	alprostadil	Upjohn	10-16-81	12-18-62	0.00
PROVENTIL (VENTONN)	albuterol	Schering (Glaxo)	5-1-81	2-22-72	7.81
RESTORIL	temazepam	Sandoz	2-27-81	1-3-67	2.85

Product Brand Name	Generic Name	Manufacturer	FDA Date of NDA Approval	Patent Issue Date	Effective Patent Life (Years)
TENATHAN	bethanidine sulfate	Robins	5-29-81	2-2-65	0.68
TENORMIN	atenolol	Stuart-ICI	8-19-81	5-16-72	7.74
XANAX	alprazolam	Upjohn	10-16-81	10-19-76	12.01

AVERAGE EFFECTIVE PATENT LIFE: 1980 - 7.06 years
1981 - 6.72 years

NOTES:

(1) Also approved in 1980 were trimethoprim and bacampicillin which are not considered to be NCEs. The former had been previously marketed and the latter is a chemical esther of ampicillin.

(2) Also approved in 1981 were four diagnostics (saralasin, secretin, isosulfan blue, cerulatide) which are not considered to be therapeutic NCEs.

RESPONSES TO QUESTIONS
OF SENATORS MATHIAS AND GRASSLEY

United States Senate

COMMITTEE ON THE JUDICIARY
WASHINGTON, D.C. 20510

June 20, 1983

The Honorable Gerald J. Mossinghoff
The Commissioner of Patents and Trademarks
Patent and Trademark Office
Washington, D.C. 20231

Dear Mr. Commissioner:

We are writing to ask for your views on a matter that has come to our attention in connection with the patent term restoration legislation now pending in the Judiciary Committee.

The situation in question involves an Ultra Vires act in which a federal agency performed and published results from a false test on the product of a patentholder who was seeking a marketing license from that agency. The test was used to deny the patentholder's license in 1966. The patent on the product was issued in 1968. In 1982, a Federal District Court for the District of Columbia granted an injunction against the agency, halting continued publication of the false test results. Thus the patentholder was involved in litigation for 15 years while the patent was running and the product could not be marketed.

We would like to know your thoughts on whether the patent term restoration bill, S. 1306, is or should be applicable to this type of situation (assuming the product is one that falls within the scope of the bill), when a patentholder is sidetracked from the normal testing process into prolonged litigation and is eventually vindicated. We would also be interested to know if there is any precedent for a court in its own right awarding a patent extension for damages to a patentholder such as those we have described.

With best wishes,

Sincerely,

Chuck Grassley
Charles E. Grassley
United States Senator

Charles McC. Mathias, Jr.
United States Senator

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

JUL 15 1983

Honorable Charles McC. Mathias, Jr.
Chairman, Subcommittee on Patents,
Copyrights and Trademarks
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Honorable Charles E. Grassley
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman and Senator Grassley:

This responds to your letter of June 20, 1983, in which you asked for my views on the possible applicability of S. 1306 to a fact situation involving a dispute between a Federal agency and a patent holder. I understand that you are referring to a controversy involving U.S. patent No. 3,376,198, owned by Impro Products, Inc.

The product produced by the patented method for which the patent holder seeks a license from USDA appears to be one to which S. 1306 would apply if its conditions are satisfied. To obtain an extension of the patent term under S. 1306, the patent must not have expired (Section 155(a)(1)(C)) and the regulatory review must have resulted in a determination that commercial marketing of the product is not prohibited (Sections 155(a)(1)(B) and 155(b)(1)(D)). If these conditions are satisfied, the patent holder would be entitled to an extension of the patent term.

It is not clear when a license to market the product produced by the method disclosed in the Impro patent will be obtained. However, any period of patent extension would be relatively minimal at best. It would be measured from the date of enactment of S. 1306 to the date on which the license was granted, provided the license is granted prior to April 1, 1985, the date on which the patent in question expires.

As a practical matter, therefore, S. 1306 will offer little or no relief to the holders of the Impro patent. Nevertheless, I believe the Patent Term Restoration Act should remain limited in its application to provide relief for delay caused by the usual Federal premarket regulatory review procedures. Circumstances such as those set forth in your letter are relatively unusual and, if addressed at all by Congress, should be the subject of a private relief bill.

In that regard, we have begun to inquire into the circumstances surrounding the Impro patent and have, thus far, found the situation to be less than clear. For example, while the District Court for the District of Columbia did enjoin the Department of Agriculture from distributing an article containing certain test results, the court did so because of inaccurate statements in the article regarding the test procedures and references that the patent holder had agreed with the test methodology. The validity of the tests themselves was not determined, however, since the Court held in an earlier ruling that the Department of Agriculture's statutory authority was sufficiently broad to foreclose judicial review of the methodology utilized in conducting such tests. Moreover, the patent holder is involved in additional litigation, still pending in the Eighth Circuit, which is relevant to this situation. Until the facts are clarified, I would be unable to comment on the merits of any private relief bill.

Finally, I am not aware of any judicial precedent awarding extension of a patent term for damages to a patent holder.

Sincerely,

Gerald J. Mossinghoff
Commissioner of Patents and Trademarks

Senator MATHIAS. Our next witness is Mr. Lewis A. Engman, president of the Pharmaceutical Manufacturers Association.

Mr. Engman, I will remind you of the 5-minute rule, and let me say to you and to all of the witnesses who will follow you that your full statements will be included in the record, even though you are not able to deliver it all orally.

STATEMENT OF LEWIS A. ENGMAN, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION, WASHINGTON, D.C.

Mr. ENGMAN. Thank you very much, Mr. Chairman. I am president of the Pharmaceutical Manufacturers Association, which represents the 140 companies that are responsible for nearly all of the new prescription medicines discovered and developed in this country.

I want to thank you for this opportunity to offer our strong support for S. 1306, legislation which is badly needed to correct the problem of patent-life loss for products that are subject to a lengthy governmental premarket clearance, and a bill which, if enacted, will contribute significantly to improving medical care in our country.

The cause of patent life loss in the pharmaceutical industry is simply explained. When a firm discovers a promising new drug compound, it must patent it immediately or risk losing the new technology to a competitor.

Generally, a new product patent is issued within 2 or 3 years of filing, and the innovator's 17 years of protection begins immediately to expire. In this respect, the pharmaceutical innovator is no different from the innovator in any other industry.

What distinguishes the pharmaceutical innovator from others is that, generally, when he gets his patent, he has no product to market. Indeed, he is likely to be some 10 years away from having a product to market—10 years which he must spend satisfying safety and efficacy requirements set down by the Food and Drug Administration.

Although Congress never intended it, the time consumed in meeting FDA requirements is, in effect, subtracted from patent life, so that the pharmaceutical innovators' new products typically enter the market with less than half the 17 years of patent protection provided by statute, and with less than half the related investment incentives provided to developers of new floor waxes or new can openers.

It seems neither fair nor wise that while innovators in most areas are receiving nearly 17 years of patent protection on their new products, the average remaining patent life on new medicines approved by FDA in 1981 was 6.8 years.

What are the adverse effects of reduced patent life? There are several. To begin with, loss of patent life discourages investment in research on new medicines. It costs today an average of over $80 million to bring a new prescription drug to market. If the innovator firm is to succeed, it must recover most of those research and development costs before imitators—who do not have research costs to amortize—enter the market offering the same product for

sale. Reduce patent life and you decrease the innovator's willingness to invest.

What we are seeing is a perversion of the patent system's purpose. As advocated from the beginning by Thomas Jefferson, our patent system was designed to promote innovation. It was never intended to dictate economic resource allocation by promoting one form of innovation more or less than another.

Yet, through the regulatory accident by which drug approval time is subtracted from drug patent lives, this is what has occurred. And the tragic part of it is that American consumers, and particularly the elderly, are the real losers in all of this.

Discouraging drug research postpones or denies the consumer's access to new medicines that might spare him discomfort or save his life. It deprives him of the savings new medicines make possible by rendering unnecessary more costly forms of treatment, such as hospitalization and surgery. It obliges him to forgo the lower price benefits of added competition that occurs when innovation is rapid and the manufacturers of products which compete with the newer innovations must cut prices in order to stay in the marketplace.

The issue of patent term restoration is especially important to us today because of the major role pharmaceuticals play in health care. Medicines constitute the most cost-effective form of medical care. They often reduce or eliminate the need for more expensive forms of treatment.

Let me conclude with this brief summary. One of society's most important and beneficial economic activities is today being retarded by regulatory accident. The public's loss in foregone therapies and unrealized savings has only begun to be felt.

Because developmental lag times are so long, there will be future losses which it is already too late to avert. But the loss to future generations can be minimized if Congress acts now.

The Patent Term Restoration Act will save lives and will reduce suffering. It will save money by hastening the invention of new medicines that drive down the prices of old medicines and obviate the need for more expensive forms of intervention, such as surgery or hospitalization.

It will increase labor productivity by reducing absenteeism, and it will help insure the international competitiveness of a vital American high-technology industry. Already, the U.S. share of worldwide pharmaceutical research has fallen from 60 percent in 1964 to 25 percent today.

In spite of all this, the problem remains unsolved. As long as it does, we Americans will be paying for it with our money and our health.

I want to thank you, Mr. Chairman. I understand my full statement will be included in the record, and I would be more than happy to answer any questions you might have.

Senator MATHIAS. Well, Mr. Engman, I have really just one question, and that is the effect of granting full patent life on the consumer. What is your best judgment on the price of drugs in the drugstore or in the supermarket where the consumer buys them, if we pass this bill?

There are two aspects to the question and let me just round it out so you can give one comprehensive answer. One is, of course,

what happens during the life of the patent; the other, after the patent has expired and the formula becomes available to the generic industry.

Mr. ENGMAN. Thank you, Mr. Chairman. Let me take a cut at that question in this fashion. First of all, let us consider all of the medicines which are currently on the market. Not one of those medicines would be affected by this legislation.

We believe, however, as I will explain in a moment, that the effect of this legislation will be a downward pressure on the price of medicines currently available to people, because of competition from new drugs.

Now, with respect to medicines which are not yet on the market and which would be covered by this legislation, I think we have to recognize the impact of two types of activities which produce competition with respect to prices.

The first is the pressure on prices which is provided by other products on the market, including generic products when the product goes off patent, and this obviously produces downward pressure on prices. Other brand name products on the market also produce that downward pressure on price.

But the second and strongest impact of this bill is the downward pressure on prices which is produced by therapeutic innovation, by new medicines, by new therapies coming on to the marketplace. In this instance, you are restoring the incentives so that it is not any longer only half as profitable to engage in research for new medicines as it is for other products. By restoring the incentives to develop new medicines and helping to produce new medicines faster, that downward pressure on prices provided by therapeutic competition from new products will be increased, and the effect has to be to benefit the consumer.

First of all, the consumer has all of the medicines available to him today which are not affected in one iota by this bill. Second, he benefits from the encouragement of new therapies, of new medicines coming on the market which provide cures not available today. But in addition to that, he will derive a benefit from the downward pressure that such new medicines will exert on the prices of other medicines on the market.

Senator MATHIAS. Now, you say it would have no effect on anything that is on the market today.

Mr. ENGMAN. Yes, except that over time there will be a downward pressure on present product prices exerted by new medicines coming on the market, just as we saw when the first hand calculators came out on the market. They were expensive and were carried by only a limited number of stores. But, with innovation, and new products continually are coming on the market. And today, you can buy such a calculator for $9 or less at the corner drug store.

Senator MATHIAS. But the reason it would not have an impact on current inventories is obviously, you cannot go back; it is not a retroactive bill.

Mr. ENGMAN. There is no retroactivity in this bill, Senator.

Senator MATHIAS. So that is the basis on which you make that statement?

Mr. ENGMAN. That is correct. But, in fact, as I indicated, it would be expected that the pressure would be downward on these prices.

Senator MATHIAS. Well, if alternatives did appear on the market, then current inventories would have to be dispersed and the tendency is to move them at lower prices. Is that the reasoning under which you foresee, then, that there will be downward pressure?

Mr. ENGMAN. That is right. If a new product is on the market which may have some better qualities, one finds it easier to buy the older product at a lower price.

Senator MATHIAS. Senator Metzenbaum?

Senator METZENBAUM. It is nice to see you again, Mr. Engman.

Mr. ENGMAN. It is always good to see you, Senator.

Senator METZENBAUM. I was out of the room, and I apologize, but I had to go to another committee. But I am told that you indicated that prices would drop as a result of this bill.

Now, I have not been here in the U.S. Senate as long as some people, but I have heard more arguments made for more bills about prices dropping and the selflessness of the proponents than probably any other argument that is made. If we have a tax bill, if we have an EPA bill, if we have a bill having to do with any one of a host of subjects—a water resources bill—everything is going to cause prices to drop.

But I really thought that the thrust of this measure was to make it possible for the pharmaceutical industry to obtain more profits so that they could use those profits for more research and development.

Now, is it for more profits or is it so that prices can drop, and what assurances are there that the prices would drop?

Mr. ENGMAN. Well, let me say this, Senator. The purpose of this bill is to equalize the incentives for doing research to find new medicines so that they will be equal, for example, with the incentives for finding new floor waxes and other household products.

That is the purpose of this bill. Because the effect over time is that the real patent life for medical products has declined for the reasons that have been indicated here.

Now, as you know from the time we worked together when I was at the Federal Trade Commission, I take a back seat to no one in my support for free and vigorous competition working in a free market economy, and which requires a strong program of antitrust enforcement to maintain that competition.

I suggest to you, Senator, that this bill will increase competition with respect to innovation in the pharmaceutical industry. This is a procompetition bill; it is a proconsumer bill.

By equalizing the incentives to invest in research for new medicines, it will tend to create more of that research, which will in turn tend to create more new products and more new cures for diseases for which cures do not exist today.

And those cures coming out on the market—in part because of the equalization of treatment under the patent law which would be produced by this bill—will by their very nature create competition in the marketplace, which will in turn tend to drive prices down for existing products as well as those new products.

Senator METZENBAUM. Well, if your argument were to be accepted, which I do not do, but if it were——

Mr. ENGMAN. I will just keep on trying to persuade you.

Senator METZENBAUM. You keep in there slugging.

Should we not increase the patent period to 40 years, because if you get that much more competition and that many more new drugs by going to 24 years, then if we go to 40 years, are we not going to improve our position that much more? At what point do we stop?

I guess the thrust of my question is, there was nothing magic about 17 years. I do not know how the 17-year figure came in, but we have accepted it for a number of years. Now, maybe it should have been 12 at the inception, maybe it should have been 10, maybe it should have been 25. But it is 17.

Now, you are here asking to go to 24, and the argument is that it will increase competition, which I have great difficulty in following, and it will bring down prices, which I do not believe.

But the basic thrust of my question is, Why should we extend it 7 years instead of 17? Why do we not extend it another 17?

Mr. ENGMAN. Let me say, first of all, Senator, that I want to correct just one matter, and that is that this bill would not extend the period to 24 years. It would only exte out in Rockville suddenly was accelerated, it would only get a 2-year restoration of its patent life. So it is not accurate, I think, to speak of a 24-year period.

I also do not know why Congress decided on 17 years. But it has been felt important from the very beginning of this country, as stated by Thomas Jefferson, "That there ought to be some period of exclusivity as an incentive for research and development and for innovation."

We are not asking for anything that other people do not have. We definitely would not want to eliminate Government testing for safety and efficacy. But what has happened is that through an accident of the regulatory review process having become quite long, the patent incentive for developing new medicines is roughly half that for developing anything else in this country. That is the problem which this bill attempts to address.

It is particularly amazing, in my judgment anyway, that this problem confronts the one set of products in the health care field, medicines, which are the most cost effective. It is medicines which are able to reduce our reliance upon more costly forms of health care, such as hospitalization or surgery.

It is exactly this kind of disincentive which we ought to be trying to correct, if we are looking at it from a public policy view—not giving the pharmaceutical or the agricultural chemical industry anything more, but putting them on an equal footing under what the Congress decided would be an appropriate patent incentive of 17 years.

Senator METZENBAUM. How would you respond to a former official of Searle Corp. who admitted that "the industry has to take a

good deal of the rap for drug lag because many drug applications are incompetent, poorly done, and do not prove anything?"

Now, if the drug companies are causing the delay, why should the Congress enact legislation to compensate them for their own incompetence?

Mr. ENGMAN. Congress should not, and I do not think that this legislation, Senator, would compensate anyone for that kind of delay.

First of all, let me say that I do not personally know the gentleman in question whom you quote. I take it he was not associated with the FDA, but was speaking his personal opinion from experience that he must have had in the private sector.

There may very well be instances—I would be surprised if there were not—where there has been some problem in a particular company's submission. But the incentives built into this bill, as it has been crafted, have been devised so that the company will have no incentive for delay.

If we are looking at a situation today where the average length of patent life left when a new medicine is approved for marketing is 7 years or less, and the maximum cap that a company can get under this bill is 7 years, that in itself is going to argue against the company taking further time.

In addition, any company that knows its business is going to be concerned about what its competitors are doing. So we believe that the incentives in this bill, as the Commissioner of Patents indicated in his statement earlier this morning, are designed to discourage delay because that cap would not fully restore the patent time lost within the approval process.

Senator METZENBAUM. Well, you say you do not know who the gentleman is. They have got a three-column spread about him in the Wall Street Journal.

Mr. ENGMAN. I read his comments.

Senator METZENBAUM. And I guess you must know his name is W. Scott Smith.

Mr. ENGMAN. I read his comment and I think there is probably some merit in that instance, as I indicated. But this bill will not aggravate that problem; it will help correct it.

Senator METZENBAUM. In fact, he goes on to say that many drugs do not need 7 or 8 years and tens of millions of dollars to pass regulatory muster, as some companies claim.

Now, I do not know anything about the man. I can only assume that if the Wall Street Journal gave him three columns and a picture, he must be a reasonably responsible spokesperson. It says that he left a cushy job at W. D. Searle & Co., and that would indicate——

Senator MATHIAS. Before or after he made the statement? [Laughter.]

Mr. ENGMAN. I have to say, Senator, I never knew you were such an advocate of the Wall Street Journal.

Senator METZENBAUM. Well, it does a good job of reporting just the facts, just the facts. [Laughter.]

Mr. ENGMAN. I can remember a couple of times when you and I were both complaining about some of their editorials.

Senator METZENBAUM. Well, when they are right, they are right. When they are wrong, it is their problem. [Laughter.]

Mr. ENGMAN. That is my philosophy, too.

Senator METZENBAUM. You are seeking additional patent protection starting from the first major health test. Would not all responsible companies perform health tests before marketing a drug even if the FDA did not exist?

Actually, is it not in the company's self-interest to make sure drugs are safe before marketing in order to avoid huge product liability suits? So is not this question of checking into the reliability of the drug a normal kind of time delay that is and must be anticipated by the drug companies?

Mr. ENGMAN. Of course, companies would do that kind of investigatory work, and I do not think there is any question about that. In fact, this bill is essentially a compromise, Senator, because in the preclinical testing period phase, which is not covered by this bill and which generally takes between 3 and 4 years, there would be no patent restoration at all.

So the period to which this bill would apply begins well into the time that a company would be testing its drugs.

Senator METZENBAUM. Now, we all understand that a person deciding to use a particular drug normally does so because a physician tells him or her to do so, not the patient. Now, is it not a fact that the industry spends a great deal of money trying to instill name brand loyalty in doctors? We know that to be the fact, of course.

Could you tell us what percentage of a product's development costs goes to advertising and marketing in the industry?

Mr. ENGMAN. I do not have that number on the top of my head, but I would be happy to provide it to you, Senator.

Senator METZENBAUM. Would you say it is extremely high? Compared to 100 percent, would you say it is 40 percent?

Mr. ENGMAN. Well, Senator, I think we have to define what we mean by the term "marketing." There is an educational process which must go on with respect to laying out what the qualities of a drug are, what the side effects of a drug are, and with what other drug it can or should not be used. There is a great deal of that activity which must go on.

I would not be able, without defining each of those segments, to give you a very precise answer, but we would be happy to find out what information we have from our companies and to provide you with that for the record.

Senator METZENBAUM. Well, whether or not we have the specific—and we do hope you will provide it for the record—the fact is you would agree that the percentage of a product's development cost that goes toward advertising and marketing is very——

Mr. ENGMAN. It is not a development cost. That is a separate cost. That is not part of the R&D process.

Senator METZENBAUM. I understand that, I understand that. But the advertising and marketing costs do represent, probably in most instances, a far greater proportion of the total cost factor than does the R&D factor.

Mr. ENGMAN. Well, again, Senator, I want to stress that that depends on what one includes within the advertising and the promo-

tional costs, because there is a very large element of basic education which is involved.

Senator METZENBAUM. I would agree, but the fact is that the education——

Mr. ENGMAN. And if we include the educational side, then that number would be higher than it would be otherwise; that is right.

Senator METZENBAUM. And it would be very substantially higher than the R&D costs?

Mr. ENGMAN. I am not prepared to say that this morning, but I would be happy to look at that information for you.

Senator METZENBAUM. Well, do you mean to say you have no idea as to what the relative costs are in bringing a product to market in your industry and you do not know the percentage that is spent on R&D as compared to the amount that is spent for education and marketing?

Whether you know the specific number, I am only asking you whether or not it is not a fact that it is substantially in excess of the total R&D costs.

Mr. ENGMAN. I do not believe that that can be supported in that sense. It costs well in excess of $80 million for research and development today to bring a new drug to market. I think it is important that we go through the reasons for these other costs, which are separate from research and development. If you are talking about detailing costs, the costs of company representatives going to the doctors' offices——

Senator METZENBAUM. Yes, I am.

Mr. ENGMAN [continuing]. If you are talking about educational costs——

Senator METZENBAUM. Yes, I am.

Mr. ENGMAN [continuing]. If you are talking about some of the public service advertising that some of the companies have now begun to undertake in order to try to provide more information for the ultimate consumer in terms of the kinds of medicines he is taking, those are several factors and I frankly confess that I do not know what that total factor is. I would not want to say something to you that I was not certain about.

Senator METZENBAUM. As a consequence of their very effective marketing strategy, does it not result in very high market shares for name-brand drugs even after the patent has expired?

It is my understanding that OTA figures show 90 percent as far as drugstore sales and 80 percent as far as hospitals.

Mr. ENGMAN. Well, my understanding of those figures, Senator, is that they were based upon a now somewhat dated study by Prof. Meir Statman.

The numbers which he came up with I say are dated because they were gathered at a time before there was any significant impact from the substitution laws which were adopted by the States.

I might just add parenthetically that even in spite of those numbers, Professor Statman made a determination that patent restoration for medicines was still a good idea.

Two years ago in the House, Leonard Schifrin, who is another economist and who actually had been brought down to testify against this bill, when questioned about this issue indicated that he

disagreed with Mr. Statman's conclusions because of the dated nature of the figures and, in fact, thought that the brand loyalty situation was rapidly falling off now with the advent of substitution laws.

Senator METZENBAUM. This Statman study was made in 1980 and it reported that 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.

That is rather impressive, would you not say? It is my understanding that the article that Mr. Statman published was in that bastian of liberalism, the American Enterprise Institute for Public Policy Research's publication in 1980. So I do not think his figures can be disregarded, nor his reliability as an authoritative researcher.

Mr. ENGMAN. Senator, let me read to you from a copy I have of the same AEI publication. This is a statement by Leonard Schifrin, and he is criticizing the Statman report.

He states, "I argue that Statman's policy recommendation of a longer patent life or some alternative is plausible because he is incorrect in his generalization that significant post-patent market erosion does not occur." [1]

This goes on for many pages, and all I can say is that the date of criticism of Statman, in my understanding and according to the copy I have here—and the full copy is in my office—is from a 1979 conference. I can only assume that the Statman material came sooner.

But in any event, if you analyze the Statman numbers, they are based upon drugs that were on the market before the real impact of the substitution laws.

Senator METZENBAUM. Mr. Chairman, I would like to make an unusual request. I do have some more questions. I am told that the Labor and Human Resources Committee is about to act in connection with an amendment that I think the Chair actively would support me on. If I do not get there to offer it, I will not have an opportunity.

Could I resume my questioning, meanwhile going forward with other witnesses, and I will be back in 10 or 15 minutes?

Senator MATHIAS. We will certainly try to accommodate the Senator from Ohio.

Senator METZENBAUM. Thank you.

Senator MATHIAS. Let me ask Mr. Engman if it is convenient for him to remain.

Mr. ENGMAN. I am always happy to wait for Senator Metzenbaum. My only question is how long?

Senator METZENBAUM. Just 10 or 15 minutes.

Mr. ENGMAN. Fine.

Senator METZENBAUM. Thank you.

---

[1] Robert B. Helms, ed., *Drugs and Health.* Economic Issues and Policy Objectives. (Proceedings of a conference held on November 15–16, 1979.) Washington: American Enterprise Institute for Public Policy Research, 1981, p. 166.

Senator MATHIAS. Mr. Engman, we will ask you to step down, please.

[The prepared statement of Mr. Engman follows:]

STATEMENT OF

LEWIS A. ENGMAN

PRESIDENT

PHARMACEUTICAL MANUFACTURERS ASSOCIATION

My name is Lewis A. Engman. I am President of the Pharmaceutical Manufacturers Association which represents the 140 companies that are responsible for nearly all of the new prescription medicines discovered and developed in this country.

I thank you for this opportunity to offer our industry's strong support for S 1306 -- legislation which is badly needed to correct the problem of patent life loss for products that are subject to lengthy, governmental pre-market clearance, and a bill which, if enacted, will contribute significantly to improving medical care in our country.

The Problem

The cause of patent life loss in the industry I represent is simply explained. When a pharmaceutical firm discovers a promising new drug compound, it must patent it immediately or risk losing the new technology to a competitor. Generally, a new product patent is issued within two or three years of filing, and the innovator's 17 years of protection begins immediately to expire. In this respect the pharmaceutical innovator is no different from the innovator in any other industry.

What distinguishes the pharmaceutical innovator from others is that generally when he gets his patent, he has no product to market. Indeed, he is likely to be some ten years away from having a product to market -- ten years which he must spend satisfying safety and efficacy requirements set down by the Food and Drug Administration.

Although Congress never intended it, the time consumed in meeting FDA

requirements is, in effect, subtracted from patent life, so that the pharmaceutical innovator's new products typically enter the market with less than half the 17 years of patent protection provided by statute and with less than half the related investment incentives provided developers of new floor waxes or can openers. It seems neither fair nor wise that while innovators in most areas are receiving nearly 17 years of patent protection on their new products, the average remaining patent life on new drugs approved by FDA in 1981 was 6.8 years.

I am not here today to complain about the length of the FDA's approval process. Most experts agree that the process could be shortened somewhat without lowering the agency's high standards, and FDA is currently reviewing its procedures toward that end. But I know of no competent authority who believes that -- even with the most thorough reforms -- the testing and approval process can be shortened by more than about 10% — or one year. Sophisticated scientific methods that make possible findings at ever finer tolerances make it inevitable that the drug approval process will continue to be very long. If the adverse effects of patent life loss on the development of cost-effective new medicines are to be eliminated, this legislation is vital.

The Consequences

What, then, are those adverse effects?

They are several.

To begin with, loss of patent life discourages investment in research on new medicines. It costs today an average of $87 million to bring a new prescription drug to market. If the innovator firm is to succeed, it must recover most of these research and development costs before imitators -- who have no research costs to amortize -- enter the market offering the same product for sale. The likelihood of the innovator recovering his costs depends in large measure on how much time he has — in other words, on the

length of effective patent life. Reduce patent life and you decrease the innovator's willingness to invest.

What we are seeing is a perversion of the patent system's purpose. As advocated from the beginning by Thomas Jefferson, our patent system was designed to promote innovation. It was never intended to dictate economic resource allocation by promoting one form of innovation more or less than another. Yet, through the regulatory accident by which drug approval time is subtracted from drug patent lives, this is what is occurring.

Major shifts in resource allocation do not come overnight; they happen over a period of years as firms and investors assess the economic environment and endeavor to determine whether the changes they see occurring are permanent, reversible, or perhaps harbingers of further changes in the same direction.

Already, however, the effects of patent life loss on investment in pharmaceutical research are evident. Effective R&D investment has declined significantly relative to sales since the sixties. Despite a relatively stable R&D to sales ratio of about 12% over the past two decades, inflation in biomedical research costs has been much faster than inflation in drug prices. That means the power of those sale dollars to purchase R&D requirements has gone down (Attachment #1).

Futhermore, the R&D costs required to put a drug on the market have increased dramatically because of greater government testing and approval demands. In 1966-69, it cost about $4 million (expressed in 1980 dollars) to put a drug on the market. By 1980, it cost $73 million (also expressed in 1980 dollars). That means that an R&D budget of $80 million that could have produced 20 drugs in 1966-69 could only produce one drug in 1980 (Attachment #2).

As a result, nearly every major research-based pharmaceutical company has moved to protect itself against the increasing riskiness of its traditional business by diversifying into other product areas — using funds that under more favorable conditions might have been used for additional drug research.

It is the American consumer who is the real loser in all this. Discouraging drug research postpones the consumer's access to new medicines that might spare him discomfort or save his life. It deprives him of the savings new medicines make possible by rendering unnecessary more costly forms of treatment such as hospitalization and surgery. It obliges him to forego the benefits of the competition that occurs when innovation is rapid and manufacturers of products which compete with the newer innovations must cut prices to stay in the market.

The issue of patent term restoration is especially important because of the major role pharmaceuticals play in health care. Medicines constitute the most cost-effective form of medical care. They often reduce or eliminate the need for more expensive forms of treatment.

The cimetidine story is a case in point. This drug has enabled thousands of ulcer patients to lead normal productive lives without having to undergo extensive hospitalization or surgery. Hundreds of millions of dollars have thus been saved.

Another example is the use of beta-blocking agents that reduce the risk of second heart attacks. According to FDA Commissioner Arthur Hull Hayes, the beta blocker timolol can save 7,000-10,000 Americans a year.

The prophylactic use of antibiotics to prevent urinary tract infections has been shown to save 37 percent of treatment costs.

Innovative drug therapy is especially important to a growing portion of

our population — the elderly. Drugs often constitute the elderly patient's only hope for a productive life outside a health care institution or their only hope of avoiding surgery which is especially risky for the elderly.

My point is this: new drugs represent formidable weapons not only against illness, but also against rising health care costs. We believe this legislation is necessary if the nation is not to see such valuable potential benefits deferred or even lost.

As we sit here today, American consumers are paying more than they might have and getting less than they should be, because nothing has been done to correct the problem of patent life loss.

When patent lives started to decline two decades ago, our industry had been producing some 50 new drugs each year. Following the 1962 drug law amendments which greatly lengthened the approval process, the number of new drugs entering the market each year dropped significantly. This was to be expected. Extending the approval process meant new compounds already in the FDA pipeline remained there longer. With no increase in the number of new drugs entering the pipeline, and with those already in the pipeline being subject to longer scrutiny, it was inevitable that the initial effect of the 1962 amendments would be to increase FDA's work-in-progress inventory while decreasing the number of new products approved.

But it is noteworthy that after this initial drop in new drug approvals, there was no recovery. In 1980, only eleven new chemical entities were approved in this country. In the past two years, the number of new drugs approved has risen. However, it is apparent that this has occurred because of expedited treatment at FDA rather than because of any underlying improvement in research incentives. And because of the effect of cleaning out the pipeline, it is unlikely that the approval pace of 1981 and 1982 can be sustained.

It is not with pleasure that I cite these statistics. Ours is a high-technology industry. It has long prided itself on being the world leader. We are precisely the sort of capital-intensive, research-intensive knowledge-based industry on which the future economic health of this country depends. It cannot, therefore, be regarded a good thing by anyone that pharmaceutical innovation is being retarded by a regulatory accident.

Because investment decisions are re-examined throughout the drug development process, the declining research incentives caused by patent life loss take their toll on potential innovation at many points — often even after large sums have already been invested. Thus it is not only projects not undertaken, but projects cancelled in mid-course that defer access to new medicines, lessen competition and raise product prices.

Because the problem of patent life loss has become acute only in recent years, its costs to the public have only begun to be felt. Are we to look forward to a future year in which we are called before Congress to explain why Americans are dependent on foreign innovators for their new medical technologies? Must we wait until the disease is certified as terminal before a cure is proffered? Must public policy change always attend the crisis rather than anticipate it? We hope not.

The Bill

These consequences need not occur. The bill before you, S 1306, essentially the same bill that passed the Senate two years ago, would, by restoring to new drug products up to a maximum of seven of the ten years currently subtracted from their average patent life, reverse the decline in research incentives, stimulate more rapid innovation, strengthen the industry's international competitive position and -- most importantly -- ensure that the American consumer in the decades ahead has access to better medicines earlier and is able to buy those medicines at lower prices than would otherwise be possible.

This bill's application is wholly prospective. It would confer no benefit whatever on any product already on the market. The bill has been drafted in this manner so as to confer no compensation for patent life already lost, even though arguably any patent life lost is an inequity and a commercial disadvantage imposed without legislative sanction.

As for drugs already patented but not yet approved, these would receive restored patent life only for time that elapses between the bill's enactment and their approval by FDA. For example -- if this legislation passed today, a drug approved one year from now would be eligible for no more than one year of additional patent life, even though it may have lost ten times that.

For drugs not yet patented no restoration could begin before the year 2000.

The Benefits

We are convinced that the Patent Restoration Act of 1983 will, if enacted, be of benefit to everyone:

-- The American consumer -- and especially elderly consumers -- as I have said, will receive several "patent restoration dividends" by getting new medicines earlier, by being spared more costly or less effective therapies such as hospitalization and surgery, and from the lower prices additional product competition will produce.

-- As a taxpayer or contributor to third party insurance programs, the consumer will also benefit from the restraining effect more rapid innovation in new medicines will have on health-care costs generally.

-- The United States economy will be strengthened by improving the competitive position of one of its high-technology growth leaders.

-- The research-based firms will benefit, because investment in finding new medicines will be put back on a more nearly equal footing with investment in other forms of innovation.

-- And the generic manufacturers will benefit from the increased number and sophistication of the new products they will, in time, be able to imitate.

Critics Charges

Before concluding, I would like to offer a few observations about the character of past debate on this issue.

Last year, after the Senate had passed a bill essentially identical to S 1306 and while a similar bill was being considered in the House, opponents of patent restoration offered some objections that were both puzzling and factually anemic.

First, they singled out several products with unusually long patent lives from among the more than 2400 on the market and suggested that they were typical cases. Our industry has never argued that all our products have lost significant patent life, only that most have, especially those approved since the mid-seventies. The citation of atypical examples only confused the debate, just as it would have confused the debate had we chosen to mention only those drugs that enter the market with no remaining patent life whatever. In fact, data from five different sources show a steady decline in effective patent life over the past fifteen years (Attachment 3).

Second, some opponents of this legislation have argued that patent restoration would raise drug prices. In fact, this legislation would result in lower prices to consumers.

I want to reemphasize that this bill would not apply to any drug

currently on the market. Consumers, especially the elderly, who rely on existing drugs should understand that these products will not be affected.

Furthermore, it is important to understand that the price of any drug on the market is affected by two competitive forces — price competition, which comes from generic and branded products alike, and therapeutic competition, which comes from alternative forms of treatment and from new drugs in the same therapeutic category. Unlike competition from generics, competition from new therapies exerts a downward pressure on the price of all other drugs in the same therapeutic category whether those other drugs are still under patent or not.

Third, some critics have claimed that this bill will hurt generic drug manufacturers. This is dubious. Generic drug manufacturers are totally dependent on drug innovation brought forth by research intensive firms. Without drugs to copy, they would be out of business. We believe this bill will give generic manufacturers greater opportunity to grow by giving them more new drugs to copy — and sooner.

The generic firms are growing rapidly. In the past five years, the sales of nine major publicly held generic companies have doubled and their profits have more than tripled, with no research investment in new medicines. It is estimated that by 1985, nearly 50 drugs whose sales in 1980 were upward of $1.2 billion will lose patent protection. None of these products would receive a single day of patent restoration under this bill, although arguably most of them deserve it. Thus, it appears that the market for generic drug products will expand dramatically over the next decade with or without this legislation.

Further, critics of the bill sought to create the impression that innovative firms were acquiring patents in constellation, pyramiding one on top of another to extend effective protection. Among people not knowlegeable about the intricacies of patent law, this understandably

occasioned alarm and suspicion. But these allegations rested on nothing more sinister than the entirely legitimate practice, common in many industries, of filing for subsequent "use" and/or "process" patents. Such patents do not normally extend the original product patent; when that original patent expires, anyone is free to make the product for its original use and by the process disclosed in the original patent. The law permits subsequent patents for new uses and new processes to encourage continuing research on new product applications and new cost-saving manufacturing efficiencies in all industries, all of which is in the public's interest.

Most importantly, the bill before you flatly prohibits the restoration of later process patents if the original product patent is restored, and no more than one patent can be extended for the same regulatory review period.

Finally, opponents of patent restoration assert repeatedly that there is nothing unusual about the pharmaceutical and chemical industry's patent predicament. Apparently forgetting their simultaneous claim that medicines and chemicals are not losing patent life, they argue that loss of patent life does not distinguish our industry and that many if not most industries are in the same boat. This assertion also is false. Most inventors do not lose patent life because most inventors are able to get their products to market within the period of several years required for the patent office to process a patent application. Many innovations reach the market long before their patents issue; hence the familiar marking "patent pending." It is true that some other innovators lose patent life, and this occurs for a variety of reasons, one of them being that sometimes, as in the case of television or the jet engine, an innovation is discovered long before a commercially viable application is found. But, contrary to what opponents of patent restoration last year were suggesting, no industry loses as much patent life as the pharmaceutical industry, loses it as regularly, or loses it under circumstances over which it is able to exercise so little control.

Conclusion

I would like to conclude with this brief summary.

One of society's most important and beneficial economic activities is today being retarded by regulatory accident. The public's loss in foregone therapies and unrealized savings has only begun to be felt. Because developmental lag times are long, there will be future losses which already it is too late to avert. But the loss to future generations can be minimized if Congress acts now.

The Patent Restoration Act will save lives and reduce suffering. It will save money by hastening the invention of new medicines that drive down the prices of old medicines and obviate the need for more expensive forms of intervention such as surgery or hospitalization. It will increase labor productivity by reducing absenteeism. And it will help ensure the international competitiveness of a vital American industry.

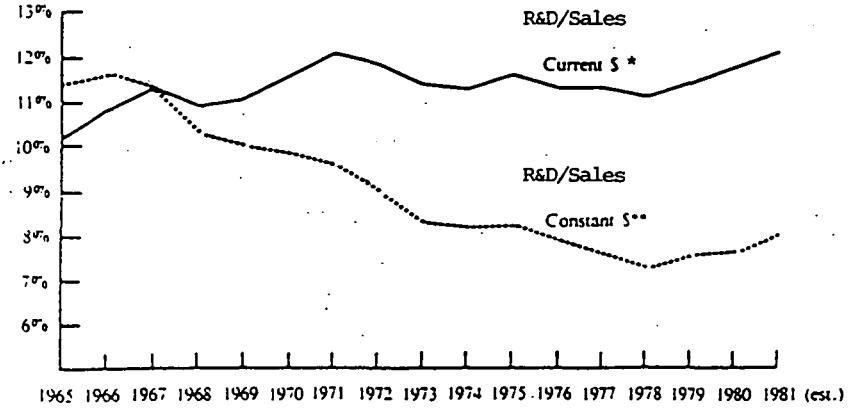
Patent life restoration is a reform that has been endorsed by the President and his Administration, by scores of economists, by dozens of medical associations and universities, by health associations such as the American Heart Association, by the Johns Hopkins University, by the Association of American Medical Colleges, by the United States Patent and Trademark Office, by the Department of Health and Human Services, by the Food and Drug Administration -- indeed, by nearly every knowledgeable expert called to give testimony. It was approved without objection by the Senate during the last Congress, and a substantial majority of the House voted for it during its consideration under suspension of the rules. Yet the problem remains unsolved. As long as it does, Americans will be paying for it with their money and their health.

Thank you, Mr. Chairman. I would like to call your attention to the statistical attachment to this testimony in which you will find data to support each of the factual assertions I have made.

ATTACHMENT #1

DECLINE IN EFFECTIVE R&D INVESTMENT

BECAUSE OF INFLATION



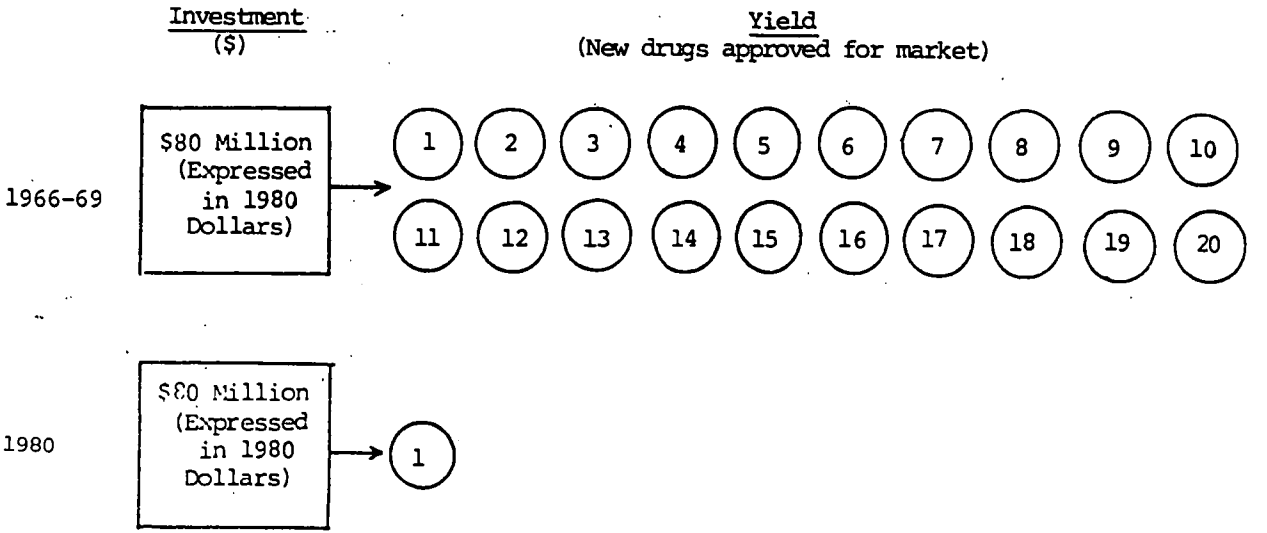
* R&D as a percentage of sales is computed by dividing human & veterinary R&D expenditures in the U.S. by domestic production, i.e., domestic sales and exports, including intra-firm transactions, times 100.

** 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, Dept. of Health and Human Services: 1967 = 100.

ATTACHMENT #2

DECLINE IN EFFECTIVE R&D INVESTMENT

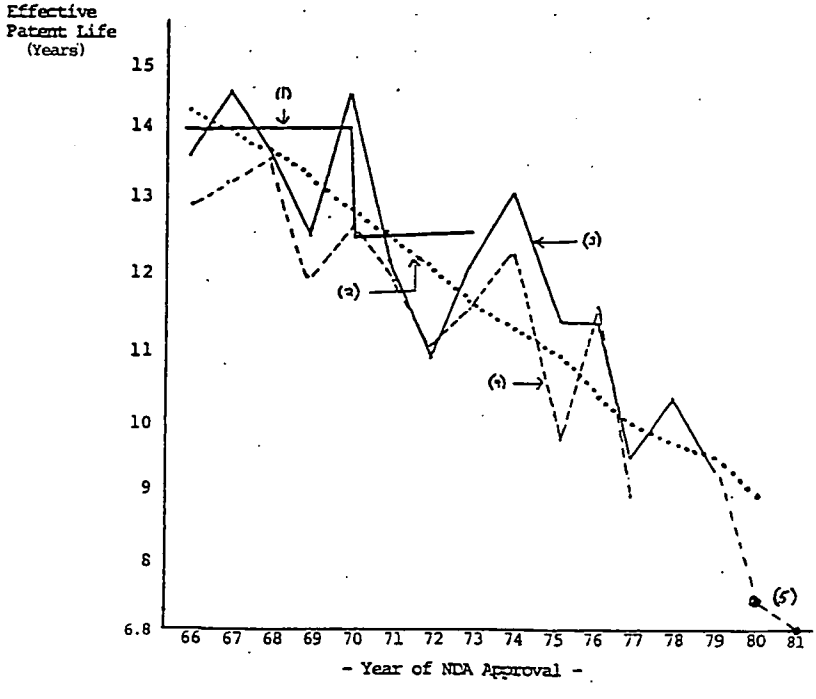
BECAUSE OF HIGHER COSTS



ATTACHMENT #3

TRENDS IN EFFECTIVE PATENT LIFE (EPL)

FROM VARIOUS SOURCES



(1) Schwartzman.

(2) Statman.

(3) Eisman & Wardell.

(4) Pracon.

(5) PMA.

Senator MATHIAS. We will now proceed with the next witness, Mr. William F. Haddad, the president of the Generic Pharmaceutical Industry Association.

STATEMENT OF WILLIAM F. HADDAD, PRESIDENT, GENERIC PHARMACEUTICALS INDUSTRY ASSOCIATION, NEW YORK, N.Y.

Mr. HADDAD. Senator, I may surprise you by saying that I totally agree with your opening statement. If patent restoration is required—if it has been lost, it should be restored.

Second, the generic industry favors patent law, and as an inventor, I favor patent law. Third, if someone does not question $87 million as a drug-development cost, I am going to explode.

Fourth, Mr. Mossinghoff was disingenuous in his statement to you about the 1980-81 numbers. What he failed to tell you is that the major loss was between the time that the company got its patent and the time that it knocked on FDA's doors.

I will move quickly through my testimony, provide my text and attachments for the record, and answer questions.

Today, the PMA comes before you to request a multibillion dollar concession, to be financed by the elderly, the chronically ill, the middle-income family with growing children, the State and the Federal Government.

Yet, the PMA refuses to release for congressional review the data in their sole possession which would resolve the issue and the question you ask: Has patent life been eroded by excessive Government intervention?

When Congressman Gore sought that information, he was told by PMA's counsel that the data would only confuse the Congress. Time was, Senator, when those were famous last words.

Patent extension, succinctly defined, is a continued monopoly on an essential product for up to 7 years, with a product price established without regard to competition. The consumer, the patient, has no alternative but to pay the monopolistic price or be deprived of the drug.

We already know from studies of the elderly that many cannot now pay for drugs. Patent extension would intensify that problem, so it behooves us to establish the facts to answer this question before we legislate another fiscal burden on consumers and the Government.

This inquiry also reminds me of the six blind men trying to visualize through touch what an elephant looks like. When you consider patent extension by itself, it is analogous to the blind man who touches the tail of an elephant and concludes that it must be small like a mouse because the tail is so short. Patent extension is the tail of the problem.

Are you aware for example, that perpetual patent extension already exists for almost every single drug which came into the marketplace after 1962? These are drugs, Senator, that are legally off patent, legally available for competition, but we cannot compete because the Food and Drug Administration has failed to promulgate the necessary procedures for competition. Any reasonable man would ask, how is that possible?

Are you aware that after a drug patent expires the originating company maintains an 80-percent consumer market share, Mr. Engman, and a 90-percent hospital share, although identical generics can be purchased at a fraction of the cost of the trade-name product? That is documented by industry studies. They are skewing the numbers, Senator, because they do not talk about branded generics.

Would it be reasonable to ask, then, what is patent extension all about? Patent extension would appear to be about competitive bidding. On the day the patent ends and generic competition is possible, about one-third of the entire prescription drug market is subjected to competitive bidding procedures. What cost $8 dollars then costs $1.

Finally, are you aware that Federal and State efforts to reduce the cost of off-patent, prescription drugs have been torpedoed in Washington? At the Medicaid Directors Conference in Nashville last month, drug costs, which are rising at three times the rate of inflation, were called the only uncapped medicaid cost. At the same time, we are told that two out of every three doctors prescribe for the higher priced drug.

We are prohibited by law from advertising that our products are approved by the FDA, and the booklet that the Government sent to doctors illustrating price differences has been canceled.

The PMA argues that patent life has been cut in half. It has not; I will document my statement for your record. The information to determine if patent life has been reduced, is available in a computer in Rochester. That data will answer your questions.

Research has not declined; innovation has not declined; patent life has not been cut in half. At the very least, the case on patent life has yet to be made. If innovation and research have not declined, what is left of the argument? Not much, I submit.

Down South, Senator, where I come from there is a conservative legislative tenet which argues, if it is not broken, do not fix it. The patent law is not broken and is not in need of fixing, especially for the pharmaceutical industry.

We hope that you will join with us in concluding that patent extension is an expensive solution for a nonexistent problem. Thank you.

Senator MATHIAS. I believe it was Mark Twain who first said, "If it is not broken, do not fix it."

Mr. HADDAD. I am glad to be in that tradition. That is my feeling about this legislation. I appreciate this hearing, Senator, because you are beginning to probe the basic premise, and you have the facilities to find the answer.

Mr. Engman, when he comes back here, can say, "Senator, we will provide the same data that we provided for 1980, for all the intervening years," and then a mathematician with a high-school education could determine if patent life has been lost.

If it is lost, who is responsible, the company or the government? If the government is responsible, restore patent life to the company.

Senator MATHIAS. Now, I am informed that there are currently around 2,400 pharmaceutical drugs on the market, of which 80 percent have reached the end of their patent and are available to

anyone who wants to manufacture them. Is that approximately true?

Mr. HADDAD. Senator, that is a blind man touching an elephant. You go at it by numbers or you go at it by volume. Some drugs do not have any market; some drugs have a big market.

Drugs are coming off patent; competition is available. But the major drugs are still covered by patent and when they do go off patent, 80 percent of the commercial market still remains in the hands of the brand name companies.

That question was legitimately asked by the PMA of the chart that I produced for you last year showing that the major drugs on the market in 1980 had an average patent life of 18.75 years, on a market share of about $1.75 billion.

PMA said, "Gee, you picked only selected drugs." We did not. We took the 25 top drugs and went down the list, and we selected those that were on patent and totaled up the results: 18.75 years.

OTA took eight of those drugs, Senator, and came up with 15.1 years. Yes, there are 2,400 drugs, but the major volume drugs are still on patent. Still, when they come off patent, 80 percent of sales remains in the hands of the major companies.

Senator MATHIAS. I have seen it estimated that 50 more major drugs will come off patent by 1985.

Mr. HADDAD. I am not sure of the number. Many are coming off. I am also glad you asked me that question, Senator. Yes; they are coming off patent, but we cannot compete. FDA does not have a procedure. We cannot go over to Rockville and say, "Here." There is no procedure for approving post-1962 drugs. No procedure.

For most drugs—there are a couple of exceptions that prove the rule—that went into the market after 1962, FDA today does not have a procedure which allows us to compete. So, while your statement is true, my statement is also true. I hope you will help us with that, Senator. That is a plea.

Senator MATHIAS. Well, it is a plea, and I understand it, because, as I view the market situation, the strength of the generic industry really depends on access to drugs coming off patent, is that not true?

Mr. HADDAD. Yes, in one sense. But what is happening to the generic industry is that they are reinvesting in research. The three public companies on which information is available indicate that research is now around 3 or 4 percent, which is a third of what the larger companies do.

And from confidential information that I have been allowed to review, I think some of our larger generic companies will be reaching 8 and 9 percent on R&D in the years ahead, like everybody else. When you are the little guy on the block; you make some money, you put it into research, and you do things differently.

The generic companies are producing drugs more economically than brand-name companies by using higher technology and better technology. We invest in better technology and when drugs come off patent and we are allowed to compete, we compete. We compete among ourselves; we kill each other by price wars.

Let me make one other point. We also manufacture generics for the trade-name companies because our technology is superior.

Senator MATHIAS. Well, now, you say you are beginning to invest in research. Do you ever cooperate with the major pharmaceuticals in research or development activities?

Mr. HADDAD. I am glad you asked that question. We are a stimulus to them, and I offer you the example of the orphan-drug legislation. For 14 years, the PMA came before you, and the Congress, and the country and said they could not do anything about orphan drugs. What the companies said privately, and honestly, was that there was no market to justify the expense.

We disagreed and established the GPIA Institute for Rare and Orphan Drugs. We "adopted" three drugs in 3 months, and I believe that action might have had some impact on PMA, and I think it might have had some impact on that legislation.

Yes, Senator; sometimes we cooperate, but we are not in that kind of a marketplace. It is a free enterprise system. If we can do it ourselves, we will do it ourselves.

Senator MATHIAS. You said earlier that we should beware of imposing a further burden on consumers.

Mr. HADDAD. Yes, sir.

Senator MATHIAS. I certainly share that sentiment.

Mr. HADDAD. I know you do.

Senator MATHIAS. What kind of profit margin do you experience in the generic-drug industry?

Mr. HADDAD. Fabulous, very good. It is the survival of the fittest. There are about 12 major generic firms left. For two decades the majors knocked many of us off in the courts, and with legislation, and politics, and State laws.

Now you have got the toughest, smartest, wisest free entrepreneurial companies in the free world in this business; they got that way to survive against all those lawyers in this audience. They survived and they know how to make money, and they are making money. There is nothing wrong with that—making money, Senator, and selling the product at a fraction of the price.

Pfizer, Squibb, Lederle, Smith-Kline-French—all those companies make branded generics, which is the identical product we make. They sell it for 4 bucks; we sell it for a buck and we make a lot of money. That might tell you something about this industry.

Senator MATHIAS. You say that the profit margin is fabulous.

Mr. HADDAD. In recent years, yes, because we have good management, smart people, and good technology.

Senator MATHIAS. Like what?

Mr. HADDAD. Well, there are only three public companies and I have the same figures that the PMA put out. They show that Zenith went from zip, under the leadership of Ken Larson, to an extraordinary return on investment. Bolar has done extraordinarily well.

But, again, you are touching the elephant. You can take all of our profits and put them in a Pfizer knapsack. Sure, we make money; there is nothing wrong with it. It is a free enterprise system. We make money by selling identical products at a lower cost.

Senator MATHIAS. I am not suggesting there is anything wrong with making money.

Mr. HADDAD. I was trying to understand the intent of that question. Maybe you can help me.

Senator MATHIAS. Well, yes. If we are talking about burden on the consumers, I think it would be interesting to know, in percentage terms, what the margin of profits is because somewhere along the line, a profit to the manufacturer becomes a burden to the consumer.

Mr. HADDAD. Absolutely.

Senator MATHIAS. Now, you cannot draw that line arbitrarily.

Mr. HADDAD. No, you cannot.

Senator MATHIAS. It is different in every case; it may be different in every product. But when we talk about burden to consumers, you invite that kind of question.

Mr. HADDAD. You are right, and let me explain how our business works. We do not have exclusive marketing rights. When a drug comes off patent, pre-1962, and we have the right to compete, the first company in the market cuts the price on the trade name by 50 percent. The second company in the market cuts it by another 25 percent, and then everybody is in there competing.

If a German or Japanese company comes in and undercuts us, we drop our price to get the business. It is a fiercely competitive business. Tomorrow, I could start a generic company and undercut somebody's price. It is a free market and anybody who wants to get into it and charge lower prices can do it.

There are limits on what you can do. The reason the profits are so high is because they went from—the percentage of profit, Senator, is what the numbers are in front of you—say it is because we went from family management to professional management, and from old technology to new technology, and from old plant to new plant. As a result generic companies are doing very well; there is nothing wrong with that, is there?.

But if you left the Senate and went into the business with Mr. Copanos of your State, for example, a company that cuts everybody's price, you would do very well. To stay in business, we must meet his prices all over the country because every time somebody gets a low price, Copanos from your State can come in and charge a dime less.

Senator MATHIAS. I understand that one of the battlegrounds that surrounds this legislation is the question of contract purchases.

Mr. HADDAD. Yes.

Senator MATHIAS. What would the effect of this bill be on large contract purchases?

Mr. HADDAD. My private conclusion about this bill is it has got nothing to do with the consumer market—it has got 20 percent to do with the consumer market.

Senator MATHIAS. The real battleground is contracts.

Mr. HADDAD. Senator, pretend I am a Defense Department person; I go over to FDA and I say, "When does it look like you are going to get competition in this drug?" They say, "Thirty days from now." I will hold up my bid. Do you know why? Because today I will pay $8; 30 days from now, I will pay $1.

I will either give the bid to the generic company or Pfizer or Lederle or Roche will drop their price to 99 cents and take the bid

away from us. So you have immediate competition when the patent ends and when we are allowed to go in the market. We are not allowed to go in the market after 1962, so what you would do is you would extend for 7 years—up to 7 years, to be accurate—the cost in any competitive bid situation.

Do you know what they do now, Senator? The last drug to come off the market—raised its price to compensate for the potential loss to generics. The bottom line brand name probit remains constant.

Senator MATHIAS. But if I am to believe Mr. Engman, might it not also be that because the companies that originally developed the drug have a longer period to recoup their research and development costs, they might actually be able to bid competitively before the patent expires?

Mr. HADDAD. They do not.

Senator MATHIAS. Well, they do not now, but——

Mr. HADDAD. Why would they do it? Their board of directors would run them out of town.

Senator MATHIAS. Well, it is just a matter of opinion. Your opinion is that they would not?

Mr. HADDAD. No. I am telling you as a businessman that the board of directors would run them out of town. If you can charge 10 bucks and you charge only $9, the guy who is sitting there with the quarterly report on which your stocks price is based—he says, "Mr. Mathias, we are going to find a new guy to run this company."

I would not ask them to do that; I do not think that is possible or logical. I would like to see them do it, but they can not do anything out of the goodness of their heart because they must be responsive to stockholders. The stockholder is investing money in a drug company to make money.

Senator MATHIAS. Is volume a function of price?

Mr. HADDAD. Volume could be a factor, but the generics could do the same thing. On the day that the patent ends and competition begins, they have to meet our dollar price or they are not going to get the bid. They want the bid so they drop the price to 99 cents. They are very interested in the volume purchasing market.

Senator MATHIAS. Well, that is an interesting aspect of this problem.

Mr. HADDAD. That is right. If we are not there, they do not drop to 99 cents. If your law goes through, it will take up to 7 years before they drop to 99 cents. It is going to cost the Government a lot of money; it is going to cost the taxpayer a lot of money—$1 billion a year.

Senator, one of the things I did not get——

Senator MATHIAS. And there will be sharper competition after a drug patent expires.

Mr. HADDAD. Why? Tell me why.

Senator MATHIAS. Well, you are telling me.

Mr. HADDAD. No, no. I do not understand the question.

Senator MATHIAS. I am asking you the question. You do not think so?

Mr. HADDAD. What happens, Senator, is it is sharper competition when we get into the marketplace. This legislation keeps us out of

the marketplace for 7 more years. If that is the question, the answer is yes.

What I did not say to you, Senator, in my statement, which I hope you will let me say now quickly, is take Mr. Engman's numbers; say, 12 cents on every dollar is spent on research. If you give them a dollar, they are going to give you 12 cents back on research.

Take the other problem. Mr. Engman says the problem is the regulatory review process. Dr. Hayes tells the Congress, "I have speeded up the process to 23 months, and if I had more money, I could do all the drugs in 23 months." Well, give him the money. That way we will have an expedited process and avoid $1 billion a year expenditure.

There are other alternatives; there are other ways to walk around this barn. I think one of the ways is to expedite the process. Another way is to direct the money to the need without any coming off the top.

Senator MATHIAS. I have just one further question which is a real-life example to get your opinion as to what the effect on the consumer price would be.

Smith-Kline developed a drug for the treatment of ulcers.

Mr. HADDAD. Tagamet.

Senator MATHIAS. Tagamet.

Mr. HADDAD. A great drug.

Senator MATHIAS. It is what?

Mr. HADDAD. A great drug.

Senator MATHIAS. A great drug.

Mr. HADDAD. It kept a lot of newspaper people in business; it solved their ulcer problems.

Senator MATHIAS. And it reduced the workload of a lot of surgeons.

Mr. HADDAD. Absolutely.

Senator MATHIAS. There is less cutting as a result of Tagamet.

Mr. HADDAD. That is right.

Senator MATHIAS. Now, Hoffmann-LaRoche has developed a new drug called Zantax——

Mr. HADDAD. I have heard about it.

Senator MATHIAS. [continuing]. Which is supposed to be even better than Tagamet. I do not know whether it is or it is not.

Mr. HADDAD. Nobody knows yet.

Senator MATHIAS. But let us assume for the purposes of this question that it is better. In any event, it will be competitive. What will the effect on the price of Tagamet be?

Mr. HADDAD. Well, that is an interesting question because that was raised. I think the better question, Senator, if you do not mind, is what will it be on the——[Laughter.]

Senator MATHIAS. I do mind; I do mind. [Laughter.]

I asked you your opinion on the price.

Mr. HADDAD. All right. That is a hard question because I do not have the data, and I asked a researcher to find out when I heard Mr. Engman speak. My impression of the marketplace is that prices do not change when brand name goes head to head with another brand-name product.

But what will change will be the Tagamet market share. The Tagamet market share would go down. Half of the profits from

SKB come from the sale of Tagamet, so that would have a serious impact on market share.

But several other things will happen. First, how much did the drug cost? Second, how did they price it? Third, you should know that the pricing policy of the industry is to get all the money back in the first 2 or 3 years.

You have all those related questions. This is a very tough business, but the big boys are doing very well. You asked about profits, Senator. In 1982, all industries' profits totaled a minus 16. For the drug industry, it was a plus 17.

So, with all this competition among the big guys on the big-market drugs—they all go for the big-market drugs—they are doing all right.

Senator MATHIAS. Thank you.

Mr. HADDAD. Thank you very much for your time.

Senator MATHIAS. Senator Metzenbaum.

Senator METZENBAUM. I cannot even see the witness, let alone ask him some questions. [Laughter.]

I have no questions. Thank you.

Senator MATHIAS. No questions?

Senator METZENBAUM. No questions.

Senator MATHIAS. I think Senator Metzenbaum and I would both agree that it takes very little to confuse the Congress. [Laughter.]

Senator METZENBAUM. We are already there.

Senator MATHIAS. We will ask Mr. Engman to resume and Senator Metzenbaum can complete his questions.

Senator METZENBAUM. I just have a few more questions.

Mr. HADDAD. Thank you for your time.

Senator METZENBAUM. I appreciate the chairman's cooperation, as well as Mr. Engman's. I apologize for having had to leave.

Mr. Engman, one of the arguments you make is that additional monopoly profits are necessary for the firms to make needed new drugs. You claim that existing incentives are not enough to keep the industry busy doing research for new products.

Now, is it not a fact that industrywide R&D has actually increased in real dollars in recent years?

Mr. ENGMAN. Can I move that stand so that we can see each other, Senator?

Senator METZENBAUM. Well, through the barricade.

Mr. ENGMAN. Mr. Haddad has many tricks. I thought he was going to leave the chart up there.

Mr. HADDAD. I would not do that to you.

Mr. ENGMAN. I must say first of all that I did not use the words "monopoly profits." That is, I would delicately say, a figment of someone else's imagination.

But real R&D expenditures have declined if you apply an R&D deflator which is used by the NIH with respect to the costs of scientific research. Now, those numbers have been disputed, but let us take a cut at it from another perspective.

In the 1960's, it cost approximately $4 million to bring a drug to market. That cost today is roughly $80 million. That number is in 1980 dollars, incidentally, corrected for inflation. In the 1960's, that $80 million research budget could have produced 20 new drugs; today, one new drug.

And I think there is another interesting phenomenon in connection with——

Senator METZENBAUM. Did you mean $80 million for research alone, or $80 million to bring a product to market?

Mr. ENGMAN. Eighty million dollars for research and development of a new drug.

Senator METZENBAUM. And that is not including——

Mr. ENGMAN. That is not marketing costs.

Senator METZENBAUM. OK.

Mr. ENGMAN. The interesting factor here is what has happened during the same course of time with respect to the position of U.S. investment in R&D in pharmaceutical products worldwide.

In the 1960's, this country accounted for 60 percent of the worldwide investment in pharmaceutical research. That has declined to approximately 25 percent today. One of the country's high-technology industries has had that kind of diminution with respect to its impact on a worldwide basis.

So we have a situation where, today, England, Japan, and West Germany are accounting for more than we are.

Senator METZENBAUM. What is the source of the $80 million figure?

Mr. ENGMAN. Let me give you that, Senator. In 1976, the National Science Foundation had a study indicating that, in 1976 dollars, the cost of developing a new drug was about $54 million. What we have done, in consultation with our economists, is multiply that $54 million figure by the NIH biomedical R&D deflator, and it gives you a figure of some $87 million in 1982.

Senator METZENBAUM. Well, on that basis, then, why do you not accept the figures that were put out, actually, by the Pharmaceutical Manufacturers Association, if I am not mistaken, indicating that the R&D investment in constant dollars has gone, from 1965 to 1978: $356, $390, $412, $429, $458, $483, $507, $512, $552, $592, $606, $618, $634, $655? Those are constant dollars.

Now, your argument is that the industry cannot afford to do this, and are not doing it, because of this limitation or the problems with respect to the patent period. Yet, the facts are that the industry has been increasing its investment in R&D.

If I am not mistaken, is it not the fact that the industry's profits have also considerably risen during that same period, or am I wrong about that?

Mr. ENGMAN. Well, it is great to play with numbers, but let me say, Senator, that——

Senator METZENBAUM. But numbers are facts. Now, am I right or wrong?

Mr. ENGMAN. They are facts, but the numbers that you have quoted are misleading insofar as they go. What I was saying at the beginning, and I am happy that we can clarify this point, is that although absolute expenditures for R&D have increased, as a percentage of sales, there has been a decrease.

There is a table at the back of my testimony which sets that out. Now, in addition to that, I indicated that our overall American investment in research for pharmaceuticals has declined over that same period from approximately 60 percent of worldwide investment to some 25 percent today.

Third, the research dollars that are available do not go as far any more. As I indicated, we now have approximately one drug being able to be produced from an $80 million research budget, as opposed to 20 drugs some 20 years ago. The actual expenditures have been increasing, but they have been increasing less rapidly than our foreign competitors, and they have been increasing less rapidly than overall sales of the industry.

Senator METZENBAUM. First, you suggest that I play with figures, but it is you——

Mr. ENGMAN. I am not suggesting that at all.

Senator METZENBAUM. All right. Let me just tell you that all I have is the published data to go by. You have access—this is your full-time occupation. Yet, when I asked you a question before about the percentage of dollars that are spent for marketing and education as compared to the amount spent for R&D, you understandably said, "Well, I will have to come back to you with that."

Now, you have just said that the percentage of dollars that are spent as compared to sales has gone down. Well, I look at the figures: for 1979 to 1981, for Abbott, the percentages were 5, 5, 6. When I look at Baxter-Travener, the percentage was 4, 4, 5.

When I look at some of the others, they remain constant. So far, I have come across none that have gone down. I look at Merck; it has gone 8, 9, 9. I look at Pfizer; it is even. Schering is 5, 5, 6. Searle is 7, 8, 9, and I am talking about percentages. Smith-Kline is 7, 8, 8. Squibb is 5, 6, 6. Warner-Lambert is 93.6, 102.7, and 115, and Upjohn is 129.3, 147.3, and 171.6. Sterling Drug was also up from 48 to 58 to 67.

What is your authority for the statement that the percentage of sales has gone down since then? Not one of those figures reflects that fact.

Mr. ENGMAN. Those figures are not a comparison of percentage of research expenditures to sales over the past 20 years. That is what I am talking about.

Now, I recall seeing the article which I believe you are quoting in Business Week a week or so ago, which, first of all, gave a sample of pharmaceutical companies, but by no means all of them.

If I further recall, and I do not have the article here, but my recollection is that the average percentage of research to sales was something in the neighborhood of 6 to 7 percent——

Senator METZENBAUM. Well, as a matter of fact, you have seen another article. I am reading from Standard and Poor's.

Mr. ENGMAN. OK, that is fine. But I would refer you to attachment No. 1 of my statement, which indicates that according to our figures, that percentage is approximately somewhere above 8 percent in 1981 as a percentage of sales.

Senator METZENBAUM. Say that again; say that again. I did not hear what you said.

Mr. ENGMAN. Approximately 8 percent, on the average, as a percentage of sales. Now, obviously, companies are going to come in all over the map. This is attachment No. 1 of my statement.

But what I am also saying is that that bottom line, which is that percentage line, is falling. In 1967, it was over 11 percent of sales. Now, that is the statement I have made; that in constant terms, R&D expenditures by the industry have been declining as a per-

centage of their sales, even though, in terms of current dollars, those expenditures have been increasing.

So, I am not sure we really are disagreeing because I accept the numbers that you are reading from Business Week or Standard and Poor's.

Senator METZENBAUM. They come from the annual reports of the companies.

Mr. ENGMAN. Senator, I think that we are saying the same thing. I am looking at it over a longer timeframe, however.

Senator METZENBAUM. In your figures in the chart that you attached, why did you include only domestic production, because the question of R&D would be applicable to foreign production, as well? Why did you just use a portion of it as your denominator?

Mr. ENGMAN. Well, those numbers are the only ones we logically could use in terms of factoring the R&D deflator. You would not want to put the NIH deflator for inflationary factors in the United States against foreign investments.

I do not know to what extent those numbers are available, but I would not want to deceive the Congress.

Senator METZENBAUM. Well, I would not want to exclude all of the foreign production, and that is what you have done. I do not understand how you could do that. Now, you say you do not have the deflator. That is a factor, but the bigger factor——

Mr. ENGMAN. My guess is, Senator, that if we included it, it would be even worse.

Senator METZENBAUM. Well, you say that, but I would say it certainly skews the figures when you eliminate all of the foreign production. And that is what you have done in using——

Mr. ENGMAN. You see, what has happened is that we have increasing foreign competition in this country.

Senator METZENBAUM. That has got nothing to do with this.

Mr. ENGMAN. Close to half of the new chemical entities approved a year ago by the FDA now come from foreign sources.

Senator METZENBAUM. That has got nothing to do with this. Now you have gone out into right field. That has got nothing to do with the question of whether the percentage of dollars being spent for research and development as compared to the percentage of sales has gone down or up.

I gave you figures from the annual reports. You referred me to a chart here. I pointed out to you that your chart does not have all the facts in it because the denominator fails to include the foreign production. And you have no basis whatsoever to exclude it.

Mr. ENGMAN. As does the numerator; both exclude foreign production.

Senator METZENBAUM. No, it does not; it does not. The numerator does not. R&D as a percentage of sales is computed by dividing human and veterinary R&D expenditures in the United States—excuse me; it does. I take it back. You are correct about that. I am sorry.

Let me say what the drug companies are saying about R&D expenditures in the next few years, and it was not based upon some anticipated legislation. The National Science Foundation:

Responses from the drug companies were optimistic. Overall R&D spending is expected to increase approximately 20 percent during 1982 and 1983. Recent major

medical breakthroughs and marketing opportunities in new and evolving technologies are the principal reasons behind the higher R&D expenditures.

In addition, both domestic and foreign competition have stimulated R&D spending by pharmaceutical companies. There is evidence that American drug companies are not only expanding their current R&D expenditures, but are also making commitments to building new facilities and expanding existing ones, indicating the drug-related research and development is likely to continue in the near future.

National Science Foundation, Science Resource Studies Highlights, September 9, 1982.

Now, your whole premise in being here and asking for this legislation is that the industry cannot and will not be spending the money needed in the area of R&D unless they get this change in the law. Yet, the facts indicate that the industry is indeed doing it without any change in the law, and is able to still make exceedingly high profits. Their profit pictures have been good; I do not mean excessive, but I say good profits.

Mr. ENGMAN. Can I comment on that, Senator?

Senator METZENBAUM. Of course, of course.

Mr. ENGMAN. Let me repeat again, of course the companies are spending as much as they can with respect to R&D expenditures in terms of finding new therapies and new medicines.

I repeat, however, that those dollars are not going as far today. That $80 million of research which goes for one drug today might have yielded drugs in 1966. Why should it be, in the United States of America in 1983 when we have a serious problem with spiraling health care costs across the board, and hospitalization and surgical costs and everything else going up, that the patent incentive that we give manufacturers for research and development of new medicines which are cost effective in the total health care scheme is approximately half that of the patent incentive we give for somebody to do research on some new mousetrap or some other household product?

That just does not make any sense. Yet, it is the situation which we have. Of course, Pfizer & Squibb and other companies are trying to put more money into R&D. But those dollars are not buying as much as they did 20 years ago.

And I repeat these numbers: 20 years ago, the R&D expenditures for new medicines in the United States accounted for 60 percent of the total in the world. Today, that figure is more like 25 percent. So whatever we are doing, we are not doing it as well as other people overseas.

Senator METZENBAUM. Do not blame it on the patent laws. We are not doing it with Ford automobiles and we are not doing it with Chevrolets and we are not doing it with General Electric and we are not doing it with TV's.

Mr. ENGMAN. I am saying that that is a hell of a note in this economy, and we would all agree.

Senator METZENBAUM. So do not blame all of those problems on the fact of a patent law. Blame some of it on the industries, and some of the problems have to be in-born.

Mr. ENGMAN. No one says there is only one cause for anything, and I know that you and I agree on that, Senator. The unfortunate thing is that in this area the patent incentive for new medicines is half that for other products.

Senator METZENBAUM. But you will also agree that the pharmaceutical industry has gained a 25-percent tax investment credit—a special consideration that other segments of industry do not get. You will agree that many pharmaceutical companies found a tax haven by taking their operations down to Puerto Rico—in the country, but not actually on the mainland. That was a special kind of thing that they did more than anybody else.

The question is, how much more do we have to do for the industry, and why should we be doing anything in view of the fact that their profits are running at an all-time high at the present time?

Mr. ENGMAN. Puerto Rico is not really an issue here, but let me just say one thing. This industry pays an effective rate of taxes, irrespective of the so-called breaks in Puerto Rico or wherever else, of over 35 percent. Pharmaceutical firms are among a handful of industries with the highest corporate effective tax rate in the United States. So I do not think that we have to worry about so-called tax breaks.

But let me talk about tax credits for enhanced R&D because I think it is a good issue. We are not asking for anything extra—those tax credits have been approved to apply across the board to all industries for all kinds of products.

What we are saying is that the patent incentives for new medicines should not be less than the incentives for creating other products.

What we are trying to do is to restore a competitive market system. I might make one other side comment, about the R&D tax credits. The tax credits actually help enable research and development of medicines that otherwise would not even be able to make it on their own.

So I would suggest that we look at this policy question from the point of view of how do we remove the inequities that now exist in the patent incentive system that are skewed against the development of new medicines and new cures for our old people.

Senator METZENBAUM. Mr. Engman, you know, before the tax law took effect, return on equity in pharmaceuticals was not good; it was magnificent: 32 percent; 21.3; 9.9, not very good; 20.6; 20.7; 23.6; 25.5; 33.4; 21.7; 19.8. There are some that are lower that I did read, and I want to make that clear. But the fact is that is a pretty good return on equity for any company, and I would say in many respects far better than most other industries in this country.

I have had enough, Mr. Chairman. I thank you, sir.

Mr. ENGMAN. I hope, Senator, I never have to apologize for representing an industry that is able to make a profit.

Senator METZENBAUM. You do not have to, but do not ask for special privilege.

Mr. ENGMAN. I am not asking for special privilege. I am asking that we be given the same incentives as everyone else has. And the real issue here is, how do we equalize the incentives so that they are the same for research and development for new medicines as they are for producing a new mousetrap.

Senator METZENBAUM. Thank you, Mr. Chairman.

Senator MATHIAS. Senator Metzenbaum, only you can judge whether you have had enough. [Laughter.]

Mr. ENGMAN. Senator Metzenbaum will never have enough, but I love him for it.

Senator METZENBAUM. Barry Goldwater and I have had enough.

Senator MATHIAS. But the clock tells me that collectively we have had too much, because we are in trouble now on our schedule.

Mr. ENGMAN. Well, I want to apologize, Mr. Chairman, for taking too much time, but I want to thank you for the opportunity of being here.

[The prepared statement of Mr. Haddad and an additional submission for the record follow:]

Testimony by

William F. Haddad

President,
Generic Pharmaceutical Industry Association

My name is William F. Haddad. I am President of the Generic Pharmaceutical Industry Association and President of the GPIA Institute of Rare and Orphan Drugs.

My interest in the pharmaceutical industry began in the United States Senate when I was a special assistant to the late Senator Estes Kefauver. The identical arguments we hear today were made in the fifties when the Senator tried to lower drug prices and attempted to pry fact from fiction. The major pharmaceutical companies argued if they were not allowed to do as they pleased, research would decline and innovation would disappear.

They used the same arguments against Senator Russell Long in the sixties when he attempted to probe the tetracycline cartel and they were used against Senator Gaylord Nelson in the seventies when he attempted to probe the pharmaceutical industry's unique ability to thwart competition.

Today the PMA comes before you to request a multi-billion dollar concession--to be financed in large measure by the elderly, the chronically ill, the middle-income family with growing children, the states, and the federal government--yet PMA refuses to release for Congressional review data in their sole control which would resolve the issue: has patent life been eroded by excessive government intervention?

When Congressman Gore sought the information, he was told by PMA's counsel that the data would only confuse the Congress. Time was when those would have been famous last words.

Patent extension--succinctly defined--is a continued monopoly on an essential product for up to seven years with a product price established without regard to competition. The consumer, the patient, has no alternative but to pay the monopolistic price or

be deprived of the drug. We already know from studies of the elderly that many cannot now afford to purchase prescribed drugs. Patent extension would intensify that problem for the elderly and for all Americans who pay for their own prescriptions. It behooves us then to move forward with full facts before we legislate another fiscal burden on consumers and governments.

This inquiry also reminds me of the six blind men trying to visualize through touch what an elephant looks like. When you consider patent extension by itself, it is analogous to the blind man who touches the tail of the elephant and concludes that it must be small, like a mouse, because its tail is so short.

Patent extension is the tail of the problem.

Are you aware, for example, that perpetual patent extension already exists for almost every drug which came into the market after 1962? These drugs are legally off patent and legally subject to competition. But there is no competition because the Food and Drug Administration has failed to promulgate procedures to approve competing drugs. Any reasonable man would ask: "How is it possible?"

Are you aware that after a drug patent expires, the originating company maintains an eighty percent consumer market share and a ninety percent hospital share although the identical generic can be purchased at a fraction of the cost of the trade-name product? Would it be reasonable to ask, if this is true, what is patent extension all about?

Patent extension would appear to be about competitive bidding. On the day a patent ends, and generic competition is possible, one-third of the entire prescription drug market is subjected to competitive bidding procedures. The product, which is offered to consumers at eight dollars under its brand name and one dollar under its generic name, is now offered under competitive bid for a dollar to the Defense Department, the Veterans Administration, HHS, state governments and public and private hospitals. Either the branded product drops its price to the dollar level or it loses the bid. Under patent extension this process would be delayed

for up to seven years. The federal and state governments, now seeking to reduce medical costs, would be blocked from the rewards of competition.

Finally, are you aware that federal and state efforts to reduce the cost of off-patent prescription drugs has been torpedoed in Washington? At the Medicaid directors conference in Nashville last month, the government reported prescription drugs were the only uncapped cost in the Medicaid program. Drug prices are rising at three times the inflation rate. Two out of every three doctors who have the option of prescribing the high-priced brand-name product, or the identical lower-priced generic product, prescribe the most costly product because many are not aware of either the cost or the procedures the FDA uses to insure that products are identical. The generic companies are prohibited from advertising that their products are approved by the FDA and efforts to change this restriction have been blocked at OMB. The federal publication which informed doctors of the variances in the cost for trade-name and generic drugs has been cancelled. And Secretary Weinberger's Maximum Allowable Cost Plan, which sets a maximum reimbursement price for certain drugs, is under attack and may be abandoned.

For the generic industry, patent extension is only part of the overall problem. As our market share increases, political--not scientific or marketing barriers--block our growth. I hope you will view patent extension in the larger framework of an all-out attack to end generic competition.

The PMA argues that patent life has been "cut in half" by the Kefauver-Harris amendments of 1962 which required that drugs not only be safe, but effective. That has resulted, they claim, in reduced expenditures for research and in declining innovation.

None of those arguments is accurate.

The Office of Technology Assessment, in its report on patent extension, said patent life on eight major drugs in 1980 averaged 15.1 years.

A GPIA study of the major drugs on the market in 1980--a market share of $1.7 billion dollars--revealed an average exclusive market life of 18.75 years!

PMA subsequently argued that patent life for drugs entering the market in 1980 would be 7.5 years. Congressman Gore convinced PMA to submit this data to OTA for analysis. OTA concluded that government regulation had not eroded patent life.

When Congressman Gore asked PMA to provide the Congress with similar data for the years 1962 to 1982, PMA refused, arguing that it would only confuse the Congress.

With that data in hand, there would be no need for these hearings. A high school mathematician could determine if patent life had eroded, and if it had, was the government or the company at fault.

What puzzles me is why the Congress, which seeks to legislate this multi-billion dollar concession for the most consistently successful industry in America, would turn a deaf ear to pleas that the PMA provide the backup for their conclusions?

At the Gore hearings, it was learned that the requested data was locked in a computer in Rochester and could be quickly made available if the PMA companies gave their approval.

Congressman Gore was also successful in obtaining under oath the admissions that neither research nor innovation had declined between 1962 and 1982.

We are now in what The New York Times calls the Golden Age of Pharmaceutical Innovation and more new drugs were approved by FDA in the last two years than in any of the years since the Kefauver-Harris amendments were enacted. There has been no decline in innovation.

In 1982, the National Science Foundation took note of the dramatic 20% yearly increase in research expenditures by pharmaceutical companies and attributed this to the 25 percent R&D Investment Tax Credit approved by the Congress in 1981. The Investment Tax Credit was approved after patent extension legislation was introduced. We submit this subsidy eliminates the need for a special break for the pharmaceutical industry.

If you are stripped of the arguments that patent life has not been cut in half--or at the very least, the case is yet to be made--and innovation and research have not declined, what is left of the PMA argument?

I submit, not much.

The Gore hearings also explored, using OTA, the multitude of reasons for patent delay. Typically, in this industry, an early patent will be sought for an extremely broad class of chemical compounds based on raw, early research indications. Since the drug product may not even have been discovered at this point, this procedure mandates a long interval between awarding of the patent and the start of the FDA process. As time refines discoveries, some patents are abandoned and new patents sought, a process known as "continuation-in-part" applications. A company can either expedite or delay the issue date of a patent according to its business or research needs.

OTA discovered in the data PMA released to OTA on the 1980 drug approvals that some companies waited up to a decade before moving from the patent to the FDA process. Why did the companies wait? And should they be entitled to patent extension for their own actions? (I am including for the record the OTA findings presented to Congressman Gore.)

During the IND process companies can either expedite or delay their process. Sometimes FDA has serious, valid questions about the earlier tests and requests additional information. We have heard that for some products incomplete reports are filed in order to string out the process. When two drugs come on line at the same time, a company may decide to pursue one and delay the other for a variety of business reasons.

Also, you can patent either the broad spectrum of your finding or the narrow finding itself; you can patent the product; you can patent the process; you can patent the use. For some specifics, let's review what Patent Attorney Alfred B. Engelberg discovered when he researched the patents for Valium and Keflex, two widely sold drugs:

"...In the case of Valium, the original patent application was filed in December 1959 and disclosed the specific chemical entity Diazepam which is sold under the Valium trademark. But the patent application also contained broad claims to a large class of compounds having a structure similar to Valium, although many of those compounds had never actually been produced or tested. In May 1960, the Patent Examiner indicated that he was willing to grant a patent which specifically covered Valium, but was unwilling to grant the claims to the broader class of compounds because of the lack of specific disclosure to support them. Rather than accept a patent which covered the specific commercial compound, Roche abandoned the original patent application in favor of a series of continuation-in-part applications which were intended to supplement the original disclosure and support the broader claims. The procedures relating to these matters consumed approximately eight years, and no patent covering Valium was issued in the United States until 1968. Since Valium had actually been discovered before the initial patent application was filed, the clinical research occurred wholly within the period when the patent application was pending and NDA approval to market Valium was granted in 1963. Accordingly, Roche will have enjoyed twenty-two years of commercial monopoly by the time its its patent expires in 1985. The laws of the United States are far more generous in this regard than the laws of other countries. In most industrial nations, the patent monopoly expires twenty years after the patent application is filed, so that any procedural delays in obtaining issuance of the patent cannot benefit the patentee. It is for that reason that the Valium patent expired in much of the rest of the world in 1980.

"The history of Keflex, generically known as cephalexin monohydrate, demonstrates a different set of circumstances affecting the length of a commercial monopoly, and undermines the assertion that the expiration of a single patent eliminates the commercial monopoly. The initial patent application describing a large new class of cephalosporin antibiotic compositions was filed by Lilly in 1962, but only the method of making those products was actually claimed in the initial patent application. The first patent application actually claiming those products was not filed until 1966, shortly before the method patent was granted. That product patent application contained a hypothetical chemical formula, which was broad enough to cover the compound know as cephalexin, although that compound had not yet been discovered. Cephalexin monohydrate, the commercial form of Keflex, was not actually discovered until a later date, while the patent application which broadly covered (but did not disclose) cephalexin was still pending in the Patent Office. Lilly then filed a new patent application claiming cephalexin monohydrate as a separate invention. The broad patent covering cephalexin was granted in 1970, and the specific patent covering cephalexin monohydrate issued in 1972. When the cephalexin patent expires in 1987, no one will be free to market Keflex because the second patent which specifically covers that compound does not expire until 1989. In short, Lilly will enjoy eighteen years of commercial monopoly on a product which was not even discovered until after the initial patent application covering that product was filed."

Should these drugs be awarded patent extension?

I am enclosing Mr. Engelberg's full statement, called an "over-reaching solution," for the record.

Permit me, in closing, to make these points:

PMA has pinpointed the FDA review process as the cause for the alleged delay and consequent alleged loss of patent life.

Commissioner Hayes has testified that he has instituted an expedited review for significant new drugs. He has explained to the Congress that only a lack of resources has prevented an expansion of that process.

Wouldn't it be more economical and logical to expedite the review process rather than provide billions of dollars of windfall profits to the incredibly profitable drug industry? It sounds like we are walking all the way around the barn to get into the opened front door, or buying the Brooklyn Bridge to go from Manhattan to Brooklyn.

Drugs sold during the extended patent period would be almost pure profit. Using the 12 cents of a dollar rule of thumb for reinvestment, wouldn't it be more prudent and conservative of the people's resources to apply this multi-billion dollar tax break more wisely? Why pay a dollar for twelve cents of research? Especially when the money comes from those least able to pay? And what assurances do we have that the monies will not go into increased marketing and advertising, or the multi-billion dollar television campaign the industry is planning to sell its pharmaceuticals? And what assurances do we have that the monies will not go into investment in unrelated businesses?

Down South, where I come from, there is a conservative legislative tenet which argues: "If it ain't broke, don't fix it."

The patent law is not broke and it is not in need of fixing for the pharmaceutical industry.

We hope you will join with us in concluding that patent extension is an expensive solution for a nonexistent problem.

Thank you.

PREPARED STATEMENT OF THE GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

PATENT EXTENSION: AN EXPENSIVE SOLUTION TO A NONEXISTENT PROBLEM

The New York Times: "(Patent extension) is unjustified, unsuited to the stated purpose of increasing research and offensive to the basic principle of a free economy."

Patent extension has been called "an expensive solution to a nonexistent problem" and characterized in a lead editorial in the New York Times as "unjustified, unsuited to the stated purpose of increasing research and offensive to the basic principle of a free economy."[1]

Strong words made more significant because, at first, newspapers throughout the country supported the concept of patent extension, but as Congress began to unravel fiction from fact, many newspapers had second thoughts. What had been presented as a matter of equity now appeared as a multi-billion windfall profit for an industry which adamantly refused to allow Congress and the media to review the data on which they based their conclusions. The Pharmaceutical Manufacturers Association maintained the data would only confuse the Congress.[2]

The PMA argues patent life has been "cut in half" by government regulations, resulting in lowered industry profits, less monies for research and, as a direct consequence, a decline in innovation.

The fact developed in congressional hearings did not support these conclusions.

PATENT LIFE HAS NOT ERODED

An independent study for the Congress concluded there is "little correlation between the length of the regulatory period and the effective patent term," and found a "statistically significant correlation" between loss of patent life and a company's delay in filing for testing with the Food and Drug Administration.[3]

For example, the new drug Meclomen, which the PMA claims has less than four years of monopoly life, was first disclosed in a 1961 patent application, but the Parke-Davis application to begin clinical testing was not filed until 1974. This delay of 13 years was obviously not caused by government regulation, but by a corporate decision to delay development of Meclomen.

The Office of Technology Assessment reported that effective market life—the exclusive marketing period between final FDA approval and competition—averaged 15.1 years for the top eight drugs in the marketplace.

The Generic Pharmaceutical Industry Association in an unchallenged study concluded that exclusive market life for the major drugs on the market in 1980 was 18.75 years.[4]

---

[1] See attachment A on p. 87.

[2] Testimony of Peter Hutt, PMA Counsel, before the Subcommittee on Investigations and Oversight, 97th Congress, second session, February 4, 1982 [No. 155], p. 123.

[3] *Ibid.* Statement of Donna Valtri, OTA, p. 2 (Times).

[4] 18.75 YEARS OF MONOPOLY MARKETING—TOP-RANKING PATENTED PRESCRIPTION DRUGS

[Dollars in millions]

Drug product	1982 [1] rank	1982 Sales [2]	NDA approval	Patent expiration	Years market protected
Tagamet (Cimetidine)	7	$393	1977	1993	16
Valium (Diazepam)	4	219	1963	1985	22
Inderal (Propranolol)	1	247	1967	1984	17
Aldomet (Methyldopa)	11	152	1962	1984	22
Keflex (Cephalexin)	10	164	1971	1987	16
Clinoril (Sulindac)	35	120	1978	1989	11
Indocin (Indomethacin)	24	88	1965	1981	[3] 16+
Naprosyn (Naproxen)	21	128	1976	1989	13
Aldoril (Methyldopa with Hydrochlorothiazide)	49	64	1962	1984	22
Diabinese (Chlorpropamide)	28	102	1958	1984	26
Mellaril (Thioridazine)	45	65	1959	1983	24
Zyloprim (Allopurinal)	44	38	1966	1986	20

[1] The top 200 drugs of 1982, "American Druggist," February 1983.

[2] IMS sales data.

[3] No generic equivalents on the market.

Note.—Average years of market protection: 18.75. Total sales vol., 1980: $1,780,000,000.

Patent law provides for 17 years of protection.

The longer patent life results from what the New York Times called "evergreening" of patents. [See attachment A, p. 87.] Three patents are possible on each product: the product, process and use patents; and it is through the manipulation of these patents that exclusive market life is extended for more than 20 years on some major drugs. [Cf. ftn. 4, p. 83.]

When a drug goes off patent, the drug company marketing that product continues to maintain an 80-percent share of the consumer market, despite competition, and a 90-percent share of the hospital market. These market shares are a direct consequence of the exclusive marketing period.

For drugs which entered the market after 1962 patent life continues indefinitely. The Food and Drug Administration has failed to develop a procedure for approval of off-patent, post-1962 drugs extending the monopolies for these products and keeping drug prices high for all Americans. If congressional relief is needed, it is to provide for competition for off-patent post-1962 drugs.

RESEARCH AND INNOVATION HAVE NOT DECLINED

Under oath at a Congressional hearing chaired by Congressman Albert Gore of Tennessee, the PMA spokesperson conceded that neither research nor innovation had declined since 1962. [See ftn. 2 on p. 83.]

The PMA pinpoints the Kefauver-Harris amendments as the cause of the lengthened FDA procedures which erode patent life. In 1962, following the Thalidomide tragedy in the United Kingdom, Congress enacted the Kefauver-Harris amendments to the Food, Drug and Cosmetics Act mandating drugs not only be safe, but effective. All pre-1962 drugs were rested for effectiveness and all post-1962 drugs are required to be both safe and effective.

OTA reported that between 1963 and 1971 FDA approved 136 New Chemical Entities, the barometer for innovation. In the next 8-year period, 1972–1980, FDA approved 175 new chemical entities.

The eighties have been called "the golden age of pharmaceutical innovation," and the number of new drugs coming into the market support that description. In 1981, 27 new drugs were approved, and in 1982, 28 drugs were approved, the highest numbers of drugs approved in a single year since the Kefauver-Harris amendments were enacted.

Pharmaceutical research expeditures, in real dollars, have steadily increased over the last 20 years. Further, Congress has already recognized the need to stimulate all American innovation, and in 1982, after patent extension bills were introduced, Congress authorized a new 25-percent tax credit to encourage research investment.

The National Science Foundation, in September 1982, cited the tax credit as the cause for the spectacular 20-percent per year growth in drug industry spending for research and development.[5]

Perhaps more significant is the NSF's look at the future: "There is evidence that American drug companies are not only expanding their current R&D expenditures but are also making commitments to building new facilities and expanding existing ones, indicating that drug-related research and development is likely to continue to grow rapidly in the near future." [See attachment B, p. 88.]

Profits for the pharmaceutical industry have always outpaced other segments of the industry, usually by a two-to-one ratio. The industry's profits are also virtually recession proof. Business Week reported on January 17, 1983 that "the pharmaceutical industry is a sure bet as a standout performer in 1983. Its sales this year could increase 20 percent to $20 billion; its profits, despite continuing losses in currency translations, could grow 15 percent to $3.5 billion." Business Week went on to report the industry is rapidly increasing its R&D expenditures.

PMA'S REFUSAL TO REVEAL DATA

The House Investigations and Oversight Committee's request for additional patent data that would prove or disprove industry claims of shortened monopoly life was refused by counsel for the PMA on the grounds that this essential information would be "too much work," and that it would only "confuse" the Congress, and that it is "irrelevant" anyway.

Witnesses at the hearing pinpointed the location of the data which Congress requested. The information is computerized at the University of Rochester and only needs PMA approval to be released. The data will reveal when a patent approval

[5] See attachment B on p. 88.

was issued and the date on which the company requested an investigatory approval (IND), the first step in the governmental process. The data will also reveal what subsequent patents have extended monopoly marketing rights. Only when the PMA makes that data available can a professional opinion be rendered on the PMA contention that patent life has been cut in half by government regulations.

It is not very often Congress is stonewalled in its efforts to obtain information on legislation which will cost consumers and government billions of dollars and eliminate competition in a free-enterprise economy.

PATENT LAW AND TRADITION

The OTA reported to Congress that few inventions enjoy a full 17 years of market exclusivity "because patents are obtained before products are ready to be marketed." A study for the Senate Anti-Trust Committee concluded it took innovators of 35 key inventions 11.6 years to bring their inventions from discovery to market.

Further, Congress recognized in 1871 that inventors would use some of the newly established 17-year patent term for developing and marketing their products and would therefore realize far less than 17 years protection in the market place.

During the congressional debate of April 20, 1871, Congressman Orestes Cleveland of New Jersey noted that it often takes 12 years before an inventor is able to succeed in "establishing his article, in demonstrating its value, and in inducing capitalists to take hold of it."

The 41st Congress was also very explicit that the 17-year term could not be extended.

By these standards, and the law itself, pharmaceutical inventors do better than other innovators. OTA reported an exclusive market life of 15.1 years for the eight best-selling drugs, and GPIA has documented an exclusive market life of 18.5 years for the major drugs on the market in 1980.

QUESTIONABLE DATA AND NON-EXISTENT ORGANIZATIONS

The widely-cited data concluding that patent life has been cut in half originates from an academic institute which is subsidized by the pharmaceutical industry, a fact which was not revealed either to the media or to Congress.

The survey, at the time it was reported, had not been concluded. Using University stationery, the investigators, who are also privately subsidized by the drug industry, wrote to Members of Congress arguing the case for patent extension, a violation of scientific protocol.

During last year's debate on patent extension, two organizations, one claiming to represent the elderly and the other generic manufacturers, wrote and wired the Congress supporting the legislation. Those communications were fraudulent.

Some data presented to the Congress in support of patent extension is also questionable. One chart used in congressional testimony charts innovation from 1950 through 1982 and notes a sharp decline in innovation.

What the chart fails to note is that in 1962, after the Kefauver-Harris amendments requiring that drugs be effective, there was a sharp decline in FDA approvals. Simply stated, ineffective drugs were no longer allowed into the marketplace. Since 1962, however, innovation has not declined.

PATENT EXTENSION FOR LICENSED PRODUCTS

Many drugs licensed for sale in the U.S. are discovered overseas. Under the proposed legislation, these licensed products, for which the U.S. companies conduct no basic research, would be eligible for up to seven years of additional patent life.

PROSPECTIVITY

The proposed legislation would allow extended patent life for already-developed drugs, a proposal that House sponsors of the legislation rejected.

The proposed legislation would also permit extension of patent life for the period prior to government review, another provision rejected by the House sponsors of patent extension. Many newspapers noted all research prior to the new drug application, the NDA, would be necessary for insurance requirements.

The proposed legislation also fails to provide for a verification procedure to sort out which delays are caused by government actions and those created by corporate decisions or errors.

When a drug patent ends, and a generic can compete, competitive bids for the product by the Defense Department, Veterans Administration, HHS, the states and the public and private hospitals instantly drop to the price of the generic competi-

tion, offering the government huge savings. Patent extension would eliminate this competition for up to seven years and dramatically increase the cost of Medicaid.

ORPHAN DRUG LEGISLATION

In the last Congress, legislation to provide patent extension and tax credits for orphan or rare drugs was originally opposed by the PMA and supported by the generic manufacturers. This legislation allows the research-intensive companies to seek solutions for rare diseases using a 73 percent government subsidy. (PMA later reversed its opposition to the legislation.)

The Generic Pharmaceutical Industry Association, without government incentives, established the Institute for Rare and Orphan Drugs to demonstrate what could be accomplished by industry and today the GPIA Institute is the leading underwriter for rare and orphan drugs.

WHO IS HURT BY PATENT EXTENSION?

Most severely impacted by patent extension are the elderly and the government.

The day a patent ends, and competition is permitted, prices drop dramatically. A GPIA survey in 1982 noted that trade-name products which are sold for $8 under their trade name, market for $1 under their generic name. Both products are certified as identical by the FDA.

The American Association of Retired Persons reported that "* * * some 70 to 75 percent of drug misuse among the elderly is due to under-utilization, most often because they cannot afford the medicine that has been prescribed." Couple that statement to the fact that drug prices increased last year at three time the rate of inflation and were called the "last uncapped cost in Medicaid."

Patent extension wold maintain the high prices in a monopoly market for up to seven additional years.

Some 80 percent of the U.S. drug bill is paid by American subsidy. American consumers will be subsidizing the pharmaceutical companies if patent extension is enacted.

Most severely and immediately impacted, however, are the government and the public and private hospitals which are required to use the competitive bid process to purchase pharmaceuticals. These sales account for roughly one-third of the market.

In most states the finite dollars available for Medicaid, coupled with the high-priced sole-source drugs, has already resulted in a reduced number of drugs available to the poor and the elderly. This process would be accelerated by patent extension. Drugs which would cost $1 would now cost $8 for up to an additional seven years.

WHERE WILL PATENT EXTENSION PROFITS GO?

Unlike the provisions in the tax credit legislation, there are no requirements that profits from patent extension be reinvested in U.S.-based research.

In recent months, the pharmaceutical industry has embarked on a massive advertising campaign and has made no secret of its plans to advertise prescription products on national television. Previous campaigns were confined to medical publications. Anticipated profits from patent extension will support a campaign which is vigorously opposed by many doctors who believes this technique of advertising brand names will put undue pressure on the independent practice of medicine.

In the past, Congressional inquiries have produced evidence that the pharmaceutical industry spends from six to nine times as much on advertising, detailing and marketing as it does on research. Coupled to that criticism was the argument that much of the industry's research expenditures were directed to the larger drug markets, aided applied research rather than basic research, and favored combinations of already existing products rather than new products.

If research expenditures are lagging, as PMA claims, why not dip into the advertising budget rather than the consumer's pocketbook?

DRUG DEVELOPMENT COSTS

The pharmaceutical industry has consistently refused to reveal the cost of drug development, preferring to rely on an academic study which estimated drug development costs at $57 million. Based on inflation, the PMA now reports the cost of a drug's development at $87 million, but refuses to make public the back-up data.

The $57 million study was questioned at an OTA hearing. Here's what developed: Not all companies which were requested to participate in the study did participate; not all drugs from the participating companies were included in the research, only

the drugs the company decided to provide the researcher; none of the information provided the researcher could be provided either to the government or other independent researchers due to company stipulations. Once again, the industry produced a widely disseminated self-serving survey which is accepted as fact without proof and with data withheld when congressional or independent verification is requested.

The courts, however, did probe the cost of drug development. In a judicial statement of facts in the Eli Lilly vs. Premo case, the following was reported:

"From 1958 to 1977, Eli Lilly invested approximately $10 million in the research and development of cephalixin.

"In addition, during the first two years of distribution, Eli Lilly expended approximately $12.3 million on a variety of activities designed to promote the prescribing by physicians of cephalexin."

Keflex—the trade name of cephalexin—is protected by patent in the marketplace for 16 years.

The rule of thumb in the pharmaceutical industry is that a successful product recovers all its expenses, and the expenses of all "dry holes" in the first two to three years in the marketplace, and the prescription drug price is established accordingly. The prevailing theory in the pharmaceutical industry is that it costs approximately $12 million to develop a new drug.

Efforts by government purchasers of pharmaceuticals to inspect the industry records of indirect costs, including those for research, development and marketing, have been successfully opposed by the pharmaceutical industry.

So, once again, Congress is thwarted from probing the truth behind the skewed allegations of self-serving pharmaceutical surveys.

WHO OPPOSES PATENT EXTENSION?

Patent extension is opposed by the elderly, represented by the American Association of Retired Persons and the National Council of Senior Citizens; by every major consumer organization, the AFL–CIO and trade unions throughout the country, by states and the Generic Pharmaceutical Industry Association which represents more than 85 percent of generic manufacturing in this country.

CONCLUSION

PMA has failed to produce the necessary evidence that patent life has eroded because of government regulation. The current evergreening of patents offers an exclusive market life for pharmaceuticals beyond the 17 years now allowed by law and far longer than patent protection for other innovations.

Sworn testimony reveals neither research expenditures nor innovation have declined because of the alleged shortened patent life.

If PMA wants the Congress to act it must respond to Congressional demands for the data which PMA refuses to release, data which could resolve the debate on professional rather than on political grounds.

Congress has already provided relief for all research when it legislated the 25 percent investment tax credit in 1981.

Patent extension would require the elderly, consumers, the states and the federal government to subsidize a multi-billion windfall to one of the nation's most consistently profitable industries.

Patent extension is an expensive solution to a non-existent problem.

[ATTACHMENT A]

[From the New York Times, Aug. 7, 1982]

AN UNWARRANTED PATENT STRETCH

The pharmaceutical industry is about to receive an extraordinary favor from Congress: the right to extend the patent protection of new drugs up to seven years beyond the conventional period of 17. Congress has let itself be persuaded, after a hasty review, that the extension is fair and will foster innovation. But the drug industry's case is dubious.

Its chief premise is that extension will restore the time unfairly lost from patent life by having to prove to the Government that new drugs are safe and effective. But the testing of drugs in animal and clinical trials is something that any responsible company would wish to do anyway.

Besides, the complaints gloss over the common practice of "evergreening"—filing a patent application early, so as to beat any rival, but then filing new applications

that modify or extend the original to postpone the time at which patent life actually starts.

For example, the original patent for the tranquilizer Valium was first filed in 1959 and gained the Food and Drug Administration's market approval in 1963. But because of a series of renewed applications, as well as a rival claim, the patent was not issued until 1968. When it expires in 1985, the drug will have enjoyed 22 years of protection.

The eight best-selling drugs in the United States in 1980 enjoyed an exceedingly healthy average patent life of 15.1 years, according to statistics kept at the Office of Technology Assessment. Even when a brand-name drug comes off patent, companies can still protect its market share by advertising; one study of off-patent drugs showed that half retained a 97 percent market share against companies selling the identical chemical under different names.

The industry contends that effective patent life-time has been dropping, from 14 years for pre-1965 patents to 10 years or less for those now being issued. But the law did not intend to guarantee every inventor a clear 17 years of market monopoly. Many inventions, not just drugs, enjoy less patent protection because of obstacles on the path to market. The drug companies complain that Government delays hold them back. But the bills that have passed both Senate and House committees grant an extension that goes far beyond any delay attributable to Government review.

The companies also contend that reduced patent life has discouraged investment in research and development. But figures from the technology assessment office show that the industry's investment in R&D has increased every year from 1965 to 1978, and has remained a strikingly constant percentage of sales. There is no proof that the windfall profits from a patent extension would in fact be plowed back into research. Even if research were in decline, Congress has many other means, like tax incentives, to reverse it.

The pharmaceutical industry is efficient, profitable and healthy. It has no demonstrable need for any special break. The patent system as a whole may need reform, but that is a different issue. Monopoly rights should not be doled out to anyone with a hard-luck story, as Congress seems to believe. The proposed extension is unjustified, unsuited to the stated purpose of increasing research and offensive to the basic principle of a free economy.

[ATTACHMENT B]

[From National Science Foundation, Washington, D.C., Sept. 9, 1982]

COMPANIES PLAN R&D EXPENDITURE INCREASES FOR 1983: GROWTH RATE DOWN

This report is based on mail responses to a National Science Foundation (NSF) inquiry to the NSF Industrial Panel on Science and Technology, and interviews with R&D officials in the major R&D performing industries. Of the 90 companies contacted during April/June 1982, replies were received from 75, including 14 of the top 15 R&D-spending companies in the United States as identified by R&D expenditures reported in 10-K submissions to the U.S. Securities and Exchange Commission. The 75 responding companies account for approximately 60 percent of all company-funded R&D expenditures. The data and comments expressed in this Highlights are solely those of the R&D officials of responding companies. The role of NSF in this presentation is to summarize and publish these views.

HIGHLIGHTS

Total company-funded expenditures for research and development in the United States are estimated to be $37 billion in 1982, an increase of about 10 percent over 1981. Most company R&D officials are currently anticipating a somewhat lower rate of growth in research and development for 1983, resulting in an estimated overall increase of 8 percent in company-funded R&D activities over 1982.

Within the R&D organization of many companies, the R&D tax credit was not cited as an important factor in planning corporate R&D budget levels. There is, however, some indication that companies will seek out and report every expenditure that falls within the 1981 Economic Recovery Tax Act's definitions. To reap full tax benefits, some firms' accountants plan a closer look at what is classified as research and development to ensure that appropriate technical improvements carried out in manufacturing units are included. This may increase R&D expenditures reported by companies for 1982 and 1983.

Limiting factors behind these overall R&D expenditure growth rates are economic uncertainty, lower profits, and high interest rates that thave persisted through mid-1982. Most R&D officials commented that current economic conditions make it extremely difficult to project company R&D spending for 1983 at this time; therefore these 1983 estimates are subject to considerable variation.

While R&D spending is increasing at a somewhat lower rate in 1982 than in recent years. R&D budgets are doing well compared to other company departments which are being cut back during the current tight financial situation. Reasons cited include the increased awareness by company management of the importance of technological improvements and the favorable tax treatment accorded R&D activities.

The chemicals industry is expected to lead all other major R&D-performing industries in R&D growth during 1982, increasing 17 percent to an estimated $5.7 billion in 1982 and growing an additional 14 percent during 1983. Recent breakthroughs in biochemistry research and the resulting marketing opportunities in new and evolving technologies have affected the entire industry. These developments, plus the Food and Drug Administration's (FDA's) movement toward shortening the time for drug approval have spurred R&D activity. In the drug segment of the industry, research and development is growing at close to 20 percent per year.

INTRODUCTION

In a special survey conducted during April/June 1982, companies estimated the growth in company-funded R&D expenditures over the previous year for 1982 and 1983, noting the factors behind these projected changes.[1] Responses stressed the high level of economic uncertainty that has persisted through mid-1982, forcing companies to review, and in numerous cases to revise, 1982 R&D budgets which were proposed last year when the overall economic outlook was more optimistic. At the present time, lower sales are affecting corporate profits and forcing most firms to cut costs wherever possible, making the forecasting of R&D expenditures for 1983 difficult. Thus, corporate strategies for R&D spending will vary tremendously for 1983, not only by industry, but also by individual companies within an industry.

COMPANY R&D EXPENDITURES IN THE MAJOR R&D PERFORMING INDUSTRIES

Of the six major R&D-performing industries, internally financed R&D expenditures made by companies in the professional and scientific instruments industry showed the highest average annual rate of growth—14.5 percent—between 1970 and 1980. Most of this increase occurred in the second half of the decade. The machinery industry ranked second with an average annual growth rate of 13.5 percent. A tremendous expansion in R&D programs supported by companies in the office, computing, and accounting machine segment led the increase which caused the machinery industry to move up from fourth place in 1970 to second place n 1980 in total company R&D expenditures.

CHEMICALS INDUSTRY

The chemicals industry is expected to exhibit the highest percentage increases in company R&D spending during 1981-83. 17 percent in 1982 and 14 percent in 1983. This upsurge is attributable to several factors. Many companies in the chemicals industry have been increasing expenditures on R&D projects aimed at exploring recent breakthroughs in biology and biochemistry, especially those involving genetic engineering. In addition, many chemical firms are rapidly diversifying into new product areas for their companies, such as agricultural chemicals and pharmaceuticals. Entering these new fields generally requires a substantial initial R&D investment.

Responses from the drug companies were optimistic. Overall R&D spending is expected to increase approximately 20 percent during 1982 and 1983. Recent major medical breakthroughs and marketing opportunities in new and evolving technologies are the principal reasons behind the higher R&D expenditures. In addition, both domestic and foreign competition have stimulated R&D spending by pharmaceutical companies.

---

[1] It is important to recognize that this study focuses on industry's use of its own funds for R&D activities. Thus, it cannot be compared directly with other studies which examine industrial R&D performance by including research and development funded by the Government.

The tax credit for increased R&D expenditures and the movement of the FDA toward shortening the time for drug approval have been positive influences on the decision to increase domestic R&D budgets.

There is evidence that American drug companies are not only expanding their current R&D expenditures but are also making commitments to building new facilities and expanding existing ones, indicating that drug-related research and development is likely to continue to grow rapidly in the near future.

PROFFESSIONAL AND SCIENTIFIC INSTRUMENTS INDUSTRY

This industry is estimated to show a continued high rate of growth in R&D expenditures—15 percent during 1982 and an additional 14 percent the following year to a level of $3.3 billion in 1983. Several reasons were cited repeatedly for the expansion in R&D activity: (1) The rate of obsolescence is increasing and the size of the market is growing; (2) each researcher requires an increasingly wider and more sophisticated array of equipment with which to conduct research and development; (3) the growing health care field is also responsible for the boom in the demand for instruments, especially diagnostic and surgical equipment; and, (4) foreign competition is necessitating a substantial commitment of financial resources to be channeled into R&D activities to develop, perfect, and produce affordable American products to compete in both domestic and world markets.

ELECTRICAL AND COMMUNICATIONS EQUIPMENT INDUSTRY

R&D officials in this industry mentioned shorter product life cycles, increasing technological depth of the industry, and growing competition as key factors in raising company R&D funds 12 percent in 1982. The increase for 1983 is expected to taper slightly to 9 percent for a total of $7.7 billion. The lower increase for 1983 is caused by the current economic uncertainties facing the industry as a whole.

Recent advances in very-large-scale integration (VLSI) and very-high-speed integrated circuit (VHSIC) technologies have presented great possibilities for improved system design, but at the same time have introduced new cost and productibility problems that must be solved by the industry. Research and development in this industry is thus expected to continue to grow rapidly. In addition, the increasing interest in robotics by U.S. manufacturing firms is expected to spur further research both here and in the machinery industry.

MACHINERY INDUSTRY

The estimated rise of 8 percent per year in R&D expenditures in this industry (which includes companies producing office, computing, and accounting machines) to a total of $6.9 billion in 1983 is a composite of different outlooks for various segments of the industry.

Responses from officials in the office, computing, and accounting machine portion of the industry indicate that softened sales currently are having a dampening influence on research and development. The computer industry, however, is striving hard to keep pace with its technological needs.

[From the New York Times, Feb. 4, 1982]

STUDY BLAMES INDUSTRY FOR NEW-DRUG DELAYS

(By Michael deCourcy Hinds)

A congressional study released today blames the pharmaceutical industry, not the Government regulatory process, for significant delays in bringing new drugs to market.

The study is expected to stir controversy over a bill before Congress intended to benfit the pharmaceutical industry by extending drug patent periods.

The drug industry has faulted the long Federal review of new drugs for diminishing the useful life of their product patents and, thereby, discouraging development of innovative drugs. Swayed by this argument, the Senate has passed, and the House of Representatives appears likely to pass, legislation that would extend patents by up to seven years from the current 17-year period.

In releasing the study, Representative Albert Gore Jr., Democrat of Tennessee, said he hoped it would block passage of the bill at least temporarily. If enacted, he said that the immediate impact would be to extend the monopoly control that pharmaceutical companies have over some widely sold drugs, thereby delaying competi-

tion from nearly identical generic drugs, at a cost to consumers of $3 billion to $5 billion in the next seven years.

Although the bill is broadly written, encompassing all inventions subject to Government review, it primarily benefits the pharmaceutical and agricultural chemical industries.

HEARING ON THURSDAY

Representative Gore, who has previously attached the legislation, is chairman of the House Subcommittee on Investigation and Oversight, which will hold a hearing on the bill Thursday. Industry groups will have their first chance at the hearing to respond to the new study.

The study, conducted by the Congressional Office of Technical Assessment, found that the time a drug spent "in the regulatory process was not a significant determinant of effective patent life." The study based this conclusion on an analysis of the 12 drugs approved for sale in 1980.

The study concluded that, had the companies acted more expeditiously, the drugs would have had a sales monopoly for an average of 11.6 years of the 17-year patent life. In contrast, the Pharmaceutical Manufacturers Association, a trade group, had calculated that these same drugs had an effective patent life averaging only 7.5 years as a result of long reviews by the Food and Drug Administration.

The report said the drug companies could have acted more expeditiously by beginning the Government review process sooner. But the report did not attempt to analyze the reasons for the delays by the companies between the time a patent was applied for and a drug was submitted for regulatory review.

Instead, the study concluded that there were strong mathematical correlations between the time "wasted" by the companies and the reduced effective patent life of their products, and little relationship between the length of Government review and the product's effective patent life.

One drug on the list, an acne cream called Meclan, made by Johnson & Johnson, actually had its patent expire two years before the Government approved it for sale. However, James Murray, a spokesman for the company, explained in an interview that the product had been "on the shelf" for many years and that the Government was not at fault.

A DECADE FOR APPROVAL

The drug industry has argued that the Government's ever-increasing vigilance since the 1962 thalidomide tragedy has created a regulatory review process that can take the better part of a decade. While the industry is encouraging the Government to streamline its approval process, the drug makers have also argued that the years a patented drug loses during its premarket review should be restored to the company.

Without the assurance of the customary 17-year patent—in which companies try to recoup their investment and earn a profit—the industry has been doing steadily less research and development over the years, according to Peter B. Hutt, an attorney for the Pharmaceutical Manufacturers Association. Consequently, he said, society is being deprived of more innovative drugs and, with fewer new drugs, consumers pay higher prices for the ones available.

The independent generic drug makers contend that the research-based companies have always been able to protect their market monopoly by periodically patenting new manufacturing processes, improved chemical variations or new uses for the drug, according to Alfred Engelberg, a patent attorney for the Generic Pharmaceutical Industry Association, a trade group that opposes the bill.

The bill, the Patent Restoration Act, passed the Senate by voice vote last year, with the only ripple of dissent coming from Senators Edward M. Kennedy, Democrat of Massachusetts, and Howard M. Metzenbaum, Democrat of Ohio, who issued a joint statement calling for more study of the complex issue. "It is unclear that the drug companies are inadequately funded to perform the necessary research and development," their statement said, noting that the drug industry is usually one of the most profitable in the country.

THE COSTS 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."—Office of Technology Assessment.

"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.

"* * * some 70–75 percent of drug misuse among the elderly is due to under-utilization, most often because they cannot afford the medicine that has been prescribed."—American Association of Retired Persons.

"Longer patents for drugs will result in dramatically higher drug prices, most of which will be paid by individuals who cannot afford such increases."—Congress Watch.

"The proposal to extend beyond the 17-year period of the life of pharmaceutical patents would harm the elderly and disabled and add to the already highly inflationary costs of health insurance protection for many workers such as those in our union."—United Auto Workers.

"At a time when America's senior citizens are facing the prospect of the loss of many federal programs and benefits, it is almost inconceivable that Congress would consider passing legislation which would increase the cost of vital drugs on which older Americans must rely."—National Council of Senior Citizens.

"Approval of this legislation will restrict competition in the pharmaceutical industry, delaying the introduction of low-cost generic drugs and working a particular hardship on the elderly, who pay one-fourth of the nation's drug bill."—Consumer Federation of America.

STATEMENTS ON 1982 PATENT EXTENSION LEGISLATION

SPEAKING OUT AGAINST DRUG PATENT EXTENSION: (H.R. 6444)

Organized labor, consumer groups and organizations representing the nation's elderly urge you to vote AGAINST H.R. 6444. Here's why.

"The proposal to extend beyond the 17-year period of the life of pharmaceutical patents would harm the elderly and disabled and add to the already highly inflationary costs of health insurance protection for many workers such as those in our union."—United Auto Workers.

"At a time when America's senior citizens are facing the prospect of the loss of many federal programs and benefits, it is almost inconceivable that Congress would consider passing legislation which would increase the cost of vital drugs on which older Americans must rely."—National Council of Senior Citizens.

"The Patent Term Restoration Act is designed to benefit only the drug companies and not the users * * *

"The Service Employees International Union encourages you to defeat this legislation. We believe that the legislation fails to address the needs of our members. It takes money from their paychecks that they can ill afford to lose."—Service Employees International Union.

"This bill takes a shot at the poorest, the sickest and the elderly of this country * * *

"The drug companies are doing well enough under the present drug patent laws. My information is that they had the fourth largest profit returns among all the industries in America. They sure as hell don't need a longer term to empty the pockets of the millions of Americans, many of whom only have holes in their prockets at the present time."—Wisconsin State AFL–CIO.

"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.

"Although the Association does not support patent term restoration, it strongly favors the Gore/Waxman/Frank 'look-alike' proposal."—American Association of Retired Persons/National Retired Teachers Association.

"The pharmaceutical industry has not reinvested its huge profits in areas which would benefit disabled and needy consumers and has refused to product sorely needed 'Orphan Drugs' to chronically ill Americans afflicted with rare disorders. We see little reason why they should be granted even larger profits at the expense of all American consumers."—National Coalition for Rare Disorders.

"Do not vote at mark-up this week for a bill whose sole aim is to increase profits at the expense of the sick, the needy and the elderly * * *

"All consumers and particularly senior citizens must look to lower prices in view of the constantly increasing medical costs, particularly represented by the cost of brand names protected by patents. The prescription drug industry is highly profit-

able and should not be further enriched at the expense of the family whose need for life sustaining drugs increases daily."—International Association of Machinists & Aerospace Workers.

"This bill would allow the large drug companies to maintain their monopolies for up to seven years beyond the existing patent term. The bill would prevent completely equivalent, but lower cost, generic pharmaceuticals from coming into the market. The bill would, therefore deprive the sick, the elderly, public and private hospitals of potential high cost savings."—AFSCME.

"This legislation will stifle competition in the drug industry. Additionally the effect of its passage would be to maintain high prices for a wide range of drugs under monopoly control. The negative impact would be felt by the segment of our population least able to bear the cost—the elderly—many of whom are dependent on drug therapy."—New York State Consumer Protection Board.

"Approval of this legislation will restrict competition in the pharmaceutical industry, delaying the introduction of low-cost generic drugs and working a particular hardship on the elderly, who pay one-fourth of the nation's drug bill."—Consumer Federation of America.

"Passage of this bill would lengthen the drug patent period from the current 17 years to 24 years, thus preventing consumers from enjoying the benefit of lower-priced generic alternatives for an additional seven years."—New York City Department of Consumer Affairs.

"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 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 be developed as part of the overall marketing of new drugs."—Public Citizen.

Health Affairs - Spring 1982

PATENT TERM EXTENSION: AN EXPENSIVE AND UNNECESSARY GIVEAWAY

by Albert Gore, Jr.

In recent years, it has become commonplace to blame the national government for virtually all of the problems that afflict our society. In view of the increasing role of government in the past fifty years, this perception is understandable and some of the criticism is justified.

The Reagan administration, however, has taken a more malign view of government as the root-of-all-evil to new extremes, creating an environment in which many industries are emboldened to seek compensation from the government for any impositions, real or imagined. The proposal to extend patent terms for new drugs is a good example of this phenomenon.

Large drug companies, often identified as research-intensive firms, claim that government safety and efficacy regulation is becoming increasingly onerous and is inhibiting the development of new drugs. As compensation, they are asking for an extension of their patent terms. Careful scrutiny of their elaborately constructed arguments, however, indicates that the factual base upon which the arguments are founded is fatally flawed and that the "problem," as they described it, does not really exist.

The inherent tension between free market competition and innovation has long been recognized. Article I, Section 8 of the U.S. Constitution grants the Congress "Power To . . . promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors exclusive Right to their respective writings and discoveries. . . ." The phrase "limited Times" indicates that the authors of the Constitution were concerned about promoting innovation, but not at the expense of precluding competition indefinitely.

Historians of the Congress agree that the seventeen-year term was enacted as a compromise. The Patent Act of 1861 evolved from legislation introduced in the House of Representatives, which specified a fourteen-year term with a conditional extension of seven years, and a

Senate bill, which provided a fixed fourteen-year term. In the years after 1861, a variety of patent extension and modification bills have been introduced, but only in the 97th Congress has the issue been given serious consideration.

The legislation which has been introduced in the 97th Congress would extend the patent term for pharmaceuticals (and a few other products subject to premarket regulatory review, such as agricultural chemicals) by the amount of time consumed in the premarket regulatory review period, up to a maximum of seven years. Enactment of this legislation is of overriding importance to the research-intensive drug firms who claim that they want to increase innovation, but who leave unsaid the fact that they stand to profit enormously from such a change in the patent law.

The relationship between research-intensive and smaller production-intensive or generic firms is strongly adversarial. Large companies view smaller generic competitors as parasitic. Generic manufacturers, on the other hand, believe that large companies seek to inhibit competition by erecting barriers to market entry by other firms.

Industry Profits Are Increasing

Implicit in the large drug companies' argument for patent term extension is the notion that the industry is in distress and thus in need of infusions of capital that would result from higher drug prices. Additional capital, according to the argument, would lead to greater innovation. This cry of distress, however, rings hollow. The Office of Technology Assessment published a thorough report in August, 1981 entitled *Patent-Term Extension and the Pharmaceutical Industry* that is recognized by both sides of the debate as the definitive work on this subject. Although it avoids taking sides, the OTA report is devastating to the large drug companies' arguments. It concludes that:

> Since the 1950's, the U.S. pharmaceutical industry has been considered one of the most profitable of all major manufacturing industries. . . . (T)he industry's after-tax rate of return on stockholder's equity has remained stable at a relatively high level and has exceeded the average after-tax rate of return for all manufacturing.

Actually, the rate of return has increased steadily since 1975.

Clearly then, the "problem" is not that the industry is unable to make enough money. It is doing fabulously well, even as other parts of the economy are withering.

The central argument for patent term extension is that innovation is declining under existing law. There are various measures of innovation, but the two that are most widely used and that are usually cited by the industry are: (1) the amount of spending on research and development,

and (2) the number of new drugs being approved for marketing by the Food and Drug Administration (FDA).

Let us take them one by one, beginning with R&D spending. Is it declining? No, it is increasing in constant dollars year by year. The large drug companies argue that spending for research and development as a percentage of sales is declining. While that contention may be true, the relevant indicator is the trend in R&D spending measured alone when adjusted for inflation. And in truth, real spending for pharmaceutical research and development has increased substantially over time, according to the OTA report. When pinned down under questioning, the Pharmaceutical Manufacturers Association (PMA), represented by Mr. Peter Hutt, did not dispute this point in hearings before the Investigations and Oversight Subcommittee of the Science and Technology Committee.

Obviously, if research and development spending is increasing in real terms, then the public is being asked to remedy a problem that does not exist. By couching their contention in terms of spending as a percentage of sales, however, the large drug companies obscure this straightforward relationship. (Moreover, they often disingenuously contract their argument into the misleading statement, "Real R&D spending has declined.")

All that is demonstrated by the relative trend cited by the PMA is that sales are increasing faster than R&D. It is fallacious to leap from that statement to the conclusion that real spending for R&D is declining. It emphatically is not. *Fortune* magazine, in its 19 October 1981 issue, documents the most recent R&D trend:

> Merck is pouring a colossal $280 million into R&D this year, nearly four times more than ten years ago, while Eli Lilly's $210 million for 1980 was three times more than in 1971. Pfizer's research expenditure, which quintupled from 1970 to 1980, will grow by nearly 16% this year, to around $180 million, while Squibb has boosted spending 84% in the last five years to $91 million.

Furthermore, there are strong indications that the trend toward increased spending for R&D will accelerate in the future. *U.S.News and World Report,* 5 October 1981, noted: "Dramatic advances in biology promise to turn the 1980s into a golden era for new drugs that can treat a wide range of diseases from depression and cancer to arthritis and heart failure." Advances in genetic engineering and better understanding of substances that occur naturally in the body, such as interferon, are creating an unprecedented surge in R&D spending. Add to that the generous new 25 percent tax credit for R&D that is just taking effect and

one must conclude that these companies really have eyes bigger than their stomachs.

There Has Been No Decline In Innovation

Examining the second measure of "innovation," approval for marketing of new chemical entities (NCEs), one is similarly hard-pressed to find any evidence of a decline in innovation. Since the landmark change of 1962, there has been no decline at all.

The PMA, however, in an argument that is even more slippery than their definition of "real R&D spending," argues that the number of NCEs approved for marketing has dropped dramatically "since 1960," and indeed, it has. But again, the drug companies make a forensic leap that is insufficient to clear the factual chasm. This "decline since 1960" is attributed to increasing government regulation. The comparison of 1960 and 1980, however, totally ignores the changes in the Food, Drug, and Cosmetic Law adopted in 1962. These changes instituted the efficacy requirement into new drug testing.

The addition of the efficacy requirement, the result of international incidents such as the Thalidomide tragedy, substantially increased the testing required prior to marketing. The result of the change, one that is supported by the PMA and most health professionals (including the current Commissioner of the Food and Drug Administration, Arthur Hull Hayes, Jr.), was to alter sharply the character of new drugs reaching the market.

The number of NCEs having "little or no therapeutic gain," that is, those drugs that were most susceptible to challenge on the grounds that they were not effective, dropped radically. This reduction has accounted entirely for the reduction of NCEs approved since 1960. For drugs having modest or important therapeutic gain, there has been no downward trend in market approvals since well before the 1962 amendments took effect. In fact, since the 1962 amendments took effect, there has been no downward trend in approvals of NCEs overall. Last year twenty-seven NCEs were approved by the FDA for marketing, the largest number since the 1962 amendments. Surely, the drug companies should not attempt to blame "onerous" government regulation for a reduction in new drug approvals that occurred fully twenty years ago when ineffective new drugs were no longer approved for marketing, particularly when the reduction resulted from a change in the law which they fully support.

It is misleading, therefore, to choose 1960 as the benchmark year from which to make comparisons. If one measures from the beginning of the modern era of drug regulation, the fall of 1962, there has been no decline

whatever. Clearly innovation, as measured by the number of NCEs annually approved for marketing, is not decreasing.

"Effective Patent Life"

To recap briefly, the state of affairs we are asked to "remedy": innovation is not declining, drug company profits are climbing steadily, and the amount spent on R&D is growing in real terms year by year. But wait, there is more. In suggesting that increasing government regulation is reducing innovation, proponents of patent term extension have focused attention on "effective patent life." Effective patent life is defined as the period of patent protection for a drug remaining once the drug is approved by the FDA for marketing. According to patent term extension proponents, the "effective patent life" has been declining, again largely as a result of increased government regulation. They cite an article by Dr. William Wardell and Martin Eisman that concludes that effective patent life declined from 13.6 years to 9.5 years between 1966 and 1979. PMA has concluded that the effective patent life for drugs approved for marketing in 1980 was 7.4 years. The suggested decline is precipitous. Once again, however, one must look much more closely to get the real story.

Since the number of drugs approved for marketing in any single year is relatively small, analysis based on mean averages such as that described above is subject to wild distortion by anomalous examples. The problem is accentuated when an effort is made to measure the simultaneous effect of two largely independent variables. In this case, the time between patent application and IND filing (IND filing is the initiation of the complex regulatory process) is time under the companies' control and is one variable that must be assessed in determining effective patent life. The other variable is the regulatory review period (defined as the time between IND filing and approval for marketing).

The declines in "effective patent life" have been measured by simple averages. Although these averages are useful, they obscure the true relationship between the variables described above. In an effort to avoid these problems, the Office of Technology Assessment evaluated patent and regulatory data for the twelve drugs approved for marketing in 1980, based on data supplied by the PMA.

OTA employed a regression analysis, a simple analytical technique that assessed the effect of the two variables on effective patent life. Both the time under the companies' control and the regulatory period were analyzed for their effect on effective patent life. The results were startling.

Contrary to assumptions previously made by individuals on both sides

of the issue, the government regulatory period was found *not* to be a statistically significant determinant of effective patent life for those drugs. And in contrast, there was a very strong relationship between effective patent life and the time the company waited after filing for a patent to begin the regulatory process.

This finding, if it holds for other years, would end the debate over patent term extension. Not surprisingly, efforts to obtain the critical public patent and regulatory data from the PMA, the best source of the information, have not been successful.

Industry has rejected efforts to obtain this information by the various excuses that it would be "too much work," that it might "confuse" the Congress, and that it is "irrelevant." Unspoken is the PMA's fear that the relationships observed in 1980 would indeed hold for the other years and that their arguments for patent term extension would be irreparably damaged.

The final argument advanced by proponents of patent term extension is that extension is warranted as a matter of equity because the patent system did not envision a significant regulatory period. However, few inventions enjoy a full seventeen years of market protection, and the Congress was fully cognizant of that fact when the balance was struck at such a long period of time. Marketing arrangements and other matters significantly shorten patent protection, even for products that are not regulated by the government. If the patent system is stimulating innovation by protecting profits of the innovator for a sufficient period of time, and clearly this is the case with pharmaceuticals, then the system is working as it was intended to work.

Moreover, the peculiar characteristics of the drug industry maintain a de facto monopoly for top-selling drugs long after the patent has technically expired. Librium, for example, had been off patent for three years in 1979, yet it still commanded 90 percent of the dollar volume in its market, compared with 10 percent for all of its competitors put together. In 1979, the brand name version of Librium was priced nearly sixteen times greater than the cheapest generic competitor. Today, the brand name price is twenty times greater than the cheapest generic competitor. Indisputably, the monopoly position of Librium has not been challenged since the drug went off patent. Nevertheless, the manufacturer has the temerity to join the collective complaints about an erosion of "effective patent life," and ask for more government protection against its pitiful "competition."

Nor is the regulatory process voraciously consuming increasing amounts of time without regard for the implications of that action. The FDA has undertaken efforts to speed the drug approval process. An FDA panel is

reviewing proposals for expediting new drug approvals overall. A new "fast track" has been instituted to assign priority in the review process to drugs with particular therapeutic potential.

The time to be saved from these efforts, however, is relatively small. Estimates of savings range from a few months to a year at most. Any additional shortcuts would undermine essential testing for safety and efficacy. The large drug companies acknowledge this point in admitting that most of the testing required by the FDA would be done even without the regulatory requirements, largely as a result of product liability requirements. Protection from potential lawsuits resulting from use of a drug would lead companies to engage in years of testing even if there were no Food, Drug, and Cosmetic Act and no FDA. Should they be compensated for that time, too?

This point is a telling blow to the large drug companies' argument. For if only a few months to a year of the regulatory period can truly be attributed to government, then it is unfair to other inventors to extend drug patents for a period of testing that would occur independent of any regulatory requirements. Moreover, since the FDA is currently taking measures to wring out some of this excess time, the rationale for patent term extension, misty at best, evaporates.

Existing Avenues For Large Drug Companies

In considering the public policy issue of patent term extension, the implications of the legislation must not be examined in isolation. Major changes in the tax law, particularly the tax credits to encourage increased expenditures for research and development, create an extremely favorable climate for R&D. Yet despite these important developments, the pharmaceutical industry remains adamant in its position that more is needed.

The interest in the industry in maximizing patent protection has long been self-evident. Under existing law, companies already utilize complicated strategies to extend patent life. This end is achieved both prior to the issuance of a patent and through subsequent patents. It is to a drug company's advantage to delay issuance of a patent simply because the seventeen-year clock does not begin to run until a patent issues. If a drug cannot be marketed for several years after discovery due to premarket testing, then the later a patent issues, the longer a drug will be protected from competition.

Patent issuance can be delayed through amendments to a patent application already pending or through dividing a single application into two or more parts. According to drug patent lawyers, these techniques are common practice in pharmaceutical patents.

Patent protection can be prolonged after issuance of an initial product patent by the subsequent issuance of patents governing manufacturing processes and uses. Generic drug companies argue strenuously that these subsequent patents effectively preclude competition long after expiration of the initial patent. The PMA recognizes the value of subsequent patents as well.

Curiously, however, the drug companies do not include mention of these subsequent patents in their calculation of effective patent life. For example, in 1980, if subsequent patents are averaged in, the mean average of effective patent life for drugs approved that year increases 25 percent over PMA's calculation.

Other supporters of the large drug companies maintain that subsequent process and use patents are not effective guards against competition. In this instance, the truth is somewhere between these extremes. In many cases, but not all, subsequent patents do afford extra market protection.

Toward Innovation and Reasonable Pricing

Large drug companies would have the public believe that pharmaceutical innovation and reasonably priced prescription drugs are incompatible social goals. This cynical argument should be rejected as being without merit. When challenged about the anticompetitive implications of patent term extension, these companies hide behind a facade of concern for the public interest.

They say that they are concerned that new lifesaving drugs may not be developed. But real spending for research and development is increasing, the number of new drugs being approved for marketing is not decreasing, and the FDA is expediting its drug approval process. All of this is occurring under existing law. Moreover, profits for drug companies have been increasing from levels already higher than those for most other manufacturing industries in the United States. These facts the companies have chosen to ignore, obscure, or misconstrue. Such actions do not serve the public interest.

Our society can have lifesaving drugs and have them at reasonable prices. Patent term extension would substantially increase prescription drug costs to consumers without any assurances whatever that any of the extra revenue derived would be reinvested in pharmaceutical R&D. Even if historical reinvestment patterns hold, with companies reinvesting either 8.5 or 12 percent of additional revenue (depending on which methodology is used, but both figures remain stable over time), it is evident that the public is getting an unjustifiably low return if it pays one dollar for twelve cents of research.

A far more sensible approach is the already-enacted investment tax credit to stimulate R&D. This change in the tax law provides a far greater degree of certainty that additional revenue will be plowed back into research and development.

After carefully weighing the evidence, one is led to the conclusion that large drug companies are anxious to have patent term extension, not to stimulate new drug development, but to buttress their patent protection during an age of rapid growth in the industry. This growth is occurring without patent term extension. If this legislation is enacted, pharmaceutical profits will be significantly enhanced. The public interest, on the other hand, will suffer. Higher prescription drug costs will limit the availability of these drugs to a growing segment of the population.

If on the other hand the Congress rejects the proposal, then growth in the industry will continue unabated. At the same time, the competitive forces in the economy that work to the advantage of consumers through accountable pricing will ensure greater access to prescription drugs.

Last year, in an atmosphere of complete sympathy and agreement with industry, the Congress passed tax breaks for large corporations, many of which were unwise and potentially devastating to the economy. By maintaining existing patent law, the Congress can avoid a repetition of the error of succumbing to facile and beguiling rhetoric in the face of common sense. The public interest requires us to do better this year.

Health Affairs - Spring 1982

PATENT TERM EXTENSION: AN OVERREACHING SOLUTION TO A NONEXISTENT PROBLEM

by Alfred B. Engelberg

The proponents of extended life for drug patents argue that the "effective patent life" of pharmaceutical composition and use patents has been cut in half due to the additional time now required to comply with government safety and efficacy regulations prior to commercial marketing. They define "effective patent life" as the period of actual commercial exploitation of a patent monopoly and claim that it has been reduced from seventeen to 7.5 years. Since the proposed legislation (S. 255; H.R. 1937) would extend patent life only for a maximum of seven years, they contend that it would provide less than the full return of time to which pharmaceutical innovators are entitled as a matter of equity.

To those who lack a basic understanding of our complex patent system, this argument seems simple and logical, and for that reason it has attracted broad support. In reality, the arguments which have been made in support of patent extension have no reasonable foundation in fact or law; and the extension legislation undermines fundamental principles on which the entire patent system is based for, at least, the following reasons:

1) Effective patent life.

The term "effective patent life" is the creation of those who are promoting patent extension legislation and has no counterpart in patent law or the fundamental philosophy on which the patent system is based. The notion that the seventeen-year patent grant carries with it any guarantee that the patent owner will enjoy seventeen years of commercial exploitation of the patented invention is contrary to that philosophy, as well as to the requirements which must be met to obtain a patent, particularly in the pharmaceutical field.

Alfred B. Engelberg is a partner in the law firm of Amster, Rothstein & Engelberg, New York City and Patent Counsel to the Generic Pharmaceutical Industry Association.

2) Government regulation.

Government regulation is only one of many factors which have an effect on the length of a commercial monopoly, and it is less significant than many others, all of which are largely under the discretion and control of the patent owner. These factors include when the patent application is filed in relation to the state of development of the invention; how long the patent application remains pending in the United States Patent and Trademark Office before a patent is granted; the scope of the patent in relation to the commercial product which it seeks to dominate; the number and type of patents which may be available to cover different aspects of the commercial development; the time at which clinical investigations are commenced in relation to the patent application and issue date; and the pace of commercial development in terms of the time, effort, and money invested to reach the commercial stage. The statistics which have been put forth in support of the proposition that "effective patent life" is now 7.5 years do not tell us which of the foregoing factors actually played a significant role in the net result and make the inaccurate assumption that regulatory delay is the exclusive cause.

3) Equity concept.

The extension legislation in its present form goes far beyond the "equity" concept on which it is being promoted. The application of equitable principles would dictate that any patent extension would be no greater, in either duration or scope, than the delay actually caused by the government. In fact, the legislation would extend the life of a product patent claim for all therapeutic end uses and not merely the end use which is the subject of regulatory review. It would also make it possible to obtain extended patent protection for compositions which were not specifically known or disclosed in the patent, but were covered by broad hypothetical composition claims. This approach will serve to discourage improvements and innovations by third parties which the patent system was designed and intended to encourage. Further, the true length of government-caused delay is, in fact, no greater than the difference between the date on which a reasonably prudent businessman, subject to product liability claims, would commercially release a product and the date on which the government commercially releases the product by approval of a new drug application (NDA). The Senate-passed bill would grant an extension from a time commencing long prior to the first clinical tests in human subjects, thereby rewarding rather than discouraging delay.

Effective Patent Life Is a Nonexistent Concept

The patent system was established to promote the progress of science and the useful arts by encouraging inventors to make early disclosure of their inventions to the public in the belief that such disclosures would prevent wasteful duplication of research. This would stimulate further inventions and improvements which would make the earlier disclosures on which they were based obsolete. The system was primarily designed to benefit society and not to create private fortunes for the owners of patents, although it has always been recognized that some reward is essential as an inducement for the invention disclosure.[1]

The inducement provided by the patent law is not a positive grant of the right to commercial exploitation of the invention for the life of a patent, but rather a negative grant, namely, the right to exclude others from making, using, or selling the invention for a period of seventeen years. Whether or not the patentee derives a commercial benefit from that exclusion is a matter which is totally divorced from the patent system and depends upon a multitude of other factors including the commercial practicality of the invention disclosed in the patent, the state of its development, the existence of a market and, of course, the existence of other laws which determine whether a particular device can be used or sold and, if so, under what conditions.

Until the present controversy concerning patent extension, no one connected with the patent system believed or argued that the grant of a patent created a positive right to exploitation for a fixed period of time. Indeed, the fundamental rules pertaining to what must be disclosed in a patent make it clear that patents are designed to disclose ideas and not necessarily to support the ultimate commercial manifestation of those ideas.

If the basic purpose of the patent system was to convey to the inventor a positive grant of a fixed period of commercial exploitation, a logical requirement of the patent system would be a full disclosure of the commercial embodiment of the invention, and the patent claims would precisely define that commercial monopoly. In contrast, one of the fundamental rules of our patent system prohibits the grant of a patent if the invention was publicly disclosed or commercially used for more than one year prior to the date on which a patent application is filed.[2] This rule exists because the patent grant is a reward solely for the early disclosure of the invention to the public and not a reward for either its discovery or for an investment in its commercial development and exploitation. If society would eventually obtain the benefit of the invention through its public disclosure or commercial use, no reward to the inventor is necessary and none is given by the patent system.

Under the United States patent system, with certain difficult-to-prove

exceptions, the patent is granted to the first inventor who actually discloses the invention in a patent application and not to the first person who may have actually made the discovery.[3] It is self-evident that this system encourages the filing of patent applications at the idea stage, rather than at a stage when they are ready for commercial exploitation.

A patent may only be obtained if the invention described in the patent is useful, but the standard for determining utility is not a commercial standard. Indeed, after the passage of the 1962 amendments to the Food and Drug Law which required pharmaceutical manufacturers to establish safety and efficacy prior to marketing therapeutic compositions, the United States Patent and Trademark Office took the position that patents covering therapeutic compositions could not be granted without proof that the claimed compositions met the Food and Drug Administration (FDA) standards with respect to safety. This position was overruled by the highest patent court, the Court of Customs and Patent Appeals, on the ground that an invention could be "useful" in the sense of the patent law, even though it might not be commercially saleable under other laws.[4] In so ruling, the court adopted the argument that one fundamental purpose of the patent grant, recognized by the *Report of the President's Commission on the Patent System*, was to stimulate the investment of additional capital needed for the further development and marketing of the invention. Having successfully taken the position that patents should be granted on therapeutic compositions which are clearly not in commercial form at the time the patent is granted as a stimulus to investment, it is completely disingenuous for the pharmaceutical companies to now urge that the grant of a patent entitles them to seventeen years of commercial exploitation.

Clearly all of the foregoing fundamental principles on which the patent system is based completely undermine the argument that the concept of "effective patent life" exists, or that, in any event, it is intended to be equal to the seventeen-year life of a patent. Pharmaceutical companies are not, as they allege, the victims of any inequity caused by the granting of a monopoly by one government agency (the Patent Office) and an alleged interference with the exploitation of that monopoly by a different agency (the FDA). Rather, they seek to redefine the concepts on which the patent system is based by urging that the patent grant is a guaranteed seventeen-year monopoly.

Factors Affecting Commercial Patent Life

Given the basic principles of the patent system, what are the factors which actually affect so-called "effective patent life", or more accurately, the length of the commercial monopoly on a therapeutic composition?

How can it be that it is demonstrably far longer than seventeen years in some instances and significantly shorter in others? Regulatory review is not the exclusive answer to these questions. There are a multitude of patent and economic factors, *largely under the discretion and control of the patent owner*, which can dramatically affect the answer.

The patent application filing date, patent issue date, and scope of a patent application are factors which may have an important effect on the length and scope of a commercial monopoly. This can be readily demonstrated by considering the following patent rules and practices:

- The patent law contains no requirement that a patentable idea be at any particular stage of development before a patent application may be filed. Obviously, if no patent application is filed until the invention is reasonably well along in the development process, it is likely that the inventor will enjoy a longer period of commercial exploitation. By waiting, the inventor runs a risk that others will file earlier patent applications on the same invention with the possible result that all patent protection will be denied and, worse yet, that someone else will possess a monopoly which will prevent the commercial practice of the invention. Not surprisingly, many patent applications are filed long before it is known if the inventions are commerically practical, solely as a defensive measure and without regard to any possible impact on the life of any subsequent commercial monopoly.
- It is perfectly permissible to file a patent application on a concept which has never been tested or which is far broader that the limited concept which has actually been tested. In pharmaceutical composition cases, for example, it is quite common to define the invention by a broad hypothetical chemical formula which encompasses hundreds or thousands of possible compounds having certain structural similarities, even though, at the time the original patent application is filed, only a small handful of compounds have actually been made and tested.
- The seventeen-year patent monopoly runs from the date on which the patent is actually granted, after it is examined by the United States Patent and Trademark Office, and does not run from the filing date of the patent application. How long a patent application remains pending in the Patent Office is highly variable and, to a significant extent, can be controlled by the inventor. It is entirely permissible to keep a patent application pending for a long time by abandoning the original patent application in favor of so-called continuation or continuation-in-part applications which supplement or expand upon the original invention disclosure, and which are based on work carried out by the inventor subsequent to the original application filing date. The use of this practice is widespread and has been common in pharmaceutical industry patents.
- By law, each patent must be limited to a single invention and, in many

instances, the method of making a product or the method of using a product. Although initially disclosed in a single patent application which also discloses the product, these methods are required to be set forth in separate, so-called divisional applications. This practice leads to a multiplicity of patent applications, all of which travel through separate tracks in the Patent Office and may issue at separate times. Indeed, it is common practice to refrain from filing divisional patent applications covering processes or methods of use until just prior to the issuance of the product patent. Thus, the expiration of a single patent cannot be automatically equated with the loss of commercial monopoly because the methods of making and using that product, which are disclosed in the expired patent, are also the subject of separately issued patents having later expiration dates. In addition, commercially crucial composition variations or methods may also be set forth in later filed continuation-in-part applications, or independent patent applications as research proceeds towards a more precise definition of the nature of the commercial products, methods, and uses.

The permissible and discretionary manipulation of the foregoing patent rules can sometimes lengthen and sometimes shorten the actual commercial monopoly. For example, the early filing of a patent application covering an extremely broad class of chemical compounds based on preliminary research with only a handful of compounds, makes it more likely that the date of initial commercial exploitation of a product may not occur until long after the patent issues. Indeed, the specific structure of the actual compound to be marketed may not even be known either at the time the patent application is filed or the time when the patent issues, despite the fact that the patent contains broad claims which cover it! One leading advocate of the patent extension concept has described this as "a situation of common occurrence" in pharmaceutical patents.[5] Obviously, any reduction in "effective patent life" which flows from the fact that the true invention was not made until after the patent was granted cannot be blamed on regulatory delay.[6]

There is, of course, a definite benefit to the patent owner which flows from the filing of early speculative patent applications, even though there is a potential loss in the length of the actual commercial monopoly. The industry rapidly becomes aware that broad patent protection is being sought by a company in a particular area of chemistry, both as a result of publication in scientific journals and the publication of corresponding foreign patent applications within eighteen months of the U.S. filing date. These publications serve to discourage competitive research, thereby preserving that area for one company on a long-term basis. Any marginal loss suffered as a result of shortened commercial life for the first broad patent application can, and often is, offset by a long

and complicated series of additional patent applications covering the methods of use, methods of production, further composition variations, varying dosage forms, and the like. It becomes a relatively simple matter in the absence of direct competition to obsolete the original commercial compounds as they near their patent expiration dates and promote the use of a variant covered by a new generation of patents.

An alternative and commonly used strategy involves the early filing of a broad speculative patent application which is eventually abandoned in favor of one or more continuation or continuation-in part applications as additional research begins to focus on the preferred compositions. The use of this procedure not only strengthens and broadens the scope of protection, but also postpones the issue date of the patent, thereby extending the period of commercial monopoly.

The possible variations are limitless, and some examples may serve to illustrate at least some of the foregoing principles. In the case of Valium, the original patent application was filed in December 1959 and disclosed the specific chemical entity Diazepam which is sold under the Valium trademark. But the patent application also contained broad claims to a large class of compounds having a structure similar to Valium, although many of those compounds had never actually been produced or tested. In May 1960, the Patent Examiner indicated that he was willing to grant a patent which specifically covered Valium, but was unwilling to grant the claims to the broader class of compounds because of the lack of specific disclosure to support them. Rather than accept a patent which covered the specific commercial compound, Roche abandoned the original patent application in favor of a series of continuation-in-part applications which were intended to supplement the original disclosure and support the broader claims. The procedures relating to these matters consumed approximately eight years, and no patent covering Valium issued in the United States until 1968. Since Valium had actually been discovered before the initial patent application was filed, the clinical research occurred wholly within the period when the patent application was pending and NDA approval to market Valium was granted in 1963. Accordingly, Roche will have enjoyed twenty-two years of commercial monopoly by the time its patent expires in 1985. The laws of the United States are far more generous in this regard than the laws of other countries. In most industrial nations, the patent monopoly expires twenty years after the patent application is filed, so that any procedural delays in obtaining issuance of the patent cannot benefit the patentee. It is for that reason that the Valium patent expired in much of the rest of the world in 1980.

The history of Keflex, generically known as cephalexin monohydrate,

demonstrates a different set of circumstances affecting the length of a commercial monopoly, and undermines the assertion that the expiration of a single patent eliminates the commercial monoply. The initial patent application describing a large new class of cephalosporin antibiotic compositions was filed by Lilly in 1962, but only the method of making those products was actually claimed in the initial patent application. The first patent application actually claiming those products was not filed until 1966, shortly before the method patent was granted. That product patent application contained a hypothetical chemical formula, which was broad enough to cover the compound known as cephalexin, although that compound had not yet been discovered. Cephalexin monohydrate, the commercial form of Keflex, was not actually discovered until a later date, while the patent application which broadly covered (but did not disclose) cephalexin was still pending in the Patent Office. Lilly then filed a new patent application claiming cephalexin monohydrate as a separate invention. The broad patent covering cephalexin was granted in 1970, and the specific patent covering cephalexin monohydrate issued in 1972.[7] When the cephalexin patent expires in 1987, no one will be free to market Keflex because the second patent which specifically covers that compound does not expire until 1989. In short, Lilly will enjoy eighteen years of commercial monopoly on a product which was not even discovered until after the initial patent application covering that product was filed.

These are clearly not isolated examples. The Generic Pharmaceutical Industry Association (GPIA) has documented the fact that the twelve top-selling patented drugs, with U.S. sales of $1.37 billion in 1980, had an average effective patent life of 18.5 years, and the twenty-five top-selling patented drugs had an average effective patent life of 16.7 years. Obviously, the rules of the patent game were effectively manipulated in those instances to ensure maximum commercial exclusivity.

Apart from patent rules, there are also important investment and marketing decisions which affect the timing and speed of research and development work and, therefore, the length of the commercial monopoly. While much has been said about the adverse impact of regulatory review on the length of effective patent life, until recently little, if any, attention was directed to the fact that the totally discretionary decision as to when a clinical investigation is started and how fast it proceeds has an impact on "effective patent life." An Office of Technology Assessment (OTA) analysis of a Pharmaceutical Manufacturers Association (PMA) chart designed to show that effective patent life for new chemical entities approved in 1980 had shrunk to 7.5 years, establishes that there is a direct correlation between the patent application filing date and the date on which clinical investigations are commenced.[8]

The low average effective patent life figure derived from the PMA

study was significantly influenced by several situations where clinical investigations were not commenced for many years after the composition and its end use were known, and jumps to 11.6 years when these situations are eliminated. PMA claims that this observation is irrelevant since the patent extension legislation would restore only such time as is lost after the patent issues. Significantly, in disputing the relevance of this finding, PMA is in the embarrassing position of disputing one of the key findings in the Eisman and Wardell study on which it has so heavily relied until this point.[9] That study concluded that the starting date of clinical testing is an important factor which influences effective patent life. Wardell also found that for the twelve-year period from 1968 to 1979, for unknown reasons, declining effective patent life can be explained, in part, by a later starting date for clinical testing in relation to the patent application filing date. Rep. Albert Gore, Jr. (D-Tenn.) has correctly observed that these facts demolish PMA's argument that the decline in effective patent life is due solely to delay caused by regulatory review.

Clearly, the search for the definition of "effective patent life," or the belief that meaningful statistics may be developed to establish that it is shrinking as a result of government regulation, is an exercise in futility. Each product has its own unique development, commercialization, and patent history, which makes any generalization in this area highly suspect. An average effective patent life figure which is derived solely by subtracting the NDA approval date from the patent expiration date without considering that history has no validity.

The Proposed Legislation Is Seriously Defective

Senate Bill S. 255 provides that "... the term of a patent which encompasses within its scope a product, or a method for using a product, subject to a regulatory review, shall be extended by the amount of time equal to the regulatory review...." The term "regulatory review" is defined as the date of initiation of a "major health or environmental effects test," a term defined as an experiment which requires at least six months to conduct. Accordingly, with respect to therapeutic compositions, the extension period would usually commence with the long-term animal toxicity test which precedes the human clinical investigation phase of drug development.

The legislation also provides that the regulatory review period will not be deemed to have started until the patent is actually granted, even though tests which would qualify as regulatory review tests were started prior to that date. Finally, the legislation would go into effect immediately for all therapeutic compositions currently under "regulatory reveiw," although the starting date for measuring the length of the extension

would be the effective date of the legislation.

The interaction between the proposed legislation and some of the basic patent and commercial practices discussed in earlier sections of this paper will clearly result in benefits which go far beyond curing any real or imagined inequity caused by current regulatory practice. The legislation will actually create broad, new, and unwarranted monopoly power. The following are some of the most obvious flaws in the legislation:

- The starting point for measuring the length of an extension precedes, by a wide margin, the date on which any reasonable and prudent businessman would place a product on the market in the total absence of any regulatory review. Surely, the entire period of long-term animal toxicity testing and clinical investigation cannot be characterized as a "delay" caused by government regulation.
- The legislation actually rewards delay. As previously noted, effective patent life is shortened when there is a long lapse between the patent application filing date and the commencement of clinical investigations. The legislation provides an incentive for lengthening rather than shortening the gap between these two dates since the regulatory review period is not considered to have started until a patent is actually granted. Accordingly, an innovator who is diligent in commencing a clinical investigation while a patent application is still pending would receive a shorter extension, whereas a party who delays "regulatory review" activities until a patent is granted would actually receive a longer patent extension.
- The regulatory review process normally relates to a single specific compound and is designed to seek approval to market that compound for a specifically defined end use or indication. As previously noted, patent claims are normally far broader in scope. Thus, a patent which claims a broad hypothetical formula encompassing thousands of compounds would be entitled to an extension, even though the specific compound or end use which is the subject of subsequent regulatory review was not disclosed in the patent.[10] Obviously, the availability of extensions under these circumstances will encourage the filing of even broader and more speculative patent applications and will eventually serve to convert patents from disclosure documents into research proposals. The research "preserve" carved out by such broad and speculative patents, coupled with a patent having a twenty-four year life, will surely serve to discourage third party investigation into the area defined by the patent.
- The extension legislation may induce the owner of a patent covering a commercially significant product to invest the time and money needed to obtain regulatory approval of some commercially insignificant new therapeutic use because the patent extension would apply to the

product, and not merely the specific new use which is subject to regulatory review. S. 255 contains the following limitation with respect to the scope of any patent extension:

> 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.

Since the extended rights are limited to "the product *or* method" and not "the product *and* method" which is subject to regulatory review, a product patent claim would be enforceable against all methods of using that product for therapeutic purposes, both old and new, during the period of any extension. The prospect of seven additional years of monopoly prices on an important drug such as Valium can certainly justify a large expenditure of research dollars on an unimportant new use for that composition as a means of extending patent life for the commercially significant old uses.

Moreover, as a result of experience gained by the medical community in using an approved drug for an approved indication, it is not uncommon for significant new therapeutic uses to be discovered, and these discoveries need not necessarily result from the efforts of the original patent owner. The discovery that Inderal (propranolol) is useful in limiting the size of a heart attack among high risk patients is a recent example of such a discovery which was funded by the government. Is the owner of the Inderal patent now properly entitled to up to seven years of additional patent protection on the product simply because it now files an NDA for the independently discovered new end use? Is there any justification for granting an extension of a scope that would provide monopoly power and monopoly prices over the original end uses of Inderal as to which the innovator has already obtained the full benefits of a patent monopoly? Will companies other than the original patentees invest time and money in developing new uses for previously patented drugs, if the discovery of those new uses will lead to extensions of the original patents, thereby blocking them from commercially exploiting the new uses? The legislation does not even recognize that these problems exist, let alone deal with them in any effective manner.

To the extent that government regulation causes delay in bringing products to market, that problem should be addressed and solved. The solution to the problem does not, however, reside in tampering with the patent system in a manner which will create broad new monopoly rights that extend well beyond any real or imagined problem caused by premarketing regulation of drug products.

NOTES

1. Motion Picture Patents Company v. Universal Film Manufacturing Co., 243 U.S. 871, 876 (1917).
2. In most other industrialized countries, the one year grace period does not exist, and any disclosure or use prior to filing a patent application bars the patent grant. Since most pharmaceutical patent applications are filed internationally, it is normally the international rules which control the decision as to when applications are filed.
3. The "first to file" rule is essentially absolute in most other patent systems.
4. Application of Anthony, 414 F2d 1383 (C.C.P.A. 1969).
5. Anderson, "Patent Term Restoration," *APLA Journal* 8, no. 4, p. 198.
6. The patent extension legislation would clearly encourage the early filing of broad, speculative patent applications on products of unknown commercial value, since it would permit the patent owner to recapture up to seven years of the time lost as a result of the fact that the commercial embodiment of the alleged invention was unknown when the initial patent application was filed.
7. See U.S. Patent No. 3,507,861 issued April 21, 1970, and U.S. Patent No. 3,655,656 issued April 11, 1972.
8. U.S., Congress, House, Hearings before the Committee on Science and Technology, Subcommittee on Investigations and Oversight, February 4, 1982.
9. Martin M. Eisman and William Wardell, "The Decline in Effective Patent Life of New Drugs," *Research Management*, January 1981, p. 18.
10. The extension would be limited in scope to the specific product which was subject to regulatory review, but this limitation in the legislation would, nevertheless, permit an extension for an undisclosed product which happens to fall within the scope of a broad patent claim.

Senator MATHIAS. Well, I think one thing is clear. Senator Metzenbaum is going to get his wish for another session because we cannot possibly conclude the testimony that is scheduled for today in the next 20 minutes, which is about what we have available.

I want to be as fair as possible to witnesses who have been kind enough to come here to testify today. On the list, I noticed that several are in town; several are here, I assume, just for this purpose today.

Mr. Cunningham and Dr. Grabowski have come the farthest, from south San Francisco and Durham. My friend, Tom Bradley, has come all the way from Baltimore. I want to accommodate all of them.

Do you have any suggestions?

Senator METZENBAUM. Yes. I would suggest, Mr. Chairman, that we take the time necessary to hear Mr. Cunningham, who certainly came the farthest, and if Dr. Grabowski wants to be heard, that we hear him.

Senator MATHIAS. Why do we not hear those two, and then in fairness to the other witnesses tell you that, unfortunately, it is not a question of going to lunch. I have to convene another meeting at 12:30, so I am under that kind of discipline. If it were otherwise, I would sit here until we got finished.

Senator METZENBAUM. Let us agree that no matter what happens, we will not spend more than 15 minutes on each witness.

Senator MATHIAS. All right.

Senator METZENBAUM. Give them 5, you 5, and me 5.

Senator MATHIAS. Then let us proceed. Mr. Cunningham had been coming as part of a panel, but we will take him individually, and Dr. Grabowski. The 5-minute rule is in effect.

STATEMENT OF BRIAN CUNNINGHAM, GENERAL COUNSEL, GENENTECH, INC., SAN FRANCISCO, CALIF.

Mr. CUNNINGHAM. Thank you, Senators. Mr. Chairman, members of the committee, my name is Brian Cunningham. I am general counsel of Genentech, Inc., one of those small, high-tech companies in California.

We were founded just 7 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. These are human insulin, human growth hormones, and interferon. All these are made by genetically engineered micro-organisms.

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.

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 pro-competitive mechanism.

We strongly endorse Senate bill 1306, 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 commonsense notion that what Government gives with the right hand it ought not to take away with the left.

According to a recent report of the Interagency Working Group on Biotechnology of the Office of Science and Technology, the average effective patent life for a new drug has shrunk to less than 10 years.

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 7 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 that 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 adaption to a host of different circumstances. In particular, we applaud the principal change in the new legislation which now makes 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 of recombinant DNA 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, 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 on raw material sources.

The present position of the Food and Drug Administration—a position with which 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 micro-organisms, and thus required to go through the new drug approval process.

Under the original bill introduced by Senator Mathias during last Congress, the provisions of the new law would not be available to restore patent term lost through the new drug regulatory review period that FDA will impose.

This bill, S. 1306, however, provides for the restoration of patent term where old products are subjected to regulatory review because manufactured by a new and patentable process.

We compliment Senator Mathias and his cosponsors on this change, which can be expected to spark innovation in the recombinant DNA field.

There is no evidence to suggest that the bill will encourage regulatory delay. To the contrary, with respect to the biotechnology industry, the FDA and USDA have shown every willingness to find ways to facilitate our growth within the bounds of their regulatory framework, and have shown sensitivity not to throw up unnecessary barriers which might threaten the competitive edge which U.S. companies currently enjoy.

Patent term restoration complements those regulatory attitudes and provides clear evidence of the importance Congress attaches to supporting new technologies in U.S. industry.

Mr. Chairman, this concludes our statement. We appreciate the opportunity to present testimony to you today on this important issue and I will be pleased to respond to any questions.

[The prepared statement of Brian Cunningham follows:]

STATEMENT OF
BRIAN CUNNINGHAM
GENERAL COUNSEL
GENENTECH, INC.

Mr. Chairman and members of the Committee, my name is Brian Cunningham. I am the chief legal counsel for Genentech, Inc., a small California company founded just seven 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. Other products are expected to enter clinical testing this year. And we have recently completed construction, in California, of the world's largest multi-product plant for products of recombinant DNA technology. In the little over two-year period since we last testified before this committee (April, 1981), our size has more than doubled.

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.

We are no veterans of industry. But nothing in our 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 S. 1306, the Patent Term Restoration Act of 1983, 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 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 seven 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.

S. 1306 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 hundred or more 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. 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

We applaud the principal change in the new legislation, which now makes 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.[9/] 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 pur-

ity, 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.[10/] 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. As now written, S. 1306 will accomplish this result, by authorizing an extension of patents on new methods of making pharmaceutical products, if the methods themselves require regulation as new drugs.

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 economical ways should be encouraged to the same extent as the making of new things. In its present form, this is exactly what the bill before you does.

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, 447 U.S. 303.

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. Seven years ago Genentech had one employee. Today it employs over 500 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. Previously, only animal insulin was available to diabetics.

10. Until recently, human growth hormone could be extracted only from human remains.

Senator MATHIAS. I have only one question, Mr. Cunningham. How much patent life have you lost on the processes that you have mentioned for producing human insulin and interferon?

Mr. CUNNINGHAM. Well, with respect to those products, our patents have yet to issue, except for a few process patents.

Senator MATHIAS. So you have not yet lost patent life on those particular products?

Mr. CUNNINGHAM. Not on those particular products. Many of the products that are moving through the product pipeline, though, will be affected by this bill.

Senator MATHIAS. Senator Metzenbaum.

Senator METZENBAUM. Mr. Cunningham, Genentech first raised money from the public how long ago?

Mr. CUNNINGHAM. That was in 1979.

Senator METZENBAUM. And how much did you raise at that time?

Mr. CUNNINGHAM. We raised approximately $30 million.

Senator METZENBAUM. Was that a stock offering?

Mr. CUNNINGHAM. Yes, it was, sir.

Senator METZENBAUM. And what has happened to that stock since then?

Mr. CUNNINGHAM. Well, immediately after the public offering, the price of the stock rose considerably. Later the price dropped below the public offering price. Then it remained stable at about the public offering price. Since then, the price has gone up considerably.

Senator METZENBAUM. To what figure?

Mr. CUNNINGHAM. Well, we have had a three-for-two stock split in the interim, so stating the price on a pre-split basis to make it comparable, it is now at a price of roughly 60, as compared to a price of 35 when it was offered to the public.

Senator METZENBAUM. Have you raised any other money publicly?

Mr. CUNNINGHAM. Not publicly, no.

Senator METZENBAUM. There was nothing in your prospectus that indicated Congress was going to change the law. You told them what the present patent laws were, did you not?

Mr. CUNNINGHAM. That is right.

Senator METZENBAUM. And you have been able to raise the money and your stock has been able to almost double, although you have not made any money, as I understand it, as of this moment.

So, apparently, the investor has really not been that apprehensive that you cannot make money under the present patent laws, and my guess is you probably did not even say anything in those caveats that are always required in the prospectuses, saying what a problem it is because the patents expire in 17 years and there is a period needed for exploration. Is that not a fair statement?

Mr. CUNNINGHAM. It is a fair statement, although it is not necessarily directed toward what one discloses in a document of that sort. Certainly, the document addresses the question of patent protection, and those underwriters of that offering and the public who bought those shares were keenly concerned with the issue of whether or not Genentech would be able to achieve meaningful patent protection.

Indeed, every investor that we have dealt with, and our industrial customers to whom we have licensed technology, are keenly concerned with patent protection. That they did not require that we address the particular question of patent restoration, I am not sure proves any more than the fact that nobody had thought of it at that time, but the general subject was very important.

Senator METZENBAUM. Well, it does go to the very heart of your presentation: "The promise of patent protection induced private risk capital investment that established the credibility of the new technology, leading to all that has followed."

And then you go on to say,

> What farmer will invest in seed if the law permits others to take his crop? A new company is a fragile thing and patents are part of its survival kit. The promise of patent protection lets us raise capital to sustain the company in these dry years.

What I am saying is that you brought out a company and you raised $30 million—I think that is the figure you used—at $35 a share.

Mr. CUNNINGHAM. Yes.

Senator METZENBAUM. The stock is now at $60. The investors obviously are not that apprehensive with respect to the presently existing patent laws. Yet, you are here saying that you need this law for the small company to be able to exist.

I think you have done a magnificant job, particularly in view of the fact that at this moment, as I understood your testimony, there have been no profits at all for this company. I gather you have not even marketed your product, although you have done some licensing. Am I correct in stating the facts?

Mr. CUNNINGHAM. That is true, Senator. I have not, and I do not believe anyone has any idea why our stock has a particular price.

Senator METZENBAUM. I know why. When there are three buyers and two sellers, it goes up. [Laughter.]

That is the way the market is, and people have confidence that you are going to make a lot of money at some point.

Mr. CUNNINGHAM. But I think that is a confidence that is borne of the technology itself and the promise of that technology and the impact it is going to have on the broad aspects of our lives for a long time to come.

With every new technology and with every company, there is a mix of risks. Now, to single out one risk, Senator, and say the consuming public, the investing public, is discounting the seriousness of this risk as evidenced by the price of the stock is, sir, I think unrealistic and not reflective of the way the market operates.

Senator METZENBAUM. Well, as a matter of fact, the price is $60, as you indicated, over the original offer price of $35 in spite of the fact, and I think I am correct, that there are some who are attacking the entire propriety of the kinds of actions in which you are involved.

I do not happen to be one of those who are attacking, and I recognize——

Mr. CUNNINGHAM. No, that is not accurate, sir. Questions have been raised in the newspapers of late concerning genetic manipulation of humans, but are not in that field at all, sir.

Senator METZENBAUM. In the recombinant DNA?

Mr. CUNNINGHAM. We are in the recombinant DNA field; that is a technique for genetic manipulation. We are not in the business of genetic manipulation of human genes, of humans; when I say "human genes," we are, of course, in the business in the sense of producing human growth hormone and human insulin as drugs. That is different from what the controversy itself is surrounding, I believe.

In addition to that, our technology applies beyond the drug industry, and indeed our company's focus is broader than just the drug industry. It also applies to animal products and to agricultural products and to industrial products.

It may well be that the market is very concerned about our drug patent protection, but thinks we are going to do well in other industries. I cannot really say, sir.

Senator METZENBAUM. Thank you. Thank you, Mr. Chairman.

Senator MATHIAS. Thank you, Senator Metzenbaum.

Senator METZENBAUM. Please note that I finished right at 12:15.

Senator MATHIAS. You observed the Metzenbaum rule.

Senator METZENBAUM. Well, the Mathias rule; you are the boss.

Senator MATHIAS. Thank you, Mr. Cunningham.

Dr. Grabowski?

STATEMENT OF HENRY GRABOWSKI, PROFESSOR OF ECONOMICS, DUKE UNIVERSITY, DURHAM, N.C.

Dr. GRABOWSKI. Thank you, Senator Mathias. I would like to direct my comments today to the issue of how patent term restoration is likely to influence the level of research and development in new drug innovation.

My colleague, John Vernon, and I have recently completed an NSF-sponsored research project involving studies on drug substitution, patent policy, and innovation in the pharmaceutical industry.

Based on the findings from this project, as well as the studies of other researchers, I believe there is a strong case for approval of patent restoration as embodied in S. 1306. In my testimony, I would like to highlight some of the major findings from this study and discuss their relevance to patent restoration. The final report of our study, which was submitted just last month, May 1983, is attached to my written statement.

First, our empirical work indicates that distribution of returns to pharmaceutical R&D is highly skewed. This means R&D is subject to high levels of uncertainty and above average riskiness. Research-oriented firms are heavily dependent on obtaining an occasional big winner to cover their R&D cost and generate a profitable return on their overall R&D investment.

Second, our analysis of break-even product lifetimes indicates that it takes 19 years for the average new drug to cover R&D costs at a real interest rate of 10 percent. If we alternatively assumed an interest rate of 8 percent, the break-even lifetime is 12 years. This range in break-even product lifetimes can be compared to the average effect of patent life for new drug introductions. Effective patent terms averaged approximately 7 years over the 1979–81 period and have been trending downward over time.

Third, our results indicate that the disincentive effects of declining patent life on the returns to innovation depend critically on the degree of product substitution and competition in the period after patent expiration. This is important, given the various programs that have been enacted at the Federal and State level to promote the use of generic drugs after patents expire and imitative drugs come on the market. There is no doubt that the degree of imitative competition has been increasing and will be greater in the future than it has been in the past.

Fourth, our study of the determinants of R&D expenditures in pharmaceuticals indicates firm outlays are sensitive to both expected returns and the availability of internally generated funds.

Since restoration of patent life increases the expected returns from new drug innovation, and also provides firms that are successful in new product introduction with increased profits and cash flow, we would expect it to lead to significant increases in R&D investments.

A final issue that we investigated in our NSF study concerned the effect of shorter regulatory approval times on break-even lifetimes and their returns to R&D. We found that a 1½-year reduction in regulatory approval time reduces the break-even time for a drug to recoup its R&D investment by a full 5 years.

This result implies that it takes more than 3 years in added time at the end of the patent period to compensate for an additional 1 year of regulatory delay in gaining NDA approval. This result reflects the time value of money; that a year at the beginning is not equivalent in economic terms to a year at the end.

These latter findings also underscore the importance of recent administrative efforts to reduce regulatory delays and streamline the regulatory process. Realistically, however, there appear to be limits to what one can expect to accomplish from these efforts.

The FDA's impact analysis of the proposed NDA rule changes indicates an expected reduction in approval time of 2 to 6 months. Hence, even after these procedural reforms are fully implemented, the regulatory-induced lags for new drug introductions will be very substantial. The average effective patent terms for new drugs will remain significantly less than in other research-oriented industries.

There is currently considerable excitement about the scientific possibilities for significant new medicines as a result of the many important advances in basic sciences. However, the translation of these promising leads from biomedical science into available new therapies for patient use is a long, costly research process that is fraught with uncertainty. It requires a favorable economic environment for R&D investment.

If patent exclusivity periods do not provide significant premiums for the relatively small number of research successes, there will be insufficient economic incentives and investment funds to exploit all of the promising opportunities for the new drugs currently available.

In an environment of declining patent protection and expanding competition from generic competition, the amount of patent protection will necessarily become an increasingly critical factor in the research-oriented firm's future decisions concerning which R&D project it invests in.

In an industry where new products take well over a decade to discover, develop and gain FDA regulatory approval, it is very important for policymakers to respond to emerging trends and policy developments with foresight rather than hindsight.

S. 1306 provides a sensible, forward-looking approach for countering the adverse economic consequences resulting from regulatory-associated delays in patent life.

These last comments relate to the future, which I think is an important aspect of this bill. I would disagree with Mr. Haddad's view that if it is not broken, do not fix it.

In terms of our high-technology industries, pharmaceuticals being a leading example, I think there are some ominous trends on the economic side as well as some beneficial trends on the technological side. We want to have a policy that will be forward looking and that will encourage innovation. This has been one of the strengths of the U.S. economy historically.

Thank you.

[The following material was received for the record:]

Testimony of Henry Grabowski

Professor of Economics, Duke University

on S.1306

Subcommittee on Patents, Copyrights and Trademarks

Ninety-Eight Congress

SUMMARY

S.1306, the Patent Restoration Act of 1983, offers a viable policy approach for countering the adverse economic consequences resulting from regulatory associated losses in patent life.

Several findings relevent to the patent restoration question are reported from a recently completed NSF sponsored study at Duke University on "Drug Substitution, Patent Policy and Innovation in the Pharmaceutical Industry."

The effective patent life for new pharmaceuticals has been declining and averaged approximately seven years for 1979 to 1981 NCE introductions. At the same time, the degree of market competition after patent expiration from imitative producers has been increasing. Our analysis indicates that this combination of shortening patent lifetimes and increasing imitative competition has significant negative effects on the expected returns from pharmaceutical R and D. Our analysis further indicates that patent restoration would increase R and D returns and the available cash flow for investigating new drug candidates.

At the present time, there is a high degree of optimism about the opportunities for new drug therapies as a result of recent advances in basic biomedical sciences. Patent restoration will help to provide a favorable economic environment for the lengthy and costly R and D investments necessary to translate promising scientific leads into new therapies. A much shorter than average patent life is neither economically warranted nor socially desirable in the case of pharmaceutical R and D.

The main alternative policy for countering regulatory associated losses in patent life would be changes in the regulatory process itself. There have been, in fact, considerable administrative efforts recently to reduce regulatory delays and streamline the review process. However, these procedural changes, while desirable, are unlikely to reduce regulatory delays by more than several months. Consequently, recent regulatory reform efforts are unlikely to have a major effect in restoring lost patent time compared to what would be provided through enactment of S.1306.

Thank you, Senator Mathias and other members of the Subcommittee for inviting me to speak on S.1306, the Patent Term Restoration Act of 1983.

I would like to direct my comments specifically to the issue of how patent term restoration is likely to influence the level of research and development and new drug innovation in the pharmaceutical industry. My colleague, John Vernon, and I have recently completed a National Science Foundation sponsored research project involving various studies on "Drug Substitution, Patent Policy and Innovation in the Pharmaceutical Industry."

Based on the findings from this NSF project as well as the studies of other researchers, I believe there is a strong case for legislative approval of patent restoration as embodied in S.1306. In my testimony today, I would like to highlight some of the major findings from our NSF study and discuss their relevance to the patent restoration issue.

First, our empirical work indicates the distribution of returns to pharmaceutical R and D is highly skewed in character. In our analysis of all the U.S. discovered new drug introductions for the period 1970 to 1976, we found only 13 of these 39 new drugs had a profitability index greater than one.[1] Hence only 1 in 3 drugs had net discounted revenues greater than expected R and D inveatment costs. This meana R and D is subject to high levels of uncertainty and above average riskiness. Research oriented firms are heavily dependent on obtaining an occasional "big winner" to cover their R and D costs and generate a profitable return on their overall R and D investment.

Our analysis of breakeven product lifetimes further indicates that it takes 19 years for the average new drug to cover R and D costs at a real interest rate of 10 percent. If we alternatively aasume an interest rate of 8 percent for pharmaceutical firm R and D investment, the breakeven lifetime is 12 years. This range in breakeven product lifetimes can be compared to the average effective patent life for new drug introductions. Effective patent terms averaged approximately 7 years over the 1979 to 1981 period and have been trending downward over time.

Our results also indicate that the effect of declining patent life on the returns to innovation depends critically on the degree of product substitution and competition in the period after patent expiration. This is important, given the various programs that have been enacted at the federal and state levels to promote the use of generic drugs after patents expire and imitative drugs come on the market. There is no doubt that the degree of imitative competition has been increasing over time and will be much greater in the future than it has in the past.[2]

In a sensitivity analysia, we found patent life and product substitution impact on expected returns from R and D in a non-linear fashion. In particular, when the effective patent life is in the range of 5 to 8 years,

the prospects of lower market shares and net revenues after patent expiration have a significant negative impact on the expected returns from R and D. On the other hand, if the patent life actually equalled the legal life of 17 years, the effects on expected returns of even very high rates of substitution would be quite small. This is because the lost revenues would occur far into the future and would be heavily discounted at prevailing interest rates.

We also investigated the interactions between patent terms and market competition using a dynamic computer simulation model of pharmaceutical competition. This study was designed to investigate the long-run evolutionary consequences of different policy environments for pharmaceutical innovation. This analysis indicates that the long term disincentive effects of relatively short patent lives combined with high substitution rates for drug innovation are much greater than one would expect on the basis of short term sensitivity analysis. This is the result of dynamic interactive effects between these policy determined variables which cummulate over time.

We also empirically analyzed the economic factors that affect pharmaceutical research intensity. Our statistical analysis indicates that pharmaceutical firms do respond to higher or lower expected returns from R and D in an adaptive fashion consistent with theoretical expectations. Our results further indicate a statistically significant positive relation between firm R and D outlays and the availability of internally generated investment funds. For the firms in our sample (10 research intensive pharmaceutical firms) a one million dollar increase in cash flow was associated on average with a quarter million dollar increase in R and D expenditures. This relation was quite robust over the 12 year period (1963-1975) analyzed by our study.

Our study of the determinants of R and D expenditures in pharmaceuticals indicates firm outlays are sensitive to both expected returns and the availability of internally generated funds. Since restoration of patent life increases the expected returns from new drug innovation and also provides firms that are successful in new product introduction with increased profits and cash flow, we would expect it to lead to significant increases in R and D investments.

A final issue that we investigated in our NSF study concerned the effect of shorter regulatory approval times on breakeven lifetimes and the returns to

drug R and D. Because regulatory approval occurs "up front", the time delays in regulatory approval can exert disproportionate disincentive effects on the profitability of new drug introductions. This point was illustrated most dramatically in our breakeven analysis. We found that a one and one-half year reduction in regulatory approval time reduces the breakeven time for a drug to recoup its R and D investment by a full five years. This result implies that it takes more than three years in added time on the end of the patent period to compensate for an additional one year of regulatory delay in gaining NDA approval.

These findings underscore the importance of recent administrative efforts to reduce regulatory delays and streamline the regulatory process. Realistically, however, there are limits to what one can expect to accomplish from these efforts. The FDA's impact analysis of the proposed NDA rule changes indicates an expected reduction in approval times of two to six months from implementing the proposed procedural changes.[3] Hence, even after these procedural reforms are fully implemented, the regulatory induced lags for new drug introductions will still be very substantial. The average effective patent terms for new drugs will remain significantly less than in other research oriented industries.

There have been a number of studies in recent years attesting to the high social benefits accruing from new drug therapies.[4] These benefits involve improvements in health status as well as gains in economic productivity and well being. There is considerable excitement about the scientific possibilities for significant new medicines as a result of the many important advances in basic sciences in recent years. However, the translation of these promising leads from basic biomedical science into available new therapies for patient use is a long costly research process that is fraught with uncertainty. It requires a favorable economic environment for R and D investment. If patent exclusivity periods do not provide significant premiums for the relatively small number of research successes, there will be insufficient economic incentives and investment funds to exploit all the promising opportunities for new drugs currently available.

In an environment of declining patent protection and expanding competition from generic competition after patent expiration, the amount of

patent protection will necessarily become an increasingly critical factor in the research oriented firm's future decisions concerning which R and D projects it invests. In an industry where new products take well over a decade to discover, develop and gain FDA regulatory approval, it is very important for policymakers to respond to emerging trends and policy developments with foresight rather than hindsight. S.1306 provides a sensible forward looking approach for countering the adverse economic consequences resulting from regulatory associated delays in patent life.

References

1. Henry Grabowski and John Vernon, Final Report for NSF Grant No. PRA-79-17524, "Studies on Drug Substitution, Patent Policy and Innovation in the Pharmaceutical Industry," May 1983, pp. 1-11. (Attachment A) and Henry Grabowski and John Vernon, "A Sensitivity Analysis of Expected Profitability of Pharmaceutical R and D," Managerial and Decision Economics, vol. 3, no. 1, March 1982, pp. 36-40 (Attachment B).
2. For further discussion and references see Henry Grabowski and John Vernon, "Studies on Drug Substitution Patent Policy and Innovation in the Pharmaceutical Industry," pp. 15-17 and Henry Grabowski and John Vernon "Substitution Laws and Innovation in the Pharmaceutical Industry," Law and Contemporary Problems, Winter-Spring 1979, pp. 43-66.
3. Food and Drug Administration, Office of Planning and Evaluation, "Preliminary Regulatory Impact Analysis of Proposed Changes to Regulations Governing the Submission and Review of New Drug Applications (Part 314, Title 21)," May 1982, pp. 32-37.
4. For a brief survey, See Chapter Two of Henry Grabowski and John Vernon, The Regulation of Pharmaceuticals: Balancing the Benefits and Risks, American Enterprise Institute for Public Policy Research, Washington, D.C. 1983, pp. 14-20.

Attachments

A. Henry Grabowski and John Vernon, Final Report for NSF Grant No. PRA-79-17524, "Studies on Drug Substitution, Patent Policy and Innovation in the Pharmaceutical Industry," May 1983, pp. 1-11.
B. Henry Grabowski and John Vernon, "A Sensitivity Analysis of Expected Profitability of Pharmaceutical R and D," Managerial and Decision Economics, vol. 3, no. 1, March 1982, pp. 36-40.

NATIONAL SCIENCE FOUNDATION
Washington, D.C. 20550

FINAL PROJECT REPORT
NSF FORM 98A

PLEASE READ INSTRUCTIONS ON REVERSE BEFORE COMPLETING

PART I–PROJECT IDENTIFICATION INFORMATION

1. Institution and Address	2. NSF Program	3. NSF Award Number
Duke University Department of Economics Durham, N. C. 27706	Policy Research & Analysis	PRA-7917524
	4. Award Period From 7/1/79 To 8/31/82	5. Cumulative Award Amount $125,979.00

6. Project Title
Studies on Drug Substitution, Patent Policy and Innovation in the Pharmaceutical Industry

PART II–SUMMARY OF COMPLETED PROJECT *(FOR PUBLIC USE)*

The main objective was to investigate how patent, substitution, and regulatory policies jointly influence the drug innovation process and the returns from research and development. This is an important issue for research because of the significant changes now occurring in these policies. The major findings are:

(1) The distribution of returns on pharmaceutical R and D is highly skewed.

(2) It takes 19 years for the average new drug introduction to cover R and D costs at a real compound interest rate of 10 percent. This breakeven product lifetime compares to an effective patent life of approximately 7 years in the 1979 to 1981 period.

(3) The effect of increased substitution rates on the expected returns from drug R and D depends critically on effective patent life. For example, if effective patent life were equal to the nominal life of 17 years, product substitution rates in excess of 50 percent would have only very modest effects on expected returns. On the other hand, when patent lifetimes are in the range of 5 to 8 years, even moderate substitution rates have significant adverse effects on the expected returns from drug R and D.

(4) Regulatory time delays, because they occur "up front", have a disproportionate effect on the expected returns to drug innovation. We found on average it takes more than three years in added time on the end of the patent period to compensate for each additional one year delay in gaining FDA regulatory approval.

(5) Prior research success and the availability of internal funds were found to be important factors influencing a pharmaceutical firm's research intensity.

(6) A computer simulation model of pharmaceutical innovation suggests the effects of short patent lives and significant product substitution rates have a cummulative interactive effect over time. Hence, long-run effects are likely to be much greater than those estimated on the basis of short-run static analyses.

PART III–TECHNICAL INFORMATION *(FOR PROGRAM MANAGEMENT USES)*

1. ITEM *(Check appropriate blocks)*	NONE	ATTACHED	PREVIOUSLY FURNISHED	TO BE FURNISHED SEPARATELY TO PROGRAM	
				Check (✓)	Approx. Date
a. Abstracts of Theses					
b. Publication Citations				x	May 1984
c. Data on Scientific Collaborators				x	May 1984
d. Information on Inventions					
e. Technical Description of Project and Results				x	May 1984
f. Other *(specify)*	[redacted]				

2. Principal Investigator/Project Director Name *(Typed)*	3. Principal Investigator/Project Director Signature	4. Date
Henry G. Grabowski	Henry G Grabowski	5/16/83

STUDIES ON DRUG SUBSTITUTION, PATENT POLICY AND INNOVATION IN THE PHARMACEUTICAL INDUSTRY

Final Report

for

NSF Grant No. PRA-79-17524

May, 1983

Henry G. Grabowski

John M. Vernon

Principal Investigators

Duke University

I. BACKGROUND AND OBJECTIVES

Most prior analyses of the innovation process in pharmaceuticals (and other industries) have examined the effects of various public policies in isolation of each other. Such an approach ignores potentially important interaction effects among these policies. It also precludes an evaluation of the net effect of frequently offsetting policy impacts on the innovation process.

A major objective of this research project is to investigate the interdependencies between patent, product substitution and regulatory policies. We wish to consider their joint effects on the drug innovation process. We feel this is an important research undertaking because of the significant changes that are currently occurring in these policies. For example, there has been a steady decline over the last decade in the effective patent term for new drugs (i.e. the patent time available after commercial introduction). Effective patent life now averages about one-half of the normal 17 year legal life. This has occurred largely as a result of increasing development and regulatory approval periods for new drugs.[1]

Whether shorter patent terms adversely impact on the returns to drug innovation or not will depend significantly on the degree of product competition and substitution after patent expiration. Historically, there have been strong "first mover" advantages in pharmaceuticals as a result of physician loyalties to the pioneering brands and the state anti-substitution laws. However, virtually all the states have recently repealed their anti-substitution laws and now allow some discretion by pharmacists to substitute among different brand and generic products.[2]

As a result of these developments, proapective innovators in the pharmaceutical industry can now expect shorter patent periods and increasing product substitution and competition compared to the historical norms for the industry. These factors operate to lower the expected returns on innovation. At the same time, there have been recent efforts by the Reagan Administration to change regulatory review procedures and reduce clearance times.[3] To the extent the latter are successful, these will operate to restore part of the lost patent time from regulation and increase the expected returns from drug innovation.

25-841 O - 84 -- 10

In order to evaluate the significance of these developments on the expected returns from R and D, and the innovation process more generally, we have undertaken a number of related research studies. These are discussed in Sections II through V of this report.

In Section II, we present an analysis of the returns on pharmaceutical R and D for 37 U.S. new drug discoveries introduced during the period 1970 to 1976. This analysis is performed at a more disaggregate level than most prior studies of pharmaceutical R and D. It analyzes how costs and returns have varied across different therapeutic categories and analyzes other properties of returns on new drug introductions in the Seventies. This empirical research provides a baseline for our sensitivity analysis.

In this sensitivity analysis, presented in Section III, we consider alternative scenarios on drug substitution, patent terms, and regulatory review times. The basic objective is to analyze how these variables jointly influence the baseline distribution of expected returns. We also compute breakeven lifetimes for these new product introductions and examine how these are influenced by alternative policy scenarios.

In section IV, we report the results of a statistical analysis of the determinants of R and D expenditures in the pharmaceutical industry. This study was undertaken to gain some insights into how changes in the expected returns and cash flows for new drug introductions influence current R and D outlays. In this regard, we analyze historical data on R and D expenditures for 10 major research intensive firms and test various hypotheses about the factors influencing R and D outlays. Our analysis, in this section, builds directly on an earlier research study by Grabowski for the pre-1962 period.[4]

In Section V, we discuss the results of an exploratory computer simulation analysis of the drug innovation process. This model is designed to examine the long run impact of various policy and parameter changes on innovation levels, concentration, and other variables of interest. In particular, using a multi-firm and multi-year analytical framework, we perform a number of simulation experiments to see how the industry is likely to evolve under different policy and environmental scenarios (i.e. scenarios on patent policy, substitution rates, regulatory decisions times, technological opportunities, etc.). The model is developed to analyze a hypothetical industry structure but it employs representative probability distributions and

parameter values from our empirical studies of the pharmaceutical industry. The main objective of this modeling effort at the present time is to provide insights into the dynamic workings of the innovation process and the interdependencies between the forces which drive this process.

The complete set of results and analyses from this NSF supported project are essentially presented in four research papers. The remainder of this paper is devoted to a detailed and integrated summary of these research papers. A full listing of these studies and related work is presented in the appendix to this report.

II. RATES OF RETURN ON NEW PHARMACEUTICAL INTRODUCTIONS IN THE SEVENTIES

This analysis was motivated by two considerations. First, we wished to estimate the distribution of returns on new pharmaceutical introductions in the 1970's using very disaggregate data. Prior studies of returns on new drug introductions have focused on earlier periods and have had a more aggregate character.[5] Second, we wanted to perform this study to use as a baseline case for the sensitivity analysis reported in the next section.

Our baseline sample consisted of 37 NCE's discovered and introduced in the United States over the 1970 to 1976 period.[6] These introductions span a broad range of therapeutic classes. Average R and D costs for these drugs were estimated using therapeutic class groupings. Net revenues were estimated using product specific data on U.S. sales revenues and promotion data from audit sources.

A. Estimation of R and D Cost

The R and D cost estimates by therapeutic class are based on a new study by Ronald Hansen performed under this grant.[7] In an earlier study, Hansen had obtained survey data from 14 pharmaceutical firms on the R & D costs for a sample of approximately 100 NCE's first tested in man from 1963 to 1975. He found that the average discovery cost for this sample was $19.6 million and the average development cost was $14.1 million, for a total of $33.7 million. The $33.7 million represents the capitalized value at 10 percent interest at the date of marketing approval (in 1967 dollars). (The corresponding value in 1976 dollars was 61.6 million dollars.)

At our request, Hansen estimated the costs per NCE in this sample on a therapeutic class basis. These are the cost estimates used in this analysis and as will be shown, reveal a rather large variation across classes. We should also point out that Hansen's estimates include the costs of NCE's that enter clinical testing but are not carried to the point of NDA approval. (Only about 1 in 8 drug candidates entering clinical testing result in a new drug application at the FDA.) Hence, the estimates should be interpreted as the average expected cost of discovering and developing a marketable NCE.

Hansen's estimate of the R and D cost estimates by therapeutic class are presented in Table 1. What is particularly striking about Table 1 is the high variability across classes. The expected capitalized value of R and D costs for a new chemical entity in anti-infectives (19.1 million dollars) is quite small compared to therapeutic classes such as psycho-pharmacology (70.0 million dollars), metabolic-anti-fertility (65.3 million dollars) and anti-inflammatory (68.3 million dollars). The observed variability in Table 1 suggests there is a significant regulatory effect on the cost of developing new entities. The anti-infectives category is the easiest area to establish efficacy using the "large and well controlled trials" criterion of the FDA. The cost estimates are also sensitive to the extent of long-run animal toxicity tests requirements which are greater for drugs used for chronic as opposed to acute conditions.

Hansen's R and D cost estimates are expressed as capitalized values at the date of marketing. For example, the capitalized expected cost of discovering and developing a cardiovascular drug at the date of marketing is $30.6 million in 1967 dollars. Because he worked with constant dollars, Hansen used real interest rates. He actually considered a range of interest rates from 5 to 15 percent. In Table 1, the interest rate is 10 percent. This is the cost of capital assumed as relevant for the pharmaceutical industry but we also performed various analyses at an alternative interest rate of 8 percent.[8]

B. Estimation of Net Revenues and Profitability Indices

The ratio of present value of net revenues to capitalized R and D costs is termed the profitability index (PI) in the finance literature. It is the main measure of expected returns used in our analysis. Clearly, a PI = 1

Table 1

Characteristics of Sample of 37 NCE's Used in Sensitivity Analysis

	Therapeutic Class	Hansen's R & D Cost (10%, 1967 dollars)	# of US NCE's
A.	Cardiovascular	30.6	4
B.	Neurologic, Analgesic	36.3	6
C.	Psycho-pharmacology	70.0	3
D.	Metabolic, Antifertiligy	65.3	5
E.	Anti-infective	19.1	12
F.	Anti-inflammatory	68.3	4
G.	Gastro-intestinal, Respiratory, Surgery	28.5	3
		Total	37

Source: Ronald W. Hansen, "Pharmaceutical Development Cost by Therapeutic Categories", Working Paper Series no. GPB-80-6, University of Rochester Graduate School of Management, March 1980; and Authors.

implies a project that just breaks even in the sense of covering its R and D and capital investment costs.

The formula for the PI for a particular drug is:

$$PI = \frac{1}{RD} \sum_{t=1}^{L} (S_t - P_t - mS_t) f e^{-r(t-1)}$$

where S_t = deflated sales revenue in year t; P_t = deflated promotion expenses in year t; m = production and administrative cost as fraction of sales; f = ratio of world-wide net revenues to US net revenues; r = real interest rate; L = product life; and RD = capitalized value of R and D costs by therapeutic class.

In our baseline analysis, the product life for a representative new drug introduction during the 1970's was assumed to be 20 years. In estimating net revenues, actual sales and promotion data were available for each NCE from its date of introduction through 1980 (10 years for NCE's introduced in 1970, 9 years for NCE's introduced in 1971, etc.). Projections of future revenues and promotion expenditures were thus necessary to complete the revenue profiles for each drug. This was accomplished using a two step procedure.[9]

Data for two additional types of variables were not available on a drug specific basis--(i) production and administrative costs; (ii) the net revenues resulting from sales in foreign countries. In both cases we have relied on estimates made by Celia Thomas as part of her Ph.D. dissertation at Duke University.[10] For example, her best estimate for production and administration costs as a fraction of sales using a variety of data sources was .30 (the m parameter in equation 1). However, because of the uncertainty about this estimate, we also examined the effect of estimates of .20 and .40. A similar approach was taken with respect to Thomas' estimate of 1.75 as the ratio of worldwide net revenues to U.S. net revenues (the f parameter in equation 1). That is, estimates of 1.5 and 2.0 were also used in our analysis.

C. Results of the Analysis

Using the data inputs and assumptions discussed above, we estimated the PI and internal rates of return for each drug in our sample. Figure 1 shows the resulting observed frequency distribution for the case where a real

interest rate of 10 percent and a 20-year lifetime is assumed. Clearly, the resulting distribution is highly skewed.[11] Even under the relatively favorable assumption of a 20-year lifetime, only 13 of the 37 projects had PI's greater than one. This implies, ex post, only about one of three new drug introductions are economic successes (i.e. earn a rate of return greater than the 10% interest rate assumed as the relevant cost of capital for the pharmaceutical industry).

The extreme skewness of the distribution is also reflected in the deviation between the mean and median PI's and corresponding internal rates of return of this distribution. The estimated weighted mean PI for this sample of 37 drugs is 1.029; while the corresponding median PI is only 0.25.

The letters in Figure 1 are codes for the innovating firms and indicate that Firm A had 3 "winners" (PI's greater than one) while the remaining 10 were spread over 10 different firms. If, alternatively, we consider the distribution across therapeutic classes of the 13 NCE's with PI's greater than one, we find that anti-infectives had the most winners during this period (5 NCE's) with the other spread out rather evenly across the other classes. One therapeutic class, metabolic and antifertility drugs, failed to have a single drug introduction with a PI above one.

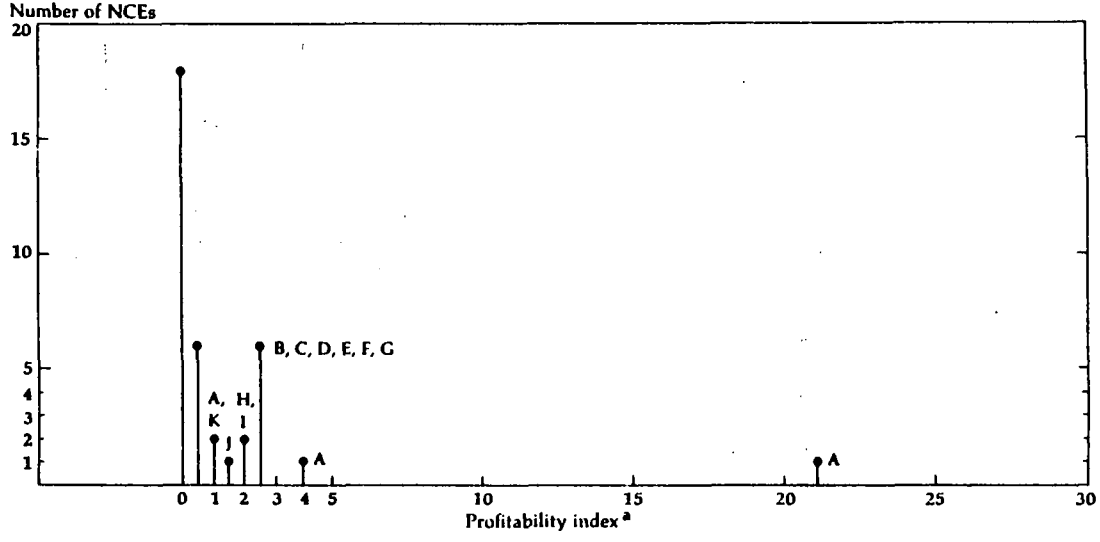
Our analyses imply that anti-infectives were by far the most profitable therapeutic category during this period. This reflects the fact that this category had the lowest expected R and D cost per new drug entity introduction and also had a disporportionate share of the observed winners. At the same time, however, the distribution of returns in anti-infectives is also very skewed and the median PI in anti-infectives is well below one in value.[12]

Our estimated mean return on R and D investment for the 37 U.S. drug introductions for early 1970's introductions is significantly greater than that computed for an earlier period by David Schwartzman. He estimated an expected rate of return between 3.3 and 7.5 percent using his sample of new drugs introduced between 1962 and 1968. His analysis, however, employed much more aggregate estimates of costs and returns and is not directly comparable to our study.

While we did not estimate an internal rate of return, the mean PI of approximately one in value for our sample implies average returns in the 1970's were in the neighborhood of 10 percent. However, this is intended only

FIGURE 1

DISTRIBUTION OF PROFITABILITY INDEXES OF THIRTY-SEVEN NEW CHEMICAL ENTITIES, 1970–1976



NOTES: Letters indicate firms introducing the thirteen NCEs with PIs ≥ 1. *Assumptions*—(1) ratio of production cost to sales = 0.30; (2) ratio of world net revenues to U.S. net revenues = 1.75; (3) Hansen's R and D costs by therapeutic class; (4) real interest rate = 10 percent; (5) product life = twenty years.

a. (Present value of net revenues)/(present value of R and D cost).

SOURCE: Authors.

to be a baseline estimate for comparative purposes in our sensitivity analysis. Specifically, it assumes a 20 year product lifetime without major revenue losses in the period after patent expiration. This is unlikely for most drugs under the currently evolving structural conditions concerning patent life and product substitution laws. Our analysis in the next section relaxes this assumption to see how the PI is affected by the prospects of significant product substitution after patent expiration.

The most interesting finding emerging from our more microeconomic analysis of expected returns relates to the extreme skewness of returns shown in Figure 1. In effect, these results indicate that pharmaceutical firms are heavily dependent on obtaining an occasional "big winner" to cover their R and D costs and generate a profitable return. While most drugs do not cover full investment costs, a small number of big winners earn several times these costs. This implies pharmaceutical drug research is not unlike oil exploration and other activities with very high degrees of riskiness. This also has implications for threshold R and D investment levels and industry structure in future periods. These issues are considered in the context of the computer simulation model presented in Section V.

III. THE SENSITIVITY OF THE RETURNS ON R AND D TO VARIOUS POLICY FACTORS

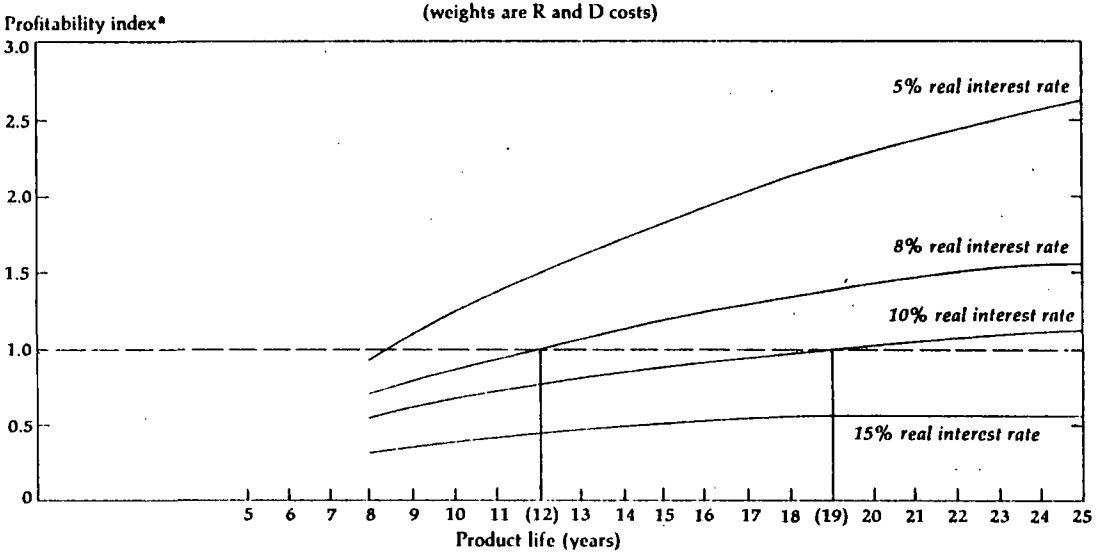
A. Patent Terms Versus Breakeven Lifetimes

Given the large up front costs and long gestation periods for new drug introductions, it is interesting to investigate how long it takes a typical new drug to recoup its R and D investments.

In Figure 2, the weighted average profitability index for the 37 drugs in our sample is shown as a function of expected commercial lifetime. This is plotted for four different values for the real interest rate (or cost of capital) for R and D investments. The point at which each curve intersects the PI=1 line define breakeven product lifetimes. In particular, this figure indicates that to achieve a real return on capital of 10 percent, it takes 19 years of projected net revenues at current rates. On the other hand, if we assume the appropriate real cost of capital (inclusive of a risk premium) is 8 percent, then the product life necessary to break even is 12 years. These

FIGURE 2

RELATION OF WEIGHTED AVERAGE PROFITABILITY INDEX TO PRODUCT LIFE AT VARIOUS INTEREST RATES
(weights are R and D costs)



NOTE: *Assumptions*—(1) thirty-seven NCEs discovered and introduced in the United States between 1970 and 1976; (2) Hansen's R and D cost by therapeutic class; (3) ratio of production cost to sales = 0.30; (4) ratio of world net revenues to U.S. net revenues = 1.75.

a. (Present value of net revenues)/(present value of R and D cost).

SOURCE: Authors.

estimates assume as before that the fraction of production costs to sales is equal to .30 and the ratio of world net revenues to U.S. revenues is 1.75.

The required product life necessary for firms to earn back their R and D investments displayed in Figure 2 can be usefully compared with the data on average effective patent life. Table 2 shows the trend in average effective patent lives of new chemical entities over the period 1963 to 1981. As the IND period and NDA approval times have lengthened over time, the average effective patent life has correspondingly declined. Over the period 1979 to 1981, average effective patent life was only 7.1 years.

As one can readily see from these comparative data, average payback periods in the 1970's tended to exceed by a substantial margin average expected patent lives. The latter were in fact trending downward, leading to an increasing divergence over time.

Of course, the extent to which declining patent life is a serious disincentive to innovation depends on how much product competition and substitution actually develops in the period after the patent expires. As discussed in Section I, the degree of such competition in future periods can be expected to increase significantly as a result of the new product selection laws and other institutional shifts now taking place. If substitution laws increase competition for the innovator's product, then the degree of patent protection will assume a more critical role in the profitability of drug innovation. A shorter effective patent life brings the impact of drug substitution forward in time, increasing the impact of revenue losses on the expected return to innovation.

B. The Interaction Between Substitution Rates and Patent Lifetimes

We examined the sensitivity of the expected profitability of R and D to joint changes in the effective patent life and the degree of substitution using the profitability index (PI) baseline analysis in Section I.[13] For this analysis, we used as our benchmark case a product life of 20 years and a real interest rate of 10 percent. The PI corresponding to these assumptions is 1.029.

In order to study the sensitivity of this PI of 1.029 to changes in the effective patent life and the degree of substitution, we imposed selected

Table 2

Average Effective Compound Patent Life for New Chemical Entities Introduced into the United States from 1963-1981

Year	Average Effective Patent Life (years)
1963	17.4
1964	17.2
1965	15.7
1966	13.0
1967	15.0
1968	14.8
1969	12.7
1970	14.5
1971	11.2
1972	11.5
1973	12.5
1974	12.4
1975	9.6
1976	11.2
1977	9.7
1978	11.3
1979	7.4
1980	7.1
1981	6.8

NOTE: Effective patent life refers to the length of time from the date of FDA approval until the date of patent expiration.

SOURCE: Computed by University of Rochester Center for the Study of Drug Development.

values of these parameters on our data and recalculated the PI's. The results for all cases are given in Table 3.

In this sensitivity analysis, we considered effective patent lives of 5, 8, 12, and 17 years and losses in income due to product substitution after patent expiration of 10, 30, and 50 percent. As noted avove, average effective patent life has been between 5 and 8 years in recent years, but there is a large variance across individual NCE introductions. The assumed range on the product substitution parameter is consistent with that observed in various studies. For example, an FTC sponsored study found median substitution rates varied across states in a range of 5.2 to 45.9 percent.[14]

As one would expect, the calculated PI's in Table 3 are lower for shorter effective patent lives and for greater percentage reductions due to substitution. Under the most unfavorable conditions for R and D activity considered here—a 5-year patent life and a 50 percent reduction in U.S. net income from substitution in the period after patent expiration the rate of return is reduced to .749, or by about 27 percent from the 1.029 benchmark. A 30 percent net income reduction causes the PI to decline by 13 percent for a 5-year effective patent life and by 10 percent for an 8-year life. These estimated effects are significant and, holding other things constant, the combination of short patent lives and substantial levels of product substitution may be expected to make several R and D projects unprofitable to pharmaceutical manufacturers that would be profitable under more favorable conditions on these parameters.

The results in Table 3 underscore the fact that the effects of substitution on R and D returns are highly sensitive to the length of patent protection. If the patent life for drugs actually equalled the legal life of seventeen years, the effects of increased substitution on R and D returns would be quite modest. For example, with a seventeen year life, even a 50 percent reduction in U.S. net income from substitution causes R and D profitability to decrease by only 3 percent in the present example. This reflects the fact that with a reasonably long patent life, the effects of substitution are discounted substantially because they occur well in the future. However, as patent lives decrease, the negative effects of drug substitution on expected returns are magnified in a non-linear fashion.

Table 3

Sensitivity Analysis Showing Profitability Index for Alternative Assumptions About the Impact of Substitution and the Effective Patent Life

Percentage Reduction US Net Income upon Patent Expiration	Effective Patent Life			
	5 Years	8 Years	12 Years	17 Years
-10	.982 (-4.6)	.996 (-3.2)	1.011 (-1.7)	1.023 (-.6)
-30	.888 (-13.7)	.930 (-9.6)	.974 (-5.3)	1.011 (-1.7)
-50	.749 (-27.2)	.863 (-16.1)	.937 (-8.9)	.998 (-3.0)

NOTES: (1) The standard against which the above Profitability Indexes(PI's) should be compared is 1.029. This is the PI for a 20-year commercial life with no reduction in US net income. It is also assumed that the ratio of production cost to sales is .3, the ratio of world net revenues to US net revenues is 1.75, and the real interest rate is .10.

(2) It is assumed that at the end of the effective patent life, substitution will result in the alternative reductions in US net income given above for the remaining years of the 20-year commercial life.

(3) The numbers in parentheses are the percentage reductions for each PI from the standard PI of 1.029.

SOURCE: Authors

C. The Effect of Shorter Regulatory Approval Times

Another simulation exercise that we performed concerned the effect of shorter regulatory approval times on breakeven lifetimes and the returns from R and D investment. Specifically, we analyzed how the breakeven curves in Figure 2 would be shifted if regulatory approval time were reduced from the 2 years or so that it now averages to lesser values (e.g. 1-1/2, 1, and 1/2 years). We found that a 1-1/2 year reduction in the time it takes for a new drug application to be approved would reduce the time it takes for a drug firm to recoup its R and D investment by a full 5 years--from 19 years to 14 years. This is shown in Figure 3 where the analysis focuses on the baseline case with the cost of capital assumed to be 10 percent. Similar findings occur when other parameters are used in the model.

These results underscore the disproportionate effect that changes in "upfront" approval times can have on research incentives. In effect, it takes more than 3 years in added time on the end of the patent period to compensate for an additional one year regulatory delay in gaining NDA approval (given the 10 percent real interest rate and other parameters assumed aove). This reflects the time value of money. A dollar received in the future has a discounted present value that is less than a dollar received today because the latter can earn interest at the firm's opportunity cost of capital.

From a policy standpoint, these results emphasize the important effects on research incentives that recent administrative regulatory reforms can have if they are successful in reducing the review times and clinical testing period for new drug introductions.

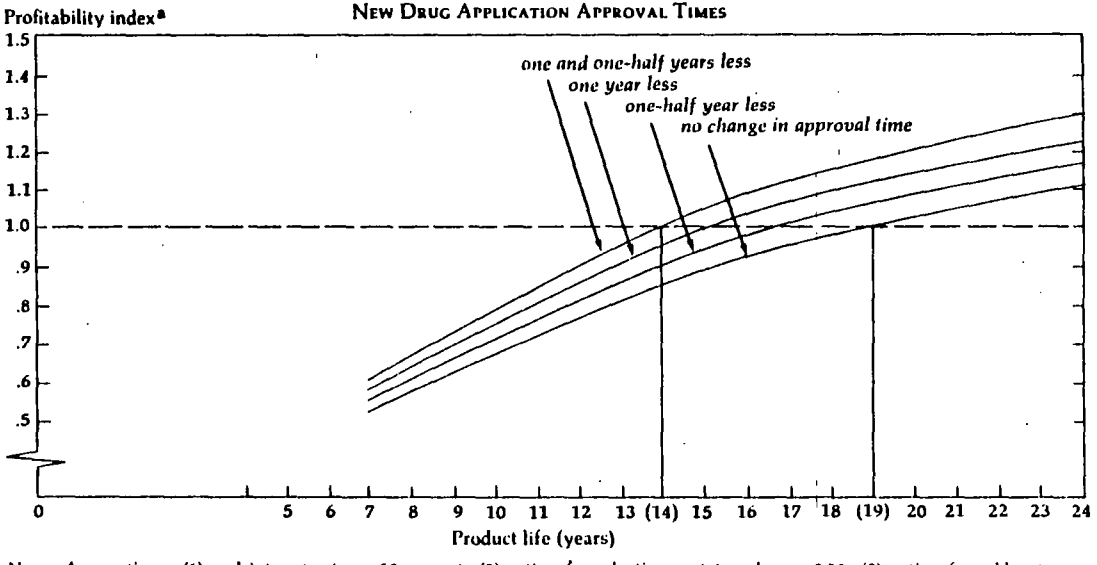
IV. DETERMINANTS OF FIRM R AND D EXPENDITURES

The analysis reported in Sections II and III is focused on the profitability and expected returns from R and D. Expected returns in turn should be a principal factor influencing the level of firm expenditures on R and D. This issue was investigated in a separate study that is reported in this section.

In particular, our study investigated the determinants of firm research intenaity for a sample of ten major pharmaceutical firms over the period 1962 to 1975.[15] Our regression equation was modeled after an earlier empirical

FIGURE 3

RELATION OF WEIGHTED-AVERAGE PROFITABILITY INDEX TO PRODUCT LIFE FOR ALTERNATIVE NEW DRUG APPLICATION APPROVAL TIMES



NOTE: *Assumptions*—(1) real interest rate = 10 percent; (2) ratio of production cost to sales = 0.30; (3) ratio of world net revenues to U.S. net revenues = 1.75; (4) thirty-seven NCEs discovered and introduced in the United States 1970–1976; (5) Hansen's R and D costs by therapeutic class

a. (Present value of net revenues)/(present value of R and D cost).

SOURCE: Authors.

study on this subject performed by Grabowski for the 1959 to 1962 period.[16] To our knowledge, there have been no studies of the determinants of pharmaceutical firm R and D expenditures for the post 1962 period. Given the important structural and policy changes that have occurred in this industry since 1962, a new analysis of this question is now warranted.

A. Hypotheses and Model Specification

The dependent variable in our analysis was research intensity or the firm's aggregate expenditures on R and D deflated by its sales. We had annual observations on this variable for ten major firms over the period 1962 to 1975.[17]

A basic assumption made in Grabowski's earlier study was that firm expectations are significantly influenced by past successes or failures from R and D. Under this hypothesis, expectations change over time as a result of the firm's cumulative track record from R and D. Significant differences in attitudes and expectations concerning R and D can be expected to arise across firms from this adaptive type of process.

The measure of past R and D success used in our analysis is a moving average of a firm's new product sales over a prior five-year period divided by its R and D expenditures over this period. This is essentially a moving average of past firm research productivity where the R and D output is measured in terms of economic success (new product sales).

In addition to expected returns, the cost and availability of investment funds is another basic factor expected to influence long-term R and D investment decisions. In Grabowski's earlier study, a highly significant relation was found between a firm's research intensity and its cash flow margin (measured as the ratio of lagged profits plus depreciation to sales).

The basic rationale for including such a cash flow variable is the hypothesis that firms impute a lower cost of capital to internal funds. This is because of the lower risks (and transaction costs) of internal funds compared with those from external sources. As discussed above, the distribution of returns to drug R and D is highly skewed. In addition, most of the firms total investment is in so-called intangible capital which does not have much, if any, collateral value if a project is unsuccessful. Given these circumstances, it is plausible that firm managers in the drug industry

would have a strong desire for secure financial underpinnings to their investments in R and D and that a positive link between R and D outlays and cash flow availability would occur. This hypothesis is also consistent with the very low debt-to-equity ratios traditionally observed for this industry.[18]

Two other firm specific explanatory variables are also included in our regression analysis of research intensity. An index of firm diversification (the Herfindahl index) across the ethical drug field was included to test Richard Nelson's hypothesis that diversification will positively influence profit expectations from R and D.[19] The basic idea is that a more diversified firm will be better able to exploit serendipitous research findings than one with a narrow base of operations. Hence, it will have the incentive to undertake more R and D, especially basic or discovery research activity.

An index of firm specialization within pharmaceuticals was included as an additional control factor. On compositional grounds, firms with a significant share of their overall operations in other fields (e.g. basic chemicals) would be expected to have lower research intensities since these other areas have less of a technological base compared to pharmaceuticals.

The regression equation estimated in our analysis thus involved variants of the following basic model:

$$(2)\quad RDS_{it} = f(NR_{it}, CFM_{it}, DVR_i, PC_{it})$$

where the variables are defined as follows:

RDS_{it} = research and development expenditures divided by sales for the ith firm in year t;

NR_{it} = index of past R & D success for ith firm in year t; in particular, it equals sales of firm's new product introductions, during first three years of product's commercial life, for all its introductions in years t = 0, -1,....,-4, divided by R & D expenditures in year t - 2.

CFM_{it} = cash flow margin for ith firm in year t; in particular, it equals lagged profits after taxes plus depreciation divided by sales.

DVR_i = a Herfindahl-type index of ith firm's diversification that equals $1 - \Sigma S_j^2$ where S_j = fraction of firm's

ethical drugs sales in jth class, calculated at a midpoint year of the sample

PC_{it} = percentage of ith firm's total sales accounted for by ethical drug sales during year t.

B. Empirical Results

In table 4, the linear regression coefficient estimates for the model specified in equation (2) are presented. The coefficients are estimated on the pooled sample for the ten pharmaceutical firms taken over the entire fourteen-year period 1962-1975 and also for the two seven-year subintervals, 1962-1968 and 1969-1975.

The two primary variables of interest, cash flow and past R and D productivity, are positive and statistically significant at normal confidence intervals. The diversification variable takes on the expected positive sign and is statistically significant at 10 percent level for the full regression period. The variable indexing the percentage of firm sales volume accounted for by pharmaceuticals also has the expected positive coefficient and is statistically significant in all cases.

The present set of estimates for the cash flow and R and D productivity variables are very similar in magnitude to the previously published results for the pre 1962 period. Thus, the model appears to be quite robust.

The coefficient estimates on the cash flow margin variable in Table 4, are very close to the 0.24 coefficient estimate on this variable in Grabowski's early study. These estimates imply that a $1 million increase (decrease) in cash flow will lead approximately to a quarter-million increase (decrease) in R and D expenditures. Estimates on the magnitude of this coefficient have remained stable for an extensive period in which a number of important structural changes have occurred in the industry.

We also found that the effects on R and D investment of the past R and D success and cash flow variables are interrelated. In particular, past R and D success influences not only a firm's expected future returns to R and D but also its level of cash flow availability to undertake R and D. We investigated this point by estimating distributed lag relations between the cash flow margin and past R and D productivity measures. We found a statistically significant relation between these variables that was characterized by relatively long mean lags—namely, seven to nine years.[20] Hence, there is a

Table 4

Determinants of Pharmaceutical R & D/Sales Ratios

Ten Major Firms over Period 1962-1975

Equation Number	Intercept	CFM	NR	DVR	PC	R^2/F	Period
(1)	-.051	.268	.019	.045	.063	.49/32.6	1962-1975
	(-1.86)	(6.07)	(3.80)	(1.73)	(5.11)		
(2)	-.057	.282	.016	.035	.084	.53/18.9	1962-1968
	(-1.36)	(4.38)	(2.49)	(.88)	(5.01)		
(3)	-.033	.255	.029	.042	.041	.44/13.1	1969-1975
	(-.85)	(3.81)	(1.96)	(1.09)	(2.18)		

SOURCE: Authors: A detailed discussion of the data underlying these estimates is presented in the Appendix to our paper "The Determinants of Research and Development in the Pharmaceutical Industry" (see footnote 15 for full reference citation).

long-term interactive relation between these variables and R and D. Specifically, if a firm's research productivity remains low for a number of years, its cash flow will also eventually be significantly affected, and there will be further negative impacts on its R and D investment.

In sum, our regression analysis indicates that both expected returns and cash flow are two major economic factors influencing firm incentives and ability to invest in R and D outlays for new drug products. From a policy standpoint, these results therefore indicate that R and D expenditures will be sensitive to the spectrum of government policies that impact on these variables. Specifically, if changes in regulatory stringency, patent term protection, or substitution practices, significantly impact on the expected returns or cash flow from new product innovation, this will result eventually in significant changes in R and D expenditures.

V. AN EXPLORATORY COMPUTER SIMULATION MODEL OF PHARMACEUTICAL INNOVATION

In the research work discussed in Section III, we performed a sensitivity analysis of how different policy parameters would affect the expected returns on drug R and D. This analysis was focused on a single firm and ignored the interactions with rival firms as well as the long run side effects on other variables of interest.

In this section, we describe a research project that provides the initial development and results for a more elaborate simulation model of the innovative competitive process in pharmaceuticals.[21] Our primary objective is to better understand the interdependencies between the variables driving this process and analyze the long-run effects of different parameter changes. In particular, the model has a multi-period and multi-firm character so that we can focus on the long-run evolutionary consequences of different research environments and policy scenarios.

Our computer simulation model has many analytical similarities to the evolutionary models studied in several recent papers by Nelson and Winter.[22] As in their work, we focus on how industry structure and innovative performance evolve over time in the presence of different specifications on various determinant factors. However, in contrast to their models, which focus on process oriented technological change and productivity shifts over time, we

analyze the case of new product innovation. Competition in pharmaceuticals centers on new product rather than new process innovation and we have formulated our model to reflect this fact.

A. Description of the Model

As in the Nelson-Winter reseach work, our simulation model involves the analysis of a hypothetical industry situation. It is constructed, however, to incorporate the relevant aspects of new drug competition in pharmaceuticals. In specifying the probability distributions and parameters of this model, we use representative values drawn from our various empirical studies of the pharmaceutical industry.

The innovation process proceeds roughly as follows in this model. Each firm in the model funds an ongoing portfolio of research projects or investigational new drugs (IND's) of different vintages. R and D projects taken to fruition are eligible for a "draw" to determine if the candidate is to be marketed. The payoff distribution of successful new drug introductions is highly skewed. It is, in fact, derived from the actual revenue distribution of all U.S. NCE introductions over the period 1970 to 1976.

Sales revenues realized by the firms in the model are interdependent in that new product sales come in part at the expense of established product sales and in part represent an expansion of the total market. The relationship specifying what percentage of new product sales are market expanding versus redistributive in nature is one of the main parameters that we experiment with in our simulation runs. Another form of interdependence built into the model is that if one firm is successful in drawing a "big winner" in a particular therapeutic class, this reduces the probability of any other firm also drawing a big winner in that class in immediately subsequent periods.

The firm's probability draws to determine the technical and marketing success of its R and D projects have a major effect on its dynamic path over time. It is possible for a firm to have a run of project successes which correspondingly lead to large cash flows, high R and D, and perhaps future successful NCE's. On the other hand, a run of project failures can lead a firm to cut back on new R and D projects, and even drop out of the business under extreme conditions.

The firm's aggregate R and D budget is determined initially as a certain percentage of its total cash flow. This percentage is based on historical experience in the pharmaceutical industry, using data from 9 major research intensive drug firms. Over time this percentage may be altered according to different decision rules built into the model. There is also a termination rule. If the firm is unable to fund ongoing R and D projects except by spending such a high fraction of its net revenues that this causes a significant probability of bankruptcy, then the firm discontinues its R and D activities entirely.

B. Simulation Experiments and Results

In our simulation experiments, we first analyzed a "baseline" case which was formulated with representative parameter values for the drug innovation during the 1970's. Then various parameter values of interest were varied in the simulation experiments and the results evaluated against the benchmark baseline case.

The parameters that were varied in the computer simulation experiments include: the probability of technical success, regulatory approval times, the degree of market substitution between new and existing drugs, the effective patent protection terms after commercial introduction, and the degree of market competition from imitative or generic drugs after patents expire.

In all of our experiments we were interested in evaluating the long-term consequences of different scenarios. Hence, our simulation experiments were run for 50 time periods where the unit of time corresponds to a year. In addition, because of the probabilistic characteristic of the model, we replicated each experiment ten times and computed average values on all the variables of interest.

It is useful here to summarize only the broad findings of our simulation experiments, since the model is still at a preliminary stage of development and we expect to increase its scope in future research. The initial results from the model experiments appear both plausible and interesting.

First, our analysis indicates that technological opportunity factors play a very important role in determining the annual level of new product introductions and the growth over time in industry sales revenues. Changes in the probability of technical success in our model had a large multiplier effect on

the annual level of new product introductions. For example, changing the odds of technical success from 1 in 10 (the baseline case) to 1 in 8 causes the average level of new drug introduction to more than double over the long run.[23]

Another factor with significant implications for long-run introduction levels is the degree of substitution betwen new and established drugs. When new drugs essentially substitute for established ones (instead of opening up new market segments) then innovation has a strong market concentrating effect. This ultimately leads in our model to fewer sources of innovation and a smaller level of new product introductions.

The policy factors considered in our previous sensitivity analysis of firm profitability (described in Section II) were also found to have significant effects on long-run innovation levels. Specifically, we found that the annual level of new product innovation was significantly related to regulatory approval times. Furthermore, the effect of patent terms and generic drug substitution rates can interact to constrain innovation output.

The results suggest that the long-run impacts of a short patent life and high rate of product substitution can be quite substantial. In particular we found that for the 8-year patent life, 50 percent substitution rate case, the annual level of new product introductions declined 30 to 40 percent compared to the baseline case. This is a much greater impact than one might expect on the basis of observed changes in expected returns, using the partial equilibrium approach of Table 2.

Overall, these initial experiments from our computer simulation model suggest that technological opportunity has a key determinative effect on an industry's potential for innovation, but that policy and economic factors also have an important effect on whether that potential is realized or not. The findings illustrate how different scenarios on future policy environment can generate very different dynamic effects over time and lead to very different structural conditions over the long run.

As emphasized above, our computer simulation model is still very much in the exploratory phase. There are also clearly a number of interesting directions for further research suggested by this modeling effort. Our analysis here abstracts from several possible strategic interactions that might be fruitfully analyzed in future work. For example, firms might be

assumed to specialize in different kinds of research activities with varying degrees of riskiness. In addition, they could pursue an adaptive strategy in setting their total R and D budgets. The actions of non-research intensive drug producers could also be brought into the model in an explicit fashion. One could also allow for probabilistic entry into particular therapeutic markets that have experienced above average profitability. We plan to incorporate these kinds of extensions in our future modeling efforts.

VI. SUMMARY AND CONCLUSIONS

In this project, a number of related studies were performed to examine the effects of economic and policy variables on the R and D decisionmaking process and the returns from pharmaceutical innovation. Several interesting findings emerged from these analyses.

First, our empirical work indicates the distribution of returns to pharmaceutical R and D is highly skewed in character. In our analysis of all the U.S. discovered new drug introductions for the period 1970 to 1976, we found only 13 of these 39 new drugs had ex post discounted revenues greater than ex ante R and D costs (i.e. a profitability index greater than one). This means R and D is subject to high levels of uncertainty and above average riskiness. Research oriented firms are heavily dependent on obtaining an occasional "big winner" to cover their R and D costs and generate a profitable return on their overall R and D investment.

Our analysis of breakeven product lifetimes indicates that it takes 19 years for the average new drug to cover R and D costs at a real interest rate of 10 percent. If we alternatively assume an interest rate of 8 percent for pharmaceutical firm R and D investment, the breakeven lifetime is 12 years. This range in breakeven product lifetimes can be compared to the average effective patent life for new drug introductions. Effective patent terms averaged approximately 7 years over the 1979 to 1981 period and have been trending downward over time.

Our results indicate that the effect of declining patent life on the returns to innovation depends critically on the degree of product substitution and competition in the period after patent expiration. In a sensitivity analysis of this issue, we found patent life and substitution impact on

returns in a non-linear fashion. If the patent life actually equalled the legal life of 17 years, the effects on expected returns of even very high rates of substitution would be quite small (because they occur so far into the future and are heavily discounted). On the other hand, if the effective patent life is in the range of 5 to 8 years, the prospects of significant substitution rates after patent expiration have a much greater negative impact on expected returns.

Another issue that we investigated concerned the effect of shorter regulatory aproval times on brekeven lifetimes and the returns to drug R and D. Because regulatory approval occurs "up front", the time delays in regulatory approval can exert disproportionate disincentive effect on the profitability of new drug introductions. This point was illustrated most dramatically in our breakeven analysis. We found that a one and one-half year reduction in regulatory approval time reduces the breakeven time for a drug to recoup its R and D investment by a full five years. This result implies that it takes more than three years in added time on the end of patent period to compensate for an additional one year of regulatory delay in gaining NDA approval. These results underscore the important incentive effects potentially realizable from current efforts to reduce regulatory delays and inefficiencies.

In our analysis of the determinants of pharmaceutical firm research intensity we found prior research success and the availability of internally generated investment funds to be significant factors positively affecting R and D investment outlays. The coefficient estimates on these variables were quite robust over a period extending back well into the Sixties. These results indicate that expectations on the profitability of R and D tend to be formed in an adaptive manner. Hence, policy variables influencing firms expectations on returns will affect firm R and D investments in a distributed lag fashion over time.

Our final research project involved the development of a computer simulation model to study competition by innovation in the pharmaceutical industry. In specifying the probability distributions and parameters of this model, we used representative values drawn from our empirical studies of the determinants and returns from pharmaceutical R and D. Our objective was to study the long run evolutionary consequences of different research environ-

ments and policy scenarios as well as the interdependencies between the various economic variables driving this process.

While this modeling effort is still at an early exploratory stage, the initial findings from the model experiments are very interesting. In particular, this analysis suggests that changes in patent terms, substitution rates and regulatory clearance times can have important dynamic interactions. For example, the long run implications for drug innovation of a relatively short patent life combined with high substitution rates are much larger in magnitude than one might predict on the basis of a static partial equilibrium analysis of this question. These particular findings point up a number of interesting directions for further research work. We plan to pursue various generalizations of our computer simulation model in future studies.

Footnotes

1. For a formal analysis of the amount of patent time lost as a result of increased regulatory review periods, see Martin M. Eisman and William Wardell, "The Decline in Effective Patent Life of New Drugs", Research Management, January 1981, p. 18-21.

2. For a discussion of the different characteristics of various state laws see Henry Grabowski and John Vernon, "Substitution Laws and Innovation in the Pharmaceutical Industry" Law and Contemporary Problems (Winter-Spring 1979) pp. 43-66.

3. In October 1982, the Reagan Administration published in the Federal Register its first proposed rule changes dealing with the new drug application phase of the approval process for new drugs. (See Federal Register, vol. 47, no. 202, Tuesday, October 19, 1982, pp. 46622-66). New regulatory rules on the investigational new drug (IND) process are scheduled for 1983.

4. Henry G. Grabowski, "The Determinants of Industrial Research and Development: A Study of the Chemical, Drug and Petroleum Industries", Journal of Political Economy, vol. 76, no. 2, March-April 1968, pp. 292-306.

5. Two major prior studies of the returns on pharmaceutical innovation are David Schwartzman, The Expected Return from Pharmaceutical Research

(Washington, D.C., American Enterprise Institute, 1975), and Martin N. Baily, "Research and Development Costs and Returns: The U.S. Pharmaceutical Industry" Journal of Political Economy (Jan/Feb. 1972).

6. The analyses presented in Sections II and III are taken from our papers "A Sensitivity Analysis of Expected Profitability of Pharmaceutical R and D" Managerial and Decision Economics (March 1982), pp. 36-40; and "Government Policy and Innovation in the Pharmaceutical Industry" in Richard R. Nelson, editor, Government and Technical Progress, A Cross-Industry Analysis (New York, N.Y.: Pergamon Press, 1982), pp.283-360.

7. Ronald W. Hansen, "Pharmaceutical Development Cost by Therapeutic Categories", Working Paper Series no. GPB-80-6, University of Rochester Graduate School of Management, March 1980.

8. The assumption of a cost of capital (in real terms) in the range of 10 percent for the pharmaceutical industry is consistent with various academic studies. For example, independent studies by Grabowski-Mueller and Clarkson calculated the realized return on stockholder equity, after correcting for the expending of intangible capital stocks to be approximately 10 percent in real terms (See, Henry Grabowski and Dennis Mueller "Industrial Research and Development, Intangible Capital Stocks, and Firm Profit Rates", Bell Journal of Economics, Autumn 1978, pp. 328-343; and Kenneth Clarkson "The Use of Pharmaceutical Profitability Measures for Public Policy Actions" in Robert Chien, ed. Issues in Pharmaceutical Economics (Lexington, Mass., Lexington Books, 1979), pp. 105-124.) Ronald Hansen assumed a cost of capital of 8 percent as his best estimate based on discussions with industry decisionmakers.

9. See, "A Sensitivity Analysis of Expected Profitability of Pharmaceutical Research and Development, op. cit., p. 38.

10. Celia Thomas "The Return to Research and Development in the Pharmaceutical Industry", Unpublished Ph.D. Dissertation Duke University, 1981, Chapter 4.

11. Another study which also found extreme skewness is John Virts and Fred Weston "Expectations and the Allocation of Research and Development Resources" in Robert Helms, editor, Drugs and Health (Washington, D.C. American

Enterprise Institute for Public Policy Research: 1981). The Virts and Weston Study, however, did not calculate the full distribution of returns as in Figure 1 and 2 but only compared the performance average of the top 25 percent of new chemical entity introductions with the average for the other 75 percent of the distribution.

12. While the mean profitability index was 2.98 in anti-infectives, the median index was only 0.17.

13. We had planned to examine the factors influencing the amount of substitution occurring in different states for drugs with recently expired patents. A preliminary analysis of this question was begun in co-operation with the Health Care Financing Administration in Washington, D.C. It was decided, however, that current data sources were not sufficient to do a rigorous empirical analysis of this issue. Instead, with the National Science Foundation approval, we did the computer simulation model reported in Section V which involved a logical extension of the analysis in our original grant proposal. A new study of substition law effect has recently been initiated by Allison Masson of the Federal Trade Commission (see footnote 14).

14. A questionnaire survey of 723 pharmacists in seven states was performed by the Federal Trade Commission to examine impacts of the new substitution laws. The states were selected on the basis of geographic distribution and variations in the provisions of the state's substitution laws. The median response by state to the question "What percentage of new prescriptions involve substitution?" varied from a low of 5.2 percent in Arkansas to 45.9 percent in Wisconsin. See, Bureau of Consumer Protection, Federal Trade Commission, Drug Product Selection, 1979.

A more recent analysis of this question by Allison Masson of the Federal Trade Commission for a sample of selected drugs using prescription audit data also revealed wide variability in substitution rates across different kinds of therapeutic categories. Allison Masson, Federal Trade Commission, "The Physician Prescribes, the Pharmacist Decides: The Effects of State Drug Product Selection Laws". Paper presented to the American Economic Association Meetings, December 1982.

15. The results in this section are taken from our study "The Determinants of Research and Development Expenditures in the Pharmaceutical Industry" in Robert Helms, editor, Drugs and Health (Washington, D.C.: American Enterprise Insitutite for Public Policy Research, 1981) pp. 3-20.

16. Henry G. Grabowski, "The Determinants of Industrial Research and Development" op. cit. , pp. 292-306.

17. We also attempted to obtain firm specific R and D expenditures by therapeutic class but an insufficient sized sample was obtained to do statistical analysis on these data.

18. Stewart Myers argues that firms that tend to invest in assets that take a relatively long term to realize returns and are not easily salable (i.e., R & D as opposed to plant and equipment) are less likely to finance with debt instruments. See Stewart Myers, "Determinants of Corporate Borrowing," Journal of Financial Ecomomics, vol. 5 (November 1977), pp. 147-75.

19. Richard Nelson "The Simple Economics of Basic Scientific Research" Journal of Political Economy June 1959, pp. 297-306.

20. Grabowski and Vernon, "The Determinants of Research and Development in the Pharmaceutical Industry" op. cit., p. 16.

21. The results in this section are discussed in more detail in our paper "A Computer Simulation Model of Pharmaceutical Innovation" presented to the Arne Ryde Symposium on Pharmaceutical Economics in Helsingborg, Sweden, September 27, 1982. The paper will be published in the Symposium Proceedings.

22. Richard R. Nelson and Sidney G. Winter, An Evolutionary Theory of Economic Change, (Cambridge, Mass: Harvard University Press, 1982.

23. This multiplier effect reflects both an R and D productivity effect (more new drug introductions from a given level of R and D investment) as well as a cash flow availability effect (higher level of internal funds available for

R and D investment over time.) These two effects work together to produce a compound interactive effect on new drug introductions and industry sales growth.

APPENDIX

Publications and Papers Resulting from NSF Grant PRA-79-17524

I. Primary Publications and Papers

(1) Grabowski, Henry and John Vernon, "A Sensitivity Analysis of Expected Profitability of Pharmaceutical R and D," Managerial and Decision Economics, vol. 3, no. 1, March 1982, pp. 36-40.

(2) Grabowski, Henry and John Vernon, "A Computer Simulation Model of Pharmaceutical Innovation," forthcoming in the Proceedings of the Arne Ryde Symposium on Pharmaceutical Economics, University of Lund, Helsingborg, Sweden, September 1982.

(3) Grabowski, Henry and John Vernon, "The Determinants of Research and Development Expenditures in the Pharmaceutical Industry," in Robert Helms, editor, Drugs and Health , (Washington, D.C. American Enterprise Institute, 1981), pp. 3-20.

(4) Hansen, Ronald W., "Pharmaceutical Cost by Therapeutic Categories", University of Rochester Graduate School of Management Working Paper Series No. GPB-80-6, March, 1980.

(5) Thomas, Celia, "The Return to Research and Development in the Pharmaceutical Industry,". Unpublished Ph.D. Dissertation, Duke University, 1981.

II. Additional Publications

(1) Grabowski, Henry and John Vernon, "Government Policy and Innovation in the Pharmaceutical Industry," in Richard R. Nelson, editor, Government and Technical Progress, A Cross-Industry Analysis, (Permagon Press, New York, N.Y., 1982), pp. 283-360.

(A broader analysis of government policy effects on drug innovation sponsored by the National Aeronautics and Space Administration under Grant NSG636. This NASA study incorporates the findings from the current NSF grant.)

(2) Grabowski, Henry, "Public Policy and Pharmaceutical Innovation," Health Care Financing Review, Volume 4, no. 1, September 1982, pp. 75-87.

(3) Grabowski, Henry and John Vernon, The Regulation of Pharmaceuticals: Balancing the Benefits and Risks. American Enterprise Institute for Public Policy Research, Washington, D.C. 1983), Chapter 4, pp. 49-62.

III. Presentations at Conferences and Meetings

(1) Grabowski, Henry and John Vernon, "The Determinants of Research and Development in the Pharmaceutical Industry," American Enterprise Institute Conference on Drugs and Health, Washington, D. C., November 1979.

(2) Grabowski, Henry and John M. Vernon, "Government Policy and Innovation in the Pharmaceutical Industry", Center for Science and Technology, New York University Graduate School of Business Administration, New York, N.Y., December 1980.

(3) Grabowski, Henry and John Vernon, "The Regulation of Pharmaceuticals," American Enterprise Conference on Health, Safety, and Environmental Regulation, Washington, D.C., November 1981.

(4) Grabowski, Henry, "Alternative Future Scenarios for the Pharmaceutical Industry," Project Hope, Institute for Health Policy, Conference on Pharmaceuticals in the Year 2000, Millwood, Virginia, March 1982.

(5) Grabowski, Henry and John Vernon, "A Computer Simulation Model of Pharmaceutical Innovation," University of Lund, Arne Ryde Symposium on Pharmaceutical Economics, Helsingborg, Sweden, September 1982.

A Sensitivity Analysis of Expected Profitability of Pharmaceutical Research and Development

HENRY GRABOWSKI and JOHN VERNON

Department of Economics, Duke University, North Carolina, USA

An indirect effect of increased regulation of the pharmaceutical industry in the USA has been a reduction in the effective patent life for a new drug. The reason is that the average time to develop a new chemical entity and gain regulatory approval far exceeds the time necessary to obtain a patent. The period of patent protection now averages only 10 years compared to the legal life of 17 years. In this article we describe a sensitivity analysis which sheds some light on the relationship between product life and profitability. Based upon a number of important assumptions, we show, for example, that at a 10% real rate of return the average 1970–1976 new drug required 19 years to break even. At an 8% real rate of return, 12 years would permit the firm to break even.

The pharmaceutical industry has been one of the most innovative industries in the USA over the past 30 years. However, the rate of new drug introductions in the past decade has been significantly lower than it was in the earlier post World War II period. As a result, the reasons for and social significance of this decline have been the subject of considerable attention by both policymakers and academicians.

The decline in new drug introductions has been accompanied by strong upward trends in costs, time and risks associated with discovering and developing new drugs. As one would expect, studies of the rate of return to drug innovation have found relatively low returns.[1,2] It is also the case that US firms are increasing their Research and Development (R and D) expenditures in foreign countries at a faster rate than in the USA. In fact, in real terms, US R and D expenditures may be declining. One important explanation for these trends has been the increased regulatory controls of the Food and Drug Administration (FDA) which resulted from the 1962 Kefauver–Harris amendments to the Food, Drug and Cosmetic Act.[3] These amendments required a new drug's efficacy, as well as safety, to be demonstrated on the basis of well controlled scientific tests prior to marketing approval by the FDA.

An indirect effect of regulation has been a reduction in the effective patent life for a new drug. The reason is that the average time to develop a new chemical entity (NCE) and gain regulatory approval far exceeds the time necessary to obtain a patent. While the length of patent protection has been of secondary import historically in the drug industry, this situation appears to be changing with the repeal of antisubstitution laws.[4] That is, the antisubstitution laws made it possible for innovating firms, through strong brand loyalties, to maintain dominant market positions for their products even after patent expiration. Now, in many states, lower cost generic products that become available upon patent expiration can be substituted by pharmacists even though the physician prescribes the original brand name products.

The period of patent protection now averages only 10 years or so as compared to the legal life of 17 years. For this reason, legislative proposals have been made to restore part or all of the patent life lost during the chemical testing and FDA review period. The objective, of course, is to stimulate innovation by increasing the expected return to pharmaceutical R and D.

Given the current interest in patent policy and its impact on the expected return to pharmaceutical R and D, we have performed a preliminary sensitivity analysis which sheds some light on the relationship between product life and profitability. Of course, the results are inadequate to support any particular product life as being the 'socially optimal' patent life. Rather, the work here is intended as a first step in understanding the quantitative effects of various product lives on profitability as well as other related issues.

Based upon a number of important assumptions, we show, for example, that at a 10% real interest rate the average 1970–1976 new drug required 19 years to break even. At an 8% interest rate, 12 years would permit the firm to break even. 'Breaking even' means to cover all R and D discovery and development costs in addition to production and marketing costs.

While the above paragraph refers to the *average*

CCC-0143-6570/82/0003-0036$02.50

investment in drug innovation, we also show that the variance in payoffs is great and highly skewed. For example, of the 37 NCEs discovered and introduced in the USA in the 1970–1976 period, only 13 were able to at *least* cover their costs (over a 20 year life). This is true despite the fact that the *average* payoff to the 37 NCEs was slightly in excess of the average cost.

An interesting finding for R and D strategic decisions is the variation of profitability across therapeutic classes. Although the small numbers of NCEs in certain classes make it dangerous to generalize, it appears that for the 1970–1976 period the anti-infective category was clearly the most profitable. The cardiovascular and anti-inflammatory drugs were apparently next in order of profitability, while the remaining classes failed, on average, to break even.

Another interesting result is the impact of reducing FDA approval time on profitability. Suppose there is no change in the amount of clinical testing performed; however, suppose the time taken by the FDA to approve a submitted New Drug Application (NDA) is reduced from the usual 24 months to 6 months. What is the impact of this shorter approval time on profitability? We show, for one set of assumptions, that the average drug's product life necessary to break even is reduced by about 5 years – from 19 years to 14 years. In other words, reducing NDA approval time by 18 months is equivalent in present value terms to adding on 5 years to the drug's life.

In the next section we shall review the data and assumptions used in the analysis. The concluding section consists largely of a set of figures which show our principal results.

DATA AND ASSUMPTIONS

The primary data used in the analysis are US sales and promotion expenses for NCEs introduced into the US market between 1970 and 1976, and R and D costs by therapeutic class estimated by Professor Ronald W. Hansen.[5,6] The sales and promotion data are Intercontinental Medical Statistics (IMS) data.

Two additional important types of data were not available – the cost of producing the NCEs after FDA approval and the net revenues resulting from sales in foreign countries. In both cases we have relied on estimates made by Celia Thomas as part of her PhD dissertation at Duke University. For example, her best estimate for production costs as a fraction of sales is 0.30. However, because of the uncertainty about this estimate, we have also examined the effect of estimates of 0.20 and 0.40. A similar approach was taken with respect to Thomas' estimate of 1.75 as the ratio of world-wide net revenues to US net revenues. That is, estimates of 1.5 and 2.0 were also used in a sensitivity analysis.

As noted above, the R and D cost estimates are based on a study by Hansen. He obtained survey data from 14 pharmaceutical firms on the R and D costs for a sample of NCEs first tested in man from 1963 to 1975. The average discovery cost was $19.6 million and the average development cost was $14.1 million, for a total of $33.7 million. The $33.7 million represents the capitalized value (at 10% interest and in 1967 dollars) at the date of marketing approval.[5]

At our request, Hansen estimated the costs per NCE on a therapeutic class basis. These are the cost estimates used in this analysis, and as will be shown, reveal a rather large variation across classes. We should also note that Hansen's estimates include the costs of NCEs that enter clinical testing but are not carried to the point of NDA approval.[6] Hence, the estimates should be interpreted as the average *expected* cost of discovering and developing a marketable NCE.

Of course, real R and D costs have probably been increasing over time. However, by restricting the analysis here to NCEs marketed between 1970 and 1976, we can assume that Hansen's estimates match our NCEs reasonably well without the need for further adjustments. We also note that our primary analysis pertains to 37 NCEs that were both discovered and introduced in the USA. Some 23 additional NCEs were discovered in foreign countries and introduced in the USA during this period. However, only limited use was made of these 23 NCEs because Hansen's R and D cost figures clearly do not apply to foreign discoveries.

As observed above, Hansen's estimates are expressed as capitalized values at the date of marketing. For example, the capitalized expected cost of discovering and developing a cardiovascular drug at the date of marketing is $30.6 million in 1967 dollars. Because he worked with constant dollars, Hansen used real interest rates; in the example

JOHN M. VERNON obtained his PhD in Economics at Massachusetts Institute of Technology in 1966. He is presently Professor of Economics at Duke University. His research interests include the economics of the pharmaceutical industry and other topics in industrial economics.

HENRY G. GRABOWSKI received his PhD in Economics from Princeton in 1967. He is also Professor of Economics at Duke University. His research interests involve the economics of regulation, industrial innovation and applied microeconomic theory.

Address: Department of Economics, Duke University, Durham, North Carolina 27706, USA.

above, the interest rate is 10%. The natural measure for comparison with Hansen's estimate is the present value of the net revenue stream resulting from the NCE. To be consistent, of course, the net revenue stream must be deflated to 1967 dollars and discounted to the date of marketing at the same real interest rate. The ratio of present value of net revenue to capitalized R and D cost is termed the profitability index (*PI*) in the finance literature, and it will be the measure of expected returns used here. Clearly, a $PI = 1$ implies a project that just breaks even.

The formula for the *PI* for a particular drug is

$$PI = \frac{1}{RD} \sum_{t=1}^{L} (S_t - P_t - mS_t) f e^{-r(t-1)}$$

where S_t = deflated sales revenue in year t; P_t = deflated promotion expenses in year t; m = production cost as fraction of sales; f = ratio of world-wide net revenues to US net revenues; r = real interest rate; L = product life; and RD = capitalized value of R and D costs by therapeutic class. Table 1 provides some general information about the data.

Actual sales and promotion data were available for 10 years for NCEs introduced in 1970, for 9 years for 1971 NCEs, and so on, so that data were available for only 4 years for 1976 NCEs.[7] Hence, projections into the future were necessary and were made in two steps. In step one, sales and promotion expenses were projected out to the tenth year after introduction for all NCEs, based on the average growth rate experience for a sample of 55 NCEs with introduction dates extending back into the mid-1960s. No projection was necessary for 1970 NCEs while 1976 NCEs required a 6 year extrapolation. In step two, sales and promotion expenses were projected beyond the tenth year, by assuming that nominal dollar increases would be exactly offset by inflation. In other words, real dollar sales and promotion were held constant at their tenth year values.

RESULTS OF THE ANALYSIS

The figures in this section are intended to be largely self-explanatory. The basic relationship is that between the *PI* and the Product Life. For the analysis here we have simply set the net revenue stream equal to zero at the end of the assumed Product Life. More reasonable assumptions about the time pattern of net revenues will be incorporated in later work. For example, we might assume that upon patent expiration there may be an immediate impact of generic competition, but that the market share diminishes gradually.

Figure 1 shows the *PI* versus Product Life relationship for four alternative real interest rates (cost of capital). As stated the *PI* variable is a weighted average *PI* for the 37 NCEs, where the weights applied are the R and D costs. The fraction of production cost to sales is held at 0.30 and the ratio of world net revenues to US net revenues is taken to be 1.75. If we assume that the appropriate real cost of capital (inclusive of a risk premium) is 10%, then the product life necessary to break even on average is 19 years. An 8% cost of capital reduces the break-even life to 12 years.

Since the assumptions about production costs and foreign sales are uncertain, Fig. 2 was prepared to reflect this uncertainty. Given the subjective probability distributions shown in Fig. 2, a band of one standard deviation in width about the weighted average *PI* is presented. The one standard deviation band brackets the break-even life between approximately 14 and 30 years.

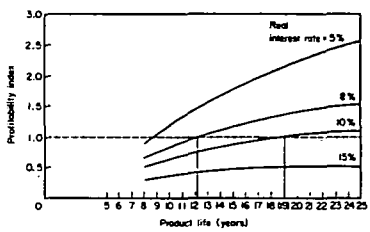


Figure 1. Weighted average *PI* versus life for various interest rates (weights are R and D costs). Assumptions: (1) 37 NCEs discovered and introduced in the USA between 1970 and 1976; (2) Hansen's R and D cost by therapeutic class; (3) ratio of production cost to sales = 0.3; and (4) ratio of world net revenues to US net revenues = 1.75.

Table 1.

Therapeutic class	Hansen's R and D cost (10%, 1967 dollars)	Number of US NCEs	Number of foreign NCEs
A. Cardiovascular	30.6	4	1
B. Neurologic, analgesic	36.3	6	2
C. Psycho-pharmacology	70.0	3	4
D. Metabolic, antifertility	65.3	5	4
E. Anti-infective	19.1	12	6
F. Anti-inflammatory	68.3	4	1
G. Gastro-intestinal, respiratory, surgery	28.5	3	5
Total		37	23

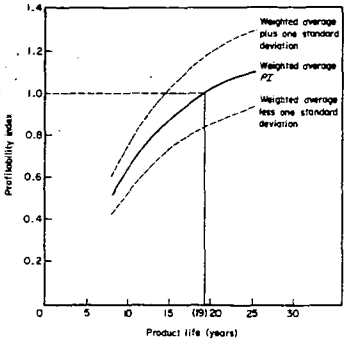


Figure 2. Weighted average *PI* versus life with uncertainty bands (uncertainty due to estimates of *m*, *f*). Assumptions: (1) 37 NCEs discovered and introduced in the USA between 1970 and 1976; (2) real interest rate = 10%; (3) Hansen's R and D costs by therapeutic class; and (4) ratio of production cost to sales, m, and ratio of world net revenues to US net revenues, *F*, have probabilities:

Probability	*m*	*f*
0.25	0.2	1.5
0.50	0.3	1.75
0.25	0.4	2.0

More specifically, we assume that there is a 50% chance that the ratio of production cost to sales is 0.3, and a 25% chance each that the ratio is 0.2 or 0.4. Similarly, we assume that the ratio of world net revenues to US net revenues is 1.75 with a 0.5 probability, and either 1.5 or 2.0 with probabilities of 0.25 each. These probability distributions give rise to a probability distribution of the weighted average *PI*, and the one standard deviation band for this distribution is shown by the dashed lines in Fig. 2.

Figure 3(a) focuses on a different type of uncertainty. It shows a frequency distribution of the *PI*s of the 37 NCEs. Clearly, the distribution is highly skewed – with only 13 of the 37 projects breaking even or better. The letters are codes for the innovating firms and indicate that firm 'A' had 3 'winners', while the remaining 10 were spread over 10 different firms. Figure 3(b) is the same figure except that the letters are codes for the therapeutic classes of the 13 NCEs that break even or better.

Of course, the 24 NCEs that have *PI*s of less than unity fail to break even only in the sense of not covering fully allocated discovery and development costs, including a share of the costs of drugs that never make it to the point of NDA submission. This is the nature of Hansen's R and D cost estimates. If we consider only the development costs of a single NCE (neglecting discovery costs and attrition costs), the capitalized R and D costs decline substantially.

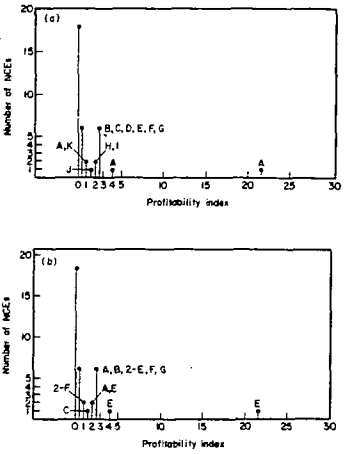


Figure 3. Distribution of *PI* of 37 NCEs 1970–1976. (a) Letters indicate firms introducing the 13 NCEs with $PI \geq 1$. Assumptions: (1) ratio of production cost to sales = 0.3; (2) ratio of world net revenues to US net revenues = 1.75; (3) Hansen's R and D costs by therapeutic class; (4) real interest rate = 0.10; and (5) product life = 20 years. (b) Letters indicate therapeutic classes of 13 NCEs with $PI \geq 1$. For identity of class, see Table 1. Assumptions: (1) ratio of production cost to sales = 0.3; (2) ratio of world net revenues to US net revenues = 1.75; (3) Hansen's R and D costs by therapeutic class; (4) real interest rate = 0.10; and (5) product life = 20 years.

For comparison with the values in Table 1, they range between $1 million and $2.3 million. As one would expect, substituting these lower R and D values into the *PI* calculations lead to a larger number of 'break-even' NCEs. In particular, the number of NCEs that fail to cover their own development costs is only 7. Hence, in only 7 of 37 cases were firms worse off by carrying through the projects to marketing.

Figure 4 indicates *PI*s by therapeutic class. Figure 4(a) shows the weighted average *PI*s while Fig. 4(b) shows the median *PI*s. One striking result is that the anti-infective class average *PI* is far above unity while the converse is true for the median *PI*. This is easily explained by reference to Fig. 3(b) which shows that one anti-infective NCE had a *PI* of about 22, far above that of any other NCE in the sample. The median *PI* is, of course, unaffected by this 'outlier' while the average is strongly affected.

Figure 5 is a comparison of the 37 US discoveries versus the 23 foreign discoveries. The incorrect assumption that the foreign NCEs had the same R and D costs as the US discoveries is made for

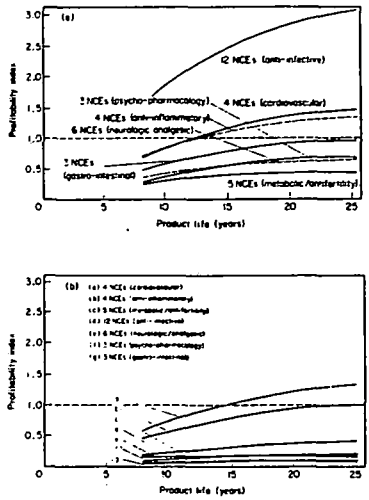


Figure 4. (a) Weighted average *PI* versus life for 7 therapeutic classes 1970–1976. Assumptions: (1) 37 NCEs discovered and introduced in USA 1970–1976; (2) Hansen's R and D cost by therapeutic class; (3) real interest rate = 10%; (4) ratio of production cost to sales = 0.3; and (5) ratio of world net revenues to US net revenues = 1.75. (b) Median *PI* of class versus life for 7 therapeutic classes 1970–1976. Assumptions: (1) 37 NCEs discovered and introduced in the USA 1970–1976; (2) Hansen's R and D cost by therapeutic class; (3) real interest rate = 10% (4) ratio of production cost to sales = 0.3; and (5) ratio of world net revenues to US net revenues = 1.75.

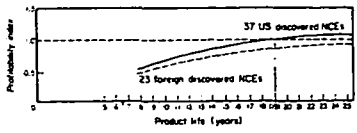


Figure 5. Weighted average *PI* versus life for US discoveries and foreign discoveries. Assumptions: (1) 37 US discoveries and 23 foreign discoveries introduced in the USA 1970–1976; (2) foreign discoveries assigned same R and D costs, production costs and foreign sales fraction as US discoveries; (3) real interest rate = 10% (4) ratio of production costs to sales = 0.3; (5) ratio of world net revenues to US net revenues = 1.75; and (6) Hansen's R and D costs by therapeutic class.

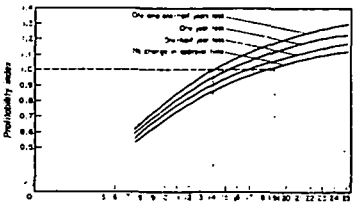


Figure 6. Weighted average *PI* versus life for alternative NDA approval times. Assumptions: (1) real interest rate = 0.10; (2) ratio of production cost to sales = 0.3; (3) ratio of world net revenues to US net revenues = 1.75; (4) 37 NCEs discovered and introduced in the USA 1970–1976; and (5) Hansen's R and D costs by therapeutic class.

purposes of the comparison. Perhaps the main message is simply that the average sales of US discoveries exceeds that of foreign ones.

The final figure, Fig. 6, shows the effect of reductions in NDA approval times. As discussed earlier, reducing NDA approval time by 18 months is equivalent in present value terms to adding on 5 years to the drug's life. That is, the break-even life with no change in approval time is 19 years, but with an 18 month reduction the life is reduced to 14 years.

Acknowledgements

This research has been supported by National Science Foundation Grant PRA-7917524 made to Duke University. Any opinions, findings, conclusions or recommendations expressed in this publication are those of the authors and do not necessarily reflect the views of the National Science Foundation. We wish to express our gratitude to Jim Snyder, our very competent research assistant.

REFERENCES

1. D. Schwartzman, *The Expected Return from Pharmaceutical Research*. American Enterprise Institute, Washington (1975).
2. J. R. Virts and J. F. Weston, in *Drugs and Health*, edited by. R. B. Helms. American Enterprise Institute, Washington (1981).
3. H. G. Grabowski, J. M. Vernon and L. G. Thomas, Estimating the effects of regulation on innovation: An international comparative analysis of the pharmaceutical industry. *Journal of Law and Economics*. (April 1978).
4. H. G. Grabowski and J. M. Vernon, Substitution laws and innovation in the pharmaceutical industry. *Laws and Contemporary Problems*. (Winter–Spring 1979).
5. R. W. Hansen, in *Issues in Pharmaceutical Economics*, edited by R. I. Chien. Lexington Books, Lexington, USA (1979).
6. R. W. Hansen, *Pharmaceutical Development Cost by Therapeutic Categories*. University of Rochester Graduate School of Management Working Paper No. GPB-80-6 (March 1980).
7. The numbers of NCEs by year of introduction are as follows: 1970(4), 1971(7), 1972(3), 1973(3), 1974(7), 1975(7) and 1976(6).

Senator MATHIAS. Thank you very much, Dr. Grabowski. Let me repeat to you a question I asked earlier which relates to the effect of patent restoration on the consumer. What do your findings suggest to you would be the effect on consumer prices?

Dr. GRABOWSKI. Our findings have been directed primarily to innovation and the research process. I think there are several effects that one could talk about. To the extent that one has more innovation as a result of patent incentive stimulation, one can expect the new drugs that come on the market to cause a decline in the prices of existing drugs. There is evidence that that occurs.

There is a tradeoff here. There is no doubt that when you delay the onset of generic competition, those generics are not available to compete with the existing pioneering brands. So it is not a price increase, but the availability of lower prices, particularly in the hospital sector, that will be delayed by the passage of this legislation.

The other factor, which I think is probably the most important factor, is the potential cost savings from new drugs—drugs like Tagamet have been mentioned but one also could look at new drugs for tuberculosis and heart disease and a variety of other areas.

Where you get new medicines and one can save a day in the hospital or one can save a day's lost work, the economic gains to the consumer dwarf anything in terms of the direct cost to the consumer for the drugs.

So, I think those are the three factors, two of which are beneficial in terms of prices; the third works in the other direction. The other factor which I guess is obvious is that the availability of better medicines is something that the consumers, I think, would benefit from.

Senator MATHIAS. Before I turn you over to the tender mercies of Senator Metzenbaum, let me insert in the record at this point a statement of former Representative Robert McClory on the subject of this bill.

[The following submissions were received for the record:]

BAKER & McKENZIE
ATTORNEYS AT LAW

815 CONNECTICUT AVENUE, N. W.
WASHINGTON, D. C. 20006
TELEPHONE (202) 298-5290
TELECOPIER (202) 338-1896
CABLE ABOGADO
TELEX 89-552 (WU)
248441 (ECA)

AMSTERDAM
BANGKOK
BOGOTA
BRUSSELS
BUENOS AIRES
CARACAS
CHICAGO
FRANKFURT
GENEVA
HONG KONG
LONDON
MADRID
MANILA
MELBOURNE
MEXICO CITY
MILAN
NEW YORK
PARIS
RIO DE JANEIRO
ROME
SAN FRANCISCO
SAO PAULO
SINGAPORE
SYDNEY
TAIPEI
TOKYO
TORONTO
ZURICH

June 16, 1983

Honorable Charles McC. Mathias, Jr.
Chairman, Subcommittee on Patents,
Copyrights and Trademarks
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Re: S. 1306, Patent Term
Restoration Act of 1983

Dear Mr. Chairman:

It has come to my attention that the Patents, Copyrights and Trademarks Subcommittee of the Senate Judiciary Committee is having a hearing on S. 1306, the Patent Term Restoration Act of 1983, on Wednesday, June 22.

It was my hope to be able to personally attend this hearing and to present a brief statement and copy of an article which I prepared some weeks ago reproduced in the Thursday, May 5, 1983, issue of the Chicago Daily Law Bulletin, a daily law journal published in Chicago for the benefit of the Chicago and the Illinois bar.

I would like you to include the enclosed copy of this article in the hearing record on this important legislation in lieu of testimony which I might otherwise present.

The only other statement which I might add would relate to the subject of the effective date of the proposed legislation.

As I read the bill, the measure would become effective on the date of its final enactment and would be prospective in the patent term which would be restored. Under the "except" clause at the end of the definition of "regulatory

review period" in proposed 35 U.S.C. 155(c)(3), a patentee whose patent was granted and whose regulatory review period commenced prior to the Act's effective date, would not be entitled to the full patent term restoration. Rather, that portion of the regulatory review period which took place prior to the effective date of the Act would be subtracted from the period to which he would otherwise be entitled.

I strongly recommend that the measure should be made retroactive so that the full restoration period would apply to patents which have already been issued and where marketing was delayed pending approval of a Federal regulatory agency. I do not believe it is fair to provide an arbitrary decrease in the restoration period for products "in the pipeline" at the time of enactment, or to provide no relief for patentees whose period expired prior to the effective date. The merits of patent term restoration are no less in these cases. In addition, without the change, it occurs to me that some applicants for patents may consider delaying application during the period while this measure is pending with the result that useful patentable products might be withheld in the hands of the inventor pending action on this measure. Such a development would be clearly understandable, having in mind that with respect to many of the most useful and sophisticated products, research and development funds totalling millions of dollars are expended.

The subject of an effective date for the proposed patent term restoration legislation was not covered in the reprint of the article which I composed. Accordingly, it would be appreciated if this letter might accompany the article and become part of the hearing record of the Committee on this highly important legislation.

As Ranking Republican on the House Judiciary Committee and one who was actively involved in the development of similar legislation in the last Congress, I would be pleased to respond to any inquiries which you or other members of the Committee or Committee staff might wish to address to me.

Sincerely yours,

Robert McClory

Enclosures

RMcC/ml

[From the Chicago Daily Law Bulletin, May 5, 1983]

LEGISLATION WOULD RESTORE TERM OF PATENTS

(By Robert McClory)

The U.S. Senate Judiciary Committee has scheduled a hearing for May 16, to consider important legislation governing the duration of patents.

A committee report sets forth the case fairly and directly in this one sentence: "The Patent Term Restoration Act will encourage American Innovation by correcting a simple but serious inequity in the patent system."

Basically, the measure would restore the term of a patent for such time as is lost (up to 7 years) on products which are required to be tested and reviewed in order to comply with governmental statutes and regulations.

Under current law, the federal government requires extensive regulatory review for certain products affecting public health and the environment before such products may be marketed.

In general, the inventor secures a patent on such products before or during the period of such governmental action with the result that the 17-year term of the patent may be reduced by as much as 10 years before the patented products can be marketed.

The value of research and development activities in our society is recognized widely. The technological and health benefits are heralded by proud Americans and by citizens around the world. However, few stop to realize that only a small fraction of the pharmaceuticals, chemicals and agricultural insecticides reach the stage of profitable marketing. The average research and development expense for bringing a new product to market is now running at approximately $87 million.

In the last Congress, which adjourned on Dec. 24, 1982, both the Senate and House Judiciary Committees conducted extensive hearings on this issue, and both committees recommended favorable action on the bills before them. It is ironic that in the waning hours of the session, some tempers flared, emotion replaced reason and the Patent Term Restoration Act of 1982 was shelved.

It is expected that this issue again will be before the Judiciary Committees of both the House and Senate with renewed hope that this time the bill will be finally enacted into law.

The pharmaceutical and agricultural chemical industries are regarded as being the most directly affected by this legislative proposal. Following extensive hearings in the last Congress, the Senate Judiciary Committee reported that only about 12 years remained in the patent life of an average pesticide once it was approved by the EPA. As little as 10 years remain on the patent life of a human drug by the time it has been tested and approved by the Food and Drug Administration and is eligible to be marketed.

The object of the Patent Term Restoration Act is to encourage innovation principally in the pharmaceutical and agricultural chemical industries by extending the terms on their patented products for the period during which EPA or FDA approval is being issued. Of course, in no event will the life of any such patent extend beyond the statutory term of 17 years.

The pharmaceutical industry with some dissension among the maufacturers of generic (or non-patented) drugs, the Patent Office and the Department of Health and Human Services have given their stamp of approval to this legislation. The perennial anti-business protagonist, Ralph Nader, has emerged as the principal opponent of this measure. Arguing that innovative drugs may cost consumers more during the period of patent extension, it has also been established that patent term extension should stimulate research and development resulting in useful products from which consumers will benefit.

Patent Term Restoration legislation may have even broader support in 1983 than was evidenced in the last Congress because of the continuing threat of foreign competition. Pharmaceutical companies in Japan, Great Britain, and Germany all invest far higher percentages of their sales in research and development than do comparable U.S. companies.

The Congressional committees have made clear that passage of the Patent Term Restoration Act should result in expanded research activities and an increase in the returns from new and improved drug therapies, useful chemicals and food additives. This, in turn, should benefit the general economy and particularly our nation's positions internationally.

The last Congress adjourned before final passage of general legislation to extend patent terms on those products subject to FDA and EPA approval. However, special relief was provided for G. D. Searle & Co.'s artificial sweetener, *Aspartame,* which

was granted an extended patent term of five years by virtue of an amendment appended to the so-called Orphan Drug Act which passed just before the last Congress adjourned in December.

While no bills have yet been introduced during the present Congress, the subject of Patent Term Restoration is on the agendas of the Judiciary Committees of both the House and the Senate. There would seem to be no insurmountable barrier to passage of this meritorious measure before the 98th Congress adjourns in 1984.

(Robert McClory served as Representative in Congress for the 13th District of Illinois until his retirement on Jan. 3. 1983. He recently joined the Washington office of Baker & McKenzie as "of counsel.")

Senator MATHIAS. Let me also once again apologize to those witnesses who were kind enough to attend and whom we will not hear today. Every cloud has its silver lining, and as a result of having gone longer today, we will clearly have another session. We will not only then hear the witnesses who were scheduled for today, but such other witnesses who wanted to testify and could not be scheduled for today.

Senator METZENBAUM. Thank you, Mr. Chairman.

Senator MATHIAS. So, Senator Metzenbaum, I give you the witness and the gavel.

[Whereupon, Senator Metzenbaum assumed the Chair.]

Senator METZENBAUM. Well, I only have one or two questions.

Dr. Grabowski, if you had this bill and it made it possible for some companies to do far better and, as a consequence, there was $100 million out there extra that they had by reason of the patent extension law, what could we reasonably expect would be put into research and development out of that $100 million?

Dr. GRABOWSKI. Well, I think you quoted a study of mine in your introductory remarks. We studied a 12-year period in research-intensive firms and the plowback figure, which is not a sacred figure, but which has been robust for a fairly long period of time, was that the plowback into R&D of profits is about 25 percent.

Senator METZENBAUM. So, out of that $100 million, we would only get $25 million more in R&D and the other $75 million would be available to the company for whatever purpose, including profits?

Dr. GRABOWSKI. Well, it is not available to the company to give away as dividends. You know, when you discover a new drug or a new invention, in any case—a better mouse trap, and all—just because you have a better product does not mean everyone will come and buy it from you. There is the saying, you know, that if you have a better mousetrap, the next thing you do is to go to Madison Avenue.

In this case we are not dealing with Madison Avenue, but we are dealing with 200,000 to 300,000 physicians, and a large number of pharmacies and hospitals all over the country. So you have to make the results known.

We found that technologically intensive industries and technologically advanced industries do more advertising and promotion than nontechnologically intensive industries, and that that is particularly true at the beginning of the product cycle.

If you look at, say, advertising and promotion as one expense, they are very heavy when you launch a new product in this industry or in cereals, or in any industry. Then, as the product matures,

the amount of advertising declines quite dramatically. So, that is one expense, to launch the product after you have it.

You also have capital investment. You have other kinds of expenditures. So, you know, the R&D ratio of 25 percent is among the highest of any industry, if not the highest in the country. So I do not see it as a small amount; I see it as a good-sized amount.

Senator METZENBAUM. I was almost about to invite you to my next filibuster. Dr. Grabowski, I do not have any further questions. Thank you very much, and that concludes the hearing.

[Whereupon, at 12:27 p.m., the subcommittee was adjourned.]

THE PATENT TERM RESTORATION ACT OF 1983

TUESDAY, JULY 19, 1983

U.S. SENATE,
SUBCOMMITTEE ON PATENTS,
COPYRIGHTS AND TRADEMARKS,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to call, at 10:33 a.m., in room 485 of the Russell Senate Office Building, Senator Charles McC. Mathias, Jr. (chairman of the subcommittee), presiding.

Staff present: Ralph Oman, chief counsel, Charlie Borden, professional staff member, and Pam Batstone, chief clerk, Subcommittee on Patents, Copyrights and Trademarks; and Wes Howard, counsel to Senator Metzenbaum.

OPENING STATEMENT OF SENATOR CHARLES McC. MATHIAS, JR.

Senator MATHIAS. The subcommittee will come to order. Today the subcommittee resumes the hearing on Senate bill 1306, the Patent Term Restoration Act of 1983. This is a bill designed in effect to give back to inventors some of the time that is lost because of the requirements of the Government for examination and testing of the ideas that are subject to the patent.

Unfortunately, at the first session of this hearing we were unable to hear all of the witnesses that were scheduled, and three of those witnesses will appear today. And we are very grateful to them for their patience in being willing to be postponed to this date.

Dr. Jack Early, president of the National Agricultural Chemicals Association; Mr. Thomas Bradley, president of the Maryland-D.C. AFL-CIO; and Mr. Jacob Clayman, president of the National Council of Senior Citizens.

The fourth witness, Esther Peterson, who will speak for the Consumer Federation of America, will appear at a third and I hope final hearing which will occur some time before the August recess.

The first hearings concentrated on the implications of Senate bill 1306 for pharmaceutical drugs. Dr. Early will testify on other products that lose patent life to exhaustive government tests. I understand the examples will be pesticides and agricultural chemicals.

So we will ask Dr. Early to begin the testimony. I would ask all witnesses, so that we can have some time for questions and some exchange of views, that they limit their oral presentations to 5 minutes. If you have additional remarks or your initial statement is longer than that, we will have it appear in the record as if fully read.

Dr. Early.

STATEMENT OF JACK D. EARLY, PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, WASHINGTON, D.C., ACCOMPANIED BY DALE E. WOLF, VICE PRESIDENT, BIOCHEMICALS, E. I. DU PONT DE NEMOURS & CO.

Dr. EARLY. Thank you, Mr. Chairman. We have submitted for the record a lengthy statement, and we would like to summarize that statement this morning for you.

Mr. Chairman, as you indicated, I am Jack Early, president of the National Agricultural Chemicals Association, and I am accompanied this morning by Dr. Dale Wolf, who is a vice president of Du Pont and serves as the chairman of our board of directors.

The National Agricultural Chemicals Association is a nonprofit trade association representing some 100 companies which manufacture or formulate virtually all of the agrichemical products in the United States.

Mr. Chairman, we appreciate the opportunity to testify and state our strong support for S. 1306. We believe the Patent Term Restoration Act of 1983 will correct a present inequity in the patent system by restoring the patent life lost on products which undergo federally mandated testing and review procedures necessary to register our products. In addition, it will stimulate agrichemical research and development and help preserve employment within our industry of some 62,000 employees.

Agrichemicals are important to agriculture, Mr. Chairman. When using agrichemicals, a farmer is looking for two things: A product that will control his specific insect, weed, or disease problem; and, secondly, a product that will insure him a return of some $3 to $4 of every dollar invested.

If a particular pesticide product falls short of either goal, he would choose competitive chemicals or nonchemical methods to control his pests. Rarely, if ever, is the farmer limited to the choice of a single control option.

In short, if an agrichemical product is not cost effective, simply the farmer will not use it.

Each use of a technical grade chemical which is processed into a formulated retail product for application to specific crops under specified environmental conditions must be separately registered with the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act. Extensive test data on agrichemicals must be submitted to the Agency to demonstrate safety to man, animals, and the environment.

Note, if there are no unforeseen delays in the time sequence, commercial sale of a newly registered agrichemical may not take place until approximately 7 years following the issuance of the patent. Thus, the loss of the patent life in this example will allow the innovator fewer than 10 years to recover his cost of investment and generate income for future research.

On the average, it now takes as much as $40 million to bring a new product from the laboratory to the farmer, and this does not include capital costs.

This Federal mandated testing and review has caused unforeseen and considerable erosion of patent life. By the time the company has obtained its registration and enters the market, a significant

portion of the patent term may be lost. As a result, an inequity has been created which needs redressing through patent restoration legislation as proposed in S. 1306.

Mr. Chairman, Dr. Wolf would like to add a few comments, if he may, please.

[The prepared statement of the National Agricultural Chemical Association follows:]

TESTIMONY OF
NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

I am Jack D. Early, President of the National Agricultural Chemicals Association (NACA). I am accompanied by Dr. Dale E. Wolf, Vice President, Biochemicals, E.I. du Pont de Nemours & Company, and Chairman of the NACA Board of Directors.

The National Agricultural Chemicals Association is a nonprofit trade association representing 100 companies which manufacture or formulate virtually all of the agrichemical products in the United States. We are speaking on behalf of producers of pesticide products known as agricultural chemicals or "agrichemicals," which include insecticides, fungicides, bactericides and herbicides or, in other words, those chemicals used to protect crops from destruction by various insects, diseases and weeds.

Mr. Chairman, we appreciate this opportunity to testify and state our strong support for S. 1306. We believe the Patent Term Restoration Act of 1983 will correct a present inequity in the patent system by restoring patent life lost on products which undergo federally mandated testing and review procedures necessary to register our products. In addition, it will stimulate agrichemical research and development and help preserve employment within our industry (62,800 employees).

American Agriculture and The Agrichemical Industry

The accomplishments of American agriculture comprise one of the most remarkable success stories ever. 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 this country and much of the rest of the world. In 1982, exports of agricultural products contributed over $36 billion to our balance of payments.

Nonetheless, the challenges confronting this country's agricultural sector in the face of an ever expanding world

population are tremendous. Nobel prize winner, Dr. Norman E. Borlaug (who received the Nobel Prize for Peace for his outstanding contribution to alleviate 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.

Despite a current overabundance of corn, wheat and other vital food commodities which threatens the economic viability of our nation's farms, worldwide demand for U.S. food and fiber will continue to grow over the long-run. To meet this future challenge, the U.S. agricultural community with its finite land base must depend increasingly upon innovative crop protection chemicals which will dramatically increase crop yields at reasonable costs. Further, utilization of these cost effective agrichemicals will often make the difference for many farmers between survival or potential bankruptcy.

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 agricultural chemicals are not readily available. Insects, disease and weeds are major contributors to the destruction of food and fiber. Agricultural chemicals significantly reduce such pest losses.

During the past forty years, the agricultural chemicals industry, through laboratory 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 cotton, corn and soybeans 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 are 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, the total dollar improvement to the U.S. farm economy from this one concept alone would be in excess of $5 billion per year.

There have been other significant improvements in agrichemicals. One is the development of biodegradeable chemicals which can be applied effectively at lower rates per acre than more persistent chemicals used years ago. Another improvement is the development of nematocides used against microscopic organisms which inhibit plant growth and yields, but which were previously unknown. All of this new technology has given better products to our nation's farmers.

EPA Regulation of Agrichemicals

Each use of a technical grade chemical, which is processed into a formulated retail product for application to specific crops under specified environmental conditions, must be separately registered with the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Extensive test data on agrichemicals must be submitted to the Agency to demonstrate safety to man, animals and the environment. A single agrichemical 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.

Historically, safety requirements for agrichemicals were first introduced in 1954 under the Miller Amendment to the Federal Food, Drug, and Cosmetic Act. The Miller provision required that tolerances be established for residues on crops that are to be used for human consumption. As a result of the tolerance setting requirement, agricultural chemical companies

had to obtain appropriate toxicological data to determine a safe maximum residue limit.

Subsequently, Congress adopted revisions to the Federal Insecticide, Fungicide, and Rodenticide Act which have dramatically increased the time and cost of developing new agrichemical products. From 1967 to 1982, the time from discovery of an agricultural chemical compound to its first commercial use increased on an average from 58 months to 108 months. In 1967, 42 months were devoted to government-required testing and regulatory approval; in 1982, that period increased to 60-84 months. Consequently, as government requirements for developing data for registration have increased, the patent terms on some new agrichemical products have been eroded substantially.

To assist the Committee in understanding the process, we have included a diagram and explanation in the Appendix which depict the chronological development of an agrichemical from initial synthesis and discovery of biological activity to the first commercial sale. We have included with the diagram an explanation of the scientific and regulatory steps which must occur between discovery of a new agrichemical and its entry into the marketplace.

Note, if there are no unforeseen delays in the time sequence, commercial sale of a newly registered agrichemical may not take place until approximately seven years following the issuance of the patent. Thus, the loss of patent life in this example will allow the innovator fewer than ten years to recover his cost of investment and generate income for future research. Consequently, the period of regulatory testing and review delays market entry and consumer benefits of new products. After first commercial use for a product, several years elapse before it reaches full market penetration and

total product utilization. This is in marked contrast to the situation of non-regulated inventions where the the patentee has no restraints on marketing activity, and may enjoy the fruits of his invention, even before the patent is issued.

Patent Term Restoration Legislation (S. 1306)

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. Continued research and development, however, must be supported by an adequate return on investment from sales of patented products. On average, it now takes up to $40 million to bring a new product from the laboratory to the farmer, and this does not include any capital costs. Normally, the construction of a new plant to produce technical grade chemicals is also required and can cost an additional $40 to $70 million. Companies may be reluctant to invest this kind of long-term, high-risk capital, unless they, in turn, receive adequate patent protection.

It is also important to note that in our industry 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 agrichemicals, the farmer is looking for two things: (1) a product that will control his specific insect, weed, or disease problem; and (2) a product that will insure him 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, if the agri-

chemical product is not cost effective, the farmer will not use it.

In summary, the patent laws were intended to promote the development of new technology and encourage the early disclosure of inventions. The mechanism chosen was to afford each inventor a set period to develop the invention without interference by others who did not contribute to the technology. For some years now, this protection period, i.e. the patent term, has been fixed by Congress at 17 years. As to agrichemicals, however, federally mandated testing and review have caused an unforeseen and inequitable erosion of patent life. As a matter of course, agrichemicals undergo substantial scientific evaluation and agency review to ensure that the public health and safety will not be impaired. Recent experience shows that the average time for registering an agrichemical is approximately five to seven years from initiating a major health or environmental effects test until first major registration of a label. During that time, the 17-year patent term may be elapsing. By the time a company has obtained its registration and enters the market, a significant portion of the patent term may be lost. As a result, an inequity has been created which needs redressing through patent restoration legislation as proposed in S. 1306.

To remain a dynamic contributor to the development of new agricultural technology, the U.S. agrichemical industry must be encouraged to devote considerable amounts of capital to research and development. 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 agrichemical research and development.

For the most part, U.S. agrichemical companies that depend upon the patent system manufacture their products domestically, resulting in the creation of many jobs. As the patent system becomes less dependable by virtue of shortened patent life,

export of these jobs to foreign copiers will occur. Expiration of U.S. patents in the agrichemical field has generally not led to increased U.S. manufacture of products. Instead, foreign manufacture of products occur, especially where patent protection is unavailable, thereby displacing U.S.-manufactured products and jobs, upon expiration of the U.S. patent.

Without adequate patent protection, our member companies may not continue to undertake the increasingly costly and time consuming research involved in discovering and developing new agrichemical products and still compete with other companies who can freely copy their successes without incurring the same costs.

Again, we appreciate the opportunity to appear today and will be happy to answer any questions from members of the Subcommittee.

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.

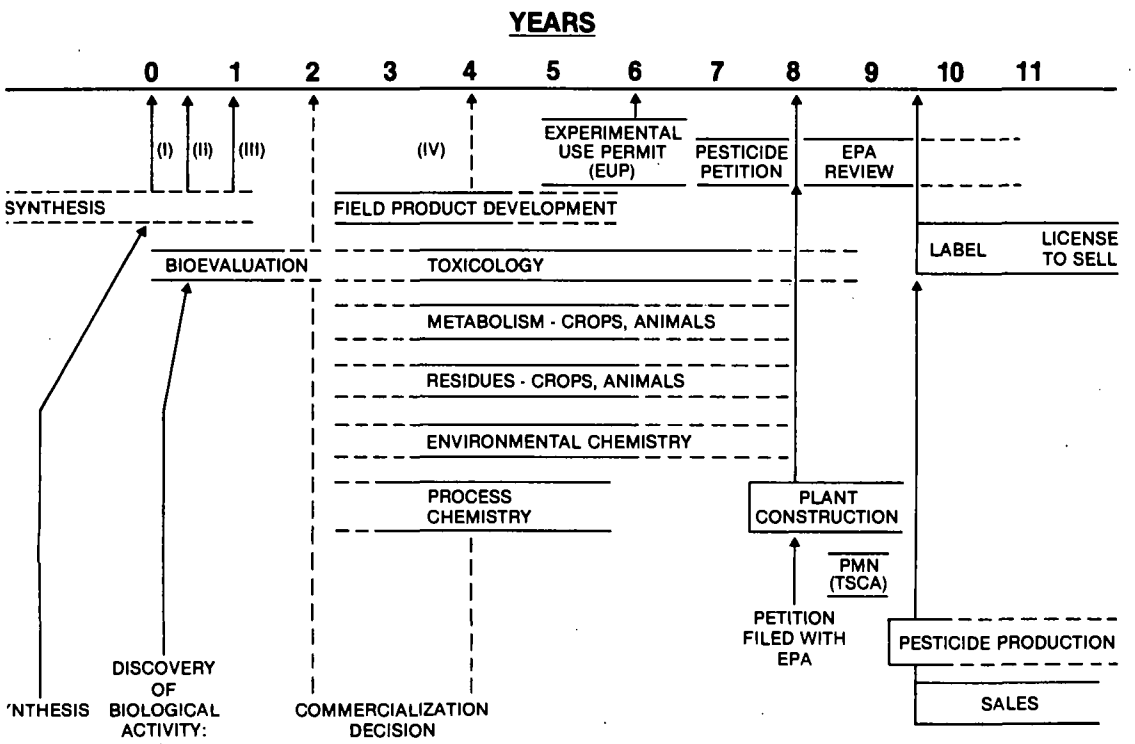
At that time, indicated by Point IV, a very lengthy and expanded research and development effort is launched. This includes generation of technical data which ultimately are used to support the registration of that commercial candidate chemical (IV). General kinds of information are depicted in rectangles. 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. Prior to a commercial decision and initiation of long-term toxicology, significant process chemistry information is necessary to produce a typical technical product for long-term toxicology testing. 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/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 a loss of five or more years in the 17-year patent life.

PESTICIDE DEVELOPMENT CHRONOLOGY FROM DISCOVERY TO SALES



STATEMENT OF DALE E. WOLF

Dr. WOLF. Senator Mathias, agrichemical research is a costly business. It is one of the highest risk research areas in which any of us engage. As a result, many companies who used to do research in this area are no longer funding this kind of research.

In my opinion, restoration of patent life would encourage the allocation of funds to research. It would increase innovation, and it would encourage the development of agrichemicals for use in minor crops, those crops of which there are not many acres.

New agrichemicals are needed by the producer to reduce the cost of production, by the consumer, all of us, to keep the food costs low.

Generally, in the agrichemical area, the result of a patent term expiration—any time a patent expires—production usually starts overseas, mostly in countries where those governments will fund the exports of those products. As a result, often there is a loss of jobs for U.S. production.

Patent term restoration, your bill, has the support of the people who pay for the use of agrichemicals. I think you have letters from a number of those producing groups, but particularly such people as the National Association of Wheat Growers, the National Cotton Council, the National Corn Growers Association, and the American Soybean Association, and many others. In other words, the people who depend on agrichemicals for their production costs are the people who are supporting your bill.

In my opinion, your bill will be a real aid to the consumer and to agriculture.

Senator MATHIAS. Thank you, gentlemen. You say it will be an aid to consumers and to agricultural producers. I suppose there is no part of our economy that is harder hit at the moment by worldwide competition, by inflationary costs of operation, by a kind of transition in the whole structure of the industry, than American agriculture, and farmers are on the ropes. They are on the ropes to the extent that we are going to probably have to spend about $30 billion this year out of the Federal treasury just to keep them alive, without restoring health to the farm economy.

So I think we have to be extremely sensitive to the effect of anything which increases the cost of production, and agricultural chemicals are now a significant part of the farm operating budget.

You say that you think that this will have a beneficial effect on the cost that the farmer pays, but can you spin that out a little bit? Why do you think that is the case?

Dr. WOLF. Yes. As we develop new agrichemicals, they have to do something different than anything that is out there now, or do it cheaper, or the farmer won't use it. It's been my experience, after 33 years in this business, that when you develop a new agrichemical that will really do a job, the farmer will buy it because he reduces his cost of producing the crop. And I can cite you a whole host of examples where that is true.

The farmer simply won't do it if it increases his cost. He will do it if he decreases his cost of production.

Senator MATHIAS. Well, now, so that I get this clearly in my own mind—maybe I am a little slow in grasping it—but you are not saying that the cost of existing chemicals that are now on the shelf

will necessarily go down, but that new and more economical chemicals, and perhaps more effective chemicals, will go on the shelf.

Dr. WOLF. Right. If I can cite an example, in the Du Pont case, for instance, we introduced a new product last year for use in weed control in wheat, and it is used at the rate of about 10 grams per acre, where most of the products before that were used at the rate of a pound or 2 pounds per acre.

And for those things that a new product will do well, it will be a real boon to the farmer; it won't be perfect, because it doesn't do everything that the farmer needs done in many areas.

But as we develop through the industry new products like this, they will either reduce his cost or the farmer won't use them.

And as the pests change in the field, either insects or diseases or weeds, the farmer is dependent on people like the industry to do research, to find new things that will keep those pests under control.

Senator MATHIAS. Now, if you could give me any prospect that we could control Johnson grass, why, you would have me leaning strongly in your direction.

Dr. WOLF. All right, we can control Johnson grass with a number of products—it depends on where that Johnson grass is and what kind of crop it's growing in.

Senator MATHIAS. That's the secret.

Dr. WOLF. Right. But we are working on that, and that is the kind of research that we are trying to stimulate throughout the industry.

Senator MATHIAS. Of course, one of the characteristics of the chemical industry, particularly agricultural chemicals, is that it is multinational, that a great many of the chemical manufacturing companies are multinational companies.

Do you detect any trend among these companies to seek at least the initial patent in other places, outside the United States, due to the premarket regulatory requirements and the consequent erosion of patent life in the United States?

Dr. WOLF. There is no question that companies who are based overseas generally file for their patents overseas first.

Senator MATHIAS. What is the favorite source of patents for these companies?

Dr. WOLF. Depending on where they are based—some countries in the world simply issue patents without examining them, and there are great examples like that in South Africa, a whole host of European Common Market countries do this without even examining the patent, so you will find patents which are published in those areas first.

But it really doesn't mean a great deal from a protection standpoint because of the fact they are not examined.

There are many products in the agrichemical area that are not sold in the United States because of the long time it takes to get approval in the United States, which may be the point of your question. It just takes longer in the United States than in most countries, although probably it takes the same length of time in Japan and Germany. But the rest of the world it is easier to get a new product on the market than it is in the United States.

Senator MATHIAS. What is the effect of a company going for its first patent in another country on jobs in America, on production in America?

Is there any tendency, if a multinational company is getting its patent somewhere else, to begin production in that country?

Dr. WOLF. I don't believe so, although one would have to study product by product. Generally, those of us in the business would produce in the countries in which there is the greatest market. The exception to that would be where you could not get a patent in a given area, and you would only produce in those countries where you could get a patent, and where you would have a patent that would hold up for the longest period of time.

Senator MATHIAS. There has been some expression of support for this legislation from the farm community, I think about 20 different organizations have expressed support, the American Farm Bureau notably.

Why do you believe that the agricultural community feels so strongly about this legislation?

Dr. EARLY. Well, I think that—incidentally, that number may be up to about 23 now, as we understand, this morning, Mr. Chairman. And we do have tremendous support for this legislation.

I believe clearly and simply the farming community recognizes that this kind of technology that our industry supplies to the farming community, which keeps reducing its price by improving effectiveness, is the kind of sophisticated technology of farming that the American farmers really just have to have these days in order to compete in the world.

So they are looking for the innovation, for the new product. As you pointed out, they would like to have that new product that would control Johnson grass among certain row crops that may not be there now. So there are any number of innovations that the farming community is hoping will come out of our industry. They believe that correcting the inequity in the patent system will help produce that sort of product that they need.

Dr. WOLF. I certainly agree with that, Senator Mathias. I believe it's absolutely essential to the productivity of the farmer that he have available, or she have available, the new agrichemicals, and the only place you can get them is through getting people to do the high-risk research that we are talking about.

Senator MATHIAS. Well, gentlemen, we thank you very much for being here.

Let me say that the record will be kept open for several weeks, in fact 2 weeks after the next hearing, which is scheduled for August 2. During that period other members of the subcommittee may wish to address questions to you, and we would request that you respond in writing so that those questions and answers can be part of the record.

Dr. EARLY. We will be delighted to respond to those, Mr. Chairman.

Senator MATHIAS. Thank you.

Dr. WOLF. May I just say, Senator, that not only do I think this bill is important to agriculture and producers, but to those of us who eat food. If we are going to keep the cost of food down, you are going to have to be able to produce low-cost food on the farm, and

for older people, younger people, and those in between, this bill, your bill, I think will really help.

Senator MATHIAS. Thank you very much. Our next witness, Mr. Thomas Bradley, the president of the Maryland State and D.C. AFL-CIO.

Well, Tom, we are grateful to you. Some of the other witnesses who were held over from the last hearing were in town; you have had to make the trip from Baltimore, and I appreciate your coming over.

STATEMENT OF THOMAS M. BRADLEY, PRESIDENT, MARYLAND STATE AND D.C. AFL-CIO, ANNAPOLIS, MD.

Mr. BRADLEY. It is a special pleasure to be here across the table from my good friend, our State Senator, the chairman of the subcommittee, Senator Mathias. However, I appear before you today not only on behalf of the 502,000 members of the Maryland State and D.C. AFL-CIO, but also on behalf of the 14,200,000 members of the AFL-CIO nationally.

Mack, we care about this legislation before you because we have been at the forefront of the fight for comprehensive health care at reasonable cost. We care about this legislation because our members are consumers of prescription drugs. We care about this legislation because our members are Federal, State, and local taxpayers who pay for drugs used in Federal, State, and local hospitals, clinics, prisons, and for the drugs purchased through medicaid and other taxpayer-funded programs. We care about this legislation because many of our members work in those public institutions and in the many private health care institutions and homes for the elderly, where every extra dollar spent unnecessarily for prescriptions means a dollar less to pay the already underpaid hospital and clinic staffs. We care about this legislation because our members are the ones who are being pressured into give-back contracts with some of America's largest but troubled corporations; and we don't think it's fair for the drug giants, who aren't troubled one bit in these tough times, to come to you, or to us, asking for a permanent take-away contract.

Because that is what this bill is, a license forever to deprive our members and all taxpayers, and all consumers, of the full benefits of free-market competition in prescription drugs.

Now, Mr. Chairman, just so we have some idea of the size of what is at stake here, I asked for the numbers of just one program in our State, the Maryland medical assistance program, essentially our medicaid program. In fiscal 1982, for just part of this program, the State spent over $26 million on prescription drugs. This doesn't include the amount for drugs added to hospital bills, and it doesn't include about another $20 million spent by the Federal Government on top of the State funds. That's not peanuts; if we could get a 20-percent savings on that cost, the State would have some $5.2 million more to spend on other things. A 10-percent savings on just this part of this program would mean $2.6 million a year.

And the way we can save money on prescription drugs is the way the Federal Trade Commission told us in their report a few years ago, and the way the Giant pharmacy newspaper ads tell us, by

buying generic drugs. The minute a generic drug goes on the market, the potential savings to individuals and institutions, and State and Federal Government, is huge. And for every day you keep the generic off the market, you are taking cash out of the pockets of every consumer and taxpayer and putting it into the pockets of these companies. I've heard this called Robin Hood in reverse, but that's too nice. This is a time when you are telling people who are poor and sick and hungry to look to private initiatives. President Reagan says to those most in need: Don't look to the Federal Government for help. But these companies come in here and ask you, the Federal Government, to help them squeeze more money out of the public.

Their excuse for this private tax, that they need more money for R&D, is ludicrous. It's the same lame story they gave to Estes Kefauver over 25 years ago. It's the same lame story they gave to Russell Long over 15 years ago. Kefauver didn't buy it. Long didn't buy it. The public won't buy it. And I hope you gentlemen are really too smart to buy it.

The companies have every incentive they could want to do drug R&D. If they invent something useful, they make profits beyond their wildest dreams, enough in the first few years to pay the R&D costs many times over. On top of that, you in your wisdom let them deduct much of that R&D expense for tax purposes. And on top of that, in the last Congress, you gave them a tax credit for R&D. And on top of that, and this should be of interest to the Chairman, last year you gave them special incentives to develop those drugs with very small markets.

I should say that after reading in the Post recently about one drug with only 23,000 users, which supposedly cost some $30 million to get on the market, but which had sales of $150 million in its first 3 years, it seems to me you may already be beyond the point where additional incentives could possibly do any good. But if you want to subsidize R&D for drugs for particular diseases, I suggest you target those areas and subsidize them directly through the National Institutes of Health.

Doing it by eliminating drug competition on the leading drugs is an expensive, inefficient, irrational way of doing it. In fact, what that approach will do is to make the richest and biggest companies richer and bigger, and make it harder for the smaller research companies to hold their own.

There is something else here that is particularly galling to me, and if I were sitting on your side of the table I would be even more perturbed. The drug giants tried to steamroller this special interest bill through the last Congress, and failed largely because they were too greedy even for their own congressional proponents to stomach. Now they are back here with the very same one-sided, extreme proposal as if nothing had happened, as if they think they can fool this Congress even though they couldn't fool the last Congress.

I am confident that with you as chairman of the responsible committee, this bill will get the scrutiny it needs.

It is also encouraging to hear that even PMA's friends in the House are not willing to go along with the kind of total stonewalling that went on last year when the House tried to get some concrete facts from PMA. Certainly PMA deserved the Alice-in-Won-

derland award for 1982 with its "verdict first, evidence never" approach to this issue. I will believe it when I see it, but if PMA really does provide the facts you need on the patent and FDA history of each major drug over the past 10 or 15 years, then at least you will be able to find out if something is really broke before you decide whether and how to fix it.

In that connection, I want to close by expressing some sense of frustration with the process here. Two-thirds of today's hearing has been devoted to proponents of the bill. There are many more opponents who need to be heard, especially the particular international unions with direct involvement and expertise in the health care field. Even more important, if some bill is going to be proposed, there eventually has to be a session where adequate attention can be given to the major flaws in the bill—extensions that are too long and too automatic, the absence of deductions for voluntary delays, the lack of offsets for marketing efforts during the FDA reviews, the coverage for already invented drugs, lack of any requirement of a showing of need for an extension, failure to assure immediate postpatent competition, and so forth.

Yet it makes no sense to go into that kind of detail, or even to have this hearing, until we can see those long-hidden facts that PMA is now promising to reveal. Once you and we have looked at the patent and regulatory histories of each drug, then we can have a meaningful dialog. In the meanwhile, I am sure this subcommittee and its parent have more pressing things to do with their time than to play Santa Claus to the rich and powerful while thumbing your noses at the old, the poor, and the taxpayer, and maintaining little concern for the human equation in the economics of our country.

Senator MATHIAS. Thank you, Tom. I agree with the emphasis that you have put on the contract purchases of drugs by the various Government agencies that need to acquire a large supply.

And that really seems to be the battleground on which this legislation turns.

Now, you were very patient in sitting through the whole hearing the other day, and you will recall that I asked Mr. Haddad the question "I understand that one of the battlegrounds that surrounds this legislation is the question of contract purchases," and he said yes. And then I went on to ask him: "What would the effect of this bill be on large contract purchases?"

And then he observed—and I quote: "My private conclusion about this bill is it has got nothing to do with the consumer market—it has got 20 percent to do with the consumer market."

And then I commented: "The real battleground is contracts," and he said "Senator, . . .," and then went on to spell out various examples, the Defense Department and other examples of how the contract market might be affected.

So I think there is general agreement that that is really where the economic impact would fall.

One of the basic questions that arises when you think about this matter is the underlying principles of the patent system, is the patent system a good idea? Should we give people, in effect, a monopoly of the use of their own invention for a period of time?

And we have concluded as a national policy that that is a good idea. But then the question is: For how long?

Do you think that 17 years is an appropriate period of time in general for patents? I am not thinking only of chemicals and drugs, but just generally?

Mr. BRADLEY. Well, Mack, one of the things that you hear—I'm not an expert on this stuff, you know. When I first started dealing in drugs, my father's forefinger was the ipecac that they do today in the market, and lard and sugar was for sore throats and was very cheap. Today we see these kinds of things going way up.

Senator MATHIAS. When I was growing up in Frederick, we had a doctor at the end of our street, and he had two pills, the pink pill or the blue pill, and you took one or the other and you either got well or you didn't.

But whatever it was, it didn't cost very much.

Mr. BRADLEY. That's correct. One of the things that disturbs me, Mack, is you hear people saying that the people in the drug business are not being treated the same as the people that create other patents, other inventions.

Well, there is a lot of difference. A person doesn't have to have a television set, but a person certainly has to have drugs to stay healthy or stay alive or stay comfortable, to have some quality in their life.

So we are talking about, I think, two different things here. And I think if I would ask you to do anything, I would ask you please to take that into consideration.

There are some documents that are going to come to you with letters and comments from senior citizens that I think you will find very enlightening as to really what is going on out there among these folks; I mean, with the cutback, with Reaganomics, with all the other business that is going on today—you know, it's like the fighter that had his first fight, he got into the ring and after the first round the manager brought him back off of the canvas and threw cold water on him and said: "You're doing fine, the guy never laid a glove on you." He went out there a second time and the same thing happened, and the manager said the same thing; he said: "Well, you better keep an eye on that referee, because somebody is beating the hell out of me."

And so, you know, the consumer in this country knows that somebody is working him over real good, but everybody says it isn't me. And we look to folks like you to make sure that we find out who these guys are and what they are, and making sure they get their fair share, but making sure that the consumer, the person that needs that drug to stay alive or to stay comfortable in his or her life, is important.

Senator MATHIAS. Well, I think that is absolutely true. Relating this question to the testimony of Dr. Early and the agricultural community, of course we have this problem: one of the things that the farmer uses is a plow or his farm machinery generally; John Deere can invent a piece of farm machinery and can proceed to manufacture it and market it without any Government supervision, or with very little Government supervision—I suppose you get OSHA somewhere into the act—so that the patent on that new in-

vention, as far as farm machinery is concerned, the patent lasts for the full 17 years.

Now, for the very reason that you point out, because the drugs are critical to life and to health, we have put the drug manufacturer into a different category from John Deere or from International Harvester; we say you can't take this invention and market it, you have to first submit it to Government examiners for testing. So the very critical nature of this drug to life and health moves it into a different category.

And that is the nub of the problem with which we are wrestling.

I was interested in the question in the previous case as to whether or not this is costing us any jobs in America, and apparently, on the basis of the testimony, that is not a critical issue, that if companies patent in other parts of the world, they won't necessarily manufacture there—they will manufacture where the market is.

But I do think we also have to be sensitive to the issue of whether or not jobs will slip away from us in the course of this whole process.

That, again, is one of the considerations that I will urge upon the members of the committee when we come to final consideration of the bill.

Well, we are grateful to you for being here, and we will carefully consider the interests of the consumer.

Thank you very much, Tom.

Mr. BRADLEY. Thank you, Senator.

Senator MATHIAS. Our final witness is Jacob Clayman, the president of the National Council of Senior Citizens. We are not starting you out with the red light now; we will give you the green light here to start.

STATEMENT OF JACOB CLAYMAN, PRESIDENT, NATIONAL COUNCIL OF SENIOR CITIZENS, WASHINGTON, D.C.

Mr. CLAYMAN. I abhor red lights. It's on my time, this kind of wisecracking, so I will continue.

I want to point out the puzzling inconsistency, the fascinating anomaly, inherent in this discussion. Let me explain.

Almost everybody I know, conservatives and liberals, progressive organizations like the National Council of Senior Citizens, the users of health care, young, old, middle aged, and even, believe it or not, President Reagan——

VOICE. Would you use the mike, please.

Mr. CLAYMAN. I am using it, but apparently improperly, and my voice is a little weak, so you will have to forgive me.

Senator MATHIAS. Well, I recall—and this won't come out of your time—when Mike Mansfield was the majority leader of the Senate, we used to say: "Keep Mike close." So I will say: Keep mike close.

Mr. CLAYMAN. I will wrap my arms around it and keep it close to my bosom.

I said almost everybody is insisting on lowering the cost of health care, all of which, in my judgment, makes profound sense. I said "almost everybody," I left room to say "except the providers of health care," namely, the hospitals, the doctors, and now the pharmaceutical manufacturers.

In the midst of this avalanche of opinion for cutting health costs, from one end of the political spectrum to the other, the question I ask is: Is it wise, is it equitable, is it proper, that now we will permit the pharmaceutical industry to increase costs as inevitably they will.

Let me take a quick look at the drug manufacturing industry. It is rich; no one contests this. It is the third industry in America in regard to profitability; it has been doing well for many years; it has sufficient earnings to do research and development, generally speaking—many drug manufacturing companies have increased research and development, and there is no reason to believe that this process cannot and will not continue.

What I am saying is that the drug industry is doing exceedingly well with the present patent law, and it doesn't need the intervention of Congress to make more money. Indeed, extending the duration of drug patents will tend to balloon industry profits to truly unconscionable heights.

In short, to coin a new expression—I've heard it a half a dozen times now; I repeat it, because it makes the point. The present law is working, and I am a firm believer in the old adage if the thing is working, don't mess with it. And that is the fact here, it's working.

Now let me talk about the people I represent, the elderly of America. We have a direct and enormous significant stake in this legislation. We, the seniors, by the millions, will be buffeted and bruised by this bill, if it becomes the law of the land. Already, we, the senior citizens, have been battered, hip and thigh, these past few years by cuts in social security, cuts in medicare and medicaid, cuts in food stamps, cuts in social programs, and on and on it goes. And now cuts in 1984 are being strongly sponsored by the administration.

We don't need higher and longer enduring price increases in the cost of prescription drugs. And I say, as some of my friends would say: Enough is enough. Most of us seniors are not wealthy; in the main, we are poor, near poor, and very modestly middle class, all of which means that we ain't rich.

We know there is a direct relationship between drug patents and drug costs, and it does make a difference. Ever since the late Senator Estes Kefauver conducted hearings in these Halls years ago, our eyes have been opened almost in awe at the fantastic difference between patent drug costs and generic drug costs, in some cases almost eight times more than generic drugs. And it's interesting that we still remember Senator Kefauver. His memory is green with many of us. And we remember him because of his sterling fight against entrenched power in those days. He made small longtime impact, but he was remembered by all of us.

We have complained bitterly about the fierce escalation in hospital physicians' costs, which are running three times the CPI rate. Prescription drugs are following exactly the same pattern. Drug costs inflated by 12 percent in 1982, while the CPI went up 3.9 percent. And that is a statistic that none of us can swallow, whether we are young or old or middle aged.

And I urge upon the chairman that he deliberate carefully and wisely on that statistic. It frightens us.

And this, Mr. Chairman, is a worse load for seniors to bear. You know that prescription drugs outside of a hospital are not paid by medicare; most supplemental medical insurance policies do not pay prescription drugs. Thus the costs of these drugs come directly out of the pockets of senior citizens.

And now a fact that I assume you know, but let me repeat it: most elderly continue to take drugs for years on end; as a matter of harsh fact, they consume 25 percent of all the prescription drugs sold in America. The older you get, the more drugs you need, and so that is why we oldsters have a prime interest in this patent extension bill.

And then a final observation, and I will quit.

As I look at the equities to be weighed in this bill—that's always a process one should indulge in—they all, in my judgment, fall on the side of the consumers, and especially the elderly consumers. I looked long and hard for genuine equities residing on the side of manufacturers; I found none.

Mr. Chairman, I trust that this committee will not strap this bill onto the backs of senior citizens. They don't deserve nor can they carry this harsh, grievous burden.

I appreciate the chairman's patience. Thank you.

Senator MATHIAS. Well, thank you very much, and it is a pleasure to have you here.

And I have very much at heart the point of view that you have expressed here today. My own mother is 87 years old, and like most people who reach the age of 87 she has various health problems and is dependent on drugs. So I get a very current continual report on the drug market as it affects the senior citizen, from a very personal point of view.

But let me say one thing I did disagree with you about. I thought you were too sweeping in your indictment of the providers of health care and their insensitivity to costs. Just for an example, Johns Hopkins Hospital has made very strenuous efforts to reduce costs, which is a difficult thing in a teaching hospital where the costs of research and training and clinical care all end up on the same set of books.

But they have made exhaustive efforts, and, in fact, the employees of Hopkins who are represented by Tom Bradley have really made a tremendous effort; they go through the laundry chute every day to find out if any surgical instruments have by chance gotten into the laundry chute and would then have to be replaced ultimately at cost to the consumer.

So while it is true that health costs have gone up too much and have reached a burdensome level for all of us, I don't think that all the providers of health care are insensitive or are not trying to do something about it.

Mr. CLAYMAN. I will accept that amendment of yours to my statement, except to say that I believe most providers are no friend of the elderly, as we see it, like the President. Even he told the doctors somewhere out west, as I recall, and said you ought to freeze your rates for at least a year. And if he has moved this way, I think it probably is a commonality.

Senator MATHIAS. You think that is the low-water mark?

Mr. CLAYMAN. Well, I am not a good judge; I want to be kind.

Senator MATHIAS. Well, charity is always a virtue.

Mr. CLAYMAN. Let me make this quick point. I don't think I know a single old person—and I meet lots of them, I will be meeting thousands of them this week—who doesn't have an atrocity story about hospitals, doctors, drug costs. And some of them, of course, are exaggerated. But there are enough of these that the common view of the public in terms of costs, whether they be drugs, whether they be hospitals, whether they be doctors, has become—I won't use the word "warped," because maybe it isn't a warped view—but it is a deeply held view.

And in too many situations it is an honestly held view that will stand up to scrutiny.

Senator MATHIAS. Well, I cannot contest that. I think that is the perception; I think that is the commonly held view. And I think that puts the entire health care community on its mark to prove its bona fides. And you are absolutely right about that, and I support that concept.

Mr. CLAYMAN. Which brings us down to the final point: why do we need to bailout, if that is the word, the prosperous industry that is doing well under the present system? Why should they be supplicants here in Congress when you consider and are aware of the problems of senior citizens, many of whom don't have two nickels to rub together at the end of the month when their Social Security check has run out?

Senator MATHIAS. Well, how do you react—and you were here during the first session, for which I am grateful to you and grateful that you had the patience to come back to the second session—but how do you react to the testimony that you heard, that patent life for medical drugs has been substantially diminished in recent years as a result of the FDA testing, which is required by the Government?

Mr. CLAYMAN. Well, my reaction is is whatever it is that they allege has been done to them, they are doing well by it, they are making money—they are making money, indeed, hand over fist. It isn't a liability to them. It may be somewhat of a block to the kind of profits they dream about, but in actuality they are making those profits, reasonable profits, and that ought to be enough in any society, including ours.

Senator MATHIAS. Of course, if the objection is profits—on Mr. Haddad's testimony last month—the generic drug industry is making a higher level of profit than the prescription drug industry.

Mr. CLAYMAN. Well, I will tell you——

Senator MATHIAS. And that is their own spokesman speaking.

Mr. CLAYMAN. I must say in response—and I don't recall literally what Mr. Haddad said—but I will tell you the same product is infinitely cheaper, and that is the important message to me.

As a matter of fact, I don't really get excited about the profits of the industry, save and except as it is reflected in higher costs for too long a period.

Senator MATHIAS. You and I are on the same ground there, because I think that is the area we should get excited about: whether it is reflected in higher cost to the consumer over an extended period.

And I would repeat what Mr. Haddad said on that; he said, my private conclusion about this bill is that it has nothing to do with the consumer market.

Mr. CLAYMAN. I don't know what he meant by that.

Senator MATHIAS. Well, I think what he meant was exactly what Tom Bradley said this morning, that the fight really is on these contracts, the big contracts. And I am trying to sort out in my own mind exactly what the effect will be as far as the big contracts to Government agencies and to large institutions, who affect your membership very much.

Mr. CLAYMAN. Senator, until I was 65 I rarely took any kind of drug; as a matter of fact I resented pills, and my wife would want to push them on me and I wouldn't accept them.

But I take them now.

Senator MATHIAS. That's another thing you and I have in common. I don't like to take more than one aspirin at a time, and not very often.

Mr. CLAYMAN. But I take them, and they are high-priced pills, and that is one of the problems of the aged, the pills they buy, the drugs they buy, are really the high-priced drugs.

And I must tell you that I shop by sight and sound, and my shopping tells me that every time I go in for the drugs—not every time—but every several months the price increases, and sometimes drastically. And I know from personal observance, and this isn't a horror story—I can afford to pay a little more for drugs if I have to, and it is not a horror story—but the point is they are going up and up and far beyond the means of too darned many ordinary people.

Senator MATHIAS. Well, now, in your statement you mentioned the diabetes drug, Orinase.

Mr. CLAYMAN. I mentioned it, yes, in my statement.

Senator MATHIAS. In your written statement. Before that drug was developed, a diabetes patient, someone in a critical stage, faced either a kidney transplant or dialysis, I am advised. Instead of those ordeals, neither of which is very pleasant to contemplate and both of which are enormously expensive from an economic point of view, the diabetes patient now can rely on this new drug, Orinase, which has been developed.

It is a subjective question, but I think it's an interesting speculation that without the patent system to provide the incentive, Orinase might never have been developed.

Mr. CLAYMAN. Senator, I have no quarrel with the patent system. I think that people who have a great idea are entitled to receive some reward from society, but I certainly don't consider that this is everlasting and without regard to profit structure and without regard to the impact on ordinary people.

Senator MATHIAS. Now, I guess you have put your finger on really where we are, how much is the right amount? Is it 17 years, which is what the law has contemplated as the right amount? If it is, is it right or wrong to diminish the 17 years as a result of Government regulations?

Mr. CLAYMAN. All I can tell, Senator, is that history and experience tell me that they are doing well enough, and I don't think that is controvertible.

Senator MATHIAS. We all seem to agree that the patent system is a good thing. Then at that point you would disagree with Mae West. You remember, she said: "Too much of a good thing is wonderful." [Laughter.]

Mr. CLAYMAN. I have no comeback to that.

Senator MATHIAS. Well, we thank you very much for being here today.

The committee will stand in recess until August 2.

[The subcommittee adjourned at 11:28 a.m.]

THE PATENT TERM RESTORATION ACT OF 1983

TUESDAY, AUGUST 2, 1983

U.S. SENATE,
SUBCOMMITTEE ON PATENTS,
COPYRIGHTS AND TRADEMARKS,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:38 a.m., in room SD-628, Dirksen Senate Office Building, Senator Charles McC. Mathias, Jr. (chairman of the subcommittee), presiding.

Also present: Senator Metzenbaum.

Staff present: Ralph Oman, chief counsel, Charlie Borden, professional staff member, and Pam Batstone, chief clerk, Subcommittee on Patents, Copyrights and Trademarks; Henry Hoberman, counsel to Senator Kennedy; Cathy Dier, counsel to Senator Leahy; Steve Johnson, counsel to Senator Specter; Wes Howard, counsel to Senator Metzenbaum; Beverly McKittrick, counsel to Senator Laxalt; Renn Patch, counsel to Senator Hatch; and Sheila Bair, counsel to Senator Dole.

OPENING STATEMENT OF SENATOR CHARLES McC. MATHIAS, JR.

Senator MATHIAS. The subcommittee will come to order.

Today the Subcommittee on Patents, Copyrights and Trademarks will conduct the third and final hearing on the Patent Term Restoration Act of 1983.

We are very pleased today to welcome an old friend, the founder of Public Citizen, Ralph Nader, as the first witness. He will be followed by Mr. James Hacking, the assistant legislative counsel for the American Association of Retired Persons.

I will ask witnesses, in view of the pressure of time and the fact that the Senate is in session and that we could be interrupted at any moment, to try to observe the 5-minute time limit for opening statements so that we will leave some opportunity for questions and answers and some dialog following the opening statement.

As has been announced at previous sessions, we will hold the record open for an additional 2 weeks following today for additional information or other statements that witnesses wish to submit for the record.

STATEMENT OF RALPH NADER WITH JANET HATHAWAY, STAFF ATTORNEY, PUBLIC CITIZEN'S CONGRESS WATCH; WILLIAM SCHULTZ, STAFF ATTORNEY, PUBLIC CITIZEN'S LITIGATION GROUP; AND DR. SIDNEY WOLFE, DIRECTOR, PUBLIC CITIZEN'S HEALTH RESEARCH GROUP

Mr. NADER. Thank you, Mr. Chairman and members of the subcommittee.

We are testifying today on S. 1306 which in a simplified description would extend the patent term for drugs and other chemical substances by a maximum of 7 years. The drug companies currently get 17 years.

Before I comment on the bill, I would like to say that any kind of revision of the patent law which singles out a portion of product innovation for this kind of proposed treatment is clearly going to raise questions of equity and questions as to whether other inventor claimants should have similar pleas recommended.

For instance, individual inventors who invent a useful product and spend the entire patent life trying to ward off corporate infringers have lost a great deal of their patent term, if not entirely, and they can make a much stronger case than any of the other claimants before this subcommittee for this kind of treatment.

So quite apart from the assertions of the drug industry which I will comment on in a moment, the mere plea by the drug industry involved in S. 1306 raises severe questions of equity concerning other product innovators in the country and opens up the patent laws to repeated claims, as have the tax laws, for portions of exemptions and special considerations.

The drug companies claim their effective patent life is much less than 17 years because of the time required to test and get approval from the FDA.

It is not the Government's fault. The FDA takes less than 2 years to approve new drugs, on the average. The drug companies have a great deal of control over how long it takes to test their drugs. So any time they lose is their responsibility.

They can take years—in fact, in one of our appendices we show that one drug was not even tested for 15 years. Naturally its patent life was reduced in terms of its patent life for sales potential.

Nor have the drug companies supplied the data which we all need to determine how much patent life they really get. Congressman Gore asked for that data last year, but it still has not been produced.

Furthermore, the drug companies have been known to manipulate patents to get longer than 17 years in some cases. Valium is an example. Congress should demand to know how often this happens.

We know that this bill will reduce competition, and competition reduced is harmful to consumers. Seven years of additional patent time means 7 years of additional monopoly prices which will be higher than competitive prices. Generic drugs often cost only a fraction of the brand name products.

By consumers I do not just mean those who purchase generic drugs for their own consumption, namely, the sick and the elderly,

but also the Federal Government, which is a big purchaser of generic drugs, could save a lot of money.

Patent extension will increase the amount of dollars laid out by Federal Government agencies.

Patent extension could be a major setback to the generic drug industry which is just getting off the ground after being excluded by State laws, many of which have now been repealed.

Antisubstitution laws have been repealed in 49 States. The Virginia pharmacy case showed that advertising of prescription drug prices is constitutionally protected, and now that competition is beginning to come in, we are confronted with a proposal to further restrict it.

It is argued by the drug industry that the bill will stimulate research. There is no evidence that research is declining. See the tables in our appendix. There is no reason to think it will decline since the drug industry is by any measure one of the most profitable in the United States. We have tables that document this assertion in our testimony.

There is also no reason to think the companies will put the money into important research. That is just a hope. Just like the investment tax credit. Congress hoped that the money would go into productive investment. Congress's hope has very much been unfulfilled over the years.

It is argued by the drug industry that the patents on drugs should be extended as a matter of fairness. Here the history of the patent laws comes into being. The PMA is complaining about losing something they never had a right to, which is a patent protected marketing period of a definite duration.

A crucial point seems to be regularly overlooked. The patent does not guarantee a 17-year period of monopoly sales. It only excludes competitors from profiting from the invention for that time.

For over 100 years, the patent laws have set 17 years as the maximum period in which the patent holder is permitted to exclude others. When the Congress set the patent term as 17 years, it noted that a substantial portion of the 17-year term may well be spent by the patent holder in "establishing his article and demonstrating its value and inducing capitalists to take hold of it." These words are from the legislative history.

The patent extension period of 17 years been recognized since 1871 as a period which runs from the day on which the patent is granted, cannot be extended and ordinarily will be used for R&D activities as well as marketing.

There is nothing inequitable about this. It is simply less than the pharmaceutical industry wants.

The proponents of patent extension are not asking for equitable treatment under the patent law. They want a radical new form of patent. Not satisfied with patents that delay competition for 17 years after patent issuance, the proponents have been advocating a restructured patent under which a monopoly sales period of less than 17 years is considered an urgent problem requiring immediate legislative attention.

The anomaly of the situation is this: Pharmaceutical manufacturers are complaining that they are not getting the full 17 years

of marketing protection under patent law which neither they nor any other industry has been entitled to for 100 years.

The drug companies get longer monopolies after patents expire de facto. The enormous sums they are spending on advertising to persuade doctors to buy their brand names, instead of substituting with generics, could go into research and development funds. Instead it goes into a type of competition known as monopolistic competition, brand name competition, which hardly has any beneficial influence for consumer health and well-being.

Furthermore, the time taken to test drugs is comparable to the time taken to develop and market other products. I do not know why the drug industry thinks it is so special. They ought to talk to the auto industry which has a leadtime bordering on infinity, and even they have not come up to ask for this kind of patent protection.

The patent system, Senator Mathias, I want to emphasize, was not intended in the congressional history of the act to guarantee 17 years of sales opportunity. When all is said and done, S. 1306 is nothing more than an income transfer bill. It is designed to transfer money from those who can least afford it, the sick, the elderly, and the chronically disabled, to the big drug companies. Since there is no evidence that the bill will benefit anyone other than the drug companies, we urge that it not be adopted.

In our testimony, we have a list of questions that we hope that the subcommittee will send to the Pharmaceutical Manufacturers Association which will provide for the data needed to support their alleged claims.

This has been going on for years, and although Counselor Peter Hutt has rhetorical eloquence in his case it falls flatly on the lack of adequate data to support these claims and these allegations that the sky is falling for the pharmaceutical industry.

I think the least that can be done for any industry that is asking for an extraordinary exception and asking the Congress to start a process of people lining up and companies lining up, inventors lining up for their slice of what they perceive to be equity away from the 17-year term, that the least the pharmaceutical industry can do is to provide the hard data accumulated from its member companies and then aggregate it for presentation to the Congress.

Thank you.

Senator MATHIAS. You will note that we have been more generous with you than with the drug industry and have granted you a patent term extension of some minutes.

Mr. NADER. I thank you.

Senator MATHIAS. First of all, let me say that I agree with you basically on the question of singling out the drug companies. What we are dealing with here is something that was not contemplated when Orestes Cleveland was addressing the House of Representatives in 1870 on the subject of the proper life of a patent.

We are dealing with a new creature of the law that the Congress has created for the benefit of public health and safety, which is the testing process in the Food and Drug Administration.

That is something that came along long after the 17-year term for patents was created, and it effects the patent life. It seems to me, to be a matter of commonsense that it does.

But I would agree with you that there probably are other government procedures that effect patent life.

Mr. NADER. Also, Senator, the FDA imprimatur is a very valuable merchandising and liability defense system so it has a plus for the drug industry that is not often noted as I might add does any kind of government regulatory imprimatur.

Senator MATHIAS. Well, in the bill as we had it drafted last year we had this language, which supports your point, although it does not appear in the bill this year, and maybe we ought to consider putting it back in, that:

> With respect to any other product or method of using a product that has been subjected to federal premarketing regulatory review, the 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 a date when such review is completed.

In other words, it would give the same kind of treatment to any product which loses patent life as a result of the requirements of Federal law, and it seems to me that this is at least a consideration that's worth thinking about.

Mr. NADER. By the way, Senator, important therapeutic advances are taking, on the average, less than a year to be approved by the FDA.

Senator MATHIAS. Well, then, it really is not such a big deal after all either way.

Mr. SCHULTZ. The problem is that the bill, as drafted, gives the companies more than just the time the FDA takes to approve drugs. It gives them the time that they take to test their products, which usually will give them the full 7 years.

Thus, even if the FDA takes a year only to approve a new drug application, the bill would give the company 7 years extension on the patent.

Senator MATHIAS. Who sets the parameters for the testing?

Mr. NADER. Dr. Wolfe would like to respond to that.

Dr. WOLFE. There are, as you know, legal standards for safety and effectiveness, but the nature of the tests, the design of them, the carrying out of the tests and their review is really totally in the control of the drug companies.

Only after this is done does the FDA take a look at it, and the taking a look at it part, just alluded to by Mr. Schultz, is really brief and it is getting briefer as FDA sets priorities so that the more important drugs get put on a faster track.

What has come up over and over again, not just in the context of the patent extension bill but in the context of this whole hullabaloo about drug lag is that one of the parties most responsible for drug lag is not the Government but the drug companies themselves.

If you talk to anyone who spends their time, the doctors, the MD's at the FDA who spend their time looking at these drug applications, they will tell you that one of the things that most slows down the drug review process is the poor quality of many of the studies submitted by the drug companies.

So that on one hand, they are trying to speed up the drug review process by blaming the FDA when, in fact, a lot of it is their fault.

In this case, they are trying to extend the patent even though a lot of the delay is really due to the poor quality of studies the drug companies do.

In other words, they are wanting to benefit, in a sense, from the fact that they themselves are responsible for a certain amount of the delay. I think that this is just not fair.

It is not as though the Government is testing drugs, the Government is designing these studies, the Government is carrying out the studies, and therefore, it is the Government's fault. Much of this is on the industry side. Someone from the industry itself, whom we quote in our testimony, Dr. Smith, who used to be a clinical investigator for Searle, says the fault for this delay is with the drug companies, and yet they are the ones seeking some special privilege.

Senator MATHIAS. Let us make a little legislative history here. Let us make it perfectly clear that we are not talking about the preclinical research. Are we agreed on that?

Dr. WOLFE. Yes. The clinical research, though, is still conducted——

Senator MATHIAS. Preclinical research.

Dr. WOLFE. Pardon?

Senator MATHIAS. We are talking about preclinical research.

Dr. WOLFE. Yes. We are talking really about both because the delay——

Senator MATHIAS. No, we are not, because the bill does not necessarily deal with preclinical research. It does not necessarily restore any time spent in preclinical research.

Dr. WOLFE. I understand that. The point that I was making, though, is that when the FDA considers a drug for approval, they are looking at clinical research; for example, that is often of very poor quality, needs to be repeated, and the process of the drug companies submitting poor clinical research itself eats up a huge amount of time.

And yet they would like to get rewarded for their inefficiency, and the bill as it's currently designed would do that for them.

Senator MATHIAS. Well, I think that is a subjective question which I think we ought to consider certainly, and perhaps if you have any supporting information you can file it for the record on that.

Dr. WOLFE. We have included one statement from a drug company official himself who says that.

Senator MATHIAS. Let us go back to the broader question of whether or not there shouldn't be patent term restoration for any article, substance, procedure which is patentable and which is delayed in access to the market as a result of Federal regulations.

Dr. WOLFE. I have just one brief comment on that. Again, one of the charts we include in the testimony shows a variety of patented items, most of which did not go through any kind of regulatory process at all and yet which had tremendous delays from the time that they were invented or patented to the time that they actually got marketed. Which is to say that one item but only one item—and sometimes a small item—that accounts for the delay from the time something is invented until the time it is marketed is the Government review process.

When you have got so many items getting delayed without a Government review process, the real issue that gets raised is, should the patent for everything be extended to 20 or 25 years because the product that cannot line up and cry Government regulation now might line up and cry and something else next year. Namely, we could not get capitalization as fast as we wanted to or we could not get our manufacturing plant set up fast enough.

Senator MATHIAS. Those are subjects beyond the control of the Congress. As the Chinese say, the longest journey starts with the first step. If we can remove one small problem that we can identify and which is within our grasp, is that not a desirable thing?

Mr. NADER. Except that, Senator, this bill clearly has a corporate bias in the sense that the lone inventor who, by the way, is still the major source of innovation in our country, the lone inventor who is subject to willful infringement and willful corporate interference and delay and ends up with no useful patent life, has absolutely no recognition in this bill, which goes to my former point.

If you are going to change the patent laws, then reading the legislative history is not very useful. But if you are going to change the patent laws, it should be done in a much more equitable manner if anything to recognize what the innovation studies have shown over the last 20 years, that for a lone inventor, a patent is largely a right to sue, and that does not amount to very much when the defendant is General Motors or Exxon or Smith, Kline & French.

And that is the kind of protection needed that I think the Congress should address in any kind of comprehensive treatment.

Now, you may say, well, in the best of all possible worlds we will do the comprehensive work later. Right now we want to deal with the heart of the problem. But I think it is the most inequitable claim by a very profitable industry to start the process of reform there.

Senator MATHIAS. Well, would you take a look at the language which I read—which is general and applies to any inventor, any product—and give us your comment on that, for the record, within the next 2 weeks, and then if you want to suggest other language which deals with problems that affect corporate infringers, why, I would be glad to have that suggestion, too.

Now, you mentioned the question of profitability several times. I find it difficult to seize upon that as a guideline here because the generic drug industry is more profitable than almost any other industry in the country.

Ms. HATHAWAY. Senator Mathias, may I make a comment? The point that we are really trying to make here is that we have not seen evidence that there is a problem with the patent laws as they now exist, and certainly we have not seen any inequities for the pharmaceutical industry by the measures that we have before us.

So what we are asking for is evidence, if they have any, that would substantiate their claims. In addition, in looking at the patent's purposes—first innovation and second disclosure of useful information after the patent period expires so there can be competition of an effective sort—we see that the pharmaceutical industry has benefited exceptionally from the patent system as it currently exists.

Senator MATHIAS. Well, the committee is as anxious as you are to see all of the evidence on all sides of this question.

Dr. WOLFE. If I can just make one further comment, if you look at the drugs that have gotten approved in this country in the last 5 to 10 years, I think it does speak to the issue of why profitability is important. From the standpoint of the drug company, if they can put out a 9th or a 10th or a 11th version of Valium as have been approved in the last several years or a 12th or 13th or 14th arthritis drug, none of which is any more effective than aspirin, so be it. They will do it. They will get a patent on it. They will cash in on a large and lucrative market, and that satisfies their business desires.

They call that innovation, and in a sense it is, but really from the patient's standpoint, it does not add anything of any importance to the therapies available, and that is unfortunately true of most of the drugs that get developed and approved in this country.

There is really no reason that we can see, from the record, that adding even more profitability, which certainly would happen if this bill passed, would change that process. They might spend more money on a 13th and 14th version of Valium or a 15th or 16th version of an arthritis drug, and that just does not do anyone any good.

Only rarely does a company come up in this country with a new breakthrough, an important therapeutic improvement. I do not think it will happen any more often if this bill passes, and that is really the question, because we are really talking about innovation.

The companies in this country are also quite content to license drugs developed somewhere else, produce them in this country, employ people to make the pills, to sell the pills, and so forth. They do not see any problem with that. That also is a major ingredient in the profitability, and I do not think that is going to be altered at all by this bill passing.

Mr. NADER. If the point is made that the Government regulations started after the 17-year term, and, therefore, invites reconsideration of the 17-year term, I can make the point that the Government regulation on the credit side is an enormous advantage for the industry.

Once they get the Government approval of a drug or a pesticide, that is an advantage similar to a more apparent one when the meat industry puts the USDA-inspected stamp on the meat that they sell.

So that one certainly balances off the other.

And second, the drug companies can get to market, mass market much faster now than in 1871, because of transportation, communications, and so forth. So that there are new developments that counteract the claim that the 17-year period is obsolete because of Government regulation.

They really have some extraordinary advantages as a result of this Government regulation.

Mr. SCHULTZ. I think there is another point which we should not miss. Most of the time that you are extending the patent for, again, is for the time taken for testing that the companies do. It is not time required for the Government review.

The assumption behind the bill seems to be that the only reason these companies are doing this testing is because of Government regulations. I seriously doubt if that is true. The State product liability laws would, in my view—and I think the drug companies would admit this if pressed—have caused these companies to test their drugs before they put them on the market. That's just one of the costs of marketing a drug. Other products have other costs. I think it is important when you are considering this issue to look at it as broadly as possible. We have encouraged Congress to look beyond the patent, at the monopoly period during the patent life, and to consider the fact that drugs have a special, extra monopoly period that they get after the patent expires. We have documented several instances where even after the patent expired, the drug company has continued to retain a monopoly, and that again more than counterbalances any so-called loss in patent life.

Mr. NADER. What you are saying, Bill, is that two-thirds of the doctors of this country extend the patent life of the drug by not using generic drugs, not prescribing them.

Dr. WOLFE. Even when generics are available.

Mr. SCHULTZ. There is no other consumer product that is like this. This is a product that the consumer does not choose. The doctor chooses the brand when he writes the prescription, and as a result of the drug companies' advertising, they are able to get the doctors to extend that monopoly.

Ms. HATHAWAY. Another factor that extends the monopoly is the fact that the Food and Drug Administration still does not have a rapid procedure by which it can approve generic versions of post-1962 drugs.

And as a consequence, most drugs that were introduced on the market after 1962 continue even after patent expiration, to be the sole drug on the market for that particular purpose. They are not being approved to be generically sold.

Senator MATHIAS. Well, I hope you will give us the benefit of your thoughts on further language that could be added to the bill to extend this benefit, if it is a benefit, and also to look at the language that was dropped from the bill last year.

We are anxious to arrive at an equitable conclusion here, and I'm sure I do not have to tell you your testimony is in direct conflict with some of the previous testimony that we have had from other witnesses.

So we are faced with weighing the evidence and we need all the help we can get. Thank you very much for being with us here this morning,

Mr. NADER. Thank you, Mr. Chairman.

[Statements of panel members and additional material, subsequently received for the record, follow:]

PREPARED STATEMENT OF RALPH NADER WITH JANET HATHAWAY, STAFF ATTORNEY, PUBLIC CITIZEN'S CONGRESS WATCH; WILLIAM SCHULTZ, STAFF ATTORNEY, PUBLIC CITIZEN'S LITIGATION GROUP; AND DR. SIDNEY WOLFE, DIRECTOR, PUBLIC CITIZEN's HEALTH RESEARCH GROUP

My name is Ralph Nader. I am accompanied by William Schultz, staff attorney at Public Citizen's Litigation Group and Janet Hathaway, staff attorney at Public Citizen's Congress Watch. Congress Watch is the legislative branch of Public Citizen, the consumer research and advocacy organization which I founded in 1971.

"We are is grateful for the opportunity to testify before this committee on S. 1306, the Patent Term Restoration Act of 1983. Public Citizen has opposed attempts to extend patents for pharmaceuticals since such legislation was first proposed.

For years, proponents of this legislation have complained that they are harmed by inequities in the patent system. To this day these complaints remain unsupported by independently verifiable evidence. Proponents claim that S. 1306 "will, if enacted, be of benefit to everyone,"[1] and that the absence of patent extension "reduces incentives to invest in drug research, retards the rate of medical innovation, ...and raises the cost of medical care."[2] Behind these broad statements there have been all too few facts, although the pharmaceutical manufacturers undoubtedly have the relevant information about the drugs they sell. The facts that do exist argue against any extension of patent, and especially against a patent extension for the duration set by S. 1306. There is simply no justification for patent extension.

The Patent System: How Does the Drug Industry Fare?

The patent system as it now exists was designed to do two important things. First, patents reward the inventor who receives a 17-year period to research, test, develop and exclusively market the product; second, patents require detailed disclosure about

useful inventions to facilitate competition after the 17-year "head start" of the patent holder has expired.

a. Incentives Exist to Develop New Drugs.

As to the first point, there exist strong incentives to develop new drugs. There is no question but that the first company to introduce an important new drug on the market reaps huge rewards. No one expects diazapam, the chemical patented and sold under the tradename of Valium, to be the goldmine for any of the generic companies that Valium has been for Hoffman La Roche. The first company to sell a drug has a chance to market and promote it in a way that ensures market dominance even after generic competitors emerge. Because 2 of 3 doctors[3] who have the option of prescribing generically still are prescribing the more expensive, brand-name drug, it is clear that original branded drugs will continue to outdistance generic competitors in sales. And despite the last decade's proliferation of state drug substitution laws, only 13.8 percent of all new prescriptions in 1982 were for generic drugs.[4] Finally, all accepted measures of profitability show the drug industry to be flourishing. (See appendix, pages i-viii.) These facts show the financial advantages received by the innovator of a new drug are of dramatic importance during the exclusive sales period and which continue to be significant after patent expiration. The patent system is fulfilling its first purpose: rewarding innovation.

b. Drug Competition Remains Sluggish Even After Patent Expiration.

With respect to pharmaceuticals, the patent system has not been as successful at achieving its second purpose, facilitating competition after the expiration of the 17-year patent period. True competition does not occur even after patent expiration because of peculiarities in the drug industry.

One might expect generics, which are often half the cost of brand-name drugs,[5] rapidly to erode the market shares of expensive branded drugs. Yet this does not occur because drugs are chosen by a third party--the physician. Doctors prescribe on the basis

of confidence in, and familiarity with, branded drugs, without respect to price. Massive advertising campaigns ensure that doctors remember the name Valium, Darvon and Librium, but the respective chemical names--diazapam, propoxyphene hydrochloride and chloridiazepoxide--are eminently forgettable. Because federal law prohibits any drug from advertising the fact of approval by the Food and Drug Administration,[6] physicians and pharmacists may be wary about generics if they have no way of knowing whether they have received FDA approval. Consumers are not free to buy the prescription drugs they prefer, but are dependent upon their doctor's choices. This results in an unusual advantage to the original patented drugs not available in other industries.

Trademark law also favors the drug patent holder. Consumers are sometimes reluctant to accept a generic drug which, although identical in therapeutic effect, is a different color or size from the original branded drug.[7] To avoid possible liability for trademark infringements, generic drug manufacturers must make their products readily distinguishable from the original branded versions. This is one more reason that the patented drug continues to dominate the market even after patents expire.[8]

Finally, generic versions of drugs introduced after 1962 are not being promptly approved by the FDA. Approximately 125 such drugs are now off-patent, but the FDA is still at least months and probably years from implementing an expedited procedure for approving the generic equivalents.[9] To date, only 12 generics of "post-62" drugs have been approved,[10] by a procedure which can be used only for those few drugs which have had safety and efficacy test results published in professional journals.

For these reasons there is no effective competition even after patent expiration. The patent system does not--and is not designed to--treat every industry identically. But if there are inequities in patent and trademark law with respect to the pharmaceutical industry, the net effect seems to be to favor the industry.

c. Patent Grants Guarantee 17-year Exclusivity--not Marketability.

The crux of this debate is whether or not the drug industry is being treated unfairly under the patent laws. The problem, as the drug industry sees it, is "declining effective patent life." The Pharmaceutical Manufacturers Association (PMA) argues, on the basis of very sketchy data, that since 1962 the period of marketing while under patent protection has declined. Let us put aside for a moment pressing questions about sufficiency of the evidence to establish any decline. Let us first consider the premise behind the PMA's claim.

The drug companies seem to be saying that if they now have less sales time under patent protection than in 1962, a legislative solution is in order. But why should this be so? Nowhere does the patent system assure patent holders any set period of sales. The patent grant is only a right to exclude competitors from selling the invention for up to 17 years. During these 17 competition-free years, the patent holder has the opportunity to research, test, develop and market the product. If the research, testing or development takes many years, obviously there will be little or no patent life remaining by the time the product goes to market.

d. Delays before Commercialization are Normal.

A significant delay between invention and marketing is not unique to the drug industry. For many products time has to be spent raising capital, designing and fabricating new machinery or factories, and satisfying health and safety codes, zoning ordinances or environmental impact statement requirements. It sometimes happens that important products cannot be marketed because supporting technology is not available--as in the case of the heart pacemaker, which was off-patent by the time appropriate medical developments made it possible to commercialize it.[11]

In its evaluation of the controversy about patent extension, the Office of Technology Assessment cited a study which found "the average lag time for 319 significant innovations originating in

the United States and introduced between 1953 and 1973, was about 7 years."[12] A study done by L. Edward Klein, Director of Licensing for Monsanto, concludes, "[T]he full process of technological innovation usually takes upward of 10 years and a quarter of a century is not an uncommon time."[13]

The PMA is complaining about "losing" something they never had a right to--a patent-protected marketing period of a definite duration. A crucial point seems to be regularly overlooked: the patent does not guarantee a 17-year period of monopoly sales--it only excludes competitors from profiting from the invention for that time.

For over a hundred years the patent laws have set 17 years as the maximum period during which the patent holder is permitted to exclude others. When the Congress set the patent term at 17 years, it noted that a substantial portion of the 17-year term may well be spent by the patent holder in "establishing his article, in demonstrating its value, and in inducing capitalists to take hold of it."[14] The patent extension period of 17 years has been recognized since 1871 as a period which runs from the date on which the patent is granted, cannot be extended, and ordinarily will be used for R & D activities as well as marketing. There is nothing inequitable about this--it is simply less than the pharmaceutical industry wants.

The proponents of patent extension are not asking for equitable treatment under the patent law; they want a radical new form of patent. Not satisfied with patents that delay competition for 17 years after patent issuance, the proponents have been advocating a restructured patent under which a monopoly sales period of less than 17 years is considered an urgent problem requiring immediate legislative attention.

The anomaly of the situation is this: pharmaceutical manufacturers are complaining that they are not getting a full 17-years of marketing protection under patent--which neither they nor any other industry has been entitled to under the patent system as it has existed for over a hundred years.

II. The Drug Industry is Responsible for Most of the Drug Lag.

Peter Hutt, counsel for the PMA, in 1982 told a Congressional hearing that it takes from 7 to 13 years to test and approve drugs.[15] If this is true, this delay is not attributable to the Food and Drug Administration (FDA). The mean period between filing a New Drug Application (NDA) and receiving FDA approval in 1982 was less than two years--only 22.4 months. After time lost due to errors, omissions and delays of the drug company is deducted, the average time actually spent by the FDA in 1982 on drug approval was even less--16.8 months.[16] And for drugs that are determined by the FDA to be important or modest therapeutic advances, the mean FDA approval time recently has been less than a year.[17]

The drug companies would like us to believe the FDA is holding them back. In reality, drug companies often decide for commercial reasons to delay tests or to abandon development of drugs which do not promise Valium-type returns. Furthermore, time is wasted when companies do shoddy tests or submit incomplete data to the FDA. The Wall Street Journal recently quoted the president of Smith Labs as faulting some drug companies for their lack of diligence.

> Dr. [W. Scott] Smith, who specialized in clinical trials at Searle, says many drugs don't need seven or eight years and tens of millions of dollars to pass regulatory muster, as some companies claim. "The industry has to take a good deal of the rap for drug lag, because many applications are incompetent, poorly done and don't prove anything," he says. . . .[I]n the rush to market, he says, diligent clinical work is sometimes neglected.[18]

III. The Period of Patent Extension in S. 1306 Rewards Industry Incompetence.

The audacity of requesting a specially extended patent for the pharmaceutical industry is only exceeded by requesting that the extension cover the entire period of time spent in testing the drug.

S. 1306 states that the patent term for products subject to regulatory review shall be extended for a time equal to the "regulatory review period."[19] The bill defines the regulatory review period for drugs as beginning when the patent holder or licensee

> (i) initiates a major health or environmental effects test. . .; or
>
> (ii) claims an exemption for investigation . . .; or
>
> (iii) submits an application or petition with respect to such product . . .[20]

and ending when the product is approved and commercial marketing is permitted. This extension is not limited to the actual period of FDA review and is not exclusive of the time wasted by the companies because of incompetence or decisions not to expedite the product to market. Such an extension period is not arguably related to the pre-marketing review at the FDA. It would reward dilatory, shoddy work by pharmaceutical companies by compensation for up to seven years of lost patent time.

IV. Proponents Have Never Adequately Documented Claims of Diminishing Patent Life or Reduced Innovation.

It is incumbent on those who seek radical legislative change to show that such change is necessary and in society's best interests. The pharmaceutical industry has never met their burden of proof on patent extension.

Only after telling a House Subcommittee on Investigations and Oversight that detailed drug approval information would only confuse the Congress,[21] did proponents submit requested data. Unfortunately, the data released was for one year only, and was incomplete and misleading.[22] The patent extension proponents asserted that the patent life remaining on drugs approved in 1980 averaged 7 1/2 years. There is no evidence that 1980 was typical, nor is it shown that a longer exclusive sales period was common earlier. Furthermore, only the first patent on each drug was mentioned, although several of these products had patents extended by later approvals of special use or method patents.[23]

This sketchy data reveals another weakness in the case for patent extension. Extension proponents point to five of the twelve drugs approved in 1980 which then had less than nine remaining years of patent protection.[24] They fail to note that in the case of all of these drugs, there were significant industry-caused delays after patents were issued before clinical testing of the drug was commenced.[25] The three drugs with the least patent life remaining upon approval had remained unstudied by the patent holders for seven, nine and fifteen years after patent issuance. Erosion of patent time in these instances was clearly attributable to the industry.

V. Patent Extension Is A Wealth Transfer From Consumers To Major Drug Companies.

The technicalities of the patent debate may occasionally obscure the fact that this is a health care issue. Even without patent-extension, since 1981 prices increased 32% on name-brand drugs dispensed by the American Association of Retired Persons' pharmacy service.[26] By keeping generics off the market for longer, S. 1306 will force consumers to finance increased profits for the drug industry.

a. The drug manufacturers already have more than adequate incentives to conduct R&D.

The drug companies argue that without additional revenues through patent term extension, the incentives to do research and development of new pharmaceuticals will decline. Unfortunately, they have not offered evidence to support the claim that incentives for innovation have diminished. In fact, R&D has increased, even when adjusted for inflation. Another measure of innovation, the number of new molecular entities approved by the Food and Drug Administration, also shows no reduction since the 1960s. The number of drug approvals FDA considered important therapeutic gains has remained constant for the past 25 years, at about 3 annually.

There are currently numerous and sufficient incentives for innovation in the pharmaceutical industry. Certainly a powerful reason to invest is the industry's enviable 16.9 return on investment, second only to the banking industry last year. The National Science Foundation, Division of Policy Research and Analysis, estimated the total value of the ERTA 25% R&D tax credit at $57 million for the chemical industry and $45 million for the drug industry, 3rd and 4th of all industries benefitting from the credit, for 1981 alone. Tax deductions are also permitted for most R&D, and a special 50% tax credit is available for research on orphan drugs. Thus it is understandable that Dow and DuPont are diversifying into the pharmaceutical industry; this is hardly an area of declining investment incentives.

b. S. 1306 would increase profits instead of encouraging innovation.

But even if there were a need to encourage R&D in this industry, patent extension legislation would be an inapt method. This legislation would not induce new innovation. Instead, should this bill pass, it would merely increase profits across the board for new drugs. The Office of Technology Assessment's 1981 report concludes that there is no evidence that additional revenues derived from patent extension would increase the percentage of R&D activity. Indeed, because patent holders would be insulated from competition for longer, there is a possiblity that innovation would decline because of a lessened demand for ingenuity to retain market dominance.

c. The high cost of prescription drugs will become exorbitant if generic competition is restricted still further.

American consumers cannot afford to give the pharmaceutical industry greater profits merely because the industry would like it. Drug prices currently are rising at about triple the Consumer Price Index.[27] Even now many elderly and ill Americans are paying from 42 to 74 percent more for their prescriptions than they would if their doctors would prescribe generically, according to the Federal Trade Commission.[28]

The Pharmaceutical Manufacturers Association says, "[T]his legislation would result in lower prices to consumers."[29] No attempts are made to reconcile this claim with the PMA's assertion that additional revenues for drug R & D will flow from patent extension. As usual, no evidence for this claim is offered beyond the bare assertion that "competition from new therapies exerts a downward pressure" on drug prices.[30] An evaluation of three drug categories within which a limited degree of substitutability exists gives no support for this claim. (See appendix, pp. x-xii for relative costs of beta blockers, tranquilizers and non-steroidal anti-inflammatory drugs.) No "downward pressure" appears to have occurred when new drugs in these therapeutic classes were introduced. Rather, in most instances the new drug was introduced at a premium price, higher than most or all of the drugs previously available. The price of cheaper drugs then rose rapidly in the following years, keeping pace with the cost of expensive "competitors." These figures challenge the PMA to demonstrate, if they can, how further restricting generic competition could possibly lower drug prices.

VI. Questions Remain for Proponents of Patent Extension.

I will conclude by reiterating that the industry which promotes patent extension has not provided Congress with the relevant data. These crucial questions remain unanswered:

1. When were patent applications filed for each drug approved since 1962?
2. When were patents approved for each drug?
3. When was a request for investigational exemption (IND) filed for each new drug?
4. When did the sponsoring pharmaceutical company file a New Drug Application (NDA) with the Food and Drug Administration for each drug?
5. When did the FDA approve each new drug for marketing?
6. What portion of the FDA approval time was attributable to industry-caused delays, i.e. inadequate documentation requiring further testing and resubmission, withdrawal of application, etc.?

7. What evidence is there for price competition between drugs within the same therapeutic category resulting in overall lower prescription drug prices for consumers?

The Committee should insist that answers be provided before this legislation receives further attention. That proponents of this legislation are reluctant to reveal the most relevant facts can only raise doubts about how well the data supports their claims.

Thank you. We will be happy to answer questions.

NOTES

1. Testimony of Lewis A. Engman, President, Pharmaceutical Manufacturers Association, Before the Senate Judiciary Committee, 6/22/83,p. 9.

2 Pharmaceutical Manufacturers Association, "Lost Patent Life, Lost Medicines and the Rising Cost of Health Care," 1983.

3 Testimony of William Haddad, President, Generic Pharmaceutical Industry Association before the Senate Judiciary Committee, 6/22/83, p.3.

4 "Rxs Jump 5.3% Spurred by a 7.2% Rise in Refills," Pharmacy Times, p. 29, April 1983.

5 American Association of Retired Persons' Pharmacy Service, "Top 50 Prescription Drug Prices with Generic Equivalents," October 1, 1981; July 1982; and February 1983. In 1981, the mean branded drug price ($8.16) was twice the mean generic price ($4.07); in 1982, branded drugs averaged 2.3 times the generic price ($9.95 for branded; $4.32 for generics); and in 1983, the cost of brand-names averaged slightly over twice the cost of generics ($10.81 to 5.27).

6 Section 301(l) of the Federal Food, Drug and Cosmetic Act, as amended, codified at 21 U.S.C. §331 (l).

7 If a generic manufacturer produces a drug in the same size, shape and color as the original drug, they can be held liable under section 32 of the Trademark Act of 1946 (Lanham Act), 60 Stat. 427, 15 U.S.C. §1051 et. seq., if the use of the look-alike capsules induces pharmacists to substitute the generic drug for the branded product and to mislabel the generic as the higher-priced drug. See Inwood Laboratories v. Ives Laboratories, US ,72 L. Ed. 606 (1982). "[I]f a manufacturer or distributor intentionally induces another to infringe a trademark, or if it continues to supply its product to one whom it knows is engaging in trademark infringement, the manufacturer or distributor is contributorially responsible for any harm done as a result of the deceit." Id., p. 615.

8 See appendix at p. xiii. These four off-patent drugs continued to have market shares near 90% even after many years.

9 Testimony of Dr. Mark Novitch, Deputy Commissioner, Food and Drug Administration, before House Subcommittee on Health & Environment, July 25, 1983.

10 Conversation on 7/28/83 with Mr. Don Hare, Special Assistant to Mr. Gene Knapp, Associate Director for Drug, Monographs, Bureau of Drugs, FDA.

11 Testimony of Norman Balmer, Project Director, Patent Term Extension Project, U.S. Congressional Office of Technology Assessment, Hearing before the House Subcommittee on Courts, Civil Liberties and the Administration of Justice, July 22, 1981, p. 61-62.

12 Gellman Research Associates,"Indicators of International Trends in Technological Innovation," Jenkintown, PA, April 1976, cited at p. 120 OTA, Patent Term Extension & the Pharmaceutical Industry (1981).

13 L. Edward Klein, "Invention to Commercialization," Nouvelles-Journal of the Licensing Executive Society, Vol. XII, #1, pp. 12-16 (March 1977).

14 Congressman Orestes Cleveland, Congressional debate on H.R. 1714, The Congressional Globe 2856 (April 20, 1870).

15 Peter Hutt, counsel, Pharmaceutical Manufacturers Association, Hearing Before the House Subcommittee on Investigations and Oversight, Committee on Science and Technology, February 4, 1982, page 156.

16 See Appendix, p. ix.

17 For FY 1981, 4th Quarter, 10.5 months; FY 1982, 1st Quarter, 10.3 months and FY 1982, 2nd Quarter, 10.5 months. New Drug Evaluation Project: Briefing Book; Department of Health & Human Services, Food & Drug Administration, Office of New Drug Evaluation, May 1982, Table 1A.

18 "Struggle for Approval of Back Drug Shows Frustrations of FDA Review," Wall Street Journal, April 25, 1983.

19 Section 155(a)(1).

20 Section 155(c)(3).

21 Peter Hutt, counsel, Pharmaceutical Manufacturers Association, responding to requests for data for all drugs approved by the FDA since 1962, including: the date of patent filing, the date of patent approval, the filing date for Investigational New Drug status, the filing date for New Drug Approval and the date FDA approved New Drug Approval status. Hearing before the Subcommittee on Investigations & Oversight, Committee on Science and Technology, February 4, 1982, p. 198-200.

22 See Appendix p.xiv,where the chart on the 1980 approved drugs is reproduced with annotations.

23 Rep. Albert Gore, Jr., "Patent Term Extension: An Expensive and Unnecessary Giveaway," Health Affairs, Spring 1982, p. 32.

24 See Appendix at p. xiv.

25 Clinical testing occurs after Investigational New Drug (IND) exemption is approved.

26 On October 31, 1981 the average cost for the top 50 brand name prescription drugs at AARP's pharmacy (in quantities of 100) was $8.16; in July 1982 the

average cost was $9.95, and in February 1983 the average cost was $10.81. (Source: American Association of Retired Persons Pharmacy Service, op. cit.)

27 Id.

28 Federal Trade Commission, "Drug Product Selection," Washington, D.C., 1979; cited by Office of Technology Assessment, Patent-Term Extension and the Pharmaceutical Industry, p. 32, August 1981.

29 Testimony of Lewis A. Engman, 6/22/83, op. cit., p. 11.

30 Id., p. 11-12.

APPENDIX

Table of Contents

BusinessWeek, "Corporate Scoreboard [for First Quarter 1983]," May 16, 1983, p. 55.

	Industry	Return on Common Equity
1.	Drugs	19.1
2.	Tobacco	19.0
3.	Personal Care Products: Cosmetics, Soaps	16.9
4.	Beverages	16.5
5.	Retailing (Food)	16.0
6.	Office Equipment, Computers	15.9
6.	Publishing, Radio, T.V.	15.9
8.	Oil Service & Supply	14.8
8.	Service Industries	14.8
10.	Electrical, electronics	14.2
	ALL-INDUSTRY COMPOSITE	10.7

BusinessWeek, "Inflation Scoreboard [for 1982]," May 2, 1983, p. 76.

	Industry	Constant Dollar Profits as Percent of Historical Cost*
1.	Drugs	82%
2.	Publishing/T.V.	81%
3.	Leisure Time	76%
4.	Aerospace	75%
5.	Instruments	73%
6.	Oil Services	70%
6.	Personal Care Products	70%
8.	Food and Lodging	68%
9.	Beverages	62%
10.	Office Equipment	60%
	ALL-INDUSTRY AVERAGE	22%

*After adjusting costs for the Consumer Price Index; costs include depreciation and cost of goods sold.

Fortune, "Who Did Best and Worst Among the 500 [for 1982]," May 2, 1983, p. 226.

	Industry	Changes in Profits
1.	Musical Instruments, Toys, Sporting Goods	291.6%
2.	Drugs	13.3%
3.	Apparel	12.5%
4.	Publishing, Printing	10.4%
5.	Soaps, Cosmetics	9.1%
6.	Office Equipment (including computers)	8.9%
7.	Beverage	8.5%
8.	Food	7.1%
9.	Textiles	4.9%
10.	Electronics, Appliances	1.1%
	ALL INDUSTRIES	-27.1%

Fortune, "Who Did Best and Worst Among the 500 [for 1982]," May 2, 1983, p. 226.

	Industry	Return on Stockholders' Equity
1.	Musical Instruments, Toys, Sporting Goods	32.6
2.	Drugs	16.9
3.	Beverages	16.7
4.	Soaps, Cosmetics	16.0
5.	Publishing, Printing	15.5
6.	Food	15.3
7.	Measuring, Scientific, Photographic Equipment	12.8
8.	Petroleum Refining	12.5
9.	Office Equipment (including computers)	12.4
10.	Apparel	12.3
	ALL INDUSTRIES	10.9

Fortune, "Who Did Best and Worst Among the 500 [for 1982]," May 2, 1983, p. 226.

	Industry	Changes in Sales
1.	Office Equipment (including Computers)	18.6%
2.	Publishing, Printing	10.0%
3.	Beverages	6.7%
4.	Soaps, Cosmetics	6.1%
5.	Musical Instruments, Toys, Sporting Goods	4.0%
6.	Drugs	3.8%
7.	Apparel	3.0%
8.	Food	2.0%
9.	Electronics, Appliances	0.7%
	ALL INDUSTRIES	-5.7%

BusinessWeek, "Corporate Scoreboard [for First Quarter 1983]," May 16, 1983, p. 55.

	Industry	Return on Invested Capital
1.	Banks	26.5
2.	Drugs	16.9
3.	Personal Care Products: Cosmetics, Soap	14.6
4.	Office Equipment (including computers)	13.9
4.	Electrical, Electronics	13.9
6.	Service Industries	13.7
7.	Beverages	12.4
8.	Retailing (Nonfood): Department, discount, mail-order, variety and specialty stores	12.3
8.	Oil Service & Supply	12.3
10.	Publishing, Radio, T.V.	11.9
	ALL-INDUSTRY COMPOSITE	9.2

BusinessWeek, "A Real Look at Earnings: 1982 Was a Dismal Year," May 2, 1983, P. 76.

PROFITS	ALL	DRUG
Constant Dollar Profits 1982, $ millions	$9432	$1336
Constant Dollar Profits, % Change from 1981	-67%	18%
Constant Dollar Profits, as % of Historical Cost,[1] After Adjusting Costs for the Consumer Price Index [2]	22%	82%
Current Cost Profits 1982,[3] $ millions	$18,680	$3971
Current Cost Profits, % Change from 1981	-57%	16%
Current Cost Profits, as % of Historical Cost, After Adjusting Costs for Changes in Specific Prices	27%	85%

BusinessWeek, Op. Cit.,

[1]Historical Cost Profits: Net income before extraordinary items as reported.

[2]Costs Include Depreciation and Costs of Goods Sold.

[3]Current-Cost Profits (C-C): Net income with depreciation and cost of goods sold calculated at current replacement or reproduction costs of assets.

BusinessWeek, "A Real Look at Earnings: 1982 Was a Dismal Year," May 2, 1983, p. 80.

RANKING THE INDUSTRIES BY PROFIT GROWTH

Average compound growth rate 1978-1982

	ALL	DRUG
Reported % Growth in Profits	6%	11%
Constant Dollar Growth in Profits [4]	2%	8%
Current Cost Growth in Profits	-2%	4%
Reported % Growth in Sales	10%	11%
Reported % Growth in Dividends	10%	13%

BusinessWeek, Op. Cit.

[4]Consumer Price Index

Fortune, "The Fortune Directory of the Largest U.S. Industrial Corporations," May 2, 1983, p. 226.

1982 COMPARISON OF THE DRUG INDUSTRY WITH ALL INDUSTRY

	ALL	DRUG
Total Return to Investors, 1982	21.22%	32.82%
Return on Stockholders' Equity	10.9%	16.9%
Return on Sales	3.6%	9.9%
% Change in Sales	-5.7%	3.8%
% Change in Profits	-27.1%	13.3%
Sales per Dollar of Stockholders' Equity	$2.74	$1.82
Assets per Employee	$66,797	$79,802

BusinessWeek, "The Recovery Fails to Lift First-Quarter Profits," May 16, 1983, p. 55.

	ALL	DRUG
Profits[1] 1st Quarter 1983 $ millions	$24,056.1	$1359.6
Profits Change from 1982	-1%	6%
Return on Invested Capital[2]	9.2	16.9
Return on Common Equity[3]	10.7	19.1
10 year Growth in Common Equity[4]	11%	13%

BusinessWeek, Op. Cit.

[1]Profits: Net income before extraordinary items and discontinued operations. For banks, profits are net income after security gains or losses.

[2]Return on Invested Capital: Ratio of net income before extraordinary items and discontinued operations, plus minority interest and interest expenses adjusted by tax rates (all for recent 12 months), to latest available total invested in company.

[3]Return on Common Equity: Ratio of net available for common stockholders (most recent 12 months), to latest available common equity, which includes common stock, capital surplus, retained earnings.

[4]Growth in Common Equity: Annual percentage growth in common equity for latest 10-year period.

TOP INDUSTRIES FOR RESEARCH & DEVELOPMENT EXPENDITURES

1979	1980	1981	1982	$ in Millions
1)Automotive	1)Automotive	1)Automotive	1)Information Processing-Computers	$4,716.9
2)Information Processing-Computers	2)Information Processing-Computers	2)Information Processing-Computers	2)Automotive	4,527.4
3)Chemicals	3)Drugs	3)Chemicals	3)Chemicals	3,032.0
4)Drugs	4)Chemicals	4)Drugs	4)Drugs	2,978.0
5)Aerospace	5)Aerospace	5)Aerospace	5)Aerospace	2,518.1
6)Fuel	6)Fuel	6)Fuel	6)Fuel	2,357.3
7)Electrical	7)Electrical	7)Electrical	7)Electrical	1,501.7

TOP INDUSTRIES FOR PROFIT

1979	1980	1981	1982	$ in Millions
1)Fuel	1)Fuel	1)Fuel	1)Personal & Home Care Products	$71,842
2)Telecommunications	2)Information Processing-Computers	2)Information Processing-Computers	2)Fuel	18,427
3)Chemicals	3)Telecommunications	3)Telecommunications	3)Telecommunications	8,296
4)Information Processing-Computers	4)Chemicals	4)Chemicals	4)Information Processing-Computers	6,415
5)Drugs	5)Drugs	5)Drugs	5)Drugs	4,988
6)Automotive	6)Food & Beverage	6)Oil Service & Supply	6)Oil Service & Supply	3,728
7)Miscellaneous Manufacturing	7)Miscellaneous Manufacturing	7)Food & Beverage	7)Chemicals	3,687

(Source: BusinessWeek, R&D Scoreboard 1979, 1980, 1981, 1982. July 7, 1980, page 47; July 6, 1981, page 61; July 5, 1982, page 55; July 20, 1983, page 123.)

COMPARISON OF THE DRUG INDUSTRY WITH INDUSTRY COMPOSITE

	1979		1980		1981		1982	
	ALL	DRUGS	ALL	DRUGS	ALL	DRUGS	ALL	DRUGS
Profits-Average Annual Percentage Change	18.6	14.2	19.3	15.0	14.6	13.2	10.3	11.2
R & D-Percent Change From Previous Year	18.9	15.7	15.4	18.5	15.1	16.3	11.5	18.7
R & D-Percent Of Sales	1.9	4.8	2.0	4.9	2.0	5.3	2.4	6.0
R & D-Percent Of Profits	32.9	49.1	38.2	51.3	39.3	57.1	56.4	59.7
R & D-Dollars Per Employee Millions	1553	2953	1834	3466	2161	4044	2562	4836
Employment - Percent Annual Change	4.0	4.5	4.7	4.9	2.1	3.2	-0.6	1.8
R & D - Total $ Millions	23,826.2	1,813.0	28,054.6	2,157.5	32,106.5	2,450.6	35,763.7	2,978.0
Profits - Total $ Millions	72,505	3,691	73,493	4,206	81,757	4,292	1,519,976	4,988

Data: Standard & Poor's Compustat Services, Inc.

GLOSSARY

Sales: Includes all sales & other operating revenues.

Profits: Net income before extraordinary items or discontinued operations.

Profits percent annual change: Average annual change in net income before extraordinary items or discontinued operations, as restated, over the last five years.*

R&D expenses 1982: Dollars spent on company-sponsored research & development for the year, as reported to the Securities & Exchange Commission on Form 10-K. Excludes any expenditures for R & D performed under contract to others, such as U.S. government agencies.

R&D percent of sales: R&D expenditures as percent of sales & other operating revenues.

R&D percent of profits: R&D expenditures as percent of net income before extraordinary items & discontinued operations.

R&D dollars per employee: R&D expenditures divided by the reported number of company employees.

Employment percent average annual change: Annual change in number of employees, using restated figures, over five years.*

Data are for calendar year except for those companies reporting on a fiscal year other than calendar basis, in which case the annual data are from the most recent fiscal year reported as of May 30.

Companies included in the survey are limited to those reporting sales of $35 million or more and R&D expenses amounting to at least $1 million or at least 1%of sales. With the exception of companies in telecommunications with significant manufacturing or research efforts, no regulated utilities or transportation companies are included in the survey.

*All rates of change are calculated using a log linear least squares method.

(Source: BusinessWeek, R & D Scoreboard 1979, 1980, 1981, 1982. July 7, 1980, page 47; July 6, 1981, page 61; July 5, 1982, page 55; June 20, 1983, page 123.)

R&D Expenditure and Tax Credit Estimates from BusinessWeek--Compustat--SEC Compilations*

Company R&D Expenditures

Industry	Number of Companies	1980	1981	Change 1980 to 1981	Expenditures Subject to Credit	Tax Credit Projection** for 1981
		[in millions of dollars]				
1. Fuel	19	1,702	2,261	559	557	70
2. Info. Proc.: Computers	26	3,335	3,846	511	512	64
3. Chemicals	45	2,176	2,635	459	460	57
4. Drugs	28	2,107	2,451	343	363	45
5. Aerospace	15	2,039	2,363	324	320	40
6. Electrical	34	1,325	1,487	162	162	20

*Source: Eisner, Robert, National Science Foundation, Division of Policy Research and Analysis, "An Early Assessment of the Effects of the Incremental Tax Credit on Industrial R&D," August 31, 1982.

**Assuming All Expenditures Eligible

Time taken for FDA to approve drugs--mean time between new drug application filing date and new drug approval date

	Number of New Molecular Entities (NMEs)	Mean time for NME approval	Total of New Drug Approvals (NDAs)	Mean time for NDA approval
1979	14	37.5 months	94	33.6 months
1980	12	34.5 months	114	21.3 months
1981	27	30.7 months	96	24.4 months
1982	28	28.8 months	116	22.4 months

Time taken by the FDA for drug approval for all New Drug Approvals--mean time between new drug application filing date and new drug approval date, exclusive of time attributable to industry for resubmitting data, withdrawing applications, etc.

1979	17.4 months
1980	15.5 months
1981	18.6 months
1982	16.8 months

Source: Data on 1979-1981 from New Drug Evaluation Project: Briefing Book, Office of New Drug Evaluation, FDA, May 1982.
Data on 1982 from conversations with Stanley A. Stringer, Chief, Product Coordination Staff, Office of New Drug Evaluation, Food and Drug Administration, July 18, 1983 and July 26, 1983.

"PRICE COMPETITION" AMONG
BETA BLOCKERS *
MAXIMUM DAILY COST*--TO DRUGGIST
top of usual range
(IN DOLLARS)

	1983	1982	1981	1980	1979	1976	1974	
Inderal (propranolol hydrochloride)	1.17	1.01	.91	.83	.71	.66	*	80 mg. dose form not available
Lopressor (metoprolol tartrate)	1.15	1.03	.86	.75	.75	---	---	
Corgard (nadolol)	1.62	1.28	1.06	---	---	---	---	
Blockadren (timolol maleate)	1.23	---	---	---	---	---	---	

(Source: Redbook, 1974-83.
Daily cost calculated from recommended dosage in the Physician's Desk Reference, 1982.)

*To treat hypertension.

"PRICE COMPETITION" AMONG
NON-STEROIDAL ANTI-INFLAMMATORY DRUGS *
PRICES PER DAILY SUPPLY--TO DRUGGIST
(IN DOLLARS)

	1983	1982	1981	1980	1979	1976	1974
Indocin (indomethacin)	1.46	1.31	1.05	.93	.81	.63	.53
Butazolidin (phenylbutazone)	1.04	.91	.73	.62	.38	.49	.43
Motrin (ibuprofen)	1.34	1.16	1.00	1.00	.96	.80	---
Naprosin (naproxen)	1.53	1.26	1.14	.95	.88	---	---
Zomax (zomepirac sodium)	1.62	1.34	1.20	---	---	---	---
Feldene (piroxicam)	.91	---	---	---	---	---	---
Tandearil (oxyphenbutazone)	1.21	1.06	.86	.73	.69	.58	.50
Tolectin (tolmetin sodium)	1.62	1.32	1.15	1.15	1.15	---	---
Nalfon (fenoprofen calcium)	1.06	.96	.88	.80	.74	---	---
Clinoril (sulindac/MSD)	1.00	.90	.78	.71	.66	---	---

(Source: Redbook, 1974-83.
Daily cost calculated from recommended dosage in the Physician's Desk Reference, 1982.)

*To treat arthritis.

"PRICE COMPETITION" AMONG
TRANQUILIZERS: BENZODIAZAPINES *
COST TO DRUGGIST OF USUAL DAILY DOSE
(IN DOLLARS)

	1983	1982	1981	1980	1979	1976	1974
Ativan (lorazepam)	.35	.32	.28	.24	.22	---	---
Centrax (prazepam)	.36	.30	---	---	---	---	---
Dalmane (flurazepam hydrochloride)	.16	.14	.13	.125	.117	.08	.06
Restoril (sleeping pill) (temazepam)	.15	.12	---	---	---	---	---
Librium (sleeping pill) (chlordiazepoxide hydrochloride)	.38	.34	.31	.30	.28	.23	.20
Serax (oxazepam)	.38	.35	.31	.26	.24	.19	.17
Tranxene (chlorazepate dipotassium)	.39	.31	.29	.24	.24	.18	.18
Valium (diazapam)	.46	.42	.38	.36	.34	.27	.24
Xanax (alprazolam)	.55	---	---	---	---	---	---

(Source: Redbook, 1974-83.
Daily cost calculated from recommended dosage in the Physician's Desk Reference, 1982.)

* To treat mild to moderate anxiety.

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 to 1
Librium (chlordiazepoxide)	Roche	3	90%	8,200,000	$57,700,000	$87.63[6]	$5.50[6] (Interstate)	15.9 to 1
Apresoline (hydralazine)	Ciba	13	86%	2,900,000	$23,200,000	$98.48[7]	$11.65[7] (Henry Schein)	8.5 to 1
Gantrisin (sulfisoxazole)	Roche	15	95%	2,900,000	$15,900,000	$52.78[8]	$14.95[8] (Wolins-Pharmical)	3.5 to 1

1 Merck 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.

PATENT LIFE REMAINING FOR NCEs APPROVED IN 1980

Product	Patent expires	IND filed	NDA approved	Effective patent life
Viroptic (trifluridine)	1982	1974	1980	2
Meclan (meclocycline sulfosalicylate)	1978	1976	1980	None
Cinobac (cinoxacin)	1989	1972	1980	9
Meclomen (meclofenamate sodium)	1984	1974	1980	4
Calderol (calcifediol)	1991	1973	1980	11
Yutopar (ritodrine HCl)	1985	1971	1980	5
Asendin (amoxapine)	1989	1969	1980	9
Zomax (zomepirac sodium)	1990	1974	1980	10
Siseptin (sisomicin sulfate)	1992	1973	1980	12
Vansil (oxamniquine)	1991	1970	1980	11
Ludiomil (maprotiline HCl)	1985	1969	1980	5
Spectrobid (bacampicillin HCl)	1992	1976	1980	12

(Source: Peter Hutt, PMA Counsel, "The case for drug patent life extension," Medical Marketing & Media, May 1982, p. 12.)

DATA NOT INCLUDED IN PATENT EXTENSION PROPOSALS

Subsequent Patents on other uses or methods of producing products	Patent Approval Date (Date of patent expiration less 17 years)	Industry Delay before Testing (Time lapsed from patent approval to IND filing)
Unknown	1965	9 years
Unknown	1961	15 years
Unknown	1972	0
Unknown	1967	7 years
Unknown	1974	0
Unknown	1968	3 years
Unknown	1972	0
Unknown	1973	1 year
Unknown	1975	0
Unknown	1974	0
Unknown	1968	1 year
Unknown	1975	1 year

TIME INTERVAL BETWEEN INVENTION AND INNOVATION
FOR 26 DIFFERENT PRODUCTS AND PROCESSES

Invention	Inventor--Date	Innovator--Date	Interval
Safety razor	Gillette--1895	Gillette Safety Razor Company--1904	9 years
Fluorescent lamp	Bacquerel--1859	General Electric, Westinghouse--1938	79
Television	Zworykin--1919	Westinghouse--1941	22
Wireless telegraph	Hertz--1889	Marconi--1897	8
Wireless telephone	Fessenden--1900	National Electric Signaling Company--1908	8
Triode vacuum tube	de Forest--1907	The Radio Telephone & Telegraph Co.--1914	7
Radio (oscillator)	de Forest--1912	Westinghouse--1920	8
Ball-point pen	I.J. Biro--1938	Argentine firm--1944	6
Cotton picker	A. Campbell--1889	International Harvester--1942	53
Crease-resistant fabrics	company scientists-1918	Tootal Broadhurst Lee Co. Ltd.--1932	14
DDT	company chemists--1939	J.R. Geigy Co.--1942	3
Electric precipitation	Sir O. Lodge--1884	Cottrell's--1909	25
Freon refrigerants	T. Midgley, Jr. & A.L. Henne--1930	Kinetic Chemicals, Inc. (General Motors & DuPont)--1931	1
Hardening of fats	W.K. Normann--1901	Crosfield's of Warrington--1909	8
Jet Engine	Sir F. Whittle--1929	Rolls Royce--1943	14
Turbo-jet engine	H. von Ohain--1934	Junkers--1944	10

Invention	Inventor--Date	Innovator--Date	Interval
Long-playing record	P. Goldmark--1945	Columbia Records--1948	3
Magnetic recording	V. Poulsen--1898	American Telegraphone Co.--1903	5
Plexiglas, lucite	W. Chalmers--1929	Imperial Chemical Industries--1932	3
Nylon	W.U. Carothers--1928	DuPont--1939	11
Power Steering	H. Vickers--1925	Vickers, Inc.--1931	6
Radar	Marconi; A.H. Taylor & L. Young--1922	Societe Francaise Radio Electrique--1935	13
Self-winding watch	J. Harwood--1922	Harwood Self-Winding Watch Co.--1928	6
Terylene, dacron	J.R. Whinfield & J.T. Dickson--1941	Imperial Chemical Industries, DuPont--1953	12
Xerography	C. Carlson--1937	Haloid Corporation--1950	13
Zipper	W.L. Judson--1891	Automatic Hook and Eye Co.--1918	27

(Source: John M. Blair, Economic Concentration: Structure, Behavior and Public Policy, Harcourt Brace Jovanovich, Inc., 1972.)

"PRICE COMPETITION" AMONG
BETA BLOCKERS *

MAXIMUM DAILY COST*--TO DRUGGIST
top of usual range
(IN DOLLARS)

	1983	1982	1981	1980	1979	1976	1974	
Inderal (propranolol hydrochloride)	1.17	1.01	.91	.83	.71	.66	*	80 mg. dose form not available
Lopressor (metoprolol tartrate)	1.15	1.03	.86	.75	.75	---	---	
Corgard (nadolol)	1.62	1.28	1.06	---	---	---	---	
Blockadren (timolol maleate)	1.23	---	---	---	---	---	---	

(Source: Redbook, 1974-83.
Daily cost calculated from recommended dosage in the Physician's Desk Reference, 1982.)

*To treat hypertension.

"PRICE COMPETITION" AMONG
NON-STEROIDAL ANTI-INFLAMMATORY DRUGS *
PRICES PER DAILY SUPPLY--TO DRUGGIST
(IN DOLLARS)

	1983	1982	1981	1980	1979	1976	1974
Indocin (indomethacin)	1.46	1.31	1.05	.93	.81	.63	.53
Butazolidin (phenylbutazone)	1.04	.91	.73	.62	.38	.49	.43
Motrin (ibuprofen)	1.34	1.16	1.00	1.00	.96	.80	---
Naprosin (naproxen)	1.53	1.26	1.14	.95	.88	---	---
Zomax (zomepirac sodium)	1.62	1.34	1.20	---	---	---	---
Feldene (piroxicam)	.91	---	---	---	---	---	---
Tandearil (oxyphenbutazone)	1.21	1.06	.86	.73	.69	.58	.50
Tolectin (tolmetin sodium)	1.62	1.32	1.15	1.15	1.15	---	---
Nalfon (fenoprofen calcium)	1.06	.96	.88	.80	.74	---	---
Clinoril (sulindac/MSD)	1.00	.90	.78	.71	.66	---	---

(Source: Redbook, 1974-83.
Daily cost calculated from recommended dosage in the Physician's Desk Reference, 1982.)

*To treat arthritis.

"PRICE COMPETITION" AMONG
TRANQUILIZERS: BENZODIAZAPINES *
COST TO DRUGGIST OF USUAL DAILY DOSE
(IN DOLLARS)

	1983	1982	1981	1980	1979	1976	1974
Ativan (lorazepam)	.35	.32	.28	.24	.22	---	---
Centrax (prazepam)	.36	.30	---	---	---	---	---
Dalmane (flurazepam hydrochloride)	.16	.14	.13	.125	.117	.08	.06
Restoril (sleeping pill) (temazepam)	.15	.12	---	---	---	---	---
Librium (sleeping pill) (chlordiazepoxide hydrochloride)	.38	.34	.31	.30	.28	.23	.20
Serax (oxazepam)	.38	.35	.31	.26	.24	.19	.17
Tranxene (chlorazepate dipotassium)	.39	.31	.29	.24	.24	.18	.18
Valium (diazapam)	.46	.42	.38	.36	.34	.27	.24
Xanax (alprazolam)	.55	---	---	---	---	---	---

(Source: Redbook, 1974-83.
Daily cost calculated from recommended doaage in the Physician's Desk Reference, 1982.)

* To treat mild to moderate anxiety.

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 to 1
Librium (chlordiazepoxide)	Roche	3	90%	8,200,000	$57,700,000	$87.63[6]	$5.50[6] (Interstate)	15.9 to 1
Apresoline (hydralazine)	Ciba	13	86%	2,900,000	$23,200,000	$98.48[7]	$11.65[7] (Henry Schein)	8.5 to 1
Gantrisin (sulfisoxazole)	Roche	15	95%	2,900,000	$15,900,000	$52.78[8]	$14.95[8] (Wolins-Pharmical)	3.5 to 1

1 Merck 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.

PATENT LIFE REMAINING FOR NCEs APPROVED IN 1980

Product	Patent expires	IND filed	NDA approved	Effective patent life
Viroptic (trifluridine)	1982	1974	1980	2
Meclan (meclocycline sulfosalicylate)	1978	1976	1980	None
Cinobac (cinoxacin)	1989	1972	1980	9
Meclomen (meclofenamate sodium)	1984	1974	1980	4
Calderol (calcifediol)	1991	1973	1980	11
Yutopar (ritodrine HCl)	1985	1971	1980	5
Asendin (amoxapine)	1989	1969	1980	9
Zomax (zomepirac sodium)	1990	1974	1980	10
Siseptin (sisomicin sulfate)	1992	1973	1980	12
Vansil (oxamniquine)	1991	1970	1980	11
Ludiomil (maprotiline HCl)	1985	1969	1980	5
Spectrobid (bacampicillin HCl)	1992	1976	1980	12

(Source: Peter Hutt, PMA Counsel, "The case for drug patent life extension," Medical Marketing & Media, May 1982, p. 12.)

DATA NOT INCLUDED BY PATENT EXTENSION PROPOSALS

Subsequent Patents on other uses or methods of producing products	Patent Approval Date (Date of patent expiration less 17 years)	Industry Delay before Testing (Time lapsed from patent approval to IND filing)
Unknown	1965	9 years
Unknown	1961	15 years
Unknown	1972	0
Unknown	1967	7 years
Unknown	1974	0
Unknown	1968	3 years
Unknown	1972	0
Unknown	1973	1 year
Unknown	1975	0
Unknown	1974	0
Unknown	1968	1 year
Unknown	1975	1 year

TIME INTERVAL BETWEEN INVENTION AND INNOVATION
FOR 26 DIFFERENT PRODUCTS AND PROCESSES

Invention	Inventor--Date	Innovator--Date	Interval
Safety razor	Gillette--1895	Gillette Safety Razor Company--1904	9 years
Fluorescent lamp	Bacquerel--1859	General Electric, Westinghouse--1938	79
Television	Zworykin--1919	Westinghouse--1941	22
Wireless telegraph	Hertz--1889	Marconi--1897	8
Wireless telephone	Fessenden--1900	National Electric Signaling Company--1908	8
Triode vacuum tube	de Forest--1907	The Radio Telephone & Telegraph Co.--1914	7
Radio (oscillator)	de Forest--1912	Westinghouse--1920	8
Ball-point pen	I.J. Biro--1938	Argentine firm--1944	6
Cotton picker	A. Campbell--1889	International Harvester--1942	53
Crease-resistant fabrics	company scientists-1918	Tootal Broadhurst Lee Co. Ltd.--1932	14
DDT	company chemists--1939	J.R. Geigy Co.--1942	3
Electric precipitation	Sir O. Lodge--1884	Cottrell's--1909	25
Freon refrigerants	T. Midgley, Jr. & A.L. Henne--1930	Kinetic Chemicals, Inc. (General Motors & DuPont)--1931	1
Hardening of fats	W.K. Normann--1901	Crosfield's of Warrington--1909	8
Jet Engine	Sir F. Whittle--1929	Rolls Royce--1943	14
Turbo-jet engine	H. von Ohain--1934	Junkers--1944	10

Invention	Inventor--Date	Innovator--Date	Interval
Long-playing record	P. Goldmark--1945	Columbia Records--1948	3
Magnetic recording	V. Poulsen--1898	American Telegraphone Co.--1903	5
Plexiglas, lucite	W. Chalmers--1929	Imperial Chemical Industries--1932	3
Nylon	W.U. Carothers--1928	DuPont--1939	11
Power Steering	H. Vickers--1925	Vickers, Inc.--1931	6
Radar	Marconi; A.H. Taylor & L. Young--1922	Societe Francaise Radio Electrique--1935	13
Self-winding watch	J. Harwood--1922	Harwood Self-Winding Watch Co.--1928	6
Terylene, dacron	J.R. Whinfield & J.T. Dickson--1941	Imperial Chemical Industries, DuPont--1953	12
Xerography	C. Carlson--1937	Haloid Corporation--1950	13
Zipper	W.L. Judson--1891	Automatic Hook and Eye Co.--1918	27

(Source: John M. Blair, Economic Concentration: Structure, Behavior and Public Policy, Harcourt Brace Jovanovich, Inc., 1972.)

September 8, 1983

Honorable Charles McC. Mathias
United States Senator
U.S. Senate
Washington, D.C.

BY HAND

Re: S. 1306 (Patent Term Extension)

Dear Senator Mathias:

In my testimony on your patent term extension bill, I discussed the problem encountered by small inventors who lose patent life as a result of unlawful infringements on their patents. At that time, you invited me to submit supplemental materials on this issue, and with this letter I am responding to your invitation.

At the outset, I want to emphasize that my long-standing concern about the rights of small inventors raises separate issues from those addressed by S. 1306, which would extend the patents on drugs and other products subject to federal regulation. As I stated in my testimony, I do not believe that there is any basis for granting an extension to the patent term for drugs and other similar products. On the other hand, there is ample justification for legislation which would modify the remedial provisions in the current statute.

With this letter, I am submitting for the record a letter I received from Roy Wepner, a patent attorney, that gives several examples of inventors who have been seriously injured by infringements, and who have been unable to obtain adequate compensation under current law. These are examples of inventors who have been fortunate enough to find attorneys willing to represent them and who have some prospect of obtaining compensation.

The inadequacy of the current law stems primarily from the expense and delays inherent in litigation. Thus, inventors who obtain representation often lose a substantial portion of their patent protection by the date litigation has concluded. In addition, the current remedy for infringement actions is that the patent holders may recover provable damages caused by the infringment or a reasonable royalty. 35 U.S.C. § 284. However, this remedy is often inadequate because infringers can manipulate their books and make it difficult for inventors to ascertain and recover the damages to which they are entitled. As a result, the defendants in patent infringement suits are often able to settle infringement cases for sums which do not adequately compensate the patent holder.

To remedy these problems, I suggest that the patent law be amended in two ways. First, inventors who substantially prevail in infringement actions should be awarded attorneys fees so that legal fees are not a barrier to such actions. Similar attorneys fees provisions have proven to be an effective way of promoting other important public policies. However, the patent laws currently provide for attorney fees only in exceptional cases. 35 U.S.C. § 285.

Second, as an alternative to remedies currently available under law, the inventor who is successful in such an action should have the right to exclude the infringer from the use of the invention after expiration of the patent, for a period equal to the duration of the infringement. Under this proposal, the infringement period would be defined as the period between the first infringement and the final judgment in the infringement action. After the 17-year patent period has expired, the inventor could then exclude the infringer from use of the invention for that additional period of time. As is true where the inventor holds a patent, the inventor could grant a license to the infringer and obtain a royalty.

Two examples may help to illustrate the proposal. Assume that the inventor obtained a patent in 1970; that the infringement began in 1974; and that the inventor obtained a final judgment against the infringer in 1984. The patent would expire in 1987, but as a remedy in the lawsuit, the inventor could exclude (or obtain royalties from) the infringer for an additional 10 years, the length of the infringement period. On the other hand, if the infringement first occurred in 1982, then the inventor could exclude the infringer for only an additional two years.

In order to deter patent infringements, a separate provision should provide that in the case of willful infringements, the inventor may obtain both the remedies available under the current statute and the new remedy being proposed. Finally, these provisions should be made applicable to actions which are pending on the effective date of the statute.

Sincerely yours,

Ralph Nader

Enclosure

LAW OFFICES

LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK

195 ELM STREET

WESTFIELD, NEW JERSEY 07090

PATENT AND TRADEMARK ATTORNEYS

(201) 654-5000
CABLE: PATLEX WESTFIELD, N.J.
TELEX: 139-125
TELECOPIER: (201) 654-3502

LAWRENCE I. LERNER
SIDNEY DAVID
JOSEPH S. LITTENBERG
ARNOLD H. KRUMHOLZ
WILLIAM L. MENTLIK
JOHN R. NELSON
MARVIN S. GITTES
RALPH W. SELITTO, JR.*
JAMES R. NELSON
STEPHEN B. GOLDMAN**
ROY H. WEPNER
SAMUEL L. SACHS
CHARLES P. KENNEDY

*NEW YORK BAR ONLY
**NEW YORK AND TEXAS BARS ONLY

August 31, 1983

Mr. Ralph Nader
Center for Study of Responsive Law
P.O. Box 19367
Washington, D.C. 20036

Dear Mr. Nader:

You have asked us to provide you with examples of situations where small inventors have obtained United States patents and have their ability to enforce those patents thwarted either by protracted infringement suits against corporations with enormous financial power or by proceedings in the Patent and Trademark Office ("PTO") subsequent to the issuance of the patent which have consumed several years of the 17-year term, during which the patent, as a practical matter, has been unenforceable by the small inventor.

The first two examples which follow involve individual inventors who have been represented by our firm, while the third example is based solely upon information set forth in a reported decision.

Frederic Lang

On March 7, 1972, Frederic Lang received U.S. Patent No. 3,646,748 covering tendons for pre-stressed concrete and a process for making such tendons. Several corporations were infringing at about the time the patent issued.

Eight months later, Lang's patent became involved in an interference (a priority contest within the PTO which may involve an issued patent during the first year of its existence (see 35 U.S.C. § 135)). A decision in the interference in Lang's favor was rendered on September 24, 1975, but the other party filed suit two months later to review that decision in the United States District Court. Eventually a consent judgment was entered on October 28, 1976 in Lang's favor.

Lang brought suit against one infringer, the Prescon Corporation, a few weeks after obtaining that judgment, on December 7, 1976. As a result of assertions by Prescon that certain prior art invalidated the Lang patent, on April 20, 1977, Lang filed an application in the PTO to reissue his patent under then existing procedures. His application was initially rejected by an Examiner, but this rejection was reversed by the PTO Board of Appeals on December 31, 1979.

Returning to the District Court, Lang moved for partial summary judgment on the issue of invalidity. However, the Court declined to give preclusive effect to the reissue proceeding. PIC, Inc. v. Prescon Corp., 485 F. Supp. 1302 (D. Del. 1980). Thereafter, the Prescon suit went to trial in March of 1982. On August 13, 1982, ten years after the issuance of the patent, the Court held the patent valid and willfully and deliberately infringed by Prescon. Lang v. Prescon Corp., 545 F. Supp. 933 (D. Del. 1982). In 1982, Lang also brought suit against another infringer, VSL Corporation, and a decision was rendered on October 5, 1982 (unreported) again holding the Lang patent valid and willfully infringed.

During the 10 years between 1972 and 1982, well over a dozen other companies were infringing the Lang patent. Prior to the favorable decisions in 1982, the Lang patent was virtually ignored by the industry and Lang received no meaningful revenues from his patent. Subsequent to the favorable decisions in 1982, several companies agreed to take a license from Lang, but numerous others continued to refuse, as result of which Lang has brought 17 additional suits for infringement of his patent.

Gordon Gould

On April 6, 1959, Gordon Gould filed a lengthy patent application disclosing numerous separate and distinct pioneering inventions relating to the laser, a term which Gould himself coined. Gould was ultimately required to carve up his original application and file several applications covering his many separate inventions. Gould's applications were involved in five separate interference proceedings against adversaries such as Bell Labs, Westinghouse and Hughes Aircraft, two of which resulted in appeals to the Court of Customs and Patent Appeals.

Ultimately, on October 5, 1977, when the laser industry had reached maturity and numerous large companies were infringing, Gould received U.S. Patent No. 4,053,845 on the optically pumped laser amplifier. A week later, Gould brought suit against one major infringer, Control Laser Corporation. In 1978, Gould brought suit against another infringer, General Photonics Corporation. Although commenced later, the General Photonics suit came to trial first, where the Gould patent was held valid and infringed. Gould v. General Photonics Corp., 534 F. Supp. 399 (N.D. Cal. 1982).

Gould's suit against Control Laser was scheduled to go to trial in September 1982. On the eve of trial, Control Laser and Bell Labs filed requests for "reexamination" of the Gould patent under a procedure which had become available on July 1, 1981 (see 35 U.S.C. §§ 301-307). The Court in which the Control Laser suit was pending first continued the trial to see whether the PTO would grant the requests and order reexamination. Because PTO regulations (i) expressly forbid the patent owner from participating in any way in that decision or even from being heard, (ii) impose no duty on the requesting party to be truthful and candid, and (iii) require that all doubts as to whether to order reexamination be resolved in favor of ordering it, the PTO did order reexamination. In doing so, the PTO chose to totally ignore the decision in the General Photonics case. The Court then stayed the Control Laser suit until the completion of reexamination, including all appeals therefrom. This potentially could involve decisions by an Examiner, an appeal to the PTO Board of Appeals, a possible civil action to review the PTO decision in the U.S. District Court for the District of Columbia, an appeal from that Court to the U.S. Court of Appeals for the Federal Circuit, and a possible petition for certiorari to the Supreme Court. Gould attempted to appeal the stay order on the theory that it was a final judgment which effectively put Gould out of Court for an indefinite period. However, Gould's appeal was dismissed. Gould v. Control Laser Corp., 705 F.2d 1340 (Fed. Cir. 1983). It is not yet known when the reexamination will be complete, or when Gould will be able to pursue infringers.

Sidney Sampson

As discussed in Sampson v. Dann, 466 F. Supp. 965 (D.D.C. 1978), in which the individual inventor appeared pro se Sidney Sampson was issued U.S. Patent No. 3,315,041 on April 18, 1967 for a track selection means for magnetic signal recording and reproducing systems. In 1967 and 1968, he brought suit against three accused infringers, including RCA and Sony. In 1968, summary judgment was entered against Sampson in these cases, holding his patent invalid because of a technical defect. Appeals of these decisions were unavailing.

In January of 1972, Sampson filed an application to reissue his patent and correct the defect. These efforts were unsuccessful before the PTO, and in 1975 Sampson brought suit against the PTO in the U.S. District Court to review that decision. In November 1976, the Court held in favor of Sampson and directed that a patent be issued. However, just before the scheduled date of issuance, through proceedings which were found by the Court to be improper, the patent was withdrawn from issue and another final rejection was entered on January 17, 1978. Sampson returned to the Court and eventually obtained a favorable decision in late 1978. The patent was not actually reissued until 1979.

* * * * *

We hope and trust this information is helpful. If we can provide any further information, please do not hesitate to call upon us.

Sincerely yours,

LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK

ROY H. WEPNER

RHW:jmt

Additional Submission From Janet Hathaway Staff Attorney, Public Citizen's Congress Watch on the Patent Extension Bill, S. 1306

August 22, 1983

Scope of Patent Extension

Senator Mathias asked during the hearing on August 2, 1983 (see transcript, page 11, lines 1-14) for our position concerning language which would grant patent extensions to all products subject to premarket regulatory review.

In our view, expanding the scope of patent extension is unwarranted and would not improve S. 1306. Our opposition to extending patents is based on the fact that proponents have not shown that a patent extension is either necessary or desirable, and it clearly will be costly to purchasers of prescription drugs including federal, state and local governments. The certain harm to consumers who will be unable to choose lower-cost generic products during the extended patent period significantly outweighs any of the speculative (and probably illusory) benefits that have been suggested. The only sure winners are the manufacturers of patented drugs. The burden of proof remains on those who have requested this legislation. The proponents must document--if they can--any genuine benefits to the public which might result from granting a longer monopoly period to patent holders.

Modifications of the bill to provide patent extensions for all products subject to premarket regulatory review would only exascerbate the problems we find with S. 1306. Such modifications would ensure that some businesses other than the pharmaceutical and chemical manufacturers would share the socially-costly privilege of patent extension. Broadening the number of beneficiaries only increases the probable cost to consumers. It in no way makes up for the proponent's failure to support claims such as that "effective patent life" has declined or that any alleged decline is attributable to regulatory review. Until it has been carefully and objectively established that there are

serious problems with the patent system best addressed by patent extension, neither S. 1306 nor a modified bill including all products subject to premarket review should be pursued.

Duration of Patent Extension

The period of patent extension defined by S. 1306 runs from the filing date for an exemption for the purpose of investigation (or from the beginning of a major health or environmental effects test) until the product is approved for marketing, for a maximum of seven years. We believe this period is excessive and will encourage delays. This provision allows the pharmaceutical industry a longer patent period for time wasted by strategic delays and/or incompetent testing. Only a small portion of the extension period in S. 1306, misleadingly entitled the "regulatory review period," is actually time attributable to the FDA review.

If any patent extension bill receives further Congressional attention, Public Citizen recommends that extensions be limited to the FDA review time--the period beginning when a New Drug Application is filed and ending when the drug is approved for marketing by the FDA (i.e. the NDA period). This limit would encourage expeditious testing and accurate documentation by industry. A provision limiting extension to the NDA period would return to the industry only the patent time actually lost during the agency's review process. Because some delays during the NDA period are industry-caused, a better measure of the extension period would be the NDA period excluding all delays during the agency's review attributable to industry.

Explanatory Note concerning Chart: "Time Interval Between Invention and Innovation" (See Appendix, pages xv-xvi.)

This chart is for the purpose of documenting our claim that delays before commercialization are normal and occur industry-wide. The point is raised to rebut the complaint that drug products have an especially lengthy delay from invention to

marketing. The chart lists a number of commonly-used products along with the period from invention to commercialization. The twenty-six items listed in the chart indicate that the lapse between useful discoveries and their applications in marketable forms varies widely. It also shows several common products which took longer to arrive on markets than the 7 to 10 years cited by the pharmaceutical industry as the average time from invention to marketing of drugs.

The chart does not indicate the date, if any, of patent approval and therefore cannot be used to compare periods of exclusive marketing under patent protection.

Respectfully submitted,

Janet Hathaway

Janet Hathaway
Staff Attorney, Congress Watch

Senator MATHIAS. Our next witness is Mr. James Hacking, the assistant legislative counsel of the American Association of Retired Persons. Mr. Hacking, I hope that you can keep your initial statement within the 5-minute limit. Let me say. I did not make this clear to Mr. Nader, but your full statement will, of course, appear in the record as will his.

STATEMENT OF JAMES HACKING, ASSISTANT LEGISLATIVE COUNSEL, AMERICAN ASSOCIATION OF RETIRED PERSONS, WASHINGTON, D.C., ACCOMPANIED BY JACK CHRISTY, LEGISLATIVE REPRESENTATIVE FOR HEALTH ISSUES, AMERICAN ASSOCIATION OF RETIRED PERSONS, WASHINGTON, D.C.

Mr. HACKING. Very well, I will summarize.

Let me begin by introducing my colleague. This is Jack Christy, who is one of our legislative representatives. He specializes in health policy issues for the association.

We are here representing the 14.7 million-member American Association of Retired Persons. Because of the incidence of chronic illness among the elderly and dread diseases which tend to be disproportionately associated with old age, the elderly have an acute interest in promoting research and development activity that results in new and innovative drug and drug therapies.

But there is another aspect of their interest. Though the elderly constitute only 11.2 percent of the U.S. population, they account for 25 percent of the expenditures on prescription drugs. Eighty-five

percent of their expenditures for prescription drugs come directly out of pocket.

These expenditures for prescription drugs represent one-third of their total out-of-pocket costs. In 1981, per capita out-of-pocket expenditures for health care on the part of the elderly were roughly $1,200 as against a per capita income in that year of roughly $8,600.

AARP as the representative of the elderly is very interested in working toward drug regulatory reform so as to devise means for achieving the essential purposes of regulation in ways that are supportive of drug innovation yet do not deny the most dependent and needy members of society access to prescription drug products because of high prices.

Having analyzed and weighed the potential benefits and the inevitable costs associated with patent term extention, AARP has concluded that the costs outweigh the benefits. We do not believe that extended patent protection would, in fact, lead to significantly more research, development, and innovation.

We, therefore, must oppose S. 1306. We question whether the rapidly increasing cost of drug R&D should be financed solely through prescription drug prices. Prescription drug prices over the last 18 months or so have risen at a rate nearly three times that of the consumer price index.

Escalating drug prices must inevitably reduce or deny access for lower income persons to needed drug therapy. If significantly greater drug R&D activity, relative to what would otherwise occur, is deemed desirable, then perhaps a direct Government subsidy or targeted tax perference would be a more equitable, less costly and more effective means for achieving that end.

The cost would be borne by all taxpayers and the cost would be specifically targetted. Patent term extension, while increasing the cash flow and profits for the pharmaceutical manufacturers will not necessarily result in a commensurate and justifiable increase in the level of R&D. At some point diminishing returns sets in.

The pharmaceutical industry is already among the Nation's most profitable. In fact, there is one major chemical firm that is in the process of diversifying into pharmaceuticals, attracted by that high degree of profitability.

Finally a number of recent legislative and administrative changes ought to be taken into account in determining the merits of patent term extension. First, the Economic Recovery Tax Act provided a 25-percent tax credit for new expenditures on research and experimentation.

Second, the recent Orphan Drug Act provides subsidies for companies investing in research on rare diseases. Third, the administration has streamlined the FDA's new drug approval procedures, resulting in an 8- to 10-month reduction in approval time, and new regulatory revisions have been proposed that are designed to reduce by an additional 6 months the time necessary to process new drug applications.

In conclusion, Mr. Chairman, the pharmaceutical industry, in our view, has not made a compelling case that extending drug patent protection is necessary or will result in significantly more research, development, and major new drug innovations.

We are certain, however, that additional years of patent protection will result in substantial increases in expenditures for drugs, and that will entail very substantial transfers of income from the elderly consumers to large brand name manufacturers.

AARP, therefore, has no choice but to oppose this legislation. Thank you.

[Submissions of Mr. Hacking follow:]

STATEMENT

OF THE

AMERICAN ASSOCIATION OF RETIRED PERSONS

Thank you Mr. Chairman for this opportunity to state the American Association of Retired Persons opposition to S. 1306, the Patent Term Extension Act of 1983.

As you and this Committee know, the elderly have a direct interest in expanding meaningful drug research and development activities. Those over the age of 65, while today representing an 11.3 percent of the population, account for over 25 percent of all expenditures on prescription drug products. Since the elderly pay about 85 percent of the total cost of their prescription drugs directly out-of-pocket, it is no wonder that the cost of prescription drugs represents over one third of their total out-of-pocket expenses for health care. This situation is compounded by the increasing incidence of chronic debilitating conditions among the elderly and their greater utilization of multiple prescription drugs.

Clearly, older Americans have much at stake in the current debate over patent term extension. In a larger sense, our Association is very interested in working toward drug regulatory reform so as to devise a means to achieve the essential purposes of regulation in a way that is affirmative and supportive of innovation, yet does not deny the most dependent and needy segments of our society access to prescription drug products because the price is too high. The real question for us arises as to the level, direction and nature of drug innovation. We are concerned about the effect patent term extension would have on competition in the drug industry, particularly price competition, and whether the benefits of patent term extension are commensurate with the direct costs to consumers (especially the elderly) such legislation would necessarily entail. We

question whether extended patent protection would, in fact, lead to significantly more research, development and innovation. We doubt that it will.

Moreover, we question whether the mounting expenses associated with drug research and development should be financed solely through prescription drug prices. Prescription drug prices over the last eighteen months or so have risen at a rate nearly three times the Consumer Price Index increase on all items. In our view, higher drug prices are an inequitable and inefficient means of spurring drug innovation because they run the risk of reducing access to essential drug therapies. AARP favors using tax incentives to spread the burden of increased drug innovation through out the entire society as a more equitable means of stimulating drug research and development.

Industry claims that meaningful patent life has been reduced to 6.8 years are based on a select sample of new chemical entities (NCE's) excluding all other drug prodcuts. That the average patent life for the twelve most frequently prescribed drugs in America is 18.5 years severely undercuts one of the industry's justifications for extended patent protection. Moreover, it is not uncommon to see brand name drugs which, despite generic competition and the Maximum Allowable Cost program, continue for years after patent expiration to outsell all competitors despite their higher prices. This "de facto" patent protection is afforded brand name manufacturers by brand name loyalty and entrenched prescription patterns.

In addition, the pyramiding effect of subsequent use, process and other patents which extend patent terms and increase monopoly life are not included in the industry's patent life calculations. Nor are the years of product protection afforded by trademark litigation to protect against competitors offering products of similar size, shape and color. Indeed, trademark

protection may be more important to the brand name manufacturers than patent protection in extending monopoly pricing and market shares.

AARP believes that the litigation aimed at generic manufacturers who produce products of a similar size, shape and color should be dropped. In a similar vein, AARP supports legislation -- the Drug Price Competition Act of 1983 -- establishing safeguards for consumer protection by requiring that generic drug products meet appropriate standards, including: standards of identity, purity, quality and strength. By establishing such standards of equivalence, and by no longer requiring new market entrants to repeat already published clinical studies to ascertain the safety and effectiveness of a chemical entity "coming-off patent", the Drug Price Competition Act of 1983 goes a long way towards lowering drug prices through increased competition and towards saving valuable research resources. AARP supports the Drug Price Competition Act of 1983 and urges its quick enactment.

The Pharmaceutical Manufacturers Association's claim that shorter patent terms reduce incentive for investment in drug research and development is contrary to actual experience. The prescription drug industry is continually among the most profitable industries in America. As a result, the relationships between industry revenues and R&D expenditures has remained highly stable over the past fifteen years. In fact, it is difficult to find a U.S. industry that offers more potential rewards for innovation than the drug industry. This is borne out by a recent National Science Foundation report that R&D spending by drug companies was expected to increase 20 percent during 1983 and that some chemical firms are diversifying into pharmaceuticals because of higher profitability.

Finally, recent administrative and legislative developments also undermine the industry's claims in support of

patent term extension. The Economic Recovery Tax Act of 1981, for example, provides a 25 percent tax credit for new expenditures on research and experimentation. This will reward actual R&D spending in a manner that distributes the costs over the whole society. In addition, the recent passage of the Orphan Drug Act, which provides subsidies for companies investing in research on rare diseases, offers a substantial incentive for developing new drug therapies.

The Administration, for its part, has streamlined FDA's new drug approval procedures resulting in an eight to ten month reduction in approval time. Moreover, former DHHS Secretary Schweiker and FDA Commissioner Hayes recently proposed new regulatory revisions designed to produce an additional six month reduction in the time necessary to process new drug applications.

All things considered, the pharmaceutical industry has not made a compelling case that extending drug patent protection is necessary or will result in significantly more research, development and major new drug innovations. We are certain, however, that additional years, of patent protection will result in real income transfers from elderly consumers to large brand name manufacturers. AARP firmly opposes patent term extension legislation.

AMERICAN
ASSOCIATION
OF RETIRED
PERSONS

August 23, 1983

The Honorable Charles McC. Mathias
U.S. Senate
Washington, D. C. 20510

Dear Senator Mathias:

Thank you for asking AARP to respond for the record to the claim that patent term extension will not result in increased prices for consumers. AARP must take issue with that claim. It defies common sense, especially given the record of lower prices generic prescription drugs have compared with brand name prescription drugs.

AARP believes that extending the patent life of brand name prescription drugs will cost consumers millions of dollars because generic prescription equivalents will not be available to compete against the higher priced brand name drugs. Consequently, brand name drugs will be able to maintain their high monopoly prices -- and increase those prices without fear of competition -- at great cost to consumers.

The AARP Pharmacy Service reports average savings of more than 50 percent on generic prescription drugs compared with the price of brand name drugs. The longer the monopoly life of brand name drugs, the more money consumers will have to pay for protected drug therapies.

Enclosed for the record is a copy of the AARP Pharmacy Service publication: "Your Money Saving Guide to Generic Prescription Drugs". The guide compares the price of 144 generic prescription drugs to the price of the generic drug's brand name equivalent. The huge differences between brand name prices and generic drug prices graphically shows the cost to consumers inherent in extending the monopoly life of brand name drugs.

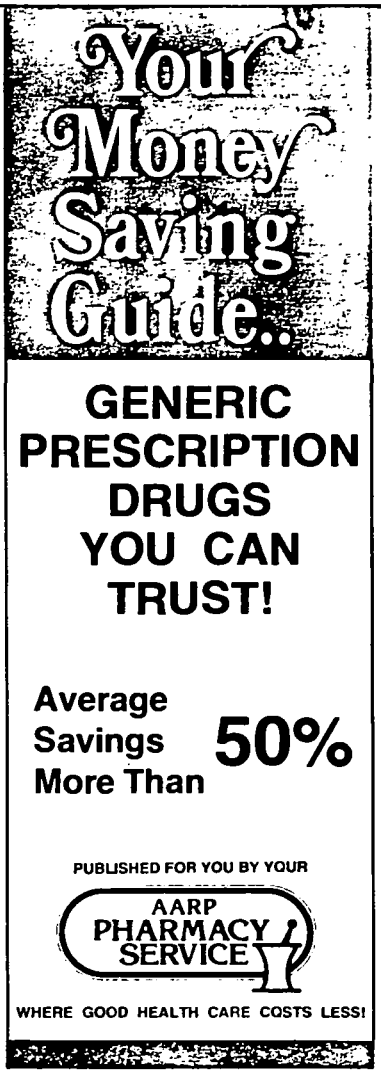
Again, thank you for allowing AARP to comment on the claim that patent term extension will not result in higher drug prices for consumers.

Sincerely,

James M. Hacking
Assistant Legislative Counsel

JMH:JEC

encl.



GENERIC DRUGS
Quality *and* Economy

Are you still paying too much money for the prescription drugs you need?

You probably are, if your prescription has been filled using a brand name drug when a Generic Equivalent Drug is available... And that's not just idle chatter!

The Federal Trade Commission came to that conclusion in a study of prescription drug prices in 1981. That study confirmed what five different Food and Drug Administration Commissioners had said earlier. All were doctors or pharmacists and all indicated that Generic Equivalent Drugs were just that. They are drugs made by reputable manufacturers, equivalent in quality, but at reduced prices to the consumer.

When you order Generic Prescription Drugs from your AARP Pharmacy, you're getting a **QUALITY DRUG** at a **REDUCED PRICE.**

The money you save (you'll be amazed at the big differences you'll see in the following lists) is money in your pocket.

I'm sure you have better ways to spend your money than giving too much of it away.

Please read the questions most members ask the AARP Pharmacy. Then look at the answers. Think about those answers while you review the list of brand name and Generic Name Drugs and compare the difference in price between the two. The price difference will amaze you and please your pocketbook.

And I hope you will start taking advantage of the money savings that your AARP Pharmacy can provide the next time you need to order a prescription drug.

Q. WHAT IS A GENERIC EQUIVALENT DRUG?

A. Prescription (Rx) Drugs all have two names. One is assigned by the drug maker and is easy for your doctor to remember. It's a trade-marked name that no one else can use.

The other is the Chemical or Generic name. Anyone can use this name.

Q. WHO MAKES "GENERIC" DRUGS?

A. Since all drugs have "GENERIC" names, you could say that all drug companies make Generic Drugs. Some also put their trademarked name on the drug, too. (And when they advertise the drug to your doctor, you pay for the advertising in the higher price charged for the brand name drug.)

Some drug companies only use the "Generic" name. They don't advertise to doctors and the price for their drugs is lower.

However, please know this. All drug companies in the U.S. must comply with the same drug manufacturing standards.

Q. ARE ALL Rx DRUGS AVAILABLE AS A LOW PRICE GENERIC EQUIVALENT?

A. No. Only about 25% of the Rx Drugs available today are also available as low cost Generic Equivalent Drugs. The companies that make brand name Rx Drugs are involved in costly research and development (R&D) of new Rx Drugs to make your life more comfortable. New drugs are patented by the Federal Government and that patent lasts for 17 years. This lets the drug companies recover their costs in the price they charge for drugs and encourages them to keep looking for more drugs to help you.

When the patent expires, other drug companies can make the drug. Since they have no R&D costs to recover, the price of the drug usually becomes lower for you.

Q. HOW CAN I ORDER LOW COST GENERIC EQUIVALENT DRUGS WHEN I GET MY PRESCRIPTION FILLED?

A. Some states permit your AARP Pharmacist to dispense Generic Drugs (if available) if **YOU** request it. Some states **require** your AARP Pharmacist to dispense Generic Drugs (if available).

Your AARP Pharmacist will fill your prescription with a generic drug (if available) if you or your doctor request and where state law permits.

Always ask your doctor to use the Generic name on your prescription. Take this list to his office on your next appointment. Show him how much money you'll save.

Q. HOW MUCH MONEY WILL I SAVE IF I ORDER GENERIC EQUIVALENT Rx DRUGS?

A. That's a question only you can answer. Our price list for Generic Drugs is included in this brochure. And the price quoted for our top quality Generic Drugs is guaranteed until December 31, 1983. Compare for yourself or return the price quote coupon (on the back page) to us. We'll give our low member price for the brand name drug you use AND our special low price for the Generic Equivalent drug.

Q. I'VE NEVER ORDERED Rx DRUGS BY MAIL BEFORE. IS IT EASY TO DO?

A. Millions of AARP Members have been ordering Rx Drugs by mail since 1959. All you have to do is get a new, written prescription from your doctor and mail it to the AARP Pharmacy that serves your state.

It will be filled promptly, safely packaged and shipped back to you, postage paid.

You won't have to pay for your prescription until you get it. (An invoice and payment slip will be enclosed).

And if your drug is one of the starred (*) drugs in this brochure, we'll also include a drug leaflet that talks about your drug. These leaflets have been designed with AARP Members in mind.

They explain:

- The drugs you take.
- What your doctor needs to know from you.
- What you should know about the drug.
- The possible side effects and more.

There is no charge for this new service from your AARP Pharmacy.

I urge you to consider your AARP Pharmacy the next time you need a prescription. You'll be glad you did when you see just how much money we can save you.

And that's the reason the AARP Pharmacy Service began back in 1959.

Thank you.

John R. McHugh
President, AARP Pharmacy Service
510 King Street, # 420
Alexandria, VA 22314

Your Average Saving is more than 50% on this list of 144 generic prescription drugs. (Compared to the price for the brand name drug.)

Brand Name / Generic Name	Form	Strength	Price Per 100
Achromycin V	Caps	250mg	$ 5.50
Tetracycline	Caps	250mg	3.05
*Aldactazide	Tabs		20.10
Spironolactone w/HCTZ	Tabs		9.20
*Aldactone	Tabs	25mg	20.05
Spironolactone	Tabs	25mg	9.00
Generic Aminophylline	Tabs	100mg	1.75
Amoxil	Caps	250mg	21.30
Amoxicillin	Caps	250mg	12.35
*Generic Ampicillin	Caps	250mg	7.95
Antivert	Tabs	12.5mg	12.10
Meclizine	Tabs	12.5mg	2.95
Antivert	Tabs	25mg	18.15
Meclizine	Tabs	25mg	3.60
*Apresoline	Tabs	10mg	7.40
Hydralazine	Tabs	10mg	2.30
*Apresoline	Tabs	25mg	10.55
Hydralazine	Tabs	25mg	3.15
*Apresoline Esidrix	Tabs		15.80
Hydralazine 25mg w/HCTZ 15mg	Tabs		4.50
Aristocort	Tabs	4mg	54.70
Triamcinolone	Tabs	4mg	7.00
Artidin	Tabs	6mg	19.60
Nylidrin	Tabs	6mg	3.20
Artidin	Tabs	12mg	27.00
Nylidrin	Tabs	12mg	4.00
Artane	Tabs	2mg	5.65
Trihexyphenidyl	Tabs	2mg	2.15
Artane	Tabs	5mg	11.00
Trihexyphenidyl	Tabs	5mg	2.75
Atarax	Tabs	10mg	18.25
Hydroxyzine	Tabs	10mg	9.25
Atarax	Tabs	25mg	24.50
Hydroxyzine	Tabs	25mg	15.00
Atarax	Tabs	50mg	28.75
Hydroxyzine	Tabs	50mg	17.50
Azo Gantrisin	Tabs		11.45
Azo-Sulfisoxazole	Tabs		8.50
Azulfidine	Tabs	500mg	13.30
Sulfasalazine	Tabs	500mg	6.50
Benadryl	Caps	25mg	7.85
Diphenhydramine	Caps	25mg	2.80
Benadryl	Caps	50mg	11.60
Diphenhydramine	Caps	50mg	3.15
*Benemid	Tabs	500mg	13.05
Probenecid	Tabs	500mg	6.50
Bentyl	Caps	10mg	8.45
Dicyclomine	Caps	10mg	3.40
Bentyl	Tabs	20mg	10.25
Dicyclomine	Tabs	20mg	4.00
Bentyl w/Phenobarb.	Caps	10mg	15.60
Dicyclomine w/Pb.	Caps	10mg	4.00
Bentyl w/Phenobarb.	Tabs	20mg	21.05
Dicyclomine w/Pb.	Tabs	20mg	4.60

Brand name prices effective until 9/30/83.
Generic name prices effective until 12/31/83.

Brand Name / Generic Name	Form	Strength	Price Per 100
Bonine (See Antivert)			
Combid	Caps		$ 29.90
Prochlorperazine w/Isopropamide	Caps		9.95
Compazine	Tabs	10mg	22.30
Prochlorperazine	Tabs	10mg	12.65
Compazine	Tabs	25mg	26.80
Prochlorperazine	Tabs	*25mg*	*14.20*
* Cortone	Tabs	25mg	23.80
Cortisone Acetate	Tabs	25mg	6.35
Cyclospasmol	Caps	200mg	11.60
Cyclandelate	Caps	200mg	4.80
Cyclospasmol	Caps	400mg	21.30
Cyclandelate	Caps	400mg	5.80
Cytomel	Tabs	25mcg	6.10
Liothyronine	Tabs	25mcg	3.95
Cytomel	Tabs	50mcg	9.25
Liothyronine	Tabs	50mcg	5.50
* Decadron	Tabs	0.75mg	24.20
Dexamethasone	Tabs	0.75mg	7.70
Diamox	Tabs	250mg	14.40
Acetazolamide	Tabs	250mg	6.95
Dimetane	Tabs	4mg	5.60
Brompheniramine	Tabs	4mg	1.95
Dimetane	Tabs	8mg	10.65
Brompheniramine	Tabs	8mg	3.95
Dimetane	Tabs	12mg	14.65
Brompheniramine	Tabs	12mg	4.95
Dimetapp Extentabs	Tabs		16.75
Brompheniramine Comp. O.A.	Tabs		5.00
Diupres	Tabs		11.25
Chlorothiazide 250mg w/Reserpine 0.125mg	Tabs		4.70
* *Duril*	Tabs	*250mg*	5.55
Chlorothiazide	Tabs	250mg	3.65
* Diuril	Tabs	500mg	8.80
Chlorothiazide	Tabs	500mg	5.70
* Donnatal	Tabs		4.35
Belladonna Alkaloids w/Ph.	Tabs		1.95
* Donnatal	Caps		5.40
Belladonna Alkaloids w/Ph.	Caps		2.35
Elavil	Tabs	10mg	6.75
Amitriptyline	Tabs	10mg	3.70
Elavil	Tabs	25mg	13.55
Amitriptyline	Tabs	25mg	4.95
Elavil	Tabs	50mg	22.25
Amitriptyline	Tabs	50mg	6.00
Elavil	Tabs	75mg	30.90
Amitriptyline	Tabs	75mg	11.45
* Enduron	Tabs	2.5mg	12.95
Methyclothiazide	Tabs	2.5mg	8.80
* Enduron	Tabs	5mg	15.25
Methyclothiazide	Tabs	5mg	10.95
Esidrix (See Hydrodiuril)			
Exna	Tabs	50mg	11.85
Benzthiazide	Tabs	50mg	4.50
Furadantin	Tabs	50mg	16.45
Nitrofurantoin	Tabs	50mg	3.95
Furadantin	Tabs	100mg	27.90
Nitrofurantoin	Tabs	100mg	4.95
Gantanol	Tabs	0.5gm	17.65
Sulfamethoxazole	Tabs	0.5gm	7.15

Brand name prices effective until 9/30/83.
Generic name prices effective until 12/31/83.

Brand Name / Generic Name	Form	Strength	Price Per 100
Gantrisin	Tabs	0.5gm	$ 8.60
Sulfisoxazole	Tabs	0.5gm	3.95
* Hydergine (Oral)	Tabs	1mg	21.70
Ergoloid Mesylate (Oral)	Tabs	1mg	14.75
* Hydergine S.L.	Tabs	0.5mg	16.15
Ergoloid Mesylate S.L.	Tabs	0.5mg	8.75
* Hydergine S.L.	Tabs	1.0mg	23.85
Ergoloid Mesylate S.L.	Tabs	1.0mg	15.50
* Hydrodiuril	Tabs	50mg	8.25
Hydrochlorothiazide	Tabs	50mg	2.95
* Hydrodiuril	Tabs	100mg	15.75
Hydrochlorothiazide	Tabs	100mg	3.35
* Hydropres—25	Tabs		11.25
Hydrochlorothiazide 25mg w/Reserpine 0.125mg	Tabs		3.00
* *Hydropres—50*	Tabs		15.40
Hydrochlorothiazide 50mg w/Reserpine 0.125mg	Tabs		3.15
* Hygroton	Tabs	25mg	17.70
Chlorthalidone	Tabs	25mg	9.50
* Hygroton	Tabs	50mg	18.00
Chlorthalidone	Tabs	50mg	9.85
Generic Isoniazid	Tabs	100mg	1.70
* Isordil	Tabs	5mg	7.25
Isosorbide Oral	Tabs	5mg	2.75
* Isordil	Tabs	10mg	8.75
Isosorbide Oral	Tabs	10mg	2.95
* Isordil	Tabs	20mg	13.80
Isosorbide Oral	Tabs	20mg	4.20
* Isordil	Tabs	40mg	16.05
Isosorbide Oral	Tabs	40mg	6.00
* Isordil	Caps	40mg	16.30
Isosorbide	Caps	40mg	6.00
* Isordil S.L.	Tabs	2.5mg	6.80
Isosorbide S.L.	Tabs	2.5mg	2.70
* Isordil S.L.	Tabs	5mg	7.35
Isosorbide S.L.	Tabs	5mg	2.95
Kenacort	Tabs	4mg	57.25
Triamcinolone	Tabs	4mg	7.00
* Lasix	Tabs	20mg	8.95
Furosemide	Tabs	20mg	6.50
* Lasix	Tabs	40mg	10.65
Furosemide	Tabs	40mg	7.50
Mandelamine	Tabs	0.5gm	9.75
Methanamine Mandelate	Tabs	0.5gm	3.00
Mandelamine	Tabs	1.0gm	15.60
Methanamine Mandelate	Tabs	1.0gm	4.15
Marax	Tabs		15.55
Hydroxyzine, Ephed. & Theophylline	Tabs		5.95
Medrol	Tabs	4mg	28.20
Methyl Prednisone	Tabs	4mg	13.35
* Motrin	Tabs	400mg	18.60
Ibuprofen	Tabs	400mg	14.75
Mycostatin Oral	Tabs	500,000 units	30.85
Nystatin Oral	Tabs	500,000 units	18.95
Mysoline	Tabs	250mg	12.05
Primidone	Tabs	250mg	5.20
Naqua	Tabs	4mg	17.10
Trichlormethiazide	Tabs	4mg	3.25

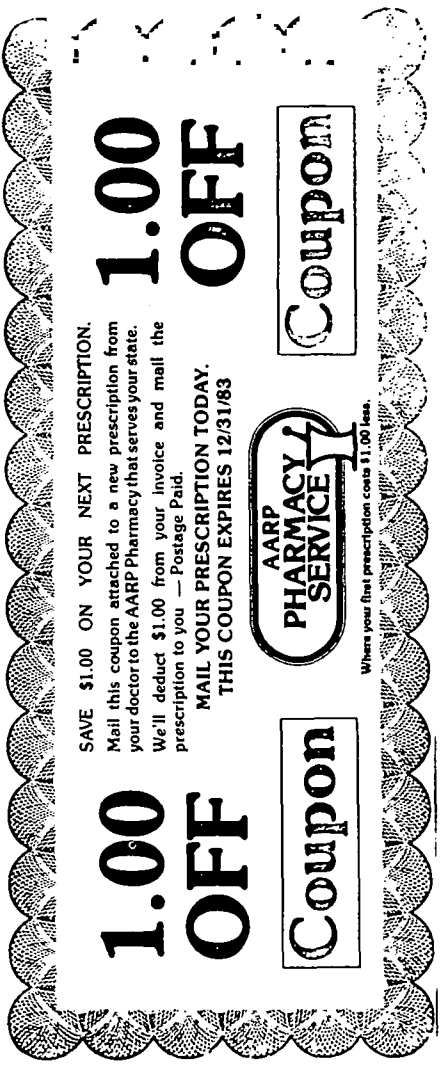
Brand name prices effective until 9/30/83.
Generic name prices effective until 12/31/83.

Brand Name / Generic Name	Form	Strength	Price Per 100
Nicobid	Caps	250mg	$ 17.85
Niacin T.D.	Caps	250mg	3.50
Nitrobid	Caps	2.5mg	12.80
Nitroglycerine T.D.	Caps	2.5mg	4.25
Nitrobid	Caps	6.5mg	16.20
Nitroglycerine T.D.	Caps	6.5mg	5.50
*Orinase	Tabs	0.5gm	14.95
Tolbutamide	Tabs	0.5gm	5.50
Parafon Forte	Tabs		23.45
Chlorzoxazone & APAP	Tabs		4.95
Pavabid	Caps	150mg	12.75
Papaverine T.D.	Caps	150mg	4.05
Pentid	Tabs	200,000 units	6.85
Penicillin G	Tabs	200,000 units	2.50
Pentid	Tabs	400,000 units	11.00
Penicillin G	Tabs	400,000 units	3.65
Pen Vee K	Tabs	250mg	11.60
Penicillin V K	Tabs	250mg	5.50
Periactin	Tabs	4mg	16.45
Cyproheptadine	Tabs	4mg	7.95
Peritrate	Tabs	10mg	7.10
PETN	Tabs	10mg	1.85
Peritrate	Tabs	20mg	9.40
PETN	Tabs	20mg	2.15
Peritrate S.A.	Tabs	80mg	21.00
PETN S.A.	Tabs	80mg	6.95
*Persantine	Tabs	25mg	11.75
Dipyridamole	Tabs	25mg	4.95
*Persantine	Tabs	50mg	21.10
Dipyridamole	Tabs	50mg	10.75
*Persantine	Tabs	75mg	27.65
Dipyridamole	Tabs	75mg	13.95
Phenergan	Tabs	12.5mg	8.50
Promethazine	Tabs	12.5mg	2.75
Phenergan	Tabs	25mg	15.05
Promethazine	Tabs	25mg	3.75
*Polycillin	Caps	250mg	17.35
Ampicillin	Caps	250mg	7.95
*Polycillin	Caps	500mg	28.80
Ampicillin	Caps	500mg	16.00
*Generic			
Prednisone	Tabs	5mg	2.45
Premarin	Tabs	0.625mg	9.30
Conjugated Estrogens	Tabs	0.625mg	6.50
Premarin	Tabs	1.25mg	13.00
Conjugated Estrogens	Tabs	1.25mg	7.95
Premarin	Tabs	2.5mg	22.60
Conjugated Estrogens	Tabs	2.5mg	15.00
Probanthine	Tabs	15mg	19.70
Propantheline	Tabs	15mg	3.15
*Pronestyl	Caps	250mg	15.65
Procainamide	Caps	250mg	4.60
*Pronestyl	Caps	375mg	21.40
Procainamide	Caps	375mg	5.75
*Pronestyl	Caps	500mg	25.25
Procainamide	Caps	500mg	6.50
*Quinora (3 gr)	Tabs	200mg	9.00
Quinidine (3 gr)	Tabs	200mg	6.90
Generic			
Quinine Sulfate	Caps	5 gr.	11.95
Raudixin	Tabs	50mg	16.45
Rauwolfia Serpentina	Tabs	50mg	2.70

Brand name prices effective until 9/30/83.
Generic name prices effective until 12/31/83.

Brand Name / Generic Name	Form	Strength	Price Per 100
Raudixin	Tabs	100mg	$ 23.65
Rauwolfia Serpentina	Tabs	100mg	3.15
Robaxin	Tabs	500mg	13.35
Methocarbamol	Tabs	500mg	4.95
Robaxin-750	Tabs	750mg	17.70
Methocarbamol	Tabs	750mg	5.95
Robaxisal	Tabs		14.30
Methocarbamol w/Aspirin	Tabs		5.00
*Ser-Ap-Es	Tabs		18.85
H.R.R.	Tabs		3.70
*Serpasil	Tabs	0.25mg	5.00
Reserpine	Tabs	0.25mg	2.45
Soma	Tabs	350mg	26.60
Carisoprodol	Tabs	350mg	7.50
Sorbitrate Tabs (See Isordil)			
Stelazine	Tabs	1mg	17.65
Trifluoperazine	Tabs	1mg	10.95
Stelazine	Tabs	2mg	21.95
Trifluoperazine	Tabs	2mg	16.50
Stelazine	Tabs	5mg	23.80
Trifluoperazine	Tabs	5mg	18.75
Stelazine	Tabs	10mg	29.50
Trifluoperazine	Tabs	10mg	21.50
*Synthroid	Tabs	0.1mg	4.05
Levothyroxine	Tabs	0.1mg	2.15
*Synthroid	Tabs	0.15mg	4.90
Levothyroxine	Tabs	0.15mg	2.35
*Synthroid	Tabs	0.2mg	5.95
Levothyroxine	Tabs	0.2mg	2.45
Generic			
Tetracycline	Caps	250mg	3.05
Thorazine	Tabs	25mg	10.20
Chlorpromazine	Tabs	25mg	3.40
Thorazine	Tabs	50mg	13.50
Chlorpromazine	Tabs	50mg	3.75
Tofranil	Tabs	10mg	12.20
Imipramine	Tabs	10mg	3.55
Tofranil	Tabs	25mg	20.35
Imipramine	Tabs	25mg	4.50
Tofranil	Tabs	50mg	31.10
Imipramine	Tabs	50mg	5.45
Trinsicon	Caps		21.00
Hematinic w/ Intrinsic Factor	Caps		5.45
Urecholine	Tabs	10mg	25.30
Bethanecol	Tabs	10mg	5.50
Urecholine	Tabs	25mg	35.75
Bethanecol	Tabs	25mg	6.00
Vasodilan	Tabs	10mg	20.05
Isoxsuprine	Tabs	10mg	6.15
Vasodilan	Tabs	20mg	27.45
Isoxsuprine	Tabs	20mg	9.70
Vistaril Caps (See Atarax)			
*Zyloprim	Tabs	100mg	8.50
Allopurinol	Tabs	100mg	6.60
*Zyloprim	Tabs	300mg	20.95
Allopurinol	Tabs	300mg	16.75

All prices listed are for Quantity of 100 unless otherwise stated.
For quantity less than 100, prorate price and add 60¢.



THIS COUPON MAY BE REDEEMED AT ANY OF THE AARP PHARMACIES LISTED BELOW.

OREGON RETIRED PERSONS PHARMACY
1501 S.W. Taylor Street
P.O. Box 2755
Portland, OR 97208
For Members in -
OR, WA, AK, HI, ID, MT, WY,
CO & NORTHERN CA ZIPS 94000-96139

PENNSYLVANIA RETIRED PERSONS PHARMACY
450 York Road
P.O. Box C5020
Warminster, PA 18974
For Members in - PA, MD, DE, DC, NJ & WESTERN NY ZIPS 13000 & UP

NEVADA RETIRED PERSONS PHARMACY
5947 Boulder Highway
P.O. Box 18422
Las Vegas, NV 89114
For Members in - NV, AZ, UT & SOUTHERN CALIFORNIA ZIPS 90001-93999

MISSOURI RETIRED PERSONS PHARMACY
3823 Broadway
P.O. Box 1444
Kansas City, MO 64141
For Members in -
MO, KS, NB, SD, ND, MN, WI, IA

AARP PHARMACY
701 Main Street
East Hartford, CT 06167
For Members in - CT, RI, MA, VT, NH, ME EASTERN NY ZIP 10000-12999

FLORIDA RETIRED PERSONS PHARMACY
6500 34th Street North
P.O. Box 14417
St. Petersburg, FL 33733
For Members in -
FL, MS, AL, GA, SC, NC, TN

INDIANA RETIRED PERSONS PHARMACY
3557 Lafayette Road
P.O. Box 7010
Indianapolis, IN 46272
For Members in -
IN, MI, IL, OH, KY, WV, VA

RETIRED PERSONS PHARMACY OF TEXAS
5050 East Belknap
P.O. Box 14869
Fort Worth, TX 76117
For Members in - TX, LA, AR, OK & NM

WALK-IN Facilities located in AARP Headquarters Buildings
RETIRED PERSONS PHARMACY
1909 K Street N.W.
Washington, D.C. 20049
For Washington D.C. Metropolitan Area

CALIFORNIA RETIRED PERSONS PHARMACY
201 Long Beach Blvd.
Long Beach, CA 90802
For Long Beach Area

FREE PRICE QUOTE ON YOUR PRESCRIPTIONS

Name of Medication _____

Strength _____ Quantity _____

Your Name _____

Address _____

City _____ State _____ Zip _____

Phone # ___ ___ ___ ___ ___ ___ ___ ___ ___ ___
(Area Code) Phone Number

Your Doctor's Name _____

Your Doctor's Phone # ___ ___ ___ ___ ___ ___ ___ ___ ___ ___
(Area Code) Phone Number

☐ CHECK HERE IF YOU WOULD LIKE TO HAVE THE LATEST EDITION OF THE AARP PHARMACY CATALOG.

MAIL YOUR PRESCRIPTION TODAY.
THIS COUPON EXPIRES 12/31/83

Senator MATHIAS. Thank you, Mr. Hacking.

First of all, let us see what areas of agreement there are in the record. You have referred to several times to profitability. When you talk about profitability, the record seems to indicate that the generic drug industry is more profitable than the prescription drug industry.

Mr. HACKING. Yes; that is true, but that does not mean that brand name manufacturers are not profitable.

Senator MATHIAS. No.

Mr. HACKING. The question is only whether increasing their profitability will result in increased R&D that will lead to new and innovative drugs. That is the question for us.

Senator MATHIAS. The record seems to also indicate that there will be no marked change in cost of drugs with or without this bill with one exception, and that is the large-scale mass purchases made by large institutions including the Government.

Is that your understanding of the situation?

Mr. HACKING. That is not our understanding. We think that the patent extension legislation will result in very increased expenditures for drugs and that will come, in large measure, from the population whose interests we are out to protect.

Senator MATHIAS. Well, other opponents of this bill have testified that they thought it would have virtually no effect on the consumer. They felt that the economic effect would be in the large contract purchases.

Mr. HACKING. We would have to question that, Mr. Chairman. But certainly we will review the record.

Senator MATHIAS. Well, I wish you would and if you have any additional statement, it would be helpful for us to have it. What is your philosophy as far as the whole patent system is concerned? Is it a good idea to have a 17-year period of protection for inventions?

Mr. HACKING. Well, the association does not have a specific policy relative to patent protection. However, I think many good points were made by the preceding panel, and I would observe there is nothing sacred about 17 years.

Senator MATHIAS. Well, I know there is nothing sacred about that, whether it is 5 years or 10 years or 17 year or 25 years. I mean, I wondered what your own personal philosophy was about the Government's creating what is, in effect, a monopoly for the inventor. Do you think that works for the general benefit of society or do you think it is in some way detrimental to society?

Mr. HACKING. Well, by giving the inventor a monopoly, the government is encouraging invention and innovation, certainly a person should be allowed to reap, to some extent, the economic benefits that flow from having been inventive and contributed to our economic system.

But whether a sufficient return requires 17 years of protection is a different question. The real question for determination is how much reward is enough. The answer has to be determined on a case-by-case basis.

Senator MATHIAS. But that really is the problem that faces us. That is the question. Will we encourage greater innovation, will we encourage a greater spectrum of drugs which will be helpful to citizens, old and young, by passing this bill or will we not?

That is the kind of question I think we have to consider as well as the consumer impact in the market. I think we have both of these questions to consider.

Mr. HACKING. Well, we think that by passing this bill we will not be encouraging a commensurate increase in R&D that results in new and innovative drugs.

Senator MATHIAS. Well, then, forget about this bill for the moment. Consider that there is no such bill as a possibility. Are you optimistic and confident about the future process of innovation in the drug industry?

Mr. HACKING. Let me ask my colleague to respond.

Mr. CHRISTY. I think the record shows that drug companies that have drugs coming off patents because of current practices have been able to hold their market share even at higher prices, and I think that the profitability of the drug industry over the years bodes well for their future, and competition in drugs from foreign countries bodes well for their future innovation of drug therapies in this country.

Senator MATHIAS. My question did not go to holding on to patents on old drugs but was what you felt about the rate of innovation, the rate of progress, rate of research and experiment for the future.

Mr. CHRISTY. Well, we really do not have an outside yardstick to measure rates of progress and rates of innovation. We do not believe there will be a collapse in innovation in drug therapy if this bill fails.

Senator MATHIAS. No; I do not believe that either. But the question is, do we not have to apply this kind of yardstick: that modern science is reaching out just as the last century was the fight of the medical profession against the dangers of infections of various kinds, it looks as though the century before us is going to be a period of exploration of body chemistry and how you affect body chemistry and when it is out of balance, how you restore the balance.

So the measure, it seems to me, lies between what is theoretically achieved in the laboratory and what can practically be made available to senior citizens and citizens generally in their corner pharmacy.

And if the industry lags too far behind in research, and in bringing the benefits of that research to the public, then it seems to me you have a pretty practical yardstick that we are not living up to our potential or discharging our duties to society.

That is really one of the things that this bill is all about, I believe.

Mr. CHRISTY. Well, I think we are really getting into speculation to try to gage what they will do if they have this bill and what they have not been doing well enough because of the infirmities they see in the marketplace. It is really very speculative.

Senator MATHIAS. Well, that is right. That is our problem. If it were not speculative, we would not be here speculating about it.

Mr. HACKING. Senator, let me add an additional observation here. It seems that if it is deemed desirable to increase R&D in order to bring new drugs onto the market, then why do it this way? Why not do it through a direct Government subsidy?

At least by doing it that way, you have the advantage of spreading the cost of the subsidy amongst society at large rather than just concentrating the cost on the purchasers of the prescription drugs as this legislation would?

Senator MATHIAS. Well, to answer your question, why not do it by way of subsidy, I could give you a long speech on what kind of problems we get into when we get into subsidies. But maybe, rather than a long speech, I could just suggest that you take a trip out to the Middle West and look at the grain silos that are filled to overflowing to see what happens when we subsidize agricultural production beyond, far beyond, the needs of the domestic market or the export market. It is an example that subsidies are just as speculative in their effect as this bill is speculative in its effect.

Let me turn to the Senator from Ohio and see if he has any questions.

Senator METZENBAUM. No questions, Mr. Chairman.

Senator MATHIAS. I think we are dealing with a very difficult subject to predict in any accurate way what the result will be. Human behavior is that way. You have to get all the facts you can possibly get and then draw some conclusions that you think are rationale and reasonable conclusions. There are clearly no guarantees.

I have no further questions except to say that if you look at the previous testimony, which I think you would find interesting, I would be glad to have your comments on the points on which that testimony is sharply in conflict with your own.

Mr. HACKING. We shall look at that and comment.

Senator MATHIAS. Thank you very much.

Mr. HACKING. Thank you.

Senator MATHIAS. Once again, the record will be held open for 2 weeks from today. The committee stands in recess subject to the call of the chair.

[Whereupon, at 11:22 a.m., the subcommittee was adjourned at the call of the Chair.]

APPENDIX

CORRESPONDENCE

NATIONAL COTTON COUNCIL OF AMERICA
EXECUTIVE BUILDING / 1030 FIFTEENTH STREET, N.W. / SUITE 700
WASHINGTON, D.C. 20005
TELEPHONE: (202) 833-2943

May 19, 1983

The Honorable Charles McC. Mathias
Chairman
Senate Judiciary Subcommittee on Patents,
Copyrights, and Trademarks
198 Russell Senate Building
Washington, D.C. 20510

Dear Mr. Chairman:

We would like to take this opportunity to express our views regarding proposed patent term restoration legislation which is now pending before the Subcommittee.

The National Cotton Council is the central organization of the U.S. raw cotton industry, representing cotton producers, ginners, merchants, warehousemen, cooperatives, cottonseed processors, and textile manufacturers from California to the Carolinas.

Our interest in this legislation relates primarily to agricultural chemicals which, under the requirements of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), are subject to extensive scientific review and testing by EPA before being approved for commercial use. Such requirements, of course, are necessary to ensure their safe and effective use. And, for this reason we have consistently supported existing FIFRA legislation and extension of EPA's Scientific Advisory Panel.

However, we also recognize that companies which manufacture agricultural chemicals have been adversely affected by often lengthy delays in bringing a new product to market. In some cases, according to EPA, the review process has taken as long as eight years. In addition to such inordinate delays, companies have suffered the loss of intended benefits of existing patent protection laws. In the case above, developers of a new agricultural chemical would have only 9 years instead of the statutorily provided 17 years to recover their substantial investment. This not only increases their financial risk, but it may even serve to discourage development of newer, safer and more effective agricultural chemcials.

The legislation now under consideration would address these concerns by restoring up to a maximum of seven years the patent protection lost while such products are under federal review. For this reason, and because of the important role agricultural chemicals play in the production of food and fiber, we strongly urge approval of this needed legislation.

Again, we appreciate the opportunity to express our views and we look forward to working with you on this and other ~~issues of~~ mutual concern.

Sincerely,

Earl W. Sears

Earl W. Sears
Executive Vice President

UNITED STATES BEET SUGAR ASSOCIATION
1156 FIFTEENTH STREET, N.W.
WASHINGTON, D. C. 20005
(202) 296-4820

May 24, 1983

Honorable Charles McC. Mathias, Jr.
Chairman
Senate Judiciary Committee
Subcommittee on Patents, Copyrights
and Trademarks
United States Senate
SR 198
Washington, D.C. 20510

Dear Senator Mathias:

The purpose of this letter, is to express support for passage of S. 1306, Patent Term Restoration Legislation. As you know, this is a proposal to encourage the research, development, registration and marketing of agri-chemical products. It is of particular importance to the beet sugar industry and consumers alike.

Despite the fact that sugarbeets provide about one-third of this nation's vital sugar requirements each year, the acreage planted to the crop is not large. With only 1.1 to 1.3 million acres planted to sugarbeets annually, stimulus for research and development of agri-chemicals for such a limited market is not present.

We believe all interests will be served by S. 1306, by providing prolonged patent protection for badly needed, new and innovative products designed to improve producer efficiency without circumventing government-mandated testing and review requirements.

Please advise us how we may be of assistance in gaining Congressional approval of this important legislation.

Sincerely,

David C. Carter
President

DCC:mlb

901 North Washington Street • Alexandria, VA 22314
Telephone: Toll Free 800/336-4743 • In Virginia: 703/836-8700 • TWX 710-832-0607

June 2, 1983

The Honorable
Charles McC. Mathias, Jr.
Chairman
Patents, Copyrights and Trademarks Subcommittee
Committee on the Judiciary
U.S. Senate
Washington, D.C. 20510

Dear Mr. Chairman:

On behalf of nearly 2,000 growers and wholesalers, and more than 6,000 retail florists in the United States, I am writing to express SAF's support of S.1306.

As the national trade association for the floral industry, SAF represents nearly 95 percent of the businesses which make up this $5 billion a year industry.

S.1306 will restore valuable patent life lost on products subject to federally mandated testing and review.

The floral industry is extremely dependent on the safe, reliable agrichemicals. By correcting the current inequities in the system, this patent term restoration legislation will help renew incentives for research and development.

Currently, a significant portion of the 17-year patent term is eroded during the five to seven years of testing to fulfill Environmental Protection Agency requirements. Non-regulated products do not experience this abbreviated patent term since they are not subject to such government testing and review requirements.

Consequently, SAF wishes to go on record as supporting this bill and hopes that your subcommittee will favorably report S.1306 to the full committee.

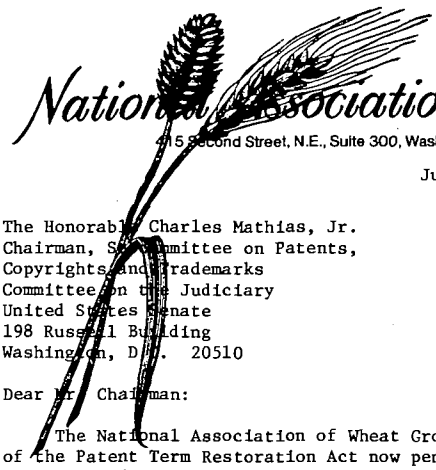
Respectfully,

Del Demaree, Jr.
President

cc: All Subcommittee Members

bcc: SAF Government Affairs Committee
Growers Council
National Agricultural Chemicals Assn.
Betty Sapp, Growers Division Director
Drew Gruenburg, Director of Publications
and Industry Relations

P.S. Additional information is available from Darryl McEwen at SAF's headquarters in Alexandria.



National Association of Wheat Growers
415 Second Street, N.E., Suite 300, Washington, D.C. 20002, (202) 547-7800

June 10, 1983

The Honorable Charles Mathias, Jr.
Chairman, Subcommittee on Patents,
Copyrights and Trademarks
Committee on the Judiciary
United States Senate
198 Russell Building
Washington, D.C. 20510

Dear Mr. Chairman:

The National Association of Wheat Growers urges your support for passage of the Patent Term Restoration Act now pending before the Congress. The Act would provide more equitable patent protection for agrichemical products which must undergo prolonged testing procedures before the federal government allows them to be marketed.

Current law provides that the 17-year patent protection begins to elapse even before the agrichemical product is marketed, while it is still in company laboratories meeting federal health and safety requirements, and final approval.

Agrichemical manufacturers concur that the average time for completion of the federal regulatory review process is from five to seven years. This means that in many cases, the marketed product receives only ten years of patent rights for the company which has ventured a great deal of research and development outlays. Since these costs can reach $25-35 million for an individual product, patent protection becomes an important consideration for companies in deciding whether to take the risk of developing a product which may or may not recover these outlays before other manufacturers can begin to market the same or similar product.

U.S. farmers are dependent upon readily available and reasonably priced chemicals for weed, insect and disease control. Scientific innovation must be encouraged, as well as moderation in pricing. Wheat farmers were faced with an eight percent increase in chemical costs in producing last year's crop. Chemical costs comprise a substantial portion of total inputs, and considering the current outlook for farm prices, cost control becomes a critical factor in improving net farm income.

In addition, as greater numbers of producers begin to adopt new cultural practices, such as low-and no-till production, in order to conserve moisture and reduce production expenditures, new chemical products to combat new diseases and other pests must be continuously available. Legislation guaranteeing full patent rights to companies developing new agrichemicals would do much to encourage aggressive research and marketing of such chemicals.

Thank you very much for taking the views of the National Association of Wheat Growers into consideration.

Sincerely,

Don Loeslie

Don Loeslie
President

DL/esh

NATIONAL ARBORIST ASSOCIATION, INC.
3537 STRATFORD ROAD, WANTAGH, NEW YORK 11793 • TELEPHONE (516) 221-3082

ROBERT FELIX
Executive Vice President

June 6, 1983

The Honorable Charles McC. Mathias, Jr.
United States Senate
Washington, D.C. 20510

Dear Senator Mathias:

The National Arborist Association supports passage of the Patent Term Restoration Act now pending in the 98th Congress.

Arborists engaged in the preservation of trees actively use chemicals on a day-to-day basis. In doing so, they are constantly in need of new chemicals to fight new pests, to reduce the hazards to non-target organisms, to protect the environment from contamination, and to more effectively control target pests.

We realize there is a current trend toward a longer and more elaborate testing and review process by EPA before a chemical can be marketed. This increasingly more expensive process, coupled with the loss of valuable patent time, reduces the likelihood of a chemical ever reaching the market place, not to mention the reluctance of agricultural chemical companies to invest in research and development.

Since there has been much legislative pressure recently to restrict our industry's use of the currently available pesticides, we need new and safer chemicals to be developed.

Therefore, we support the passage of the Patent Term Restoration Act now pending in the 98th Congress in hopes it will restore some of the patent protection originally intended for these agricultural chemical companies.

Yours truly,

NATIONAL ARBORIST ASSOCIATION, INC.

Robert Felix
Executive Vice President

RF/db
cc: Lee L. Lesh
Robert Mullane

united fresh fruit and vegetable association
NORTH WASHINGTON AT MADISON, ALEXANDRIA, VIRGINIA 22314, 703/836-3410, Cable: UNIFRESH

June 13, 1983

Senator Charles Mathias
United States Senate
Washington, D.C. 20510

Dear Senator Mathias:

On behalf of United and its 2500 member companies I am writing in support of the "Patent Term Restoration Act of 1983" (S.1306), which you have introduced. Because this legislation will restore valuable patent life lost on products subject to federally-mandated testing and review, such as agricultural pesticides, United fully supports your efforts in this area.

The members of United produce and market more than eighty percent of the fresh fruits and vegetables in the United States. The availability of a wide variety of high quality fresh produce is related to the safe and proper use of federally-approved agricultural chemicals. Under federal law, chemical manufacturers spend five to seven years fulfilling the data requirements of the Environmental Protection Agency in seeking its approval to market their agrichemical products. During this elaborate testing and review process, the seventeen year patent protection period is dwindling. Consequently, a significant portion of the patent term on newly registered agrichemicals is lost. By contrast, non-regulated products cannot experience similar abbreviated patent terms as a result of government testing and review requirements.

The adoption of S.1306 will restore equal protection to all inventions and discoveries which result in new products, will provide investment incentives to engage in the expensive research and development which results in new products, and will result in better and less expensive products.

Accordingly, United fully supports the patent term restoration legislation and commend you for sponsoring it.

Sincerely,

Bernard J. Imming, CAE
President

BJI:sb

interior plantscape association

11800 sunrise valley drive reston, virginia 22091 (703) 476-8550

June 17, 1983

Senator Mac Mathias
U.S. Senate
Washington D.C. 20510

Dear Senator Mathias,

In the interests of the Interior Plantscapers we represent I would like to encourage you on their behalf to support S. 1306 scheduled for hearings June 22, 1983.

We feel that it would correct an inequity in the patent system as it now exists and provide incentives for agrichemical research for the future.

We thank you for your attention to this matter.

Sincerely,

Jane Dockery
Associate Director
Interior Plantscape Association

JD:vpt

Corn Refiners Association, Inc.

1001 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 331-1634

Executive Offices

June 21, 1983

Hon. Charles Mathias
Chairman
Subcommittee on Patents,
Copyrights and Trademarks
United States Senate
Washington, D. C. 20510

Dear Mr. Chairman:

We are writing to urge that the your subcommittee favorably consider S. 1306, the Patent Term Restoration Act of 1983. We commend you for your actions in addressing this serious problem, and hope that the subcommittee will favorably report the bill.

Members of the Corn Refiners Association, Inc. (membership list attached), provide a wide array of food products for the American consumer. In order to provide this dependable, economical ingredient of the food supply, our members depend on a healthy corn economy, and an assurance of an abundant corn crop. Over the past four decades, great strides have been made by agronomists in achieving this goal. Corn refiners currently utilize around 550 million bushels of U. S. corn annually - up from around 200 million bushels in the 1960s. Had crop production not increased the way it has over the past several decades, it would have been very difficult to provide the reliable supplies needed for our industry to grow.

Much of the credit toward supply of a reliable crop goes to the plant protection aids which are available to the farmer today. As you are aware, however, it is imperative that research and development in crop protection continue to provide products which will combat new diseases and pests. In addition to the crop supplies necessary for the growth of the corn refining industry, members of the industry and suppliers to the industry have made great strides in the development of innovative food processing technology - much of it dependent on patentable processes which require regulatory review. As genetic engineering techniques become better defined and commercially viable, this trend will increase.

The regulatory review processes which apply both to industry process developments and crop protection agents can, and do, substantially negate the benefits of U. S. government patent protection. The incentive to develop proprietary processes is greatly lessened when a major portion of the life of the prospective patent will be consumed in pre-market review. We do not seek special consideration in such reviews for patentable discoveries. However, we feel that inventors who have declared their willingness to devote the large amounts of time and money to develop novel products should be assured of the full protection

of the patent laws which was originally contemplated by the Congress. S. 1306 would provide that protection without weakening consumer protection and we urge its adoption.

Sincerely,

Robert C. Liebenow
President

Enclosure

MEMBER COMPANIES
Corn Refiners Association, Inc.
1001 Connecticut Avenue, N.W.
Washington, D. C. 20036

ADM Foods (A division of Archer Daniels Midland Company) P. O. Box 1445 Cedar Rapids, Iowa 52406	Plants: Cedar Rapids, Iowa Decatur, Illinois Clinton, Iowa Montezuma, New York
American Maize-Products Company 41 Harbor Plaza Drive Stamford, Connecticut 06904	Plants: Hammond, Indiana Decatur, Alabama
Amstar Corporation 50 California Street San Francisco, California 94111	Plant: Dimmitt, Texas
Cargill, Incorporated P. O. Box 9300 Minneapolis, Minnesota 55440	Plants: Cedar Rapids, Iowa Dayton, Ohio Memphis, Tennessee
CPC International Inc. International Plaza P. O. Box 8000 Englewood Cliffs, New Jersey 07632	Plants: Argo, Illinois North Kansas City, Missouri Stockton, California Winston-Salem, North Carolina
Hubinger (A subsidiary of H. J. Heinz Company) One Progress Street Keokuk, Iowa 52632	Plant: Keokuk, Iowa
National Starch and Chemical Corporation P. O. Box 6500 Bridgewater, New Jersey 08807	Plant: Indianapolis, Indiana
Penick & Ford, Limited (A subsidiary of Univar Corporation) P. O. Box 428 Cedar Rapids, Iowa 52406	Plant: Cedar Rapids, Iowa
A. E. Staley Manufacturing Company P. O. Box 151 Decatur, Illinois 62525	Plants: Decatur, Illinois Morrisville, Pennsylvania Lafayette, Indiana (2) Loudon, Tennessee

American College of Cardiology

HEART HOUSE 9111 OLD GEORGETOWN ROAD
BETHESDA, MARYLAND 20814 (301) 897-5400

June 22, 1983

American Heart Association

National Center • 7320 Greenville Avenue
Dallas, Texas 75231 • (214) 750-5300

Honorable Charles McC. Mathias
Chairman
Subcommittee on Patents, Copyrights
and Trademarks
Committee on the Judiciary
United States Senate
SR-198 Russell Senate Office Building
Washington, D.C. 20510

Dear Mr. Chairman:

The following comments are submitted on behalf of the American College of Cardiology and the American Heart Association. Both of these organizations represent thousands of physicians, health professionals, scientists, and educators who specialize in diseases of the heart and circulatory system and related disorders. In addition, the American Heart Association represents over 110,000 volunteers and 55 affiliates who are consumer advocates for the patient with cardiovascular disease. As Presidents of these two organizations, we take this opportunity to reaffirm the support we gave in the last Congress to legislation which would extend the patent term to account reasonably and equitably for the time expended in reviewing and approving FDA-regulated products. Because of your particular interest in this issue, we are pleased to let you know of both groups' continuing endorsement of such legislation as it relates to the impact on progress in patient care.

It is a consensus that drug research and development have declined in recent years and that so too has the number of new medications available in America. This trend is disturbing to those of us who treat patients with cardiovascular diseases - conditions which account for more than one-half of all deaths in the United States. The potential for progress in combatting hypertension, arteriosclerosis, coronary artery disease, and the myriad of disorders of the cardiovascular system is great; developments in beta blocker and calcium blocker compounds, as well as medical devices and technologies such as echocardiography, attest to this. We are well aware that the Federal contribution to drug and device research, in the form of biomedical research appropriations, is not keeping place with inflation. The development and testing of new chemical entities is a costly and lengthy process and adequate incentives for those activities must be provided to universities, pharmaceutical companies, private research firms, and clinical investigators. The assurance of patent protection for a sufficient period of time is an incentive which has clearly been reduced in recent years.

This type of legislation would counter the recent erosion of the patent term caused by extensive FDA regulatory review and likely would provide greater incentive for the development of safe and effective drugs and technologies. In addition, the approach is simple, flexible, and equitable.

On behalf of the memberships of the American College of Cardiology and the American Heart Association, and the millions of Americans who may derive benefit from an expanded array of innovative medicines and therapies, we urge approval of legislation which would accomplish these goals.

If we can provide you with any further information or assistance, please let us know.

Sincerely,

Paul A. Ebert, M.D.
Paul A. Ebert, M.D.
President
American College of Cardiology

Mary Jane Jesse, M.D.
Mary Jane Jesse, M.D.
President
American Heart Association

CHEMICAL MANUFACTURERS ASSOCIATION

ROBERT A. ROLAND
President

June 22, 1983

The Honorable Charles McC. Mathias, Jr.
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Re: S.1306, Patent Term Restoration Legislation

Dear Senator Mathias:

The Committee on the Judiciary is now examining proposed legislation, S.1306, that would restore to the term of the patent grant the period of time that regulatory approval procedures delay commercial marketing of a patented product or patented use of a product.

This letter is being submitted on behalf of the Chemical Manufacturers Association (CMA). The Chemical Manufacturers Association is a nonprofit trade association whose company members represent more than 90 percent of the productive capacity of basic industrial chemicals within this country. CMA urges the Committee to act favorably on S.1306. CMA's member companies conduct extensive research and development on new and existing chemicals for application to new and ever-expanding uses in pharmaceuticals, pesticides, fertilizers, plastics, building materials, and many other applications in the industrial as well as consumer segments of our economy. Accordingly, CMA members are directly and substantially affected by regulatory clearance procedures before new products can be commercially distributed.

Economic progress is encouraged by an investor's expectation of a seventeen year term of patent exclusivity, a term during which he can hope to get a reasonable return for bringing an innovation forward for the use of society. In the chemical field, unlike many other fields of innovation, the Government subjects new chemicals or significant new uses of existing chemicals to an assessment for unreasonable risk of injury to health or environment.

For example, many chemicals manufactured by our member companies are formulated into products subject to premarket regulatory clearance under provisions of the Food, Drug, and Cosmetic Act, (FDCA) and the Federal Insecticide, Fungicide, and Rodenticide

Act (FIFRA). Furthermore, basic industrial chemicals are also subject to an initial regulatory clearance hurdle under provisions of the Toxic Substances Control Act of 1976 (TSCA), 15 U.S.C. 2601, et seq. As a result of testimony given in support of S.255 (97th Congress), it is, we believe, clear that each of those statutes has an impact on the effective term of patents owned by our member companies. Herein, we would like specifically to focus on the marketing delays caused by TSCA, since we are aware that the Pharmaceutical Manufacturers Association and the National Agricultural Chemicals Association will address FDCA and FIFRA.

While many of the rules implementing TSCA have not been in effect for a sufficient period of time to permit precise impact analysis, it is not premature for our expression of concern over the potential for delays in regulatory approval caused by TSCA, encroaching on the normal patent term. This is especially true in the event that the Environmental Protection Agency finds that a substance presents an unreasonable risk of injury to health or the environment, orders major additional testing, or delays the manufacture, processing, or distribution of the substance. Thus, the term of the patent covering the substance or its use may begin to expire before the inventor is able to obtain an economic benefit from his innovaton.

This concern for the potential marketing delays due to regulation under TSCA comes from historical observation of what has happened to the effective life of patents covering products regulated under FDCA and FIFRA. CMA is concerned that, as TSCA matures, there will be a similar evolution of ever-increasing time and costs to comply with agency clearances. The body of knowledge on chemicals is clearly growing and, as a result, more testing may be necessary to satisfy the agency's concern that all that is known be explored.

By restoring the patent term, chemical innovators are given the same incentive for research and development and commensurate rewards for progress that are available to the mechanical, electronic, and other areas of science and useful arts.

CMA believes that S.1306 is a fair and equitable bill and that it is designed to be administered objectively with a minimum of costs. We strongly urge the Committee to support this bill.

Sincerely,

Robert A. Roland
President

American Association of Nurserymen, Inc.

230 SOUTHERN BUILDING, 15TH & H STREETS, N.W., WASHINGTON, D.C. 20005 • (202) 737-4060

June 23, 1983

The Honorable Charles McC Mathias
U.S. Senate
Washington, D.C. 20510

Dear Senator Mathias:

This letter is written on behalf of the American Association of Nurserymen and the National Association of Plant Patent Owners concerning the Patent Term Restoration Act (S-1306) introduced by you and others.

The American Association of Nurserymen is a national trade association which represents in excess of 3300 firms engaged in the production, installation and sale of enviromental plants, fruit and nut trees, vines and berries. The National Association of Plant Patent Owners is comprised of 52 members who are involved in the research and development of new varieties of asexually reproduced plants both in the United States and foreign countries.

The bill will restore to the patent holder any time lost by virtue of federally mandated testing or review requirements. Under current law the patent term commences on the day of the grant. The clock continues to run despite the pact that reviews by other government agencies are required in some instances before the product can be marketed. Examples of these products are pharmaceuticals, agricultural chemicals and imported plants.

Nursery farmers are dependent upon availability of agricultural chemicals not only for production but also to satisfy the phyto-sanitary requirements of state and federal plant quarantine laws. As a consequence, in light of the enormous investment in research and development of a new agricultural chemical, we support S-1306 and urge its enactment.

On behalf of the National Association of Plant Patent Owners, it is recommended that the proposed Section 155 be modified to include plants and trees which are subjected to post entry quarantines under provisions of 7CFR 319.37-7. Satisfaction of this post entry quarantine can take from 2 to 5 or more years. Plant Patent holders who lose a portion of their protection term because of this regulatory requirment should be made "whole" on the same basis as other patent holders.

Your bill will correct a long term inequity to a limited number of patent holders and will be extremely beneficial to the users of their products.

Sincerely,

Leo J. Donahue
Director of Governmental Affairs

LJD:lkh
CC: The Honorable Howard M. Metzenbaum

American Farm Bureau Federation

WASHINGTON OFFICE
600 MARYLAND AVE., S.W.
SUITE 800
WASHINGTON, D.C. 20024
AREA CODE 202 - 484-2222

June 24, 1983

Honorable Charles McC. Mathias, Jr.
Chairman
Subcommittee on Patents, Copyrights and
Trademarks
Committee on Judiciary
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

The American Farm Bureau supports your bill, S. 1306, and urges the Subcommittee to report the bill in its present form.

Farm Bureau does not develop, manufacture, or patent agricultural chemicals, yet we believe the "Patent Term Restoration Act," if enacted, would be of significant benefit to our members. Farm Bureau's three million family members account for over 85 percent of the agricultural chemicals used in agriculture, either through personal or contractual arrangements. These pesticides and animal drugs are a necessary component of today's agricultural production system.

Since the passage of the 1972 amendments to FIFRA, the Pesticide Control Act, registrations representing nearly half the amount used in agriculture have been cancelled. As these regulatory actions to protect man and the environment are undertaken by EPA, it is critical that adequate incentive be maintained for the development and marketing of safe, effective and environmentally acceptable alternatives.

S. 1306 is a narrowly drafted bill with important safeguards to protect against multiple use of its provisions in an anticompetitive manner. The bill also limits the length of patent extensions and assures that provisions of the bill can be utilized only when justified by regulatory actions.

Our goal is continued access to as wide a range of crop, livestock, forestry and aquaculture protection products as possible. This goal can only be achieved if research and development costs of chemical manufacturers can be justified by their management. We believe affording such companies reasonable patent protection is a reasonable compensation to pay for the benefits of their research efforts.

Sincerely,

John

John C. Datt
Secretary and Director
Washington Office

cc: Subcommittee Members

American Wood Preservers Institute
1651 Old Meadow Road, McLean, Virginia 22102 (703) 893-4005

June 24, 1983

The Honorable Charles McC. Mathias, Jr.
U.S. Senate
Washington, D.C. 20510

Dear Senator Mathias:

I am writing to you on behalf of the members of the American Wood Preservers Institute (AWPI). AWPI is a national trade association representing manufacturers and users of wood preserving chemicals.

AWPI supports passage of the Patent Term Restoration Act, S. 1306, now pending before Congress. This legislation would restore part of the patent term that is lost to those products that must meet federal regulatory requirements before they can be marketed.

AWPI urges you to support enactment of the Patent Term Restoration Act. The Act would encourage chemical companies to continue to invest long-term, high risk capital in research and development of safer, new wood preservatives, as well as correct an inequity in the present patent system, which denies full and adequate protection to regulated wood preservatives.

Thank you for your attention to this matter.

Sincerely yours,

Walter G. Talarek
General Counsel

WGT:jem

NATIONAL
CORN GROWERS
ASSOCIATION

Suite 201
1015 15th Street, N.W.
Washington, D.C. 20005
Telephone: (202) 371-1450

The Honorable Charles McC. Mathias, Jr.
United States Senate
Washington, D. C. 20510

June 24, 1983

Dear Senator Mathias:

The National Corn Growers Association wishes to add our strong support to your bill, S.1306, the Patent Term Restoration Act of 1983. Our association is composed of a total of corn farmers from seventeen affiliated corn producing states, the aggregate of which account for over 90 percent of U.S. average annual corn production. We are also supported by twenty Agri-Industry companies that have an interest in corn production and marketing.

To continue as the world's leader, United States agriculture, and especially the agrochemical industry, must be encouraged to devote increasing amounts of capital to research and development. Corn farmers certainly recognize the need for a patent system to motivate this costly, high-risk, long-term research and development necessary to provide them with more effective production inputs.

Mr. Chairman, your bill, S.1306, will be of immense value to U.S. corn farmers to ensure that they continue to recieve an uninterrupted flow of new production technology. We think that it is vital to agriculture that the patent system which fosters innovation not be further eroded by federally mandated testing and review. We applaud your efforts to ensure innovative organizations receive the 17 years of protection fixed by Congress. We sincerely appreciated your support of agriculture.

Sincerely yours,

Michael L. Hall

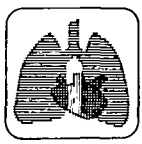
Michael L. Hall
Washington Representative

MLH:lh

cc: The Honorable Howard M. Metzenbaum

A PROFESSIONAL SOCIETY
FOR CONTINUING
EDUCATION IN
CIRCULATION, RESPIRATION
AND RELATED SYSTEMS

AMERICAN COLLEGE OF CHEST PHYSICIANS
AN INTERNATIONAL SOCIETY



June 27, 1983

The Honorable Charles McC. Mathias, Jr.
United States Senate
Washington, D.C. 20510

Dear Senator Mathias:

The American College of Chest Physicians is a professional medical specialty society of more than 11,000 physicians, scientists, and educators, who specialize in the diseases of the heart, lungs, and circulatory system. As President of this organization, and as an individual who conducts pharmacologic research, I wish to express our support for S. 1306, "The Patent Term Restoration Act of 1983," which is now pending before the Senate Judiciary Committee.

Great strides have been made in combatting cardiopulmonary diseases in recent years. Promising new beta-blockers and other therapeutic agents are demonstrating that the death rate from cardiovascular diseases can be further reduced. In the pulmonary area, drug therapies are under development for debilitating chronic lung diseases, such as bronchitis and emphysema, which afflict 15 million Americans.

It is imperative that the Federal Government assure sufficient incentives for universities, pharmaceutical companies, and other research institutions to sustain and expand current efforts in research and development of new, more effective drugs, biologicals, and other health care products necessary for the prevention, treatment and control of these major health problems.

The original intent of the patent law was to provide incentives for American research and innovation in scientific fields. Over the last 20 years, the time between approval of patents on compounds and the actual approval of new therapeutic agents for use in patients has

911 BUSSE HIGHWAY • PARK RIDGE, ILLINOIS 60068 U.S.A. 312: 698-2200 / CABLE AMCHEST

AMERICAN COLLEGE OF CHEST PHYSICIANS • 911 BUSSE HIGHWAY • PARK RIDGE, ILLINOIS 60068 U.S.A. 312: 698-2200

grown significantly, effectively reducing from 17 to less than 10 years patent protection guaranteed to the innovator/researcher.

Concurrently, the costs of conducting research have grown substantially. We are pleased that FDA is currently implementing and considering changes in the IND and NDA processes which may expedite the approval process in a manner which will not compromise the rigorous safety and effectiveness standards required by law in considering new drug applications. However, until the time that such reforms are implemented, pharmaceutical manufacturers should be afforded adequate incentive for the conduct of the often time-consuming studies required for approval.

We believe that the availability of a "real" 17-year patent life, one which reflects the time required for approval of a drug, would provide such an incentive. Accordingly, we recommend that you, as a member of the Senate Judiciary Committee, support S. 1306.

On behalf of our membership and our millions of patients, we appreciate your attention to this important matter.

Sincerely,

Gerald Rainer

W. Gerald Rainer, M.D., F.C.C.P
President

THE FERTILIZER INSTITUTE
1015 18th Street, N.W.
Washington, D.C. 20036

GARY D. MYERS
President

(202) 861-4900
Telex: 89-2699

June 30, 1983

The Honorable Charles McC. Mathias, Jr.
United States Senate
Washington, D. C. 20510

Dear Senator Mathias:

The Fertilizer Institute supports S. 1306, Patent Term Restoration, and requests your support in moving the measure through the legislative process.

The farm sector has increased its productivity dramatically over the years through continued innovation. S. 1306 would greatly renew the incentives for farm input product research and development by better insuring an adequate return on investment for the inventor. This protection will greatly enhance continued innovation and productivity to the benefit of not only the farm sector, but the general public as well.

Thus, your favorable assistance for S. 1306 would be most helpful.

Sincerely,

Gary D. Myers

GDM:pdg

National Food Processors Association
1133 Twentieth Street N.W., Washington, D.C. 20036
Telephone 202/331-5900

Legislative Affairs Division
Richard W. Murphy
Vice President/Director
202/331-5939

1 July 1983

The Honorable Charles McC. Mathias, Jr.
Chairman, Patents, Copyrights and
Trademarks Subcommittee
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The National Food Processors Association (NFPA) is pleased to endorse S. 1306, the Patent Term Restoration Act of 1983.

NFPA represents approximately 550 member companies which pack processed-prepared fruits, vegetables, juices, meats, fish, and specialty products, including frozen, dehydrated, pickled, and other preserved food items. Also included among NFPA's members are companies that provide equipment, supplies, and services to the food processing industry.

Most of the foods utilized in this industry are highly perishable in their natural state and are purchased directly from growers or are carefully selected for processing in the open market. Most NFPA members, and seasonal fruit and vegetable packers in particular, depend upon the availability of a range of safe, effective, and reasonably priced pesticides to produce wholesome, nutritious, and affordable food products.

The 1972 Amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) introduced extensive and rigorous safety, environmental, and efficacy testing requirements for all new pesticide products. These requirements have substantially lengthened the review period, and dramatically increased the costs, for new pesticide applications. This has created strong disincentives for development and registration of new minor use (low volume) pesticides, such as those used on seasonal fruits and vegetables. Congress recognized this problem by including in the 1978 FIFRA Amendments an addition to section 3 of the Act directing EPA, in setting data requirements for monor use pesticides, to consider potential national volume and registration costs on the incentives for potential registrants to undertake development of required data. Restoration of patent periods lost during the registration process would provide a further valuable mechanism for reducing the current disincentives for development of minor use pesticides, including those used on processing crops. For this reason, NFPA strongly supports S. 1306.

I ask that this letter be made a part of the printed record of the Subcommittee's hearing on S. 1306 of 22 June 1983.

Sincerely,

Richard W. Murphy
Vice President, Legislative Affairs

RWM:mmc
cc: Members of the Subcommittee

Founded 1914

Suite 1120
1001 Connecticut Avenue, NW
Washington, DC 20036

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

202/872-8110

PRESIDENT
RALPH ENGEL

July 5, 1983

The Honorable Charles Mathias
U. S. Senate
SR-387A Russell Senate Office Building
Washington, D. C. 20510

Dear Senator Mathias:

I want to express our appreciation for your introduction of S. 1306, the Patent Term Restoration Act of 1983.

CSMA has a membership of nearly 400 firms engaged in the manufacture, formulation, distribution, and sale of insecticides; disinfectants and sanitizers; detergents and cleaning compounds; automotive chemicals; and waxes, polishes, and floor finishes for household, institutional, and industrial uses. A significant number of these products have pesticidal claims and are, therefore, subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Patent Term Restoration Act.

Since Congress enacted the first U. S. patent laws, an innovator of a new product or method has been entitled to exclusive commercial control of it for 17 years. This method was intended to encourage and reward innovation and, thus, provide for disclosure of inventions.

Because of federal agency registration requirements which must be met before a patented product can be brought onto the market, the effective 17-year patent life of the product is greatly reduced. As a result, the ability of a company to recover its research and development expenditures and developmental costs, and stake out a share of the market, is likewise reduced.

In recent years and especially since the early 1960's, new federal laws and regulations of such agencies as EPA and FDA have led to a steady lengthening of the pre-market testing and clearance process. Recently, EPA estimated that patent life for chemical products has been reduced to about 12 years, including household products for the home, lawn and garden.

Substantially shortened patent terms provide insufficient time for companies to recover their investments. In a very real sense, the curtailment of incentives to pursue important technological advancements operates against the public interest by depriving people of important products in addition to the jobs required to produce them. Exacerbating the problem is the increased competition from foreign companies which threatens our country's traditional role as the world leader in innovation.

Legislation was introduced in the 96th and 97th Congresses to restore some of the patent life lost due to federal agency review requirements. While a bill passed the Senate in 1981 and had the support of almost two-thirds of the members of the House in 1982, it died in the House Rules Committee during the final days of the 97th Congress.

S. 1306 is substantially the same as the bill which passed the Senate, except for its inclusion of patent restoration for "process" patents in addition to "compound" and "use" patents. Specifically, the bill would restore up to a maximum of 7 years the patent life for chemical products regulated under the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, equal to the marketing period lost between the time that significant animal studies are commenced and the product is registered by the EPA or is lawfully permitted to be manufactured.

We at CSMA support S. 1306 because it would:

- o Restore some of the patent protection lost in the Federal regulatory process.
- o Sustain the incentive needed for our member companies to continue to invest long-term capital in research and development.
- o Enable U. S. chemical specialty companies to maintain their leadership position internationally.
- o Correct a present inequity in the system which denies appropriate protection to regulated products.
- o Especially benefit small businesses for which the contribution of innovation is proportionately greater than for large companies. Lengthened patent protection for them provides long-term stability to enhance cost recovery and outside financing opportunities and to make additional investments in capital and employment.

We believe that patent life should be restored for chemical specialties products which are lost due to federal agency pre-market testing and regulatory review requirements.

Again, we thank you for your introduction of S. 1306. We appreciate your interest and concern for this much-needed legislation.

Sincerely,

Ralph Engel

Ralph Engel
President

RE:mk

The Adhesive & Sealant Council ASC
Suite 910 – 1600 North Wilson Boulevard – Arlington, Virginia 22209
Phone: (703) 841-1112

July 7, 1983

The Honorable Charles Mathias
Chairman, Subcommittee on Patents,
Trademarks and Copyrights
U.S. Senate
Washington, D.C. 20510

Dear Senator Mathias:

On behalf of The Adhesive and Sealant Council, Inc., I wish to congratulate you on your sponsorship of S. 1306, The Patent Term Restoration Act of 1983. This bill is quite important to several of our member companies, and as an allied association of the chemical/pharmaceutical industries, The Adhesive and Sealant Council endorses passage of this measure.

The rationale for this legislation is compelling: It will provide needed incentives for new investments in research and development to promote the discovery of new medicines to help cure and prevent disease. At a time when the Congress and the Administration are considering policies to reduce the increasing costs of health care, it seems reasonable to promote legislation that will encourage the development of drugs which we know are a very cost-effective form of therapy.

Beyond the economic benefits of improved drug therapy is the elimination of human suffering. In the past 40 years, thanks to pharmaceuticals, there has been an almost total elimination of diptheria, measles, polio, and whooping cough.

Another important justification for passage of S. 1306 is the need to grant a measure of equity to those corporations that invest tens of millions of dollars in pharmaceuticals and agricultural chemicals and yet which are denied the full 17 years of patent protection. It seems incongruous that our society should grant 17 years of market exclusivity for all other patented inventions, yet through the requirement for government-mandated testing and review, pharmaceuticals and agricultural chemicals have substantially shortened periods of patent protections.

Thank you for your consideration of my views.

Sincerely,

Jules Rapp

Jules Rapp
Executive
Vice President

NATIONAL CATTLEMEN'S ASSOCIATION
425 13th Street, N.W. • Suite 1032 • Washington, D.C. 20004 • (202) 347-0228

National Headquarters
5420 S. Quebec St. • P.O. Box 3469 • Englewood, CO 80155 • (303) 694-0305

July 18, 1983

Honorable Charles McC. Mathias, Jr.
Room 387-A
Russell Senate Office Building
United States Senate
Washington, D.C. 20510

Dear Senator Mathias:

The National Cattlemen's Association is pleased that you have introduced the long needed Patent Term Restoration legislation.

The cattle producers in this country depend on a steady supply of safe and efficacious products to enhance the health and production status of our cattle. We rely on drug and pesticide manufacturers to develop such products through research. Considering the expense of developing a new product, with no guarantee that it will be approved or that it will be adopted by livestock producers, drug and pesticide manufacturers must have considerable incentive to invest in research which may lead to a new product. We depend on these companies for innovation and we cannot expect innovation without incentive.

As you are aware, a major deterrent to innovation in developing new animal drug and pesticide products is the loss of patent life occasioned by products subject to pre-marketing regulatory review. Advancements in science which have led to more accurate testing for impurities, effectiveness and general safety have also contributed to what is commonly known as "drug lag." At present, "drug lag" is a major problem which affects not only drug and pesticide manufacturers but also producers. This "drug lag" has dramatically reduced the period of time for which drug or pesticide originators can benefit from their considerable investment in research and development.

As users of new animal drug and pesticide products, cattle producers support this legislation which could restore the patent life of these products which are so vital to our success. We believe that passage of this legislation would result in more innovation from drug and pesticide manufacturers which will in turn allow us to continue to supply the safest, most wholesome and most affordable food supply available in the world.

Once again, we appreciate your interest in this legislation which will have a considerable impact on livestock producers.

Sincerely,

Bill Gallagher
Chairman
NCA Animal Health and
Identification Committee

Walter LeFevre
Chairman
NCA Environmental
Management Committee

NATIONAL PORK
Producers Council®

S. Michael Mishoe
Assistant Director of Government Affairs
for Congressional Relations
Suite 515, 499 S. Capitol St., S.W.
Washington, D.C. 20003
Ph. 202-484-3772

• P.O. BOX 10383 • DES MOINES, IOWA 50306 • PH. 515/223-2600

July 18, 1983

The Honorable Charles McC. Mathias, Jr.
Chairman
Patents, Copyrights and Trademarks Subcommittee
Senate Judiciary Committee
U.S. Senate
Washington, DC 20510

Dear Senator Mathias:

The National Pork Producers Council has over 110,000 dues-paying pork producer farm families in 38 member states. The primary goal of our relatively young organization is to improve the profitability of pork production.

One important element of a profitable pork industry and the continuation of an abundant supply of nutritious pork for consumers at an affordable price, is the availability of products to maintain and ensure animal health. Presently, as you know, companies can spend several years fulfilling federal agency requirements to demonstrate the safety and efficacy of new animal drugs. During this period, time is running against the patent life of the product and companies are not able to benefit from their research.

The legislation you introduced, S. 1306, the Patent Term Restoration Act of 1983, corrects this inequity and will help renew incentives for research into the development of significant new products. The National Pork Producers Council supports S. 1306 and urges that your Subcommittee move forward with this legislation.

If we can be of further assistance regarding our position on this legislation, please do not hesitate to contact me.

Sincerely,

Michael Mishoe

S. Michael Mishoe
Director of Government Affairs

SMM/jjk

cc: Patents, Copyrights and Trademarks Subcommittee

AMERICAN VETERINARY MEDICAL ASSOCIATION
WASHINGTON OFFICE – SUITE 828
1522 K STREET N.W. • WASHINGTON, D.C. 20005 • PHONE: AREA CODE 202 / 659-2040

August 4, 1983

The Honorable Charles McC. Mathias, Chairman
Subcommittee on Patents, Copyrights and Trademarks
Senate Judiciary Committee
SR 198 Russell Senate Office Bldg.
Washington, D.C. 20510

Dear Senator Mathias:

The American Veterinary Medical Association supports the enactment of S. 1306, and we hope you will include this letter in the record of hearings of your subcommittee on the bill. We encourage the subcommittee to act as soon as possible to report S. 1306 favorably to the full committee.

We have for many years been concerned about the limited availability of new animal drugs for use by veterinarians in the treatment and control of animal diseases. New incentives for product development are absolutely essential to encourage manufacturers of drugs, biologics, and pesticides to invest greater resources in their research and development programs. We believe that extensions of the patent term on products subject to federal pre-market clearance procedures are only equitable, and would afford the sponsors of the products with the patent protection Congress intended for all inventors and innovators. We feel that adequate patent protection for drugs, biologics, and pesticides will encourage the firms in these industries to expand their vital new product development efforts. S. 1306 offers an appropriate incentive and should be enacted.

We appreciate the attention you have given to this matter and encourage your continued effort.

Sincerely,

W M Decker

W. M. Decker, D.V.M.
Washington Representative

THE UNITED STATES HISPANIC CHAMBER OF COMMERCE

August 6, 1983

The Honorable Charles McC. Mathias, Jr.
358 RSOB
Russell Senate Office Building
Delaware & Constitution Avenues, NE
Washington, D.C. 20510

Dear Senator Mathias:

The United States Hispanic Chamber of Commerce enthusiastically supports and endorses your House bill S1306 the Patent Term Restoration Act now pending before the Congress. You are to be commended for your vision and foresight in leading the fight to correct a situation with grave implications for this nation's high technology pharmaceutical and chemical industries.

The Act would provide more equitable patent protection for investment in the research and development of products such as drugs and chemicals.

Restored research incentives would stimulate the flow of new and improved therapies publically. Better medicines would obviate the need for more costly forms of therapy, such as surgery or hospitalization. Furthermore, the competition fostered by the flow of new products would result in lower prices for existing products.

Our Hispanic business, and community as a whole, depend upon readily available and reasonably priced products affected by this Act.

The pharmaceutical industry has been the most successful high technology industry in the world economy, leader in therapeutic innovation through its ability to discover and develop new drug products.

This has permitted the creation of new employment and our Hispanic community is well represented in these ranks. Your efforts in support of this Act will permit us to further increase our work force in this high technology industry in an effort to reduce our above national level underemployment.

Your support will turn the tide in the declining U.S. position in innovation and decreasing market share for the U.S.-based companies in the future.

Thank you very much for considering our views of the United States Hispanic Chamber of Commerce, its chapters throughout this nation and Puerto Rico, and its over 30,000 member business community.

Sincerely,

Hector Barreto
President

HB/kat

829 Southwest Boulevard Kansas City, Missouri 64108 816-842-2228

napim
NATIONAL ASSOCIATION OF PRINTING INK MANUFACTURERS, INC.
550 Mamaroneck Avenue, Harrison, New York 10528 / 914-698-1004
JAMES E. RENSON, Executive Director

August 8, 1983

The Honorable Charles Mc. Mathias, Jr.
Chairman, Sub-Committee on Patents, Copyrights & Trademarks
U.S. Senate
Washington, DC 20510

My dear Senator Mc. Mathias:

The National Association of Printing Ink Manufacturers (NAPIM) would like to comment on S.1306, the Patent Term Restoration Act of 1983 on behalf of the printing ink industry. NAPIM is a trade association representing small, medium and large printing ink manufacturers in the United States and accounting for nearly 90% of total U.S. printing ink production. There are about 213 ink companies in the United States and most of them are small, privately owned businesses.

We believe that legislation is necessary to grant a recovery period of up to seven years of patent life lost due to government mandated testing and review. The Toxic Substances Control Act requires that new chemical products undergo years of premarket testing and federal agency review before they can be marketed and during much of this time patents on these products are elapsing. NAPIM believes that this shortening of the marketable patent term seriously decreases incentive for investment in research and development on new products.

The printing ink industry is vitally dependent on new technology in such chemical products as pigments, resins and other specialty chemicals. While we strongly concur in the objectives of the Toxic Substances Control Act, it must be acknowedged that the premarket testing requirements of this Act do pose a deterrent to new developments which are vital to the printing ink industry. The loss of marketable patent terms resulting from the extensive testing requirement poses a further deterrent to research and development. For this reason, NAPIM believes that chemicasls subject to PMN under the Toxic Substances Control Act should be eligible for patent life recovery as proposed by S.1306.

Therefore, NAPIM thanks you for your sponsorship of S.1306 and urges that every effort be made to enact this legislation.

Sincerely,

James E. Renson
Executive Director

jjr

UNITED STATES HIDE, SKIN & LEATHER ASSOCIATION

1707 N STREET, N.W., WASHINGTON, D.C. 20036 (202) 833-2405

August 8, 1983

Hon. Charles McC. Mathias
387 Senate Russell Office Building
Washington, D.C. 20510

Dear Senator Mathias:

The United States Hide, Skin & Leather Association is the national trade association representing the hide and skin industry. Our membership includes meat packers, hide processors, brokers, dealers and exporters. We wish to express our support for Senate Bill 1306, the "Patent Term Restoration Act of 1983".

Our trade is dependent upon the agricultural and specialty chemical industries for products which are used to preserve hides and also for those products used to treat animals to insure high quality hides. The inequity in the patent system works as a disincentive to our suppliers and makes the development of new products more expensive and at times uneconomical. We are concerned that unless the problems are resolved, the supply of products which is important to our trade will disappear.

We urge you and your colleagues to act favorably on this legislation.

Sincerely,

Jerome J. Breiter
President

JJB/sa

NATIONAL PEST CONTROL ASSOCIATION, inc.
P. O. Box 377 • 8100 Oak Street
Dunn Loring, VA 22027 • (703) 573-8330

protecting our health and property

August 10, 1983

The Honorable Charles McC. Mathias
Senate Russell Building
Washington, DC 20510

Dear Senator Mathias:

We wish to support the Patent Term Restoration Legislation (S.1306) which you have sponsored and introduced in this session of the legislature. We urge your continuing efforts to have this legislation passed in this session of congress.

Thank you for your help in this important industrial concern that effects the price of products used by members of our industry.

Sincerely,

A. Jack Grimes
Director of Government Affairs

AJG/adn

Founded 1914

Suite 1120
1001 Connecticut Avenue, NW
Washington, DC 20036

CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

202/872-8110

PRESIDENT
RALPH ENGEL

August 12, 1983

The Honorable Charles Mathias
U. S. Senate
SD-317 Dirksen Senate Office Building
Washington, D. C. 20510

Dear Senator Mathias:

I respectfully request that these comments be included in the hearing record on S. 1306, the Patent Term Restoration Act of 1983.

CSMA has a membership of nearly 400 firms engaged in the manufacture, formulation, distribution, and sale of insecticides; disinfectants and sanitizers; detergents and cleaning compounds; automotive chemicals; and waxes, polishes, and floor finishes for household, institutional, and industrial uses. A significant number of these products have pesticidal claims and are, therefore, subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Patent Term Restoration Act.

Several hearings were held on S. 1306 between June 22 and August 2, 1983. We respectfully urge this subcommittee to mark up this much-needed bill, and move it through the legislative process.

Since Congress enacted the first U. S. patent laws, an innovator of a new product or method has been entitled to exclusive commercial control of it for 17 years. This method was intended to encourage and reward innovation and, thus, provide for disclosure of inventions.

Because of federal agency registration requirements which must be met before a patented product can be brought into the market, the effective 17-year patent life of the product is greatly reduced. As a result, the ability of a company to recover its research and development expenditures and developmental costs, and stake out a share of the market, is likewise reduced.

In recent years and especially since the early 1960's, new federal laws and regulations of such agencies as EPA and FDA have led to a steady lengthening of the pre-market testing and clearance process. Recently, EPA estimated that patent life for chemical products has been reduced to about 12 years, including household products for the home, lawn and garden. We suspect that it is closer to 10 years.

Substantially shortened patent terms provide insufficient time for companies to recover their investments. In a very real sense, the curtailment of incentives to pursue important technological advancements operates against the

public interest by depriving people of important products in addition to the jobs required to produce them. Exacerbating the problem is the increased competition from foreign companies which threatens our country's traditional role as the world leader in innovation.

Legislation was introduced in the 96th and 97th Congresses to restore some of the patent life lost due to federal agency review requirements. While a bill passed the Senate in 1981 and had the support of almost two-thirds of the members of the House in 1982, it died in the House Rules Committee during the final days of the 97th Congress.

S. 1306 is substantially the same as the bill which passed the Senate, except for its inclusion of patent restoration for "process" patents in addition to "compound" and "use" patents. Specifically, the bill would restore up to a maximum of 7 years the patent life for chemical products regulated under the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, equal to the marketing period lost between the time that significant animal studies are commenced and the product is registered by the EPA or is lawfully permitted to be manufactured.

We at CSMA support S. 1306 because it would:

- o Restore some of the patent protection lost in the Federal regulatory process.
- o Sustain the incentive needed for our member companies to continue to invest long-term capital in research and development.
- o Enable U. S. chemical specialty companies to maintain their leadership position internationally.
- o Correct a present inequity in the system which denies appropriate protection to regulated products.
- o Especially benefit small businesses for which the contribution of innovation is proportionately greater than for large companies. Lengthened patent protection for them provides long-term stability to enhance cost recovery and outside financing opportunities and to make additional investments in capital and employment.

We believe that patent life should be restored for chemical specialties products which are lost due to federal agency pre-market testing and regulatory review requirements.

We respectfully urge the passage of S. 1306. We thank you and the subcommittee for considering this important matter.

Sincerely,

Ralph Engel
President

RE:mk

socma SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION, INC.
1075 CENTRAL PARK AVENUE, SCARSDALE, N. Y. 10583 • (914) 725-1492

August 15, 1983

The Honorable Charles McC. Mathias, Jr.
Chairman, Subcommittee on Patents,
Copyrights and Trademarks
Committee on Judiciary
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

The Synthetic Organic Chemical Manufacturers Association (SOCMA) strongly supports S. 1306, Patent Term Restoration legislation, and urges the Subcommittee to report this bill shortly after the Labor Day recess. SOCMA is a non-profit trade association representing over 100 organic chemical companies, the majority of which are small companies with annual organic chemical sales under $30 million. SOCMA member companies produce more than 5,000 distinct synthetic organic chemical products for various industrial uses which are regulated by the Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA).

Under TSCA, any party seeking to manufacture a new chemical substance must submit a premanufacture notice (PMN) with supporting information to EPA prior to the manufacture and sale of the substance. Recent EPA studies have shown that these premanufacture notice requirements have had a disproportionate adverse impact on small chemical company innovation. These small chemical manufacturers are highly innovative and are responsible for the development of many new chemical substances which enhance the quality of life. Typically, small firms engage in low-volume chemical production which has low profit potential. As a result, the regulatory costs associated with the PMN process often far outweigh the potential return on investment for these low-volume chemicals. To help offset these government-created disincentives to innovation, Congress should restore some of the valuable patent life lost on substances subject to regulation under TSCA.

SOCMA believes that S.1306 will promote small chemical company innovation by helping ensure an adequate return on investment since all new chemical substances are subject to federal premarket testing and review. Moreover, this legislation will promote voluntary testing on the part of industry by allowing for additional patent life based on time spent performing "major health or environmental effects tests." It will give small innovative firms an economic foundation which would justify the cost of performing long-term tests. In the long run, this legislation will encourage product safety and it will also ensure that new low-volume products which are beneficial to the public will be made available.

In sum, Patent Term Restoration legislation, as embodied in S.1306, will correct a serious inequity in the patent system and stimulate domestic research and development which is so badly needed at this time. In addition, it will encourage innovative firms to perform long-term tests which will help to ensure product safety.

For these reasons, SOCMA encourages you and the Members of the Subcommittee to report favorably this worthwhile legislation.

Sincerely,

Ronald A. Lang

Ronald A. Lang
Executive Director

THE WISTAR INSTITUTE

HILARY KOPROWSKI, M.D.
DIRECTOR

WARREN B. CHESTON, Ph.D.
ASSOCIATE DIRECTOR
(215) 898-3706

THIRTY-SIXTH STREET AT SPRUCE
PHILADELPHIA, PA. 19104

August 15, 1983

The Hon. Charles McC. Mathias
Chairman, Judiciary Subcommittee on
Patents, Copyrights and Trademarks
137 Dirkson Senate Office Building
United States Senate
Washington, DC 20510

RE: H.R. 3502

Dear Senator Mathias:

I am writing on behalf of The Wistar Institute in support of H. R. 3502. The Wistar Institute is a non-profit, independent biomedical research institute receiving most of its support in the form of grants from The National Institute of Health. Two viral vaccines in widespread use in the United States, a rubella vaccine and a vaccine against human rabies, were developed by Wistar and commercialized by American pharmaceutical firms.

We believe that some recognition must be made of the time consumed by U. S. regulatory agencies in reviewing applications for licensing certain products for sale and use in the United States.

The Wistar Institute has had some experience with the effect of the U. S. Bureau of Biologics procedures on the duration of Wistar's proprietary rights in U. S. Patent No. 3,397,267 "Method of Producing Human Rabies Vaccine" issued on August 13, 1968. The rights Wistar holds under this patent were granted to it in a Letter of Determination issued by the Assistant Secretary of Health and Scientific Affairs on February 16, 1969. Wistar's commercial licensee in the United States is Wyeth Laboratories, Inc. of Radnor, Pennsylvania. Wyeth began its attempt to obtain B.O.B. marketing approval for its human rabies vaccine based on the Wistar held patent on May 20, 1977. Approximately six years elapsed before Wyeth was granted marketing approval.

Under the existing patent laws, Wistar's proprietary rights in the human rabbies vaccine will expire in August 1985. As a consequence, Wistar's patent will expire 3 1/2 years after Wyeth was able to market a rabies vaccine. This is significantly less time than Wyeth spent attempting to obtain marketing approval from the B.O.B.

Our concerns in this matter are quite parochial. It is true that Wistar will only earn some royalties from sales of the human rabies vaccine in the United states by Wyeth based on an unexpired patent. Although much of the research which led to the development of the human rabies vaccine was sponsored by the U. S. National Institutes of Health, Wistar itself subsidized the research using its own funds. With such a brief time remaining on the life time of Wistar's patent, it is unlikely that Wistar will earn enough royalty income to compensate for its subsidy. If a patent term restoration statute had been in place which extended patents for a sufficiently long period, Wistar would have been able to recover its subsidy through earned royalty income.

The human rabies vaccine example discussed above is typical of the situation which arises in attempting to get a biological product approved for marketing in the United States. The Bureau of Biologics is required by law to examine very carefully the safety and efficacy of any biological material before issuing marketing approval. Somehow the Congress must recognize this responsibility of the B.O.B. without unduly restricting the proprietary rights of patent holders and their licensees by fixed term patents. H.R. 3502 is an excellent approach to this matter.

Sincerely yours,

Warren B. Cheston

Warren B. Cheston
Associate Director

IPO INTELLECTUAL PROPERTY OWNERS, INC.

August 16, 1983

The Honorable Charles McC. Mathias, Jr.
Chairman, Judiciary Subcommittee on Patents,
Copyrights and Trademarks
United States Senate
Washington, DC 20510

Dear Senator Mathias:

On behalf of Intellectual Property Owners, Inc., I am writing in support of S.1306, the "Patent Term Restoration Act of 1983."

IPO is a nonprofit association whose members own patents, copyrights and trademarks. Our members include large corporations, small businesses, universities and individuals. Our members include companies from most of the major fields of American industry.

IPO believes that the incentives provided by the patent system are responsible for much of the research conducted in the United States. A major factor affecting the strength of patent incentives is the length of the patent term.

Overwhelming evidence has been presented to your subcommittee that the effective length of the patent term for pharmaceutical inventions and agricultural chemical inventions is many years shorter than the 17 year term enjoyed by other inventions. The effect which Federal regulatory review has on patent life was never foreseen or intended by the Congress.

IPO believes the benefits of patent protection should be available to the same extent for innovators in all fields of technology. Any other policy not only is unfair but deprives the American public of the benefits of new technology in the fields adversely affected.

S.1306 would have a positive influence on competition in the pharmaceutical and agricultural chemical industries. The stronger incentives provided by restored patent terms would make available improved products and a greater variety of products.

These additional products in many cases would compete with products already on the market. In the long run this would mean lower prices for consumers and a stronger national economy.

We urge early, favorable action on S.1306.

Sincerely,

Donald W. Banner

Donald W. Banner
President

DWB/ntc

August 5, 1983

The Honorable
Charles McC. Mathias, Jr.
Chairman
Subcommittee on Patents, Copyrights
and Trademarks
SR-198 Russell Senate Office Building
Washington, D.C. 20510

Dear Senator Mathias:

Enclosed is the prepared statement of the Animal Health Institute in support of your bill, S. 1306, the "Patent Term Restoration Act of 1983." We request that this statement be included in the published hearings of your subcommittee. AHI commends you not only for sponsoring this important legislation, but for holding hearings expeditiously.

A related matter, the "exportation" of U.S. jobs, was touched upon July 19 in the testimony of Mr. Jack D. Early, president of the National Agricultural Chemicals Association. He noted that "U.S. agrichemical companies that depend upon the patent system manufacture their products domestically, resulting in the creation of many jobs. As the patent system becomes less dependable by virtue of shortened patent life, export of these jobs to foreign copiers will occur."

The Animal Health Institute agrees with NACA that the diminished patent terms currently available to innovative U.S. companies, and the prospect of ever earlier "me too" competition from abroad, are additional factors that discourage R&D investments. In this same vein, AHI has long advocated modification of the Federal Food, Drug, and Cosmetic Act to permit the domestic manufacture "for export only" of animal health and nutrition products that are not approved for U.S. marketing. We have drafted amendments to the Act that would eliminate these export prohibitions while at the same time making certain that the products manufactured here for export were fully acceptable to the destination countries and that they would create no public health or safety hazards. We mention this subject because it relates also to the loss of domestic jobs and revenues.

If you would like AHI to elaborate upon any aspect of our prepared statement, or upon the additional matters discussed in this letter, please do not hesitate to contact me.

Very truly yours,

Fritz Kessinger

Fritz Kessinger
Vice President - Government Relations

Encl.

FK:dbk

119 Oronoco Street • Box 1417-D50 • Alexandria, Virginia 22313 • Telephone: 703/684-0011

PREPARED STATEMENT OF THE ANIMAL HEALTH INSTITUTE

The Animal Health Institute is the national trade association representing the principal U.S. manufacturers of animal health products, including pharmaceuticals, feed additives and biologicals used in livestock and poultry production and those used to treat household pets and horses. AHI represents fifty-five companies, which by virtue of our criteria for membership must be engaged in research. In 1982 alone, based on a membership survey, it has been estimated by the independent accounting firm Ernst & Whinney, that AHI members spent $191.0 million in research and development.

AHI urges enactment of S. 1306, the Patent Term Restoration Act of 1983, to restore patent life lost during regulatory review of new animal drugs and other chemicals. Enactment will restore important incentives for research into new animal drugs to maintain the vitality of animal agriculture and an abundant food supply.

Of the nearly two billion dollars in U.S. manufacturers' level sales of animal health products in 1982, sales by members of the Animal Health Institute totaled over 1.32 billion dollars. These products have proven to be invaluable tools to the producers of America's livestock and poultry. They are essential to the well-being of American agriculture and, consequently, of the American consumer. The animal health industry plays a major role in putting billions of pounds of red meat and poultry, eggs and dairy products on the dinner tables of American consumers. A further contribution of the industry which should not be overlooked is safeguarding the health of our pets. Dogs, cats, horses, and even wildlife benefit from the items marketed by animal health product manufacturers.

Of the almost 200 million dollars our members spent on research last year, 85% -- over 160 million dollars -- paid for innovative research in the search for new animal health products. To justify the tremendous expenditures by the industry for this type of research, a fair return on investment dollars must be anticipated. Such compensation for research activities was recognized by the

leaders of our country nearly two hundred years ago. Exercising an explicit provision of the Constitution, the U.S. Congress in 1790 adopted the patent system, with the major goal of encouraging innovation. The 17-year span of patent protection was established by Congress in 1861, and that time period ostensibly remains in place today.

Manufacturers of animal health and nutrition products are finding, however, that in reality, patent protection exists for much less than 17 years. A substantial amount of this patent protection loss can be attributed to the U.S. regulatory approval system for animal health products. Patent-life loss has come about with the lengthening of drug approval procedures starting with the 1962 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic (FD&C) Act. These amendments created massive requirements for efficacy data for both human and animal drugs. This loss has become even more dramatic since 1968, when the Animal Drug Amendments became part of the FD&C Act and primary administrative responsibility for these products was given to the newly-crated Bureau of Veterinary Medicine (BVM). However, because products intended for food-producing animals were considered part of the human food supply, authority over the human food safety aspects of these products remained vested with the Bureau of Foods, which, prior to 1968, had regulated animal drugs used in food-producing animals under the food additive provisions of the FD&C Act. This dual jurisdiction existed until this year, when responsibility for human food safety activities was moved to the Bureau of Veterinary Medicine, thus consolidating the total approval process in that Bureau. Unfortunately, it is too soon to tell if this much sought consolidation of regulatory responsibilities will have the effect of accelerating the animal drug review process.

But the separation of authority between two Food and Drug Administration Bureaus is just one factor that has contributed to the lengthy delays animal health product manufacturers must endure to gain approvals to market new products. Numerous causes have been identified by our industry as contributing to the lengthy approval process. The excessively long periods during which products languish in the regulatory process, especially compared to approval time in nations with comparable regulatory systems, has become known as the "animal drug

lag". AHI has prepared an extensive paper on this subject, which is attached to this statement (Appendix A). This paper lists a number of suggestions our industry has made for improving the animal drug approval process in the United States.

Based on data provided by our member companies, the average length of time necessary to obtain Food and Drug Administration approval a of new food animal drug from the time of the Investigational New Animal Drug Application (INAD) to formal approval of the New Animal Drug Application (NADA) is approximately 6.5 years. Not so coincidentally, for the same products the average patent time lost is 6.1 years. Since major research investment decisions are largely based on prospects for patent coverage of the results, a shortened patent term inherently affects R&D investment. Moreover, fundamental fairness is being denied holders of patented products that undergo lengthy approval processes prior to marketing. Congress' intent -- that all inventions be accorded equal protection -- is being thwarted. We therefore applaud the scope of S. 1306 that would "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."

Even if the regulatory review period is shortened through administrative efficiencies, the time savings are not likely to redress this inequity. In any event, a shortened review period would simply mean a shortened period of patent term extension.

Some specific examples which have been provided by our member companies are offered for the subcommittee's consideration:

- For one company, a composition patent on a product was granted in November 1975, three months after the initial INAD filing. Approval of this product has yet to be granted. If it were approved today, 8-1/2 years of the product's patent life will have already expired. This same product received marketing approval in the United Kingdom in September 1979. Ironically, this product was granted BVM's "Fast Track" status in July 1980. "Fast Track" is a system for the priority review of New Animal Drug Applications for innovative, therapeutically-important

drugs which are new chemical entities. It has been nearly three years since this drug received fast track status and yet it still remains to be approved despite diligent attempts by its manufacturer to expedite approval. The first European approval of this product was granted in Ireland in January 1978.

- Another company has lost nine years on one form of a newly-approved product, and more than ten years to date on a yet-to-be-approved form of the same product. Patent protection for this product was received in 1972, a year before the company filed its INAD with the Bureau of Veterinary Medicine. One form of the drug was finally approved in 1982; the company is still awaiting FDA approval of a second form.

- In December 1970, Pfizer received patent protection for Morantel, a beef and dairy cattle anthelmintic. The INAD on Morantel was filed in July 1970, and more than 11 years later, in October 1981, the NADA on this product was granted FDA approval. Close to 11 years of patent protection were lost. This same product received regulatory approval in the U.K. in 1970.

- Another of AHI's member companies has lost more than 11 years to date on a yet-to-be-approved product. The INAD for this product was filed with FDA in November 1972; the NADA was filed one year later. Patent protection for this product was granted in February 1972. This same product received clearance in the U.K. in August 1976, just slightly more than one year after approval was sought by the company.

- One final example. In 1972 the Upjohn Company filed an INAD on Dinoprost Lutalyse with FDA and received patent protection in the same year. This product was finally approved seven years later, with an attendant loss of patent protection. This same product was approved in the U.K. in 1975, following a 10-month review period.

The attached chart (Appendix B) gives additional examples of patent protection loss on our industry's products.

These examples clearly and dramatically serve to underscore the necessity of passage of S. 1306, the Patent Term Restoration Act. In addition to FDA regulation of our member companies' drug products, our biological producers are subject to the regulations of the U.S. Department of Agriculture under the Virus-Serum-Toxin Act, and makers of animal pesticides must adhere to the rules of the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA) to manufacture and market their products. As it should be, relief in all these areas is covered by the proposed legislation.

In addition to the equitable aspects of the legislation, other factors should not be overlooked. Modern animal drugs and biologicals make a major contribution toward controlling and treating animal diseases and in preventing costly epidemics. Animal health products fall into three major categories: biologicals which provide immunity to a disease, dosage-form pharmaceuticals which are used to treat, prevent or control disease and eliminate infectious conditions and finally, animal feed additives which are used to curb disease incidence and to improve feed efficiency by reducing the time and amount of feed needed to bring farm animals to top market weight. Products to protect the health and promote the growth of meat-producing animals give the producer the capability to obtain maximum yields from the resources available. Thus, the producer receives a fair return from his operation and assures the availability of meat and poultry products at a fair price to the consumer.

Going beyond U.S. shores, the animal health products industry also has the potential to make a contribution. It has been projected that, in the coming decades, food animals and fish will be the most significant sources of high quality protein available to mankind. As new food production technologies, which include animal health products, are passed on to the rest of the world, underdeveloped countries may eventually find ways to end suffering from protein starvation and ease the resultant socio-economic pressures. These benefits will depend, however, upon the U.S. dollars invested in research under the prevailing expectations for profitable returns.

Improved animal genetics, together with use of new animal health and nutrition products, have made it possible to produce more high quality protein for human consumption from fewer acres of land and fewer pounds of food. The health of food animals is a major factor in the production of high quality meat, poultry, milk and eggs in large supply.

Research and development within the pharmaceutical and chemical industries have aided significantly in making large-scale production of livestock and poultry possible. However, as stated previously, investment in the research and development of products such as animal drugs and biologics that require lengthy governmental approval is discouraged by shortened patent lives. A decline in new animal drug introductions has paralleled the decline in real patent life and must be reversed. Increasing research incentives will stimulate the flow of new and improved dosage forms, feed additives, and biological drugs for the livestock and poultry industries to use to attack the current billions of dollars in disease losses and condemnations. Reducing livestock and poultry losses and improving growing efficiency ultimately benefits the consumers of animal-derived protein products.

As a result of the 17-year patent clock ticking away during the drug regulatory approval process, a significant portion of the expected patent term that rewards innovation and research is lost for important new animal drugs, pesticides and biologics. By correcting this inequity in the patent system, the pending patent term restoration legislation will help to renew incentives for research into the development of significant new products to benefit the livestock and poultry industries. These new products, through improvements in animal husbandry, will ultimately benefit the American consumer.

APPENDIX A

An

Animal Health Institute

Position Paper

On

"THE ANIMAL DRUG LAG"

EXECUTIVE SUMMARY

Drug lag, recognized as a problem that has delayed access to pharmaceuticals in human medicine, also is an important problem for those trying to protect the health and increase the productivity of food producing animals. The animal drug lag delays the introduction of new animal health technology in the U.S. Because of this drug lag, useful animal health products are often available to livestock producers and veterinarians in western Europe years before they are approved for use in the United States.

The extent of animal drug lag is documented in a "Drug Lag Report"* prepared by the Animal Health Institute, a trade association representing the producers of most of the animal health and nutritional products used in the U.S. AHI has also examined the reasons for drug lag in the U.S., and developed recommendations for its reduction. AHI finds the problem primarily arises out of the administration of the Food, Drug and Cosmetic Act by the U.S. Food and Drug Administration. AHI's findings and recommendations have been presented to and discussed with FDA leadership.

AHI finds that the animal drug lag:

> . . . deprives consumers of substantial economic benefits which result from reducing costs of food production
>
> . . . impedes the effort to reduce disease in food animals which the U. S. Department of Agriculture estimates still costs farmers $12 billion per year
>
> . . . delays access to useful and proven products which can improve food animal health production efficiency
>
> . . . unnecessarily increases the cost of developing and marketing new animal health products
>
> . . . discourages animal health research and development efforts by U.S. firms
>
> . . . reduces the efficiency of FDA personnel engaged in reviewing and approving New Animal Drug Applications (NADAs)

*Copies of the report are available from AHI upon request.

AHI recommends that FDA reduce the animal drug lag by:

> . . . reducing requirements for metabolism data to that required to assure safety to consumers
>
> . . . initiating tissue residue validations early in the review process
>
> . . . placing all animal drug application review responsibility within the FDA's Bureau of Veterinary Medicine (BVM)
>
> . . . revising guidelines for approval of combination drugs
>
> . . . adhering to statutory time requirements in responding to NADAs and indicating all noted deficiencies in the first response to the sponsor of the new product
>
> . . . eliminating entirely the requirement that the approval of an NADA be published in the Federal Register

This position paper documents the impact of the animal drug lag, using the results of the "AHI Drug Lag Report," and explains AHI's recommendations for the elimination of this problem.

The FDA should act promptly to eliminate the animal drug lag. Its actions and success in this effort should be seen as a measure of the efficiency with which it meets its statutory responsibilities and the economy with which it spends budgeted, taxpayer funds. Elimination of the drug lag is important to livestock and poultry producers, animal health professionals, consumers, Congress and the animal health industry.

INTRODUCTION

The animal health industry has played a key role in helping agriculture meet the growing consumer demand for an adequate supply of wholesome and economical meat, dairy and poultry products. The industry supplies health and nutrition products which have been approved by the U.S. Food and Drug Administration (FDA) for use in food-producing animals. These products have made possible dramatic improvements in livestock health and productivity.

Yet disease losses are still huge: U.S. Department of Agriculture's (USDA) Agricultural Research Service estimates they cost farmers $12 billion a year. The animal health industry is committed to reducing those losses. In 1981, members of the Animal Health Institute (AHI), which represents the producers of most of the animal health and nutritional products used in the U.S., spent more than $182 million on research and development.

However, research and development is not enough: the compounds developed must be approved by the FDA in order to reach America's farms before any benefit is achieved. This process often takes much longer than is necessary to assure safety and efficacy. Regulatory approvals which can require only a few months in western European nations may take years in this country.

The animal health industry provides nutritional and medicated feed additives, pharmaceuticals and biologicals which prevent or cure disease, improve production efficiency and permit food-producing animals and poultry to more nearly achieve their genetic potential. In addition, by reducing the threat of devastating epidemics, animal drugs reduce the risk inherent in assembling large numbers of animals in the efficient production units essential to producing food economically.

Prevention or effective treatment of disease is essential to providing high quality meat, poultry and dairy products at prices consumers can afford. Products of the animal health industry which increase production efficiency also save consumers billions of dollars a year. While it is difficult to determine the total savings, economists have calculated that the growth promotion and feed efficiency benefits of adding antibiotics to animal feeds save consumers more than $3.2 billion annually.

Animal agriculture in the U.S. is as diverse as are Americans themselves. Swine raised in Georgia face completely different environmental, disease and management influences than those reared in Iowa. Cattle on Nevada rangeland have different needs and problems than those in a Nebraska feedlot. Disease, nutrition and stress problems can be different on farms a state apart. A wide variety of animal health products are essential to meeting a wide variety of animal health needs. Thus, regulations and policies which discourage the development or delay the introduction of new products place a serious, often unjustified, burden on food production.

SAFE AND EFFECTIVE

The Food, Drug and Cosmetic (FD&C) Act under which animal drugs are regulated requires that the drugs be effective for the use intended, safe for the animals in which they are used and safe for people consuming food produced by the treated animals.

Efficacy is first studied in the laboratory. If the results are promising, the drug undergoes controlled field testing.

Once the new compound is approved for marketing, most farmers do their own testing for effectiveness: each closely observes the results of its use in his own operation. While one farmer may be pleased with the results, another may find a different compound performs better under his operating conditions.

Laboratory and field testing also yield information on the compound's safety for the animals in which it is to be used, as well as safety to the environment.

However, the primary concern is the compound's safety to consumers. Testing for consumer safety has grown from 37 percent of the cost of developing a new animal drug in 1974 to 57 percent in 1977. In addition, substantial sums are spent to answer new questions about animal health products already approved for marketing. Such "defensive" research cost nearly $33 million in 1981, 18 percent of the industry's total research and development expenditures for the year.

Testing for human safety is conducted using laboratory animals. Depending on the nature of the compound and its intended use, studies range from short term (90-day) tests to determine toxicity to lifetime and multiple generation studies to determine whether the drug may cause cancer or have adverse effects on reproduction. Testing involves administering the compound to groups of animals in various doses ranging up to a "maximum

tolerated dose," the highest level at which the animal will tolerate the chemical. The object is to determine both what happens with maximum exposure and to determine the level at which no effect of any kind is observed.

Other studies determine what happens to the drug when it is administered to the animals for which it is intended, and how rapidly it is eliminated from the animals' edible tisaues and organs. These metabolism studies reveal whether residues of the compound may appear in edible products at the time the animal or its products are marketed.

If residues are going to be found in food, FDA's Bureau of Foods establishes a safe residue level or "tolerance" which is no greater than one-one hundredth of the "no effect" level in laboratory animals. To assure this safe level, a withdrawal period will be established. This is a period of time before the animal's meat, milk or eggs can be marketed during which the compound must not be used. Such withdrawal times permit the drug to be eliminated from the animal's system so no illegal residues will occur. The drug producer, or sponsor, must develop and provide an analytical method to be used to aasure that residues do not exceed the approved tolerance level.

Laboratories operated by the FDA and the USDA validate the analytical method to determine that it gives consistently accurate results. The method is then used in the USDA's extensive drug residue monitoring program to assure that meat, dairy and poultry products do not contain unsafe residues. If an illegal level of drug residue is found, USDA can hold an entire shipment of food animals for additional testing. Future shipments from the livestock producer may also be kept off the market until USDA is assured that the problem which led to the illegal residues has been solved.

The FDA and individual state regulatory agencies also conduct wide-ranging feed manufacturing registration and inspection programs. This system assures that drugs added to animal feeds are in the proper concentrations and the feeds are correctly labeled, so the user is aware of proper use and, if necessary, withdrawal times required.

USDA's Extension Service, the FDA and the animal health industry all conduct programs to assure that users of animal health products have the information necessary to assure safe and effective use of the products. Livestock and poultry producer associations and feed manufacturers all cooperate in these efforts.

The Animal Health Institute (AHI) has established its own educational and information programs urging the livestock and poultry producer to "read the label" and to aasure adequate withdrawal, where required.

RESEARCH AND DEVELOPMENT: MORE DOLLARS FEWER PRODUCTS

To meet the needs of animal agriculture, AHI member companies have given research and development top priority. In 1981, they devoted more than $182 million to research and development (R&D), an expenditure increase of 18 percent over 1980's $154 million.

Although the animal health industry leads many other U.S. industries in apending for new product R&D the payoff in recent years has been disappointing.

The reason is aimple: it is becoming increasingly difficult and expensive to secure regulatory approval of new chemical substances for use as animal drugs. Indeed, AHI points out that the difficulties and costs in-

volved in developing and obtaining FDA approvals for new animal drugs was a factor in the decision of a number of major companies to discontinue such research. (The companies named included Abbott, Shell, Dow, Parke-Davis and Norwich.)

During 1965-67, AHI members spent more than $96 million on R&D, and nine new drugs were approved by FDA. During 1968-70, $136.4 million in R&D produced 15 new drugs.

After 1970, the number of new drugs approved began to decline until during the period between 1976 and 1980 when only four new drugs were approved despite the expenditure of $570 million for R&D. In 1981 only one new chemical entity was approved for use in food-producing animals.

With disease losses costing American farmers $12 billion dollars a year, and costing consumers billions more in increased food prices, it is obvious that many problems remain to be solved. The U.S. needs more animal health products; research should be encouraged, not discouraged.

OTHER NATIONS DO IT BETTER

Drugs developed by AHI member firms frequently are approved for marketing in European nations long before U.S. approval is granted. The following tables show the difference in time required for approval of identical drugs for use in food animals in the U.S. and the United Kingdom.

New Drug	Animal Species	United States Approved	United States Mos.*	United Kingdom Approved	United Kingdom Mos.*
Lincomycin	Swine	1969	19	1977	9
Decoquinate	Poultry	1970	22	1968	11
Monensin	Poultry	1970	27	1973	14
	Cattle	1975	28	1976	12
Carbadox	Swine	1972	46	1975	14
Pyrantel	Swine	1973	38	1966	17
Bambermycins	Broiler	1973	41	1975	32
	Swine	1975	23	1975	32
Virginiamycin	Swine	1974	20	1980	6
	Poultry	1974	24	1978	5
Furosemide	Cattle	1975	98	1974	26
Amoxicillin	Swine	1978	32	1976	15
Dinoprost tromethamine	Cattle	1979	33	1976	5

Over the entire 11-year period, approval averaged 35 months in the U.S. compared to less than half as long, 15 months, in the U.K. Note that in only one case, approval of bambermycins for use in swine, did U.K. approval take a longer period of time than in the U.S. On the other hand, clearance of furosemide which required 26 months in England took more than eight years in this country!

*Number of months from time appropriate application was filed until regulatory approval was received.

Not shown on the table is albendazole, a broad-spectrum anthelmintic effective against gastrointestinal roundworms, lungworms, tapeworms and liver flukes in cattle and sheep. Five months were required for its approval in the United Kingdom in 1978. A New Animal Drug Application (NADA), requesting approval for the same claims approved in the U.K. was filed with the Food and Drug Administration in 1977. Because of a serious liver fluke problem and lack of a therapeutic agent, FDA authorized the sale of albendazole for control of cattle and sheep liver flukes in a limited number of states under a special Investigative New Animal Drug (INAD) approval in 1979. However, in 1981, four years after the NADA was filed, approval which required five months in the U.K. still has not been awarded by FDA.

Another anthelmintic for cattle, morantel tartrate, has been in widespread use in food-producing animals since 1970 in countries outside the U.S. It was approved for use in the U.K. in 1970. At the time morantel was a valuable addition to the then-limited number of available anthelmintic agents. During December 1972, an NADA was filed with FDA requesting approval for the use of morantel as a medicated feed premix to be incorporated into cattle feed for therapeutic (single dose) treatment. All technical isaues except those relating to metabolism and the drug tissue residue assay were resolved by 1974. All metabolism related problems were resolved by 1976. The inability of FDA to validate the analytical method to be used to test tissues residues delayed approval of the NADA until October 1981, nearly nine years after its first submission to FDA. It is ironic that validation of the drug tisaue residue assay should delay the approval of morantel, since the use pattern of therapeutic anthelmintics precludes the finding of violative drug residues in the tissues of animala slaughtered for human consumption.

The cattle anthelmintic market in the U.S. has increased steadily since the introduction of thiabendazole in 1964. During the five years 1975 through 1979, the U.S. sales of cattle anthelmintics were $240 million. If morantel had been approved by FDA within a reasonable period of time after filing of the NADA, for example, three years, the drug sponsor would have been selling morantel during this five year period. If it is assumed that morantel could have acquired 20 percent of the U.S. anthelmintic market total income to the sponsor over this period of time would have been $48 million. A portion of this amount would have been made available for new animal drug research. Thus, the drug lag not only delays the availability of newly discovered animal health products but also delays the discovery of new ones. Since the U.S. patent for morantel expires in 1987, the drug sponsor has only six years of exclusivity instead of the seventeen years intended by Congress when it enacted the patent law.

The bambermycins are an antibiotic complex, comprised of at least four closely related active components, approved as a feed additive in countries outside the U.S. (and for some animal species in the U.S.) to improve the growth rate and feed efficiency of broilers, turkeys, swine and cattle. The history of regulatory approvals in the U.S. and Germany is given below:

Regulatory Review Time of Bambermycins in the U.S. and Germany for Various Species of Food-Producing Animals

Species	Initial Filing	U.S. Approval	Months To Approve	Initial Filing	Germany Approval	Months To Approve
Broiler	6/70	1/73	31	6/65	5/66	11
Turkey	6/74	12/81	90	6/65	10/68	40
Swine	9/73	8/75	23	6/65	10/68	40
Cattle	8/74	Not Approved	?	6/65	10/68	40

In only one instance, that of swine, was a species application review time in the U.S. less than in Germany. The initial drug approval (for use in broilers) took only 11 months in Germany but 31 months in the U.S. Also significant is the fact that although the basic new agent was approved by FDA in 1973, requests for extension of the claims to use in turkeys and cattle are not approved after 83 and 80 months, respectively.

In some cases, drug producers simply abandon hope of securing FDA approval of a new animal drug and withdraw the New Animal Drug Application.

Xylazine is a pre-anesthetic sedative-analgesic which has been used in food-producing animals in countries outside the U.S. since 1969. It was approved for use in Germany in 1969 (regulatory approval took five months) and in the U.K. in 1971. The drug was approved for use in nonfood animals (dogs, cats, horses) in the U.S. in July 1972. An Investigational New Drug Application (INAD) for use in cattle was filed in the U.S. during May 1972 and approved during October 1972. A Supplemental NADA requesting approval for use in cattle was filed during July 1975. In July 1980, after several submissions of additional data and meetings with FDA, the sponsor withdrew the Supplemental NADA on the grounds that the ever-changing and increasing data requirements of FDA had run up the development costs to the point that further expenditures could not be justified even by the substantial market potential.

One combination of antibiotics* has been available for control of mastitis in countries outside the U.S. since 1975. (Mastitis, an inflammation of mammary glands which may be caused by a variety of organisms, is estimated to cost American dairy farmers $225 per cow per year.) An NADA requesting approval for use in mastitis was filed with FDA in March 1971. Because of the impossibility of fulfilling FDA's combination drug guidelines, the sponsor discontinued its attempt to obtain approval of an NADA.

Altogether, an AHI survey in 1979-80 revealed that 35 new chemical entities -- new animal drugs -- available in one or more key European countries (Germany, France, U.K.) are not available for food animal use in the U.S. Indeed, during the decade 1970-79, 24 new animal drugs were approved for use in the U.K. which are still not available to farmers here.

Included are compounds which:

- Treat or prevent bacterial disease
- Control gastrointestinal worms and liver flukes
- Control mastitis
- Combat coccidiosis, an intestinal disease especially damaging in poultry
- Improve the rate of animal growth and/or reduce the amount of feed required per unit of production

Drugs which serve many of the same purposes may be available to U.S. farmers. However, the lack of access to other drugs which are used safely and effectively in other nations reduces farmers ability to respond effectively to the wide range of health and management conditions encountered in this country.

*Benzathin nafcillin, procaine penicillin and dihydrostreptomycin sulfate

WHY DRUG LAG

Several factors identified by the General Accounting Office as slowing approvals for human drugs are generic within FDA, and therefore also contribute to delays in animal drug approvals. Of particular concern are the lack of an impartial mechanism for resolving professional disagreements between industry and FDA, and slow feedback and lack of promptness in notifying drug sponsors of alleged deficiencies in applications. Other major factors are specific to food animal drugs. Among these are:

- o Division of responsibility between the Bureau of Veterinary Medicine (BVM) and the Bureau of Foods (BF) for approval of new animal health drugs for food-producing animals
- o Excessively complex and stringent Bureau of Foods "consumer safety" requirements for approval of drugs for food-producing animals
- o Inefficient Bureau of Foods procedures for validating drug tissue residue assays
- o Unrealistic Bureau of Veterinary Medicine combination drug guidelines

Resolving Disagreements

Good scientists may legitimately disagree on or fail to understand the significance of information developed by research. Because there is no body to resolve such disagreements, the drug sponsor must resort to direct negotiation. Since there is no incentive for a regulator to approve a compound, the sponsor negotiates from weakness.

Slow Feedback

During the years 1976 and 1977, AHI member firms filed nine New Animal Drug Applications requesting approval to market new compounds for use in food-producing animals. The law requires that a response be made within 180 days, yet four of the nine received no response within the mandatory limit and three were answered at 180 days. The time range of responses was 45 to 270 days. In no case was the first response an approval: all were requests for additional information. A drug sponsor can expect a number of such letters before an NADA is finally approved.

In many cases, such letters are based on trivial objections, questions or misunderstandings which could be resolved quickly by telephone. However, the issuance of the letter legally gives FDA another 180 days of review time.

The Bureau of Foods' Requirements

FDA regulations give the Agency's Bureau of Foods principal responsibility for approving the safety of drugs for humans consuming food from treated animals. Each year since its initial participation in the NADA approval process, the Bureau's requirements for metabolism and toxicology data and its drug residue analytical requirements have become more demanding and more difficult to fulfill.

During March of 1979, FDA published a Bureau of Foods-proposed regulation which attempts to define the level at which drug residues can be considered "absent," that is, of no toxicological significance, from food produced by treated animals. This proposal, know as "Sensitivity of Method" or SOM, has not yet been put into final form. However, FDA is informally incorporating many of its concepts into the NADA approval process. (A detailed critique of the SOM proposal is available from AHI.)

Validating Methods for Detecting Residues

A new Animal Drug Application must show that residues will not occur in edible tissues from treated animals, or it must include an analytical method or assay which will assure that residues can be detected reliably. As discussed earlier, such a method is necessary to assure that any residues do not exceed levels established by FDA. Thus it must be simple and rapid enough to give reliable results when used in the USDA residue monitoring program. To assure this reliability, the method must be "validated" or verified by two FDA and one USDA laboratory.

It has been standard practice in FDA that such validation will not be attempted until all other sections of the NADA are found to be "approvable," even though validation may be the most time-consuming part of the process. In the case of the drug morantel, cited earlier, all other parts of the NADA were approvable in 1976. FDA spent more than four years attempting to validate the residue assay. (The same method has been accepted for years in Europe, and has been validated successfully by four independent U.S. laboratories.)

FDA is imposing ever more demanding criteria for residue assay performance on the one hand, and on the other requiring that procedures be "rugged" enough to be conducted rapidly by USDA field personnel without prior instruction. These two requirements are often incompatible.

In addition, when problems or questions arise the chemist attempting the validation is not permitted direct contact with the industry chemist who developed the method. Questions or comments must be relayed through FDA channels via Washington.

The government laboratories which must perform the validation work have other responsibilities. Validation, requested by an outside agency or bureau, becomes simply added work without any special priority. The AHI survey identified three animal drugs in which validating the analytical method for residues required from five to 48 months with an average of nearly two years. FDA has recently said it will reform its residue assay validation policy and allow direct contact between reviewers and the drug sponsor, but more serious problems remain.

Combination Drug Guidelines

To meet the complex needs of animal agriculture and the realities of administering treatment to large numbers of individual animals, good animal health management frequently calls for the administration of two or more animal health products simultaneously. In recent years, it has been nearly impossible to secure FDA approval to market such combinations. FDA's combination drug guidelines have been an issue of contention between FDA and industry for years.

Frequently the primary approval for a new feed additive is of little practical significance without approval to use the drug in combination with

one or more other approved drugs. However, while approval to combine two approved drugs is relatively easy to obtain in other countries, FDA requirements are so stringent that obtaining such approval may be more difficult than securing approval for a new drug.

DRUG LAG CAN BE REDUCED

It is clear that the animal drug lag in the United States is a real problem. It is also expensive. It permits a high level of disease costs and production inefficiency to continue, thus raising the cost of food for consumers. It reduces the well-being of food-producing animals and poultry. It increases the cost of developing new drugs, and thus the cost of drugs to producers. It discourages the investment of additional funds in research and development.

Few of the most important causes of drug lag are inherent in the law. Regulatory reform by the Food and Drug Administration itself can substantially reduce the time required to process New Animal Drug Applications. FDA has begun to make some effort to reduce drug lag. That effort must be expanded to address all the factors which contribute to the problem, and it must be pursued diligently.

The Animal Health Institute has identified, in this paper and directly to FDA, a series of actions which FDA can take to improve the Agency's efficiency, expedite the approval of new animal drugs, encourage research into important animal health problems and increase the number of safe, effective animal health products available to American farmers and veterinarians.

AHI recommendations for FDA actions are reviewed below.

1. FDA should install or enforce management controls which assure that its employees meet statutory time requirements in responding to New Animal Drug Applications. Reviewers should be required to attempt to resolve questions and misunderatandings by telephone before resorting to correspondence. NADA reviews should be organized in such a manner that the first, statutory response notes all deficiencies, if any, in the NADA.

2. Drug metabolism information is important in assessing the potential exposure to residues of people consuming food produced by treated animals. However, such studies are both costly and time consuming. FDA should change its policy to require only those metabolism studies which realistically contribute to a judgment of human food safety.

3. FDA can, under existing authority, and should make more use of advisory groups or third party mediators when the Agency and drug sponsors disagree on scientific questions. Disagreements arise not only over the significance of data, but also over the amount of information necessary to permit an informed judgment on safety.

4. Validation of tissue residue assays is a major factor in alowing approvals of new animal drugs, primarily because validation is not begun until the balance of the NADA is determined to be "approvable" and because of the low priority of this work in validating laboratories. Drug producers do not submit NADAs unless they expect the applications to be approved, and the record shows that most eventually are approved. The time required for NADA approvals will be reduced substantially as FDA initiates the validation process early in NADA review in compliance with existing regulations.

The validation process can also be expected to accelerate as the industry chemists who developed a method are allowed to demonstrate it to the government chemists who must validate it.

5. FDA should revise its combination drug guidelines to eliminate excessive requirements. Such action will improve animal agriculture's ability to respond to the needs of food producing animals while assuring the continued safety of animal-based foods.

6. Animal drugs are the only class of regulated chemicals for which the law requires publication of marketing approval in the Federal Register. Until the law is changed to eliminate this requirement FDA should act to reduce the time interval between approval of the NADA by the Bureau of Veterinary Medicine and publication of the approval in the Federal Register. This time saving can be achieved, in part, by ending the practice of attorneys in the Office of General Counsel questioning the professional judgments of scientists in the Bureau of Veterinary Medicine and the Bureau of Foods.

People at higher management levels of the Food and Drug Administration have displayed a real interest in reducing the time lag between applications and approvals of both human and animal drugs. The Animal Health Institute and its members applaud both this interest and the steps which FDA has taken as a result. More action is required for New Animal Drug Applications to move as expeditiously as possible through regulatory review.

"Zero drug approvals equals zero risk" is not a valid philosophy on which to base regulatory review. People at all levels of FDA have an important role in assuring that American consumers continue to enjoy an abundant supply of wholesome, economical meat, eggs and dairy products from healthy and well-nourished livestock and poultry. FDA can best fulfill this role by seeing that safe, effective food animal drugs reach the market as quickly as possible.

#

ANIMAL HEALTH INSTITUTE

APPENDIX B

EXAMPLES OF PATENT PROTECTION LOSS

COMPANY	PRODUCT(S)	PATENT PROTECTION DATE	DATE OF INAD FILING	DATE OF NADA FILING	NADA APPROVAL	# MOS. TO APPROVE NADA	TIME LOST ON PATENT	U.K. APPROVAL
BAYVET	Praziquantel	May 1977	July 1975	Sept. 1977	Feb. 1981 (dogs) Dec. 1981 (cats)	42 (dogs) 54 (cats)	3 yrs., 10 mos. 4 yrs., 7 mos.	Sept. 1979/ 4 mos.
MERCK	Cambendazole	Feb. 1972	Jan. 1972	June 1973	July 1975	24	3 yrs., 6 mos.	May 1976/ 2 yrs., 3 mos.
PFIZER	Carbadox	Feb. 1968	May 1967		October 1972	46	4 yrs., 9 mos.	Dec. 1975
	Morantel Tartrate	Dec. 1970	July 1970	Dec. 1972	October 1981	106	10 yrs., 10 mos.	1970
UPJOHN	Lincomycin 4 gram	(Compound (April 1963 (	1964	April 1966	May 1970	49	7 yrs.	
	premix	(Composition (April 1964	1972	April 1974	June 1976	26	13 yrs.	Dec. 1977/ 11 mos.
	Dinoprost lutalyse	Dec. 1972	Feb. 1972	Feb. 1977	Nov. 1979	34	7 yrs.	May 1974/ 10 mos.
COMPANY A	Product 1	(Composition- (November 1975 (Use-Oct. 1976	Aug. 1975	Jan. 1983	pending		> 8 years	1979
	Product 2	May 1979	June 1975	Under active development	to be filed		> 4 years	
COMPANY B	Product 1	1972	1973	Form 1 - 1976	Form 1 - 1982	Form 1 - 67	Form 1-9 yrs.	Form 1-1978/ 2 mos.
		1972		Form 2 - 1980	Form 2 - pending	Form 2 - 30+	Form 2- > 10 yrs.	Form 2-1979/ 5 mos.

EXAMPLES OF PATENT PROTECTION LOSS

COMPANY	PRODUCT(S)	PATENT PROTECTION DATE	DATE OF INAD FILING	DATE OF NADA FILING	NADA APPROVAL	# MOS. TO APPROVE NADA	TIME LOST ON PATENT	U.K. APPROVAL
COMPANY C	Product 1	Nov. 1974	Feb. 1979	Oct. 1979	pending		>8 yrs.	1979
	Product 2	Feb. 1972	Nov. 1972	Nov. 1973	pending		>11 yrs.	Aug. 1976/ 1 yr. 3 mos.
COMPANY D	Product 1							
	Species 1	Jan. 1962	Sept. 1972	Feb. 1979	March 1981	24	19 yrs.	1971
	Species 2	Jan. 1962	March 1971	June 1972	Dec. 1974	30	13 yrs.	1971
COMPANY E	Product 1	May 1972	Feb. 1975	not filed			>11 yrs.	March 1981/ 53 mos.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF NURSERYMEN AND NATIONAL ASSOCIATION OF PLANT PATENT OWNERS

This statement is submitted on behalf of the American Association of Nurserymen and the National Association of Plant Patent Owners concerning the Patent Term Restoration Act (S-1306).

The American Association of Nurserymen is a national trade association which represents in excess of 3300 firms engaged in the production, installation and sale of enviromental plants, fruit and nut trees, vines and berries. The National Association of Plant Patent Owners is comprised of 52 members who are involved in the research and development of new varieties of asexually reproduced plants both in the United States and foreign countries.

The bill will restore to the patent holder any time lost by virtue of federally mandated testing or review requirements. Under current law, the patent term commences on the day of the grant. The clock continues to run despite the fact that reviews by other government agencies are required in some instances before the product can be marketed. Examples of these products are pharmaceuticals, agricultural chemicals and imported plants.

Nursery farmers are dependent upon availability of agricultural chemicals not only for production but also to satisfy the phyto-sanitary requirements of state and federal plant quarantine laws. As a consequence, in light of the enormous investment in research and development of a new agricultural chemical, we support S-1306 and urge its enactment.

On behalf of the National Association of Plant Patent Owners, it is recommended that the proposed Section 155 be modified to include plants and trees which are subjected to post entry quarantines under provisions of 7CFR 319.37-7. Satisfaction of this post entry quarantine can in some instances take from 2 or 5 or more years. Plant Patent holders who lose a portion of their protection term because of this regulatory requirement should be made "whole" on the same basis as other patent holders.

This bill would correct a long term inequity to a limited number of patent holders and would be extremely beneficial to the users of their products.

PREPARED STATEMENT OF THE AMERICAN BAR ASSOCIATION SECTION OF PATENT, TRADEMARK AND COPYRIGHT LAW

I am W. Thomas Hofstetter, Chairman of the Section of Patent, Trademark and Copyright Law of the American Bar Association. My statement on S.1306, the "Patent Term Restoration Act of 1983", 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 Meeing 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 long standing 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 encompassed S.255, which was passed by the Senate on July 9, 1981, and its companion bill in the House of Representatives, H.R.1937, and encompasses S.1306.

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.

One such recommendation is the improvement in the patent law represented by S.1306. 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 May 17, 1983 remarks introducing S.1306, there is serious concern that the result of this deterrent to innovation from loss of patent life will not permit the pharmaceutical and agricultural chemical industries to continue to provide the breakthroughs needed by society.

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 S.1306. 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.1306 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 and to one patent applicable to the product as selected by the patent owner.

Moreover, the Section of Patent, Trademark and Copyright Law supports the limited application of this legislation only to the specific purpose of use for which the patented product becomes involved in the regulatory approval and not to the entire range

of product uses that others may find for the patented invention. 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 1983 is also commendable for its use of objectively identifiable criteria to define the applicable "regulatory review period". Under the bill, 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 a 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 S.1306 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.

The enactment in 1980 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 S.1306 and restoring to the life of a patent the amount of time required for government approval of a new product.

PREPARED STATEMENT OF THE
AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES

AUGUST 2, 1983

The American Federation of State, County and Municipal Employees (AFSCME) represents over one million members working in state and local governments around the country. We have severe reservations with S. 1306, the Patent Term Restoration Act of 1983.

Our union represents over 300,000 workers in the health care delivery system. As health care workers and consumers, we are concerned with the escalating costs of health care delivery. As these costs are escalating the federal commitment in terms of Medicare and Medicaid has been declining. While this commitment is in decline, we further see prescription drugs as an escalating cost with no controls. Drug prices alone last year increased at three times the rate of inflation. If patent extension were enacted the monopoly and higher prices would continue for up to an additional seven years.

We know that the pharmaceutical industry is already our country's third most profitable industry -- lagging only to tobacco and oil. And yet extension of the patent monopolies would cost consumers an additional $3 - $5 billion in the next seven years. In its January 17, 1983 issue, Business Week stated that "the pharmaceutical industry is a sure bet as a standout performer in 1983. Its sales this year could increase 20% to $20 billion; its profits, despite continuing losses in currency translations, could grow 15% to $3.5 billion."

The government and the elderly will bear the largest burden if S. 1306 becomes public law. In public hospitals around the country we frequently find 30% or more of a hospital's budget

in the "no pay" category. These costs are from patients who are not eligible for Medicare or Medicaid and do not have private insurance. Therefore, this 30% of the budget has to be made up through the local tax base. To keep costs down hospitals engage in competitive bidding for most purchasing. The Federal Trade Commission has shown us that the price of drugs goes downward sharply when generic equivalent is available. With the extension of patent life, we would deny local governments the ability to have competitive bidding for the purchase of drugs for several years.

In addition, states are running their Medicaid program with the severe cutbacks imposed by the Reagan Administration. States have had to cut back on eligibility and in services provided. Drug prices, which tripled at three times the rate of inflation in 1981, have been called the "last uncapped cost in Medicaid." It is absured that while some states do not provide Medicaid coverage for women carrying their first child, Medicaid must pay $8 for a trade name drug while the generic equivalent would cost just $1.

Over 25% of prescription drugs are purchased by senior citizens who are living on Social Security. Medicare does not pay for prescription drugs. Senior citizens live on a fixed income -- it is not right that their limited dollars should help subsidize the profit of the drug companies.

S. 1306, the Patent Term Restoration Act, is unacceptable to AFSCME and we urge the Committee not to move this bill.

PREPARED STATEMENT OF CONSUMER FEDERATION OF AMERICA
PRESENTED BY ESTHER PETERSON

JUNE 22, 1983

Mr. Chairman and Members of the Subcommittee. I am Esther Peterson and I am here to testify on behalf of the Consumer Federation of America (CFA). I thank you for the opportunity to testify on S. 1306, the Patent Term Restoration Act of 1983.

CFA, which represents over 200 consumer, senior citizen, labor, farm and cooperative groups with a combined membership of over 30 million people, believes this legislation is unfair, unnecessary and extraordinarily costly to consumers and the elderly. Based on over 40 years of experience working on consumer and public policy issues for three Presidents and a major corporation, I agree that this legislation must not pass.

The arguments for and against this bill are by now quite familiar. But perhaps some historical perspective will cast light on why consumers oppose this bill so vigorously. The fight for competition in the drug industry has been a long and exhausting one. Consumers have carried this fight to dozens of state legislatures, where the pharmaceutical companies and their trade associations worked to defeat generic substitution laws. The battle has also been joined in the courts, where the public was forced to go all the way to the U.S. Supreme Court in order to vindicate their right to advertised prices for drugs. Now that those efforts are finally bearing fruit for the millions of senior citizens and ill persons so dependent on pharmaceutical medicines, industry is making a last ditch effort before Congress.

Congress must recognize the enormous stakes riding on the outcome of this legislation. This nation's elderly comprise 11% of the population. Yet they make fully 25% of all drug purchases. As a consequence, seniors will pay a disproportionate share of the estimated $3-$5 billion in drug price increases that Congressman Albert Gore (D-TN) has estimated this bill would impose on consumers.

That economic toll is hard enough to contemplate for the elderly on fixed incomes. But we must push the analysis one step further. Already, AARP finds that 70-75% of the misuse of drugs by senior citizens results from underutilization, most frequently because they cannot afford the medicine that has been prescribed for them. I shudder to think what could happen to these statistics and many of the people that lie behind them if S. 1306 were enacted. As you know, generic drugs can cost as little as 1/8 their name brand equivalent. If the sick and the elderly are denied access to future generics, how many may be forced to choose between heat and medicine? Between eating and buying necessary drugs? Between their rent and their health? All of these choices are possible if Congress passes this bill.

If Congress does choose to act favorably on the legislation before us today, who will reap the benefits of the costs imposed on old and sick people? The answer is as straightforward as it is distressing: Drug companies which, according to financial reports, are doing very, very well.

Let's look at some financial facts about the drug industry. First, it is very profitable--profits rose 25% in 1981, 20% in 1982. Both of these figures are consistent with the industry's admirable record of returning 20% to its shareholders over the last decade. Second, drug company research and development expenditures continue at their robust rate of 11% of sales, a fivefold multiple of the U. S. industry average. Third, as the earnings data indicate, these R&D expenditures provide handsome and long-lasting returns. Despite the expiration of patents, major phramaceutical companies are able to keep a lion's share of the market for their brand name drugs. Last year, the New York Times cited a study that put the market share retained at 97%.

Given their strong financial showing, its not surprising that drug companies' claims about the erosion of their patent terms do not stand up to scrutiny. Take industry's core assertion that drug patent life has dwindled to an average of 9.5 years. When the Office of Technology Assessment (OTA) examined this figure, it found an important flaw. Because the underlying study examined a category of chemicals which produced "the most extreme

reductions in patent life," the claim of 9.5 years was not representative. In fact, OTA's review of eight best-selling drugs showed that they enjoy an average patent life of 15 years.

Similar skepticism should greet the industry's argument that government regulation is the culprit in reducing effective patent terms. FDA statistics reveal that pre-market approval time for drugs is actually dropping, from an average of 37.5 months in 1979 to 31.2 months in 1981. More strikingly, the lag time for the drugs considered most important has fallen from 17 months in 1976-78 to only 10 months in 1979-81.

Finally, the implication that effective drug patent time is shorter than those enjoyed by other products is just not accurate. John Blair's pioneering study of 35 important inventions revealed that an average of 11 years was consumed between patent approval and actual product marketing. What Blair demonstrated 20 years ago is still a fact of business life today. It takes time to get a product to the market--and that's true for all products, whether or not they require extensive governmental action. There's no unfairness foist on the drug industry.

No, Mr. Chairman, the only unfairness in this legislative debate would be the unfairness visited upon the consuming public by a requirement that it pay exorbitant increases in health care costs. CFA cannot support such an effort, nor can I. And to clarify one important historical point, the Carter Administration did not support this type of legislation. Even its Industrial Advisory Committee on Patents and Information Policy--which was composed largely of drug and chemical company lawyers--could not reach a unanimous verdict on patent extension. The failure of an industry committee to agree on this issue reflects what consumers knew then and know now. Drug patent legislation is neither necessary nor appropriate.

Thank you, Mr. Chairman, for giving Consumer Federation of America the opportunity to testify.

PREPARED STATEMENT OF CONSUMER FEDERATION OF AMERICA
PRESENTED BY ESTHER PETERSON

AUGUST 8, 1983

As I listened to the testimony of others at the first hearing on S. 1306, the patent extension bill, I became distressed at the misleading and false claims being made by those supporting patent extension. Because of the respectibility of some of the people who made these claims, there is a great danger that people will take these statements as fact. This is the reason I wish to emphasize a few central points.

To begin with, let me reiterate: this bill does nothing good for consumers. Not a thing. The Pharmaceutical Manufacturers Association had Mr. Engman, their president, tell us that S. 1306 provides something for everyone--greater incentives (in the form of greater profits during patent extension) for the drug industry, and lower prices for consumers. Only the first half of this claim is correct. If this bill provides the cornucopia of goodies that the PMA depicts, why are consumers, labor and seniors united in denouncing it? If it would really give us more and better drugs at lower prices, who would oppose it?

But the fact is, as we all know, that the bill keeps generic competition off the market all the longer. All of us who have had to buy prescription drugs know that generic versions cost less, and often much less, than the branded drug. For example, Lasix, an anti-hypertensive costs $10.65 for 100 tablets from the American Association for Retired Person's pharmacy, but the generic equivalent costs $7.50. Orinase, a drug used to treat diabetes, costs $12.25 for 100, but generically is available for only $5.50. Motrin, a frequently-prescribed anti-arthritic is priced at $18.60, while its identical generic counterpart is only

$14.75. For people regularly taking prescription drugs, the differential can mean hundreds of dollars each year in medical costs. And any clear-thinker can see what is in this for the PMA--greater profits.

Who is to shell out these greater profits? Obviously the additional revenues will come from those who buy prescription drugs--hospitals, clinics, HMOs, state and federal agencies, and the people like you and me. Ultimately, individual consumers, those for whom the drug is prescribed, are going to bear the cost. These are the people who are expected to finance a windfall to the major drug companies--the elderly and the sick, and those who would be sick if not for their medications. Many of these people can scarcely afford their prescription drugs now, as the costs continue to soar at triple the Consumer Price Index. If we compound this problem with a longer patent term, drugs will be unaffordable to those who can just manage today.

It is one thing to ask consumers to pay more by the year for luxury products. But to price items that are essential for the health and survival of our citizens beyond the means of many is cruel. Particularly when the only justification for such a measure is that powerful and wealthy manufacturers want ever greater profits, granting a special favor to the few at excessive costs to the many is a mockery of democratic principles.

Pharmaceutical manufacturers may appear to be "good guys" because of the human suffering reduced by their products. But this impression should not make consumer representatives or Senators fearful to stand up to them. Drug companies, like other businesses, are motivated by profit. They too will take as much as they can get, and as this legislation shows, they too can be greedy.

Those companies promoting the patent extension bill are manipulating all of our fears of illness by threatening to cut research on new medical advances unless their demands for patent extension are met. But these scare tactics must be ignored if we

are to protect the people least able to defend themselves from being ruthlessly exploited by these giant companies. Research will continue as long as return on investment in the drug industry is second only to banking--but the question is: Will only the privileged few be able to afford the benefits of research if patents are extended.

The companies forming the PMA should be ashamed to squeeze the sick and elderly for even more money. But they are not. And they won't stop this campaign until Senators begin to turn a deaf ear to their pleas for another special privilege at consumers' expense.

Prepared Statement of the National Association of Pharmaceutical Manufacturers (NAPM)

The National Association of Pharmaceutical Manufacturers(NAPM), a nonprofit trade association representing a broad cross-section of U.S. generic drug manufacturers and distributors, submits the following statement for the record on "The Patent Term Restoration Act of 1983."

NAPM opposes this legislation.

As proposed by Sen. Charles Mathias(R-Md.), the legislation would extend the marketing monopolies of highly-profitable, brand-name drug companies, thus delaying the entry to the marketplace of generic competition which would result in dramatically reduced drug costs to our elderly and other consumers who need important pharmaceuticals.

The generic drug industry is not opposed to the U.S. patent system, which has provided necessary incentives to important research and development for well over 100 years.

However, NAPM cannot support this proposal to alter drastically the patent system because it flies in the face of stated U.S. national policy to bring our health care system under control through cost containment measures. Simply stated, patent extension legislation would perpetuate inflated drug prices to those members of our society who are least able to afford them.

NAPM believes that if Congress wishes to undertake such a major revision of existing patent law -- especially a revision that would provide continued profit windfalls

to an already highly-successful special interest at the expense of consumers -- it must act on the basis of incontrovertible evidence that the brand-name pharmaceutical industry is in serious need of additional help to assure its continued viability.

Based on the evidence provided to the Senate panel reviewing this legislation, and that submitted to two House panels in 1982, NAPM believes there is overriding doubt as to the need for patent extension.

1. PATENT EXTENSION AS AN "EQUITY" OR "FAIRNESS" ISSUE

The generic drug industry has great difficulty in comprehending the "equity" and "fairness" issue as argued by supporters of patent extension.

The extent of the "inequity" -- the alleged loss of patent protection for high-priced brand-name pharmaceuticals -- often is equated with regulatory requirements imposed by the U.S. Food and Drug Administration.

NAPM points out that whatever the FDA requirements may be, the patent system does not guarantee to a patent holder the right to sell or market an invention. Rather, the patent system grants to an inventor the right only to exclude others from making, using or selling that invention.

Thus, even though a patent holder for a drug may be barred from marketing his product until such time as FDA approval has been granted, he has the same rights as other patent holders who are not required to seek pre-marketing approval from FDA: exclusive monopoly rights to make and use the product and to prevent others from doing so.

The "Mousetrap"

Supporters of patent extension are fond of referring to this legislation as a "fairness" and "equity" measure. They argue that it is unfair for the inventor of a better mousetrap to enjoy longer patent protection than the inventor of an important new drug.

NAPM does not understand the mousetrap analogy because inventors of new drugs do not compete in the same marketplace with inventors of better mousetraps; rather, they compete with other drug inventors, all of whom must play by the same rules of FDA approval. In addition, the patent laws do not guarantee -- and the mousetrap inventor does not receive -- specific marketing rights. As with the studies conducted by the drug inventor, the mousetrap inventor sees some patent protection eaten away by his need to obtain financing, conduct marketing and sales tests and establish manufacturing facilities.

With all due respect to the important contributions made by the brand-name research-intensive pharmaceutical companies, NAPM believes that the performance of laboratory, animal and human clinical studies are, quite appropriately, the cost of doing business in the research segment of the pharmaceutical industry today -- the rewards for which cost are patent protection and the impressive profits and market share realized by that segment. In addition, the fact that a patent has expired does not mean that an innovator's market share is suddenly washed away. On the contrary, the heavy advertising and personal visits to physicians by the drug firms' sales forces tend to pro-

long the vast majority of market share well after patent expiration, for most major drugs.

The Patent System Works -- Very Well

A recent California court decision points up the fact that generic manufacturers face real "equity" and "fairness" issues under existing patent law. In the court's decision in Pfizer v. International Rectifier, a generic manufacturer was found to have infringed upon Pfizer's patent for a drug merely by making the drug for investigational purposes in order to obtain data for submission of an application for approval to FDA.

NAPM notes that, to the extent this case is upheld in other jurisdictions, it will provide a form of de facto patent extension to brand-name firms, by prohibiting generic companies from preparing the data necessary to obtain FDA approval until after a patent has expired.

If, in fact, a generic firm is precluded from conducting tests to gain marketing approval until after the patent on an original drug has expired, then the innovator will, in fact, enjoyed a continued marketing monopoly for the additional three or so years required for the generic firm to conduct tests and obtain approval of its lower-priced version.

Patent extension would, therefore, exist for a period of years beyond patent expiration even without this legislation.

2. THE LEGISLATION AS PROPOSED: "FAIRNESS"?

Even were it established beyond doubt that patent

extension is reasonable approach to creating new research incentive -- which cannot be done -- the legislation as proposed goes far beyond the boundaries of "equity" and "fairness" and thus represents a special interest bill of outrageous proportions. NAPM herein addresses the two key provisions of the legislation now under consideration.

A. Amount of "Lost" Patent Life Eligible For Patent Extension

Developers of new drugs would receive up to seven years' reimbursement for patent life allegedly lost to FDA regulatory review requirements. The reimbursement would cover the time expended between the drug sponsor's initiation of a "major health or environmental effects test" and the date of FDA approval of the product.

Aside from being unsupportably vague, this provision gives to developers of new drugs carte blanche in determining the diligence with which they pursue FDA approval of their potential product.

"Due diligence" in pursuing FDA approval is an important point, NAPM believes, because sponsor delays easily could violate the spirit of the legislation, e.g.,.to provide compensation for patent life lost to FDA requirements.

For example, there are demonstrable instances in which a developer may find it beneficial to withhold from the market a new product that would compete with another of his own drugs already marketed.

Furthermore, and more importantly, the provision seems to imply that companies would market new drugs without con-

ducting any testing at all, assuming the absence of the allegedly burdensome FDA requirements for which they seek compensation. It is, of course, absurd to assume that responsible research firms would rush to the marketplace without some testing, and NAPM does not draw any such inference here.

However, the ethical and moral obligations inherent in providing a safe and effective new remedy to the public requires some form of testing. With or without formal FDA regulations governing the approval of drugs, NAPM believes, extensive animal, laboratory and human testing is part and parcel of doing business in the research-intensive drug industry, and thus is not in and of itself a reason for extension of patent life.

To the extent that patent extension is justifiable in any respect, Congress must consider as eligible for reimbursement only that period of time required by FDA for review and approval of a new drug application(NDA).

Such a limitation would acknowledge the amount of testing that would be expected of any drug developer in the absence of any FDA controls, and would provide extension of patent life only for that period which is most out of the developer's control -- the NDA Review period.

Furthermore, Congress should refuse to provide any patent extension for delays in FDA's review process that are caused by the drug developer, and for any delays in the granting of a patent which are attributable to the drug developer.

B. Application of Patent Extension: Effective Date

As proposed, the legislation would apply to drug products already patented and under review by FDA at the time the legislation is enacted. NAPM strongly opposes this provision, since it goes well beyond any reasonable criterion of "equity" or "fairness."

Simply stated, there is no justifiable reason for extending patent life on a product already patented and under FDA review because no further incentive for research is needed for that product.

That this provision is the most controversial and unsupportable section of the legislation was well -recognized in 1982 by the House sponsor of patent extension at that time, Congressman Robert Kastenmeier(D-Wis.).

During consideration of the 1982 legislation by the House Judiciary Committee in July, 1982, Kastenmeier was successful in urging that patent extension be offered only for drug products patented after the effective date of the legislation.

Kastenmeier explained his rationale in a May 28, 1982 letter to Judiciary Committee Chairman Peter Rodino(D-N.J.) in which he requested a delay in the consideration of his own bill:

> "You may know the legislation has been severely criticized by certain of our colleagues, consumer groups, organized labor and the generic industry as providing unjustified windfall to the pharmaceutical industry." In my view, this criticism was particularly justified with respect to the original bill. Under that legislation, extension of patent term would be granted to products which had already been patented.

> "Yet, the purpose of the legislation is to stimulate investment in new technology; in other words, to encourage investment in products yet to be patented."

Kastenmeier went on to explain to Rodino that he had been successful in amending the legislation to provide patent extension only to products patented after the effective date.

> "The amendment responded to the criticism of opponents (of the bill) because, although the incentive of a definite 17-year term for all new technology will be available to investors immediately upon enactment of the bill, generic pharmaceutical houses and therefore consumers will not experience any negative price impact for nearly 20 years. By that time, the advantages of the bill should have outweighed the negative consumer impact and the now fledgling generic industry should be in a strong competitive position."

It is well-recognized by both supporters and opponents of patent extension that Kastenmeier would have opposed his own legislation had there been attempts to extend its coverage to drugs already patented.

3. THE REGULATORY "BURDEN": FDA REVIEW AND APPROVAL

The premise upon which patent extension legislation is based is that incentives for new research and development have decreased due to "lost" patent life stemming from FDA regulatory requirements.

To the extent this premise is true, NAPM urges Congress to abandon consideration of patent extension legislation in favor of assuring the continuation of FDA's recent progress in reviewing and approving new chemical entities.

Supporters of the legislation claim that it requires between seven and 10 years to clear FDA testing and review requirements before a new drug can be brought to market.

This claim is true only on the most superficial level.

If one takes as a given the ethical and moral obligation of new drug sponsors to conduct extensive drug testing even in the absence of FDA rules, then the only real regulatory "burden" is the length of time that FDA takes in reviewing and approving an NDA.

Supporters of this legislation are fond of citing the phenomenon known as "drug lag," which is a term referring to the delays of the U.S. FDA in approving drugs already marketed overseas.

Without going into the merits of the existence of a "drug lag," it is quite clear that the phenomenon no longer applies. Indeed, the experiences of the U.S. in the thalidomide and Oraflex cases might indicate that a "drug lag" is not per se totally negative.

Furthermore, NAPM believes that the only "drug lag" in existence today applies to the refusal of FDA to permit clearance of safe and effective generic drugs which are equivalent to products no longer under patent.

In any event, FDA has undertaken a massive revision of its NDA requirements in order to facilitate the review and approval of new drugs.

Even though this revision is not yet totally complete, the results of FDA's activities are dramatic:

* As of March, 1982, the mean review time for drugs regarded by FDA's classification system as representing "important" or "modest" therapeutic gains

stood at 11.9 months. This figure, representing 32 approvals granted between October 1, 1978 and March, 1982, compares with a mean of 17.5 months for the previous two-year period, 1976-1978.

* The mean approval time for the 27 new molecular entities approved in 1981 decreased to 30.7 months, down from 34.5 months in 1980 and 37.5 months in 1979.
* Overall, for the 96 NDAs approved in 1981, the mean review time was 24.4 months, down from the 33.6 months required for each of 94 NDAs approved in 1979 (mean review time).

Supporters of patent extension also argue that alleged delays in FDA's review process are resulting in the approval of fewer new drugs. This clearly is not true.

In 1982, FDA approved a record 27 new drug applications, surpassing by one the number of NDAs that received approval in 1981. FDA is doing a better, not worse, job of bringing important therapies to the marketplace.

NAPM would be willing to consider, even support, some form of patent extension if it could be shown, in real terms, that FDA's regulatory review is a true burden in the context of extending patent life. The data is just not there.

4. R&D DATA DO NOT INDICATE INNOVATION INCENTIVE "PROBLEMS"

According to supporters of patent extension, research and development expenditures are increasing because of inflation, but decreasing in terms of real dollars. It is

said the R&D decrease is due in large part to a lack of incentive for new development caused by reduced patent life.

Aside from the fact that the inflation factor has in recent months decreased to its lowest point in years, there exists no data to show that R&D expenditures are decreasing, for whatever reason. Quite the contrary; there has been a steady increase in real dollar terms in drug R&D.

Rather than recite the existing data in detail here, NAPM refers Congress to the report published in 1981 by its own Office Of Technology Assessment("Patent Term Extension and the Pharmaceutical Industry," Library of Congress Number 81-600113). On page 12, the report shows a clear, unbroken steady increase in real R&D expenses, which more than doubled during the years 1975-1978.

Supporters of the legislation, notably the Pharmaceutical Manufacturers Association, argue that the OTA data is flawed and out-of-date. However, PMA has not provided any alternative data to the Congress.

As the representative of production-intensive drug manufacturers, who invest heavily in state-of-the-art manufacturing and quality control techniques, NAPM does not have access to R&D data.

In the spirit of "fairness" and "equity," though, NAPM believes strongly that the Congress should not consider seriously any claims that existing data is flawed when alternative data is not forthcoming.

Finally, with regard to the question of incentive as it relates to R&D expenditures, NAPM points out that, in 1981, the Congress authorized a 25% tax CREDIT for R&D expenses; and in 1982, Congress provided further tax incentives for R&D in the critical "orphan drug" area.

5. PATENT EXTENSION AND PRESCRIPTION DRUG PRICES

Supporters of patent extension insist that it will result in lower prices to consumers, primarily by generating incentives to develop new therapies that may replace more costly surgery or hospital treatment.

This reduced-cost argument is false not only on its face, but also when considered in light of the evidence available.

Of all the arguments put forth with regard to patent extension, none is more true than the fact that the legislation will extend the marketing monopolies of research-oriented drug companies. NAPM notes that it is an equally-well accepted fact that a lack of competition, in any industry, does not tend to result in reduced prices for a given product.

In almost every instance, the availability of generic competition in any drug class has resulted in dramatic cost savings to consumers. It is not unusual for the cost difference to be on the order of several hundred percent.

Even the congressional Office of Technology Assessment, in its report on patent extension, found that under reasonable application of the legislation, consumer costs could be expected to be "one hundred forty percent of the cost without patent term extension."

A more specific, and more dramatic, example of the absurd reduced cost-through-less competition argument is found in the U.S. Defense Department's procurement of the drug metronidazole.

In 1980, the drug was supplied to the government

by the brand-name manufacturer, G.D. Searle, for $53.24 per bottle. This price remained in effect until May, 1982, when a generic manufacturer, Zenith Laboratories, received approval for its own version of metronidazole and entered the marketplace. Zenith bid for the Defense Department contract with a price per bottle of $32, while Searle had increased its price to $69.74. In September, 1982, Zenith came in at $28, while Searle remained at $69.74. In February, Searle reduced its bid dramatically to $26.40, beating Zenith's bid of $26.60. In April, 1983, a new entry, Cord Laboratories, won the Defense Department contract with a low bid of $19.67.

As a clear result of generic competition, the government has saved $1.16 million over Searle's price -- from only one drug!

Aside from being totally unprovable, the argument that patent extension will reduce the cost of healthcare in the longterm ignores the plight of our elderly and poor populations now.

It is a fact that in 1982, prescription drug prices, as measured by the Department of Commerce, rose 12% -- a rate three times higher than the increase in the Consumer Price Index for all items.

So far in 1983, prescription drug prices already have increased at an annual rate of 11.8% -- once again, more than three times the rate of increase in the Consumer Price Index.

However, during 1982, the cost-of-living increase for Social Security recipients amounted to only 7.4%, causing them to lose ground in their efforts to keep up

with drug prices. In addition, the elderly will, in 1983, be subjected to a six-month delay in Social Security cost-of-living increases.

There is little doubt that one of the most important issues facing the U.S. today is the financial crisis in healthcare. Our stated national policy is to reduce the staggering increase of healthcare through programs of cost-containment.

Congress should not abet continued drug price increases, restraints to competition in the marketplace, and the denial to more and more patients of the medications they need. Those are the true implications of patent extension legislation.

6. THE PROFIT QUESTION

NAPM does not begrudge the legitimately-obtained profits of the research-intensive pharmaceutical industry. As with the need for some form of patent protection for inventors through the current laws, NAPM recognizes that a profit potential must exist in order for the research and development of new medical entities to continue.

However, NAPM questions the need for instituting a dramatic change in the patent laws to show "fairness" and "equity" to an industry as profitable as the brand-name manufacturers of prescription drugs.

According to figures published by the Department of Commerce, the pharmaceutical industry is the third most

profitable in the U.S. It is not hurting in any known sense of the word.

Profit trends compiled by the Federal Trade Commission show a 24-year profit stability(1956-1980) that is not matched by any other industry. During those years, after-tax rates on return of equity ranged from a low of 16.7%(in 1961) to a high of 20.8%(first three quarters of 1980), with the rate holding at 18% or higher during the most recent years of the FTC data, 1976-1980.

In addition, figures developed by the Pharmaceutical Manufacturers Association show that drug industry revenues have grown significantly since 1965, even on a constant-dollar basis.(PMA Office of Policy Analysis, report of April, 1981).

NAPM believes that such a solid track record does not exactly cry out for "equity" and "fairness" measures which would maintain and increase high profits and revenues, while at the same time preventing consumers from obtaining lower-cost safe and effective drugs.

As the trade representative of small-sized generic manufacturers as well as larger firms, NAPM well understands the significance of profits to business growth. Generic industry profits have increased in recent years, due in large part to the expiration of patents for a few important and widely-selling drugs.

NAPM believes that profitability is essential for this fledgling segment of the drug marketplace to continue to be able to offer lower-priced, safe and effective

products manufactured under state-of-the art conditions. Some of that profitability also is going to research. As an example, several of the drug products identified by FDA as being potential "Orphan Drugs" are under development by generic firms.

Therefore, NAPM does not oppose the high profits now realized by brand-name firms. It merely notes that generic manufacturers, unlike their brand-name counterparts, are not seeking rewards for their success in the form of new barriers to competition.

NAPM believes that, rather than correcting an allegedly wrongful situation, patent extension legislation will provide a bonus to an industry that does not need it, at the expense of consumers and our elderly -- and to the exclusion of other industries, none of whom realize the magical 17 years of patent protection. The legislation as proposed is, unfortunately, protectionist and anti-consumer.

As a final note, NAPM quotes the 1981 report on patent extension by the Office of Technology Assessment on the implications of this legislation:

> "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 attractiveness of research on drugs with smaller markets.
>
> "The bulk of revenues generated by patent 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."

○