INNOVATION AND PATENT LAW REFORM

HEARINGS

BEFORE THE

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

OF THE

COMMITTEE ON THE JUDICIARY HOUSE OF REPRESENTATIVES

NINETY-EIGHTH CONGRESS

SECOND SESSION

ON

H.R. 3285, H.R. 3286, and H.R. 3605

INNOVATION AND PATENT LAW REFORM

MARCH 28, APRIL 26, AND JUNE 6, 27, 1984

Part 1

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INNOVATION AND PATENT LAW REFORM

WEDNESDAY, MARCH 28, 1984

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

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

Present: Representatives Kastenmeier, Synar, Berman, Moorhead, Hyde, DeWine, and Kindness.

Staff present: Michael J. Remington, counsel; David W. Beier, assistant counsel; Thomas E. Mooney and Joseph V. Wolfe, associate counsel; Audrey K. Marcus, clerical staff.

Mr. KASTENMEIER. The subcommittee will come to order.

This morning the subcommittee commences hearings on patent law reform innovation, and the public interest.

In a related area of intellectual property law, the subcommittee already has devoted considerable time to the issue of technological change and copyright law. In a sense, today's hearing is closely connected to the subject of our copyright inquiry, during which we pondered the role of law and Government institutions in promoting or structuring societal, technological, and economic changes. We also analyzed the role of intellectual property law in stimulating creativity and in improving the public good.

I would, therefore, like the theme of this hearing and subsequent hearings on the subject to be both innovation and the public interest.

In this regard, I would like to set the stage for our inquiry by quoting from a good friend and former professor of mine, Prof. John Stedman, of the University of Wisconsin Law School:

> Despite an occasional mystic who persists in viewing our patent system as a sacred cow, not to be touched, much less slaughtered, I take it there is no serious challenge today of the proposition that the patent system has for its primary purpose the advancement of the public interest and that it must be evaluated in the light of that interest—and, if necessary, changed to promote it.

As many of you know, John Stedman passed away several months ago. His intellectual skills, his enormous knowledge of patent law, his commitment to public interest goals, and his friendliness I still recall.

In addition to dedicating this hearing to John, I will also put to each and every witness the two questions that he would have asked: "Does our present system further or retard the public inter-

est?" and "Would proposed changes make matters better or worse?"

We have many bills before us, falling within three distinct categories: Inventors' rights, administrative improvements to the Patent and Trademark Office, and substantive patent law changes.

Mr. KASTENMEIER. Our first witness this morning is Hon. Gerald J. Mossinghoff, the Assistant Secretary of Commerce and Commissioner of Patents and Trademarks. Commissioner Mossinghoff also chairs the Working Group on Intellectual Property of the Cabinet Council of Commerce and Trade at the White House.

Commissioner Mossinghoff has just returned from Geneva, Switzerland, where he has ably represented the U.S. interest at the fourth session of the diplomatic conference on the revision of the Paris Convention.

We are most pleased to greet you, Commissioner. We appreciate your taking time from your busy schedule to be here. We are always pleased to have you. You may proceed, sir, as you wish.

TESTIMONY OF HON. GERALD J. MOSSINGHOFF, ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS, ACCOMPANIED BY DONALD QUIGG, DEPUTY ASSISTANT SECRETARY AND DEPUTY COMMISSIONER OF PATENTS AND TRADEMARKS, AND RENE D. TEGTMEYER, ASSISTANT COMMISSIONER FOR PATENTS

Mr. MOSSINGHOFF. Thank you, Mr. Chairman.

Mr. Chairman, accompanying me this morning, to my right, is Donald Quigg, the Deputy Commissioner, Deputy Assistant Secretary of Commerce, and to my left is Rene D. Tegtmeyer, the Assistant Commissioner for Patents.

We welcome this opportunity to testify on the number of bills which would amend the patent laws. As you requested, Mr. Chairman, I will consider these bills in three categories: First, those dealing with regulation of inventors' rights; second, those that concern changes in the administration of the Patent and Trademark Office or the patent system generally; and finally, those bills which would bring about substantive changes in the patent laws.

Mr. Chairman, my statement is rather lengthy, given the number of bills that we are covering this morning. With your permission, I would like to read only those portions of the statement which highlight our views on each of the bills as we come to them.

I ask your indulgence. I will skip through and try to guide you through the parts that I will focus on this morning.

Mr. KASTENMEIER. The committee would appreciate that. Without objection, your 36-page statement will be received and made part of the record.

I realize we have given you a great deal to chew on in a relatively short period of time in terms of policy areas, different areas within the scope of your competence. Do the best you can in terms of summarizing, nonetheless, your views on all these issues.

Mr. MOSSINGHOFF. Thank you, Mr. Chairman.

First, the regulation of inventors' rights concerns bills H.R. 3285 and H.R. 3286. Each of these bills would establish a Federal statutory scheme to regulate patent rights of employed inventors. Both

bills would apply to Federal and private sector employees. H.R. 3285 would include military personnel, as well, and would mandate adequate compensation of an employee when the employer acquired rights to or used the employee's invention.

In the private sector, an employer's rights to inventions made by his or her employees are determined by contracts between the employers and their employees, by common law, or in several States by State statutes, which circumscribe the contracts that can be enforced. Rights to inventions made by most Federal employees are determined by Executive Order No. 10096, issued by President Truman in 1950.

At common law, rights in inventions depend on the nature of the employment relationship, the relation of the invention to the employer's business, and any contribution by the employer to the invention.

Basically, the employer owns inventions made by persons who are employed to invent when the inventions are made within the scope of their employment. The employee owns inventions made outside the scope of employment, even where he or she is hired to invent in other areas.

This ownership may be subject to a shop right—a nonexclusive right for the employer to practice the invention—if the employee uses the materials, equipment, facilities, or other resources of the employer in making the invention.

The existence of a fiduciary relationship or other special relationship between the employer and employee can also affect the ownership of the invention. In the absence of an agreement, the final determination of rights involves a balancing of interests.

In five States, Mr. Chairman—North Carolina, California, Minnesota, Washington, and Illinois—the common law has been supplemented by statutes which specify the nature of employment agreements governing invention rights.

The provisions of these statutes vary somewhat, but generally they take into account the contribution of the employer and the duties of the employee in determining what rights an employer may contractually require an employee to assign.

I have provided to the subcommittee a paper written by William L. Respess, which discusses these State statutes in some detail. Since that paper was written, Illinois has enacted a similar statute.

In the case of Federal employees, rights to an invention are allocated by Executive Order 10096 in one of three ways: one, either the Government acquires the entire right and title to the invention; two, the employee takes title, subject to a license to the Government; or three, the employee retains the entire right and title.

A determination of these rights depends on whether the invention was within the scope of, or directly related to, an employee's duties, was made during working hours or was made with a Government contribution.

Determinations by Federal agencies on employee rights are reviewable by the Commissioner of Patents and Trademarks to assure uniform, Government-wide application of the criteria.

H.R. 3286 would define an "employment invention" and proscribe any preinvention assignment agreement that would reach any other inventions made by an employee. An employer could re-

quire a nontransferable, nonexclusive license in inventions other than an "employment invention" if the invention resulted from a substantial use of the employer's time, materials, facilities or funds. To qualify as an employment invention, the invention would have to satisfy the criteria specified in the new section which would be added, 35 USC 222(4) (A), (B), or (C).

Significantly, no preinvention assignment agreement could reach an invention conceived after termination of employment. An employer could require disclosure of all inventions made during the term of the employment provided the disclosures were kept in confidence. Disagreements are to be settled by arbitration.

With respect to inventions made by Federal employees, we do not recommend that the criteria of Executive Order No. 10096 be changed by statute, as is contemplated by H.R. 3286. That Executive order has worked well for more than 30 years, and its criteria and procedures are well understood by Federal agencies and by their employees.

In the private sector, since employment agreements have traditionally been governed by State, rather than Federal law, we do not recommend the enactment of H.R. 3286, which would preempt State law in this area. However, if the subcommittee determines that a Federal standard is necessary, we strongly recommend that H.R. 3286 be amended along the lines of the State statutes that have been enacted.

A particularly troublesome provision of H.R. 3286 appears in subsection 223(c), which would proscribe altogether a preinvention assignment agreement with respect to an invention conceived after termination of employment. That subsection would apply even if an invention were to be conceived one day after the employment ceased and even if it were related directly to the employee's responsibilities.

The subsection would have the tendency to induce employees who knew they were changing jobs to withhold the submission of ideas to their employers. Difficult and complex questions of fact and proof would inevitably arise.

With respect to H.R. 3285, this bill would add 20 new sections to title 35. Section 402 would define as "service inventions" those inventions either growing out of the type of work performed by employees for their employers, or derived from job experience related to the employer's operations. All other inventions would be "free inventions."

Mr. Chairman, on pages 4, 5 and 6 of my statement I indicate in some detail the very complex provisions of this bill and, with your permission, would like to skip to page 6.

For the reasons outlined in my prepared statement, we do not favor the creation of a system such as contained in H.R. 3285. Even my cryptic explanation of the bill reveals the administrative complexities and substantial burdens it would impose on both industry and the Government. The costs of implementing H.R. 3285 would be particularly unfortunate for small, innovative firms which could ill afford to divert their limited resources to comply with its many requirements and deadlines.

I am concerned that H.R. 3285 would retard the free flow of information among employees of companies. An employee may be

hesitant to share the results of his or her research with a coworker for fear that the coworker may make an improvement or even a separate invention, either of which possibilities would reduce the potential compensation to the first employee.

At a time when the United States needs more inventions and innovation to compete in world markets, we cannot afford unnecessary barriers to creativity in our corporate and Government laboratories.

I am also concerned that the system which would be established under H.R. 3285 would not take appropriate account of the contributions made by others in the organizations which affect the value of a service invention.

Directors of research laboratories who chart the course and direction of employees' efforts, production engineers who translate laboratory prototypes into marketable products, and marketing personnel who design and direct advertising campaigns which create demand for new products, are among those in corporate settings whose contributions frequently approach that of the inventor. Failure also to recognize such contributions could be counterproductive.

Finally, Mr. Chairman, it seems to me that in view of the sweeping definition of a "service invention" in H.R. 3285—which is really much broader than any of the State laws or the Executive order—employees could actually receive title to fewer inventions under that bill than they would either receive under H.R. 3286, Executive Order No. 10096, or the State laws that I have mentioned.

Mr. Chairman, moving on to H.R. 4525——

Mr. KASTENMEIER. Excuse me. Before you do move on to that, the Chair notes a photographer in the room. Let me state that without objection the subcommittee permit the meeting this morning to be covered in whole or in part by broadcast or still photography, pursuant to rule V of the committee rules, if there is no objection.

Mr. MOSSINGHOFF. Moving on, Mr. Chairman, to H.R. 4525, that bill would clarify an inventor's rights to receive a patent by specifying in 35 U.S.C. 103 that:

> Prior art shall not include unpublished information which is developed by the applicant singly or jointly with others, or which is known to the applicant only by virtue of his or her employment.

As you pointed out in your introductory statement of that bill, Mr. Chairman, prior art is the existing technical information against which the patentability of an invention is judged. Publicly known information is always considered in judging whether an invention is obvious.

But a complex and growing body of jurisprudence, begun by In re *Bass,* regards unpublished information within an organization as prior art if an inventor was aware of it. If unknown to the inventor, however, the same organizational information would not be taken into account in judging nonobviousness. As a consequence, scientists or researchers unaware of such secret organizational information have a better chance of obtaining a patent than those to whom it was known.

We are concerned that this body of jurisprudence will discourage the communication of technical information among scientists and

researchers in an organization. It is, therefore, counterproductive and should be reversed if the efforts of corporate and team research are to be fairly rewarded under the patent system.

Neither research laboratories nor technology-oriented businesses conduct research and development in a vacuum. New technology is often developed on the basis of background scientific or technical information known within the organization but unknown to the public.

Productive research usually depends on the continuing development and communication of this secret information among researchers and scientists. I think this is true, Mr. Chairman, clearly either in a university setting or in a corporate team research setting.

Inventions are far less likely to arise from isolated research efforts by those unaware of available background technology and out of communication with others in the organization.

Thus, we believe that a change in the patent laws is needed to assure that unpublished technical information not be regarded as prior art in judging nonobviousness, if that technical information is developed by the patent applicant alone or in collaboration with others or obtained by the applicant from coresearchers during the course of employment.

Drafting an appropriate provision, however, has proven to be an elusive and complex task. We believe H.R. 4525 is too broad. It is not limited for example, to exchanges of background information among co-workers in a single organization. Information learned from or transmitted to outsiders could be disqualified as prior art.

Concerned patent law associations have devoted much effort to the development of a provision that reverses this body of jurisprudence without upsetting other legal principles. We understand that on March 15, 1984, the American Intellectual Property Law Association forwarded to you, Mr. Chairman, proposals for amending sections 103, 116, and 120 of title 35.

We believe that the amendment of section 103 along the line proposed by AIPLA appears to have the potential of overcoming the problems created by the *Bass* decision and its progeny in the corporate context. It may also be useful in solving the difficulties addressed in the next bill I want to discuss, H.R. 4527. I will comment on this and their suggestions for amending that bill in a moment.

In summary, Mr. Chairman, we think that the letter which you received from the American Intellectual Property Law Association represents an improvement over H.R. 4525 in trying to solve the problem that you mentioned in your introductory remarks of that bill; that is, the so-called issue of intracorporate prior art.

Turning to H.R. 4527, this bill would amend 35 U.S.C. 116 in regard to the naming of inventors. Section 116 has been asserted by many to require that the invention defined in every claim in an application be invented by all of the named coinventors. Complying with this requirement is sometimes difficult and, at times, impossible.

The preparation of patent applications for inventions resulting from team efforts, such as corporate efforts, nevertheless requires the attorney to determine the inventorship of each claim to be included in the application.

Adequate protection for an invention may require the filing of several applications to cover the separate contributions to all of its aspects, embodiments and portions. Some inventorship problems would require the filing of separate applications that may not be separately patentable. To do otherwise risks noncompliance with present 35 U.S.C. 116, thereby jeopardizing the rights of all the inventors. These requirements seem especially hypertechnical when in most cases a single organization owns patent rights from all the contributors to the invention.

Admittedly, good-faith errors in the naming of inventors, either in an application or a patent, may be corrected. Nonetheless, it is still necessary to determine inventorship.

Mr. Chairman, again I have some more detailed discussion of the case law here, but I would say, in summary, that the amendment to section 116 proposed by the American Intellectual Property Law Association in its letter to you of March 15, expresses the concepts that we support in a clearer fashion than does H.R. 4527, and that we support the amendment that you received from them.

Concern has also been expressed regarding the broad range of H.R. 4527, which could permit patent applicants to buy up information that would otherwise constitute prior art by hiring persons, for instance, whose unpublished inventive contributions could otherwise be patent defeating. Such persons would, under H.R. 4527, be considered joint inventors with the patent applicant.

In our view, the amendment to section 103 proposed by the American Intellectual Property Law Association may alleviate this concern because of its provision that the subject matter developed by another and the claimed invention be commonly owned at the time the invention was made.

So, it prevents what we see as a potential abuse of the provision of H.R. 4527 by not permitting people after an invention is made to, in effect, buy up someone else's prior art. It requires that the contributions be jointly or coowned at the time the invention was made. We think that is a safeguard in the public interest.

Skipping to page 11, the second category of bills that we are commenting on this morning concerns changes in the administration of the Patent and Trademark Office or the patent system generally. First, H.R. 2610, the Patent Law Amendments of 1983, which I am sure will be 1984, or hopefully will be 1984.

This measure was introduced at the request of the administration. I briefly addressed the substance of this bill before this subcommittee during the hearing on oversight of the Patent and Trademark Office on April 20, 1983. An identical measure was introduced in the Senate as S. 1538. The Senate version has been ordered reported, as amended, by the Subcommittee on Patents, Copyrights and Trademarks under Chairman Mathias.

The most significant aspect of this proposed legislation is section 2, which would authorize the issue of a patent without examination. In addition, sections 3 to 11 contain a number of clarifying amendments to the patent laws.

In reporting S. 1538, the Senate Subcommittee on Patents, Copyrights and Trademarks amended S. 1538 to create a statutory invention recording instead of a patent without examination.

The statutory invention recording would be an unexamined publication having all of the attributes of a patent except for the remedies associated with the patent. It would, in effect, provide all of the shield of a patent to protect against later parties patenting an invention but none of the sword of a patent. It would not permit anyone to sue or enjoin on the basis of a statutory invention recording.

Thus, an inventor would receive the same benefits from a defensive point of view, from a statutory invention recording, as he or she would from a patent. We agree with the change in terminology made by the Senate subcommittee and recommend a similar change in H.R. 2610. In my testimony today I will refer to a statutory invention recording, with your permission, Mr. Chairman.

At present there is no simple, practical method by which an inventor may safeguard the right to work an invention without obtaining a patent. Section 2 of H.R. 2610 would establish a new procedure by which an inventor could acquire a statutory invention recording that would be valid for all defensive purposes.

Like a patent dedicated to the public, this instrument would not permit an inventor to exclude others from working the invention, but it would protect the inventor from having a patent on the same invention later issued to someone else. In addition, this instrument could be obtained more quickly and less expensively than a traditional patent.

To qualify for a statutory invention recording under the bill, an applicant would execute a waiver of enforceability. This waiver would become effective at the time of publication of the statutory invention recording and would apply to remedies for patent infringement under title 35, remedies against unfair competition in the importation of patented inventions under title 19, and unauthorized disclosure or use by the Federal Government under titles 22 and 28, respectively.

By making the waiver, the applicant would authorize the free exploitation in the United States of the invention claimed in the instrument. A statutory invention recording under this section would be the same as a traditional patent in other respects, including serving as the basis for a priority claim in a foreign application.

Mr. Chairman, the rest of that section on this bill, pages 13 and 14, concern the details of what are really housekeeping amendments to title 35. With your permission, I will skip to the bottom of page 14 and talk about the Small Business Independent Inventor Patent Fee Assistance Act of 1983, H.R. 3462.

This measure concerns the fees paid by individual inventors, small businesses and nonprofit organizations. In 1980, and again in 1982, this subcommittee played a major role in developing and enacting Public Laws 96-517 and 97-247.

These laws created our user fee system, now providing the stable funding we desperately need. Under the user-fee system, fees are charged not only during the processing of an application, but maintenance fees are charged during the life of the patent.

In effect, maintenance fees shift some of the payment for the processing of an application to a period when the invention has been commercialized and the patentee is normally in a better position to afford the payments. If the patented invention is not com-

mercialized, the patent owner could stop paying maintenance fees and allow the patent to lapse.

These maintenance fees are due three times during the lifetime of the patent: $400 is due 3½ years after the patent is issued, $800 after 7½ years, and $1,200 after 11½ years.

Congress has authorized and appropriated a 50 percent subsidy for individual inventors, small businesses and nonprofit institutions so that these entities only pay $200, $400 and $600 respectively. These fees can be adjusted administratively in fiscal year 1986 and every third year thereafter, but only to reflect changes in the Consumer Price Index.

Significant revenues from maintenance fees will not be received until fiscal year 1987 and full recovery will not occur until about 1996 because of the lapse of time between the grant of the patent and the payment of maintenance fees.

H.R. 3462 would exempt independent inventors, small businesses and nonprofit organizations—we call those small entities in our regulations—from paying any maintenance fees.

In addition, other fees for small entities would not be adjusted to reflect changes in the Consumer Price Index. We estimate that if the bill were enacted, the Patent and Trademark Office would lose more than $10 million in the 3-year period beginning in fiscal year 1986. That is a conservative estimate, Mr. Chairman. It really would be higher than that, we believe. The amount lost would be even more in later years.

If we do not receive these funds, our plan to reduce the average pendency time for applications to 18 months by 1987 would be seriously undermined. Even if we could reach the 18-month pendency time, we probably would not be able to maintain it in the years following 1987. In addition, our efforts to automate the PTO by 1990 would be seriously curtailed.

The record of filings since Public Law 97-247 came into effect indicates that the prospect of maintenance fees has not deterred small entities from filing patent applications. Since the new fees went into effect on October 1, 1983, the percentage of U.S. small entities entering the patent system is essentially the same as before the new fees were enacted.

Small entities are not, therefore, being adversely affected by the new fee structure with its 50 percent subsidy. Enactment of the bill is unnecessary and would seriously undermine our efforts to improve our services to inventors and industry. We, therefore, strongly oppose its enactment.

Mr. KASTENMEIER. May I interrupt there, as long as the point has been made.

Do you see any reduction in applications as a result of fees in either category?

Mr. MOSSINGHOFF. No, Mr. Chairman, 1983 was kind of an unusual year because of what we refer to unceremoniously as "the September dump." We received 12,000 more applications in September 1982 than we expected. Every patent attorney in the country cleaned off his or her desk to file applications before the new fees went into effect. Therefore, in fiscal year 1983 there was a corresponding dip in applications. In October-November we received a lot fewer than normal.

At this point—and let me turn to Mr. Tegtmeyer—the last figures I saw were about 104 percent. Is that right, Rene?

Mr. TEGTMEYER. In terms of recovery on fees, we are at about 104 percent. In terms of applications filed, we are a little over 100 percent, 101.4 or .5 percent.

Mr. MOSSINGHOFF. So, the effects of the September dump I think are well dissipated and we are right up at the level that we were prior to the new fees.

With respect to small entities, prior to the new fees—and this goes back to 1981 even—the percentage of independent inventors entering the patent system was about 16 percent—these are U.S. independent inventors—about 16 percent of the total. It is now running at about 16.2 percent.

In terms of other small entities, small business and nonprofit institutions, it was about 8 percent prior to the new fees and is now running at about 8.5 percent. So, we are really slightly higher in 1984 than we were before the new fees went into effect.

I think the key to this has been the subsidy. I think that the two-tier system that you enacted has proven its effectiveness. We have not deterred these people from entering the system. Therefore, we don't see any real reason for this bill, which would really make life complicated for us from a financial point of view. It has not really addressed any problem that we can see.

Mr. KASTENMEIER. Actually, of course, going to the European system, there was a rationale involved that if you are small business or not, you can make the periodic judgments of whether you want to maintain these patents and if they are economic to do so. If they are not, you can let them lapse, I guess.

Really, what you would be doing is enabling a whole class of inventors to the exclusion of other inventors, freeing them up from making any decision whatsoever about maintaining a patent. Then the system would be substantially different. It isn't just a quantum of 50 percent difference in fees. It is also other factors involved, which I would think would raise other policy questions.

Mr. MOSSINGHOFF. We agree with that.

Turning to H.R. 4462, the Patent and Trademark Office Procedures Act of 1983, this measure was introduced at the request of the administration. Similar provisions have been incorporated by amendment into S. 1538, which has been reported favorably by the Senate Subcommittee on Patents, Copyrights and Trademarks.

This proposal would improve procedures in the PTO for determining inventorship in interference proceedings. Since evidence of the dates of when an invention was conceived and made and the diligence exercised by an inventor between conception and making may be necessary to prove first inventorship, interference proceedings can be extremely complex, lengthy and expensive.

For example, the longest interference proceeding, involving polypropylene, a very important patent, consumed over 13 years in the office alone. Fortunately, Mr. Chairman, we have with us the Deputy Commissioner, the world's expert on that. He was former patent counsel of Phillips Petroleum. They won the polypropylene interference. It is a long and complex procedure that we go through.

While most interferences are not that long, delays in issuing a patent due to lengthy interference proceedings are harmful to both the applicants and the public. Applicants are unsure of what rights they will be granted and, consequently, often delay the marketing of their inventions. As a consequence, the public may be harmed by a delay in access to the products involved and to the underlying technology.

One of the reasons for such lengthy proceedings in the Office is a jurisdictional problem. By statute, the tribunal responsible for determining patentability is the statutory Board of Appeals in the Office.

The Board of Patent Interferences, on the other hand, the statutory tribunal responsible for determining the first inventor, is not authorized to address questions of patentability of the invention.

If a question of patentability arises during an interference, the proceeding may be suspended pending a determination by the patent examiner and possibly by the Board of Appeals or may even be delayed until after the interference is completed. This restriction on the jurisdiction of the Board of Patent Interferences unduly complicates the procedures for obtaining patents.

We propose in this bill that the Board of Appeals and the Board of Patent Interferences be combined. This new board, to be called the Board of Appeals and Interferences, could decide questions of patentability and inventor priority in a more timely manner. Procedures for patent applicants and patentees involved in interferences would be simpler, faster and less costly.

On January 30, 1984, after consultations with the staff of this subcommittee, we published a proposed set of regulations to simplify and streamline the interference practices in the office. Those regulations were spearheaded by Don Quigg, the Deputy Commissioner, after numerous consultations with industry and bar groups on their effectiveness.

Those draft regulations took into account the potential enactment of H.R. 4462. We did this while H.R. 4462 is pending—again, after discussions with the subcommittee staff—to allow the public maximum time to comment on this complex matter. There is no intent to usurp the prerogatives of the Congress on the pending legislation and the final rules will, of course, reflect whatever actions Congress takes.

We believe that enactment of this legislation and promulgation of regulations along the line of our draft proposal will result in a fair, speedy and inexpensive determination of inventorship in patent interferences.

Turning to H.R. 4524, this bill would clarify certain provisions of the patent laws relating to the filing of patent applications in foreign countries. According to present 35 U.S.C. 184, a patent application for an invention made in the United States cannot be filed in a foreign country unless the applicant first obtains a foreign filing license from the Patent and Trademark Office, or unless the corresponding or equivalent application has been pending in the Patent and Trademark Office for at least 6 months and no secrecy order has been imposed.

Section 184 also proscribes the filing without a supplemental license of any modification, amendment, supplement or division to,

or of, a foreign application; that is, any paper disclosing additional subject matter. For the sake of simplicity, I will refer to them collectively as a modification.

In situations where an application or modification was filed abroad without a license, the patent applicant may have an opportunity to obtain a retroactive license. A retroactive license is available where the applicant can establish that the filing abroad was inadvertent and that the application or modification does not contain subject matter within the secrecy order scope of section 181, the disclosure of which might be detrimental to national security.

Failing to obtain a license either prior to filing abroad or retroactively, however, invalidates the corresponding U.S. patent and may subject the applicant to criminal penalties.

Section 1 of H.R. 4524 would amend section 184 in the following manner. First, it would replace the standard of inadvertence for receiving a retroactive license with the phrase "through error and without deceptive intent." Mr. Chairman, I discuss that in some detail on the next page. We support that new standard, for the reasons I set forth.

Continuing on the bottom of page 19, the second part of section 1 would add a paragraph to 35 U.S.C. 184, exempting an applicant from the obligation to obtain a supplemental license for any modification to be filed abroad, if the modification consists only of the illustration, exemplification, comparison or explanation of subject matter previously disclosed either in a licensed foreign application or in an application that did not require a license for foreign filing.

Under this provision, the applicant would be given authority to apply the statutory test to determine whether the subject matter of the modification requires a license.

The proposed amendment of section 184 is intended to moderate the stricter test imposed by the former U.S. Court of Customs and Patent Appeals in in re *Gaertner* for receiving a retroactive license.

In that case, the court indicated that the subject matter of a modification is exempted from the license requirement only when it is recited in haec verbia in the application or is so commonly known that it can be said to be in fact expressly disclosed.

While we agree with the general concept of the second part of section 1 of the bill, corrective legislation seems unnecessary since the Commissioner already has the authority to adopt appropriate rules under the present statute.

The obtaining of foreign filing licenses is better handled by appropriate modification of our rules of practice under the present statute. This provides a flexibility and degree of detail not available from a statutory provision while still guarding national security and the rights of applicants. We have developed appropriate rules along these lines and expect to promulgate them shortly, within the next week or two.

I go on to say, on page 21, that even though strictly speaking we do not require statutory authority, additional authority is not necessary for the Office to promulgate its regulations. We have no objection to the addition of a requirement in section 184 that the Commissioner institute rules along the lines of the new regulations, provided it leaves sufficient latitude to fix conditions assuring protection of national security interests.

Addition of the following paragraph to section 184 as a substitute for that of the second part of section 1 of H.R. 4524 would be acceptable to us. Mr. Chairman, earlier I quoted the paragraph that we recommend.

Skipping to page 23, consideration of H.R. 4528, that bill contains two proposals concerned with our interference practice. Section 1 would permit the parties to an interference to resolve it through arbitration. We strongly support the principles of this section. Logically, the arbitration provisions of section 294, applicable to the settlement of patent validity and infringement issues, should be extended to interference issues, insofar as this is not already the case.

Arbitration provides a faster and less expensive alternative to present administrative or judicial resolution of interferences. Arbitration would spare inventors and the Patent and Trademark Office considerable expense without encroaching on the right of the public to have interferences correctly resolved.

Skipping to page 24, when an interference is settled privately by the parties involved, the settlement agreement must be filed with the Patent and Trademark Office. Section 135(c) requires this filing to be made before the interference is terminated.

The Commissioner may, on a showing of good cause as to why the agreement was not filed on time, accept the filing of the agreement up to 6 months after the interference is terminated.

The time for filing cannot be extended further, nor can a settlement agreement or any patent involved in the interference be enforced if the agreement is not filed. The penalty for failure to file is unenforceability of both the settlement agreement and any patents involved.

Section 2 of the bill would amend section 135(c) of title 35 to provide that the penalties for failing to file an agreement would not apply if the failure was the consequence of an error committed without deceptive intent. Section 2 would not have any effect on the kinds of agreements that must be filed.

The section would further amend section 135(c) by enlarging the Commissioner's authority to accept the filing of a settlement agreement more than 6 months after the interference is terminated. The Commissioner would still possess statutory authority to demand a showing of good cause as to why the agreement was not earlier filed, and the lateness of the filing would remain a factor to be considered in whether to accept the settlement agreement.

The Department of Justice opposes enactment of section 2 of the bill on the ground that its potential benefits are outweighed by the possibility that interference parties may enter into collusive interference settlement agreements. On this matter, Mr. Chairman, we defer to the Department of Justice.

It is not clear whether section 3 would permit arbitration of an interference declared prior to enactment of this bill. Since parties to such interferences may wish to arbitrate their dispute, we suggest that interferences in progress at the time of enactment also can be settled by arbitration.

Mr. Chairman, the next several pages of my statement have to do with the issue of patent term restoration, about which I have testified, I believe, in November of 1981.

Mr. KASTENMEIER. You have, and not only that, but I think it is fair to say that in another committee there is contemplated another version of this bill, the introduction of which we are awaiting, and which may or may not replace H.R. 3502 as a vehicle for consideration in the field.

We do not have that before us today, but your comments are received with that in mind. We may within weeks have another vehicle before us.

Mr. MOSSINGHOFF. I had heard that, Mr. Chairman. We are, of course, anxious to see what that compromise looks like, to see whether our position would in any way change. As it stands now, the administration strongly supports patent term restoration for pharmaceuticals and agricultural chemicals.

The only development since my testimony before the Subcommittee was that the bipartisan Presidential Commission on Industrial Competitiveness within the last month has endorsed patent term restoration as being something that they feel is necessary in these two very important, high technology industries.

So, with your permission, I will skip my entire discussion of that part of the bills and turn to three bills collective on page 29, H.R. 3577, H.R. 4526 and H.R. 4814.

These bills would protect owners of patented processes from infringement of their inventions by excluding others from using or selling products produced by the patented process. The main difference between these bills is that H.R. 3577 would apply to products wherever made by the patented process, while H.R. 4526 and H.R. 4814 would only cover products made abroad by the patented process. In addition, H.R. 4526 and H.R. 4814 would also provide a remedy for another aspect of infringement, which I will address later in my statement.

Presently, the infringement of a patent for a product occurs if the patented invention is made, used, or sold in the United States. Someone cannot avoid infringement of a product patent by manufacturing the product overseas and then importing it into this country because use or sale of the product in the United States would infringe the patent.

A process patent, however, only protects a process or method of making an article or product. Today, the holder of a United States process patent cannot use the patent law to prevent someone from practicing the patented process abroad and selling or using the resulting product in the United States.

Technically, no one has used the patented process in this country. Nor do remedies available under section 337(a) of the Tariff Act of 1930, as amended, always provide an adequate remedy.

The importance of process patent protection to the national economy, especially in such vital technical fields as industrial chemical and pharmaceutical manufacturing, microbiology, and solid state electronics cannot be overstated. Those are three of the very high technology areas where the United States is a clear leader.

The addition of section 271(e), as proposed by H.R. 4526 and H.R. 4814, as well as the amendments proposed by H.R. 3577, would close the gap in our patent laws, which presently leave owners of patented processes without an adequate remedy against the importation of products made abroad by their patented processes.

As I have mentioned, however, H.R. 4526 and H.R. 4814 are limited only to foreign produced products. The Office of the U.S. Trade Representative has expressed concern that H.R. 4526 and H.R. 4814 would violate our obligation under article III of the General Agreement on Tariffs and Trade not to discriminate against foreign made products.

The importation, use or sale of products made abroad by a patented process would constitute infringement under H.R. 4256 and H.R. 4814. There is no remedy under the bills, however, against use or sale of a product made in the United States by infringing a process patent.

Foreign products are, therefore, treated less favorably than domestic products. H.R. 3577, on the other hand, does not suffer this deficiency. Use or sale of a product made without authorization either in the United States or abroad would be an infringement under that bill.

As a practical matter, Mr. Chairman, since patentees like to sue their competitors more than they like to sue their customers, I think the result of the two bills would be the same and we would be not subject to the challenge that we were in any way violating our responsibilities under the General Agreement on Tariffs and Trade.

In addition, H.R. 3577 would apply to products used or sold during the term of the process patent, regardless of when the product was made. We prefer this concept of added process patent protection over that expressed in H.R. 4526. The provisions of that bill would limit infringement to the importation, use or sale of products made during the patent term.

Because H.R. 4814 does not expressly contain this limitation, its provision is somewhat ambiguous but could still be interpreted in the same way as H.R. 4526. Further, both H.R. 4526 and H.R. 4814 are unclear on whether a process patent is infringed if a product is made during the patent term, but imported, sold or used after the patent expires. For all these reasons, we prefer the formulation of H.R. 3577 over that of either of the other two bills, H.R. 4526 or H.R. 4814.

H.R. 3577 also includes a provision on proving infringement not found in the other two bills. We believe that is important. This again was specifically addressed in your introductory statements and it is something the subcommittee, I am sure, is going to look at carefully.

In suing for infringement of a process patent, the burden of establishing infringement now rests entirely on the patent owner. New section 295, proposed in H.R. 3577, would in certain carefully prescribed circumstances establish a presumption that a product that could have been made by a patented process was actually made by that process. This new section may be of particular benefit to the owner of a process patent who seeks a remedy against the importer of a product made abroad by that process since the laws of most countries do not provide the discovery procedures available through U.S. courts. This frequently makes it very difficult to secure proof of actions taken in a foreign country.

Shifting the burden of proof, as would be done in H.R. 3577, should create no substantial hardship since the alleged infringer is

in a much better position to establish that the product was made by another method. An accused infringer, if not actually the manufacturer, has direct or at least indirect contact with the manufacturer.

An infringer will be protected against frivolous suits by a requirement that the patentee first show a substantial likelihood that an allegedly infringing product, which could have been made by the patented process, was in fact so produced. Such factors as the absence of other economically viable processes or the presence of telltale side effects or trace elements could satisfy the requirement.

The patentee would also be required to make a reasonable effort to determine how the product was actually made and also show that he or she was unable to make that determination. Because, in our view, H.R. 3577 offers stronger protection to patent owners, we prefer its provision in this respect to the other two bills.

The other two bills do include a feature not found in H.R. 3577. The second part of section 1 of H.R. 4526 and of section 2 of H.R. 4814 addresses the problem identified by the 1972 decision of the Supreme Court in *Deepsouth Packing Company* v. *Laitram Corp.* It would add a new section 271(f) to title 35.

The Supreme Court, in a narrow decision, based entirely on the wording of the current patent laws and not based on any broad, sweeping public policy, interpreting the patent owner's right to exclude others from making a patented invention, held that this right only covers the making of the patented invention in the United States.

The patent claimed a machine for deveining shrimp. All of the machine's parts were manufactured by the accused infringer in the United States. To avoid infringement, the parts were shipped separately to foreign purchasers with instructions for assembly. Assembly was a simple matter, taking about 1 hour.

The Supreme Court decided that since the machine was not built in the United States, section 271, the patent infringement provision, did not apply. Moreover, the accused infringer was not even guilty of contributory infringement or inducement to infringe because the requirement that there must first be direct infringement in the United States was not satisfied.

The Supreme Court acknowledged the narrowness of the law and stated that legislation is needed if the patentee is to have a remedy in these situations. Legislative remedies have been included in past comprehensive patent reform bills, but to date none has been enacted. A legislative remedy against such activities is necessary to provide the patentee with effective protection.

We have two suggestions for sharpening the remedy provided in those two bills. As presently drafted, these bills might deter the sale of components which are staple articles suitable for substantial noninfringing use.

We believe the bills should be limited to the sale of components which are especially made or adapted for use in an infringement of a patent. This approach was taken by Congress in 1952 in section 271(c) of the patent laws dealing with contributory infringement. In order to avoid interference with the export sale of staple articles of

commerce, the limitations of section 271(c) should be incorporated into proposed section 271(f).

Second, we suggest deletion of the phrase in proposed section 271(f) requiring the infringer to have knowledge that combining the inventions' components in the United States would be an infringement. Under the patent laws today, a patent may be infringed without the infringer's knowing that he is doing so.

It is inconsistent and unfair, therefore, to provide a remedy for overseas assembly of a patented device only if the exporter knows that such assembly will infringe the patent. It is enough that the infringer intends for the components of the invention to be combined outside of the United States in the way that he specially designed and gave instructions. The patent owner, in cases of assembly abroad, deserves the same rights as those available to other patent owners.

We would suggest that section 3 of H.R. 4526 apply only to acts committed after the bill was introduced, regardless of when the patent issued. Acts not regarded as infringements prior to introduction of the bill should not upon its enactment automatically become infringements. This would be unfair to persons who in good faith prior to introduction imported, used or marketed an article made abroad by a patented process or sold components of a patented article for foreign assembly. Also, extensive preparations before introduction for such practices should not be unfairly penalized.

Other bills strengthening the protection now available to process patent owners are also pending. Specifically, title V in H.R. 3878 and sections 1, 2, and 3 of H.R. 4288 are the same as appear in H.R. 3577. My comments, therefore, apply also to those other bills.

The final bill, Mr. Chairman, is H.R. 4529. This bill would codify the decision in *Lear* v. *Adkins,* in which the Supreme Court in 1969 overturned the judicial doctrine of licensee estoppel. Prior to the *Lear* decision, a licensee was precluded from questioning the validity of any patent under which he was licensed. The *Lear* case, however, assures a licensee the right to challenge the validity of any such patent. The Supreme Court recognized the public interest in freedom from invalid patents and, therefore, that the licensee is the party most able and most likely to challenge validity.

As a result of *Lear,* however, the licensee is at times able to attack patent validity under conditions completely unfair to the licensor or patent owner. A licensee, for example, can negotiate the best license terms available from the licensor, accept the contract, and then question patent validity without relinquishing the license. If he wins the validity suit he can, of course, practice the invention safe in the knowledge that the patent is invalid.

If he loses, he can merely continue to pay the agreed-upon royalties. He can have his cake and eat it, too, risking nothing but attorney fees. In fact, some courts have even held that it may be possible for the licensee to pay royalties to an escrow account during pendency of a suit over validity, rather than directly to the licensor.

A fairer balance, in our opinion, needs to be struck between the rights of the licensor and those of the licensee without compromising the public interest.

New section 295(b) proposed by H.R. 4529 would achieve this balance with a number of straightforward principles. Either the licensee or the licensor could terminate the license once the licensee asserts invalidity in a judicial action. However, the licensee would have to continue paying royalties directly to the licensor and not into an escrow account, unless the license is terminated. Upon termination by either party, further unlicensed practice of the patented invention would subject the former licensee to the infringement provisions of the patent laws.

We support these principles for their basic fairness both to the parties and the public. Various court decisions have upheld such conditions for challenging validity, but they are not widespread or uniform enough to be safely relied upon by licensing parties. A Federal statute is needed.

However, we believe the statute should not be drafted in the form of H.R. 4529, which would increase Federal interference in patent licensing. We believe the correct approach is to do exactly the opposite, and on this, Mr. Chairman, we have consulted widely with the Department of Justice.

Parties should properly be able to negotiate contracts containing provisions, for instance, that a licensor or a licensee could terminate the license if the licensee challenged the validity of the licensed patent in a judicial proceeding. The bill should, therefore, assure the parties that any such licensing provisions which they negotiate at arms' length would not be deemed unenforceable as being inconsistent with Federal objectives.

This approach will, I believe, adequately remedy the inequities resulting from the *Lear* decision insofar as prospective patent license arrangements are concerned. It does, however, leave unanswered the problems faced by those patentees who have entered into license agreements since *Lear*. We would be pleased to work with the subcommittee to find an acceptable solution to this problem.

I should point out another avenue open to the licensee which is not addressed in this bill, and that is the licensee's option to test the validity of the licensed patent in some instances without resorting to litigation. By instituting a reexamination procedure, as you authorized in Public Law 96-517, in the Patent and Trademark Office, the validity of a patent can often be more easily determined and at much less expense to the licensee than litigation would require. Any subsequent judicial review would not involve the licensee and, consequently, in such a case the provisions of the bill would not permit the licensor to terminate the license.

As we understand section 2 of H.R. 4529, it properly would apply the provisions of this bill retroactively to patents already granted at the time of enactment. This will assure the resolution of validity challenges under conditions as fair as possible to both parties. Even more important, it will encourage the licensing of patents and the maximum utilization of new technology for the benefit of the public.

Mr. Chairman, this concludes my rather lengthy statement, and I appreciate your patience and that of the subcommittee with this long statement. We would be pleased to respond to any questions you or the subcommittee may have.

[Mr. Mossinghoff's full statement follows:]

STATEMENT OF GERALD J. MOSSINGHOFF
ASSISTANT SECRETARY AND
COMMISSIONER OF PATENTS AND TRADEMARKS
BEFORE THE
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES AND THE
ADMINISTRATION OF JUSTICE
OF THE
COMMITTEE ON THE JUDICIARY
U.S. HOUSE OF REPRESENTATIVES
MARCH 28, 1984

Mr. Chairman and Members of the Subcommittee:

I welcome this opportunity to testify on a number of bills which would amend the patent laws. As you requested, I will consider these bills in three categories: (1) those dealing with regulation of inventors' rights; (2) those that concern changes in the administration of the Patent and Trademark Office or the patent system generally; and (3) those bills which would bring about substantive changes in the patent laws.

I. Regulation of Inventors' Rights

H.R. 3285 and H.R. 3286

Each of these bills would establish a Federal statutory scheme to regulate patent rights of employed inventors. Both bills would apply to Federal and private sector employees. H.R. 3285 would include military personnel as well, and would mandate "adequate compensation" of an employee when the employer acquired rights to, or used, the employee's invention.

In the private sector, an employer's rights to inventions made by his or her employees are determined by contracts between the employers and their employees, by common law, or in several states by state statutes which circumscribe the contracts that can be

enforced. Rights to inventions made by most Federal employees are determined by Executive Order No. 10096, issued by President Truman in 1950.

At common law, rights in inventions depend on the nature of the employment relationship, the relation of the invention to the employer's business, and any contribution by the employer to the invention. Basically, the employer owns inventions made by persons who are employed to invent when the inventions are made within the scope of their employment. The employee owns inventions made outside the scope of employment, even where he or she is hired to invent. This ownership may be subject to a "shop right" - a non-exclusive right for the employer to practice the invention - if the employee uses the materials, equipment, facilities, or other resources of the employer in making the invention. The existence of a fiduciary relationship or other special relationship between the employer and employee can also affect the ownership of the invention. In the absence of an agreement, the final determination of rights involves a balancing of interests.

In five states, the common law has been supplemented by statutes which specify the nature of employment agreements governing invention rights. The provisions of these statutes vary somewhat, but generally they take into account the contribution of the employer and the duties of the employee in determining what rights an employer may contractually require an employee to assign. I have provided to the Subcommittee a paper written by William L. Respess, which discusses these state statutes in some detail. Since that paper was written, Illinois has enacted a similar statute.

In the case of Federal employees, rights to an invention are allocated by Executive Order 10096 in one of three ways: (1) the Government acquires the entire right and title to the invention; (2) the employee takes title, subject to a license in the Government; or (3) the employee retains the entire right and title. A determination of these rights depends on whether the invention was within

the scope of, or directly related to, an employee's duties, was made during working hours, or was made with a Government contribution.

Determinations by Federal agencies on employee rights are reviewable by the Commissioner of Patents and Trademarks to assure uniform, Government-wide application of the criteria.

H.R. 3286 would define an "employment invention" and proscribe any preinvention assignment agreement that would reach any other inventions made by an employee. An employer could require a nontransferable, nonexclusive license in inventions other than an "employment invention" if the invention resulted from a substantial use of the employer's time, materials, facilities or funds. To qualify as an "employment invention," the invention would have to satisfy the criteria specified in the new 35 USC 222(4)(A), (B) or (C). Significantly, no preinvention assignment agreement could reach an invention conceived after termination of employment. An employer could require disclosure of all inventions made during the term of the employment provided the disclosures were kept in confidence. Disagreements are to be settled by arbitration.

With respect to inventions made by Federal employees, we do not recommend that the criteria of Executive Order No. 10096 be changed by statute, as contemplated by H.R. 3286. That Executive Order has worked well for more than 30 years, and its criteria and procedures are well understood by Federal agencies and employees.

In the private sector, since employment agreements have traditionally been governed by state, rather than Federal law, we do not recommend the enactment of H.R. 3286, which would preempt state law in this area. However, if the Subcommittee determines that a Federal standard is necessary, we strongly recommend that H.R. 3286 be amended along the lines of the state statutes that have been enacted.

A particularly troublesome provision of H.R. 3286 appears in subsection 223(c), which would proscribe altogether a preinvention assignment agreement with respect to an invention conceived after termination of employment. That subsection would apply even if an invention were to be conceived one day after the employment ceased and even if it were related directly to the employee's responsibilities. The subsection would have the tendency to induce employees who knew they were changing jobs to withhold the submission of ideas to their employers. Difficult and complex questions of fact and proof would inevitably arise.

With respect to H.R. 3285, this bill would add 20 new sections to title 35. Section 402 would define as "service inventions" those inventions (1) growing out of the type of work performed by employees for their employers, or (2) derived from job experience related to the employer's operations. All other inventions would be "free inventions."

Section 411 would require employees who have made service inventions to give notice, including a complete description in a manner prescribed by the Commissioner of Patents and Trademarks, to their employers without undue delay. The employer would be required to acknowledge receipt of that notice in writing, again without undue delay, and to advise the employee of any deficiencies in that notice within two months of receipt.

To obtain rights to a service invention, section 412 would require the employer to give a written declaration to the employee within such time as the Commissioner prescribed. Failure of an employer to act under section 411 or to file a patent application as required by section 421, unless such failure is justified under section 425 to protect trade secrets, would result in a service invention becoming a free invention. Under section 414, an employee would be entitled to adequate compensation representing the fair market value of the employer's exclusive rights in accordance with guidelines to be issued by the Secretary of Labor under section 437. Employer and

employee would be required to enter into an agreement specifying the kind and amount of compensation for a service invention, before grant of a patent. Where an agreement could not be reached, the matter would be referred to an Arbitration Board to be established in the Patent and Trademark Office. With respect to foreign countries where the employer does not file a patent application on a service invention, the employer would be required to release the invention to the employee.

Section 431 would require employees also to give prompt notice to their employers of the making of a free invention, and would permit employers to contest whether such invention was a free invention by filing a written declaration within three months of notice. Disputes would again be referred to the Arbitration Board.

Section 438 would preclude any adverse action against employees who instituted actions or filed complaints to receive the rights accorded them under H.R. 3285. Violations would be investigated by the Secretary of Labor who could bring a civil action against the appropriate person in a United States district court.

Mr. Chairman, I strongly believe that organizations should have awards programs to stimulate invention and innovation by their employees. I am well acquainted with the awards program of NASA and believe that many corporations also have generous programs to reward deserving inventors.

NASA has direct authority under section 306 of the National Aeronautics and Space Act of 1958, as amended, 42 U.S.C. 2458, to grant monetary awards for scientific and technical contributions to NASA's activities. This authority is not limited to patentable inventions, but is applied to all employee inventions for which a patent application is filed. Evaluation factors include the creativity and significance of the invention, its actual or expected use by NASA and other agencies, and commercial use and potential. A minimum award is always given, and a number of much more substantial

awards have been made under this authority for both patented inventions and other contributions. The NASA program has worked well, and there is no reason to expect it will not continue to do so.

The Secretary's Report to the President and Congress on the Stevenson-Wydler Act calls for the development of incentives for Federal employees. But since the laws and regulations that apply to Federal employees are unique, we believe their incentives should be developed in that context, not in legislation applying to all inventors, such as H.R. 3285 and H.R. 3286.

For all these reasons I do not favor the creation of a system such as that contained in H.R. 3285. Even my cryptic explanation of the bill reveals the administrative complexities and burdens it would impose on both industry and the Government. The costs of implementing H.R. 3285 would be particularly unfortunate for small, innovative firms which could ill afford to divert their limited resources to comply with its many requirements and deadlines.

I am concerned that H.R. 3285 would retard the free flow of information among employees of companies. An employee may be hesitant to share the results of his or her research with a co-worker for fear that the co-worker may make an improvement or even a separate invention, either of which possibilities would reduce the potential compensation to the first employee. At a time when the United States needs more invention and innovation to compete in world markets, we cannot afford unnecessary barriers to creativity in our corporate and Government laboratories.

I am also concerned that the system which would be established under H.R. 3285 would not take appropriate account of the contributions made by others in the organization which affect the value of a service invention. Directors of research laboratories who chart the course and direction of employees' efforts, production engineers who translate laboratory prototypes into marketable products, and marketing personnel who design and direct advertising campaigns

which create demand for new products are among those in corporate settings whose contributions frequently approach that of the inventor. Failure also to recognize such contributions could be counterproductive.

Finally, Mr. Chairman, it seems to me that in view of the sweeping definition of a "service invention" in H.R. 3285 employees could actually receive title to fewer inventions under that bill than they would under either H.R. 3286, Executive Order No. 10096, or the State laws that I have mentioned.

H.R. 4525

H.R. 4525 would clarify an inventor's right to receive a patent by specifying in 35 USC 103 that:

> "Prior art shall not include unpublished information which is developed by the applicant singly or jointly with others, or which is known to the applicant only by virtue of his or her employment."

Prior art is the existing technical information against which the patentability of an invention is judged. Publicly known information is always considered in judging whether an invention is obvious. But a complex and growing body of jurisprudence (begun by In re Bass, 59 C.C.P.A. 1342, 474 F.2d 1976, 177 U.S.P.Q. 178 (1973), and continued in large part by its progeny, including In re Clemens, 622 F.2d 1029, 206 U.S.P.Q. 289 (C.C.P.A. 1980)) regards unpublished information within an organization as prior art if an inventor was aware of it. If unknown to the inventor, however, the same organizational information would not be taken into account in judging nonobviousness. As a consequence, scientists or researchers unaware of such secret organizational information have a better chance of obtaining a patent than those to whom it was known.

We are concerned that this body of jurisprudence will discourage the communication of technical information among scientists and researchers in an organization. It is therefore counterproductive and should be reversed if the efforts of corporate and team research are to be fairly rewarded under the patent system. Neither research laboratories nor technology-oriented businesses conduct research and development in a vacuum. New technology is often developed on the basis of background scientific or technical information known within the organization but unknown to the public. And productive research usually depends on the continuing development and communication of this secret information among researchers and scientists. Inventions are far less likely to arise from isolated research efforts by those unaware of available background technology and out of communication with others in the organization.

Thus, we believe that a change in the patent laws is needed to assure that unpublished technical information not be regarded as prior art in judging nonobviousness, if that technical information is developed by the patent applicant alone or in collaboration with others, or obtained by the applicant from co-researchers during the course of employment.

Drafting an appropriate provision, however, has proven to be an elusive and complex task. H.R. 4525 is too broad. It is not limited, for example, to exchanges of background information among co-workers in a single organization. Information learned from or transmitted to outsiders could be disqualified as prior art.

Concerned patent law organizations have devoted much effort to the development of a provision that reverses this body of jurisprudence without upsetting other legal principles. We understand that on March 15, 1984, the American Intellectual Property Law Association (AIPLA) forwarded to you, Mr. Chairman, proposals for amending sections 103, 116 and 120 of title 35. We believe that the amendment of section 103 along the line proposed by AIPLA appears to have the potential of overcoming the problems created by Bass and

its progeny in the corporate context. It also may be useful in solving the difficulties addressed by H.R. 4527. I will comment on this and AIPLA's suggestions for amending sections 116 and 120 in my discussion of H.R. 4527.

H.R. 4527

This bill would amend 35 USC 116 in regard to the naming of inventors. Section 116 has been asserted by many to require that the invention defined in every claim in an application be invented by all of the named co-inventors. Complying with this requirement is sometimes difficult and at times impossible.

Scientists or researchers in an organization often work on a particular aspect or embodiment of the invention, or on only a portion of the invention, while others work on different aspects, embodiments or portions. Scientists are continually added to a research team, while other scientists leave the team. Concepts and development plans generated through brainstorming cannot always be accurately attributed.

The preparation of patent applications for inventions resulting from team efforts such as these nevertheless requires the attorney to determine the inventorship of each claim to be included in the application. Adequate protection for an invention may require the filing of several applications to cover the separate contributions to all of its aspects, embodiments and portions. Some inventorship problems would require the filing of separate applications that may not be separately patentable. To do otherwise risks noncompliance with 35 USC 116, thereby jeopardizing the rights of all the inventors. These requirements seem especially hypertechnical when in most cases a single organization owns patent rights from all the contributors to the invention.

Admittedly, good faith errors in the naming of inventors, either in an application or a patent, may be corrected. Nonetheless, it is

still necessary to determine inventorship. H.R. 4527 would eliminate the need for making these sometimes chancy, complex and time-consuming determinations by specifying that joint inventors need not have contributed jointly to each claim in an application. As we understand the provision, inventors would also be regarded as joint inventors whether or not they physically worked together at the same place or at the same time in developing the invention. Further, joint inventorship would not require that each inventor make the same type or amount of contribution to the invention or that each make a contribution to the subject matter of each claim of the patent. Thus, in our view, the provision would incorporate the rationale in decisions such as SAB Industri AB v. Bendix Corp., 199 U.S.P.Q. 95 (E.D. Va. 1978), and Monsanto Co. v. Kamp, 269 F. Supp. 818, 154 U.S.P.Q. 259 (D.D.C. 1967). The amendment to section 116 proposed by AIPLA in its letter of March 15 to you, Mr. Chairman, expresses these concepts in a clearer fashion than does H.R. 4527, and we support this amendment.

Concern has also been expressed regarding the broad range of H.R. 4527, which could permit patent applicants to "buy up" information that would otherwise constitute prior art by hiring persons, for instance, whose unpublished inventive contributions could otherwise be patent defeating. Such persons would, under H.R. 4527, be considered joint inventors with the patent applicant. In our view, the amendment to section 103 proposed by AIPLA may alleviate this concern because of its provision that the subject matter developed by another and the claimed invention be commonly owned at the time the invention was made.

Like any other applications, jointly-filed applications will continue to be subject to the requirement of 35 USC 121 that an application be directed to only a single invention. Other inventions claimed in the application may each be the subject of a separate (divisional) application. Under existing law, however, the inventive entity in the divisional application must be the same as that in the earlier-filed one, if the divisional application is to

be accorded the filing date of the original application. When joint inventors file an application, divisional applications based on it will sometimes have to name different inventive entities, and in these cases the earlier filing date is not available under present law.

To assure that divisional applications receive this earlier filing date, which may be crucial to patentability, an amendment in present 35 USC 120 would be advisable. Here also, AIPLA has made a suggestion which, in our view, may solve this problem.

Section 2 of the bill would apply the new naming requirements for joint inventors to patents granted either before or after enactment of the bill. We foresee no special difficulty in applying these new provisions retroactively.

In summary, Mr. Chairman, we strongly support the principles of H.R. 4527. We view the amendments proposed by AIPLA as a possible improvement over the language of the bill itself.

II. Changes in the Administration of the Patent and Trademark Office or the Patent System Generally

H.R. 2610 - "Patent Law Amendments of 1983"

This measure was introduced at the request of the Administration and I briefly addressed the substance of this bill before this Subcommittee during the Hearing on Oversight of the Patent and Trademark Office on April 20, 1983. An identical measure was introduced in the Senate as S. 1538. The Senate version has been ordered reported, as amended, by the Subcommittee on Patents, Copyrights and Trademarks.

The most significant aspect of this proposed legislation is Section 2 which would authorize the issue of a patent without examination. In addition, Sections 3 to 11 contain a number of clarifying amendments to the patent laws.

In reporting S. 1538, the Senate Subcommittee on Patents, Copyrights and Trademarks amended S. 1538 to create a "statutory invention recording" instead of a patent without examination. The "statutory invention recording" would be an unexamined publication having all of the attributes of a patent except for the remedies associated with it. Thus, an inventor would receive the same benefits, from a defensive point of view, from a "statutory invention recording" as he or she would from a patent. We agree with the change in terminology made by the Senate Subcommittee and recommend a similar change in H.R. 2610. In my testimony I will refer to a "statutory invention recording," with your permission, Mr. Chairman.

At present, there is no simple, practical method by which an inventor may safeguard the right to work an invention without obtaining a patent. Section 2 of H.R. 2610 would establish a new procedure by which an inventor could acquire a statutory invention recording that would be valid for all defensive purposes. Like a patent dedicated to the public, this instrument would not permit an inventor to exclude others from working the invention, but it would protect the inventor from having a patent on the same invention later issued to someone else. In addition, this instrument could be obtained more quickly and less expensively than a traditional patent.

To qualify for a statutory invention recording under the bill, an applicant would execute a waiver of enforceability. This waiver would become effective at the time of publication of the statutory invention recording and would apply to remedies for patent infringement under title 35, remedies against unfair competition in the importation of patented inventions under title 19, and unauthorized disclosure or use by the Federal Government under titles 22 and 28, respectively. By making the waiver, the applicant would authorize the free exploitation in the United States of the invention claimed in the instrument. A statutory invention recording under this Section would be the same as a traditional patent in other respects, including serving as the basis for a priority claim in a foreign application.

A statutory invention recording could become involved in an "interference," the proceeding that determines which one of rival inventors was the first to invent. This instrument would constitute "prior art," that is, evidence of the state-of-the-art against which later-filed applications will be measured for patentability. This particular aspect is intended to overcome inherent shortcomings in our defensive publication program and with private defensive-type publications. Finally, this instrument would be published, classified, and cross-referenced like a patent, disseminated to foreign patent offices, stored in the Patent and Trademark Office computer tapes made available for commercial data bases, and announced in the Official Gazette.

An application for a statutory invention recording under this Section would not be subject to the normal examination process. The Patent and Trademark Office would only review the application for adherence to formal requirements and make a cursory check to ensure that the disclosure requirements were satisfied. Because there would be no substantive examination, fees charged by the Patent and Trademark Office could be less than those charged for examined patents. In addition, maintenance fees would not be charged for an instrument issued under this Section.

The instrument would be available to any applicant. It would be of special interest to Government agencies and corporations that obtain patents for defensive purposes. Under this bill, its use would be strictly optional, and an applicant would be free to change to a regular patent application prior to its issuance. Of course, a statutory invention recording would not be useful to every applicant, since it would lack the exclusivity associated with a patent. However, it would provide inventors with one more option for the protection of their intellectual property.

Concerning the remainder of the bill, Section 3 would permit an appeal from a second rejection of the claims by any examiner. As present law only permits appeal from second rejections by primary examiners, this amendment would expedite examination proceedings.

Section 4 provides authority for the Commissioner to set a period shorter than three months for the payment of an issue fee. While a full three months may be needed in some cases, e.g., when there is a need for a new oath or drawing, we believe that some of this time could have been reduced in the interest of prompt disclosure of technology. This Section also deletes references to payments and fees that were abolished by P.L. 97-247. The Senate Subcommittee, however, deleted this Section when it amended S. 1538.

Sections 5-9 contain technical amendments to the patent laws that would provide greater flexibility for our processing of international applications under the Patent Cooperation Treaty. The amendments would also accord international applicants benefits similar to those given to national applicants, and we strongly favor this enactment.

Section 10 replaces references to the "Patent Office" with the term "Patent and Trademark Office", where the older name was used inadvertently.

Section 11 ensures that no maintenance fees would be charged for plant patents, regardless of when filed. Without this provision, plant patent owners whose applications were filed between the dates of enactment of P.L. 96-517 and P.L. 97-247 would be subject to payment of maintenance fees, while those whose applications were filed after enactment of P.L. 97-247 would not. This provision eliminates that inconsistency and we favor its enactment.

H.R. 3462 - "Small Business Independent Inventor Patent Fee Assistance Act of 1983"

This measure concerns the fees paid by individual inventors, small businesses, and nonprofit organizations.

In 1980 and 1982, this Subcommittee played a major role in developing and enacting Public Laws 96-517 and 97-247. These laws

created our "user fee" system, now providing the stable funding we desperately needed. Under the "user fee" system, fees are charged not only during the processing of an application, but maintenance fees are charged during the life of the patent. In effect, maintenance fees shift some of the payment for the processing of an application to a period when the invention has been commercialized and the patentee is normally in a better position to afford the payments. If the patented invention is not commercialized, the patent owner could stop paying maintenance fees and allow the patent to lapse.

These maintenance fees are due three times during the lifetime of the patent: $400 is due 3 1/2 years after the patent is issued, $800 after 7 1/2 years, and $1200 after 11 1/2 years. Congress has authorized a 50% subsidy for individual inventors, small businesses, and nonprofit institutions, so that these entities only pay $200, $400, and $600, respectively. These fees can be adjusted administratively in FY 1986 and every third year thereafter, but only to reflect changes in the Consumer Price Index (CPI). Significant revenues from maintenance fees will not be received until FY 1987 and full recovery will not occur until about 1996.

H.R. 3462 would exempt independent inventors, small businesses, and nonprofit organizations, i.e., small entities, from paying any maintenance fees. In addition, other fees for small entities would not be adjusted to reflect changes in the CPI. We estimate that if the bill were enacted, the PTO would lose more than $10,000,000 in the three year period beginning in FY 1986. The amount lost would be even more in later years.

If we do not receive these funds, our plan to reduce the average pendency time for applications to 18 months by 1987 would be seriously undermined. And even if we could reach the 18 month pendency time, we probably would not be able to maintain it in the years following 1987. In addition, our efforts to automate the PTO by 1990 would be seriously curtailed.

The record of filings since P.L. 97-247 came into effect indicates that the prospect of maintenance fees has not deterred small entities from filing patent applications. Since the new fees went into effect, the percentage of U.S. small entities entering the patent system is essentially the same as before the new fees were enacted.

Small entities are not being adversely affected by the new fee structure with its 50% subsidy. Enactment of the bill is unnecessary and would seriously undermine our efforts to improve our services to inventors and industry. We, therefore, strongly oppose its enactment.

H.R. 4462 - "Patent and Trademark Office Procedures Act of 1983"

This measure was introduced at the request of the Administration. Similar provisions have been incorporated by amendment into S. 1538, which has been reported by the Senate Subcommittee on Patents, Copyrights and Trademarks.

This proposal would improve procedures in the PTO for determining inventorship in interference proceedings. Since evidence of the dates of when an invention was conceived and made, and the diligence exercised by an inventor between conception and making, may be necessary to prove first inventorship, interference proceedings can be extremely complex, lengthy, and expensive. For example, the longest interference proceeding (involving polypropylene) consumed over 13 years in the Office alone.

While most interferences are not that long, delays in issuing a patent due to lengthy interference proceedings are harmful to both the applicants and the public. Applicants are unsure of what rights they will be granted and, consequently, often delay the marketing of their inventions. As a consequence, the public may be harmed by a delay in access to the products involved and to the underlying technology.

One of the reasons for such lengthy proceedings in the Office is a jurisdictional problem. By statute, the tribunal responsible for determining patentability is the Board of Appeals. The Board of Patent Interferences, on the other hand, the statutory tribunal responsible for determining the first inventor, is not authorized to address questions of patentability of the invention. If a question of patentability arises during an interference, the proceeding may be suspended pending a determination by the patent examiner and possibly, by the Board of Appeals or may even be delayed until after the interference is completed. This restriction on the jurisdiction of the Board of Patent Interferences unduly complicates the procedures for obtaining patents.

We propose that the Board of Appeals and the Board of Patent Interferences be combined. This new board, to be called the Board of Appeals and Interferences, could decide questions of patentability and inventor priority in a more timely manner. Procedures for patent applicants and patentees involved in interferences would be simpler, faster, and less costly.

On January 30, 1984, after consultations with the staff of this Subcommittee, we published a proposed set of regulations to simplify and streamline the interference practices in the Office. Those draft regulations took into account the potential enactment of H.R. 4462. We did this while H.R. 4462 is pending to allow the public maximum time to comment on this complex matter. There is no intent to usurp the prerogatives of the Congress on the pending legislation and the final rules will, of course, reflect Congressional action.

We believe that enactment of this legislation and promulgation of regulations along the line of our draft proposal will result in a fair, speedy, and inexpensive determination of inventorship in patent interferences.

H.R. 4524

This bill would clarify certain provisions of the patent laws relating to the filing of patent applications in foreign countries. According to present 35 USC 184, a patent application for an invention made in the United States cannot be filed in a foreign country unless the applicant first obtains a foreign filing license from the Office, or unless the corresponding or equivalent application has been pending in the Patent and Trademark Office for at least six months and no secrecy order has been imposed. Section 184 also proscribes the filing without a supplemental license of any modification, amendment, supplement or division to, or of, a foreign application, that is, any paper disclosing additional subject matter. For the sake of simplicity, I will refer to them collectively as a modification.

In situations where an application or modification was filed abroad without a license, the patent applicant may have an opportunity to obtain a retroactive license. A retroactive license is available where the applicant can establish that the filing abroad was inadvertent and that the application or modification does not contain subject matter within the secrecy order scope of section 181, the disclosure of which might be detrimental to national security. Failing to obtain a license either prior to filing abroad or retroactively, however, invalidates the corresponding United States patent (section 185) and may subject the applicant to criminal penalties (section 186).

Section 1 of H.R. 4524 would amend section 184 in the following manner: First, it would replace the standard of "inadvertence" for receiving a retroactive license with the phrase "through error and without deceptive intent." This new standard, which we support, properly takes into account the fact that failing to obtain a needed license can be a willful act, even though done with the best intentions and without any realization of a failure to comply with the license requirement. "Inadvertence," on the other hand, carries a

connotation that the applicant did something he did not intend to do. Harmless judgmental errors made in good faith would, therefore, under the new standard no longer preclude the grant of a retroactive license. Even with the amendment, a retroactive license could not be granted under the bill if the subject matter filed abroad comes within the secrecy order scope of 35 USC 181.

To implement this provision, we could establish by rule a modified "diligence" requirement for obtaining a retroactive license. Currently, there is no mention either in the present law, or in H.R. 4524, of any time limit or period by which an applicant or patent owner must apply for a retroactive license, once the need for such a license is discovered. Moreover, no court has imposed a "diligence" requirement. In exercising his discretionary authority, however, the Commissioner has demanded diligence by applicants and patent owners in applying for retroactive licenses, and the courts have agreed with the Commissioner's right to require such diligence.

Our contemplated regulations would not require a patent owner to review or inspect every patent file to determine if a retroactive license was needed but not obtained. Applicants would, of course, be expected to be diligent during the pendency of an application in seeking a retroactive license if they learn of a problem, since it is in the national interest to learn of disclosures of security sensitive information at the earliest possible date. In addition, the public has an interest in knowing at the earliest possible date that a patent is invalid under Section 185.

The second part of Section 1 would add a paragraph to 35 USC 184, exempting an applicant from the obligation to obtain a supplemental license for any modification to be filed abroad, if the modification consists only of the illustration, exemplification, comparison or explanation of subject matter previously disclosed either in a licensed foreign application or in an application that did not require a license for foreign filing. Under this provision, the

applicant would be given authority to apply the statutory test to determine whether the subject matter of the modification requires a license.

The proposed amendment of section 184 is intended to moderate the stricter test imposed by the former United States Court of Customs and Patent Appeals in In re Gaertner, 604 F.2d 1348, 202 U.S.P.Q. 714 (C.C.P.A. 1979), for receiving a retroactive license. In that case, the Court indicated that the subject matter of a modification is exempted from the license requirement only when it is recited in haec verbis in the application or is so commonly known that it can be said to be in fact expressly disclosed.

While we agree with the general concept of the second part of Section 1 of the bill, corrective legislation seems unnecessary since the Commissioner already has the authority to adopt appropriate rules under the present statute. The obtaining of foreign filing licenses is better handled by appropriate modification of our Rules of Practice under the present statute. This provides a flexibility and degree of detail not available from a statutory provision, while still guarding national security and the rights of applicants. We have developed appropriate rules along these lines and expect to promulgate them shortly.

Approximately 93% of the patent applications filed do not contain subject matter which might be detrimental to national security. These applications need not be referred to the defense agencies for review. The rules adopted in 1983 already provide that the filing of an application is considered a petition for a license, and applications not needing referral to a defense agency now receive a license as part of the filing receipt.

The proposed rules will further simplify the matter by providing a broader scope license for foreign filing permitting also the filing of a subsequent modification containing added subject matter in these cases without obtaining a supplemental license, provided that

such modification does not change the general nature of the subject matter described in the originally filed foreign application and does not involve certain sensitive technologies. The term "general nature of the subject matter described" would be further defined in our rules by specific examples.

The remaining 7% of applications must each be reviewed by a defense agency, and the subject matter of each may or may not be eligible for a foreign filing license. If a foreign filing license is granted, a supplemental license will be needed for filing any modification.

H.R. 4524 would not protect national security interests in this 7% segment of cases as completely as would our proposed regulations. Once a foreign filing license is granted for an application, H.R. 4524 does not require review by a defense agency to determine if a supplemental license is needed for the filing of a modification. Making even minor additions to the subject matter licensed for foreign filing might, in borderline cases, introduce national security considerations which would not come to the attention of a defense agency.

Although additional statutory authority is not necessary for the Office to promulgate its new regulations, we have no objection to the addition of a requirement in section 184 that the Commissioner institute rules along the lines of the new regulations, provided it leaves sufficient latitude to fix conditions assuring protection of national security interests. Addition of the following paragraph to section 184 as a substitute for that of the second part of Section 1 of H.R. 4524 would be acceptable:

> "Subject to such conditions as the Commissioner may set by regulations, the scope of a license shall permit subsequent modifications, amendments, and supplements containing additional subject matter when the application upon which a license request is based is not required to be made available for inspection under section 181 of this title."

Section 2 of the bill complements the first part of section 1 by amending section 185 of the patent laws. It is intended to shield a patent from invalidation for failure to obtain a license, if that failure was the result of error without deceptive intent and the subject matter was not within the scope of section 181. We do not believe it is necessary, however, to amend section 185 in order to achieve this result. The amendment to section 184 would apply both to patents and applications for which a retroactive license is sought, and the amendment to section 185 is redundant.

Section 186 of the patent laws sets criminal penalties for failing, innocently or not, to obtain a license under section 184, and not correcting that failure, if possible, by obtaining a retroactive license. Section 3 of the bill would amend section 186 to decriminalize section 184 violations. The bill, therefore, makes a distinction between violations of section 184 and violations of section 181. Criminal penalties would apply only to section 181 violations. Section 184 violations would be punished only by loss of patent rights.

Under the newly proposed standard for granting retroactive licenses under section 184, a retroactive license is always available to remedy judgmental errors made without deceptive intent, unless subject matter is involved which the Commmissioner determines might be detrimental to national security under section 181. We see no reason, therefore, to excuse from criminal penalties a failure to obtain a license when that failure was not the consequence of an error made without deceptive intent. Accordingly, we oppose enactment of Section 3.

Section 4 would make the bill effective for unexpired patents granted before enactment and patents issued after enactment. Through innocent misunderstandings of the new and more rigorous legal restrictions on transmitting technical information to a foreign country, as established in the Gaertner decision, some patent owners, we understand, may find themselves unable to satisfy

the requirements for obtaining retroactive licenses. These disadvantaged patent owners are primarily American businesses, since the provisions of section 184 do not apply to inventions made outside of the United States. The new standard for obtaining a retroactive license, however, will apply to these patents and enable their owners now to avoid civil and criminal penalties. We strongly support this provision, but favor extending it to pending patent applications and to expired as well as unexpired patents. Because there is a six-year statute of limitations for patent infringement actions, patent litigation often involves patents that have expired. Therefore, unless retroactivity extends to expired as well as unexpired patents, the applicable laws would differ in suits involving the two types of patents.

H.R. 4528

This bill contains two proposals concerned with our interference practice. Section 1 would permit the parties to an interference to resolve it through arbitration. We strongly support the principles of this section. Logically, the arbitration provisions of section 294, applicable to the settlement of patent validity and infringement issues, should be extended to interference issues, insofar as this is not already the case. Arbitration provides a faster and less expensive alternative to present administrative or judicial resolution of interferences. Arbitration would spare inventors and the Patent and Trademark Office considerable expense, without encroaching on the right of the public to have interferences correctly resolved.

The phrase "with respect to the parties" in the third sentence of proposed new subsection 135(d) seems intended to assure that an arbitration award can only bind the arbitrating parties. This would, for example, permit another person to raise matters in court which previously had been resolved during arbitration, when sued for infringement of a patent granted as a result of the arbitrated interference. Since the same concept is also embodied in the first

sentence of present section 294(c), however, we suggest that the phrase be deleted and the first sentence in section 294(c) be used instead.

The last sentence of Section 1 would continue the present authority of the Patent and Trademark Office to decide the patentability of inventions. Continuation of this authority is vital to the patent system. The Office should not be required to issue a patent for an invention it knows to be unpatentable. The Commissioner would not decide other matters settled by the arbitration, however.

When an interference is settled privately by the parties involved, the settlement agreement must be filed with the Patent and Trademark Office. Section 135(c) requires this filing to be made before the interference is terminated. The Commissioner may, on a showing of good cause as to why the agreement was not filed on time, accept the filing of the agreement up to six months after the interference is terminated. The time for filing cannot be extended further, nor can a settlement agreement or any patent involved in the interference be enforced if the agreement is not filed. The penalty for failure to file is unenforceability of both the settlement agreement and any patents involved.

Section 2 of the bill would amend section 135(c) to provide that the penalties for failing to file an agreement would not apply if the failure was the consequence of an error committed without deceptive intent. Section 2 would not have any effect on the kinds of agreements that must be filed.

The Section would further amend section 135(c) by enlarging the Commissioner's authority to accept the filing of a settlement agreement more than six months after the interference is terminated. The Commissioner would still possess statutory authority to demand a showing of good cause as to why the agreement was not earlier filed, and the lateness of filing would remain a factor to be considered in whether to accept the settlement agreement.

The Department of Justice opposes enactment of Section 2 of the bill on the ground that its potential benefits are outweighed by the possibility that interference parties may enter into collusive interference settlement agreements. We defer to the Department of Justice on this provision.

It is not clear whether Section 3 would permit arbitration of an interference declared prior to enactment of this bill. Since parties to such interferences may wish to arbitrate their dispute, we suggest that interferences in progress at the time of enactment can be settled by arbitration.

III. Substantive Changes to the Patent Laws

H.R. 3502 - Patent Term Restoration Act of 1983

The inequity to certain industries, 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 35 USC 155 to provide for an extension of the patent term for patented products, or patented methods for using or producing products, 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 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) specifies 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 promptly to publish 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, and 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 industry displays in exploiting those inventions. This interest is healthy, and open competition 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 financial commitments to research and development. But it certainly ranks high among other alternatives in providing the opportunity for rewards to those whose labors have proved successful. Enactment of the Patent Term Restoration Act will redress an inequity by restoring to patentees a part of their patent term which has been eroded by Federal premarket regulatory review. Because the patent term is a form of compensation to the inventor for having fully disclosed the invention to the public, one inventor

should not be treated differently from another. The Federal Government should not induce full public disclosure of an invention through a patent grant of 17 years, and then reduce the effective life of the patent through premarket regulatory review procedures.

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 effective 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 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. This concern assumes 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 fully safeguard health, safety and protection of the environment. There is no reason, however, why both objectives cannot be met. Adequate regulatory review is necessary. But, 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 which has been suggested 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 contained in the patent could contribute to wasteful duplication of research and development. Efforts by competitors to develop improved products and methods in unregulated fields could also be adversely affected, as the patent may well be broader than the product for which regulatory review is sought.

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. The mechanics of applying for and receiving a restoration of the patent term are

administratively simple. Enactment of H.R. 3502 would not, therefore, impose undue costs or burdens on the Patent and Trademark Office.

The effective date for extending a patent under H.R. 3502 is measured from either January 3, 1983, or the date on which the regulatory review period commences, whichever is later. In so providing, the bill would strike recently enacted sections 155 and 155A of title 35. To preserve statutory authority for extending the term of patents which would be entitled to an extension under these provisions, I would suggest that another section be added to H.R. 3502, to the effect that the provisions of Section 11 of P.L. 97-414 of January 4, 1983, and Section 4 of P.L. 98-127 of October 13, 1983, shall remain in effect.

H.R. 3577, H.R. 4526 and H.R. 4814

These bills would protect owners of patented processes from infringement of their inventions by excluding others from using or selling products produced by the patented process. The main difference between these bills is that H.R. 3577 would apply to products wherever made by the patented process, while H.R. 4526 and H.R. 4814 would only cover products made abroad by the patented process. In addition, H.R. 4526 and H.R. 4814 would also provide a remedy for another aspect of infringement, which I will address later in my statement.

Presently, the infringement of a patent for a product occurs if the patented invention is made, used or sold in the United States. Someone cannot avoid infringement of a product patent by manufacturing the product overseas and then importing it into this country, because use or sale of the product in the United States would infringe the patent.

A process patent, however, only protects a process or method of making an article or product. Today, the holder of a United States

process patent cannot use the patent law to prevent someone from practicing the patented process abroad and selling or using the resulting product in the United States. Technically, no one has used the patented process in this country. Nor do the remedies available under section 337a of the Tariff Act of 1930, as amended, always provide an adequate remedy.

The importance of process patent protection to the national economy, especially in such vital technical fields as industrial chemical and pharmaceutical manufacturing, microbiology and solid state electronics, cannot be overestimated.

The addition of section 271(e), as proposed by H.R. 4526, and H.R. 4814, as well as the amendments proposed by H.R. 3577, would close the gap in our patent laws, which presently leave owners of patented processes without an adequate remedy against the importation of products made abroad by their patented processes. As I have mentioned, however, H.R. 4526 and H.R. 4814 are limited only to foreign produced products. The Office of the United States Trade Representative has expressed concern that H.R. 4526 and H.R. 4814 would violate our obligation under Article III of the GATT not to discriminate against foreign made products. The importation, use or sale of products made abroad by a patented process would constitute infringement under H.R. 4526 and H.R. 4814. There is no remedy under the bills, however, against use or sale of a product made in the United States by infringing a process patent. Foreign products are, therefore, treated less favorably than domestic products. H.R. 3577, on the other hand, does not suffer this deficiency. Use or sale of a product made without authorization either in the United States or abroad would be an infringement under that bill.

In addition, H.R. 3577 would apply to products used or sold during the term of the process patent, regardless of when the product was made. We prefer this concept of added process patent protection over that expressed in H.R. 4526. The provisions of that bill would limit infringement to the importation, use or sale of products made

during the patent term. Because H.R. 4814 does not expressly contain this limitation, its provision is somewhat ambiguous but could still be interpreted in the same way as H.R. 4526. Further, both H.R. 4526 and H.R. 4814 are unclear on whether a process patent is infringed if a product is made during the patent term, but imported, sold or used after the patent expires. For all these reasons, we prefer the formulation of H.R. 3577 over that of either H.R. 4526 or H.R. 4814.

H.R. 3577 also includes a provision on proving infringement, not found in H.R. 4526 or H.R. 4814, that is very important to patent owners. In suing for infringement of a process patent, the burden of establishing infringement now rests entirely on the patent owner. New section 295, proposed in H.R. 3577, would in certain carefully prescribed circumstances establish a presumption that a product that could have been made by a patented process was actually made by that process. This new section may be of particular benefit to the owner of a process patent who seeks a remedy against the importer of a product made abroad by that process, since the laws of most countries do not provide the discovery procedures available through United States courts. This frequently makes it very difficult to secure proof of actions taken in a foreign country.

Shifting the burden of proof, as would H.R. 3577, should create no substantial hardship, since the alleged infringer is in a much better position to establish that the product was made by another method. An accused infringer, if not actually the manufacturer, has direct or at least indirect contact with the manufacturer.

An infringer will be protected against frivolous suits by a requirement that the patentee first show a substantial likelihood that an allegedly infringing product, which could have been made by the patented process, was in fact so produced. Such factors as the absence of other economically viable processes or the presence of tell-tale side effects or trace elements could satisfy the requirement. The patentee would also be required to make a reasonable

effort to determine how the product was actually made, and also show that he or she was unable to make that determination.

Because, in our view, H.R. 3577 offers stronger protection to patent owners, we prefer its provisions in this respect over the proposals of H.R. 4526 and H.R. 4814 to add a new section 271(e) to title 35.

H.R. 4526 and H.R. 4814 include a feature not found in H.R. 3577. The second part of Section 1 of H.R. 4526 and of Section 2 of H.R. 4814 addresses the problem identified by the 1972 decision of the Supreme Court in Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 173 U.S.P.Q. 769 (1972), by adding new section 271(f). The Supreme Court, in a narrow decision interpreting the patent owner's right to exclude others from making a patented invention, held that this right only covers the making of the patented invention in the United States. The patent claimed a machine for deveining shrimp. All of the machine's parts were manufactured by the accused infringer in the United States. To avoid infringement, however, the machine was not assembled in the United States. Rather, the parts were shipped separately to foreign purchasers with instructions for assembly. Assembly was a simple matter, taking about an hour.

The Supreme Court decided that since the machine was not built in the United States, section 271 (the patent infringement provision) did not apply. Moreover, the accused infringer was not even guilty of contributory infringement or inducement to infringe, because the requirement that there must first be direct infringement in the United States was not satisfied.

The Supreme Court acknowledged the narrowness of the law and stated that legislation is needed if the patentee is to have a remedy in these situations. Legislative remedies have been included in past comprehensive patent reform bills, but none has been enacted. A legislative remedy against such activities is necessary to provide the patentee with effective protection.

We have two suggestions for sharpening the remedy provided in H.R. 4526 and H.R. 4814. As presently drafted, these bills might deter the sale of components which are staple articles suitable for substantial noninfringing use. We believe the bills should be limited to the sale of components which are especially made or adapted for use in an infringement of a patent. This approach was taken by Congress in section 271(c) of the patent laws dealing with contributory infringement. In order to avoid interference with the export sale of staple articles of commerce, the limitations of section 271(c) should be incorporated into proposed section 271(f).

Secondly, we suggest deletion of the phrase in proposed section 271(f) requiring the infringer to have knowledge that combining the invention's components in the United States would be an infringement. Under the patent laws today, a patent may be infringed without the infringer's knowing that he is doing so. It is inconsistent and unfair, therefore, to provide a remedy for overseas assembly of a patented device only if the exporter knows that such assembly will infringe the patent. It is enough that the infringer intends for the components of the invention to be combined outside of the United States. The patent owner, in cases of assembly abroad, deserves the same rights as those available to other patent owners.

We would suggest that Section 3 of H.R. 4526 apply only to acts committed after the bill was introduced, regardless of when the patent issued. Acts not regarded as infringements prior to introduction of the bill should not upon its enactment automatically become infringements. This would be unfair to persons who in good faith prior to introduction imported, used or marketed an article made abroad by a patented process or sold components of a patented article for foreign assembly. Also, extensive preparations before introduction for such practices should not be unfairly penalized.

Other bills strengthening the protection now available to process patent owners are also pending. Specifically, title V in H.R. 3878 and sections 1, 2 and 3 of H.R. 4288, are the same as H.R. 3577. My comments, therefore, apply also to those other bills.

H.R. 4529

This bill would codify the decision in Lear, Inc. v. Adkins, 395 U.S. 653, 162 U.S.P.Q. 1 (1969), in which the Supreme Court overturned the judicial doctrine of "licensee estoppel." Prior to the Lear decision, a licensee was precluded from questioning the validity of any patent under which he was licensed. The Lear case, however, assures a licensee the right to challenge the validity of any such patent. The Supreme Court recognized the public interest in freedom from invalid patents and, further, that the licensee is the party most able and most likely to challenge validity.

As a result of Lear, however, the licensee is at times able to attack patent validity under conditions completely unfair to the licensor. A licensee, for example, can negotiate the best license terms available from the licensor, accept the contract, and then question patent validity without relinquishing the license. If he wins the validity suit, he can, of course, practice the invention safe in the knowledge that the patent is invalid. If he loses, the licensee merely continues to pay the agreed-upon royalties. He can "have his cake and eat it," risking nothing but attorney's fees. In fact, some courts have even held that it may be possible for the licensee to pay royalties to an escrow account during pendency of the suit over validity, rather than directly to the licensor.

A fairer balance between the rights of the licensor and those of the licensee is needed, without compromising the public interest. New section 295(b) proposed by H.R. 4529, would achieve this balance with a number of straight-forward principles. Either the licensee or licensor could terminate the license once the licensee asserts invalidity in a judicial action. However, the licensee would have to continue paying royalties directly to the licensor (not into an escrow account) unless the license is terminated. Upon termination by either party, further unlicensed practice of the patented invention would subject the former licensee to the infringement provisions of the patent laws.

We support these principles for their basic fairness both to the parties and the public. Various court decisions have upheld such conditions for challenging validity, but they are not widespread or uniform enough to be safely relied upon by licensing parties. A Federal statute is needed.

However, the statute should not be drafted in the form of H.R. 4529, which would increase Federal interference in patent licensing. The correct approach is to do exactly the opposite. Parties should properly be able to negotiate contracts containing provisions, for instance, that a licensor or licensee could terminate the license if the licensee challenged the validity of the licensed patent in a judicial proceeding. The bill should, therefore, assure the parties that any such licensing provisions which they negotiate will not be deemed unenforceable as inconsistent with Federal objectives.

This approach will, I believe, adequately remedy the inequities resulting from the Lear decision insofar as prospective patent license arrangements are concerned. It does, however, leave unanswered the problems faced by those patentees who have entered into license agreements since Lear. We would be pleased to work with the Subcommittee to find an acceptable solution to this problem.

I should point out another avenue open to the licensee which is not addressed by this bill and that is the licensee's option to test the validity of the licensed patent in some instances without resorting to litigation. By instituting a reexamination proceeding in the Patent and Trademark Office under chapter 30 of title 35, the validity of a patent can often be more easily determined and at much less expense to the licensee than litigation would require. Any subsequent judicial review would not involve the licensee and, consequently, in such case the provisions of this bill would not permit the licensor to terminate the license.

As we understand Section 2 of H.R. 4529, it properly would apply the provisions of this bill retroactively to patents already granted at the time of enactment. This will assure the resolution of validity challenges under conditions as fair as possible to both parties. Even more important, it will encourage the licensing of patents and the maximum utilization of new technology for the benefit of the public.

This completes my prepared statement, Mr. Chairman. I would be pleased to respond to any questions on these bills which you or the other members of this Subcommittee may have.

Mr. KASTENMEIER. Thank you, Mr. Mossinghoff, for your presentation. Of course, I fear that perhaps members of the subcommittee may be subjected to more than they have ever wanted to know about patent law, but I did feel it necessary to have hearings on the broad range of questions, even though it is difficult to focus on one or two aspects of these issues, which we will later have to do.

It will indicate to the committee, I think, really just about all the statutory issues in statutory form that are before us dealing precisely with patent law, and we will be better able to judge where there is consensus and what can move and what is meritorious.

I wanted to state again, it is not that I did not wish for your comments on the patent restoration bill but, rather, I do think that it is very probable that in a relatively short period of time another bill will be available and we can look at not only 3502, that deals with patent restoration, and any new bill that may be introduced at the same time.

I would like to yield to my colleagues first. I have a few questions, but I will put them last. I would like to yield to the gentleman from Ohio, Mr. DeWine, for any questions he may have.

Mr. DEWINE. I have no questions, Mr. Chairman.

Mr. KASTENMEIER. I would like to yield, then, to the gentleman from California, Mr. Berman.

Mr. BERMAN. I have no questions, Mr. Chairman.

Mr. KASTENMEIER. I would like to yield to our other colleague from Ohio, Mr. Kindness.

Mr. KINDNESS. Thank you, Mr. Chairman. I have a lot of questions, but none that I can formulate at the moment.

I want to express my appreciation for the depth and coverage of the testimony that you have presented here this morning, Mr. Mossinghoff. It is a subject for me and perhaps other members of the subcommittee to study at greater length.

I would yield back my time, Mr. Chairman.

Mr. KASTENMEIER. I thank my colleague.

I do have a couple questions on H.R. 4524, which extends process patent protection to situations where the patent process is practiced outside the United States and the resulting goods are imported into the United States.

The Trade Regulations Committee of the Association of the Bar of the City of New York opposes this bill because, as they claim, in the United States we do not either have, in their words, a working requirement or a compulsory license agreement. They claim that consequently the proposed change would permit a U.S. patent owner, including a foreign entity, to prevent importation into the United States of goods made by a patent process while, at the same time, preventing anyone from practicing the invention in the United States.

That seems to be the heart of their position. How do you respond to that?

Mr. MOSSINGHOFF. I wasn't aware of that opposition. I think, first, the position is strongly supported by all of the bar associations that we talked to, I believe, the American Bar Association, the American Intellectual Property Law Association. I believe it is a very strongly supported position. It brings the U.S. laws general-

ly in line with other countries in terms of giving better protection to process patent owners.

I think the issue of whether or not we have compulsory licensing is really a much broader one. We would oppose compulsory licensing. I think that the United States stands as a good example to the rest of the world that we use the patent system in a very pure form and it has served us very well for 200 years.

I do not really see how the issue of whether we have or don't have compulsory licensing affects this particular provision. If you have a patent on a article, we don't have working requirements and we don't have compulsory licensing requirements, so the patentee can stop people from working it. This, we think, is the legitimate right of a patentee.

It goes to the heart of the U.S. patent system, and we are saying let us just extend that same provision to people who have process patents, particularly in the areas of biotechnology where, in many cases, the product itself is an old product, is a nonpatentable product, but the methods of making it, for example using bioengineering, are extremely beneficial to everyone.

We think those should be covered. If I may ask you, was this the patent section of the bar?

Mr. KASTENMEIER. No. I want to make that quite clear. It is the Trade Regulation Committee. They have a different interest in the patent or intellectual property section of the same organization.

Mr. MOSSINGHOFF. It would surprise me. I had thought that the support among the patent law associations, and the industry associations more importantly, perhaps, than the patent law associations, was just about unanimous that this is a long overdue provision that should be added.

Mr. KASTENMEIER. That is one reason I raise this. We have to be interested in a broad spectrum of how a proposed law will impact, and since this came to our attention, I wanted to raise it with you.

They also claim adversely that the bill would limit the importation of patent processes by foreign manufacturers because the foreign manufacturers would have to disclose proprietary information in order to possibly rebut a claim or an interference and they may not want to do that and, therefore, it would inhibit some movement in international trade in that respect.

Mr. MOSSINGHOFF. Our comment would be that with respect to H.R. 4526, we do not support that bill as it was written because it only applies to foreigners. I could see where a trade regulation bar could be concerned about that. Indeed, the U.S. Trade Representative is concerned about it and wrote us a letter advising us to testify in favor of what we think is the more favorable approach, which appears in H.R. 3577, and that simply applies across the board.

To that extent we do agree with the Trade Regulation Committee of the New York Bar.

With respect to the disclosure of proprietary processes, that is also why we favor the presumption that is included in H.R. 3577. That says that if you can establish the reasonable likelihood that, for example, the unpatented product was made by a patented process abroad, then the burden shifts to the importer and the importer, indeed, has a choice.

They can disclose proprietary information, and that obviously can be done in court in an in-camera proceeding and I think most district courts would receive proprietary information in camera, or the presumption is on you, in other words, to show that you did not infringe. I think that goes to the heart of why we think that presumption is a good idea, because if you didn't have it, it could prove impossible to prove that the process used abroad was indeed patented in the United States.

I think that our bills maybe do not take care of all of their concerns, but it takes care of some of them by those two aspects.

Mr. KASTENMEIER. The U.S. Trade Representative continues to be interested in GATT and other things, including matters outside the parameters of patents, about copyright, the manufacturing clause. GATT has been raised again and that is not a subject here this morning, but does the treatment of process patents in this bill, H.R. 4524, violate in any respect the General Agreement on Tariffs and Trade, GATT, by discriminating against foreign products?

Mr. MOSSINGHOFF. The Office of the U.S. Trade Representative thinks that there is a problem. They think that it does and they favor our approach, the approach of the administration, that was introduced. It is actually a spinoff of the administration bill introduced by Congressman Moorhead, H.R. 3577, and that does not apply just to foreign-made products; it applies to all products manufactured by a patented process, whether the process is practiced in this country or abroad.

They prefer that as not having any problems under GATT. H.R. 4526, they think, does have some problems.

The international recognition of this type of protection is written explicitly into the Paris Convention in article 5. Article 5 specifically addresses it because most nations do have this kind of protection and specifically addresses this as being something that is appropriate under the Paris convention. As long as it is applied evenhandedly it is not inappropriate under the General Agreement on Tariffs and Trade.

Mr. KASTENMEIER. In a different area, on employee inventor's rights, H.R. 3286 provides a national standard for the nature and extent of permissible employee pre-invention assignment agreements.

One of the reasons some think the bill might be attractive to large companies is that it sets a uniform national standard and won't be subject to State-by-State regulations or standards, but I note that you tend to oppose that.

I know that the administration does not uniformly oppose national standards. My colleague from Wisconsin, for example, Senator Kasten, has a product liability bill which preempts States and establishes national standards, which is being supported by the Department of Commerce. So apparently that isn't the reason for your opposition.

Mr. MOSSINGHOFF. We don't recommend enactment of a Federal standard here, but our position is that if the Subcommittee determines that a Federal standard is appropriate, based on testimony and your consideration, we would not oppose that. It is not a matter of hard opposition; it is a matter that this has traditionally

been left to State law. Employer-employee agreements have been a matter of State law.

We do recommend, and a much stronger view is, that if there is to be a Federal standard, that the Subcommittee consider carefully the five State laws that have been enacted. They have, as I understand it, worked well, and the principles of those laws are really better thought through, we think, than H.R. 3286.

So if there is to be a Federal standard on that, we would not oppose enaction by the subcommittee if you determine that there is to be one. We would recommend very strongly, though, that the State laws that have been enacted be looked at carefully, as perhaps containing a proper balance between the rights of the employer and the employee.

Mr. KASTENMEIER. With respect to H.R. 2610 relating to defensive patents, it has been suggested in some quarters that the Government be required to limit their patent applications to just such defensive patents.

Do you support such an amendment, and what interplay might there be between this bill and the present rather confusing state of Government patent policy?

Mr. MOSSINGHOFF. My position is that the Government agencies, if they have an invention that they intend to somehow commercialize, and if the exclusive rights of a patent can help them issue licenses which will stimulate business executives to take on the added cost of taking an invention, say, coming out of the space program and turning it into a commercially viable invention, that the Federal agencies be able to get regular patents.

But I think if they are getting a patent, as is the case with a lot of the 28,000 patents that the U.S. Government currently owns, solely for defensive purposes—that is, solely to assure the right of the Defense Department or the Energy Department or NASA to be able to continue to procure products free of patent infringement liabililty—that there they should be required to use the statutory invention recording. I think there should be a uniform standard around Government on making that determination. It ought to be made at a fairly high level within an agency, based on some standard criteria.

So in summary, then, if the patent system and exclusivity is going to help commercialize it and they view that as one of their responsibilities, then I think a regular U.S. patent is the way to go. But if it is to assure procurement, I think the agency should be required to file for statutory invention recording under some uniform criteria.

Mr. KASTENMEIER. One last question, and we may have other questions, but I think if we do we will submit them to you in writing.

But as a followup on questions I had earlier as a result of Mr. Mitchell's bill, our colleague who introduced a bill on patent fees, I guess, relieving small businesses and universities from paying the followon maintenance fees, the fee system—and you have already been very forthcoming about the impact of the fee system to date, and I think you indicated that other than the last-minute splurge before moving up to higher fees in terms of filings—that it did not

appear to have any adverse impact on numbers of applications with respect to either category to date.

What would you forecast in that connection? Would you forecast into the future any discernible impact with respect to discouraging filings in either group, that is, small business, university or other corporate inventors?

Mr. MOSSINGHOFF. Nothing in the experience we have had now, and we have gone almost a year and a half under the fees, would lead us to believe that there is going to be any significant change from the present, and the present is that in 1984 so far—I think it runs from October 1 midway through February—the trends are good. It is actually a higher percentage of independent inventors, small business, and nonprofits that are coming in; slightly higher. I don't know if it is statistically valid, but it is up a little bit.

Second, for 1984, another good trend is that the percentage of foreign applications as a percentage of the total is actually slightly less than it has been for the other couple years. I don't know if that trend is going to continue.

Again, I don't know if these are statistically important trends, but clearly, nothing in the data we have seen would lead us to conclude that there needs to be any further relief. We think that the 50-percent subsidy is working well and they are coming into the system at about the same ratio as they did before. Even in 1984 it is slightly up.

Mr. KASTENMEIER. Suppose we had not done that, that it had a two-tiered system. Suppose we had imposed a maintenance fee system, the schedule of fees, as opposed on all other inventors, including large corporate inventors, on small business, individuals, and others.

Do you think we would have discouraged, by virtue of such a fee schedule, applications and filings in that group?

Mr. MOSSINGHOFF. It is hard to answer that, Mr. Chairman. The actual cost of filing is not that much money when you compare the cost, first, of the research and development that goes into an invention, the cost of marketing and the cost of attorneys to prepare and prosecute applications.

Our original predictions were—the administration took the position—that it would not, but then when we saw the concern that was expressed up here and the concern expressed by small business and independent inventors' associations around the country, we then, as you know, agreed to the 50-percent subsidy.

In some ways, sometimes, these are self-fulfilling prophecies. If someone says they are going to be less if you have high fees, then maybe people would be discouraged from filing. I guess I would just add that I think we have a pretty good system, it works well, and I think it was a good example of cooperation between the legislative and executive branches in putting that system in place.

Mr. KASTENMEIER. I want to thank you.

Do either of my colleagues have any questions?

Mr. KINDNESS. Mr. Chairman, I wonder if I might add one question with respect to the statutory invention recording proposal.

What would be the status of that statutory invention recording under the Paris Convention, in your view?

Mr. MOSSINGHOFF. Until the time it was actually published as a statutory invention recording, it would be a regularly filed U.S. patent application and could serve as a basis for priority internationally in all countries.

Then at the time the case would be otherwise granted as a patent, we would simply not grant it as a patent but, rather, publish it as a statutory invention recording, in which case it would have no effect of a patent within the meaning of the Paris Convention.

We think that is an advantage; that by calling it something other than a defensive patent—that was our original proposal—by adopting the Senate language, calling it a statutory invention recording, we really avoid all problems we might otherwise might have under the Paris Convention.

Mr. KINDNESS. So it has an evidentiary function basically.

Mr. MOSSINGHOFF. It would clearly have an evidentiary function, and with respect to U.S. law it has a patent-defeating function. It can defeat other patents, and that is the whole purpose of it. It can prevent a later patent from being obtained on the invention, and we think that, particularly for Government agencies, that is a very beneficial thing because they could otherwise be subjected to substantial royalties if they let a later patent be issued.

Mr. KINDNESS. But it would not have that effect in another country under the Paris Convention.

Mr. MOSSINGHOFF. It can serve as the basis for priority. While it is pending, it would be an application that could serve the basis for—if you were to, say, file in the United Kingdom, you would be able to get back to the date that you filed your application in the United States, so it would have that effect.

Mr. KINDNESS. Thank you.

Thank you, Mr. Chairman.

Mr. KASTENMEIER. We wish to thank you for your excellent testimony this morning. I know you have produced considerable work here for us. It is doubtless the committee will need to be in further contact with you on the matters raised this morning, as on some issues we will proceed into markup and we will want the benefit of your further views.

In any event, it has, as always, been a pleasure.

Mr. MOSSINGHOFF. Thank you, Mr. Chairman. We really welcome the opportunity to get the administration's position on the record on these important bills. Some of them we think are relatively noncontroversial; for example, merger of the two boards, the Board of Appeals and the Board of Patent Interferences. That is a very noncontroversial matter. I think all the Bar Associations support it.

There are things like that which we would really be anxious to see moved during this session, if it is at all possible. I know it is going to be a tough session for all the committees, but we do welcome this opportunity.

Mr. KASTENMEIER. Thank you. And we also appreciate your introducing your colleagues, who have also appeared before this and other committees of the Congress.

Our second and last witness this morning is Harry F. Manbeck, Jr., General Patent Counsel for the General Electric Co. Mr. Man-

beck is representing the views this morning of the Ad Hoc Committee to Improve the Patent Laws.

It is with mixed feelings that I note that the Ad Hoc Committee has lost its Chair, Pauline Newman. That is the bad news. The good news is that she has been named to be a circuit judge on the Court of Appeals for the Federal Circuit and will be joining us here in Washington, DC. I must observe, however, that the Ad Hoc Committee will miss her energy and her intelligence.

We are very pleased to have Mr. Manbeck, who has previously been a witness before this committee and other committees of the Congress and has always been a superb witness.

Mr. Manbeck, you may proceed.

TESTIMONY OF HARRY F. MANBECK, JR., GENERAL PATENT COUNSEL, GENERAL ELECTRIC CO.

Mr. MANBECK. Thank you, Mr. Chairman.

I would like to open my testimony by saying we will also miss Dr. Newman's sparkling personality in our deliberations.

As the chairman has indicated, I am today testifying in behalf of an ad hoc committee. This committee is composed of the Chief Patent Counsel or former Chief Patent Counsel of a number of major American corporations who are large users of the patent system and have a significant interest in its effective functioning.

The patent system plays a vital role in the technological and industrial advancement of the Nation, and starting in 1981, members of the ad hoc committee have devoted considerable time in developing and proposing some needed improvements in the system. These proposed improvements are included or reflected in a number of bills which are among the subjects of this hearing, and the ad hoc committee wishes to urge your thoughtful consideration and passage of them.

For record purposes, the members of the ad hoc committee are listed in exhibit A to the typewritten copies of my testimony.

Turning now to the first subject of the hearing, the regulation of inventors' rights, the ad hoc committee strongly supports the provisions of H.R. 4525, Kastenmeier, and H.R. 4527, Kastenmeier.

The amendment to section 103 of the patent code to be affected by H.R. 4525 will bring that section into line with the realities of modern day industrial research and development. Much, if not most, of today's industrial research and development is done in corporate laboratories where unpublished proprietary information of the corporations is shared or otherwise made available to the engineers or scientists attempting to solve a problem or bring forth a new product.

The availability and use of this confidential corporate information among coworkers can contribute greatly to the efficacy of the research effort and its innovative results and should be encouraged as an efficiency in our national effort to advance technologically.

Unfortunately, under present law an organization's own unpublished information developed by one employee or team member can be used as prior art in judging the nonobviousness of an invention of a second employee or team member if the second individual is aware of the work of the first individual.

This may have the result that no meaningful patent can be obtained on an overall significant development. Although the organization will have contributed something of worth to society using nobody's information but its own, no patent may be available due to legal technicalities arising out of the fact that one employee built on information received from another employee, rather than doing everything himself.

This is clearly bad, for it militates against, really penalizes, the use of team research to solve problems. It not only detracts from the prime function of the patent system in stimulating invention; it may even cause organizations to hold completed developments on a confidential basis insofar as they can.

Thus, it is very desirable that *Bass* and its progeny be overturned or limited as contemplated by H.R. 4525 so as to accommodate modern research and development by corporations, universities, and others using team efforts.

I will note, incidentally, that H.R. 4525, if passed, would not remove or change prior art as it is generally understood. It will, however, remove a significant problem that research organizations are now faced with if they encourage, as usually they must, a free flow of up-to-date internal information among their scientists and engineers.

Mr. Chairman, the next paragraph of my written testimony deals with some language improvements which it is my understanding that the PTO and what used to be the American Patent Law Association have cooperated on. I was furnished with this changed language by a member of the AILPA board and it is attached to my testimony as exhibit B.

It is my understanding that most of the members of the ad hoc committee would not object to the proposal which they are making, although we still feel our own language, or the language of—I shouldn't say our own language—but the language of H.R. 4525 is good language.

If we turn now to H.R. 4527, it, too, deals with possibly invalidating inventorship problems which are created in modern-day research. Under the existing case law, it is required when inventors are joined in a patent application that each should have contributed to every claim of the application.

In team research, however, new scientists may join the team part way through the development so that although they may make important contributions, they cannot truthfully say that they were joint inventors of everything claimed in the patent application covering the development.

Yet, to divide the application into two or more detailed applications would result in inadequate coverage of the overall effort. H.R. 4527 cures this problem by stating that joint inventors need not have made a contribution to each claim contained in the application.

Here, again, the AIPLA and the PTO have proposed a refinement, and the refinement is taken up in the typed copy of the testimony.

It appears to us that the PTO–AIPLA proposals for H.R. 4525 and H.R. 4527 merely add specificity to the principles now in the bills. Some of our members feel these matters would be better han-

dled in the legislative history than by amendment of the bills. Others, however, would prefer the amendment route.

Changing subjects, the remaining two bills dealing with the regulation of inventors' rights are H.R 3285 and H.R. 3286. These bills are concerned with the terms of employee invention assignment agreements and are not among the subjects on which the ad hoc committee proposed legislation. However, in the thought that the viewpoint of the ad hoc members would be of interest to the subcommittee as reflecting the position of representative, technically active corporations, we have taken a poll so that it might be communicated to you.

Taking the higher numbered bill first, H.R. 3286 is directed toward the establishment of national standards for so-called employee preinvention assignment agreements. These are the agreements which most employers ask their employees to sign so that the employee's inventions resulting from their work-related activity will become the property of the employer.

This is believed to be eminently fair, since customarily the employees are provided with a place to work, the tools to work with, the problems to solve, and a regular salary, all at the expense of the employer.

Presumably there have been questions raised as to the terms of at least some of these agreements, for regulating legislation affecting them has been passed in a number of States. These are Minnesota, California, Washington, North Carolina, and Illinois, to my knowledge, and in each of them industry, and presumably the universities, have accommodated themselves to the statutory requirements without severe problems.

Certain of the ad hoc members believe that Federal legislation is unnecessary, and that invention assignments, wherever made, are matters of contract law which should be left to the States. Others, however, of which I am one, feel overall Federal standards, provided they are fair and sensible, might be acceptable since then the national corporations would not have to deal in different forms or riders on their agreements from State to State.

Also, there is some logic to the argument that all professional employees of a national corporation should be treated the same insofar as their obligations to assign are concerned; in other words, that there shouldn't be a variation from State to State.

Having said this, and recognizing that the subcommittee chairman, in introducing H.R. 3286, is looking for standards or terms which will not disadvantage industry but which, at the same time, will be fair to the employees, we feel that some changes should be made in H.R. 3286 to accomplish this. Doubtless, various people would suggest different changes, but I am submitting as exhibit C to my testimony a marked up version of H.R. 3286 which I believe makes some needed clarifications in the bill without destroying its purpose or overall effect.

I can't say how much of industry would agree with this markup, but I know it is acceptable to at least one leading American corporation, namely, my own employer. Also, it has been looked at by other members of the ad hoc committee and is satisfactory to them, but not to all members. I don't mean to imply that.

Time was short, so as I said, I couldn't get it reviewed by all members of the ad hoc committee before today, and I presume they will not hesitate to point out to the subcommittee any and all faults they may find in it. Now, certain members of the ad hoc committee would also urge that the laws which now exist in the States I mentioned be looked at since industry has gotten along, as far as I know, well under those laws.

We have, for example, provided riders on our nationwide agreements so as to accommodate them to the States.

Now, and this is something that the Commissioner touched on before, in speaking favorably from my own viewpoint of an amended version of H.R. 3286, I would be remiss, however, if I did not point out that at least some corporations today use invention assignment agreements which capture inventions made within a short period, usually 6 months, after the termination of employment.

These corporations believe that this extended term is necessary to prevent a very few disloyal employees from conceiving something important and then terminating their employment to avoid the obligation to assign. Those who have this postemployment obligation—my employer does not—feel strongly about it and the subcommittee may wish to solicit their comments as it considers the bill.

Although I have indicated there is support among the ad hoc committee members for a modified version of H.R. 3286, this is not the case for H.R. 3285. To a person, they oppose its provisions, believing that they would produce serious adverse effects in the working of our industrial system. For the record, I have included in the written copies of my testimony 6 factors which militate against special compensation for employee inventors as proposed by H.R. 3286.

Mr. Chairman, in order to shorten my time and your time here, I will not read all these factors unless you would like me to do so. They will be in the record.

Mr. KASTENMEIER. It is not necessary. It is part of the record, and I appreciate that. I also appreciate that there is opposition to this particular bill, although one of the justifications for the second bill is that it does work in some places, in Germany. Does General Electric have an agreement with Germany?

Mr. MANBECK. May I comment on that, sir, right now?

Mr. KASTENMEIER. Surely.

Mr. MANBECK. I became concerned a few years ago as to whether or not we, as a Nation, were missing something in not having something like the German system. I made my own private survey. I went to Germany and went around and talked to the manager of the Patent Department or Director of Patents from a number of leading companies, deliberately selected from the electrical, chemical, and mechanical fields.

There was, with one exception, either a mild dislike for the system or active opposition to it as being counterproductive. The manager of the Siemans patent department, and Siemens is our largest competitor worldwide, said to me, "Mr. Manbeck, if there is anything I could wish on you as our competitor it is the German employee inventor system."

I have a bowderlized version of a report I wrote on that, taking out names, and company names, which I would be glad to make available to the subcommittee if they would like to have it. This represents my own view, my own survey, and I don't advance it for anything further than that.

Mr. KASTENMEIER. If you would care to make it available to us, we would be pleased to have it.

Mr. MANBECK. My testimony, the six factors I list, are matters of principle. Mr. Homer Blair has, I believe, has submitted already comments on the languge of the bill itself and what it would do to Patent Office workload, and things like that, which are not included in my testimony.

The second major subject of the hearing is Changes in the Administration of the Patent and Trademark Office. The first bill under this section is H.R. 2610, Kastenmeier, which would create a so-called defensive patent that would be issued without examination and would not have any enforcement rights. This bill has not been studied as such by the ad hoc committee, but there seems to be general agreement among its members that the concept involved is a desirable one.

If the government agencies not needing the full patent right for commercial purposes would utilize the defensive patent approach, the workload on the PTO would be substantially reduced, to the benefit of all users of the patent system. Also, in certain instances industry may wish to use the defensive patent rather than other means to make a permanent record of developments for which full patent coverage is not desired.

In a markup of the corresponding bill in the Senate, S. 1538, Mathias, the defensive patent has been given the name of Statutory Invention Recording. Since there seems to be a consensus among Bar groups that the new name is desirable, perhaps this subcommittee will wish to take the same approach.

The ad hoc committee has not studied H.R. 4462, the next bill under the subject of PTO administration. It deals with internal organization matters within the PTO, and we defer to the Commissioner and the Deputy Commissioner as to the need for the bill.

We have, as individuals, considered H.R. 3462, Mitchell, which would exempt independent inventors, nonprofit organizations, and small business entities from maintenance fees. It would also prevent the Commissioner from adjusting application and issuance fees upwardly for these entities as needed to support the PTO when there is inflation in the national economy.

As a general consensus, we, as patent counsel for large corporations, are sympathetic with the real needs of small entities wishing to use the patent system. We don't like to see them priced out of the system, although there is some question as to whether governmental fees will do this.

The real problem is how the shortfall in funds resulting from the passage of H.R. 3462 would be made up. We understand from the PTO that it would be significant, in the millions of dollars each year. If the Congress will make up the shortfall from general tax revenues, then we would not oppose the bill. However, if its passage would result in the fees for all other entities being raised, then we must necessarily decline our support.

The present two-tier system gives a significant benefit to the small entities as contrasted to other users of the patent system. If they are to be afforded still further privileges, the public as a whole should provide the needed funding. Also, not all small entities are poor; many small businessmen are wealthy. Should there not be a hardship test before there is further fee forgiveness?

The chairman may recall that when the present fees were before the Congress, I testified then in behalf of a number of corporate patent counsel that we were not opposed to the two-fee system and we are not opposed to individual inventors and universities that need relief being given relief. But on the other hand, we would hate to have our own fees go up as a result.

Turning next to H.R. 4524, it would amend the Patent Code in respect to licenses for the foreign filing of U.S. patent applications so as to overcome some difficulties and unfair results of the present law. The ad hoc committee strongly supports the provisions of this bill.

The first section of H.R. 4524 changes the standard for the grant of a retroactive license from one of inadvertence to one of error without deceptive intent. It would, for example, relieve the harshness to an applicant in situations as that present in in re *Gaertner.*

The Commissioner has already discussed the *Gaertner* case and I will skip the next paragraph of my testimony in that regard, although I would appreciate it being in the record. I will not read through it.

The present language, turning now to the middle of page 12, which permits retroactive grant of the license when an application has been inadvertently filed abroad without grant of a license does not provide relief for an applicant such as *Gaertner,* who had considered whether a license was necessary and intentionally but mistakenly decided it was not.

Changing the requirement from inadvertence to error with deceptive intent would broaden the availability of a retroactive license, applying the CCPA construction of that term as found in its reissue cases. Such cases extend to an intentional act which is erroneous but not motivated by deception.

Thus, the changed standard provided by paragraph (1) of section 1 of H.R. 4524, which is also applied to issued patents under section 2 of the bill, is a most desirable modification of the patent law.

The amendment provided by paragraph (2) of section 1 would relieve the overly strict requirements of 35 U.S.C. 184 that a Commissioner's license must be obtained for any modifications or supplements to foreign applications.

I will not read the remaining portion of that paragraph in my testimony, except to say the Commissioner indicated this morning that he did not feel that this part of H.R. 4524 was necessary. We respectfully don't agree. We are talking about a court decision, and we are not confident that the Commissioner's regulations would be able to take care of the problem, and we feel that the relief should be incorporated in the statute.

In summary, it is believed that legislation is particularly appropriate at this time of expanding worldwide markets to enable U.S. inventors to solicit foreign coverage effectively without risking a bar to their U.S. patent rights for conduct which does not involve

national security. Failure to procure a license because of error without deceptive intent and minor changes to a foreign application should no longer be allowed to be the cause for an applicant to lose his U.S. patent rights.

The ad hoc committee has not studied the Synar bill, H.R. 3502, on the subject of patent term restoration. However, as a general matter, our members support the concept of patent term restoration when regulatory delays in marketing are involved.

The next 3 bills, H.R. 3577, Moorhead, H.R. 4526, Kastenmeier, and H.R. 4814, Albosta, are all concerned with the scope of protection to be afforded to process patents. They would extend that scope to cover products which are made by the patented process, in the case of H.R. 4526 and H.R. 4814 to foreign-made products, and in the case of H.R. 3577 to all products wherever made.

We feel very strongly that legislation is needed to provide the owners of process patents with adequate remedies so that foreign manufacturers cannot continue to use our patented processes to make products for sale in the United States without any infringement liability attaching to those products.

Under current U.S. law, process patent protection does not extend to the products of the patented process. As a result, when an unpatented product is made offshore by a patented process, it can be sold here without constituting an infringement. This gives the foreign manufacturer a significant unfair advantage over not only the patent owner, but also in respect to U.S. manufacturers seeking to use the patented process. Such U.S. manufacturers must, of course, reach an accommodation with the patent owner by licensing or otherwise.

In contrast with our present law, the domestic patent law of most major industrial countries would apply to products imported into those countries by U.S. manufacturers. For example, the European Patent Convention states, and I quote:

> If the subject matter of the European patent is a process, the protection conferred by the patent is extended to products directly obtained by such process.

Much more can be said about the proposed legislation, but in short, we believe it is particularly appropriate at this time of ever-increasing worldwide competition so as to close the loophole which allows for foreign manufacturers to avoid the effects of U.S. process patents to which their American competition is subject.

Mr. Chairman, to conserve time, I will not take up the next paragraph of the testimony, which deals with reasons why the present ITC proceeding is not adequate to cure this problem, and go to the second paragraph on page 16.

The proposal of the ad hoc committee in this area of process patents went only to foreign-made goods, since this is where we perceive the real inequity to exist. However, we are aware that a letter from the Office of the U.S. Trade Representative states that limiting the remedial legislation to foreign-made goods, as contrasted to covering products wherever made, may result in a violation of GATT.

Although we have not urged coverage beyond foreign-made products, we would not want to see the baby thrown out with the bathwater. Therefore, if it is necessary to meet U.S. treaty obligations,

we are in agreement to an extension of the legislation to cover domestically-made products as well as foreign-made products.

The ad hoc committee has not studied section 3 of H.R. 3577, which would establish a presumption in actions alleging infringement of a process patent. Therefore, we express no opinion as to whether it is necessary. However, we trust the presumption will receive careful consideration by the subcommittee since, on its face, it appears to be reasonable.

Besides provisions relating to process patent protection, H.R. 4526 and H.R. 4514 include a section which would reverse the *Deep South* case. These bills would establish infringement liability where everything pertaining to the manufacture of a patented product except the final assembly is accomplished in the United States and the material components are then shipped abroad for assembly.

This legislation is needed to close off the subterfuge permitted by present law which is disadvantageous to an innovative economy, encourages offshore manufacturing, and is unfair to inventors. We urge that it be included in the legislation reported out by the subcommittee.

The final bill to be taken up is H.R. 4529, which deals with the relationship of licensor and licensee when the licensee has raised a challenge of invalidity to the licensed patent. Under *Lear* v. *Adkins,* the licensee cannot be estopped by contract or otherwise from attacking the validity of a licensed patent.

Without taking up the wisdom, or lack of wisdom, of this general rule, particularly under our current law where anybody, including a licensee, can request reexamination of a patent in the PTO, there is no question but that lower court decisions subsequent to Lear have created situations which are manifestly unfair to the patent owner/licensor.

The rights of the licensor to cancel the license agreement or to receive royalties if the licensee refuses to terminate the license while attacking the patent have been severely limited or effectively held unenforceable.

It has gotten to the point that the licensee may risk nothing by challenging the licensed patent. He can refuse to pay the agreed upon royalties during the litigation, or perhaps deposit them in escrow so that if he wins, he gets his money back. Yet if he loses, all he has to do is pay up the royalties that he agreed to pay in the first place. Thus, the licensee gets all the benefits and protection of the license agreement, even though he tries to destroy what he has contracted for.

This situation encourages litigation, and even worse, encourages it in situations where there has probably been a compromise in the first place. The proposed legislation does not intend to block legitimate challenges to licensed patents; rather, it is designed to place the licensor in a fair position relative to the licensee upon a challenge of the invalidity being raised.

Specifically, H.R. 4529 will give both the licensor and the licensee the right to terminate the license agreement if the licensee asserts invalidity of the licensed patent in a judicial action. Thus, either party can cancel the agreement in light of the supposedly new circumstance causing the licensee to challenge the patent.

The licensee does not have to pay any further, but yet the licensor can be relieved, at his option, of the bargain which the licensee is now repudiating. This seems fair, for if one party will not abide by its contract, why should the other party be held to it?

On the other hand, perhaps both parties will wish to keep the contract in being during the litigation. H.R. 4529 provides for this by requiring the licensee to pay and the licensor to receive the agreed upon royalty until one party or the other terminates the agreement. Thus, if the licensee wants the protection of the agreement and the licensor prefers its terms rather than relying on whatever damages it might get from the court, the agreement will continue until the question of invalidity is settled and, of course, thereafter if the patent is upheld.

We believe that passage of H.R. 4529 will redress the present disturbing imbalance between the rights of licensors and licensees and will add to the effectiveness of the patent system. We strongly support it.

In closing, I would like to call your attention to the list of corporate patent counsel which is attached to the copy of my testimony as exhibit D. This list, which was furnished to me by Intellectual Property Owners, Inc., gives the names of over 60 corporate and university patent counsel who support, in principle, the passage of the several bills H.R. 4524 through H.R. 4529.

Thank you very much for giving me this opportunity to present the viewpoint of the ad hoc committee.

[Mr. Manbeck's full statement follows:]

TESTIMONY

of

HARRY F. MANBECK, JR.
General Patent Counsel
General Electric Company

My name is Harry F. Manbeck, Jr. and I am the General Patent Counsel of the General Electric Company. I am testifying today in behalf of an Ad Hoc Committee to Improve the Patent Laws. This committee is composed of the chief patent counsel, or former chief patent counsel, of a number of major American corporations who are large users of the patent system and have a significant interest in its effective functioning. The patent system plays a vital role in the technological and industrial advancement of the nation, and starting in 1981, the members of the Ad Hoc Committee have devoted considerable time in developing and proposing some needed improvements in the system. These proposed improvements are included or reflected in a number of bills which are among the subjects of this hearing, and the Ad Hoc Committee wishes to urge your thoughtful consideration and passage of them. For record purposes the members of the Ad Hoc Committee are listed in Exhibit A to the copies of my testimony which are being submitted to you.

Turning now to the first subject of the hearing, the Regulation of Inventors' Rights, the Ad Hoc Committee strongly supports the provisions of H.R.4525-Kastenmeier and H.R.4527-Kastenmeier.

The amendment to Section 103 of the Patent Code to be effected by H.R.4525 will bring that Section into line with the realities of modern day industrial research and development. Much, if not most, of today's industrial research and development is done in corporate laboratories where unpublished proprietary information of the

corporations is shared or otherwise made available to the engineers and scientists attempting to solve a problem or bring forth a new product. The availability and use of this confidential corporate information among co-workers can contribute greatly to the efficacy of the research effort and its inventive results, and should be encouraged as an efficiency in our national effort to advance technologically.

Unfortunately, under present law an organization's own unpublished information developed by one employee or team member can be used as "prior art" in judging the non-obviousness of an invention of a second employee or team member if the second individual is aware of the work of the first individual. [See In re Bass, 177 USPQ 178 (CCPA 1973) and In re Clemens 206 USPQ 289 (CCPA 1980]. This may have the result that no meaningful patent can be obtained on an overall significant development. Although the organization will have contributed something of worth to society, using nobody's information but its own, no patent may be available due to legal technicalities arising out of the fact that one employee built on information received from another employee rather than doing everything himself.

This is clearly bad for it militates against, really penalizes, the use of team research to solve problems. It not only detracts from the prime function of the patent system in stimulating innovation, it may even cause organizations to hold completed developments on a confidential basis insofar as they can. Thus it

is very desirable that Bass and its progeny be overturned or limited as contemplated by H.R.4525 so as to accommodate modern research and development by corporations, universities and others using team efforts.

I will note, incidentally, that H.R.4525 if passed would not remove or change prior art as it is generally understood. It will, however, remove a significant problem that research organizations are now faced with if they encourage, as usually they must, a free flow of up-to-date internal information among their scientists and engineers.

Since H.R.4525 was introduced, some suggestions have been made by other organizations interested in the patent system for refinement of the language of the proposed amendment to Section 103. The American Intellectual Property Law Association and the Patent and Trademark Office have jointly developed one version which makes specific reference to prior art under Section 101(f) and (g). A copy of this proposal is attached to the copies of my testimony as Exhibit B and it is my understanding that most of the members of the Ad Hoc Committee would not object to this version.

Turning now to H.R.4527, it too deals with possibly invalidating inventorship problems which are created in modern day research. Under the existing case law it is required when inventors are joined in a patent application, each should have contributed to every claim of the application. In team research, however, new scientists may join the team part way through the development so that although they

may make important contributions, they can not truthfully say that they were joint inventors of everything claimed in the patent application covering the development. Yet to divide the application into two more detailed applications would result in inadequate coverage of the overall effort. H.R.4527 cures this problem by stating that "joint inventors" need not have made a contribution to each claim contained in the application.

Here again, the AIPLA and the PTO have proposed a refinement of the language proposed by the Ad Hoc Committee. This refinement also appears in Exhibit B to my testimony and I am not aware of any objection by our members to this refinement. Also, AIPLA and PTO propose an amendment to Section 120 which would provide that a later filed patent application by an inventor or inventors of a previously filed pending application may claim the benefit of the filing date of that previously filed pending application, even though the later filed application does not name all of the same inventors as the previously filed application. This proposed amendment to Section 120 merits your attention since it may be desirable to accommodate certain situations which could arise under Section 116 as proposed for revision.

Actually, it appears that the PTO/AIPLA proposals for H.R.4525 merely add specificity to the principle now in the Bill. Some of our members feel that these matters would be better handled in the legislative history than by amendment of the statute. Others, however, would prefer the amendment route.

The remaining two bills dealing with the Regulation of Inventors' Rights are H.R.3285 and H.R.3286. These bills are concerned with the terms of employee invention assignment agreements and are not among the subjects on which the Ad Hoc Committee proposed legislation. However, in the thought that the viewpoint of Ad Hoc members would be of interest to the Subcommittee, as reflecting the position of representative, technically active corporations, we have taken a poll so it might be communicated to you.

Taking the higher numbered bill first, H.R.3286 is directed toward the establishment of national standards for so-called employee pre-invention assignment agreements. These are the agreements which most employers ask their employees to sign so that the employee's inventions resulting from their work related activity will become the property of the employers. This is believed to be eminently fair since customarily the employees are provided with a place to work, the tools to work with, the problems to solve, and a regular salary all at the expense of the employer.

Presumably there have been questions raised as to the terms of at least some of these agreements, for regulating legislation affecting them has been passed in a number of states. These are Minnesota, California, Washington, North Carolina and Illinois to my knowledge and in each of them industry and presumably the universities, have accommodated themselves to the statutory requirements without severe problems. Certain of the Ad Hoc members

believe that federal legislation is unnecessary, and that invention assignments, wherever made, are matters of contract law which should be left to the states. Others, however, of which I am one, feel overall federal standards, provided they are fair and sensible, might be acceptable since then the national corporations would not have to deal in different forms or riders on their agreements from state to state. Also, there is some logic to the argument that all professional employees of a national corporation should be treated the same insofar as their obligations to assign are concerned.

Having said this, and recognizing that the Subcommittee Chairman in introducing H.R.3286 is looking for standards or terms which will not disadvantage industry but which at the same time will be fair to the employees, we feel some changes should be made in H.R.3286 to accomplish this. Doubtless various people would suggest different changes but I am submitting as Exhibit C to my testimony a marked-up version of H.R.3286 which I believe makes some needed clarifications in the bill without destroying its purpose or overall effect. I can't say how much of industry would agree with this mark-up, but I know it is acceptable to at least one leading American corporation, namely my employer. Time was so short that I could not get it reviewed by all members of the Ad Hoc Committee before today, but I presume they will not hesitate to point out to the Subcommittee any and all faults they may find in it.

In speaking favorably from my own viewpoint of an amended version of H.R.3286, I would be remiss, however, if I did not point

out that at least some corporations today use invention assignment agreements which capture inventions made within a short period (usually six months) after the termination of employment. They believe this is necessary to prevent a very few disloyal employees from conceiving something important and then terminating their employment to avoid the obligation to assign. Those who have this post employment obligation (my employer does not) feel strongly about it and the Subcommittee may wish to solicit their comments as it considers the bill.

Although I have indicated there is support among the Ad Hoc members for a modified version of H.R.3286, this is not the case for H.R.3285. To a person they oppose its provisions, believing that they would produce serious adverse effects in the working of our industrial system. For the record, I would like to state six factors which militate against special compensation for employed inventors as proposed by H.R.3286.

(1) In order that any technically based business progress and thereby provide job security for its employees it is essential that a spirit of cooperation exists not only in the laboratory and engineering groups, but throughout the entire professional staff. Scientists and engineers are not the only employees who provide creative solutions to business problems. Innovative ideas helpful to the business are contributed regularly by employees in finance, marketing, personnel and other areas, which ideas may be at least as important to the profitability of the business as are technical advances. No one has ever suggested that there should be a massive award system for creative ideas from these other functions and it would be divisive to reward technical employees disproportionately for their contributions.

In all the functions be they technical, marketing, finance or otherwise, creative solutions to problems result because the employee has been provided with company facilities, is supported by the company, and is made aware of the problems. The creative people who provide solutions should and are rewarded through salary progressions and promotions, and to single out technical employees for something more would be detrimental to the interfunctional relationships.

(2) Another serious problem with systems providing large awards is that they tend to create competition and antagonism between members of the technical staff rather than the team effort so necessary for effective results. If the outcome of a technical solution is that someone will receive an award of thousands of dollars, people necessarily hide their ideas from each other, and many may even try to take credit for advances which are only questionably their own work. The effect within laboratory or engineering section can be divisive and counterproductive thereby harming the business.

(3) There has been abolutely no data produced indicating that the present system followed by American industry is inefficient to generate technical advances or to bring them to fruition in commercial products. Before anyone asks for a change to a system which would necessarily increase industry's costs and thereby possibly detract from its competitiveness in the world market, some hard data supporting the need for such a change should be presented.

(4) In my own experience creative employees are really not stimulated by the thought of a large reward for any individual solution. Either an employee is creative or he is not, and the possibility of large awards will probably not bring out any worthwhile inventions, it will merely cause more pedestrian thinking by the routineers to the detriment of other work which needs to be done. The possibility of a large award may also cause technical employees to work on schemes of their own, which have little chance of success, instead of following a better path suggested by someone else. Incidentally, awards or royalty sharing are certainly not needed to stimulate disclosures since creative people are ordinarily quick to bring forth their ideas.

(5) If a technical employee feels that his contributions are not being appropriately recognized, there is always the opportunity to move to another employer or to establish

himself as an individual consultant or inventor. The latter route is, however, very difficult and unsatisfactory to almost all scientists and engineers, leading to the conclusion that they really are being fairly paid today for what they contribute.

(6) The administration of award systems other than those which award predetermined exact amounts for each invention can cause real administrative problems. Not only is there the rival claimant problem, but also there is considerable difficulty in determining how much an invention is worth, if anything at all. For example, what is one minor improvement worth in a major space problem, and how much does one patent contribute to a technology assistance agreement involving data transfer, technical consultation and manufacturing know-how as well as a license under many patents.

There are, I am sure, other factors besides those which might be considered in respect to special compensation schemes for inventors. But succintly stated, I am aware of no support for such schemes or programs among the industry representatives with whom I am in contact. All believe that special inventor compensation should not be mandated by the Congress.

The second major subject of this hearing is Changes in the Administration of the Patent and Trademark Office. The first bill under this subject is H.R.2610-Kastenmeier, which would create a so-called defensive patent that would be issued without examination and would not have any enforcement rights. This bill has not been studied as such by the Ad Hoc Committee but there seems to be general agreement among its members that the concept involved is a desirable one. If the government agencies not needing the full patent right for commercial purposes would utilize the defensive patent approach, the workload on the PTO should be substantially

reduced to the benefit of all users of the patent system. Also, in certain instances industry may wish to use the defensive patent rather than other means to make a permanent record of developments for which full patent coverage is not desired. In a mark-up of the corresponding bill in the Senate S.1538-Mathias, the defensive patent has been given the name of Statutory Invention Recording. Since there seems to be a consensus among bar groups that the new name is desirable, perhaps this Subcommittee will wish to take the same action.

The Ad Hoc Committee has not studied H.R.4462, the next bill under the subject of PTO administration. It deals with internal organization matters within the PTO and we defer to the Commissioner and Deputy Commissioner as to the need for the bill.

We have, as individuals, considered H.R.3462-Mitchell which would exempt independent inventors, nonprofit organizations and small business entities from maintenance fees. It would also prevent the Commissioner from adjusting application and issuance fees upwardly for these entities as needed to support the PTO when there is inflation in the national economy. As a general consensus we as patent counsel for large corporations are sympathetic with the real needs of small entities wishing to use the patent system. We don't like to see them priced out of the system although there is some question as to whether governmental fees will do this.

The real problem is how the short fall in funds resulting from the passage of H.R.3462 would be made up. We understand from the

PTO that it would be significant, in the millions of dollars each year. If the Congress will make up the shortfall from general tax revenues, then we would not oppose the bill. However, if its passage would result in the fees for all other entities being raised, then we must necessarily decline our support. The present two tier system gives a significant benefit to the small entities as contrasted to other users of the patent system and if they are to be afforded still further privileges the public as a whole should provide the needed funding. Also, not all small entities are poor; many small businessmen are wealthy. Should there not be a hardship test before there is further fee forgiveness?.

Turning next to H.R.4524-Kastenmeier, it would amend the Patent Code in respect to licenses for the foreign filing of U.S. patent applications so as to overcome some difficulties and unfair results of the present law. The Ad Hoc Committee strongly supports the provisions of this bill.

The first section of H.R.4524 changes the standard for the grant of a retroactive license from one of inadvertence to one of error without deceptive intent. It would, for example, relieve the harshness to an applicant in situations as that presented in In re Gaertner, 604 F2d 1348, 202 USPQ 714 (CCPA 1979).

In that case, an applicant's continuation-in-part patent application was rejected because foreign counterparts of the continuation-in-part patent had been filed without a license within six months of its U.S. filing. However, the U.S. patent or original

application had been on file by that time for more than six months. The continuation-in-part patent application differed from the parent application only by adding an example showing the use of a known starting material to produce compounds, which material was not disclosed in the original application, but was well within the generic claim already present in the parent case. Gaertner's counsel, as discussed in fn. 6 of the reported decision, had considered whether a license was necessary and had come to the good faith conclusion that it was not. Applying a strict construction to the license-to-file statute, the CCPA affirmed the rejection of all claims in the application.

The present language, which permits retroactive grant of the license where an application has been "inadvertently" filed abroad without grant of a license, does not provide relief for an applicant, such as Gaertner, who had considered whether a license was necessary and intentionally but mistakenly decided that it was not. Changing the requirement from inadvertence to "error without deceptive intention" would broaden the availability of a retroactive license, applying the CCPA constructions of that term as found in its reissue cases. Such cases extend to an intentional act which is erroneous but not motivated by deception, In re Wadlinger, et al., 496 F2d 1200, 181 USPQ 826 (CCPA 1974).

Thus the changed standard provided by paragraph (1) of Section 1 of H.R.4524, which is also applied to issued patents under Section 2 of the Bill, is a most desirable modification of the Patent Law.

The amendment provided by paragraph (2) of Section 1, would relieve the overly strict requirement of 35 USC 184 that a Commissioner's license must be obtained for any modification or supplements to the foreign applications. The proposed amendment provides some latitude to allow for changes which only illustrate or exemplify the matter previously disclosed, specifically or generically, in the earlier application, thereby to avoid the harshness of the result obtained in Gaertner. Such changes while providing more detail and being helpful to the U.S. applicant in his quest for foreign patent coverage are by their nature not of concern to national security, and there is no reason to continue any requirement for a Commissioner's license to be obtained before they can be made. The amendment to the statute would eliminate senseless paper work for both the applicant and the Patent and Trademark Office, and will remove an unjustified risk from the shoulders of United States applicants who also file abroad.

In summary, it is believed that legislation is particularly appropriate at this time of expanding worldwide markets to enable United States inventors to solicit foreign patent coverage effectively without risking a bar to their U.S. patent rights for conduct which does not involve national security. Failure to procure a license because of error without deceptive intent, and minor changes to a foreign application, should no longer be allowed to be the cause for an applicant to lose his United States patent rights.

Coming now to the third subject of the hearing, Substantive Patent Law Reform, the first bill is H.R.3502-Synar. This bill deals with patent term restoration for patents whose effective term has been shortened because of regulatory delays preventing the marketing of the patented product. The Ad Hoc Committee has not studied the Synar bill and, therefore, will not comment on its specific provisions. However, as a general matter, our members support the concept of patent term restoration where regulatory delays in marketing are involved.

The next three bills, H.R.3577-Moorhead, H.R.4526-Kastenmeier and H.R.4814-Albosta are all concerned with the scope of protection to be afforded to process patents. They would extend that scope to cover products which are made by the patented process, in the case of H.R.4526 and H.R.4814 to foreign made products and in the case of H.R.3577 to all products wherever made.

We feel very strongly that legislation is needed to provide the owners of process patents with adequate remedies so that foreign manufacturers cannot continue to use our patented processes to make products for sale in the United States without any infringement liability attaching to those products.

Under current United States law, process patent protection does not extend to the products of the patented process. As a result when an unpatented product is made offshore by a patented process it can be sold here without constituting an infringement. This gives the foreign manufacturer a significant unfair advantage over not

only the patent owner but also in respect to U.S. manufacturers seeking to use the patented process. Such U.S. manufacturers must, of course, reach an accommodation with the patent owner by licensing or otherwise.

In contrast with our present law, the domestic patent law of most major industrial countries would apply to products imported into those countries by U.S. manufacturers. For example, the European Patent Convention states "if the subject matter of the European patent is a process, the protection conferred by the patent is extended to products directly obtained by such process." Convention on the Grant of European patents, Art 64(2).

Much more can be said about the proposed legislation but, in short, we believe it is particularly appropriate at this time of ever increasing worldwide competition so as to close the loophole which allows for manufacturers to avoid the effects of U.S. process patents to which their American competition is subject.

We recognize, of course, that in certain circumstances the importation of products produced abroad by a U.S. patented process may be actionable in this country before the U.S. International Trade Commission as an unfair method of competition. The ITC proceedings under 19 USC 1337(a) provide for an exclusion order to be issued against the products. But these proceedings are not a completely satisfactory remedy for the process patentee for a number of reasons. Specifically, the ITC proceedings do not provide for the recovery of damages; they involve the active participation by

the staff of the ITC whether the patent owner wants that participation or not; they require proof that there is an efficient and economically operated industry in the U.S. (which can be very difficult for an individual or small business patentee) and they result only in an order which is subject to Presidential disapproval which might be given for some policy or political reason. Thus we need an appropriate amendment in the patent statutes.

The proposal of the Ad Hoc Committee in this area went only to foreign made goods since this is where we perceive the real inequity to exist. However, we are aware that a letter from the Office of the U.S. Trade Representative states that limiting the remedial legislation to foreign made goods, as contrasted to covering products wherever made, may result in a violation of GAAT. Although we have not urged coverage beyond foreign made products, we would not want to see the baby thrown out with the bath water. Therefore, if it is necessary to meet U.S. treaty obligations, we are in agreement to an extension of the legislation to cover domestically made products as well as foreign made products.

The Ad Hoc Committee has not studied Section 3 of H.R.3577 which would establish a presumption in actions alleging infringment of a process patent. Therefore, we express no opinion as to whether it is necessary. However, we trust that the presumption will receive careful consideration by the Subcommittee since on its face it appears to be reasonable.

Besides provisions relating to process patent protection,

H.R.4526 and H.R.4514 also include a section which would reverse the Deep South case 406 US 518 . These bills would establish infringement liability when everything pertaining to the manufacture of a patented product except the final assembly is accomplished in the U.S. and the material components are then shipped abroad for assembly. This legislation is needed to close off the subterfuge permitted by present law which is disadvantageous to an innovative economy, encourages offshore manufacturing and is unfair to inventors. We urge that it be included in the legislation reported out by the Subcommittee.

The final bill to be taken is H.R.4529-Kastenmeier which deals with the relationship of licensor and licensee when the licensee has raised a challenge of invalidity to the licensed patent. Under Lear v. Adkins 395 U.S. 653 (1967) the licensee cannot be estopped by contract or otherwise from attacking the validity of a licensed patent.

Without taking up the wisdom, or lack of wisdom, of this general rule, particularly under our current law where anybody, including a licensee, can request re-examination of a patent in the PTO, there is no question but that lower court decisions subsequent to Lear have created situations which are manifestly unfair to the patent owner/licensor. The rights of the licensor to cancel the license agreement or to receive royalties if the licensee refuses to terminate the license while attacking the patent, have been severely limited or effectively held unforceable.

It has gotten to the point that the licensee may risk nothing by challenging the licensed patent. He can refuse to pay the agreed upon royalties during the litigation, or perhaps deposit them in escrow so that if he wins, he gets his money back. Yet if he loses, all he has to do is pay up the royalties that he agreed to pay in the first place. Thus the licensee gets all benefits and protection of the license agreement even though he tries to destroy what he has contracted for.

This situation encourages litigation, and even worse encourages it in situations where there has probably been a compromise in the first place. The proposed legislation does not intend to block legitimate challenges to licensed patents, rather it is designed to place the licensor in a fair position relative to the licensee upon a challenge of invalidity being raised.

Specifically H.R.4529 will give both the licensor and the licensee the right to terminate the license agreement if the licensee asserts invalidity of the licensed patent in a judicial action. Thus either party can cancel the agreement in light of the supposedly new circumstance causing the licensee to challenge the patent. The licensee does not have to pay any further, but yet the licensor can be relieved, at his option, of the bargain which the licensee is now repudiating. This seems fair for if one party will not abide by its contract, why should the other party be held to it.

On the other hand, perhaps both parties will wish to keep the contract in being during the litigation. H.R.4529 provides for this

by requiring the licensee to pay and the licensor to receive the agreed upon royalty until one party or the other terminates the agreement. Thus if the licensee wants the protection of the agreement and the licensor prefers its terms rather than relying on whatever damages it might get from the court, the agreement will continue until the question of invalidity is settled, and, of course, thereafter if the patent is upheld.

We believe that passage of H.R.4529 will redress the present disturbing imbalance between the rights of licensors and licensees, and will add to the effectiveness of the patent system. We strongly support it.

In closing, I would like to call your attention to the list of corporate patent counsel which is attached to the copy of my testimony as Exhibit D. This list, which was furnished to me by Intellectual Property Owners, Inc. gives the names of over sixty corporate and university patent counsel who support, in principle, the passage of the several bills H.R.4524 through H.R.4529.

EXHIBIT A

The Ad Hoc Committee To
Improve the Patent Laws

Rudolph J. Anderson, Jr.	Merck & Company, Inc. (to 12/31/83) Monsanto Company (1984-)
Donald J. Banner	Intellectual Property Owners, Inc. (formerly Chief Patent Counsel Borg Warner Corporation, and U.S. Commissioner of Patent & Trademarks)
Homer O. Blair	Itek Corporation
Robert B. Benson	Allis-Chalmers Corporation
Eldon H. Luther	Combustion Engineering, Inc.
Harry F. Manbeck, Jr.	General Electric Company
John E. Maurer	Monsanto Company
Pauline Newman	FMC Corporation
Donald J. Quigg	Phillips Petroleum Company (to 1981)
Jon S. Saxe	Hoffmann-LaRoche, Inc.
Leroy G. Sinn	American Hoechst Corporation
Arthur R. Whale	Eli Lilly and Company
Richard C. Witte	Procter & Gamble Company

EXHIBIT B

PTO/AIPLA Draft Bill Provisions

Proposed Amendments to Section 103, 116 and 120

(1) Amend 35 U.S.C. §103 by adding at the end:

In addition, subject matter developed by another which qualifies as prior art only under sections 102(f) or (g) of this title shall not negative patentability, when the subject matter and the claimed invention were commonly owned at the time the invention was made.

(2) Amend 35 U.S.C. §116 and 120 to expand the definition of joint inventors as follows:

Section 116 is amended as follows:

When an invention is made by two or more persons jointly, they shall apply for patent jointly and each [shall sign the application and] make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (i) they did not physically work together or at the same time, (ii) each did not make the same type or amount of contribution or (iii) each did not make a contribution to the subject matter of every claim of the patent.

Section 120 is amended as follows:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, by an [the same] inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the beneift of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

EXHIBIT C

I

98TH CONGRESS
1ST SESSION

H. R. 3286

To amend title 35, United States Code, to set Federal standards for permissible employee preinvention, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 13, 1983

Mr. KASTENMEIER introduced the following bill; which was referred to the Committee on the Judiciary

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A BILL

To amend title 35, United States Code, to set Federal standards for permissible employee preinvention, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That part II of title 35, United States Code, is amended by adding at the end thereof the following new chapter:

CHAPTER 19—EMPLOYEE INVENTIONS

"Sec.
"221. Declaration of purpose and policy.
"222. Definitions.
"223. Limitation upon terms of an employee preinvention assignment agreement.

"§ 221. Declaration of purpose and policy

"In order to promote the progress of the useful arts, and in order to encourage the free flow of commerce by the cre-

ation of new products and processes, it is the purpose and policy of this chapter to make available to employees, for inventions made by them that are unrelated to their employment, those incentives provided by the patent laws to encourage individuals to make inventions, to disclose them to the public, and to commercialize them, while at the same time to maintain an incentive for employers to support research and development activities and to commercialize inventions by their employees that are related to that employment.

"§ 222. Definitions

"For purposes of this chapter—

"(1) the terms 'employer' and 'employee' have the meanings given those terms in section 3 of the Fair Labor Standards Act of 1938 (29 U.S.C. 203);

"(2) the term 'invention' means an invention which is patentable under chapter 10 of this title;

"(3) the term 'preinvention assignment agreement' means an agreement which an employee executes at the request of his or her employer that gives any rights to the employer in any inventions of the employee not yet made at the time of the execution of the agreement;

"(4) the term 'employment invention' means an invention that is made by an employee during a term of employment—

(D) with substantial use of the employer's time, materials, facilities or funds; and

3

"(A) as a result of the employee's normal or specifically assigned duties; or

"(B) based in significant part upon technical data or information ~~possessed by and acquired from~~ of the employer ~~of the employee, and~~ which is not generally known to the public; or

"(C) ~~wherein the employee enjoyed a special position of trust or confidence or a fiduciary relationship with his or her employer at the time of making the invention, and the~~ When the invention is related to the employer's actual or contemplated business known to the employee; ~~and~~ or

"(5) an invention is deemed to have been 'made' when it is conceived or first actually reduced to practice.

"§ 223. Limitation upon terms of an employee preinvention assignment agreement

"(a) A preinvention assignment agreement shall not be enforceable to transfer any rights to the employer in any invention that is not an employment invention ~~, except that an employer may require an employee of the employer to grant to the employer a nontransferable, nonexclusive license to practice an invention that is not an employment invention whenever such invention is made by the employee with a~~

~~substantial use of the employer's time, materials, facilities, or funds.~~

"(b) An employer may require that the employee of the employer disclose to the employer all inventions made by the employee, solely or jointly with others, during the term of the employee's employment with the employer, ~~if the disclosures are~~ provided, however, that the employee may request that inventions which are not employment inventions be received and kept in confidence.

"(c) A preinvention assignment agreement shall not be enforceable to transfer any rights to an employer in any invention that is conceived by an employee of the employer after termination of employment with the employer.

"(d) In case of any disagreement or conflict with respect to any provision of this chapter, the matter shall be settled by arbitration in the State in which the employee is employed in accordance with the rules of the American Arbitration Association, at the request of either party.

"(e) This section shall not affect rights in any invention conceived prior to January 1, 1984.".

SEC. 2. The analysis of part II of title 35, United States Code, is amended by adding after the item relating to chapter 18 of the following new item:

"19. Employee Inventions ..... 221".

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EXHIBIT C

(continued)

Comments on Proposed Markup of H.R.3286

(1) §222(1). It is assumed that definition of "employee" covers only employees whose place of work is located in the United States, its territories and possessions. Otherwise conflicts with the laws of certain foreign countries could occur.

(2) §222(4)B. The existing language of this subparagraph could be construed to require that the invention be a lineal descendant of whatever is taught by the employer's data or information. Inventions often involve alternate ways of accomplishing a result, the impetus for the invention arising out of the existing information and its teaching but not, at least in one sense, being based on it. Thus it is necessary to add the concept of "suggested by".

The remaining changes are intended to simplify the language of the subparagraph with, it is believed, much the same result. What is meant by "information possessed by... the employer" if it is something different than "information of the employer"?

(3) §222(4)C. If the invention is related to the employer's business known to the employee, it is essential that the employment agreement be permitted to cover it irrespective of whether the employee enjoys a special position of trust, etc. In many corporations the research scientists and development engineers will be familiar with aspects of the employer's business on which they may not be working any given time but as to which they may make an invention because of their knowledge of the internal corporate efforts. To prevent the employer from acquiring such inventions would force the corporations to limit the in-house flow of information to the obvious detriment of the overall industrial system. The employer who is paying for the full time effort and loyalty of its employees should be entitled to assignment of their business related inventions, otherwise there could be serious conflicts of interest between the employees and the employer.

(4) §222(4)D. (new subparagraph) If the employee makes substantial use of the employer's time, materials, facilities of funds, the employer should be entitled to the resulting invention. In this circumstance the employer has made everything possible. It not only paid the employee a salary; it also has given him the tools to make the invention; and it should benefit accordingly.

(5) §223(a). The last part of this paragraph is deleted because the situation would be covered by new subparagraph 222(4)D.

(6) §223(b). As originally written, this paragraph would require the employer to maintain all employee inventions on a confidential basis, including the ones which it unquestionably owns. This was probably not intended and, hopefully, the suggested interlineation clears up the problem.

(7) §223(d). The change in line 13 is primarily editorial. As for the rules, AAA has now issued Patent Arbitration Rules specially directed to patent controversies. The Subcommittee might consider specifying them as they would insure the appointment of an arbitrator who would be familiar with both technical subject matter and the law pertaining to inventions.

SCHEDULE D

3/22/84

SUPPORTERS OF PATENT CODE REFORM BILLS

S. 1535 (MATHIAS) AND H. R. 4524 TO 29 (KASTENMEIER)

AIR PRODUCTS AND CHEMICALS, INC.
Allentown, PA
E. Eugene Innis
Assistant General Counsel

ALLIED CORPORATION
Morristown, NJ
Roy H. Massengill
Assistant General Counsel
Chief Patent Counsel

ALLIS-CHALMERS CORPORATION
Milwaukee, WI
Robert B. Benson
Counsel and Director
Patent Law Department

ALUMINUM COMPANY OF AMERICA
Alcoa Center, PA
David W. Brownlee
Patent Counsel

AMERICAN HOECHST CORPORATION
Somerville, NJ
Leroy G. Sinn
Patent Counsel

AMERICAN STANDARD INC.
New York, NY
Robert G. Crooks
Chief Patent and
Trademark Counsel

AMERICAN TELEPHONE & TELEGRAPH CO.
New York, NY
Paul Enlow
General Patent Attorney

ATLANTIC RICHFIELD COMPANY
Philadelphia, PA
Blucher S. Tharp
Senior Counsel
Technology and Intellectual Property

AVCO CORPORATION
Greenwich, CT
Irwin P. Garfinkle
General Patent Counsel

BAXTER TRAVENOL LABORATORIES, INC.
Deerfield, IL
Paul C. Flattery
Associate General Counsel

BECKMAN INSTRUMENTS, INC.
Fullerton, CA
R. J. Steinmeyer
Vice President
Legal

BELL LABORATORIES
Murray Hill, NJ
Seymour E. Hollander
General Legal & Patent Counsel

THE BLACK & DECKER MANUFACTURING CO.
Towson, MD
Ronald B. Sherer
Director, Patents & Licenses

BORDEN, INC.
Columbus, OH
George P. Maskas
Chief Patent Counsel

BORG-WARNER CORPORATION
Chicago, IL
Robert L. Zieg
General Patent Counsel

BRISTOL-MYERS COMPANY
New York, NY
Isaac Jarkovsky
Assistant General Counsel
Patents

BRUNSWICK CORPORATION
Skokie, IL
William G. Lawler, Jr.
Chief Patent Counsel

BURLINGTON INDUSTRIES
Greensboro, NC
John B. Maier
Patent Counsel

CATERPILLAR TRACTOR CO.
Peoria, IL
W. S. Thompson
Manager, Patent Department

CHEVRON RESEARCH COMPANY
San Francisco, CA
James A. Buchanan, Jr.
Vice President

CIBA-GEIGY CORPORATION
Ardsley, NY
Karl F. Jorda
Corporate Patent Counsel

CLARK EQUIPMENT COMPANY
Buchanan, MI
John C. Wiessler
General Patent Counsel

CPC INTERNATIONAL INC.
Englewood Cliffs, NJ
Ellen P. Trevors
Corporate Patent Counsel

COLORADO STATE UNIVERSITY RESEARCH FOUNDATION
Fort Collins, CO
Kathleen Byington
Vice President

COMBUSTION ENGINEERING, INC.
Windsor, CT
Eldon H. Luther
Corporate Patent Counsel

CORNING GLASS WORKS
Corning, NY
Alfred L. Michaelsen
General Patent Counsel

DEERE & COMPANY
Moline, IL
H. Vincent Harsha
Director of Patents

DOW CHEMICAL COMPANY
Midland, MI
Dr. Richard G. Waterman
General Patent Counsel

DRESSER INDUSTRIES, INC.
Dallas, TX
Mr. Edward Fiorito
Director of Patents and Licensing

E. I. DU PONT DE NEMOURS & COMPANY
Wilmington, DE
Robert C. Kline
Chief Patent Counsel

EATON CORPORATION
Cleveland, OH
Dr. Charles H. Grace
General Patent Counsel

ETHYL CORPORATION
Baton Rouge, LA
Donald L. Johnson
Patent Counsel

FMC CORPORATION
Philadelphia, PA
Dr. Pauline Newman
Director
Patent & Licensing Department

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Gene O. Enockson
Senior Associate Counsel
Intellectual Property Law

GENERAL MOTORS CORPORATION
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Eugene W. Christen
Director
Patent Section

THE GILLETTE COMPANY
Boston, MA
Scott R. Foster
Patent Counsel

THE GOODYEAR TIRE & RUBBER COMPANY
Akron, OH
Richard H. Childress
Director of Patents and Trademarks

HOBART CORPORATION
Troy, OH
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Patent Counsel

INTERNATIONAL HARVESTER COMPANY
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General Patent & Trademark Counsel

ITEK CORPORATION
Lexington, MA
Homer Blair
Patent Counsel

ELI LILLY & COMPANY
Indianapolis, IN
Arthur R. Whale
General Patent Counsel

LITTON INDUSTRIES, INC.
Beverly Hills, CA
Walter R. Thiel
Director
Patents & Licensing

MANVILLE CORPORATION
Denver, CO
Ronald M. Halvorsen
Senior Director
Patents & Licensing

MERCK & COMPANY, INC.
Rahway, NJ
Rudolph J. Anderson, Jr.
Associate General Counsel
& Director of Patents

MILLIKEN & CO.
Spartanburg, SC
H. William Petry
Vice President - Legal

MINE SAFETY APPLIANCES
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Corporate Patent Counsel

MINNESOTA MINING AND
MANUFACTURING COMPANY
St. Paul, MN
Cruzan Alexander
Special Counsel

MONSANTO COMPANY
St. Louis, MO
John E. Maurer
General Patent Counsel

PENNWALT CORPORATION
Philadelphia, PA
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Manager, Patent Department

PFIZER, INC.
New York, NY
Charles J. Knuth
Director, Patents

PRINCIPLE BUSINESS ENTERPRISES, INC.
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James G. Mitchell
Chairman

THE PROCTER & GAMBLE COMPANY
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Chief Patent Counsel

PURDUE RESEARCH FOUNDATION
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Associate Director

SISA LABORATORIES, INC.
Cambridge, MA
Dr. Harry G. Pars
Chairman & Chief Executive Officer

SMITHKLINE BECKMAN CORPORATION
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Alan D. Lourie, Ph.D.
Vice President

SPERRY CORPORATION
Great Neck, NY
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TENNESSEE TECHNOLOGY FOUNDATION
Knoxville, TN
Auzville Jackson
President

TUBE-ALLOY CORPORATION
Houston, TX
Gerald Beard

UNION CARBIDE CORPORATION
Danbury, CT
Thomas I. O'Brien
Chief Patent Counsel

UNION OIL COMPANY OF CALIFORNIA
Brea, CA
Dean Sandford
Chief Patent & License Counsel

UNIVERSITY PATENTS, INC.
Norwalk, CT
George M. Yahwak
Patent Counsel

UOP, INC.
Des Plains, IL
William H. Page
Acting Patent Counsel

USM CORPORATION
Beverly, MA
Owen J. Meegan
Assistant General Counsel

WESTINGHOUSE ELECTRIC CORPORATION
Pittsburgh, PA
Clement L. McHale
General Patent Counsel

THE WISTAR INSTITUTE
Philadelphia, PA
Warren Cheston
Associate Director

Mr. KASTENMEIER. Thank you, Mr. Manbeck, for your presentation, which was an excellent one.

The list you refer to is a list of Intellectual Property Owners, Inc. Is it your own list?

Mr. MANBECK. This schedule D?

Mr. KASTENMEIER. Yes.

Mr. MANBECK. No, it is not my own list. It was furnished to me by the Executive Director of IPO, who I understand wrote to the IPO members asking if they supported these bills, and that was the response.

He is here in the room, Mr. Kastenmeier, and could perhaps add to that, if you wish to ask him.

Mr. KASTENMEIER. I appreciate your taking a constructive look at the bill H.R. 3286, and I think it is a very useful thing for you to have gone through it and made certain suggested changes. I must state at this point in time I have not analyzed your suggested changes in terms of the impact on the bill, but it does offer us something to examine and I appreciate it, as I say, as a constructive thing to do.

Mr. MANBECK. May I add just one more thing?

I have included some comments as to the reasons for the changes which you may wish to considser.

Mr. KASTENMEIER. Of course, your testimony as originally printed in full, together with its several appendices or exhibits, will be a part of the record, in addition to your oral presentation.

As far as H.R. 4524 is concerned, process patent protection, and the differences between yourself and the administration, is it essentially because of the trade policy of the United States? Is this the heart of the difference between you and Mr. Mossinghoff?

Mr. MANBECK. I am not sure we have a real difference. We originally suggested that the revision of the statute apply only to foreign-made goods, since we felt the remedies against infringing U.S. producers were adequate as they are. In other words, if the process is infringed in the United States, you can enforce the process patent against the producer, go right to the source of the problem.

With foreign-made goods, however, you cannot assert the process patent against anybody, so you can have unlicensed competition using your process invention which you can't touch. That was the reason that we suggested that it apply only to foreign-made goods.

The administration, as I understand it, feels that in order to meet the GATT language it must apply to domestic goods, and I have a copy of their memorandum which I will furnish to your staff. That is sort of beyond my ken and I will not comment, but we don't have a feeling that it should not be extended to domestic-made goods because I think those of us who have thought about it think you would still strike at the heart of the matter, which would be the infringing producer.

Mr. KASTENMEIER. You heard my questions to Mr. Mossinghoff with respect to the Trade Regulation Committee of the Bar Association of the city of New York. Do you have any comments on that?

Mr. MANBECK. I think, first of all, as you have already recognized, that is not a position of the overall bar association, since an-

other group, namely, the patent committee of that association, feels otherwise.

Mr. KASTENMEIER. I realize that.

Mr. MANBECK. But beyond that, I think it postulates, first of all, an unreal possibility. It is saying, as I understand it, a foreign patent owner could refuse licenses to somebody in this country and would himself not produce abroad, so that nothing would come in.

I have yet, in my experience, to see any really worthwhile invention be sequestered that way; I mean sequestered, period, let alone that way. If the foreigner has a good process that is going to let him produce goods, either better goods or goods more inexpensively, he is going to do it to get his profit margin.

Second, the same situation in a sense would occur today. After all, the foreign patent process owner could come in here and get his patent and refuse to license in the United States and import from abroad today.

So if there is an unfairness to U.S. manufacturers, it could exist under today's law, too.

Mr. KASTENMEIER. Of course, the reasons for raising these questions, and even the first question, the question is: Is there divergence of policy interests on the part of the United States or certain trade interests within the United States under its treaties or otherwise, or in practice, and what we see as patent policy changes that would achieve certain things.

It is incumbent upon this committee to examine really both of those, even though I don't know whether we will have, first of all, trade interests before us to actually testify.

I suppose perhaps I ought to ask about H.R. 4529, so far as it modifies the law with respect to the treatment of patent licensees in certain situations.

Apparently some segments in the Department of Justice object to the changes because they feel that the results of Lear should not be disturbed in any way. Is it a fair statement to say that H.R. 4529 does not modify the result in *Lear;* rather, it deals with the collateral consequences of the licensee who challenged the validity of the license patent? Can you comment on that?

Mr. MANBECK. I, and the other members of the ad hoc committee, insofar as I know, do not feel that the bill as proposed would in any way overrule *Lear* v. *Adkins.* The licensee would still have a full right to challenge the validity of the patent at any time he wished to do it.

The bill only affects, as you have termed them, the collateral effects of *Lear* v. *Adkins* on the respective rights of the licensor and licensee during that challenge.

Mr. KASTENMEIER. One last question on something not really at issue this morning, but which was in fact authorized in the public law that we passed in the 96th Congress, Public Law 517. I recall that you were one of the stalwart supporters of the use of arbitration in patent cases and we did finally include that in the law.

I wanted to ask you whether that reform has worked, what experience we have had with it or you have had with it, or you would note, and whether we should go further with it?

Mr. MANBECK. What, to my knowledge, has happened since arbitration was authorized as a means of settling patent disputes is

that the American Arbitration Association established a Patent Advisory Committee and this committee spent some months to draft a set of patent arbitration rules which are based on the commercial rules of the association but yet take into consideration some specific needs, some limited discovery, and this sort of thing, that exists in patent arbitration.

These rules were finally printed and established some time last year. Since that time, the arbitration association has conducted a number of seminars and is in the process of establishing a national panel of patent arbitrators, people who are skilled in the patent law or in various technical matters.

All of this has taken time. I think the members of the corporate Bar are still strongly in favor of the use of arbitration. We are starting to put arbitration clauses in our contracts, and there have been some, but not a lot, of full arbitrations handled. I am familiar with some, for example, in the aircraft industry.

I think that arbitration will come into the resolution of patent disputes slowly. If you talk to Mr. Coulson, the head of the American Arbitration Association, you will find that the vast majority of arbitrations come from contracts that include arbitration clauses and, of course, we are just starting out with those clauses today.

So although the patent bar is, I think, strongly interested in alternate forms of dispute resolution other than litigation, and arbitration is viewed as a tool they are glad to have, it is going to take a while until it is used to a very substantial extent.

Mr. KASTENMEIER. I take it it would be perhaps a period of 2 or 3 more years before we will have enough experience in the use of it to comment intelligently on how effective and how widely used it may be.

Mr. MANBECK. Yes. I might even say 5 years.

Mr. KASTENMEIER. Five years.

Mr. MANBECK. It is going to take a while.

Mr. KASTENMEIER. Thank you very much. I would have other questions for you, but as with Mr. Mossinghoff, I think as we tend to develop these bills individually, and since the ad hoc committee has such a keen interest in really a number of the bills before this subcommittee, we will have occasion to be in contact with you as things develop.

I appreciate very much, as members of this committee do, whether they are here at the moment or not this morning, your appearance. Thank you very much, Mr. Manbeck.

Mr. MANBECK. Thank you, Mr. Chairman.

Mr. KASTENMEIER. That concludes this morning's hearing, and the committee, accordingly, will stand adjourned.

[Whereupon, at 12:15 p.m. the subcommittee adjourned, to reconvene at the call of the Chair.]

INNOVATION AND PATENT LAW REFORM

THURSDAY, APRIL 26, 1984

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

The subcommittee met, pursuant to call, at 10:25 a.m., in room B-352, Rayburn House Office Building, Hon. Robert W. Kastenmeier (chairman of the subcommittee) presiding.

Present: Representatives Kastenmeier, Schroeder, Moorhead, and Hyde.

Staff present: Michael J. Remington, counsel; David W. Beier, assistant counsel; Thomas E. Mooney, associate counsel.

Mr. KASTENMEIER. I am informed that members are on their way. I regret the delay in getting started this morning. Before we proceed, consent will be given that the subcommittee permit the meeting to be covered in whole or in part by still photography or by broadcast pursuant to rule 5 of the Committee Rules.

This morning the subcommittee continues its hearing on patent law reform, innovation, and the public interest. During our first day of hearings we heard from two distinguished witnesses—Commissioner Mossinghoff and Harry Manbeck—who provided a general overview of the bills before us. Today we continue the task of examining the merits of these various legislative suggestions.

While some of my colleagues may find this work too detailed or boring, I am afraid I have a different view. Intellectual property law is a central actor in the modern marketplace. The development of the United States as a prime economic force initially came from the combination of our natural resources and our intelligence.

In these times of economic interdependence we will increasingly have to learn how to prosper using our wits. Part and parcel of any improvement of our position in world trade is a firm grasp of how intellectual property law can stimulate innovation. If we fail to take the time to review our intellectual property laws we may well find ourselves without the ability to protect our greatest assets—ingenuity and inventiveness.

Before turning to the introduction of our witnesses, I would like to raise some troubling statistics:

Between 1972 and 1980, the number of patents to American citizens declined dramatically from 225 per million persons to 169 per million.

The percentage of U.S. Patents issued to foreign persons—largely West Germans and Japanese—increased from 25 percent of the total to nearly 40 percent of the total.

During 1983 7 of the top 10 corporations receiving U.S. patents were not American.

These statistics raise a profound question about why we appear to be losing our edge in the intellectual property marketplace. As tempting as it might seem to create trade barriers to prevent foreign persons from continuing this trend, we must look to the cause of these symptoms.

For example, are individual American inventors adequately compensated?

Does the availability of compulsory licenses or working requirements, retard or further innovation? Do our trade law relationships, on questions of property law, with the Third World need to be restructured?

It is my hope that through these hearings on specific bills we will be able to shed some light on these larger questions.

This morning I am very pleased to greet the distinguished witness who has been before us many times on the subject in numerous capacities including as Commissioner of Patents. He is well known, Donald Banner; who will this morning be representing Intellectual Property Owners, Inc., known as IPO.

Mr. Banner, you are indeed welcome. Pleased to see you again, and of course you may proceed as you wish.

Actually, of course, you have a 25-page statement together with 2 pages of addenda. Perhaps you can summarize, even though I say this because the challenge to the witnesses is enormous. The scope of bills is considerable and you may decide what sort of priorities you might want to give to the various measures before us.

TESTIMONY OF DONALD W. BANNER, PRESIDENT, INTELLECTUAL PROPERTY OWNERS, INC.

Mr. BANNER. Thank you very much, Mr. Chairman.

Personally and on behalf of IPO, we are concerned about what is happening in our country and you have mentioned some of the important statistics which raise certain questions about where we are going and what is happening. I add one or two more and then with your permission, sir, I would briefly go through some of the highlights of our statement and if you have any questions, I would be more than happy to try to answer them.

On the statistical side, we are very interested to see that in 1983 only three U.S. companies received more U.S. patents than did Hitachi Nissan Motor Co. received about the same number of U.S. patents as Ford and General Motors combined. I spent some years in the automotive industry. I find that rather significant.

In our statement, we have included a quotation from a recent speech by the Assistant Attorney General to which I invite your attention. You know the statistics already so I won't bother to read them at this time. This is included on page 3 of our statement.

But it points up the very significant importance of technological progress to our country and I suppose points out why we should be concerned. It is a good sign, I think, that this concern is being more

universally reflected. In the Washington Post just last Sunday there was a separate section on this issue pointing out the trade deficit this year may be $100 billion. For each billion dollars, you are talking about 25,000 U.S. jobs.

Yesterday, the Chicago Tribune had an article entitled "America, Land of Invention and Need for Reindustrialization." One of the things they said in the article was, quote: The United States is losing its dominant position in aircraft, plastics, steel, and drugs.

We at IPO are concerned. We are afraid that we are surrendering much of our leading industrial position.

One of the things that we think will help to correct this trend is strengthening the patent system incentives. Strengthening the patent system by modernizing it, by making it more reliable, more understandable and indeed, if I might use the expression, eliminating some of the Mickey Mouse in it.

We have made some substantial improvement, I think, in the last couple of years. There is a long way to go. We have reexamination, and we have the Court of Appeals for the Federal Circuit and that is very substantial progress. IPO commends you, Mr. Chairman, for conducting hearings like this in addition to those otner items. These hearings are very significant forward-moving steps. There is a lot to do and we are very pleased to be able to say a few words about some of the pending legislation.

The paper that we have presented to you, sir, is organized in accordance with the suggestion we received as to how it should be organized and my brief comments will follow that pattern.

The two bills that we might start with, H.R. 4525 and 4527, H.R. 4525 relates to the so-called secret prior arts issue, which impacts primarily on teams of inventors that are now used in our industrial programs, and we are in favor of the provision of H.R. 4525 that would make so-called secret prior art in certain circumstances not available to invalidate U.S. patents. We think that is a step forward.

Also H.R. 4525 provides that you don't have to have only inventors named on the patent who contributed to every claim of the patent. That is progress. That is a good Mickey Mouse elimination.

The section of H.R. 4525 to which I particularly invite your attention talks about the fact that this would apply to U.S. patents already granted as well as to patents issued after enactment of the legislation. That is a rather interesting problem. As our paper points out on page 4, we feel that some provision is necessary to prevent unfairness, if any exists, to parties who have relied on the present state of the patent law. Particularly we might point out this secret prior art issue is the place where that ought to be considered.

The foreign license topic is a section of the legislation where some kind of intervening rights to use the patent law expression might apply and also to interferences. We would be pleased to supply language, if you would like.

Mr. KASTENMEIER. Well, we welcome such language. That is always one of the questions when, as you say at least on the surface you are attempting to eliminate, to streamline and to eliminate the difficulties on complexities of the system or at least the

Mickey Mouse aspects of it, whether or not other parties might be in one way or another disadvantaged by the changes inequitably.

Mr. BANNER. Yes; and there may be some people and in order to be perfectly fair about this we have given some thought to some language that may be of use to you.

Mr. KASTENMEIER. We welcome that language.

Mr. BANNER. Thank you, sir.

On the point of inventors rights, that is to say, the bills which would provide for compensation to be paid to inventors and would set Federal standards for contracts, I would like to say at the outset that we feel very strongly that American inventors are a very, very important natural resource. We think that they should have greater recognition, greater rewards. We think that companies that have awards programs for inventors should be encouraged to do that.

Indeed, if we might go for a moment beyond the scope of the paper, we think it would be a very good idea to pay a lot more attention to the inventors in the sense of really strengthening the idea of an inventor's hall of fame. I know we have a very small one here in town. Baseball players have a hall of fame, football players a hall of fame, that is good; that should be. Inventors are some of the people who change the world; contribute so much to our country. I think they should have more recognition than they do.

On the other hand, we have concern about the bills concerning compensation and concerning preemployment assignment. First of all, the matter of how a particular employee's invention fits into a particular corporate scheme, and who else also contributes to the result of that particular invention. For example, a trade secret in the manufacture of the product, marketing people, manufacturing expertise—all of those things are involved.

Also, there is the question of secrecy. How does that impact on a cooperative venture? Would people tend to keep their ideas to themselves? Is that a possibility?

We were concerned about that. We are not sure that the bill would work the way it is intended to work. We are not sure it would be a good idea without more thinking about that subject.

There are of course other countries that have schemes, Germany and Japan, for example—for compensating inventors. Many people in IPO have had experience with those systems. I have had experience with those systems because I was general patent counsel of a large industrial corporation for many years. Obviously with worldwide facilities you run into those issues.

I think, though, we might say that the complement is different, it is a different environment today, the litigious nature of our modern society is quite different than in some other places. We are not sure this would work out this way.

The same thing with preassignment agreements. There are some States; five States, that have passed legislation on this subject. We think it could be better. If we want uniformity we would do it through a model State law rather than Federal legislation.

Furthermore, the present proposed legislation has some certain provisions that are troubling. It would prohibit agreements for an assignment of inventions made after the termination of employment. This could be a very serious problem if someone made an in-

vention and was going to change jobs, could he be quiet for a couple of days and take it with him? That is a big problem. Even people with the best of intentions, though, that is a problem.

Those ideas come oftentimes, I think, sometimes after they resign, and again, is this a real problem? We think those companies that have inventors working for them do in their own interest, their company's own interest, try to take care of their creative people properly. They don't want them to leave; they want them to be compensated. There are undoubtedly some inequities someplace. We think overall it's equitable.

Mr. KASTENMEIER. As you point out, Mr. Banner, the Japanese and West Germans have made that work and indeed may be beating us in the process.

Mr. BANNER. Well, Mr. Chairman, let's talk about the West German system.

The question, it seems to me, is how much has it really contributed; how much has it really done. I have had some experience with that issue. One of the things that it does, it gives a lot of employment to patent lawyers. I suppose as a patent lawyer, I should be happy about that. But whether the amounts involved really are enough to make any difference is highly questionable.

In Japan, the other side of the world, their system works. But frankly I have grave doubts that it is because of this feature. They have a society in which so many other factors are important in their invention system. They have a society in which even in the schools they have rewards for inventions. In the high schools and grammar schools the Governor comes and shakes their hands and the national winner gets invited to the palace. It is a system in which everyone knows that it is important to their country to make inventions. It is a whole different attitude than we have here.

It was not so many years ago that we had a justice of the U.S. Supreme Court say the only patent that was valid in the United States was one that the Court had not had a chance to get its fingers on yet. Ours is a different system entirely.

Going then to the section of our outline on the administration of the Patent and Trademark Office, the defensive patent. I think that breaks down to two parts; one private sector part and one Government part.

In brief, we think the defensive patent would be a good idea. Some private sector people would like to have this. It is better than a publication of an invention because the publication does not permit participation in an interference. Defensive patents would.

Second, a defensive patent would be a reduction to practice. Of course, the publication is not a reduction to practice. That is very important later in litigation if it should come up. So we are in favor of that proposed legislation.

We think it is particularly well suited for Government agencies.

As you know, the Government owns about 28,000 unexpired U.S. patents, about twice as many as anybody else. We have about 2,000 Government patent applications a year and 300 patent lawyers working for the Government. Some have spent substantially their whole time on patent applications.

You realize that the thing you get from the U.S. patent is the right to exclude, as distinguished from the right to make anything. You have to ask yourself, who are you going to exclude.

Furthermore, commercialization of these patents is highly questionable from a cost standpoint. Commissioner Mossinghoff said when he was with NASA, only about 1 percent of the patents were commercialized and estimates were made, that about 4 percent of the patents that were Government patents are licensed. Not very cost effective, I suggest.

We think Federal agencies should definitely use such a defensive system. As a matter of fact, the Senate Judiciary Committee, as you know, has approved a provision in which defensive patent for Government inventions would be the norm and we think that is a very, very good idea. We recommend it to you.

There is another aspect of defensive patents to which we invite your attention and we suggest another amendment. One of the problems with the present language is that somebody could file in the Patent Office an application and then under section 120 of the law, abandon the first one and file a second one and continue this for a while.

When the final defensive patent is issued it would be effective as prior art as of the filing date of the very first one. So that would affect the validity of other people's patents. Secret prior art would be created.

As I discussed earlier, with respect to H.R. 4625 and H.R. 4627, those bills would go in the direction of reducing the amount of secret prior art. H.R. 2610, would expand secret prior art unless it is amended as I have suggested.

H.R. 2610 also has a section 4 to which we are strongly in opposition to. That section 4 would shorten the time for paying the final fee to some period that might be as short as 1 month. I invite your attention to the fact that Commissioner Mossinghoff in his Senate testimony said that that provision was not necessary for his program to reduce average pendency to 18 months.

The issue of whether or not to pay the final fee, particularly in large organizations may require cooperation of a lot of people. It takes time. One month simply is not enough time. The present statute says 3 months. We think it ought to stay that way.

The consolidation of the Board of Patent Interference and Board of Appeals: IPO has not taken any position with respect to that.

Fees for independent inventors, as we said before, we certainly sympathize with this concept. We feel that if there is a practical way that this can be done we are all in favor of it. Small individual inventors, small companies, and nonprofit organizations, we think, would benefit by such legislation. There is a caveat I might make, however. Commissioner Mossinghoff has testified that $10 million over a 3-year period would be what would be taken out of his funding. We would hope that before any such legislation was passed there would be some kind of agreement with the Congress that that additional funding would come from the Congress and not just be pushed on to other people who don't benefit from this legislation.

When we increased the fees in 1982, IPO expressed concern about the fact that, in the light of need for more inventions in our

country, it was rather unusual to increase the tax on ingenuity. We don't feel that it is a very good idea to further increase it at this time.

We do feel, however, that can be worked out so that we can by reducing the burden on our small inventors, our small companies, our nonprofit groups, would be a good idea.

FOREIGN FILING LICENSES

If I may disagree just briefly, there is some confusion in this area I think. At the present time, if I put information in my briefcase about let us say, an oven cleaner * * * I am using an oven cleaner because in the first place I don't think that it has anything whatsoever to do with national security and furthermore there is an actual case that relates to oven cleaners.

If I took a briefcase full of technical information on an oven cleaner, and if I was in Detroit and I walked across the bridge to Canada, there really isn't any security problem. Nothing happens. No Federal law is violated.

The other side of the coin is the case I mentioned to you; somebody filed in the United States for a patent on an oven cleaner, waited 6 months, got his license from the Commissioner, and then filed a patent application in Canada, in which certain additional technical information concerning the oven cleaner was included. Well, the U.S. patent was held invalid. Why? Mickey Mouse, silly. No national security impact anywhere. In other words, the statute is so broad that national security is not what we are talking about.

There are national security aspects of course, but the present language in the statute is far broader than national security issues.

Not only can United States patents be invalid, but there are criminal penalties.

That is why we heartily approve H.R. 4524. The details we have spelled out in our paper. We think that the present statutory language is far too broad. We want to emphasize the fact that this is something which the Congress should act; we should not leave this to the rulemaking authority of the Commissioner.

We are invalidating, potentially invalidating U.S. patents in a way which doesn't do anybody any good.

Patent interferences. We certainly are in favor of H.R. 4528, which extends arbitration and would cut down on the litigation costs, it would extend the period of time in which the Commissioner could accept the filing of settlement agreements. We think that is a good idea.

Under substantive patent law reform, the first item has to do with the patent term restoration which we support. Of course it is a good idea to have very careful scrutiny of new products, in the pharmaceutical industry and the agricultural chemical industry; but when that reduces the 17-year term of the patent, we don't think that arrangement was ever forseen or intended by the Congress. We think it is basically an unfair thing to do.

We favor the enactment of H.R. 3506. We are aware that there is a proposed compromise bill circulated, we have not studied it and I will not attempt to comment on it. If agreement cannot be reached on a legislative solution this year, we would also be in favor of the

Commissioner of Patents and Trademarks, under his rulemaking authority, delaying the issuance of patents in this area to in effect restore their term.

On manufacturing outside the United States, three bills are discussed in our paper beginning on page 20. We are in favor of such legislation which would eliminate important problems that we have, eliminate loopholes, and would encourage the manufacturer of patented inventions in the United States, and provide jobs in the United States. That is a good idea as we said.

The Tariff Act already has provisions for excluding products manufactured abroad by processes patented in the United States, but that is far from satisfactory in the long run. The Tariff Act does not give monetary relief.

Also, to use the Tariff Act you have to show that you are an efficiently and economically operating industry. Sometimes if you are a small patentee, you haven't been able to start manufacturing, the Tariff Act would be useless under that circumstance.

We think it is in the best interests of the U.S. manufacturer and U.S. workers to stop the foreign manufacturer from taking a free ride on research and development expenses of U.S. companies. It will provide employment in this country.

H.R. 3577 has a provision which provides that it would be presumed that a product was made by a patented process if (1) there was a substantial likelihood that the product was so made and the patentowner had exhausted all reasonably available means in the foreign country to establish that the product was made by the patented process.

We are concerned about this latter provision. First of all, we think that there should be a presumption that the patent was made by the patented process, if there is a substantial likelihood that it was so produced.

But we are very concerned about the provision for exhausting all reasonably available means in foreign countries. How do you do that?

Suppose the product came from an iron curtain country, the Peoples Republic of China or other countries which have laws which do not provide for discovery like we have in the United States. We could be marching folks around the world trying to establish that the information is available—this is awfully expensive, we don't think it is at all necessary.

We noticed that the U.S. Trade Representative is concerned about the GATT issue as to whether or not H.R. 4526 and 4814 would violate our country's obligations under GATT and if that is the case we should of course modify the language as it has been suggested to eliminate that problem.

The second part of these bills relates to the so-called Deepsouth issue. The *Deep South* case was one in which the Supreme Court itself invited Congress to look at this situation and possibly come up with some legislative action. We think now is the time to do it. Existing patent law on this subject is basicaslly unfair.

Mr. KASTENMEIER. Regrettably, I am going to have to interrupt your testimony so that the committee can vote on the proposition on the House floor. The buzzers indicate that a vote is on and the second bells indicate that we have just enough time to get there.

So, accordingly, I will have to recess the committee for about 10 minutes and we will resume.

Mr. BANNER. Thank you.

[Recess.]

Mr. KASTENMEIER. The committee will come to order.

The committee recessed we were hearing from Mr. Banner, who is testifying. Mr. Banner, you are almost at the end of your statement; you may want to conclude.

Mr. BANNER. I have just one other section, Mr. Chairman, and that has to do with H.R. 4529. It is in our view one of the key bills being considered today which we strongly support. Under it, as you know, either party could terminate a patent license agreement after the licensee had asserted in court that the patent is invalid.

As you know, this might not necessarily occur until after the licensee actually had had an opportunity to have the patent reexamined under the reexamination provision which we now have in our law.

The reason that we feel this legislation is sorely needed is because under the results at least of the Supreme Court decision in *Lear* v. *Adkins,* the present situation is one in which a licensee, after having agreed to pay certain royalties under a patent license can stop paying. He is in a position of "heads I win, tails you lose," because he can continue to have all the benefits of the license. The license itself prevents the possibility of any injunction against this person.

If the licensee loses, then all he has to do is pay the royalties that he agreed to pay in the first place. As far as I know we are the only country that has such a peculiar position: The process may very well result in the licensor just not having the money to continue the litigation because as we all know, patent litigation is notoriously expensive.

The administration has recommended that the bill be recast merely to restore the freedom of the licensor to negotiate for the rights which are now mentioned in H.R. 4529 instead of guaranting those rights to every party.

We do not favor that approach. In the first place, it would apply only prospectively; and in the second place, it would favor those somewhat highly sophisticated licensors who have been putting the right to terminate in their license at the present time while other people have not been putting it in. We don't think that approach would be fair.

Mr. Chairman, again I want to thank you very much for this opportunity to testify before you today.

Mr. KASTENMEIER. Thank you, Mr. Banner.

I just have one or two questions. Several of the bills contain, really at least four of them contain language such as the following language, "The amendments made by the bill shall apply to any unexpired United States patent granted before the date of the enactment of this Act."

Generally, absent a compelling rational reason, I believe the Congress would oppose retroactive legislation. Can you give me any compelling reasons for the retroactive provisions?

Mr. BANNER. What we are trying to do is to create a situation which would put the incentive back into the patent system which,

unfortunately, we have tended to neglect. We therefore think that all these provisions should apply to existing patents; otherwise we would not start them now but only at some time in the future possibly they might be useful. We don't think we can or should wait. Maybe this is going to be the only patent you are going to get—the one that exists now. We think you should be able to use it and use it fruitfully for our country.

As I said before, however, we favor therefore having it apply to existing patents but there are certain situations in which if someone has relied on a present situation it would be fair to let him have the benefit of that reliance, I mentioned that there are three areas that probably are the ones where parties who relied should be protested. The secret prior art one, the foreign license one and the interference settlement agreements one. Those probably are the areas.

Mr. KASTENMEIER. Now of course there are a number of bills that your organization supports but to what extent deriving out of my statement and yours at the outset, in fact I thought you have dramatically pointed out that Nissan had more U.S. patents in a given year than both General Motors and Ford Motor Co. put together. To what extent does the adoption of these particular bills leave the parties in essentially the same position, or to what extent and why does it favor U.S. corporations over Nissan?

Mr. BANNER. The enactment of this legislation we feel would be very important. As I mentioned we now have reexamination. As I mentioned, we now have the Court of Appeals for the Federal Circuit. Neither one by themselves individually would change the world sufficiently. Probably nothing here is going to change the world sufficiently. But there are definitely steps forward. They are advances, they are improvements.

We think that should happen. How would it happen? These bills would make the patent laws more reliable, it would make the patent laws more uniform, they would make the patent laws fairer, they would eliminate some of the Mickey Mouse and we think that is important. That is very important.

And it would say also to the people of the United States that the Congress thinks that the patent system's result is significantly important that would permit management to have a better feeling about where the patent system is going.

The reason we don't have the kind of invention and innovation we need in our country particularly in large corporations is a result of something. It just didn't happen because the stars crossed each other in the wrong way. These are practical business people and these practical business people should be encouraged in the areas of promoting the progress of the useful arts as provided in the Constitution. We can do that under the patent system.

Mr. KASTENMEIER. Thank you, Mr. Banner.

Does counsel have questions?

Mr. MOONEY. Mr. Chairman, Mr. Sawyer has an interest in one matter if I could briefly run this by Mr. Banner for the purpose of the record.

This is a bill pending before the subcommittee, H.R. 4462, which would merge the Board of Patent Appeals, which has 30 judges,

and are paid at the rate of GS–17, with the Board of Patent Interference which has eight judges paid at GS–16.

The Senate counterpart to that measure, was amended and they added to that the Trademark Trial Appeals Board with regard to seven judges at GS–15.

Just with regard to their salary, not merging that particular board, but with regard to their salary, they increased that to GS–16. Mr. Sawyer was interested in, one, if you support that, and, two, is there any justification for any differentiation between the three or among the three boards?

Mr. BANNER. Well, first of all I definitely support the idea of increasing the level of the people who are on the Trademark Board. I definitely support that.

Their position like that of the Board of Appeals, and the Board of Interference is a quasi-judicial position. In addition, if anything, the members of the Trademark Trial and Appeal Board are required to be more familiar with the federal rules of civil procedure than even the other two boards. The reason for that is because the Trademark trial and Appeal Board becomes involved with discovery provisions, in trademark matters. The determination of those trademark matters, of course, is extremely important, the impact very substantial.

As an answer to the second part, I think, of your question is there any reason for the difference. The only reason why there is really any difference is one of historical development. Thee is no reason in any kind of a logical sense for it in my view, it has sort of been that way and it is difficult to change. But it should be changed. It definitely is something which needs changing and has needed changing for sometime.

Mr. MOONEY. Thank you, Mr. Chairman.

Mr. KASTENMEIER. We thank you very much for your appearance here this morning. Good to have you back.

Mr. BANNER. Thank you, Mr. Chairman.

[The statement of Donald W. Banner follows:]

IPO INTELLECTUAL PROPERTY OWNERS, INC.

SUMMARY OF STATEMENT OF
DONALD W. BANNER, PRESIDENT
INTELLECTUAL PROPERTY OWNERS, INC.
BEFORE
HOUSE JUDICIARY SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES AND
THE ADMINISTRATION OF JUSTICE

APRIL 26, 1984

* Statistics on U.S. patents show a decline in "Yankee ingenuity":

  --In 1983 six of the nine corporations which received the largest numbers of U.S. patents were foreign or foreign-controlled.

  --In 1983 Nissan Motor Company received about the same number of U.S. patents as General Motors and Ford combined.

* IPO believes the decline is attributable in part to weaknesses in the patent system which have weakened the incentives patents provide for research and development.

* IPO recommends as follows:

  --Favors legislation providing that unpublished information within the inventor's organization cannot be used to defeat a patent (H.R.4525 and 27).

  --Believes Federal legislation is not desirable concerning employed inventors' compensation (H.R.3285) or emoloyee invention assignment contracts (H.R.3286).

  --Favors defensive patents legislation (H.R.2610) with amendment to require government agencies to elect defensive patents.

  --Takes no position on consolidation of patent boards (H.R.4462).

  --Favors freeze on fees for small inventors only if additional appropriations are available (H.R.3462).

  --Favors reducing burden of requirement to obtain a license from Patent and Trademark Office before filing abroad (H.R.4524).

  --Favors changing patent interferences proceedings by allowing arbitration and relaxing penalties (H.R.4528).

  --Favors restoring patent terms to compensate patent owners for delays in obtaining regulatory clearances (H.R.3502).

  --Favors eliminating loopholes that encourage manufacture of patent inventions outside the U.S. (H.R.3577,4526 and 4814).

  --Favors strengthening rights of licensors in patent license contracts (H.R.4529).

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IPO INTELLECTUAL PROPERTY OWNERS, INC.

STATEMENT OF
DONALD W. BANNER, PRESIDENT
INTELLECTUAL PROPERTY OWNERS, INC.
BEFORE
SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES AND
THE ADMINISTRATION OF JUSTICE
HOUSE COMMITTEE ON THE JUDICIARY

APRIL 26, 1984

Mr. Chairman and members of the Subcommittee:

Thank you for this opportunity to discuss proposals for amending the patent laws. I am appearing here today on behalf of Intellectual Property Owners, Inc. IPO is a nonprofit association whose members own patents, trademarks and copyrights. Our members include large corporations, small businesses, universities, and individuals.

IPO members are responsible for a large portion of the research conducted in the United States. Because of the importance of patents in encouraging research and commercial development of new technology, we are deeply interested in having the patent system operate effectively.

I. INTRODUCTION

Lagging American Technology

IPO believes the United States no longer can afford to neglect matters which affect the climate for national invention

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and innovation. We have experienced a decline in "Yankee ingenuity."

One way to show this is with statistics on the number of patents issued by the U. S. Patent and Trademark Office. Those statistics show the United States losing ground to its competitors in some of the most active and commercially important technologies--organic chemicals, synthetic resins, telecommunications, and digital logic circuits.

In 1983 six of the nine corporations which received the largest numbers of U. S. patents were foreign or foreign-controlled. In 1973 only one of the top nine was foreign or foreign-controlled.

Only three American companies received more U. S. patents in 1983 than Hitachi--General Electric, IBM and RCA. Nissan Motor Company received about the same number of U. S. patents as General Motors and Ford combined.

In 1973 we were issuing 26 patents to our nationals per 100,000 residents. By 1983 that figure was down to 16 per 100,000 residents. In terms of raw numbers of patents issued to U. S. nationals, we issued 55,000 in 1973 and 37,000 in 1983.

Fifteen years ago the percentage of U. S. patents going to foreign nationals was about 20 percent. Now it is about 40 percent. The share going to Japanese nationals alone has now risen to 15 percent.

Statistics such as these probably were interesting only to patent lawyers at one time. Today more and more people are

beginning to realize that such trends have a definite correlation to the numbers of jobs in our country.

Assistant Attorney General J. Paul McGrath recently said the following:

> . . .over the last eighty years, technological progress has accounted for almost one-half of the growth in per capita real income. More generally, companies that invest heavily in research and development of new technologies have about three times the growth rate, twice the productivity rate, one-sixth the price increase, and nine times the employment growth as companies with relatively low investments in such R & D.

This year predictions are that our trade deficit may be 100 billion dollars. A special section on the trade challenge in the Washington Post this past Sunday reported that every billion dollars in excess imports eliminates about 25,000 U. S. jobs.

We are surrendering our leading industrial position.

Stronger Patent Incentives Needed

IPO believes the declining share of patents going to our own citizens can be attributed in part to weaknesses in the patent system which, in turn, have weakened the incentives for our citizens to make inventions. We must provide greater incentives for American firms to invest in research, development and commercialization of technology.

The 17-year exclusive patent right to manufacture, use and sell inventions can give powerful incentives, but the incentives are strong only when the patent laws and procedures operate effectively. Several studies, going back at least as far as the President's Commission Report of 1966, have recommended improvements in the functioning of the patent system.

Congress already has made some important improvements. Legislation was enacted in the 96th Congress which authorizes the Patent and Trademark Office to reexamine patents after they have been issued. Legislation in the 97th Congress established the Court of Appeals for the Federal Circuit to help bring uniformity and certainty to Federal court decisions in patent cases. These are significant reforms, but much remains to be done.

IPO commends the Chairman for conducting these hearings. Several of the bills being considered today would modernize or simplify the patent code or strengthen the rights of patent owners in ways that would bolster the incentives for American firms to engage in research and development.

Turning now to specific provisions of the legislation, I shall discuss the bills in three categories as you suggested: (1) those that concern regulation of inventors' rights; (2) those that concern changes in the administration of the Patent and Trademark Office; and (3) those that make substantive changes in the patent laws. Although we are not wed to any particular language for the bills, an appendix to my statement lists certain refinements in language which we believe are improvements. We have obtained some of those suggestions from other organizations.

I. REGULATION OF INVENTORS' RIGHTS

Team Research

IPO strongly supports H. R. 4525 and H. R. 4527, which would adapt the patent laws to the realities of team research.

H. R. 4525 provides that unpublished information known only within the inventor's organization (that is, so-called "secret prior art") may not be used to defeat the granting of a patent. Today confidential technology developed by one member of a corporate or university research team can be used against the invention of another team member. The present state of the law penalizes the larger organizations which have teams of inventors working on research. H. R. 4525 would put an end to this discrimination. The appendix to my statement contains a draft prepared by interested patent lawyers which we believe represents an improvement in language over the original bill.

H. R. 4527 makes clear that two or more inventors may obtain a patent jointly even though each inventor has not contributed to every "claim" of the patent. This change complements H. R. 4525. Inventors often work on a particular aspect of an invention while someone else works on different aspects. It is often difficult or impossible to draft the claims of the patent so that each co-inventor has his contribution recited in each of the claims.

H. R. 4527 follows those court decisions which have held that neither the statute nor any rule of the Patent and Trademark Office requires each claim in the patent to cover subject matter which was invented through joint efforts of all the inventors

named in the patent. The appendix sets forth suggested language which refines H. R. 4527 as originally proposed.

Section 2 of H. R. 4525, section 2 of H. R. 4527, and identical provisions in some of the other bills state that the bills would apply to United States patents already granted, as well as to patents issued after enactment. We agree with this principle. In order for the bills to have maximum effect in strengthening the patent law, they must apply to patents already in force. Given the urgent need to provide incentives to strengthen America's technological leadership, we cannot afford to wait years for the bills to have an impact.

On the other hand, a provision is needed to prevent unfairness to parties who have made investments or taken positions relying on the existing state of the patent law. Language should be added to insure that the effects of the bills are equitable in this regard.

Employed Inventor Rights

The remaining bills relating to regulation of inventors' rights are H. R. 3285, which would create a comprehensive federal system for determining the amount of compensation to be paid to employees who make inventions, and H. R. 3286, which would set federal standards for contracts between employers and employees regarding ownership of inventions made by employees.

American inventors, of course, are an important national resource. We are in favor of increasing the amount of research and development and thereby increasing the demand for services of

inventors. This should result in greater recognition and rewards for employed inventors.

We also believe it is sound policy for companies to have awards programs for inventors and other creative employees. Many companies have had such programs in place for years. If such programs are effective in providing incentives for inventors, well-managed companies will maintain and expand them.

We do not, however, recommend enactment of H. R. 3285 or H. R. 3286. We believe insufficient need has been shown for the Federal government to legislate in this area.

Considering first H. R. 3285--relating to compensation--it would fundamentally change the market forces which govern relationships between employers and employees. In the American system generally employers compensate those who do an especially good job. It is in their company's interest to do so.

Under H. R. 3285 insufficient credit would be given to employees other than the inventors. The success of an invention in the marketplace depends not only upon the creative effort of the individual who is named as the inventor, but also upon the efforts of research directors, production engineers, marketing personnel, and others. The employer is in the best position to judge the relative importance of the contributions made by the inventor and other employees.

As a general rule, as stated earlier, we believe that the salaries of creative employees are adjusted in proportion to the value of their contributions. Employees with long track records of creativity, of course, are likely to receive greater

compensation. Companies need to be able to take into account proven ability to invent when establishing compensation, instead of compensating inventors on a piece-work basis.

Finally, the administrative expenses of the many requirements and deadlines in H. R. 3285 would be burdensome, particularly for smaller companies and universities.

We are aware, of course, that some European countries and Japan have laws requiring special compensation for employee inventors. The German system is notorious for its complexity. Opinion is divided on whether German law serves as a net positive stimulus to technological progress. Even if it does, labor-management practices which exist in other countries cannot necessarily be transplanted in the United States, where the labor relations traditions and cultural factors are different. The litigious nature of U. S. society is entirely different from what is found, for example, in Japan.

Turning now to H. R. 3286, we believe it too may well have an adverse effect on the climate for innovation in industry. Employment agreements are by tradition matters of state law in this area.

In five states--Illinois, Minnesota, California, North Carolina and Washington--statutes have been enacted to govern employment agreements covering invention rights. These statutes apparently have caused no great problems for industry, but--once again--we see no need for the federal government to legislate.

We have not heard of signficant problems of lack of uniformity of state law. If problems should arise relating to

lack of uniformity, a better solution than federal legislation would be a model state statute which states could be encouraged to follow.

Moreover, H. R. 3286 raises problems that are not present in the state laws. H. R. 3286 prohibits agreements requiring assignment of invention rights to the employer for inventions conceived even one day after employment ends. This provision could encourage unscrupulous employees who knew they were changing jobs to withhold ideas from their employers. Furthermore employees with the best of intentions can conceive of inventions relating directly to their former employer's business and based on that employer's secret information weeks and months after leaving the employer.

H. R. 3286 also would give the invention rights to the employee in some cases where the invention was made with substantial use of the employer's time, materials, facilities or funds. The bill would give invention rights to the employee in some circumstances where the invention was related to aspects of the employer's business on which the employee was not working, but on which the employee was able to make an invention because of his or her knowledge of the employer's business. Employers who are paying for the full-time effort of their employees should be entitled to own business-related inventions made by employees.

And, once again, is this really a problem? How often have inequities arisen under the present system? We favor inventor's rights and support their improvement, but we feel far-reaching

changes should not be made unless there is good reason to make them and unless we fully understand the impact of the changes.

II. ADMINISTRATION OF THE PATENT AND TRADEMARK OFFICE

Defensive Patents

The main purpose of H. R. 2610 is to authorize the Patent and Trademark Office to issue so-called "defensive patents." The bill would allow both private sector patent applicants and Federal agency patent applicants to waive their rights to enforce patents, and obtain instead "patents" useful only for defensive purposes. I would like to address private sector applicants first.

We favor making defensive patents available for ~~patent~~ public sector applicants. If the defensive patent option were available, most private sector patent applicants would, of course, still seek normal patent protection. Many private sector companies and inventors who desired to prevent others from obtaining patents on the same subject matter would continue to do what they do today--publish a description of the invention in a technical journal. It is easier and less expensive to publish in a journal than it is to prepare a patent application and pay the fees for the Patent and Trademark Office to publish it.

But some patent applicants might prefer defensive patenting. For instance, the defensive patent route would preserve the right to participate in interferences and the defensive patent application, unlike a publication, would constitute a reduction to practice at the date of filing. We believe enough applicants

would be interested in defensive patents to make the bill worthwhile.

Defensive patents for private sector patent applicants would yield savings in patent prosecution expenses for applicants and some savings in examining and appeal expenses for the PTO. In addition, the defensive patent option should encourage some applicants to publish their applications for the benefit of the public when the applicants otherwise might maintain their inventions in secret.

The defensive patent option would be particularly well-suited for government agencies. The United States government owns about 28,000 unexpired United States patents--about twice as many as does anybody else in the United States. Some 2,000 government-owned applications are being filed every year in the PTO. This is about two percent of all of the patent applications that are filed.

Over 300 patent lawyers and patent agents work for government agencies. Many of those individuals spend substantially all of their time filing and prosecuting United States patent applications.

Why are all these patents being obtained? The only thing a patent grants is the right to exclude someone from making, using, or selling the patented subject matter; who is it that the government plans to exclude?

It is said that the government uses U. S. patents to stimulate commercialization of inventions. But the government's record of being able to license inventions is dismal.

Commissioner Mossinghoff has stated that when he was with NASA only about one percent of NASA-owned patents on inventions made by contractors were commercialized. Estimates have been made that overall no more than 4 percent of government patents are licensed.

The government obtains patents on technologies which, in the opinion of the private sector, do not provide attractive business opportunities. Moreover, the government is not able to market its patents as aggressively as private sector patent holders can. It is obvious that it is not cost effective for the government to obtain normal patent protection for anything but a very small percentage--at best--of government inventions.

If Federal agencies obtained defensive patents, the Patent and Trademark Office would be relieved of the burden of examining about two percent of the applications that must be examined today. Moreover, it would save money now spent by the agencies for salaries of patent attorneys who prepare and prosecute patent applications filed in the Patent and Trademark Office. And it would give the government all of the patent benefits that the government truly needs.

The Senate Judiciary Committee recently has approved the Senate counterpart to H. R. 2610 with an amendment which would require government agencies to obtain defensive patents in many situations. IPO urges incorporation of that amendment into H. R. 2610. Indeed, we would propose going further by amending H. R. 2610 to require that <u>all</u> U. S. patents obtained by Federal agencies be defensive patents. In those situations where the

government developed technology for which incentives were needed to promote commercialization, the government could sell the patent rights to a private concern which could obtain a patent and market the invention.

Finally with respect to defensive patents, we suggest an amendment for H. R. 2610 so that it would not encourage applicants to keep secret a series of "continuing" patent applications for a long period of time and then convert to a defensive patent. Language is set forth in the appendix to my statement which would accomplish this change.

Situations should be kept to a minimum in which the public can be surprised by so-called "secret prior art" which has a patent defeating effect earlier than the date of the application on which the defensive patent is being issued. One of the purposes of the patent system is to encourage early publication of technological information.

Under the bill as written, a defensive patent is entitled to the benefit of the filing date of earlier patent applications pursuant to section 120 of the patent code, in the same manner that normal patent applications are entitled to such benefits. Continuing patent applications give applicants extra time to prosecute their patent claims in the Patent and Trademark Office so that they can shape the claims for the best legal protection. Defensive patent applicants do not need this extra time.

H. R. 4525 and H. R. 4527, the bills I discussed earlier relating to team research, go in the direction reducing the amount

of secret prior art. Unless H. R. 2610 is amended, it would expand secret prior art.

Time to Pay Issue Fees

We strongly oppose the part of Section 4 of H. R. 2610 which authorizes the Commissioner to shorten the time for paying the patent issue fee from the present three months to a period not less than one month.

The Patent and Trademark Office is planning to reduce the average pendency time of patent applications to 18 months, but the Commissioner has stated a shorter period for paying the issue fee is not necessary to his program to reduce patent pendency.

The decision whether to pay the patent issue fee is often a complex, mixed business and legal matter which requires exercise of judgment. Frequently, several people must be consulted, and they often are in geographically separated locations. The decision cannot be made instantly. Patent applicants cannot anticipate when the PTO is likely to notify them that a particular patent application is ready to issue. Mail delays occur in communications between the PTO and the patent attorneys, and between patent attorneys and their clients.

Before paying the issue fee, an applicant sometimes must reevaluate whether patent or trade secret protection is better; conditions may have changed since the patent application was filed. Frequently the applicant must evaluate the desirability of abandoning the application in favor of a continuing application under 35 USC 120.

In 1982 Congress raised the patent issue fee from an average of about $150 to $500. Many applicants have to evaluate carefully whether it is worth $500 to them to obtain a patent with the particular claims that have been allowed by the PTO examiner.

We urge that paragraph 1 of Section 4 of H. R. 2610 be deleted.

Consolidation of Boards

H. R. 4462 would consolidate the Board of Patent Interferences and Board of Appeals within the Patent and Trademark Office. IPO has no position on the merits of this legislation. It is primarily an internal Patent and Trademark Office matter, and we defer to the judgment of the Commissioner that it would facilitate PTO proceedings.

We note that the Senate has made a useful amendment by changing the name of the consolidated board from the Board of Appeals and Interferences to the Board of Patent Appeals and Interferences, to make clear that the consolidated board does not handle trademark matters.

Fees for Independent Inventors

H. R. 3462 would exempt independent inventors, nonprofit organizations and small businesses from paying maintenance fees, and would prevent the Patent and Trademark Office from increasing other fees for these categories of patent applicants in the future.

We sympathize with this legislation. When fees were adjusted by Public Law 97-247 in 1982, we expressed concern about the high levels of fees. In light of the need of more invention and innovation in our country, we questioned increasing the tax on ingenuity. We would not like to see applicants priced out of the patent system.

On the other hand, H. R. 3462 should not be enacted unless Congress is willing to appropriate additional funds to cover the revenue loss which would be caused by the bill. Commissioner Mossinghoff has testified that $10 million would be needed. We believe appropriations of this magnitude could be a good investment to help stimulate U. S. research and development, but urge that the committee obtain some assurance that appropriations will be forthcoming before approving the bill. Otherwise larger corporations will wind up paying an even larger tax as its share of the cost of supporting the Patent and Trademark Office than under current law.

Foreign Filing Licenses

Until the Patent and Trademark Office changed its rules recently, the requirements for obtaining a license from the Office before filing a patent application abroad were causing enormous volumes of paper to flow through the Office on often trivial material. Applicants had to obtain licenses from the Patent and Trademark Office in many cases where no national security purpose conceivably could be served, and where the same technology could be shipped to a foreign country in a form other than a patent

application with absolutely no problem. This was wasteful and downright silly.

H. R. 4524 preserves protection for national security while reducing the burdens on users of the patent system. The bill allows supplementary material for a patent application to be filed in a foreign country without a license from the Patent and Trademark Office, provided the supplementary material is an "illustration, exemplification, comparison, or explanation" or subject matter already licensed. The "illustration, exemplification. . ." language relaxes the licensing requirements for supplementary material.

We compliment the Patent and Trademark Office on using its rulemaking authority to alleviate some of the burdens on patent applicants, but we still recommend adding the "illustration, exemplification. . ." passage, or similar language, to the statute. This will avoid the possibility of burdensome requirements being reimposed on patent applicants at some future date without Congressional approval.

H. R. 4524 relaxes the "inadvertence" standard that must be met in order to obtain a license from the Patent and Trademark Office retroactively. The bill substitutes "through error and without deceptive intent." We support this change because it will make it possible for all applicants who have failed to comply with the licensing requirements in good faith to obtain a license retroactively, as long as the subject matter sent abroad is not important to national security. Similar language is also added by section 2 of the bill.

In addition, section 3 of H. R. 4524 exempts applicants from criminal penalties for failure to obtain a license. We support this provision, because it eliminates a penalty which is too harsh for failure to comply with regulations which cover primarily subject matter unimportant to national security. Section 184 of the patent code would still provide criminal penalties for disclosing subject matter which has been ordered to be kept secret.

Patent Interferences

H. R. 4528 relates to patent interferences. Interferences are administrative proceedings in the U. S. Patent and Trademark Office for deciding which of two or more rival inventors made an invention first.

We support the bill. Section 1 authorizes parties to arbitrate issues arising in patent interferences. In 1982 Congress enacted section 294 of the patent law, which makes arbitration available for settling disputes over validity and infringement. It is logical to extend arbitration to patent interference issues as well. Arbitration is a quicker and cheaper alternative to other forms of dispute resolution in many cases.

Under section 2 of H. R. 4528, the penalty for failing to file a settlement agreement in the Patent and Trademark Office would not apply if the failure was "through error and without deceptive intent." This is the same standard discussed earlier in connection with H. R. 4524 for judging whether or not a patent

owner is entitled to a retroactive license to file an application abroad.

Section 2 also deletes the six-month time limit on the Commissioner's discretion to excuse failure to file a settlement agreement, giving parties a greater opportunity to comply with the filing requirement. We can see no reason to limit the Commissioner's discretion to a six-month period. The bill would still preclude the Commissioner from accepting a late filing except upon a showing of good cause for failure to file on time.

III. SUBSTANTIVE PATENT LAW REFORM

Patent Term Restoration

The first bill in the substantive patent law reform category is H. R. 3502, which would extend patents to compensate owners for the portion of the 17 year term lost as a result of delay in obtaining regulatory clearance from federal agencies. This legislation is important to the pharmaceutical industry and the agricultural chemical industry.

We support H. R. 3502. Convincing evidence has been presented 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 adverse effect which federal regulatory review has had on patent life was never, we believe, 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.

We believe H. R. 3502 would have a positive influence on competition. The stronger incentives provided by restored patent terms would make available improved products and a greater variety of products. The 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 favor enactment of H. R. 3502. We are aware that a proposed compromise patent term restoration/abbreviated new drug application bill has been circulated recently, but we have not studied it and I will not attempt to comment on it.

If agreement cannot be reached this year on a legislative solution, we would also be in favor of the Commissioner of Patents and Trademarks using his rulemaking authority to establish a limited system for "restoring" terms of patents. The Commissioner possesses authority to delay the issuance of future patents when the invention is subject to regulatory review. Delaying the issuance in effect would lengthen the terms of such patents.

Manufacture Outside the United States

H. R. 3577, H. R. 4526 and H. R. 4814 eliminate loopholes in existing patent law that encourage manufacture of patented inventions outside the United States. All three bills make it

infringement to market in the United States a product manufactured abroad using a process patented in the United States. The remedies available to the patent owner through this provision would strengthen the patent system for the benefit of U. S. patent owners.

Offshore production using patented processes has long been in need of a remedy in the patent law. Such a remedy was recommended in the 1966 report of the President's Commission on the Patent System. Our major trading partners have provisions in their patent laws similar to the subject proposal.

Although the Tariff Act already makes it a potential unfair method of competition to import a product made abroad by a patented process, the Tariff Act's remedies are limited.

The Tariff Act does not give monetary relief, but only exclusion orders preventing importation. Patent owners may incur millions of dollars in damages from unfair imports before an exclusion order can be obtained. Also, the requirement in the Tariff Act to show the existence of an efficiently and economically operated industry in the U. S. can impose an undue burden on patent owners in new industries. In addition, the President can overrule the International Trade Commission after it has found that products being imported infringe a valid U. S. patent.

The process patents provisions is widely supported by patent owners. It is also supported by the Administration. It probably would have been enacted several years ago except that it was tied to other, more controversial proposals for patent law reform.

The proposal is in the best interest of U. S. manufacturers and U. S. workers. It would put a stop to foreign manufacturers taking a free ride on the research and development expenditures of U. S. companies. It would be helpful in providing employment in this country.

We prefer H. R. 4526 or H. R. 4814 with the refinements shown in the appendix over H. R. 3577. H. R. 3577 states it will be presumed that a product was made by a patented process if (1) a substantial likelihood exists that the product was produced by the patented process and (2) the patent owner has exhausted all reasonably available means in the foreign country to establish that the product was made by the patented process. Although we agree that courts should presume in appropriate situations that the product was made by a patented process, we are concerned that the requirement to exhaust discovery or other procedures abroad could be unduly expensive for patent owners. We believe the presumption should apply whenever the first requirement of H. R. 3577 is satisfied--namely, whenever a substantial likelihood exists that the product was produced by the patented process.

We are aware that the office of the United States Trade Representative has expressed concern that H. R. 4526 and H. R. 4814 would violate our country's obligation under the General Agreement on Tariffs and Trade (GATT) not to discriminate against foreign-made products. The office of the Trade Representative apparently believes that foreign products are treated less favorably than domestic products under the bill, because there is no remedy under the bill against the use or sale of a product

manufactured in the United States by a process patent.

If the Committee should decide that the GATT requires the broadening of the legislation to cover use or sale of products manufactured in the United States by a process patent, H. R. 4526 and H. R. 4814 could be broadened by deleting the phrase "in another country" in section 1.

The second part of H. R. 4526 and H. R. 4814 makes it infringement to supply components of a patented process for final assembly abroad, if supplied for the purpose of avoiding the patent. This would change the present law as interpreted by the United States Supreme Court in 1972 in the Deepsouth case. In that case the Supreme Court noted that legislative action is needed if a patent owner is to have a remedy in a circumstance where the components of an invention are made in the United States and final assembly is performed offshore for the purpose of avoiding the United States patent.

The existing patent law on this point is unfair. It permits a subterfuge. The law should not permit substantially all the manufacturing activity to take place in the United States and yet allow the patent to be avoided by a technicality.

License Agreements

H. R. 4529 is one of the key bills being considered today. We strongly support it. The bill allows either party to terminate a patent license agreement after the licensee has asserted in court that the patent is invalid. The section also makes the

licensee liable for royalties under the agreement until the license has been terminated.

Before the Supreme Court's 1969 decision in Lear v. Adkins, a licensee was "estopped" from questioning the validity of a patent under which he was licensed. This was similar to the law that a lessee is "estopped" to challenge the lessor's title. When it abolished the license estoppel doctrine, the Supreme Court stressed the public interest in allowing the licensee to challenge patent validity, because the licensee often is the party with the most incentive to mount a challenge. Unfortunately the Lear opinion and subsequent lower court interpretations left the licensor in an unfair bargaining position. Moreover, conflicting rulings by lower courts have caused confusion over how to apply the Lear doctrine to particular fact situations.

Under existing law, an unscrupulous licensee can negotiate a license on favorable royalty terms and immediately begin litigation on the patent while continuing to enjoy the benefits of the license, for the license prevents any injunction against the licensee. The licensee can withhold payment of all royalties during the period of litigation without giving up the license. If the licensee loses, he only has to pay what he agreed to pay in the first place.

This process may result in a licensor becoming cash starved during the pendency of the litigation. This can be particularly unfair for a licensor who was forced to license the product in the first place because the licensor did not have enough capital to produce the invention.

The Administration has recommended recasting the bill so that it would merely restore the freedom of the licensor and the licensee to negotiate for the rights mentioned in H. R. 4529, instead of guaranteeing the rights to every party. It is said that this approach would decrease Federal interference in patent licensing.

Although we agree that ordinarily the federal government should not interfere with freedom of private parties to negotiate contracts, we do not perceive any advantages in the approach recommended by the Administration in this case. The Federal government interfered with patent licensing when the Supreme Court decided Lear. We can see no way to decrease Federal interference significantly at this point without overruling at least this one result of the Lear holding.

* * *

I appreciate the opportunity to present our views and I will be pleased to answer any questions.

APPENDIX: LANGUAGE REFINEMENTS FOR H. R. 2610 AND H. R. 4524 TO H. R. 4529 SUGGESTED BY INTELLECTUAL PROPERTY OWNERS, INC.

1. In H. R. 4526, section 1, page 1, line 8, delete "made" and insert "imported, used or sold."

   Comment: Provides that the importing, using or selling must take place during the term of the process patent for there to be infringement.

2. Add a section to H. R. 4626 inserting a new section 295 in title 35, United States Code, reading as follows: "In actions alleging infringement of a process patent based on importation, use or sale of a product produced by the patented process, if the court finds that a substantial likelihood exists that the product was produced by the patented process, then the product shall be presumed to have been so produced, and the burden of establishing that the product was not produced by the process shall be on the party asserting that it was not so produced."

   Comment: Similar to section 3 of H. R. 3577, but omits requirement to exhaust "all reasonably available means through discovery or otherwise to determine the process actually used in the production of the product. . ."

3. Replace section 1 of H. R. 4525 with the following language: "Section 103 of title 35, United States Code, is amended by adding at the end thereof the following: 'In addition, subject matter developed by another which qualifies as prior art only under sections 102(e), (f) or (g) of this title shall not negate patentability, when the subject matter and the claimed invention were commonly owned at the time the invention was made.'"

   Comment: Differs from some other drafts by referring to section 102(e) as well as (f) and (g).

4. Amend section 1 of H. R. 4527 by substituting the following: "(a) Section 116 of title 35, United States Code, is amended by amending the first paragraph to read as follows: 'When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath,

except as otherwise provided in this title. Inventors may apply for a patent jointly even though (i) they did not physically work together or at the same time, (ii) each did not make the same type or amount of contribution or (iii) each did not make a contribution to the subject matter of every claim of the patent.'"

"(b) Section 120 of title 35, United States Code, is amended to read: 'An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by Section 363 of this title, by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.'"

Comment: Elaborates on the definition of joint inventorship in 35 USC 116 and provides in 35 USC 120 that a continuing application can obtain the benefit of an earlier application naming different joint inventors.

5. Amend the retroactive effect section in H. R. 4524 to 29 to read as follows: "The amendment made by this Act shall apply to all United States patents granted before the date of enactment of this Act and to any United States patent granted on or after such date."

Comment: Makes bill apply to all patents on which suits can still be brought, even if patents are expired. Further amendment of the retroactive effect section of at least some of the six bills is needed in order to avoid unfairness to parties who have taken positions relying on existing patent law.

6. In H. R. 2610, section 2, at the end of line 7 of page 2, insert the following: "and waives the benefit of any earlier filing date under section 120 of this title,".

Comment: Denies defensive patents the benefit of filing dates of earlier applications and thereby minimizes the "secret prior art" effect of defensive patents.

Mr. KASTENMEIER. Our next witness this morning is Professor Herbert F. Schwartz. Professor Schwartz is currently teaching law at the University of Pennsylvania Law School on the subjects of patent, trade secrets, and trademarks and in addition to his fine academic background, Professor Schwartz is a partner in a New York law firm and has practiced law specializing in patent law both for plaintiffs and defendants. We have received a copy of your written statement. It is not very long. You may proceed as you wish.

TESTIMONY OF HERBERT SCHWARTZ, LECTURER IN LAW, UNIVERSITY OF PENNSYLVANIA SCHOOL OF LAW

Mr. SCHWARTZ. Thank you, Representative Kastenmeier. I will try to make my remarks brief as I have covered my basic views in my statement.

I would like to address a few of the bills in particular and, namely, those which I think have the largest significance, as I view it.

First I would like to talk about the process patent and assembly abroad bills. I believe those are substantial and that they deal with a basic gap in the patent statutes as they now exist—a gap that cannot be filled by the courts. It is a gap that, if it is to be filled, has to be filled by legislation.

I believe that the basic purpose of the bills as proposed is consistent with the patent system. It is essential to the exploitation of U.S. processes. The current law unfairly discriminates against U.S. patent process holders. In large measure, this law would conform the U.S. situation to the law in other countries abroad.

Now, the version that I would endorse or approve is a markup of 4526, which I believe I attached to my statement and which would provide a new category of infringement, that is, infringement by a party who sells or uses a U.S. product made by a process patented in the United States. I believe that such a provision would not be an unreasonable burden on innocent consumers. I think it is no different from the current statute which covers infringement by someone who makes, uses, or sells any patented invention within the United States. It would effect the ordinary consumer, but, as a practical matter, licensing and litigation would really be directed against the entity which is the basic source of the infringement, namely, the processor or maker of the goods.

For instance, the ordinary consumer who purchases a camera or purchases a copier or some other piece of hi-fi equipment doesn't know whether it is patented or not; yet if this consumer uses the product, he or she infringes a patent and could be sued. Usually, that doesn't happen and usually you don't license ordinary consumers in their home; these things are taken care of at the manufacturer level. I believe the same would be true, or should be true, in the process patent area. I believe the proposal, at least as I have modified it, would accomplish that result.

Mr. KASTENMEIER. I suggest that might be increasingly true in the computer field.

Mr. SCHWARTZ. I believe that is so, too. It would be true in the computer field. I think the basis of our patent law is that you don't

have to be on notice to be an infringer. There are infringers all the time in the sense of users of very large things in the home which are really covered by patents. The point of the patent system is to work out an arrangement so that the inventor is compensated at the source. That is the basis of our contributory infringement legislation, section 271. I believe that modifications of this bill could be drafted which would accomplish that result and would be nondiscriminatory. I think it would be a very signficant addition to our legislation and also comparable to the situation abroad.

Mr. KASTENMEIER. I want to compliment you for including as addenda to your statement a markup of the three bills. It is a very useful way to illustrate precisely the points you want to make. Of course, together with your statement that will be made part of the record.

Mr. SCHWARTZ. Thank you.

I also believe as part of the process patent situation that it is not necessary, or even desirable, to have statutes that deal with presumptions. The courts have been, and still are, capable of taking care of matters like this in conventional ways. I think legislation of the presumption is unreasonably cumbersome and I would not be in favor of it. I have also modified the proposed *Deepsouth* bill because I believe it goes too far as drafted, by use of the phrase "material components" instead of the word "all." I believe that the *Deepsouth* bill, as a practical matter, improperly confuses contributory infringement and direct infringement. What I mean by that is that in order to infringe a patent in the United States you must assemble all of the components. It is not an act of infringement if you take all of the components and put them in a box but do not put them together. If you combine only the material components in the United States, you haven't committed an act of infringement and you also haven't committed an act of contributory infringement.

I believe the legislation, as now drafted, is an attempt to go beyond the notion of an act of infringement. The clarification I propose would pick that up. I do believe that the *Deepsouth* decision points out that there is a gap in the statutory language. I believe it is a gap that should be filled.

Going on to the Licensee Estoppel bill, this is an attempt to deal with the consequences of the Supreme Court decision in the *Lear* case. I think it has turned out to certainly be so that *Lear* has resulted in situations where licensees have been able to, as Mr. Banner said, have a heads-you-win, tails-you-lose approach to it, in that you can keep your license, challenge validity and be back to where you were. The question is how far you should go to remedy this situation.

I believe the proposal now put forth goes too far. I believe that what will happen with the proposal that is now put forth is that it would have a chilling effect on a licensee's willingness to challenge validity in a situation which arises commonly; namely, the licensee is operating under a patent after a few years and a fact comes to light suggesting that the patent is invalid, or there is some other reason to challenge it. If his price to challenge is the termination of his license at a time when he has a big investment in the process, and he has no reason to believe he would get the license back if he

is wrong on the challenge, then that would have a very chilling effect on his willingness to go to court. That to me is troublesome.

On the other hand, as I see it, the *Lear* decision has gone too far and there ought to be some middle ground that would be more helpful to licensors and to industry in general. I believe the approach of Commissioner Mossinghoff has some merit and I marked up the bill along those lines for that purpose, namely, to allow parties to contract between themselves to accomplish that result.

I realize that there are more sophisticated licensors who would take advantage of that and maybe there are some other licensors who might not. I believe that the markup is preferable to the bill as proposed or the situation as it now exists.

Mr. KASTENMEIER. In your markup of H.R. 4529, you really do apparently very little at least in terms of changing words.

Mr. SCHWARTZ. That is correct.

Mr. KASTENMEIER. You strike out "licensor and licensee can agree that," and strike out "30 days."

Mr. SCHWARTZ. I believe I put in the "licensor and licensee."

Mr. KASTENMEIER. You put that in.

Mr. SCHWARTZ. I think that is what changes the whole import of the bill.

Mr. KASTENMEIER. Giving appropriate notice.

Mr. SCHWARTZ. Because if you change it from being mandatory to by agreement between the licensor and licensee, I think you eliminate the problem I see with the bill as now drafted.

So I think that change has a significant impact on it, and I think the proposed language is consistent with Commissioner Mossinghoff——

Mr. KASTENMEIER. You think those parties who complain about *Lear* would agree that this moves them forward?

Mr. SCHWARTZ. When you say "those parties complain about *Lear,*" I think it depends on what side of the fence you are sitting on when you complain, whether it is a licensee or licensor. I suppose a licensor would say this doesn't go far enough. But on the other hand I think there is an interest in removing the cloud of invalid patents.

Assuming that the *Lear* decision is sound and that there is an interest in not having invalid patents out there, it seems reasonable to me to have some basis upon which they can be challenged. Whether this doesn't go far enough for licensors I am not sure. I believe this is a fairer result than is now proposed, and I think certainly for the licensors who complain about the present situation. This would allow them to enter into agreement which would give them the power to terminate.

So it seems to me, to that extent, it would satisfy what they want and it would also satisfy the other piece that they want—that there will be no escrow of royalties during the time of challenging, which I think has caused some people trouble.

Beyond that, as far as the bills relating to unpublished information and joint inventions, I believe that both of these issues involve interpretations of existing statutes which are broad enough as they now are written to deal with the questions presented. The issues raised by different courts in the past. One of its purposes is to interpret the law uniformly in the patent area. The Court of Appeals

for the Federal Circuit has yet to address either of these two issues. Under the current set of facts, and in light of the legislative proposals as I read them, I believe that at the moment it is appropriate to leave those issues to that court. I am sure they will deal with them in the context of various cases.

As a sort of aside on the notion of which interests the patent laws promote, I believe the concept of corporate or team research is talked about greatly in those proposed bills. This concept relates primarily to activities of large corporations; it doesn't deal as much with the activities of smaller inventors. One thing I would recommend as part of the record for someone who is interested to read another view on that subject would be an article written by Dr. Edwin H. Land entitled "The Role of Patents in the Growth of New Companies". That appears in the Journal of the Patent Office Society in July 1959 at page 502. It is provocative and provides a different point of view as to that issue.

Going on, I will make my remarks brief as to the remaining bills because I believe I have covered them in my statement. I believe one bill I would like to say a little bit about is employee inventions. To me, H.R. 3285 is a very significant and far-reaching piece of legislation and, at least as far as I can tell, the administrative, financial, and practical ramifications of that legislation are not sufficiently explored at this time to have a firm view as to whether it is a good thing or bad thing. I think that some more comprehensive and serious studies need to be made comparing our industrial environment and those of the countries which have such legislation. To me, there is no hard evidence yet that there is not very significant technological strength in this country, and it is not clear to me precisely how that bill will further it——

Mr. KASTENMEIER. Have you had access to "The Law of Employee Inventions in Foreign Countries," prepared by the Library of Congress, June 1983?

Mr. SCHWARTZ. I don't believe I have read that. I have read a number of articles on the subject and I read the bills, the legislation as it exists in Germany and as it exists in England. I think I am familiar with the legislation in detail in various writings about it, but I am not familiar with the particular document.

As far as the remaining bills, I would be delighted to answer any questions you might have. I set forth my views as to each of them, at least briefly, in the statement as prepared.

[The statement of Professor Schwartz follows:]

STATEMENT OF HERBERT F. SCHWARTZ

UNIVERSITY OF PENNSYLVANIA LAW SCHOOL

PRIVATE PRACTITIONER

BEFORE THE

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES AND THE

ADMINISTRATION OF JUSTICE

OF THE

COMMITTEE ON THE JUDICIARY

U.S. HOUSE OF REPRESENTATIVES

APRIL 26, 1984

Mr. Chairman and Members of the Subcommittee:

My name is Herbert F. Schwartz. I teach courses in patents, trade secrets, trademarks and unfair competition at the University of Pennsylvania Law School. I am also a member of the law firm Fish & Neave, New York, New York, where I specialize in litigation in these areas. I am here at the invitation of the Subcommittee to testify on innovation and patent law reform.

My prepared remarks are addressed primarily to the bills that are meant to reform the patent laws, rather than those concerning the administration of the Patent and Trademark Office. These proposals are meant to support your encouragement of technological innovation and advancement.

This statement first addresses those proposals which I favor either as drafted or with suggested modification (e.g., Process Patent and Assembly Abroad -- H.R. 3577, H.R. 4526, H.R. 4814; Licensee Estoppel -- H.R. 4529; Foreign Filings Licenses -- H.R. 4524; Patent Interference Practice -- H.R. 4528). Next considered are those measures which I believe are appropriate for legislation but for which I defer to others for specific language (e.g., Board of Appeals and Interferences -- H.R. 4462; Defensive Patents -- H.R. 2610; Patent Restoration -- H.R. 3502). Finally come those measures which I believe are inappropriate for legislation at this time (e.g., Small Business Fees -- H.R. 3462; Unpublished Information and Joint Inventions -- H.R. 4525, H.R. 4527; Employee Invention -- H.R. 3285, H.R. 3286).

PROCESS PATENTS & ASSEMBLY ABROAD:
H.R. 3577, H.R. 4526, H.R. 4814

These three bills are concerned with two significant gaps in the current scope of patent protection -- use or sale of a product in the United States made outside of the United States by a process which infringes a United States process patent, and exportation of components to be assembled into a product which, if assembled in the United States, would infringe a United States patent.

The first part of both H.R. 4526 and H.R. 4814 would amend 35 U.S.C. "§ 271 Infringement of Patent" by adding a paragraph (e) to forbid the use or sale in the

United States of products made abroad by a patented process. The attached mark-up of H.R. 4526, which should overcome foreign discrimination (GATT) objections and employs conventional statutory language, accomplishes this result. This measure is consistent with the laws of many other countries. (See, e.g. Japan Patent Law, Article 2, ¶ 3; European Patent Convention, Article 64, ¶ 2). The corresponding provision of H.R. 3577, although acceptable in principle, is not needed in light of the above mark-up. The notice requirement in section 2 of H.R. 4526 is inappropriate in light of 35 U.S.C. § 287 and the authorities which have applied that section to process patents. See Appliance Co. v. Equipment Co., 297 U.S. 387, 398 (1936); Hartford National Bank And Trust Co. v. E.F. Drew & Co., 188 F.Supp. 353 (D.Del. 1960), affirmed per curiam 290 F.2d 589 (3 Cir. 1961).

The proposed presumption in H.R. 3577 is unwarranted and potentially unfair. Existing rules of discovery and evidence sufficiently address the allocation of burdens of proof in infringement actions.

The second part of H.R. 4526 and 4814 adds a paragraph (f) to § 271 directed to infringement by supplying components of a patented invention which are not assembled in the United States. It is designed to plug the gap suggested by Deepsouth Packing Co. v. Laitram

Corp., 406 U.S. 518 (1972). The language of the proposal, however, could be improved. One suggested approach is in the attached mark-up.

LICENSEE ESTOPPEL: H.R. 4529

Lear, Inc. v. Adkins, 395 U.S. 653 (1969) abolished the doctrine of licensee estoppel and permitted licensees to challenge the validity of licensed patents without jeopardizing their licenses. H.R. 4529 purports to codify that holding. However, as written, the bill modifies Lear to such an extent that it disrupts a fair balance between the rights of licensors and licensees.

Section 295(a), as proposed, is appropriate although unnecessary by itself, as it merely codifies Lear. Section 295(b) should be modified to permit a licensor's right of termination to be negotiable between the parties to a license agreement. H.R. 4529, as now proposed, provides licensors a power to terminate which would necessarily chill judicial challenges to patent validity by licensees. Such a result runs counter to Lear and the public interest of encouraging licensees to remove the cloud of invalid patents. A proposed modification to H.R. 4529 to remedy this defect is attached.

FOREIGN FILING LICENSES: H.R. 4524

The purpose of H.R. 4524 is to minimize the chance of invalidation of a United States patent because of a failure by the patent owner to obtain properly a

license to file a corresponding patent application in a foreign country. This assists United States patent owners to exploit non-secret technology outside the United States. The bill modifies portions of 35 U.S.C. §§ 184, 185 and 186 to accomplish this result. Annexed is a proposed further modification which will leave for regulation by the Commissioner of Patents and Trademarks, rather than by legislation, the feature set forth in paragraph 2 of section 1.

PATENT INTERFERENCE PRACTICE: H.R. 4528

Patent interference proceedings resolve questions of priority of invention between patent applicants. This bill proposes the resolution of patent interferences by arbitration instead of the current extensive administrative and judicial proceedings. The ability to make these determinations promptly and inexpensively is in the public interest as well as that of parties to interferences and the Patent and Trademark Office.

The second provision of the bill relaxes certain aspects of the requirements associated with filing settlement agreements in the Patent and Trademark Office but retains for the Commissioner the ultimate say as to the propriety of late filing. The form of the bill as drafted is satisfactory.

BOARD OF APPEALS AND INTERFERENCES: H.R. 4462

This bill, requested by the Commissioner of Patents and Trademarks, relates to improving procedures in the Patent and Trademark Office for determining priority of inventorship in interference proceedings. This proposal is appropriate for the reasons previously mentioned concerning H.R. 4528. I defer to the expertise of the Commissioner as to the specific features of the proposal.

DEFENSIVE DISCLOSURE: H.R. 2610

This provision appears to be primarily for the benefit of government agencies that might desire to disclose their inventions and prevent others from patenting them. It may well be that private inventors will also want to take advantage of the provision. This bill is desirable in that it provides a relatively speedy and inexpensive way for those who desire to disclose their inventions "defensively" in the United States to do so and still retain the right to obtain patents abroad. Again, I defer to the Commissioner's expertise as to the appropriateness of the language.

PATENT RESTORATION: H.R. 3502

H.R. 3502 addresses the problem of a shortened useful patent life because of delays resulting from government regulatory action before products under the patent can be commercialized. The general concept of patent

restoration is an appropriate response to this problem so long as (a) restoration has a specific upper time limit and (b) adequate safeguards against administrative abuse are provided. H.R. 3502 appears on its face to address these concerns. I am not prepared at this time to make comments as to its specific language.

SMALL BUSINESS FEES: H.R. 3462

Although an exemption from maintenance fees for small businesses is laudable, the practical implications of such a move need to be analyzed further. For example, such issues as the real need of these entities for this relief and the revenue sources to make up the Patent and Trademark Office operating deficiencies due to the exemption should be appraised.

UNPUBLISHED INFORMATION AND JOINT INVENTIONS: H.R. 4525, H.R. 4527

Whether or not unpublished information known to an inventor disqualifies an otherwise patentable invention because it is "prior art" under 35 U.S.C. § 103 or a bar to a patent under other sections of the patent law (e.g., 35 U.S.C. §§ 102(f) and (g)) has been addressed in specific factual settings by various courts. See, e.g., General Motors Corp. v. Toyota Motor Co., Ltd., 467 F.Supp. 1142 (S.D.Ohio 1979), affirmed in pertinent part 667 F.2d 504, 506-07 (6 Cir. 1981); Hughes Aircraft Co. v. General Instrument Corp., 275 F.Supp.

961, 982-83 (D.R.I. 1967), affirmed in pertinent part 399 F.2d 373, 384 (1 Cir. 1968). Compare Dale Electronics, Inc. v. R.C.L. Electronics, Inc., 488 F.2d 382, 386-87 (1 Cir. 1973), with Shanklin Corp. v. Springfield Photo Mount Co. 521 F.2d 609, 618-19 (1 Cir. 1975).

H.R 4525 is an unwarranted interference with the proper development of a uniform doctrine of law in this area by the new Court of Appeals for the Federal Circuit. It attempts to render two specific decisions by a predecessor court in In re Bass, 474 F.2d 1276 (CCPA 1973), and In re Clemens, 622 F.2d 1029 (CCPA 1980), inapplicable to "team" research efforts by corporate employees. The Court of Appeals for the Federal Circuit can deal with this issue under the patent statutes (e.g., 35 U.S.C. §§ 102, 103) as they now exist.

H.R. 4527 suffers from the same problem. Title 35 U.S.C., § 116 as now written does not compel the conclusion that joint inventors must have collaborated simultaneously or contributed to each and every claim in their patent applications. See, e.g., Clairol Inc. v. Save-Way Industries, Inc., 210 USPQ 459, 465-66 (S.D.Fla. 1980), and Monsanto Company v. Kamp, 269 F.Supp. 818, 824 (D.D.C. 1967), concerning the nature of cooperation required. Compare Vekamaf Holland B.V. v. Pipe Benders, Inc., 211 USPQ 955, 966 (D.Minn. 1981), and SAB Industri AB v. Bendix Corp., 199 USPQ 95, 104 (E.D.Va. 1978), with

Rival Manufacturing Company v. Dazey Products Company, 358 F.Supp. 91, 101 (W.D.Mo. 1973), with respect to joint invention of every claim. To the extent that the proper interpretation of § 116 is not well settled, any disagreement can be resolved by the new Court of Appeals for the Federal Circuit.

EMPLOYEE INVENTIONS: H.R. 3285, H.R. 3286

H.R. 3285 would enact major changes in the relationship between employers and employees concerning inventions made by employees. The administrative, financial and practical ramifications of this legislation have not been sufficiently explored to warrant its adoption now. While several foreign countries, such as England, Germany and Japan, have established systems for compensating employees for their inventions comparable to that proposed in this legislation, it has not been demonstrated that such measures have been a positive or negative factor in technological innovation in those countries. There also is no evidence that the technological strength of the United States has diminished in any way because our patent laws do not include a formal structure for compensating employee inventions. Before such a significant change in the traditional relationship between employers and employees is mandated by Congress, a comprehensive study should be made, taking into account, among other things, the operation of such laws in the countries which now have them and a comparison between

the industrial cultures of those countries and the United States.

H.R. 3286, regarding pre-invention assignment agreements, targets one relatively narrow aspect of the law governing employment contracts for federal regulation. The necessity for such legislation in this very limited area is unclear. The legislation's potential preemptive effect on state law is another reason for caution. Federal intervention at this time and in this manner does not appear to be warranted.

* * *

This completes my prepared statement, Mr. Chairman. I am prepared to elaborate on the summary of my views expressed above and to respond to any questions which you or the other members of this Subcommittee may have.

H.R. 4526

A BILL

To amend title 35, United States Code, with respect to use of patented inventions outside the United States.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,
That section 271 of title 35, United States Code, is amended by adding at the end thereof the following new subsections:

"(e) Whoever without authority ~~imports into or~~ sells or uses within the United States a product which is made ~~in another country~~ by a process patented in the United States shall be liable as an infringer, if the product is made during the term of such process patent.

"(f) Whoever without authority makes or sells ~~supplies or causes to be supplied~~ in the United States ~~the material~~ components of a patented invention, where such components are uncombined in whole or in part, intending that such components will be combined outside the United States to make such patented invention, ~~and knowing that if such components were combined within the United States the combination would be an infringement of the patent~~, shall be liable as an infringer.".

~~SEC. 2. Section 287 of title 35, United States Code, is amended by adding at the end thereof the following: "No damages may be recovered for an infringement under section 271(e) of this title unless the infringer was on notice that the product was made by a process patented in the United States.".~~

SEC. 2 ~~3~~. The amendments made by this Act shall apply to any United States patent granted before the date of the enactment of this Act and to any United States patent granted on or after such date.

H.R. 4529

A BILL

To amend title 35, United States Code, with respect to assertions of invalidity of a patent by a licensee of that patent.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,
That (a) title 35, United States Code, is amended by adding after section 294 the following new section:

"§ 295. Licensee estoppel

"(a) A licensee of a patent shall not be estopped from asserting in a judicial action the invalidity of that patent. Any agreement, or provision thereof, between a licensee and a licensor the effect ~~purpose~~ of which is to bar the licensee from asserting the invalidity of the patent involved shall be unenforceable as to that agreement or provision.

"(b) A licensor and licensee can agree that, in ~~In~~ the event of an assertion by a licensee in a judicial action of the invalidity of the patent involved, the licensee and the licensor shall each have the right to terminate the license at any time after such assertion, after giving appropriate notice ~~at least thirty days notice of such termination~~ to the other party to the license agreement. Until so terminated, the licensee shall pay and the licensor shall receive the consideration provided for in their license agreement.

"(c) For purposes of this section -

"(1) the term 'licensee' means a person who is granted, directly or indirectly, from the holder of rights in a patent a license under the patent to manufacture, use, or sell the patented invention; and

"(2) the term 'licensor' means the holder of rights in a patent who, directly or indirectly, grants to another person a license under the patent to manufacture, use, or sell the patented invention.".

(b) The table of sections for chapter 29 of title 35, United States Code, is amended by adding after the item relating to section 294 the following:

"295. Licensee estoppel.".

SEC. 2. The amendments made by the first section of this Act shall apply to any unexpired United States patent granted before the date of the enactment of this Act and to any United States patent granted on or after such date.

H.R. 4524

A BILL

To amend title 35, United States Code, to clarify certain provisions relating to filing of patent applications in foreign countries.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That (a) section 184 of title 35, United States Code, is amended by --

(1) amending the third sentence thereof by striking out "inadvertently" and inserting after "filed abroad" the words "through error and without deceptive intent";

(2) adding at the end thereof the following new paragraph:

"Subject to such conditions as the Commissioner may set by regulations, the scope of a license shall permit subsequent modifications, amendments, and supplements containing additional subject matter when the application upon which a license request is based is not required to be made available for inspection under section 181 of this title.".

~~"In the case of an application for which a license has been obtained from the Commissioner or an application which has been filed in the United States Patent and Trademark Office more than six months before the filing of an~~

~~application in a foreign country, and with respect to which no order has been issued by the Commission pursuant to section 181 of this title, a license shall not be required for any modifications, amendments, supplements, divisions, or other information filed in or transmitted to the foreign country in connection with such application if such modifications, amendments, supplements, divisions, or other information consists only of the illustration, exemplification, comparison, or explanation of subject matter disclosed in such application.".~~

SEC. 2. Section 185 of title 35, United States Code, is amended by inserting immediately before the period in the last sentence the following: ", unless the failure to procure such license was through error and without deceptive intent, and the patent does not disclose subject matter within the scope of section 181 of this title".

SEC. 3. Section 186 of title 35, United States Code, is amended --

(1) by striking out "whoever, in violation of the provisions of section 184 of this title,"; and

(2) by inserting "such" after "in respect of any".

SEC. 4. The amendments made by this Act shall apply to any unexpired United States patent granted before the date of the enactment of this Act and to any United States patent granted on or after such date.

Mr. KASTENMEIER. Thank you very much, Professor Schwartz. It is very useful, as I said before, particularly your willingness to be very specific in terms of actual legislative language change in several of the bills. On the last area, employee inventions, my question really is a followup to what you have said. If you can be more specific, what do you think we need to learn comparatively with other nations or otherwise, in order to make a judgment about what changes might be appropriate in law goerning employee patents?

Mr. SCHWARTZ. Well, to me it is not clear at all how that legislation as it exists in Germany correlates at all with both the level of innovation in West Germany and the extent to which such innovation is reflected in issued patents. To me, innovation really fits into two categories, (1) significant contributions made by people which are reflected in patents and (2) lots of other contributions which are also reflected in patents. It is hard for me to tell at the moment precisely how this type of legislation, which has a lot of administrative complexities and has a lot of detailed ramifications in terms of each employee trying to sort out his or her piece of the pie, ultimately leads to protecting both the significant innovation and also the remainder of the inventions that we find in patents.

I also am not clear as to how compensation of employee inventions operates in a culture such as West Germany or Japan which is in many ways different from our industrial culture as concerns both large companies and small companies. A lot of innovation in emerging technology—people use the term Silicon Valley—in this country is accomplished in small companies. It is not clear to me how any of this type of legislation would be helpful to that sector which I believe is very significant in keeping us at the forefront of technological development.

Mr. KASTENMEIER. But can one not say adversely that apparently the foreign employee inventors rights as in West Germany and Japan do not seem to have adversely affected their ability to innovate?

Mr. SCHWARTZ. I don't feel I am competent to answer that or even believe that that is so. I would say that this country still has a very high level of innovation, if you look at things like Nobel Prizes and significant progress in the forefront of most new technologies in the world.

I think a lot of what we are talking about is conversion of that innovation into industrial products and manufacturing capabilities. I am not so sure that is advanced by this type of legislation.

Mr. KASTENMEIER. Well, let me ask you, both the preceding witness and you alluded to the fact that we seem to be doing comparatively worse with respect to other nations, perhaps West Germany and Japan. How are these bills, if implemented, if passed, going to permit General Motors to catch up with Nissan? Do not basically the extent we streamline our own system, and we get rid of "Mickey Mouse" types of provisions, equally advantage Nissan as well as General Motors?

Mr. SCHWARTZ. Taking the process patent bill, it corrects a disadvantage in this country and would plainly benefit U.S. companies vis-a-vis foreign interests insofar as laws now operate in those

countries. So I think that is one bill that is plainly important, and would significantly benefit U.S. industry.

Bills like the *Lear* bill are important in that they enhance the ability to exploit patented technology and thus help U.S. industry in our own country. Presumably they would also help foreign interests. But I think our main purpose is to stimulate innovation—hopefully it will rub off primarily on our own country—and I believe at least some of these proposals are very significant in encouraging innovation per se.

Others, as Mr. Banner has mentioned, are more in the nature of streamlining or cleaning up provisions, which also are important and helpful.

Mr. KASTENMEIER. Things based on recent decisions could not have been anticipated, but does it not seem to you that in terms of reforms in the U.S. patent system, we are a little bit late. We had the Blue Ribbon Commission recommendations of 1966 which went absolutely nowhere as you remember. They were massively opposed by the patent bar groups and others and, of course, this went down the tube. That was 18 years ago.

Mr. SCHWARTZ. I don't think we are too late at all. I think that there has been demonstrable change in emphasis and interest in this area in recent years. It has certainly been evidenced by legislation concerning the Court of Appeals for the Federal Circuit, and by hearings such as we have held here and in the Senate. I believe it is never too late. It is not too late now. To the extent that some of these reforms are important, then they are equally as important now as then.

Mr. KASTENMEIER. Well, thank you, Professor. Your testimony has been very helpful. I appreciate your presentation and I appreciate the way you have tried to help the committee.

Mr. SCHWARTZ. Thank you.

Mr. KASTENMEIER. Our next witness is Prof. Neal Orkin. Professor Orkin is an attorney and engineer; he has written widely in the area of employee inventors' rights, most notably a provocative article in the January-February issue of Harvard Business Review. Professor Orkin, we have your brief statement, actually, but you may proceed as you wish.

TESTIMONY OF NEAL ORKIN, ATTORNEY

Mr. ORKIN. Good morning, Mr. Chairman. I am Neal Orkin, an attorney at law and an adjunct assistant professor of legal studies at Drexel University in Philadelphia. I have been active in pursuing greater rights for employee inventors for the past 10 years. I have coauthored a text and have published many articles on this subject, the latest one appearing in the January-February issue of Harvard Business Review, which I am including in my statement. My views on the two bills—H.R. 3285 and H.R. 3286, are well-known from my previous statement at the 1982 hearings. I advocate enactement of H.R. 3285 with the minor changes as listed in my Harvard Business Review article. As I mentioned in my previous statement, H.R. 3286 merely codifies existing common law principles and may give an engineer or scientist less rights than the common law provides. I believe that any court in this country

would grant an employee inventor full rights to a so-called free invention that did not relate to the employee's work related duties, notwithstanding H.R. 3286.

My purpose today is to present a concept that I feel will enable our great action to compete effectively with our European and Asian trading partners. In addition to the enactment of H.R. 3285—with the amendments proposed in the HBR piece—I advocate the tax proposals found in that article. These proposals would enhance the innovation cycle by rewarding the inventor, innovator, and employer, and would reduce intracorporate rivalries, if they so exist. I have entitled this theorem "Orkinomics" or "tricle-up-economics," because the fruits or profits of innovation will trickle up through the corporation.

The present research and development tax credits do not foster innovation. Testimony in 1983 by John E. Chapoton, Assistant Treasury Secretary for tax policy, before the Senate Finance Subcommittee on Taxation and Debt Management revealed that approxiamtely half of all firms claiming the R&D tax credit were nonmanufacturing firms, including fast-food restaurants, bakeries, homebuilders, publishers, bankers, stockbrokers, and movie producers.

My idea of fostering innovation comprises more than hamburgers and computer printouts. Orkinomics is derived from the writings of the late Harvard economist Joseph A. Schumpeter which are synopsized in an article by Pete F. Drucker in the May 23, 1983 issue of Forbes. Schumpeter theorized, perhaps prophesized, that innovation is the very essence of a modern economy, as the profit made from innovation is the source of future jobs and labor income. Thus, Schumpeter's question in his economics is whether there is sufficient profit and adequate capital to provide the costs of the future. Orkinomics merely expands Schumpeter's theorem by including employees as innovators, for Schumpeter had written that the Government that deprives the innovator of his reward is hindering the creative process.

As you may note from my brief statement the issue of employee inventor rights transcends moral, individual, or equal rights. It affects our present and future economic well being. If we as a nation hope to compete internationally, we must transform horse and buggy law into high-tech law.

If I might read from the study done last summer by the Library of Congress concerning the employee inventor law in West Germany. In the Federal Republic of Germany, the employee invetion law has been in effect for more than 25 years, and it is the general opinion of both industry and labor that the law has been successfully implemented and has proven beneficial to the German economy.

The employee invention law promotes technological progress in two ways. First, the expectation of reaping sizable financial benefits and personal recognition from an invention is an incentive that spurs employees on to greater efforts.

Second, since the law has the effect that most inventions actually are patented, the publicity of the patent application creates an impetus for further research and speeds up the development of new technologies.

German industry, nevertheless, has a very positive attitude toward the employee inventions law. This can be seen, for instance, from a statement made in 1979 by the employee inventions committee of the Federal Organization of Employer Associations. In discussing the possibility of unifying employee invention law within the European communities, the committee expresses the hope that unification would not lead to changes in the German law to the detriment of the balance inherent in the German system.

And last, but not least, most employee inventions are compensated without controversy, as can be seen from the statistics of the German patent office. During the period from 1957 to 1981, the arbitration board in Munich was invoked in 1,730 cases; it proposed 1,073 settlements, 763 of which were accepted. In 1981, 72 applications were received, and 65 were pending at the end of the year. These figures have to be viewed within the context of the patent and utility model statistics. In 1981, there were 49,002 patent applications and 36,333 utility model applications that were received by the German patent office. Of these 64 percent of the patent applications and 79 percent of the utility model applications were submitted by German applicants. If my mathematics are correct, that means there were 61,000 plus applications from West German citizens and only 72 of these cases were to be arbitrated. That is a very significant percentage.

I should be glad to answer any questions concerning employee inventor rights or my associated tax proposal.

[The statement of Mr. Orkin follows:]

STATEMENT OF NEAL ORKIN

ATTORNEY AT LAW

Good morning Mr. Chairman. I am Neal Orkin, an attorney at law and an adjunct assistant professor of legal studies at Drexel University in Philadelphia. I have been active in pursuing greater rights for employee inventors for the past ten years. I have co-authored a text and have published many articles on this subject, the latest one appearing in the January-February issue of the Harvard Business Review, which I am including in my statement. My views on the two bills - H.R. 3285 and H.R. 3286 are well-known from my previous statement at the 1982 hearings.

My purpose today is to present a concept that I feel will enable our great nation to compete effectively with our European and Asian trading partners. In addition to the enactment of H.R.3285 - with the amendments proposed in the HBR piece - I advocate the tax proposals found in that article. These proposals would enhance the innovation cycle by rewarding the inventor, innovator, and employer, and would reduce intra-corporate rivalries. I have entitled this theorem "ORKINOMICS" or "TRICKLE-UP-ECONOMICS", because the fruits or profits of innovation will trickle up through the corporation.

The present research and development tax credits do not foster innovation. Testimony in 1983 by John E. Chapoton, assistant treasury secretary for tax policy, before the Senate Finance Subcommittee on Taxation and Debt Management revealed that approximately half of all firms claiming the R&D tax credit were non-manufacturing firms, including fast-food restaurants, bakeries, home builders, publishers, bankers, stockbrokers, and movie producers.

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I should be glad to answer any questions concerning employee inventor rights or my associated tax proposals.

Ideas for Action

Rewarding employee invention: time for change

Neal Orkin

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Rewarding employee invention: time for change



Neal Orkin

Mr. Orkin is a Philadelphia-area attorney and adjunct assistant professor of business law at Drexel University who also holds a degree in electrical engineering. A student of employee-inventors' rights since 1967, he is coauthor of Employees' Inventions: A Comparative Study *(Fernsway Publications, Sunderland, England, 1981).*

By relying on a voluntary system of rewarding employees for inventions and innovations, U.S. corporations are losing out on new ideas that would help them compete effectively in the world race for new technology. Proposals that would remedy this situation have come before Congress on several occasions in recent years, but industry has consistently opposed them. Now the time for reappraisal has come. Lest American innovation and inventiveness decline even further, we must enact a national statutory award scheme for employed inventors.

Although patents are not an absolute indicator of innovation, their growth – or decline – provides one measure of industrial creativity. By this gauge, American inventiveness decreased during the 1970s. The number of U.S. patents per million population issued to American citizens and corporations fell from 225 in 1970 to 169 in 1980; the number per billion dollars of GNP, measured in constant 1972 dollars, dropped from 53.7 in 1972 to 25.8 in 1980. During the same decade the percentage of U.S. patents granted to foreigners – mostly residents of West Germany and Japan – increased from 25% to 38.9%.

Were these foreign scientists and engineers inherently more creative than their U.S. counterparts? I think not. If one assumes, as I do, that royalties are an effective way to stimulate invention, then our reward system stifles new ideas.

Rewards American style

Whereas most industrial nations protect employees' patent rights by statute, American workers often must sign preemployment contracts that turn over these rights to their companies. At most large corporations, employee-inventors do receive nominal awards; these range from pen sets and plaques to bonuses of a few hundred dollars. But management reserves for itself large bonuses based on the sales and profits those inventions generate. That this generally accepted policy tends to sour employer-employee relations should come as no surprise. Nor should it be hard to understand why it leads scientists and engineers to abandon invention for management.

To encourage innovation, one segment of U.S. industry has tried a new approach. Video game manufacturers give their designers optimal working conditions and highly visible personal recognition. More important, they pay them royalties that range from 10% to 15% of the profits on their games. The industry's rapid growth demonstrates the advantage of this more equitable system of rewards.

Rewards European style

Many Western European nations have enacted statutes to protect the rights of employers and employees. These laws differ in several ways, but all divide employees' inventions into two general categories: free inventions, which are non-work-related, and service inventions, which derive from work-related tasks. The second is more significant, because 80% to 90% of all patented inventions develop out of the employment relationship.

West Germany's statute, enacted in 1957, is the most comprehensive of the Western European service-invention laws. Like most others, it covers inventions that are kept as company trade secrets as well as those that are actually patented. In addition, it extends protection to cost-saving, technical improvement suggestions, which are not eligible for patents.

Guidelines for computing the compensation due the employee are also included in the German statute, so that the amount can be adjusted according to the employee's duties and participation in the creative process as well as the invention's value to the business and the company's investment in developing it.

Employer-employee negotiations usually determine compensation, with arbitration before a tribunal as a last – or next-to-last – resort. Although an appeal through the judicial system is possible if either party is dissatisfied with the settlement proposed by the arbitration board, few cases follow this route. In the first 17 years of the law's existence, only 1,100 cases came to arbitration, and 75% of these were settled amicably before the board had to impose a decision.

Not all the European statutes have been drafted this equitably. For example, although many countries allow emplnyees to present claims regardless of the invention's profitability, the United Kingdom's 1977 patents act allows compensation only for patents of "outstanding benefit to the employer." As defined during the parliamentary debates, this means that the patent must be "a humdinger of a

(4)

winner," "a bonanza for the employer," or "the sort of invention that may revolutionize a company or even perhaps a whole industry." If the English courts uphold these interpretations, most employee-inventors will not be entitled to compensation.

Rewards Japanese style

Japan's 1959 patent compensation statute contains provisions similar to those in the Western European laws. Compliance is voluntary, not mandatory as in Europe. As of 1980 almost 75% of Japan's corporations had adopted service-invention regulations modeled on those published by the Japanese patent office. Most of the others have their own schemes for rewarding employee-inventors.

Companies that follow the model regulations establish service-invention review boards composed of a chairman, a vice chairman, and some employee members appointed by the chairman. Each board determines the compensation due its company's employees. With the chairman's permission, inventors may attend the board meetings to express their views.

The amount of money involved in these awards is small by American standards: the maximum is less than $10,000. Nevertheless, in conjunction with employment practices that also reward innovative contributions, they have had a noticeable effect on Japanese inventiveness. Within ten years of the law's enactment, the number of patent applications from Japanese citizens had more than tripled to well over 100,000 a year.

Learning from experience

Proposed legislation based on the West German employee-inventors law now appears as H.R. 3285 of the 98th Congress. Although similar to its prototype in many respects, it differs in this way. The German arbitration board's findings can be appealed through the courts. The U.S. board's factual conclusions cannot, unless there has been a mistake of law or the holding has been capricious.

Representatives of American industry contend that such a law would disrupt team effort and that worthless patent applications would flood the patent office. In addition, Americans who have dealt with the German legislation argue – and German industrial leaders do not deny – that it necessitates cumbersome paperwork and is very time consuming.

But according to a report recently issued by the U.S. Library of Congress, most German business people believe that the innovation the law fosters outweighs its faults. Therefore, I suggest that we draw on the Germans' experience to improve the pending legislation. The following changes should make the proposed law more acceptable to U.S. corporate managers without changing its fundamental principles:

- ☐ Appeals to an arbitration board would be limited to inventions that have earned more than $20,000 for the company. Inventions that fall short of this amount would entitle the inventor to a modest compensation award (perhaps $200) payable when the patent is granted. This change would minimize the number of appeals and reduce paperwork. The National Labor Relations Board and certain federal court actions provide precedents in stipulating that a minimum monetary amount must be satisfied before they assert jurisdiction.
- ☐ Time limits that are now ill-defined or too restrictive would be altered to reflect industry practice.
- ☐ H.R. 3285 allows compensation to be redetermined when a major change in circumstances occurs – for example, when an invention becomes profitable in mid-life, after the parties have agreed to a minimum compensatory amount. This section would be limited to cases in which charges of fraud or misrepresentation appear.
- ☐ H.R. 3285 also mandates the release of all rights to the employee if the company abandons a patent or allows it to lapse. Although this arrangement may be equitable under most circumstances, it could create a hardship for an employer that is holding back the invention to protect trade secrets or to avoid making other products obsolete. A "use it or lose it" provision would resolve such problems by requiring an employer to pay a nominal rental fee for unused inventions.
- ☐ Finally, tax policy should be designed to reward real invention and innovation. Current tax laws, which allow a 15-year, 25% tax credit for increases in corporate R&D expenditures, arguably encourage as much creative accounting as invention. I propose that employee-inventors be allowed to reduce the amount of taxes due on their royalties for one year, that employers be entitled to claim a one- or two-year deduction and a credit equal to the aggregate royalties paid, and that innovators be eligible to receive partially tax-free bonuses for their work. In addition to stimulating invention, these tax benefits would promote team effort by rewarding those who contribute to an invention's commercial success as well as its creator.

'A piece of the action'

Invention and innovation require more than the minimum effort needed to complete an assigned task. Yet our present system of rewards does little – or nothing – to encourage this extra push. Remuneration is still the most effective way to motivate employees, particularly if it includes "a piece of the action."

The Supreme Court has long recognized the link between invention and the prospect of personal gain. The time has come for the laws governing employee inventions to do the same. By enacting a comprehensive service-invention law with properly channeled tax incentives, we will give our scientists and engineers their overdue fair share and prevent a drain of talent from the R&D ranks to management, where rewards are greater. In so doing, we will better our chances of competing successfully in the world market.

Mr. KASTENMEIER. Thank you, Professor Orkin.

I gather your employee tax proposal would, if I introduced it, be referred to the Ways and Means Committee rather than this committee, although there may be concurrent jurisdiction. That has not been introduced.

Mr. ORKIN. I do not believe it has.

Mr. KASTENMEIER. Have you sought to have the matter put into legislative form?

Mr. ORKIN. No, I have not.

Mr. KASTENMEIER. Let me return to H.R. 3285. To make sure I understand your position, you support H.R. 3285 in its present form or would you make certain changes?

Mr. ORKIN. I would make the modifications that I list in my Harvard Business Review article. I would limit an appeal to the arbitration board to inventions that have earned $20,000 or more for the corporation. That would get rid of frivolous claims and just make profitable inventions appealable.

Mr. KASTENMEIER. You absolutely differ from the preceding witnesses. So far you apparently feel that two things, one that there is presently enough information or enough statistical data and experience in terms of comparative law with respect to West Germany or perhaps Japan to in fact proceed with a legislative proposal with respect to inventor rights, because I believe Professor Schwartz talked currently there is really not enough known about it to be sanguine about what they are doing in the area.

Mr. ORKIN. It has worked very well in most of Europe. Sweden has had a law since 1949 and the West German law has existed since 1957. Japan's law has existed since 1959.

Mr. KASTENMEIER. The other conclusion Professor Schwartz had reached was that even though those laws have been in existence for sometime, it is difficult if not impossible to assume, to conclude that the success of their system vis-a-vis the United States in recent years can be attributable to their laws on employee inventor rights.

Mr. ORKIN. The only source I would have for that is the Library of Congress study that was done last summer and the book which I coauthored entitled "Employee Interventions: A Comparative Study" which goes into detail about the laws in six nations. We are the only one of the six that does not have an employee invention law.

Mr. KASTENMEIER. Do you think there is any reason historically for that? The only nation that doesn't have an employees inventors law?

Mr. ORKIN. I think perhaps most of Europe, not necessarily England, has taken a different attitude toward the employee. They know that the employee is a source of good ideas and their labor management relationships have not been as adversarial as ours.

Mr. KASTENMEIER. Earlier the first witness, Mr. Banner, suggested that there are some very practical difficulties with respect to employee inventors rights in terms of team work on development of inventions and who else contributes, and trade secrecy questions, I believe, he raised. Do they not continue to be major problems in trying to move toward something like H.R. 3285?

Mr. ORKIN. That is why I have a tax proposal that I have introduced because if you give a voluntary bonus to a so-called innovator—a marketing individual, a sales person, a production engineer, and make part of the voluntary bonus tax free, then you are satisfying both the employee inventor and the employee innovator. So there wouldn't be as much intra-corporate rivalry.

Mr. KASTENMEIER. Is it your view that eventually the tax proposal should be enacted, and a modified employee inventors' rights bill such as H.R. 3285 ought to be enacted, or are you suggesting that the former should have higher priority than the latter?

Mr. ORKIN. I would say that 3285 is the most important step to begin with, then the tax proposal should be considered because the R&D tax credits, as I mentioned in my statement, are not fostering the innovation that they might have initially sought.

Mr. KASTENMEIER. Thank you very much, Professor Orkin.

I would like to yield to my colleague from California, Mr. Moorhead.

Mr. MOORHEAD. I do not have any questions to ask.

Mr. KASTENMEIER. If not, the committee is very appreciative of your appearance this morning.

Mr. ORKIN. Thank you very much.

Mr. MOORHEAD. I do want to thank all of the witnesses for coming today. This happens to be a day that there is a great impact on all kinds of committees and operations that are taking place, so I couldn't be here the whole time. This is a very important area, as far as I am concerned, and one I hope we can get some legislation.

Mr. KASTENMEIER. One of the difficulties, if I may engage my colleague in colloquy, is that there are many people who are knowledgeable in this area, and in these areas I am talking about, the patent bills, and the bills cover a wide spectrum, some are not necessarily related, yet I think we must proceed in this way to reach these policy questions, in these areas in some sort of fashion. It is probably impossible for us to make enough time to hear every person or every organization that can make a contribution, even a major contribution. This is one of the frustrating aspects, for example, I know that we would like to hear from others who I think would make a contribution and we perhaps can schedule subsequent hearings on this subject, but that is one of the more difficult areas. We have had I think, only five witnesses, three this morning, and obviously we would like to have double or triple that number to cover the subject quality and I am not sure we are going to be able to do it except I wanted to share the Chair's frustrations with the subject in this connection.

Mr. MOORHEAD. I want to thank you for holding this hearing this morning and I know you are determined to have other hearings in the near future, so maybe we can come up with something.

Mr. KASTENMEIER. We thank you, Professor Orkin.

Mr. ORKIN. Thank you.

Mr. KASTENMEIER. Than concludes this morning's hearing until the committee next meets.

The committee stands adjourned.

[Whereupon, at 12:10 p.m., the subcommittee was adjourned.]

INNOVATION AND PATENT LAW REFORM

WEDNESDAY, JUNE 6, 1984

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

The subcommittee met, pursuant to call, at 10 a.m., in room 2137, Rayburn House Office Building, Hon. Jack Brooks presiding.

Present: Representatives Brooks, Glickman, DeWine, Hyde, Sawyer, and Mazzoli.

Staff present: David Beier, assistant counsel; and Thomas Mooney, associate counsel.

Mr. BROOKS. The subcommittee will come to order. This morning I have been asked by my distinguished and able friend, Bob Kastenmeier, to chair this hearing due to the death of his mother-in-law, a fine lady who lived about 40 miles north of my farm in east Texas. I am to chair this Subcommittee on Courts, Civil Liberties, and Administration of Justice. I know my deep sympathies are with him and his wife Dorothy and his boys.

This morning's hearing is the third day of a set of hearings on patent law, innovation, and the public interest. During earlier hearings attention was focused on suggested improvements in the administration of the patent laws. This morning's hearing will primarily focus on the subject of patent term extension. The ostensible focus for the hearing will be H.R. 5529 by my colleagues Dan Glickman and Mike DeWine. This bill represents in modified form the same kind of patent term extension which the Judiciary Committee reported last Congress. H.R. 5529 is more limited in coverage than previous patent term bills in that it only relates to substances regulated by the Federal Insecticide, Fungicide, and Rodenticide Act, Toxic Control Substances Act, and Virus-Serum Act. For the most part, these chemical and agricultural chemical substances were not the focus of the controversy that focused last session on the patent term bill. Through this hearing we will be exploring the merit of pursuing a separate patent term bill for these substances.

Our first and only witness this morning is Vaughn Bryson, representing the National Agricultural Chemical Association. Mr. Bryson, we have received a copy of your statement and, without objection, it will be made a part of the record. Please proceed as you see fit.

Mr. BROOKS. I would yield now to Dan Glickman, one of the authors of this legislation, among that which we are considering today, for an opening statement. Mr. Glickman.

Mr. GLICKMAN. Thank you, Mr. Chairman. First, Mr. Chairman, I would like to ask unanimous consent to include a statement by our colleague, Congressman Rose of North Carolina and a statement submitted by Mary Collins, and ask that they be made a part of the record.

Mr. BROOKS. Without objection.

[The information follows:]

STATEMENT OF REPRESENTATIVE DAN GLICKMAN

Mr. Chairman, as sponsor of H.R. 5529, I am very pleased that this hearing is taking place today. I regret that Chairman Kastenmeier isn't able to be with us because of death in his family. He has been most helpful, as has been the subcommittee staff, in seeing that H.R. 5529 and the other legislative proposals before us today are given consideration.

As evidenced by the approval this subcommittee and the full Judiciary Committee gave in the last Congress to broad patent term restoration legislation, there seems to be a widely held view that patent term restoration is a sound concept and one we should pursue. Given that, I would urge the subcommittee to focus on two particular aspects of my bill—which was introduced with my good friend from Ohio, Mr. DeWine and cosponsored by a number of other members of the committee—and the legislation being developed by Mr. Waxman dealing with patent term restoration for human pharmaceuticals and, as I understand it, animal drugs under FDA purview:

(1) H.R. 5529 and the Waxman bill, based on my understanding of what it will contain, treat patents on animal drugs differently. We need to consider those differences and which is the best course of action to take. Of course, I find the more straight-forward approach in H.R. 5529 to be more appropriate for a number of reasons. I am sure we will discuss that at greater length later.

(2) We need to weigh whether or not the bills as they now stand need technical revisions or additions of any types of products not now covered. For example, the National Association of Nurserymen has contacted me about whether or not it would be appropriate to amend the bill to provide the same extension for newly patented plants quarantined when initially brought into this country under requirements of the Plant Quarantine Act of 1912.

Again, I am encouraged by past actions that the subcommittee members share my view that reasonably crafted patent term legislation makes sense and should be adopted. I am also pleased to note that both the Environmental Protection Agency and USDA have indicated support for H.R. 5529. I feel sure the hearing today will reaffirm the consensus that exists on H.R. 5529. I trust it will lead to an early mark-up of this noncontroversial measure. It is a step that needs to be taken, and I hope my colleagues will agree that it should not be encumbered by controversies it has specifically been crafted to avoid.

TESTIMONY OF CONGRESSMAN CHARLIE ROSE ON H.R. 2882

Mr. Chairman, Members of the Subcommittee, I would like to thank you for the opportunity to testify before you today on my bill, H.R. 2882, a patent relief bill introduced to remedy a particularly egregious set of facts and circumstances. With me today is Mary Collins in whose behalf I introduced this bill, and she will be available today to answer any technical questions you may have.

Before I discuss the reasons behind this bill, I would like to take a moment of your time to thank you, Mr. Chairman, for your interest and concern in the area of private relief legislation. By supporting the consideration of measures such as this bill, you give the American people and their representatives an opportunity to exercise important rights critical to the equitable functioning of our system of representative government.

Additionally, I would also like to thank you for assuring a fair and orderly process of consideration with regard to private relief legislation, as well as your staff for all of the courteous and thoughtful assistance they have rendered me, my staff, and Mary Collins.

In September 1978, as Chairman of the House Agriculture Committee, Subcommittee on Dairy and Poultry, I held hearings on the use of antibiotics as an alternative in animal health maintenance for both poultry and dairy cattle.

I first met Mary Collins, President of Impro, at that time. Mary testified before the Subcommittee, and described to me and the other Members of the Subcommit-

tee, her particular circumstances. She asked the Subcommittee to investigate the validity of the USDA testing procedure used to determine the efficacy of Impro's patented product.

The Subcommittee attempted many times to get the true story out of the Department, to no avail. Two Under Secretaries of Agriculture in both Democratic and Republican Administrations requested either full disclosure or a new test, but their requests were ignored within their own Department.

I have introduced H.R. 2882 to allow the extension of patent protection to Impro Products, Inc., a small family-owned business, which in 1968, was granted a patent on a process used to increase milk production in dairy cows. Unfortunately, Impro has been unable to make full commercial use of its product due to a preliminary report published by the Department of Agriculture containing false and misleading information about the testing of the product. The report, in effect, prevented the granting of a license to Impro to market the product nationwide.

Impro applied for a patent in 1965 and a license to market its product. While the patent was approved, the marketing license was never granted.

USDA claimed its test data showed Impro's product did not actually increase milk production and refused to extend a temporary license for marketing the product. Impro then began a 15 year battle to correct USDA.

After exhausting all administrative remedies to obtain the USDA test records, with Freedom of Information act requests being denied and congressional directives not fully complied with, Impro sued in Federal Court.

In 1982, senior U.S. Judge Howard Corcoran of the District of Columbia Circuit ruled that the published report which had been disseminated throughout the veterinary, university and agricultural communities contained several false or misleading statements, and that the release of the article by USDA constituted "arbitrary and capricious action and an abuse of discretion."

USDA appealed on procedural grounds. The findings of fact were not appealed and the Appeals Court reversed, based on tolling of the Statute of Limitations.

Impro's 17 year patent will expire next year. At that time, Impro's exclusive rights to its patent will lapse and any manufacturer or developer will be allowed the opportunity to exploit the product Impro has never had the chance to market nationally.

This bill would allow an extension of Impro's patent so that it may again try to license and market its product. No other remedy is available to compensate Impro for lost time on its patent due to unjustified government involvement.

I think it is significant that all of the members of the Iowa delegation have chosen to support me in this effort to rectify a very inequitable situation.

Once again, I would like to thank you for the opportunity to appear before you today, and I thank you for your consideration of H.R. 2882.

IMPRO PRODUCTS, INC.,
Waukon, IA, January 12, 1984.

Hon ROBERT W. KASTENMEIER,
Chairman, Subcommittee on Courts, Civil Liberties and Administration of Justice, Committee on the Judiciary, Rayburn Building, House Office Building, Washington, DC.

DEAR CONGRESSMAN KASTENMEIER: On November 3, 1983 the Secretary of Agriculture sent you a letter submitting what he described as "a summary of facts relevant to your consideration of H.R. 2882" and opposing enactment of the bill. The allegation of facts set forth therein are incomplete and misleading in many respects, and the opposition to the bill is not well founded. The facts set forth below in this letter were all established in the record of a case brought be Impro Products, Inc. ("Impro") against the Secretary of Agriculture in the U.S. District Court for the District of Columbia. We will be glad to furnish the evidence to you if you so desire.

In June 1965 Impro submitted a New Drug Application to the Food and Drug Administration ("FDA") for a product produced by Impro under its patent number 3,376,198 for "use as an aid for production increase in dairy cows". FDA concluded it did not have jurisdiction over the product and transferred the application to the Veterinary Biologics Division ("VBD") of the U.S. Department of Agriculture ("USDA"), which Division administered the Virus, Serum, Toxin Act, 21 U.S.C. 151-158 ("VST Act"). Impro then submitted a revised application for licensing the product under the VST Act on USDA forms. Impro submitted to VBD substantial data collected during field tests of the Impro product and VBD decided to issue a special unrestricted two-year license to Impro. Under that license Impro was to conduct further field tests in several geographic locations. Issuance of a permanent license was

to be considered upon the basis of those tests. VBD sent out an official announcement regarding the issuance of the special license. When a USDA scientist, who was in a research agency of USDA and had no position in VBD nor any regulatory responsibilities under the VST Act, received a call from an outside source regarding the intention of VBD to issue the special license, the scientist immediately contacted VBD officials and persuaded them to hold up issuance of the license for six months so he could run his own test on the product at the Agricultural Research Center at Beltsville, Maryland ("the Beltsville test"). This was the first and only time a research scientist of USDA intervened in a decision of VBD officials regarding a license under the June

Impro was then requested to submit 450 doses of its product to the USDA scientist for use in the test. The project outline or protocol for the test prepared by the USDA scientist and his associates provided that more than 400 cows would be divided into two groups, a treatment group to be injected with the Impro product and a control group to be injected with a placebo, and that: "Each treated cow will receive a 50cc subcutaneous injection 5–10 days prior to the expected date of calving". This treatment procedure was compatible with that set forth on the label of the product.

While the Beltsville test was underway, VBD decided to issue the special license to Impro on the basis of the data Impro had previously submitted. The purpose of the special license was to permit Impro to conduct field tests "in several widespread geographical areas to determine the effect of different environmental situations" for consideration in connection with issuance of a permanent license. Impro prepared for such test in Arkansas, California, Iowa, Illinois, Minnesota, and Wisconsin.

Upon learning that VBD had issued the special license, the USDA scientist immediately ordered a subordinate scientist to prepare a preliminary report on the Beltsville test. The subordinate objected because the test had not been going on very long, the data on the cows had not been recorded, and the injection of the cows had not been verified. Nevertheless, the superior directed that the preliminary report be prepared "posthaste, that it was needed in a hurry". The USDA scientist sent the negative preliminary report to VBD to "convince . . . [VBD] to suspend Impro's special license." In response to the preliminary report VBD noted significant differences in the data between the treated animals and those receiving the placebo. VBD advised the USDA scientist that they "felt that possible gains in production might result from the autogenous nature of the product" and therefore they had Impro "set up additional field trials in widespread locations". The USDA scientist disagreed and VBD ultimately bowed to pressures from the USDA scientist and his associates and terminated the special license.

Impro then contacted VBD and sought an extension or reissuance of the license. A meeting was scheduled between representatives of VBD and Impro. On the day before that meeting, the USDA scientist sent VBD a second preliminary report on the Beltsville test, two and one-half months prior to the completion of that test, stating that: "Our conclusions can only be that Impro has not had a beneficial effect". An extension or reissuance of Impro's special license was denied on the basis of that preliminary report. A regulatory official of VBD testified that the Beltsville test, even if valid, would not have established that the Impro product was not effective in other areas of the country and additional data from other areas would be necesary for a permanent license. However, by termination of Impro's special license and the refusal to extend or reissue the license, Impro was prevented from completing the tests in widespread locations and thereby acquiring the necesary data.

Upon termination of its special license in September 1967, Impro requested USDA to furnish it "the complete data" on the test and was assured by USDA that the data would be furnished. The data were not furnished to Impro, however. For the next fourteen years Impro actively sought from USDA the records and completed data regarding the Beltsville test.

In October 1967 USDA advised Impro that it would "send all available data" to one or two university professors for "review and recommendations". In September 1980, one of the professors stated in an affidavit that USDA only sent him the protocol for the Beltsville test and that they did not send him any of the test documents or records, which would have revealed the fact that most of the cows were not injected as required. Upon learning that most of the animals were not properly injected, the professor retracted his endorsement of the Beltsville test and stated: "I want absolutely no part of endorsing the results of a test that was not run according to the protocol".

In 1968 Impro again pursued its request for the test records and was assured by a USDA official that the records would be furnished. They were not furnished, however. In June 1969 upon learning that USDA had reported to the American Dairy Sci-

ence Association regarding the Beltsville test, Impro again requested the test records. They were not furnished. In August and September 1969 Congressman Gross requested the test records. Summary data in tabular form was furnished but the records were not provided. After the Freedom of Information Act was enacted, Impro was able to obtain some records regarding the Beltsville test but it was only pursuant to subpoenas during discovery in the litigation in 1981-82 referred to below that Impro was able to gain access to all of the test records.

In 1969 a report on the Beltsville test was prepared and submitted to the American Journal of Veterinary Research ("AJVR") for publication. The editorial staff rejected the report for publication. The USDA scientist then personally carried a copy of the manuscript to Ames, Iowa, delivered it to an Extension Veterinarian at Iowa State University, who was then President of the American Veterinary Medical Association, and solicited his assistance in getting the report published. The president of the Association then directed the Editor of the AJVR to publish the report and it was published in August 1970.

That report on the Beltsville test was the subject of the decision issued by the U.S. District Court for the District of Columbia on September 2, 1982, in a case brought by Impro against the Secretary of Agriculture. The Court found that the report contained "several false or misleading statements" and that the release of the report by USDA constituted "arbitrary and capricious action and an abuse of discretion". The Court stated that "the most glaring inaccuracy" in the report was that "each treated cow was inoculated [with the Impro product] . . . 5 to 7 days before the anticipated date of calving" whereas in fact "fewer then one third of the treated cows were actually injected" during that period. The Court also found that the report did not reveal that the data from two distinct herds were combined in the data analysis even though there was "general agreement amongst the scientists involved here that between-herd comparisons are not valid in tests such as this"; that the data showed that the Impro product "provided a significant increase in milk production in the Breeding Herd"; and that the combining of the data "masked evidence of the effectiveness" of the Impro product. The Court further found that the report did not reveal that crossbreeds were used in the test and that the "use of crossbred cows is significant" because "they are generally considered unpredictable" and there are no "mature equivalent factors" for crossbreeds which "are essential for analyzing data in a milk production study".

The decision of the District Court was appealed by USDA to the U.S. Court of Appeals for the District of Columbia Circuit. USDA did not appeal the findings by the District Court that the report on the Beltsville test contained several false and misleading statements. In fact, USDA admitted that the statement in the report that "each treated cow with inoculated [with the Impro product] . . . 5 to 7 days before the anticipated date of calving" was false. USDA argued, however, that the Secretary of Agriculture has unreviewable discretion to disseminate any kind of a report on a scientific test conducted by USDA, including a report containing false and misleading statements. USDA's appeal related to jurisdictional issues. The Court issued an opinion on December 16, 1983, reversing the District Court on the jurisdictional basis of a six year statue of limitations and remanded the case to the District Court for further proceedings with respect to a constitutional claim. Impro is considering filing a petition with the Court of Appeals for rehearing, or a petition to the Supreme Court for Certiorari, because Impro believes there were specific agency actions regarding the Beltsville test report within the six year period prior to instituting the case and furthermore that the six year limitation does not apply to cases in equity which do not involve any monetary claim against the Government.

USDA knew that the statement regarding the injection of the cows was false prior to the publication of the AJVR report in 1970. The testimony of a USDA employee who participated in the Beltsville test established that during the test he discovered that the cows were not being properly injected with the Impro product and that he so advised the USDA scientist. Furthermore, the USDA records regarding the test revealed that more then two-thirds of the cows were not treated with the Impro product during the 5 to 7 day period. Nevertheless, USDA falsely advised Congressman Gross of Iowa in 1967 that cows were injected with the Impro product during the required 5 to 7 day period and published the false statement in the AJVR report published in August attention of USDA on several occasions between 1970 and 1981. Nevertheless, USDA continued to distribute the false report far and wide until enjoined by the U.S. District Court for the District of Columbia.

USDA received "a lot of requests" over the years for information regarding Impro and they "would just send them a copy" of the AJVR report. The report was distributed regularly by the numerous USDA-State Extension Service offices throughout

the United States. In addition, the report was distributed to numerous other individuals, as well as to state agencies. Furthermore, Hoard's Dairyman, one leading lay dairy publication, refused Impro's advertising on the basis of the false and misleading AJVR report. Also, an abstract of the report was published in the Dairy Science Abstract, an international publication which is translated into 42 different languages and distributed worldwide. That abstract effectively destroyed Impro's marketing efforts in Taiwan, Japan, South America and Europe.

In the November 3 report on H.R. 2882 from the Secretary of Agriculture it is stated that: "The Judge did not find that the conclusion that the product had not been demonstrated to be efficacious was invalid". It is apparent, however, that the effectiveness of the product could not have been demonstrated in the beltsville test since so few of the animals were properly injected with the Impro product. An official of USDA testified in the case that: "* * * less than 20 percent or so, or less, [of the cows] were given the product in the time [5 to 7 days prior to the anticipated date of calving] and there weren't enough animals remaining . . . to make any valid conclusions regarding the beltsville test. A biostatistician who was a witness for USDA testified that if only 25 percent of the cows were properly injected there would be only a 10 percent chance of a significant increase in milk production being detected. Furthermore, as pointed out above, unpredictable crossbred cows were improperly used in the test, and data from two separate herds were combined thereby masking evidence of the effectiveness of the product.

In the November 3 report the Secretary also stated that USDA did not extend the temporary license based on the preliminary report on the Beltsville test and "the lack of adequate tests by Impro showing contrary results" and that USDA denied Impro a permanent license not only because USDA "believed" that our test results showed that the product was not efficacious, but also because Impro failed to provide the necessary data to support its application" (emphasis added). It is significant to note that the Secretary stated that USDA only "believed" that the test results were negative, rather than standing behind the test and stating that the test "proved" or "established" that the product was not efficacious. With reference to the AJVR report on the test, the Secretary stated that the "results, as reported, indicated that the product did not produce the claimed increase in milk production in dairy cows under the conditions of the test" (emphasis added), in other words, under the infirmatives of the test, such as less than one-third of the cows being injected during the required time period, crossbreeds being used in the test, and combining data which masked the effectiveness of the product. Of course, in view of the false and misleading statements in the test report and the factors referred to above regarding the test, the Secretary was not in a position to state that the test results were reliable.

It is also highly important to note that, as pointed out above, it was the USDA's own unfounded actions of terminating the special license which VBD issued to Impro for the purpose of conducting tests in widespread locations which deprived Impro of an opportunity "to provide the necessary data to support its application".

In his November 3 report on H.R. 2882 the Secretary referred to a review conducted in 1978 by USDA and the FDA of the Beltsville test data pursuant to the request of Congressman Charles Rose, Chairman of the Subcommittee on Dairy and Poultry of the House Committee on Agriculture. Congressman Rose requested the agencies to "take another look at these tests that were conducted at Beltsville with an eye towards possibly conducting them again". USDA and FDA advised Congressman Rose that Dr. Fred Kingma of FDA would conduct the review for FDA and that Dr. C. John Mare of the University of Arizona would conduct the review for USDA. Subsequently, USDA and FDA advised Congressman Rose that Dr. Kingma and Dr. Mare had made the reviews and furnished the Congressman with reports regarding the reviews. Impro was shocked to learn during the depositions in the litigation that Congressman Rose had been inaccurately advised. Dr. Kingma did not conduct the review. For some unexplained reason the assignment was given to Dr. R.E. Miller who was then with FDA but who had already accepted a position with Philips Roxane, Inc., a competitor of Impro, and at that time FDA had put Dr. Miller "on the shelf" insofar as any official work for FDA was concerned because of possible conflict of interest. Impro was also shocked to learn during the depositions that although Dr. Miller and Dr. Mare knew that the USDA scientists had stated in their AJVR report that the cows were injected 5 to 7 days before the anticipated date of calving, Dr. Miller used the cows injected during the period of 21 days prior to calving until 7 days after calving and Dr. Mare used the cows injected 14 days prior to calving until 5 days after calving, for their analyses of the test. Neither Dr. Miller nor Dr. Mare could, or would, explain why those injection periods were used rather than the 5–7 day period required for the test. However, it was stated in Dr. Miller's

report that: "The deviations from the protocol, both intended and unexpected, in carrying out the [Beltsville test] . . . possibly affected the adequacy of the study". Furthermore, Dr. Mare stated in his report that: "a major criticism leveled at the Beltsville [test] . . . is that the inoculation schedule on the experimental protocol was not followed" and that "[t]he statement is true . . ." Nevertheless, in January 1979 USDA and FDA advised Congressman Rose that based upon the review of the matter by Dr. Kingma [Dr. Miller] and Dr. Mare they did not recommend that the Beltsville test be rerun. It should also be noted that Dr. H. Graham Purchase, an official of the Science and Education Administration of USDA, in a memorandum to his superior, stated that: ". . . some of the criticisms of the Beltsville [test] . . . are valid," and in a note at the end of the memorandum he stated: "There are only two copies of this memo, the original and one copy in my file. I will destroy the copy in my file when I receive word that you have read this memo.

In view of the circumstances briefly described above, it is readily apparent that this situation presents the "egregious circumstance clearly warranting such extraordinary relief" which the Department of Justice in its report stated should be the criteria for a private relief bill; that these are "the most extraordinary circumstances" which the Commissioner of Patents and Trademarks stated in his report should be the criteria for private relief bills making individual exceptions to the general patent laws; and that the circumstances constitute the "delay, misfeasance or malfeasance" which the Secretary of Agriculture stated should be the criteria for an extension of a patent.

MARY E. COLLINGS,
President, Impro Products, Inc.

Mr. GLICKMAN. Thank you, Mr. Chairman. Along with my colleague Mike DeWine we have introduced this bill, H.R. 5529, as evidenced by the approval of this subcommittee and the full Judiciary Committee given in the last Congress to broaden patent term restoration legislation. There seems to be a widely held view that patent term restoration is a sound concept, one which we should pursue. Therefore, I would urge the subcommittee to focus on two particular aspects of our bill, which is sponsored by Mr. DeWine and I, and cosponsored by many members of the full committee, as well as the legislation being developed by Mr. Waxman dealing with patent term restoration for human pharmaceuticals and, as I understand it, animal drugs under FDA purview.

The two items I would suggest we need to focus on is H.R. 5529 and the Waxman bill, based upon my understanding of what it will contain, and that may not be the final understanding, Mr. Chairman, but they treat patents on animal drugs differently. We need to consider those differences and which is the best course of action to take. Of course, I find the more straightforward approach in H.R. 5529 to be more appropriate for a number of reasons we will discuss later.

Second, we need to weigh whether or not the bills, as they stand, need technical revisions or additions of other types of products not now covered. The National Association of Nurserymen contacted me about whether or not it would be appropriate to amend the bill to provide the same extension for newly patented plants quarantined when initially brought into this country under the requirements of the 1912 act.

Again, I am encouraged by past actions of the subcommittee members who share my view that reasonably crafted patent legislation makes sense. I am also pleased to note that EPA and the Department of Agriculture have indicated support for the bill. I feel sure the hearing for the bill today will reaffirm the consensus that exists on the bill, and I trust will lead to an early markup of this

noncontroversial measure. It is a step that needs to be taken primarily for the efficient and continued production of food and fiber in this country.

I hope my colleagues will agree it should not be encumbered by controversies it's specifically been crafted to avoid and I thank my chairman.

Mr. Chairman, I ask unanimous consent that the subcommittee permit the meeting this morning to be covered in whole or part by television broadcast, radio broadcast, still photography pursuant to committee rules.

Mr. BROOKS. Is there objection? Without objection, I must say I welcome our former Republican colleague, a distinguished member of the committee for many years, Tom Railsback, in the amen row there. I trust he's doing the Lord's work.

Mr. DeWine.

Mr. DEWINE. I have a brief statement, Mr. Chairman.

This bill will do a great deal to assist the American farmer and those of us who consume farm products. Whenever a new product is marketed which makes farming more efficient and economical, we certainly all benefit. This bill encourages the marketing of such products.

The purpose of patent law is to encourage the type of research and development that has made us a world leader in innovation and new technologies. It is important to keep in mind, though, that this R&D is very expensive and time consuming.

Return on investment is not at all immediate or certain. Unfortunately the regulatory process through which these new products must go has become a disincentive to new research and development.

I might say that this bill should not in any way be considered antienvironment. It does not change the process that has to be gone through or the testing that has to be done in any way. This process may take upwards of 7 years or more. All the while the patent clock is ticking away. Very quickly a 17-year patent has an effective patent life of 10 years or even less many times. H.R. 5529 serves to remedy this inequity by restoring up to 5 years of the patent life loss to regulatory testing and review.

The bill covers agricultural chemicals and animal drugs. It does not involve human drugs. It is supported by farm groups and organizations throughout the country. It is an uncontroversial bill which simply seeks to restore that which was taken away by Government regulatory review.

Mr. Chairman, I hope we can move quickly on this very important and much needed legislation. Thank you.

Mr. BROOKS. Thank you very much.

The gentleman is recognized.

TESTIMONY OF VAUGHN BRYSON, PRESIDENT, ELANCO PRODUCTS CO., A DIVISION OF ELI LILLY & CO.; JOHN MAURER, GENERAL CONSULTING ATTORNEY, MONSANTO CO.; AND DR. KLAUS A. SAEGEBARTH, DIRECTOR OF RESEARCH AND DEVELOPMENT, AGRICULTURAL CHEMICALS DEPARTMENT, DU PONT CO.

Mr. BRYSON. Thank you, Mr. Chairman.

Mr. BROOKS. You are accompanied by?

Mr. BRYSON. By Mr. Jack Maurer, general consulting attorney for the Monsanto Co. and Dr. Klaus Saegebarth, director of R&D of the Agricultural Chemicals Department, du Pont Co.

Mr. BROOKS. Is either of them working on the bark beetles? If you don't know what bark beetles are, it is a very dangerous animal. While you are working on all these things, why don't you all figure out a way to eliminate the bark beetles besides cutting the tree down and burning it.

Mr. BRYSON. Is that similar to the fire ant, Mr. Chairman?

Mr. BROOKS. No, the bark beetles work on the trees. Fire ants work on people, animals, the little children's feet, and you, if you get close enough. You haven't figured out a good way on that yet. They say they have got new stuff that will kill the queen. Six weeks later then, they are all going to die. In the meantime, they will just bite the fool out of you. Around the house, it is a little dangerous to wait. You don't know whether they are waiting to die or waiting to get you.

Pardon me, go ahead. Both of them are problems worthy of your consideration.

Mr. BRYSON. Thank you, we will take that under advisement.

I am Vaughn Bryson, president of Elanco Products Co., a division of Eli Lilly & Co. Elanco is engaged in the research, development, and marketing of both agricultural chemicals and animal health products. Accompanying me are Mr. John Maurer, general consulting attorney, Monsanto Co., and Dr. Klaus A. Saegebarth, director of research and development, Agricultural Chemicals Department, du Pont Co. We are testifying today on behalf of the National Agricultural Chemicals Association, Chemical Manufacturers Association, Animal Health Institute, and their member companies. We support H.R. 5529, the Agricultural Patent Reform Act of 1984. The changes proposed in this bill will encourage investment in the research and development of new crop protection and animal health products used in agriculture.

Extensive testing of these products must be done to assure effectiveness and an acceptable margin of safety, even before initiating regulatory review. The long period of regulatory review contributes to a reduction of the time a company has to achieve a satisfactory return on its investment. These compounds, therefore, receive only a portion of the patent protection given to other products. This inequity must be remedied to encourage increased investment in agricultural product research. H.R. 5529 will help accomplish this goal.

In the remainder of this testimony, I wish to stress three points. First, the benefits that our products bring to agriculture and, ultimately, the consumer are based on aggressive research for new dis-

coveries and on patent protection for those products. Second, necessary environmental and human safety tests and regulatory review have eroded the patent life of these products. Third, this patent erosion will adversely impact new product development. Our remarks are amplified in a written statement.

During the last 40 years there has been significant progress in agricultural technology. Crop protection chemicals have revolutionized production techniques. Preemergent herbicides save U.S. farms in excess of $5 billion a year. Crop yields and quality have improved dramatically, ensuring adequate supplies of human food and animal feeds. Animal health products developed by U.S. technology have made it possible to ensure that a greater supply of meat, poultry, and dairy products are available at affordable prices to consumers. It is estimated that U.S. consumers pay 9 percent less for animal-derived foods than they would if animal drugs did not exist. But further development of American agricultural technology must be encouraged. Industry must be encouraged to discover new, safe, and more effective products which will allow a continued abundant supply of affordable foods.

During the past few years, however, a potentially serious deterrent to the progress of agricultural technology has developed. There has been an ever-increasing time requirement for product testing to ensure that there will be no unreasonable toxic effects from these compounds on either human health or the environment. Evaluation of this data has led to longer regulatory review periods. While careful reviews and testing requirements are necessary, the result is a significant shortening of the effective patent life. On the average, 5 to 7 years of a patent's life are consumed by these testing and regulatory processes.

As I mentioned earlier in my testimony, our industries are not only intensely regulated but we also must take significant economic risks. If it were not for the patent system, there would be fewer financial risks taken. This would lead to fewer new developments in agricultural technology by private industry. These financial uncertainties can be characterized in several ways. Only 1 in about 12,000 chemicals tested by a company will possess the unique ability to selectively control a pest or disease with the necessary margin of safety. The cost of this process of identifying and screening these chemicals is significant. On the average, it now takes up to $40 million to bring a new product from discovery to market. If a new manufacturing facility is required, an additional expenditure of $30 to $70 million may be necessary. When expenditures of this magnitude are coupled with a 6-year erosion in the life of the patent, it becomes difficult to achieve a suitable financial return on these investments. Within the past 5 years, for example, one major pesticide company terminated four research and development efforts in part because of insufficient patent life. The company eventually shelved miticide and aphicide candidates after a difficult development left them with insufficient patent life to justify further expenses.

Economic considerations such as this have also caused the animal health industry to experience some "shrinkage." In the past decade, several major corporations have divested themselves of their animal health components, apparently because of insufficient

return on investment. The ever-increasing costs of obtaining marketing approval, along with fewer years of patent protection, simply did not produce adequate returns.

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 and sell his product. The necessary testing and federally mandated review of agrichemicals and animal health products have caused an unforeseen and inequitable erosion of this patent life. H.R. 5529 addresses many of the problems and concerns I have thus far mentioned.

This legislation is similar to Chairman Kastenmeier's patent term restoration bill approved by this subcommittee and the full Judiciary Committee in 1982. There are, however, several significant differences that should be mentioned. First, H.R. 5529 contains provisions to make certain that the patent holder exercises due diligence in its testing and regulatory efforts. Second, it places a cap of 5 years on the amount of restoration available. Third, H.R. 5529 contains language which assures generic manufacturers that a series of patent extensions cannot be used to prolong the patent term for any single product. Finally, this bill provides limited restoration relief for products undergoing regulatory review as of the date of enactment.

Mr. Chairman, I think it is important to mention the broad range of support for this proposal throughout the agricultural community. Over 30 farm organizations including the American Farm Bureau, the National Cattlemen's Association, the National Association of Wheat Growers, the Cotton Council, the National Pork Producers Council, the American Soybean Association, and the American Veterinary Medical Association, to name a few, support this bill. These organizations represent the principal consumers of our products, who are best able to judge the economic consequences of the proposed legislation. They recognize that increased incentives to develop new agricultural technology will ultimately reduce their cost of production.

In summary, without adequate patent protection, our member companies will be less able to undertake the increasingly costly and time-consuming research involved in discovering and developing new agricultural technology. This technology, combined with the ingenuity and efforts of the American farmer, have made this country the most productive agricultural nation in the world. Your support of H.R. 5529 will enable us to maintain this leadership.

We appreciate this opportunity to appear today and will be happy to answer any questions.

[The statement of Mr. Bryson follows:]

WRITTEN STATEMENT

OF THE

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,

CHEMICAL MANUFACTURERS ASSOCIATION, AND

ANIMAL HEALTH INSTITUTE

BEFORE THE

SUBCOMMITTEE ON COURTS, CIVIL LIBERTIES AND THE

ADMINISTRATION OF JUSTICE

OF THE

U.S. HOUSE JUDICIARY COMMITTEE

ON

PATENT REFORM

June 6, 1984

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APPENDICES

EXECUTIVE SUMMARY

This written statement is submitted on behalf of the National Agricultural Chemicals Association (NACA) 1/, Animal Health Institute (AHI) 2/, and Chemical Manufacturers Association (CMA) 3/. Our member firms are directly and significantly affected by the legislative changes being considered by the Subcommittee. Our specific views are as follows:

1. H.R. 5529 -- Agricultural Patents - We support the bill to correct a present inequity in the patent law giving inadequate protection to Federally regulated products used for livestock and crop protection.

2. H.R. 4525 & H.R. 4527 -- Team Research - We support both bills in adapting current law to the realities of today's team research.

3. H.R. 2610 -- Defensive Patents - We support the bill, agreeing that defensive patents or statutory invention recordings are desirable.

1/ NACA is an industry association of approximately 100 agricultural pesticide manufacturers and formulators. NACA's member companies supply virtually all of the $4 billion U.S. agricultural pesticide market.

2/ AHI is a 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 AHI's criteria for membership, must be engaged in research.

3/ CMA is a nonprofit trade association whose company members represent more than 90 percent of the productive capacity of basic industrial chemicals within this country.

4. H.R. 3462 -- Fees for Independent Inventors - The bill should include a provision to cover revenue losses out of general tax funds.

5. H.R. 4524 -- Foreign Filing Licenses - We support H.R. 4524 which will streamline the filing and prosecution of foreign patent applications without jeopardizing U.S. security interests.

6. H.R. 3285 & H.R. 3286 -- Employed Inventor Rights - We do not believe that there is a demonstrated need for federal legislation in this area.

7. H.R. 4528 -- Patent Interferences - We support the bill to permit arbitration for patent interferences.

8. H.R. 3577, 4526 and 4814 -- Manufacture Outside U.S. - We support these bills to eliminate unauthorized manufacture of U.S. patented inventions.

9. H.R. 4529 -- License Agreements - We support H.R. 4529 to remedy situations that are manifestly unfair to patent owners/licensors.

Our views are explained in greater detail in the following discussion.

I. H.R. 5529 -- AGRICULTURAL PATENTS

A. INTRODUCTION

We strongly support H.R. 5529, the "Agricultural Patent Reform Act." Animal health and crop protection chemicals are some of the most important products of American industry. Each year animal drugs and pesticides are responsible for billions of dollars in savings to the American farmer. Yet, ironically and inequitably, Federal premarket testing and review requirements have shortened the effective patent life of these important products. Such requirements typically consume 5-7 years of patent life, so it is not unusual for a pesticide or animal drug to have 12 years or less of patent life remaining when it reaches the market. As a result, one of the major incentives for engaging in the costly research and development on agricultural chemicals has been seriously undermined. H.R. 5529 will restore this incentive.

B. IMPORTANCE OF AGRICHEMICAL INNOVATION

Pesticides and modern animal drugs have made major contributions toward controlling and treating pests and animal diseases and in preventing costly epidemics. These products are now an essential part of the farming business. Farmers use agrichemicals because the cost of our products are more than offset by increased yields and higher productivity.

Animal health products -- pharmaceuticals, biologicals and animal pesticides -- are used in food-producing animals

throughout the U.S. While emphasis is frequently placed on the undeniable fact that these products make the producers' herds and flocks more profitable, it should be recognized too that this very fact makes wholesome, animal-derived foods more affordable to the American consumer. A recent study shows that U.S. consumers pay nine percent less for animal-derived foods than they would if these products were not used. In reality, that nine percent is only a fraction of the saving realized, since the study does not take into account the fact that livestock and poultry production would have to be conducted on a smaller scale to reduce disease if animal health products were not available.

The agricultural pesticide industry offers similar benefits. The invention of pre-emergence herbicides has created a technical revolution in the production of corn, soybeans, cotton and many other grain crops throughout the world. Yield increases resulting from weed control with these chemicals can range from 10 to 50 percent or more, depending on weed intensity. The value to the farmer and total dollar improvement to the U.S. farm economy from pre-emergence herbicides alone is in excess of $5 billion per year and is a major contributor to the spectacular increase in farm productivity over the past 20 years. A graphic illustration of pesticide benefits to the food consumer is shown in Figure 1.

The search for compounds to control insects has lead to similar successes. We are developing powerful new weapons

against insects as a result of our increased understanding of insect enzymes and hormone systems. For example, hormones which trigger stages of growth in particular insects can be synthesized and used to disrupt growth patterns. Molting inhibitors, insect behavior modifiers and other chemicals that interfere with larval development are just a few examples.

In recent years, a major pesticide producer introduced an insecticide for use on vegetables which offered the farmer the ability to control pests within hours of application. In addition, the insecticide had low dermal toxicity and rapid environmental degradation. Many of the insecticides in use at that time displayed very few of these characteristics. Over time, continuing research and development efforts on the part of the manufacturer led to the insecticide's application on other crops including cotton, soybeans, fruit, wheat and tobacco. Breakthroughs such as this have enabled the farmer to effectively control various insects which reduce crop quality, salability and yields.

As significant as our past successes have been, much more needs to be done. We estimate that pests still destroy over 30% or $20 billion worth of crops annually in the United States. U.S. farmers typically lose anywhere from 2% to 10% of their crops each year because of damage from plant viruses. All told, these viruses cause billions of dollars in damage annually to the world's commercial crops.

In his Congressional Record statement when he introduced his Agricultural Patent Reform bill last month, Congressman Glickman took note of the devastation inflicted upon poultry last winter by avian influenza. Nearly 13 million layers, broilers and turkeys had to be destroyed in Pennsylvania, Maryland, New Jersey and Virginia to prevent the disease from spreading. Federal indemnities in the neighborhood of $30 million have been paid, and this does not begin to compensate the poultrymen for their losses. At present, there is no vaccine to protect broilers against avian flu. Research and innovation is critical if we are going to reduce these and other losses.

The agrichemical industries have traditionally been very research and innovation oriented. The pesticide industry spent over $500 million on research and development in 1982. See Graph 1. The animal health industry spent almost $200 million on R & D last year. Despite these significant outlays, there are disturbing indications that innovative research in the agrichemical area is on the decline in the U.S. According to a study published in the September 1983 GIFAP Bulletin 1/, the proportion of total research and development expenditures directed towards innovation in the pesticide area has been on the decline since the late 1960s. According to a 1980 study by the OECD, entitled "Technical Change and Economic Policy: The

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1/ Bulletin published by the International Group of National Association of Agrichemical Product Manufacturers.

Fertilizers and Pesticides Industry," 83% of pesticide research expenditures in 1967 went to research into new products and 17 per cent went to meeting approval requirements and on defensive research, i.e. new uses for already standardized products. In 1976, the percentages were 67% and 33% respectively. The same study also points out that a declining trend in innovation is also evidenced if one looks at new products introduced. In the period 1956-1970, between 110-120 new products were marketed every five years, or an average of over 20 new products per year. The number of new products in the period 1971 - 1975 fell to 70. Moreover, according to the same study, at least half of these new products are only defensive products, whereas the great majority of new substances marketed in the previous 20 years were radically new products.

The explanation for this disturbing trend is relatively simple: it is becoming increasingly difficult for companies to recoup the significant investment required to bring a new agrichemical product to market. For example, it now costs approximately $40 million and takes as much as 10 years to develop a new pesticide. In addition, another $30 million investment in manufacturing facilities may be necessary. Altogether, a new product may have $70 million of investment riding on it before it gets to market. This is an enormous outlay to make before any returns are achieved from the product.

Once this product gets to market there is no assurance that the product will be a success. Any new product will be competing with a number of well established products for a relatively small market. Indeed, while the R & D costs and process in our industry are similar to the pharmaceutical industry, the global pharmaceutical market is six to seven times larger than ours.

There are only six or seven major crop markets for a pesticide product, and approximately 30 companies engaged in innovative research and development in pesticides in the U.S. compete for these same markets. To make inroads on this market, a new product must provide significant advantages to the farmer. The farmer must be convinced that the product will be more labor saving, more potent, or cover a wider pest spectra than other available products.

Even assuming that a pesticide product is initially successful, the product will face generic competition, typically from a foreign source, just as soon as its patent expires. Our customer is a businessman who is constantly looking for ways to save money in his own business. Thus, if there is a cheaper version of our product on the market there is little likelihood that he will continue to use our product just because he is accustomed to it.

It is not surprising then that the return on investment in the pesticide chemical industry is relatively low. The industry pre-tax margin as a percentage of sales is a modest 15.5%.

Again, to help the Subcommittee place this in perspective, it is useful to compare this figure with the pharmaceutical industry, where R & D risks are commensurate. The pre-tax margin as a percentage of sales turnovers in the pharmaceutical industry is 21.5%.

C. *COSTS AND RISKS OF RESEARCH*

To fully understand the importance of an adequate return on investment to encourage innovation, one must understand just how risky and costly the agrichemical R & D process is. In the pesticide industry almost 2 million chemicals were tested for pesticide potential between 1972 and 1981, with only 80 new chemicals registered as pesticides in that period. As a general rule, a manufacturer can expect that only 1 out of every 12,000 chemicals tested will possess the unique ability to control a target pest without adversely affecting humans or the environment. The increasing number of screening tests required is shown in Graph 2.

The animal health industry is up against comparable odds in its R & D programs; many chemical entities show early promise, but only a tiny fraction of these make it all the way to FDA approval, and the process of attaining that approval consumes an average of more than six years.

The magnitude of research costs can best be illustrated by the costs for a single new product. It generally costs $20

million to $40 million in research for a new pesticide. Some estimates place research and development costs as high as $70 million. By contrast, development of a pesticide in the late 1950's cost well under $1 million. This trend in increasing costs is shown in Graph 3.

Likewise, the time to bring a new product to market has also increased substantially. In the period 1950-60 it took about 2.75 years to develop a new product (from first synthesis to marketing the approved product). This period increased to 4.6 years in the period 1960-1970, 7 years in the period 1965-75, and 10 years today. A recent study by NACA for a nineteen-year period determined that 5-7 years of the process is spent in registering a pesticide, i.e. from initiation of the first major health test until first registration.

D. FEDERAL REGULATORY REQUIREMENTS

A major contributor to these increases in cost and time is the research and testing required by Federal law. No animal drug or pesticide may be marketed in the United States until the manufacturer satisfies either FDA, EPA or U.S.D.A. that the product is both safe and effective.

Our tests to determine safety and efficacy are much more sophisticated, time-consuming and exacting than they were even a decade ago. Today Federal testing requirements under the pesticide and animal drug laws may encompass hundreds, and

sometimes thousands, of individual studies on health and safety effects, chemical residue and environmental fate. Most of these tests are not optional. They are explicitly required by Federal regulations, described in detail, with specified test protocols and laboratory practices. For example, such regulations require tests to determine acute toxic effects through oral, dermal and inhalation exposure, chronic toxic effects such as cancer, birth defects and reproductive harm, and the efficacy of the product. Detailed studies must be made of the possibility of residues remaining on the crop or in the animal, of effects on soil microfauna and microflora, and of possible dangers, either directly or indirectly, to fish, birds and other wildlife.

Many of these tests are quite time-consuming. For example, the minimum acceptable duration for certain chronic feeding and oncogenicity studies required by the EPA is 24 months. When tests to determine acceptable feeding doses, and the time required for data interpretation and report preparation are included, the time required overall for a single test may easily exceed 3 years.

The data from such testing is ultimately submitted to FDA or EPA for review during the final phase of the regulatory review process. It is not surprising that even this stage of the process may take one and a half to two years. The volume and complexity of the scientific data submitted to the government in support of registrations is overwhelming. It is not unusual for

a pesticide or animal drug application to consist of 50 thousand pages. Over 200 scientists, technicians and administrators at EPA and FDA are involved in the review process. These individuals must keep up-to-date in the latest scientific developments in interpreting and evaluating test data. Moreover, not only must these individuals make certain our data satisfies the agency's rigorous scientific criteria, but in addition, they must also be able to satisfy the demands created by a growing public awareness and concern about chemicals.

E. PATENT LIFE LOST TO REGULATION

None of us would want to turn back the clock and deprive ourselves and society of the knowledge our testing capabilities now provide. But we must recognize that as a direct consequence of this testing and review, the time required to bring these products to market has increased dramatically. Consequently patent erosion has become a very serious problem for pesticides, animal health products, and other regulated chemicals.

Examples are numerous. For an animal health product company, a composition patent on a product was granted in November 1975, three months after the initial filing with FDA. Approval of this product has yet to be granted. Ironically, in July 1980 this product was granted FDA's "Fast Track" status for the priority review of New Animal Drug Applications (NADA) for innovative, therapeutically-important new animal drugs. It has

been nearly three years since this drug received fast track status and yet it still remains to be approved. If it were approved today, 8-1/2 years of the product's patent life will have already expired.

A pesticide company lost over seven years on a newly-approved product. Patent protection for this product was received in 1975, the same year the company initiated its first major health study for registration. The company did not receive conditional approval on the product until 1982, and it is awaiting full EPA approval of the product.

In December 1970, an animal drug manufacturer received patent protection for a beef and dairy cattle anthelmintic (for treatment of worms). The application to initiate testing was filed with FDA in July 1970, and more than 11 years later, in October 1981, the product was granted FDA approval. Close to 11 years of patent life have been lost.

F. IMPACT OF PATENT EROSION

The significant erosion of the patent life has made it increasingly difficult for a manufacturer to recoup its substantial investment in a product and to provide an incentive for additional R & D investment. It is not unusual for a successful pesticide to be on the market eight years before it even reaches the breakeven point. The significant erosion of the patent term that now occurs means that the manufacturer can

expect only three to four years of patent protection during which to realize a profit on its product. This is precious little time when one considers the significant initial investment required and the risks that the product may not be successful.

Given this difficulty in recouping the high R & D investment, it is not surprising that many agrichemical companies have curtailed research, terminated new product introductions, and in some cases, even departed the industry altogether. This is easy to understand when one recognizes that investments promising greater returns at less risk compete for the same limited company resources that are directed to agricultural investments.

An additional side-effect has been the loss of incentive to develop pesticide products specifically for use on a minor crop. In order to generate adequate revenues to recover investment costs, a product must target the major crops, such as corn and wheat. If these minor crops have unique pesticidal problems, these problems may simply go unmet.

The same problem exists with regard to animal drugs as well. A shortened patent life makes it is difficult for a company to justify the expenditure to develop a product for use against rarely-occurring diseases in major animal species or for use in a minor food animal species, such as rabbits, goats, ducks, or catfish.

G. NEED FOR PATENT REFORM

Extending patent life to restore the time lost to regulatory delays will provide innovating companies the increased time needed to recover their research investment and make sufficient returns on that investment. This correspondingly will provide sufficient financial incentive to encourage further research on other new regulated products. In a recent survey of the pesticide industry, virtually all companies stated that a favorable patent position was a critical factor in determining whether to invest in new product development. Restoring patent life should contribute substantially to continued long-range research planning and funding on new product development. It would alleviate the inequitable result of federal premarket clearance requirements that deprive the investor of the opportunity for a full patent life compared to research investment in non-regulated products.

H. PROPOSED LEGISLATION

Expanded research on new products will provide increased crop and animal protection options, especially in smaller markets, will enhance competition, and will likely reduce costs to both the farmer and consumer. We believe the Agricultural Patent Reform Act, H.R. 5529, will encourage such expanded research.

H.R. 5529 is very similar to the Kastenmeier patent restoration bill approved by this Subcommittee and the full Judiciary Committee in 1982. Like its predecessor, H.R. 5529 allows the patent holder to restore the patent term by a period equal to the time the patented product spent undergoing regulatory testing and review before it went on the market. We believe this is the most equitable way to compensate the patent holder for the time its product was kept off the market because of Federal regulatory requirements.

Although the bills are substantially similar, there are some significant differences between H.R. 5529 and the prior legislation that warrant some discussion. First, H.R. 5529 does not include human pharmaceuticals. We support patent restoration for pharmaceuticals and expect these products will be included in separate legislation.

The other major differences between H.R. 5529 and the previous bill are generally designed to meet concerns expressed in the debate during the last Congress. For example, H.R. 5529 contains two provisions to make certain that the patent holder exercises due diligence in its testing and regulatory review efforts. First, the bill puts a cap of 5 years on the amount of restoration available. Thus, even if it takes more than 5 years to complete the required testing and regulatory review process, the patent holder will be able to add only an additional five-year period at the end of its normal patent term. This is two

years less than the seven-year cap contained in the prior legislation. Such a cap will most certainly assure due diligence since on average it currently takes 5-7 years to conduct the required testing and agency review. The 5 year restoration, moreover, is equal year for year up to 5 years of the review period during the 10 years after patent application filing and only one-half of each year of the regulatory review period between 10 and 20 years from patent application filing. Thus any unnecessary delays may well result in a restoration period shorter than the actual time of the regulatory review period.

In addition to the cap, H.R. 5529 contains a second provision to assure due diligence. Under H.R. 5529, the restoration period may be reduced by any period during which the patent holder failed to act with due diligence. Due diligence may be raised as a defense in an infringement proceeding, and the court may reduce the restored patent term. Moreover, if the testing or review segments of the regulatory review period exceed certain defined limits, then a suit for declaratory judgment can be brought against the patent holder to reduce the restoration period for lack of due diligence. The declaratory judgment action can be brought at any time during the restoration period or during the one year just prior to it. We believe this is the logical time to permit such challenges because a generic manufacturer's interest in making the product will be sufficient at that time to motivate such suits. If a due diligence

challenge had to be made just after the restoration were granted when a product is newly on the market, it is unlikely that any generic company would be sufficiently interested to bring a challenge then. It is unrealistic to expect a generic manufacturer to know 10 or 12 years in advance whether it has enough of an interest in a patented product to challenge the restoration of the patent term.

Another important feature of H.R. 5529 is that it expressly states that no pesticide may be the subject of more than one patent extension. This provision assures generic manufacturers that a series of patent extensions cannot be used to prolong the patent term on any one product.

A final major feature of H.R. 5529 is that it allows up to three years of patent restoration for products currently undergoing major testing or regulatory review. Of course there will be no restoration for any of the regulatory review or testing that occurred prior to the date of enactment of the legislation, and no restoration for any products already on the market.

Coverage of products currently undergoing regulatory testing or review is equitable, and it is important from an innovation standpoint. The prospect of an eroded patent term is just as inequitable to a manufacturer whose product is already in the testing or review stage as it is to a manufacturer whose research and development efforts have not yet reached such a formal

stage. Furthermore, patent restoration may be just as important to this first manufacturer to provide the incentive to complete the testing and review process, which is lengthy and expensive, and bring the product to market. Within the past 5 years, for example, one major pesticide company terminated at least 4 research and development efforts in process, in part because of insufficient patent life. The company eventually shelved miticide and aphicide candidates after difficult development left them with insufficient proprietary life to justify further expenses.

The same experience occurs in the animal drug industry. Throughout the testing and review process, the sponsoring firm must repeatedly re-evaluate the status of, and prospects for, a product. If it will cost another $500,000 to conduct the additional field trials demanded by FDA -- and the sponsor has already invested $15 million -- and if the sponsor is likely to have only 10 patent term years remaining once approval is granted, will his 10-year sales be sufficient to recover his investment? If not, the only prudent decision may be to abandon the product.

We believe it is significant that this legislation has been endorsed by the major associations representing producers of food animals and crops -- the National Cattlemen's Association, the National Pork Producers Council, the National Broiler Council, American Soybean Association, Cotton Council, and American Farm

Bureau Federation -- as well as by the American Feed Manufacturers Association, National Association of Wheat Growers, the American Veterinary Medical Association, and many more.

It is noteworthy, also, that patent term restoration was recommended to the Congress by its own scientific adjunct, the Office of Technology Assessment, in a February 1984 report entitled Commercial Biotechnology and International Analysis. The White House Office of Science and Technology Policy likewise recommended patent term restoration to enhance the competitiveness of the biotechnology industry. Unquestionably, the products of biotechnology will include new pesticides, animal health products and other chemicals for the betterment of agriculture as well as all mankind. With a restoration of patent term equity, the future of America's agricultural productivity can be bright indeed.

I. CONCLUSION

Patent term erosion has become a significant problem for agricultural and other chemical products. It is extremely inequitable for an inventor to lose effective patent life on a product because the inventor is complying with testing and review requirements imposed by Federal law. Moreover, it is bad public policy to permit patent erosion to continue to undermine the incentive for innovation in an industry whose products are so important to the American consumer. H.R. 5529 addresses the

problem in a balanced and effective manner. We urge its adoption by the Subcommittee and ultimately by the full Congress.

II. H.R. 4525 & H.R. 4527 -- TEAM RESEARCH

We strongly support H.R. 4525 and H.R. 4527, which would adapt the current patent laws to the realities of team research.

H.R. 4525 provides that unpublished information known only within the inventor's organization may not be used to defeat the granting of a patent. This assures that patentability is not sacrificed by the use of team effort to solve a problem.

H.R. 4527 makes clear, moreover, that two or more inventors may obtain a patent jointly even though each inventor has not contributed to every "claim" of the patent. This change complements H.R. 4525. In team research, one inventor often works on a particular aspect of an invention while someone else works on different aspects. It is often difficult or impossible to draft the claims of the patent so that each co-inventor has his contribution recited in each of the claims.

III. H.R. 2610 -- DEFENSIVE PATENTS

Defensive patents should be available for patent applicants through H.R. 2610. Defensive patents for private sector patent applicants would yield savings in patent prosecution expenses for applicants and some savings in examining and appeal expenses for the Patent and Trademark Office. In addition, the defensive

patent option should encourage some applicants to publish their applications for the benefit of the public when the applicants otherwise might maintain their inventions in secret.

IV. H.R. 3462 -- FEES FOR INDEPENDENT INVENTORS

H.R. 3462 should not be enacted unless Congress is willing to appropriate additional funds to cover the revenue loss which would be caused by the bill. Commissioner Mossinghoff has testified that $10 million would be needed. We believe appropriations of this magnitude could be a good investment to help stimulate U.S. research and development, but urge that the committee obtain some assurance that appropriations will be forthcoming before approving the bill. Otherwise, larger corporations will be assessed an even larger tax, as their share of the cost of supporting the Patent and Trademark Office.

V. H.R. 4524 -- FOREIGN FILING LICENSES

We support H.R. 4524. The bill allows supplementary material for a patent application to be filed in a foreign country without a license from the Patent and Trademark Office, provided the supplementary material is an "illustration, exemplification, comparison, or explanation" or subject matter already licensed. The "illustration, exemplification. . ." language is consistent with the licensing requirements for supplementary material recently issued by the U.S. Patent and Trademark Office.

H.R. 4524 also revises the "inadvertence" standard that must be met in order to obtain a license from the Patent and Trademark Office retroactively. The bill substitutes "through error and without deceptive intent". We support this change because it will allow applicants who have failed to comply with the licensing requirements in good faith to obtain a license retroactively, as long as the subject matter sent abroad is not important to national security.

VI. H.R. 3285 & H.R. 3286 -- EMPLOYED INVENTOR RIGHTS

We oppose H.R. 3285 and H.R. 3286. We believe there is no need for the Federal government to legislate in this area.

H.R. 3285 -- relating to compensation -- would fundamentally change the market forces which govern relationships between employers and employees. Employers specially compensate those who do a good job. It is in their company's interest to do so. Federal legislation that would modify this employment relationship is not only unnecessary, it is damaging.

Under H.R. 3285 non-inventor employees would be slighted. The success of an invention in the marketplace depends not only upon the creative effort of the individual inventor, but also upon the efforts of research directors, production engineers, marketing personnel, and others. The employer is best able to judge the relative contributions made by the inventor and other employees. The Federal government should not interfere.

H.R. 3286 would also adversely affect innovation in

industry. Employment agreements are by tradition matters of state law. We have not heard of significant problems of lack of uniformity of state law. If problems should arise, a better solution than Federal legislation would be a model state statute.

VII. H.R. 4528 -- PATENT INTERFERENCES

We support H.R. 4528. It seems to us appropriate to extend an arbitration option to patent interference, as it is now to patent validity and infringement. Arbitration offers a quicker and cheaper alternative to litigation.

VIII. H.R. 3577, H.R. 4526, & H.R. 4814 -- MANUFACTURE OUTSIDE THE UNITED STATES

We support legislation to eliminate loopholes in existing patent law that encourage unauthorized manufacture of U.S. patented inventions outside the United States. The proposals would stop foreign manufacturers from exploiting the research and development expenditures of U.S. companies and would be helpful in providing employment in this country.

We prefer H.R. 4526 or H.R. 4814 over H.R. 3577, however. H.R. 3577 states it will be presumed that a product was made by a patented process if (1) a substantial likelihood exists that the product was produced by the patented process, and (2) the patent owner has exhausted all reasonably available means in the foreign country to establish that the product was made by the patented process. Although we agree that courts should presume in appropriate situations that the product was made by a patented process, we are concerned that the requirement to exhaust

discovery or other procedures abroad could be unduly expensive for patent owners. We believe the presumption should apply whenever the first requirement of H.R. 3577 is satisfied -- namely, whenever a substantial likelihood exists that the product was produced by the patented process.

IX. H.R. 4529 -- LICENSE AGREEMENTS

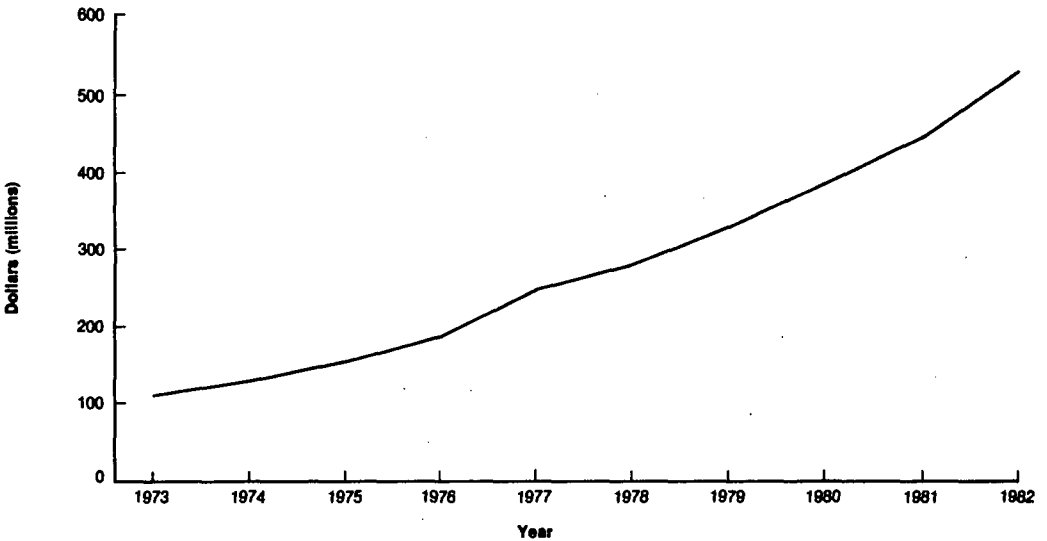
We strongly support H.R. 4529. The bill allows either party to terminate a patent license agreement after the licensee has asserted in court that the patent is invalid. The section also makes the licensee liable for royalties under the agreement until the license has been terminated.

Under existing law, an unscrupulous licensee can negotiate a license on favorable royalty terms and immediately begin litigation on the patent while continuing to enjoy the benefits of the license. The licensee can withhold payment of all royalties during the period of litigation without giving up the license. If the licensee loses, he only has to pay what he agreed to pay in the first place. This manifestly unjust condition should be corrected.


WHERE ARE THE WORLD'S BEST FOOD BARGAINS?
If you are a typical American homemaker, you shop at the nearest supermarket. It's more convenient than spending time and gas driving further in search of food bargains.
But suppose you had a magic carpet which could whisk you away to any supermarket in the world. Price alone could determine where to shop. Then where would you go?
For a pound of boneless sirloin, which costs $3.95 in the U.S., you might go to Paris. But there it would cost $5.14; in Rome, $5.64; Copenhagen, $6.86; Tokyo, $15.75. (Better to buy it at home. (Prices stated prevailed in indicated cities in late 1980.)
Boneless pork roast? It runs $1.66 in Washington, D.C., $1.75 in Ottawa, Canada; $2.12 in Canberra, Australia; $3.32 in Madrid; $3.75 in Rome; $4.31 in Tokyo; $6.45 in Stockholm. American prices are looking good.
A broiler chicken brings 78¢ a pound in Washington; $1.53 in Brussels; $1.87 in Paris; $2.21 in Stockholm; $4.50 in Lagos, Nigeria, if it is available ... and inexplicably, it isn't.
A dozen eggs: up to $2.48 in Stockholm; $3.25 in Lagos. A pound of butter: $3.07 in Buenos Aires; $3.95 in Bern. Margarine: 45¢ in Washington; $1.19 in London. Apples: $1.00 a pound in Paris; $1.28 in Tokyo.
The comparisons go on and on. And what do they say? Leave the magic carpet parked in the garage. The food bargains are right here where you've been shopping all along.
SOVIET UNION
18%
35%
– $8.1 BILLION
UNITED STATES
2%
14%
+ $15 BILLION
FRANCE
10%
19%
+ $.1 BILLION
CHINA
75%
55%
– $2 BILLION
JAPAN
14%
20%
– $13 BILLION
INDIA
65%
50%
+ $.5 BILLION
BRAZIL
40%
37%
+ $6 BILLION
NIGERIA
65%
25%
– $.3 BILLION
AUSTRALIA
6%
16%
+ $5 BILLION
% Population involved in agriculture
Never have so few produced so much for so many. One reason why food prices are lower in America than anywhere else is American farm efficiency. A mere 2% of our population is employed in food production. Modern, mechanized American farms use the most up-to-date agricultural technology. This results in the most production when it means lower per-unit costs to produce, hence, lower per-unit prices to buy. In some countries, backward methods require half the population just to produce food. In China, it's even higher. Chinese farms require three-fourths of the population, and still China must import food to feed its huge population.
% Disposable income spent for food
When all the prices of all foods are added up and compared to total income after taxes, the result is the percentage of disposable income spent for food. In America today, it is 14 percent. That's down from 20 percent in 1960 and 17½ percent in 1970. In relation to other costs, food is getting cheaper. If hamburger had increased in price at the same rate as medical costs since 1940, it would cost $4.20 a pound; if milk had gone up as much as housing, it would cost $2.24 per half gallon. The map shows how the 14 percent figure compares with other countries and explains why we have money left over to support the standard of living which the rest of the world can only envy.
$ Positive food trade balance
When food goes overseas, dollars come home. For almond twenty years, the value of our farm exports has been higher than the value of food imports. (Fish, a cutback in protective food trade (subsidies and penalties) has important benefits for every American. First, it reduces our overall balance of trade deficit, stores planning the dollar so it will buy more. Second, every $1 billion in farm exports creates some 11,700 jobs for U.S. workers on farms, food processing, transportation ... and a second list of industries supplying the first with goods and services.
$ Negative food trade balance
The economic advantages we enjoy as a net food exporter are awesome. In terms of countries which must buy more food than they sell. Those high (retail) prices on Tokyo's small, tear-jerk Japan cannot produce all the meat it needs. So it must pay foreign plant, transportation and harboring costs to get it from exporting countries such as us. Food is a $11 billion drain on the Japanese economy, an $8.1 billion drain on the Russian economy, and so on around the world. And what about quality? Food items pored long distances can hardly compare with fresh products from local farms, such as your local supermarket.

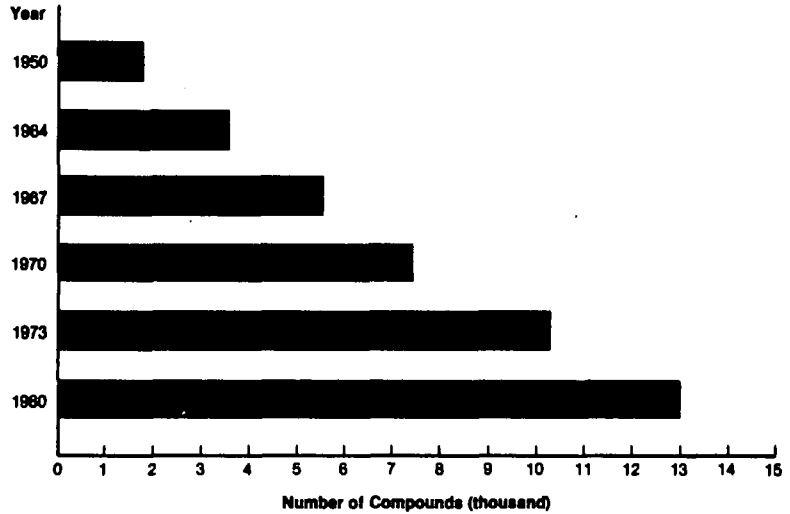
GRAPH 1

TOTAL INDUSTRY PESTICIDE R&D EXPENDITURES
DOMESTIC MANUFACTURERS REPORTING TO NACA
1973 - 1982



SOURCE: National Agricultural Chemicals Association, Industry Profile Surveys.

NUMBER OF COMPOUNDS SCREENED TO OBTAIN ONE COMMERCIAL PESTICIDE SUCCESS



SOURCES: *Farm Chemicals*, April 1978 (C. H. Gilbert).
National Agricultural Chemicals Association, Industry Profile Surveys.

PESTICIDE R&D EXPENDITURES PER NEW CHEMICAL ENTITY
DOMESTIC MANUFACTURERS REPORTING TO NACA
1973 - 1981



SOURCE: National Agricultural Chemicals Association, Industry Profile Surveys.

Mr. BROOKS. Thank you very much. In testimony before this subcommittee last Congress, the National Agricultural Chemical Association, your folks, cited a Conservation Foundation report. Yet that report, page VJ 26, states that patent term legislation would have at least two potential adverse consequences: one, reduce competition; two, reduce incentives for the manufacturers to proceed with speed through the regulatory process. And the report goes on to oppose inclusion, a patent term bill of any substance regulated under, because to do so would encourage submission of data to EPA as close as possible to the time the substance would be marketed, thereby limiting changes of effective EPA review. How do you respond to these comments?

Mr. BRYSON. Mr. Chairman, as you say, the report stated competition might be reduced. But I understand that, on balance, the report recommended passage of patent term restoration to restore equity in the patent law.

This report is making a key assumption, which is that the period of patent exclusivity is noncompetitive. We don't think that is very reflective of today's marketplace.

This is a very competitive industry. If you look at certain segments, for example, let's say a fungicide or herbicide segment, this report is implying that patent exclusivity basically precludes the competitive factor in the marketplace. We know today that existing products that are patented and generic products do compete very effectively in this marketplace.

Mr. BROOKS. You assume that only about a third of the agricultural chemical companies are based in the United States, one-third of them. How will passage of this bill affect American innovation and/or our balance of trade?

Mr. BRYSON. That is a tough question, Mr. Chairman. History shows that if you look at the markets around the world, companies tend to do best in their home market in terms of market share. Obviously, ours is the largest market in the world. To a certain extent U.S. companies are disadvantaged in the U.S. marketplace today because the regulatory process here is generally more time consuming. Therefore, the economic return on investment in research and development comes much slower in this country than in other major developed countries. Japan may be an exception, but other than rice, Japan is not a particularly large market. Our perception is, since this legislation will improve the economics of this industry, it should enable American companies to compete better. Whether it will ultimately change the number of American companies competing in this industry is hard to tell. But as you say, foreign based companies are very, very important in the agriculture chemicals industry.

Mr. BROOKS. I have three or four other questions——

Mr. BRYSON. I'm sorry, Mr. Chairman. Could I add one comment?

Mr. BROOKS. Sure, go ahead.

Mr. BRYSON. There are really two other aspects to that that I think are important.

Mr. BROOKS. I kind of wish you would. I wasn't really, you know, ecstatic about that one.

Mr. BRYSON. Fair enough.

I think it is also very important—you are asking me to predict what is likely to happen in terms of the number of companies that are going to be in this business after this legislation is enacted.

Mr. BROOKS. We are working so hard for it. You are going to get the benefit or two-thirds of the other manufacturers throughout the other part of the world going to get the benefit? This is the factor, you know. Why are we going through this exercise? We don't have but a third of the take.

Mr. BRYSON. I am not sure. I am not sure whether a third in this case represents a number of companies, or represent American companies' dollar share of the worldwide market.

Mr. BROOKS. Semantics, all right.

Mr. BRYSON. I think American companies' share of the worldwide market would be much bigger than one-third.

I don't have the exact numbers, but we could submit that for the record.

I do think, though, the other thing that is very important here is that encouraging research and development is very critical to us maintaining an indigenous research and development capability in this country. And this legislation will hopefully encourage further investment in agricultural technology. As it pertains to agricultural exports, in all honesty I don't know the exact amount of agricultural, chemical, and animal drug exports from the United States. The thing that is very important to this economy, as I am sure you recognize, is that although it has declined in the last 2 or 3 years, we still have a positive trade balance in agricultural exports of about $35 billion, almost half of our negative trade balance in our oil import bill. And to the extent that improved agricultural technology enhances the American farmer's ability to compete effectively in the worldwide agricultural markets, this bill could be very, very beneficial to the American farmer, the American consumer, the balance of payments, and hopefully to American jobs as well.

Mr. BROOKS. Why should toxic substances be granted an extension of patent life when the Government review period is only 90 or 180 days?

Mr. SAEGEBARTH. I would like to respond to that and maybe make some comments to the earlier question.

From the standpoint of the patent extension, I believe this will stimulate competition, and it will do some other things for this country in that it will open up market opportunities to the manufacturer that they might not otherwise consider. Your example of the bark beetles is an east Texas loblolly problem, isn't it?

Mr. BROOKS. Loblolly or slash.

Mr. SAEGEBARTH. As for the incentive to address that market, the only way we are going to touch it now is if the material we find that controls the bark beetles also has applications in a very major market, so that with the longer period of time to be able to fund our research, we would be addressing those applications.

Now, as to the question that you asked about TSCA and why these materials or TSCA regulated materials should be included: First, they are key intermediates to our agricultural chemicals. And so, if it takes 180 days, we would like to get those 180 days.

Also TSCA regulates many chemicals used in packaging food that the farmer raises. Therefore, some TSCA-regulated materials may also fall under FDA regulation.

Lastly, EPA has for some time been considering some regulation requiring testing which could possibly extend this period.

Mr. BROOKS. All right.

Mr. GLICKMAN. I ask unanimous consent to submit a few questions to you, Mr. Bryson. I have four or five other questions you can answer for the record if you would.

Mr. BROOKS. Mr. Glickman.

Mr. GLICKMAN. Thank you, Mr. Chairman.

In the first place, I want to thank you for excellent testimony and would ask you—the Environmental Protection Agency has written a letter to Chairman Kastenmeier dated May 24, basically in support of this legislation, but offering a variety of changes, most of which I consider to be fairly technical. Have you had a chance to review that letter and those proposed changes to the bill?

Mr. BRYSON. Yes.

Mr. GLICKMAN. Do you have any comments on their recommendations?

Mr. BRYSON. May I defer to the scientist in our group, please?

Mr. GLICKMAN. Sure.

Mr. SAEGEBARTH. In 90 percent of the cases where the agricultural regulatory process is concerned the initial triggering is by actual testing. We then submit an application for an experimental use permit, which includes those tests we have already conducted and an actual protocol of tests that are done by Government prescription. There is a constant sense of urgency in this business; being there first with the best mouse trap is the best thing for us and for the consumer. Now, by the time of this application for the experimental use with the early testing, we have made a commitment of around $1 million of testing that will go on. Once you start that, I think it is pretty obvious that we are pretty darn serious.

There is also the matter of the other 10 percent that doesn't fall into this category, and we, with the committee and the EPA, would be very happy to develop suitable language to handle that.

Mr. GLICKMAN. Well, specifically, their comment number two has to do with the commencement of the regulatory review period for determining the amount of patent term restoration. That seems to be their key comment. And the bill provides the period should begin with the filing of a request for a grant of an experimental user permit. They say the agency is concerned that parties seeking restoration rights may have an incentive to submit incomplete questions, applications, or notices earlier to extend the period of eligibility. Then they offer after that a variety of proposed changes. Do you have problems with the proposed changes they talk about?

Mr. SAEGEBARTH. I guess my point is that it is, I think, highly unlikely for this industry to submit incomplete data, because in doing so the regulatory delays will be extended. Our objective is to get into the marketplace as rapidly as possible. Right now there are materials in the EUP stage where, while my company may have a patent, three or four other companies are also developing products with similar applications. They are not totally interchangeable, but they are competitive with each other. So what we

want to do is get there first to establish ourselves, and convince the grower that our material has merit, and we will live by the merit.

Mr. GLICKMAN. What I suggest, maybe, is you review their comments and maybe respond in writing as to each of these things where you might agree or might not agree and deal with the problems they present.

Mr. SAEGEBARTH. We shall do that.

Mr. GLICKMAN. As long as they are generally supportive, I would like concurrence all the way through.

Mr. SAEGEBARTH. Could I make one comment about that, though?

Mr. GLICKMAN. Sure.

Mr. BRYSON. I think in many ways some of EPA's concerns are also addressed by the due diligence provision. I do think as a businessman, not a scientist, it is inconceivable that a company would intentionally delay the regulatory process by submitting incomplete or inadequate data. Any time value-of-money analysis would show it is not a very good decision, if your payback is going to come 5, 8, 10 years from now. Consider the diligence provision with a 5-year cap. Whenever you submit incomplete data, you are starting the clock; so a 5-year cap is one provision by which I think companies will be discouraged from submitting inadequate data.

In addition, there is a provision of this bill allowing a court challenge. This enables somebody at a later date to come back and question whether or not the companies were properly diligent.

Mr. GLICKMAN. I think that is a good point, to determine whether the due diligence issue encompasses the questions EPA has raised. But I would like to get a consensus with the EPA before the bill moves.

Mr. BRYSON. Agreed.

Mr. GLICKMAN. The second thing concerns the Waxman bill. We don't know what, if any, bill is actually going to be dropped in by Congressman Waxman on the issue of human pharmaceuticals. But Congressman Waxman treats animal drugs differently, I think, than human drugs in his proposed bill. Do you have any idea what the differences are between that bill and this one, how they differ, and how they differ generically—that is probably the wrong term to use—but in the way that they are handled at the FDA?

Mr. BRYSON. Let me first say that we are not part of the negotiations with Congressman Waxman. Even the animal health industry is not taking part in the negotiations with Mr. Waxman on this legislation. Therefore, we haven't seen the latest draft. As we understand it, though, this bill is a delicately balanced compromise between the consumer groups, research-and-development-oriented pharmaceutical companies, and generic drug producers.

The animal drug provision in the draft I saw a while back did not distinguish in any great way in terms of patent restoration coverage between animal drugs and human pharmaceuticals. The animal drug portion is really a fallout of that negotiation. Again, we weren't party to it. I will say, though, that from our information—which may be out of date—it appears that the patent restoration period available for animal drugs would be somewhere between 2 and 3 years. Our feeling is that this would be very insufficient to restore the research incentive we are trying to accomplish with this particular bill.

Finally, I think maybe the most cogent point is in contrast to the proposals on the pharmaceutical side. We do have the support of our customers on the animal side. Many of the associations I mentioned are basically customers of the animal drug industry and they strongly support H.R. 5529.

Mr. GLICKMAN. Two quick questions. Are there any spinoffs in the development of human drugs from animal drug research?

Mr. BRYSON. I am not sure we have the adequate person here, but I am sure in the early process, compounds are probably screened, for companies that have both lines of business, for pharmaceutical activity or animal productivity, and maybe even agrichemical activity, if appropriate. So, I would say early on in the research process, there is probably some synergy in the basic research effort. But that is long before you ever begin the initial regulatory process that would essentially be covered by patent term restoration. Finally, I wanted to say that at the end of our longer testimony we do have some statistics about the percentage of basic research and development as a percentage of expenditures generally, in terms of both the aggregate industry as well as potential specific products.

Mr. GLICKMAN. I would like to ask your scientist, are you finding it more and more difficult to develop efficacious pesticides, as perhaps bacteria are more resistant to the development of the pesticides on the market today? Is it becoming more difficult to develop pesticides which are resistant to bacteria and disease?

From the standpoint of extending the patent period, my farmers are naturally concerned. I don't have the bark bettle problem, but I have other problems with respect to—we have had a lot of rain this year, and wheat has been particularly resistant to bugs, bacteria, and the like. And my farmers as well as a lot of my people at Kansas State University tell me that a lot of the products on the market today don't work as well as they did 10, 15, 20 years ago because of the bacteria being more resistant. They think it has very dangerous consequences the next 15, 20 years unless we are moving ahead of that process and developing more efficacious drugs.

Mr. SAEGEBARTH. You are absolutely correct. There are many examples. We have a product, "Lannate," which is an insecticide, primarily used on cotton. With time, the boll weevil developed resistance. This is really a biological mutation of that weevil that can survive under the new conditions.

With the corn root worm, the product of choice is "Furadan," not my company's product. In time, the bacteria in the soil have learned how to literally live off that material. So instead of the insecticide being there, it is being consumed in another fashion.

There is also another trend—and I know the Secretary of Agriculture is having a conference on this in October—toward no-till or limited-till farming, a discrete change over the past 10 years, so that you are planting literally in the stubble and debris that is left on that field. This presents an entirely new array of pest problems. In west Texas, there are infestations of literally a perennial array in wheat fields. If you do not control that, the farmer will decrease his yield and get insubstantial revenue for his product because it's got trash in it. We are working very actively and have a product to

solve that problem. So that literally what nature is doing for us is presenting us new and probably far more sophisticated challenges than we have had in the past.

Mr. BRYSON. There is also a USDA study looking at the batting average for discovering a safe and efficacious pesticide. In the 1960's it was one in the low thousands. We are now in the range of one in every 12,000. They are forecasting in the early eighties, it is going to be one in 20,000 to clear the hurdle; they are saying one in 80,000 by the end of the decade. That is one more reason to provide the right incentive to do the research necessary to control these disease problems.

Mr. SAEGEBARTH. This one in 12,000, I believe, is a 1980 figure. In 1984, it is probably approaching 20,000. One approach we are discussing, which takes a substantial amount of up-front money, is to use the modern biology and biotechnology that you all read about in the Wall Street Journal and the New York Times, in order to approach this from a directed solution.

In other words, if you are going to attack the corn root worm, how do you attack it in a biological fashion, understanding his growth mechanism which is different than that of a human being, so that you cannot rely on doing that kind of work in human health sciences that must be supported by this industry? Here we are talking of payouts 15 or 20 years away, because all the chips aren't on the table yet. So there is a learning process.

Mr. GLICKMAN. Thank you, Mr. Chairman.

Mr. BROOKS. Thank you Mr. Glickman. Mr. Hyde.

Mr. HYDE. Well, I just want to say that you couldn't get better sponsors than Mr. Glickman or Mr. DeWine for this salutory legislation. Luckily, you don't have to fight the political opposition of the generic drug industry, who opposes this sort of legislation. I think there are so many benefits to protecting the patent holder during the testing period which can be increasingly complex as we get the agent orange syndrome pervading our society. And so we need to develop new and better agricultural chemicals, and we need the incentives to do so. This is certainly one. So I support the legislation, and I congratulate you on your testimony. Thank you.

Mr. BRYSON. Thank you, Mr. Hyde.

Mr. BROOKS. Thank you. Mr. Mazzoli?

Mr. MAZZOLI. Mr. Chairman, I have no questions. I came in late and apologize. It is interesting testimony.

My general disposition, because of my fondness for the gentleman from Kansas and knowing his olympic knowledge of things agricultural, to probably support his view in this thing; and my fondness for the gentleman from Ohio whose olympian knowledge I am not quite as familiar with but——

Mr. BROOKS. Mr. DeWine.

Mr. HYDE. It is Periclean.

Mr. MAZZOLI. I think I will stop while I am ahead. No questions, Mr. Chairman.

Mr. BROOKS. Mr. Sawyer.

Mr. SAWYER. Thank you, Mr. Chairman. I am strongly in support of the legislation. I pushed a bill in the last Congress that included this subject matter plus unfortunately pharmaceuticals, which ran on the reef over in Waxman's committee, and hasn't come out yet.

So this one hopefully will avoid that problem. But it hasn't made any sense to me that we give a toy in effect 17 years of patent protection, whereas a life-saving drug or very critical agricultural chemical or other chemical projects, maybe as low as 8 or 9 years when you get finished with the regulatory process. I, too, am fond of both Mr. DeWine and Mr. Glickman, which would be good reason standing alone to support it. I don't know about immigration bills, but——

Mr. MAZZOLI. Different subject.

Mr. SAWYER. I yield back, Mr. Chairman.

Mr. BROOKS. Thank you, Mr. Sawyer. I want to thank you all very much, gentlemen, for coming in. The committee will continue its evaluation of this matter. You know that the hearing is still considering patent term. It may include other than for those substances with which you are so vitally concerned.

Mr. BRYSON. Well, Mr. Chairman, we obviously believe, as Mr. Sawyer said, "that the fundamental principles do apply to other product categories." We are not really opposed to the Waxman compromise. We do feel that animal drugs are treated more equitably under H.R. 5529, and we think that is justifiable. Thank you for your consideration.

Mr. BROOKS. Thank you very much. The subcommittee is adjourned.

[Whereupon, at 11 a.m., the subcommittee was adjourned.]

NATIONAL ARBORIST ASSOCIATION, INC.

1400 WANTAGH AVENUE, SUITE 207, WANTAGH, NEW YORK 11793 • TELEPHONE (516) 221-3082

ROBERT FELIX
Executive Vice President

May 30, 1984

The Honorable Robert W. Kastenmeier
House of Representatives
Washington, D.C. 20515

Dear Congressman Kastenmeier:

The National Arborist Association urges positive action on H.R. 5929, the Agricultural Patent Reform Act.

Although the trees, shrubs and lawns of the urban environment are considered part of horticulture, those chemicals that are needed to preserve this important segment of our environment are generally agricultural chemicals. Therefore, preservation of our ability to have such materials available to us is, obviously, very important.

We hope you will give this every consideration.

Yours truly,

NATIONAL ARBORIST ASSOCIATION, INC.

Robert Felix
Executive Vice President

RF/db
cc: Robert Mullane
Neil Engledow
Jack D. Early
Congressman Dan Glickman
Congressman Michael DeWine

DB AR.

CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

ALBERT D. BOURLAND
VICE PRESIDENT
CONGRESSIONAL AND POLITICAL AFFAIRS

1615 H STREET, N.W.
WASHINGTON, D.C. 20062
202/463-5600

June 12, 1984

The Honorable Robert W. Kastenmeier, Chairman
Subcommittee on Courts, Civil Liberties and the
Administration of Justice
Committee on Judiciary
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

On behalf of the Chamber of Commerce of the United States, I appreciate the opportunity to support H.R. 5529, the Agricultural Patent Reform Act of 1984.

In instances where patented products are subject to review by a regulatory agency prior to the marketing of the product, any term of the patent lost, due to testing required to meet the regulatory standards and the period of regulatory review, should be restored to the patent owner. Restoration of an adequate patent term is an essential incentive to assure private investment in research and commercial development of new products.

H.R. 5529 addresses this issue as it relates to agriculture by restoring up to five years of patent life lost during premarket testing and review of pesticides, veterinary medicines, biological substances, and related agricultural chemicals. The bill does not extend to human pharmaceuticals.

Patents on agricultural chemicals and veterinary medicines are granted and begin to expire long before the federal government approves them for sale. A new pesticide product, for example, typically takes seven years and $40 million to bring to market. This means seven years lost from the 17-year patent life before the first sale is made and before the firm can begin to recoup its investment and reinvest in new product research and development.

(over)

Lost patent life is unfair to investors who discover new agricultural chemicals. But it also is unfair to farmers, ranchers, the food industry and consumers. Lost patent life reduces incentives to invest in agricultural research, retards the rate of agricultural innovation, raises the cost of food and fiber at home and erodes the international competitiveness of America's largest export industry.

The Agricultural Patent Reform Act will do much to remedy this situation. By restoring a portion (up to five years) of the patent life lost during the government approval process, the Act could put agricultural research investment back on a competitive footing with investment in other forms of innovation. It would accelerate the flow of new products, and it would help assure the vigor of an industry which must survive in highly competitive world markets.

Modern agriculture is a highly technological industry, increasingly dependent upon the steady flow of safe and effective pesticides, animal drugs and other agricultural chemicals. Exciting new biotechnologies and genetically engineered products will help assure agriculture's place at the forefront of innovation. Some of these promising new products may require more extensive and time consuming premarket testing than current pesticides and animal drugs. Consequently, patent term restoration is especially needed to stimulate research in these new technologies, to accelerate innovation, and to assure the enormous benefits of commercial application.

I will appreciate your consideration of our views and inclusion of this letter in the hearings record.

Sincerely,

Albert D. Bourland

cc: Subcommittee Members
Michael Remington, Majority Staff Director
Thomas E. Mooney, Minority Staff Director

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D. C. 20250

JUN 6 1984

The Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts, Civil
Liberties and the Administration of Justice
Committee on the Judiciary
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your request for our views on H.R. 5529, a bill "To amend the patent law to restore the term of the patent grant in the case of certain products for the time of the regulatory review period preventing the marketing of a product claimed in a patent."

The U. S. Department of Agriculture supports enactment of H.R. 5529.

Under the bill, the term of a patent would be extended for inventions pertaining to certain agricultural chemicals, toxic substances and animal drugs. More specifically, a patent's life would be extended beyond the standard seventeen years to compensate the patent owner for the period of time required under the regulatory review process to obtain approval to manufacture, use or sell the patented invention. We favor the bill because the patent extension provides additional incentive to private industry for the investment of risk capital and expenditures to develop new agriculturally-related inventions and bring such technology to practical application.

The Office of Management and Budget advises that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

Richard E. Lyng

Richard E. Lyng
Deputy Secretary

Acting

SECRETARY

NATIONAL PORK
Producers Council

WASHINGTON OFFICE: 1015 FIFTEENTH STREET, N.W., WASHINGTON, D.C. 20005
PHONE 202-347-0911

NATIONAL HEADQUARTERS: P.O. BOX 10383, DES MOINES, IOWA 50306
PHONE 515-223-2600

June 4, 1984

The Committee on the Judiciary
c/o Mr. Michael Remington
2137 Rayburn House Office Building
Washington, D.C. 20515

Statement by the National Pork Producers Council (NPPC)
submitted to the U.S. House of Representatives
Committee on the Judiciary
Sub-committee on Courts
(Civil Liberties and the Administration of Justice)
by Doyle Talkington, Administrator of Government Affairs
for the hearing record on the Agricultural Patent Reform Act -
HR-5529

The National Pork Producers Council represents over 100,000 members in the 38 affiliated states and is the largest commodity organization in the nation with an identified membership. NPPC is a grass roots organization, with every producer, regardless of size, having a voice in policy-making through a state-elected delegates system.

The NPPC appreciates the opportunity to submit our comments on HR-5529, a bill that NPPC believes will benefit consumers by producing healthier and more nutritious products at a more reasonable price. The development of new and improved agricultural chemicals and animal drugs will also benefit our nations' producers by allowing them to produce food more economically. Companies must have adequate incentives to procede with the expensive and long term process of developing new products for consumers. Adequate patent life is very important to encourage research so agriculture technology can advance to meet the needs of farmers; who in turn will produce better and more economical food for consumers.

Our U.S. companies must stay competitive with foreign competition to help our economy grow stronger.

Our producers lose millions of dollars each year to animal diseases. Livestock producers are over burdened with debt, and safe new animal drugs are most welcomed by our livestock producers.

NPPC supports HR-5529 extending the life of agriculture patents by five years so companies will have a greater incentive to do research and development; and agriculture producers will produce more food that benefits consumers.

Thank you for allowing us to present our statements for the record.

Doyle Talkington
Administrator of
Government Affairs

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The Honorable Peter W. Rodino, Jr.
Chairman, Committee on the Judiciary
House of Representatives
Washington D.C. 20515

Dear Mr. Chairman:

There is pending before your Committee H.R. 6034, the "Agricultural Patent Reform Act of 1984". The Environmental Protection Agency (EPA) has been monitoring the progress of this bill as it has made its way to the full Committee. While EPA supports the equitable notion of patent term restoration, we do have serious concerns about §156(b)(1)(C), the "due diligence" portion of the bill, which we would like to bring to your attention.

Due Diligence

Section 156(b)(1)(C) would require the Administrator of the EPA to "determine if the product sponsor acted with due diligence during the applicable regulatory review period". Any interested party would then be free to request a hearing to take exception to the Administrator's determination.

EPA recommends that the provisions related to due diligence be deleted. EPA believes that the determination of due diligence and the hearings that would follow would require the Agency to expend additional resources on a new issue that is not related to the protection of public health. Further, it would force the Agency to use its attorneys on patent related issues rather than on environmental enforcement.

The Office of Management and Budget has advised that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

Josephine S. Cooper
Assistant Administrator
for External Affairs

MAY 24 1984

Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts
Civil Liberties and the
Administration of Justice
U.S. House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

I am writing in response to your letter of May 2, 1984 requesting the comments of the Environmental Protection Agency (EPA) on H.R. 5529, the "Agricultural Patent Reform Act of 1984." The Agricultural Patent Reform Act of 1984 would restore the term of the patent grant, in the case of certain products, for the time a regulatory review period prevented the marketing of the product.

The EPA has historically supported the notion of patent term extensions (or patent term restoration) for products regulated under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). It is clear that several years of patent life are lost to a manufacturer while the appropriate clearances are being obtained. Therefore, we support the equitable notion of extending a patent's term for a time proportionate to the regulatory review period.

The Agency does, however, have several comments concerning the proposed legislation that we would like to bring to your attention. Those comments are enclosed.

The Office of Management and Budget has advised us that there is no objection to the submission of this report from the standpoint of the President's programs.

Sincerely,

Josephine S. Cooper
Assistant Administrator
for External Affairs

Enclosure

Comments of the
Environmental Protection Agency on H.R. 5529
"Agricultural Patent Reform Act of 1984"

1. Our first comment relates to the title of the bill, "Agricultural Patent Reform Act of 1984." This title is misleading in that the bill potentially affects hundreds of new industrial chemicals regulated under the Toxic Substances Control Act which have nothing to do with agriculture. We suggest the following title: "Agricultural and Industrial Chemicals Patent Reform Act of 1984."

2. The second comment relates to the commencement of the "regulatory review period" for determining the amount of patent term restoration. For purposes of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), §156(d)(5)(B) of the bill provides that the period could begin with the filing of a request for the grant of an experimental use permit or with the filing of an application for registration. For purposes of the Toxic Substances Control Act (TSCA), §156(d)(5)(C) of the bill provides that the period could begin with the filing of a notice under section 5(a) of TSCA. The Agency is concerned that parties seeking restoration rights may have an incentive to submit incomplete requests, applications, or notices earlier to extend the period of eligibility for restoration to the maximum allowed. Under this circumstance, the Agency would be burdened with these incomplete submissions and with extra, unnecessary work. Therefore, the Agency suggests that the following changes be made to clarify that the commencement of the regulatory review period in such circumstances is contingent upon the Agency's determination that the submission is valid and complete:

(a) In §155(d)(5)(B)(i), on page 11, line 13, after "Act" delete the comma and insert the following: "and such request is judged to be acceptable for review under applicable rules,"

(b) In §155(d)(5)(B)(ii), on page 11, line 20, after "Act" insert the following: "and such application is judged to be acceptable for review under applicable rules,"

(c) In §155(d)(5)(C)(ii), on page 12, lines 18 and 19, delete the current language and insert the following: "submits a notice under section 5(a) of such Act and the notice is judged to be complete under applicable rules,"

3. Under section 5(a) of TSCA, there are two types of notices submitted--premanufacture notices for new chemical substances and significant new use notices for substances subject to significant new use rules. Accordingly, we recommend that the references to "premanufacture notice" be revised by deleting the term "premanufacture" wherever it appears in §155(d)(5)(c): page 12, lines 8, 18, and 23.

4. The bill would provide patent restoration for products subject to regulatory review under section 5(a) of TSCA. Section 5(a) of TSCA applies only to chemical substances, not to mixtures. Accordingly, we recommend that §155(d)(5)(C) be changed by deleting the phrase "or mixture" wherever it appears: page 11, line 24, and page 12, lines 9 - 10, 22, and 25.

5. We suggest modifying the definition of "major health or environmental effects test" in §155(d)(2) of the bill by inserting after the word "experiment" on page 9, line 15, the words "or study" to recognize the fact that in some cases a study of existing information is undertaken rather than a specific test (e.g. an epidemiological study). Appropriate legislative history language could be incorporated as an alternative to indicate a broad meaning for the words "test" and "experiment."

6. With respect to FIFRA, §155(a)(2)(D) of the bill states that all formulations of a pesticide "containing the identical active ingredient shall be considered the same pesticide and no pesticide may be the subject of more than one patent extension." This provision apparently is intended to limit patent extension for pesticides which contain the same active ingredient. However, the wording of the paragraph is ambiguous. Some pesticide formulations contain more than one active ingredient. For example, active ingredient A might occur in formulations both by itself and in conjunction with other active ingredients such as A and B, A and C, and A and D. Under the bill it is not clear whether, if active ingredient A had been the subject of a regulatory review, formulations of A with other active ingredients, such as B, C, and D, would be considered the same pesticide. If that is the intention of the bill, we recommend changing page 5, line 15, to read: "pesticide containing an identical active ingredient shall be...." If the opposite is intended, we recommend changing page 5, line 15, to read: "pesticide containing identical active ingredients shall be...."

IPO INTELLECTUAL PROPERTY OWNERS, INC.

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July 24, 1984

The Honorable Robert W. Kastenmeier
Chairman
Judiciary Subcommittee on Courts, Civil
Liberties and the Administration of Justice
U. S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

I am writing on behalf of Intellectual Property Owners, Inc. in support of H. R. 5529, the "Agricultural Patent Reform Act of 1984."

IPO is a nonprofit association whose members own patents, trademarks and copyrights. Our members include large corporations, small businesses, universities, and individuals. Our members include companies from most of the major fields in American industry.

We believe 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 patent term.

H. R. 5529 would extend the terms of patents in the agricultural chemical and animal drug fields to compensate patent owners for delays during regulatory review prior to marketing. The effect which federal regulatory review has had on patent life was never foreseen or intended by the Congress.

IPO believes H. R. 5529 would encourage research and development in the agricultural chemical and animal drug industries, and would have a positive influence on competition. 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 prompt enactment of H. R. 5529, either as separate legislation or in combination with appropriate legislation for restoring patent terms for pharmaceuticals.

Sincerely,

Donald W. Banner
President

DWB/111

cc: Hon. Howard L. Berman
Hon. Jack Brooks
Hon. Michael DeWine
Hon. Barney Frank
Hon. Dan Glickman
Hon. Henry J. Hyde
Hon. Thomas N. Kindness
Hon. Romano L. Mazzoli
Hon. Carlos J. Moorhead
Hon. Bruce A. Morrison
Hon. Harold S. Sawyer
Hon. Patricia Schroeder
Hon. Mike Synar



Congressman Robert W. Kastenmeier
Rayburn House Office Building
Room 2232
Washington, D.C. 20515

July 12, 1984

RE: Patent Term Restoration Act, HR 3605

Dear Congressman Kastenmeier:

Agrigenetics Corporation is a leading plant science and genetic research company. Our Jacques Seed Division headquartered in Prescott, Wisconsin is one of the nation's successful hybrid seed operations, and our Advanced Research Division Laboratory in Madison, Wisconsin is surely one of the world's outstanding centers for innovative research in plant molecular biology.

Since the value of medicinally active molecules from plant sources is universally recognized, the research programs currently underway at Agrigenetics, particularly at our Madison laboratories, not only promise benefits in the realm of crop agriculture, but also in the area of human pharmaceuticals. The emerging ability to target novel molecular arrangements of therapeutic significance which are also the products of plant genes is an exciting scientific frontier. The expression and utilization of such plant genes in fermentation systems, for example, is an apt illustration of how our strong research investment in plant molecular biology could provide novel pharmaceutical products valuable to human health and healing. We therefore have a direct interest in HR 3605 which is now before you. We are familiar with your desire to preserve American technological leadership and your appreciation that enterprises engaged in technological innovation and the creation of new products depend heavily on an equitable and effective patent system.

The genius of our patent system provides a limited period of proprietary exclusivity for useful innovative products, affording innovators a worthwhile reward on research investments, and providing an incentive to undertake the substantial risks inherent in any pioneering venture. Agrigenetics believes that the 17-year period of exclusivity provided by the patent statute should be enjoyed, in a practical sense, by all patentees, whether their inventions are mechanical, chemical, electrical or pharmaceutical in nature. We therefore support the restoration to pharmaceutical patent holders of the period of exclusivity not actually realized due to regulations governing extensive pre-market clearance. Section 202 of the Bill however, seeks to assist generic drug manufacturers by permitting them to intrude upon an issued patent for the purpose of obtaining advantageous pre-market clearance for their own versions of patented pharmaceuticals. This section not only makes in-roads on the extended period of exclusivity but also on patents whose period of exclusivity was not extended. Section 202, therefore, has the effect of diminishing the period of exclusivity enjoyed by pharmaceutical patentees and represents a serious erosion of our intellectual properly system.

3375 MITCHELL LANE, BOULDER, COLORADO, U.S.A. 80301 -2244 TEL: 303-443-5900 TELEX: 450188

The process of discovering, developing, and introducing new products involves great risks and high costs. Substantial amounts must be invested in research whose results cannot always be predicted and which often fails to yield marketable products. In addition to the high inherent costs of an enterprise based upon discovery and innovation, there are the substantial costs imposed by government action including regulatory reviews, pre-market clearance proceedings, as well as the normal costs of testing for efficacy, reproducibility, and suitability for consumers' needs. In addition, the costs of obtaining, enforcing and defending patent rights are, in some cases, enormous. Any government action which increases the financial burdens and diminishes the degree of protection afforded by patent rights necessarily raises the cost of innovation, and decreases the opportunity to profit from it. Frankly, it has a "chilling effect" on our propensity to invest in certain lines of research. Such action creates substantial disadvantages both to the public and to young companies, such as Agrigenetics, engaged in research and development. Changing the risk-reward ratios of our social and economic system should involve a far-sighted understanding of the repercussions.

On balance, we believe that Section 202 of HR 3605 has greater potential for harm to the public interest and to the country's innovative strength than any potential value to be gained by protecting the interests of generic drug manufacturers. The latter are neither innovators nor risk takers and are, therefore, in principle, neither benefited nor harmed by the patent system except as it protects the innovations of others. We would, therefore, recommend that, in general, the recommendations of Commissioner Mossinghoff be adopted, and in particular that Section 202 of HR 3605 be deleted.

The next time you are in your home district with time to spare, we would be proud and delighted to give you an extended tour of our Advanced Research Division laboratory and a tangible insight to the points outlined above.

Sincerely,

David Padwa
Chairman

DP/kw

RECEIVED
AUG 7 1984
JUDICIARY COMMITTEE

August 7, 1984

The Honorable Peter W. Rodino
Room 2462 Rayburn
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Rodino:

The National Audubon Society and the Sierra Club urge you to vote against H.R. 6034, The Agricultural Patent Reform Act of 1984, as it comes to the full judiciary committee for mark up on Wednesday, August 8, 1984.

The original purpose of this legislation was to extend patent terms for pesticides and animal drugs in compensation for time spent on tests required by regulatory agencies prior to commercial marketing of patented compounds. H.R. 6034 however, virtually grants automatic patent extension of eight years, for a total of 25 years of patent life for pesticides, toxic substances, animal drugs, and DNA products (despite the lack of a regulatory apparatus or statutory framework for the latter).

H.R. 6034 contains no assurance as to the quality of tests for which a patent extension is given. Moreover, the patent extension relies on a showing of "due diligence" by the patentee. That showing is only what "may reasonably be expected from, and ordinarily exercised by" the patentee during the regulatory review period. High standards of performance have not been "ordinarily exercised" in a large percentage of studies submitted to EPA over the past decade. Finally, H.R. 6034 only requires the patentee to certify that the regulatory review period has ended, and not that registration requirements have been met in full.

As H.R. 6034 moved from subcommittee to full committee, the only changes that were allowed to be put into the legislation were those that industry approved. Close examination revealed that new language put in by proponents of the legislation would not only have unravelled the Supreme Court decision on data disclosure of June 26, 1984 , it posed jurisdictional threats to other committees. Corrective language was drawn up and will be offered in mark up on Wednesday as an "environmental" amendment. However, the prohibition on disclosure should never have been allowed in the legislation in the first place. Corrective amendments have not added environmental benefits.

Environmental amendments should be included, and they should address the quality of studies conducted by companies and provide the public at large with greater confidence in an agency notoriously lax in registration approvals. The Waxman food safety bill, H.R. 5495, would amend the Food Drug and Cosmetic Act by requiring adequate testing prior to allowing residues on food and provides for a process of revocation for tolerances regarded as an imminent hazard to the public.

The organizations signing below therefore ask that you vote against H.R. 6034 unless a commitment is made in the committee mark up to join the substance of H.R. 5495 (Waxman's food safety bill) to H.R. 6034 when the agricultural patent bill is considered on the floor.

Sincerely,

Maureen Hinkle, Coordinator
Agriculture Policy
National Audubon Society/547-9009

A. Blakeman Early
Washington Representative
Sierra Club/547-1144

GENERAL COUNSEL OF THE
UNITED STATES DEPARTMENT OF COMMERCE
Washington, D.C. 20230

JUN 20 1984

Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts, Civil Liberties
and the Administration of Justice
Committee on the Judiciary
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This responds to your request for our comments on H.R. 5529, the "Agricultural Patent Reform Act of 1984." This legislation would add a new Section 156 to title 35, United States Code, to provide for an extension of the patent term for patented products, or patented methods for using or producing products, which are subject to Federal regulatory review before commercial use. The products to which this legislation would apply are limited to agricultural and industrial chemicals and animal drugs.

Commissioner Mossinghoff's prepared statement submitted at the hearings before your Subcommittee on March 28, 1984, included a comprehensive part dealing with H.R. 3502, the "Patent Term Restoration Act of 1983." He did not discuss this bill in detail because, as you mentioned during the hearing, another Committee was working on a different bill which might replace H.R. 3502 as a vehicle for consideration of the issue of patent term restoration. That bill is H.R. 3605, as amended on June 12, 1984. It is our understanding that negotiations leading to H.R. 3605 as amended, involved the pharmaceutical industry with no participation by the agricultural chemical and industrial chemical industries. For this and other reasons, that bill does not extend patent term restoration to agricultural and industrial chemicals.

This Administration has been consistent in its strong support of patent term restoration for inventions which are denied a full, effective patent term because of Federal premarket regulatory review. This support extends to corrective legislation not only for agricultural and industrial chemicals, but also for pharmaceutical products. In this light, our support for H.R. 5529 does not imply any diminished support of patent term restoration for other products covered by H.R. 3502.

H.R. 5529 would deal with patent term restoration in a manner somewhat different from that of H.R. 3502. Instead of authorizing a patent term extension equal to the regulatory review period up to seven years, H.R. 5529 would limit the extension to a maximum of five years. It would also set a maximum extension period of three years for products already under Federal regulatory review and permit no extension for any part of regulatory testing and review which occurred prior to enactment of the bill.

In our letter to you of July 27, 1981, supporting enactment of H.R. 1937 in the 97th Congress, we noted our strong support for the objective of that bill, which was to permit adjustments of the patent term to compensate for the loss of a certain period of commercial exclusivity caused by Federally mandated testing and regulatory review requirements. The reasons given in that letter, as well as subsequent testimony given by Commissioner Mossinghoff before your Subcommittee, apply equally to H.R. 5529. Although this bill does not cover all the products eligible for patent term restoration under H.R. 1937, we consider H.R. 5529 to be a desirable first step. Enactment of H.R. 5529 will alleviate the unfairness of artificially shortened patent terms caused by Federal pre-market regulatory review requirements in the area of agricultural and industrial chemicals and animal drugs. We note, however, that animal drugs are also covered in H.R. 3605 as amended, a redundancy that the Subcommittee may wish to consider.

I am enclosing for your consideration our detailed comments on the provisions of H.R. 5529. We will be pleased to provide you with any additional assistance.

The Office of Management and Budget has advised us that there is no objection to the submission of this report from the standpoint of the President's programs.

Sincerely,

Irving P. Margulies

Irving P. Margulies
General Counsel

DETAILED COMMENTS ON H.R. 5529

Subsections 156(a)(3)(A) and (B) would establish a formula for the length of time which a patent term may be extended. For regulatory review during the first ten years from the filing date of the earliest patent application, full credit would be given toward patent term extension. Between ten and twenty years from that filing date, only half the regulatory review period would count toward extension. Finally, no term could exceed 27 years from the earliest filing date of the application.

This formula strikes us as being somewhat arbitrary. Under the definition of "earliest application" in subsection 156(d)(3) of the bill, foreign priority filing dates would trigger the running of the first ten-year segment. This requirement may be in conflict with the Paris Convention for the Protection of Industrial Property, which provides that a foreign priority date may not be considered in the allocation of the length of a patent term. Also, applicants would have to weigh the advantages of filing continuation applications under Section 120 of title 35, United States Code, against getting full credit for patent term extension purposes for the regulatory review period during the first ten years from the earliest filing date. This may militate against the filing of continuation applications, resulting in patents which may not cover all the subject matter to which a patentee could have been entitled. Since H.R. 5529 already contains a five-year cap of maximum allowable patent term restoration, we would have preferred the simpler approach of counting the full regulatory review period up to a fixed number of years toward obtaining an extension of the patent term.

Another area of concern involves subsections 156(a)(1)(D)(i) and (ii) and 156(a)(1)(E). Reference is made there to methods of manufacturing products which do or do not "primarily use recombinant DNA technology." Our concern is with the term "primarily." For instance, if recombinant DNA technology is used to make an intermediate product which in turn is used in the manufacturing method claimed in the patent to be extended, it is unclear whether the conditions of subsection (i), (ii) or those of (E) would apply.

Subsection 156(c)(1) of H.R. 5529 also introduces the concept of "due diligence" according to which a product sponsor would be required to exercise due diligence during the regulatory review period upon which the extension is based. In a civil infringement action involving a patent whose term had been extended, the court would reduce the extended patent term by the amount of time which it found the product sponsor not to have acted with due diligence during the regulatory review period. Although we support this concept, it may be useful to clarify in the legislative history the meaning of the phrase "degree of attention, sustained effort and timeliness" used in subsection 156(c)(3) to define "due diligence." This might help to prevent protracted litigation and long discovery proceedings.

We understand that the Environmental Protection Agency may be raising some technical concerns, mainly regarding the completeness of requests, applications or notices which would trigger the beginning of the regulatory review period. In this respect, we defer to that Agency's judgment.

Another point concerns the language of subsection 156(a)(3)(D). This subsection is unclear as to whether it would provide patent term extension for a product having two or more active ingredients where one of these ingredients had been claimed in a previously extended patent. We believe it would be unwise to deny patent term extension to compositions with multiple active ingredients solely on the basis that one of those ingredients was protected by a patent which had already been extended. The product covered by the previously extended patent can be used by all upon expiration of the patent. To deny patent extension to another product simply because it included one ingredient which was claimed in an earlier extended patent would serve as a disincentive to further research on products using that ingredient -- a result contrary to the purposes of the bill.

socma

June 29, 1984

The Honorable Robert W. Kastenmeier
Chairman, House Judiciary Subcommittee
United States House of Representatives
2232 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

The Synthetic Organic Chemical Manufacturers Association (SOCMA) strongly supports H.R. 5529, introduced by Congressmen Dan Glickman and Michael DeWine, which seeks legislative resolution of the Patent Term Restoration issue. SOCMA is a non-profit trade association which represents over 100 organic chemical companies, the majority being 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).

H.R. 5529, an "agriculture only" bill, is an immediate means for attaining agricultural patent improvements in the time remaining in this Congress. SOCMA believes that this measure, although more limited in scope than the legislation introduced by you in the last Congress, is important in dealing specifically with such agricultural concerns as animal vetinary products, agrichemicals and chemicals covered by TSCA.

The impact of TSCA on innovation is a particular concern of our Association. 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.

For the concerns raised above, SOCMA encourages you and Members of the Committee to report favorably this worthwhile legislation.

Sincerely,

Ronald A. Lang
Executive Director

cc: Congressman Dan Glickman
Congressman Michael DeWine
Mr. Jack D. Early, NACA
Mr. Thomas Sager, E.I. du Pont

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION
THE MADISON BUILDING
1155 Fifteenth Street, N.W., Washington, D. C. 20005
202 • 296-1585 Cable: NAGRCHEM

Dr. Jack D. Early
President

June 26, 1984

Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts, Civil Liberties
and the Administration of Justice
Committee on the Judiciary
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

When we appeared on June 6, 1984 before your Subcommittee in support of H.R. 5529, we were asked to provide for the record our response to six Environmental Protection Agency comments on the bill.

We are pleased to provide the Subcommittee with our enclosed response.

Sincerely,

Jack D. Early

Encl.

JDE:kab

cc: Vaughn Bryson

Responses of National Agricultural Chemical Association
to the Comments of the EPA on H.R. 5529

The following responses are numbered to correspond to the numbered comments of EPA.

1. Change title of legislation -- NACA believes the title of H.R. 5529, should remain unchanged. The name "Agricultural Patent Reform Act" has been used extensively in "Dear Colleague" letters, testimony, and in discussions soliciting co-sponsors. Changing the name now would cause some unnecessary confusion. Moreover, 3 of the 4 categories of products covered by the bill are exclusively agricultural products, and the fourth category, i.e. chemicals regulated under the Toxic Substances Control Act, contain many chemicals used as intermediates and otherwise associated with the manufacture of agricultural chemicals. Coverage of all these products is important to increase the incentive for agricultural product innovation.

2. Commencement of regulatory review period -- NACA supports a clarification to make certain that incomplete submissions to EPA of experimental use permits, applications, or notices do not trigger the beginning of the regulatory review period. A patent holder should not be able to unfairly lengthen the regulatory review period by premature filings of permits, applications, or notices. We note, however, that in most cases commencement of the regulatory review period would be triggered by the initiation of a major 6 month test. Thus, EPA's concern is applicable to only a few filings. Moreover, the 5 year cap in H.R. 5529 minimizes any likelihood of premature filings, since the normal regulatory review period now takes five years. Any

regulatory delays beyond 5 years will not be compensated by patent restoration. Finally, any person who submits a premature application and does not promptly provide all the requisite information could be open to charges of failure to exercise due diligence.

Nonetheless, we agree that EPA's concern about premature filings should be addressed. We do not, however, believe the language suggested by EPA is the best way to accomplish this objective. The EPA language would require the EPA Administrator to issue a determination stating that the submission is complete and acceptable for review. We do not think it is advisable to impose any additional burdens on EPA. Moreover we question whether the Judiciary Committee has the jurisdictional authority to impose any new obligations on E.P.A. and believe the inclusion of such a provision would pose an unnecessary procedural risk to the legislation.

We believe the same objective can be accomplished without creating new duties for E.P.A. H.R. 5529 should be amended to require that any request, application or notice submitted to E.P.A. must comply with the already existing regulations that spell out in detail what must be included in the submission. For example, at 40 C.F.R. 172.4(b) EPA specifies the information that must be included in an application for an experimental use permit. Similarly at 40 C.F.R. 162, E.P.A. specifies the information and data requirements for registration applications. Finally, at 40 C.F.R. 720.45 and 720.50, EPA

specifies the information and data that must be included in notices under the Toxic Substances Control Act.

Accordingly, we would suggest the following alternative language:

(a) in section 156(d) (5) (B) (i), on page 11, line 10, after "requests" insert ", in accordance with regulations issued by the Administrator,"

(b) in §156(d) (5) (B) (ii), on page 11, line 18, after "submitted" insert ", in accordance with regulations issued by the Administrator,"

(c) in §156 (d) (5) (C) (ii), on page 12, line 19 after "notice" insert, ", in accordance with regulations issued by the Administrator".

3. "Premanufacture" notices -- We agree that the reference to "premanufacture notice" should be revised to eliminate "premanufacture". We suggest the following changes:

(a) page 11, line 24 and 25 strike "notification" and insert in lieu thereof "notice";

(b) page 12, lines 8 thru 9, strike "premanufacture notification period of" and insert in lieu thereof "notice period under section 5 for";

(c) page 12, line 18 strike "a premanufacture notice" and insert "notice under section 5";

(d) page 12, line 23-24, strike "premanufacture notification period" and insert in lieu thereof "notice period under section 5".

4. Deletion of "mixture" -- We oppose the suggestion to delete the term "mixture" altogether from H.R. 5529. H.R. 5529 must continue to refer to mixtures because the patent subject to restoration may cover a mixture rather than one of the specific chemical ingredients in the mixture. While section 5 of the Toxic Substances Control Act refers explicitly only to "chemical substances" and not to "mixtures", the mixture itself is patentable and the marketing of the mixture may have been delayed due to the notice requirements of section 5 because the mixture contains a new chemical substance or because it contains an existing chemical substance subject to "new use" notice requirements. We do believe the following technical changes would be appropriate to accurately reflect the explicit provisions of section 5 of TSCA:

page 11, line 24, delete "or mixture";

page 12, line 2, after "Act" insert "or a mixture that contains a substance for which notification is required under such section";

page 12, lines 9 and 10, delete "or mixture";

page 12, line 25, delete "or mixture".

5. Major health and environmental studies -- We agree that the words "or study" should be added to the definition of a major health or environmental effects test since in some cases a study of existing information is undertaken rather than a specific test.

6. Identical active ingredients -- We agree with EPA that there is an ambiguity in section 156(a)(2)(D). To accomplish this objective and to eliminate the ambiguity, we agree with EPA's suggestion that page 5, line 15 be changed to read "pesticide containing identical active ingredients shall be . . ." .

In addition to the above changes, we note that the reference to "section 5" on page 12, line 15, should be "section 4".

NINETY-EIGHTH CONGRESS

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U.S. House of Representatives
Committee on the Judiciary
Washington, D.C. 20515
Telephone: 202-225-3951

July 6, 1984

Mr. Jack D. Early
National Agricultural Chemicals Association
1155 - 15th Street, N.W.
Washington, D.C. 20005

Dear Mr. Early:

In order to complete our hearing record on patent term legislation, I am submitting some additional questions for the hearing record. Please submit answers to those questions which you feel were not adequately addressed at the hearing. As you know, the Subcommittee will be marking up this legislation during the week of July 23rd. Therefore, if possible, please submit your answers to the Subcommittee by July 20th.

Thank you in advance for your cooperation.

Sincerely,

ROBERT W. KASTENMEIER
Chairman,
Subcommittee on Courts,
Civil Liberties and the
Administration of Justice

RWK:dbs

Enclosure

JUL 25 1984

Honorable Robert W. Kastenmeier
Chairman, Subcommittee on Courts, Civil Liberties
and Administration of Justice
Committee on the Judiciary
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

I am writing to inform you of a meeting that EPA held with the National Agricultural Chemicals Association (NACA) and the Chemical Manufacturers Association (CMA) on July 15 to discuss H.R. 5529, the Agricultural Patent Reform Act of 1984. First, a review of the events leading up to this meeting might prove useful. On May 2, 1984, EPA received a request to comment on H.R. 5529. Our comments were sent to you on May 24. On June 6, Jack Early, President of NACA appeared before your Subcommittee to give its views on this bill. At that time you requested that NACA respond to our comments. In its response of June 26, NACA agreed with four of our comments and disagreed with two, those relating to the citation name of the bill, and §156(d)(5), the commencement of the regulatory review period. NACA and CMA requested a meeting to discuss these outstanding differences on this bill.

The Bill's Citation Name

EPA's first comment on the bill concerned the bill's citation name, the Agricultural Patent Reform Act of 1984. EPA thought that this name was potentially misleading because the bill could also affect hundreds of industrial chemicals regulated under the Toxic Substances Control Act. We therefore suggested that the citation name of the bill be changed to the "Agricultural and Industrial Chemicals Patent Reform Act of 1984.

NACA's main concern with our suggestion related to the confusion that might result from changing the name of the bill, since the present name had been used extensively in "Dear Colleague" letters, testimony, and in discussions soliciting co-sponsers.

It was agreed that we would submit for your consideration a change in the title of the bill as follows:

> To amend the patent law to restore the term of the patent grant in the case of certain industrial and agricultural products for the time of the regulatory review period preventing the marketing of a product claimed in a patent. (Suggested change is underlined)

Section 156(d)(5)

The final area of disagreement with NACA concerned §156(d)(5) of the bill which deals with the commencement of the regulatory review period for determining the amount of the patent term restoration. EPA was concerned that the language of the bill might provide parties seeking restoration rights with an incentive to submit incomplete requests, applications, or notices earlier in order to extend the period of eligibility for restoration to the maximum allowed, thus burdening the Agency with extra, unnecessary work. EPA submitted language that we thought would make it clear that such incomplete submissions would not be acceptable.

NACA and CMA recognized the legitimacy of our concern, but thought that our suggested language might cause jurisdictional problems for your Committee. It was therefore agreed that we submit for your consideration the following language for inclusion in the Committee's report on the bill.

> In some instances, the regulatory review period commences with the filing of an application for an experimental use permit, or a registration under the Federal Insecticide, Fungicide, and Rodenticide Act or the filing of a notice under section 5 of the Toxic Substances Control Act. In order to trigger the regulatory review period, these applications or notices must be filed in accordance with the applicable regulations issued by the EPA Administrator; that is, the filing must comply with the requirements spelled out by the Administrator in regulations as to the content such of an application or notice. For example, existing regulations at 40 C.F.R. 172.4(b) list the items required to be contained in an application for an experimental use permit. If an application or notice fails to contain relevant required material needed by EPA to properly process and review the application or notice, then for purposes of patent extension the regulatory review period would not be deemed to have started.

EPA has historically supported the equitable notion of patent term extensions. We hope that your Committee will give careful consideration to our comments as outlined in our letter of May 24, and today.

Sincerely

Josephine S. Cooper
Assistant Administrator
for External Affairs

NATIONAL WILDLIFE FEDERATION, 1412 Sixteenth Street, N.W., Washington, D.C. 20036 (202) 797-6842
Office of the Executive Vice President

August 7, 1984

The Honorable Robert W. Kastenmeier
2232 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Kastenmeier:

On behalf of the National Wildlife Federation, and its over 4 million members and supporters, I urge you to ask Chairman Rodino to cancel the mark-up of H.R. 6034, the agricultural patent bill, which has been scheduled for committee consideration tomorrow. Patent legislation shouldn't be passed unless the range of needed pesticide reforms is addressed.

We are concerned that through H.R. 6034, this Congress would grant to pesticide manufacturers a significant economic windfall while ignoring the serious health and safety problems of pesticides. For the past several years, needed reform of the pesticide laws (FIFRA) has lagged; and a more recent food safety bill, Representative Waxman's H.R. 5495, remains stalled in the Health and Environment Subcommittee. While the public calls for improved pesticide safety and regulation, it is only H.R. 6034, which benefits industry alone, that moves forward.

At the NWF annual meeting in March of 1977, the members of the Federation passed a resolution calling on responsible executive agencies of the Federal Government, as well as the U.S. Congress, "to adopt a coordinated national policy on pesticide use ... expeditiously reducing the human, wildlife, and environmental health hazards caused by improper pesticide use by ... [among other things] closer examination of the safety and effectiveness of pesticides." (Resolution attached.)

Representative Glickman's patent bill offers nothing to further the safe use of pesticides or the closer examination of safety data for which the NWF resolution calls. In fact one provision of the bill would allow the disclosure of even less health and safety data than does current law under FIFRA and a recent Supreme Court decision.

Pesticide use and regulation are complex issues. There are many conflicting needs and interests which surround the use of agricultural chemicals. These issues need careful consideration in hearings which cover all the interrelated parts of the problem.

H.R. 6034 troubles the Federation precisely because it gives industry what it wants while ignoring the pressing need for improved health, safety and environmental regulation of these chemicals. Moreover, there has been scant consideration of H.R. 6034. Only one hearing has been held in which three industry witnesses testified.

If H.R. 6034 is to be salvaged by the Judiciary Committee, environmental amendments must be included, to address not only the quality of studies conducted by pesticide companies but also the problem of pesticide residues in food. The Waxman food safety bill, H.R. 5495, addresses these issues in the context of the Food, Drug and Cosmetic Act, and would be an appropriate addition to pesticide patent legislation.

The National Wildlife Federation asks you to oppose mark-up, or failing that, vote against H.R. 6034 unless the committee adds the substance of H.R. 5495 to H.R. 6034.

Sincerely,

Jay D. Hair

JAY D. HAIR

Resolution No. 3

NATIONAL POLICY ON PESTICIDE USE

WHEREAS, the same and intelligent use of pesticides can bring benefits to all Americans; and

WHEREAS, the improper use of pesticides can result in immediate poisoning, kidney and liver damage, lowered resistance to disease, damage to the central nervous system, cancer, genetic mutations, and birth defects with enormous human, societal and monetary costs; and

WHEREAS, pesticides have proven harmful to many species of fish and wildlife; and

WHEREAS, the outright costs of pesticides continue to rise each year; and

WHEREAS, farmers and foresters often have been advised to use pesticides routinely whether or not there was evidence of the presence of a pest; and

WHEREAS, pressures to purchase pesticides have continued long after the target pest became resistant to the pesticide and pesticide users have been urged to purchase quantities well in excess of actual need; and

WHEREAS, great progress has been achieved in the development of biological controls for many pests and integrated pest management practices have been proven successful;

NOW, THEREFORE, BE IT RESOLVED that the National Wildlife Federation, in annual meeting assembled March 24-27, 1977, in Washington, D.C., hereby urges the responsible executive agencies of the Federal Government to adopt a coordinated national policy on pesticide use, expeditiously reducing the human, wildlife, and environmental health hazards caused by improper pesticide use by the timely application of existing law and reducing the excessive costs of pesticide use through education, tighter controls on the application of pesticides, and closer examination of the safety and effectiveness of pesticides; and

BE IT FURTHER RESOLVED that this organization urges the Congress to support a safe and sane pest control program, providing adequate funds to more rapidly develop biological pest control measures and to accelerate such integrated pest management practices through such measures as induced sterility, genetic manipulation, the use of attractants and repellents, hormones, biologic and chemical agents, physical quarantines, seed certification and seed laws as appropriate to specific pest problems.

Chevron
ORTHO Chevron Chemical Company
940 Hensley Street, Richmond, CA 94804

Consumer Products Division

July 25, 1984

HR 5529
File No: 770.110

The Honorable Peter W. Rodino, Jr.
Chairman, House Judiciary Committee
U. S. House of Representatives
2464 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Rodino:

I am writing to you about the Agricultural Patent Reform Act of 1984, HR 5529, which is currently under consideration by the House Judiciary Committee.

The Consumer Products Division of Chevron Chemical Company manufactures and distributes pesticide and fertilizer products which are specifically designed for use by consumers. We are required to submit information to federal agencies to support our license to sell these products. When new and unique active ingredients are developed, much testing is required before we can commercialize the chemical. At the present time, it often requires five to seven years after the chemical is patented to develop the data to prove efficacy and safety of the chemical. This is time that is lost by the developer of the chemical, as far as the patent protection is concerned.

At the present time, many millions of dollars are required to complete the required efficacy and safety testing and frequently half of the life of the patent is spent in development. This means that developers have less time to recover their developmental costs and thus the price of the product containing that chemical is artificially high. For chemicals used in food crop protection, that translates into higher food costs.

I urge you to consider passage of HR 5529 as a step toward protection of domestic innovation and technology as well as holding food costs at reasonable levels. Thank you for your positive consideration of HR 5529.

Very truly yours,

William L. Chase, Jr.

William L. Chase, Jr., Coordinator
Registration and Government Liaison

WLC/cmn:Wk-D4

[From the Washington Post, Aug. 9, 1984]

PANEL PASSES PATENT BILL FOR MAKERS OF FARM PESTICIDES, ANIMAL DRUGS

(By Ward Sinclair)

The House Judiciary Committee yesterday approved a controversial bill that would extend the life of patents on animal drugs and farm pesticides in cases where products' marketing has been delayed because of federal testing requirements.

The measure, crafted after one day of hearings that included only industry witnesses, became controversial after environmentalists learned last week that added language would have reversed a recent Supreme Court ruling that granted public access to health and safety data on pesticides.

Rep. Dan Glickman (D-Kan.), the chief sponsor, removed the bill from the committee calendar at that point, then brought it up again yesterday with the offensive language removed. The final vote was 20 to 6.

Glickman and his allies argued that the legislation was needed to encourage pesticide and animal-drug companies to invest more in product research and development, secure in knowing that they would have 17 years of patent protection even if marketing were slowed by federal pre-market testing.

The legislation would extend protection to a maximum of 25 years. And, for the first time, it would allow certain biotechnology procedures used in the development of animal drugs and pesticides to be covered by patent extension.

Rep. John F. Seiberling (D-Ohio), a critic of the bill, complained that the measure would provide a windfall to the industry by giving its products three years' more patent protection than drugs for humans would get under another bill adopted by the committee last week.

"We should not lightly grant monopoly powers to anyone," Seiberling said. "There is no logic to giving animal drugs longer-term protection than human drugs."

Glickman and other committee members indicated that they would consider a proposal by several environmental and public-interest groups to take the bill to the House floor in tandem with another bill.

That measure, pushed by Rep. Henry A. Waxman (D-Calif.), would tighten pesticide-residue standards for food.

Public Voice for Food and Health Policy, Congress Watch, the Natural Resources Defense Council and the Consumer Federation of America, questioned the patent extensions.

In a letter to committee members, they wrote that "at a minimum" Congress should include "important consumer benefits to balance industry's economic gain."

PATENT TERM RESTORATION
FOR
ANIMAL HEALTH PRODUCTS

By
Animal Health Institute

July 1984

PATENT TERM RESTORATION

FOR

ANIMAL HEALTH PRODUCTS

By

*Animal Health Institute

July 1984

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F. AHI Membership (list of member firms).

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* The Animal Health Institute is the industry trade association representing the manufacturers of animal health products marketed in the United States. These products include animal drugs, regulated by the Food & Drug Administration, and veterinary biologicals, regulated by the U.S. Department of Agriculture. For further information contact Fred Holt or Fritz Kessinger at AHI [(703) 684-0011].

DRUGS USED IN HUMANS VS. DRUGS USED IN ANIMALS

SOME IMPORTANT DIFFERENCES

	HUMAN-USE DRUGS	ANIMAL DRUGS
OBJECTIVES	Primarily, treatment of human illnesses	Primary objective is prevention and control of diseases and, in food-producing animals, growth promotion and feed efficiency.
CRITERIA FOR APPROVAL	Safe and effective in man.	Safe and effective in target animal species, and--in food-producing animals--positive assurance of no harm to consumers of animal-derived foods.
PRIMARY REASONS FOR USE	To save human lives and to alleviate pain and suffering. Cost is a secondary consideration.	In food-producing species, animal health products are used almost entirely for economic purposes, to control/reduce the costs of production. Products must be cost-effective or they will not be purchased.
COMPETITIVE FACTORS	Major brandname prescription drug firms compete by attempting to persuade physicians that their products are safer and more effective.	Animal drug firms market their products to livestock and poultry producers on economic grounds. Producers are discriminating, sophisticated "consumers," businessmen who purchase drugs on the basis of tangible economic returns. Animal production profit margins have narrowed markedly, and no producer will re-order an ineffective animal drug. Approximately 55 manufacturers compete with each other for the three major market areas -- swine, poultry, cattle. New products have to be priced to compete with products already servicing these markets.

	HUMAN-USE DRUGS	ANIMAL DRUGS
GENERIC COMPETITION	A vigorous generic industry is represented by the Generic Pharmaceutical Industry Association Growth of the generic industry is stimulated by Federal programs (Medicare, Medicaid, etc.) that reimburse covered patients for prescription drugs.	Generic animal drugs are marketed by many of the 55 AHI member firms. Competition is keen throughout this industry, but it is not ordinarily delineated along brandname vs. generic lines. There are no government programs remotely comparable to those that affect pricing in the human-use drug industry.
MARKET SIZE	Annual U.S. sales of human-use pharmaceuticals total nearly $18 billion.	The animal drug market is much smaller. Total animal drug sales in 1983 were $2 billion. The worldwide market for human-use pharmaceuticals is 10 to 12 times that for animal drugs.
MEANS OF ADMINISTRATION	One-on-one, and for prescription drugs, pursuant to a physician-patient relationship.	Food-producing animals typically receive drugs in their feed. Whole herds and flocks are treated simultaneously. When veterinarians are involved, they commonly prescribe the appropriate medication for the entire herd or flock.

SUMMARY

PATENT TERM RESTORATION FOR ANIMAL HEALTH PRODUCTS

BY THE ANIMAL HEALTH INSTITUTE

July 1984

THE BILLS: H.R. 5529 (Glickman-DeWine), the "Agricultural Patent Reform Act of 1984."

S. 2748 (Hatch) and H.R. 3605 (Waxman), the "Drug Competition and Patent Term Restoration Act of 1984".

Both proposals provide Patent Term Restoration (PTR) for animal health products, but their provisions are extremely different.

AHI POSITION: The Animal Health Institute (AHI) urges enactment of the legislative language of H.R. 5529. This would accord the same treatment to animal health products as the bill provides for other agricultural chemicals, including pesticides.

AHI RATIONALE:

1. H.R. 5529 deals primarily with agricultural chemical patents. H.R. 3605 and S. 2748 represent a compromise between the two elements -- brandname and generic -- of the human-use prescription drug industry.

2. H.R. 5529 is very similar to, but less generous to the affected industries than, legislation approved by substantial majorities, but not enacted, during the 97th Congress.

3. Appropriately, H.R. 5529 deals primarily with one broad class of chemicals, those used in agriculture -- animal health products and pesticides.

4. The preponderance (82 percent in 1983) of animal drugs are used in food-producing animals. They should receive the same PTR treatment as pesticides.

5. Animal drugs, like pesticides, are used in food animals almost exclusively for economic reasons. Food animals are not treated like humans. Whole herds and flocks are treated simultaneously. PTR under H.R. 5529 would encourage development of useful new products.

6. All major animal agriculture organizations, plus veterinarians, support H.R. 5529 wholeheartedly. These are our customers.

7. Two Administration departments, Commerce and Agriculture, have expressed their support of H.R. 5529.

8. H.R. 5529 provides equitable PTR treatment for agricultural products. As they pertain to animal health products, H.R. 3605 and S. 2748 are much more restrictive, and their formulas for computing the amount of PTR allowed would provide far less R&D innovation incentive.

9. Animal health products were never involved in the lengthy negotiations that produced H.R. 3605 and S. 2748.

10. The animal health industry is a unique mix of companies that make drugs and biologicals, brandname and generic. There is no separate "generic" animal health products industry, and AHI is the only trade association.

[For further details, call AHI, (703) 684-0011.]

# # #

ANIMAL HEALTH INSTITUTE*

DISCUSSION OF PATENT TERM RESTORATION

FOR ANIMAL HEALTH PRODUCTS

July 1984

Introduction

Animal health products -- drugs regulated by HHS/FDA and biologicals, by USDA/APHIS -- would receive Patent Term Restoration (PTR) under two legislative proposals currently under active consideration.

Legislation

- H.R. 5529, the "Agricultural Patent Reform Act of 1984" (Glickman-DeWine), also covering pesticides (EPA/FIFRA) and precursor chemicals (EPA/TSCA).

- S. 2748 (Hatch-Kennedy) and H.R. 3605 (Waxman), the "Drug Competition and Patent Term Restoration Act of 1984," identical bills designed principally to provide PTR for human-use prescription drugs and to expedite FDA approval of "me-too" generics after brandname Rx drugs' patents expire.

Animal Health Institute Position

* The Animal Health Institute (AHI) is the national industry trade association representing the 55 firms that manufacture nearly all of the animal drugs and biologicals, brandname and generic, marketed in the United States. There is no separate association of generic animal health products manufacturers analogous to those involved in the negotiations that resulted in the Drug Competition-PTR legislation. AHI urges enactment of PTR provisions pertaining to animal health products that conform to the legislative language of H.R. 5529, the "Agricultural Patent Reform" bill. The rationale for this position follows.

1. AGRICULTURAL BILL DEALS PRIMARILY WITH PATENTS OF AGRICULTURAL CHEMICALS; COMPETITION-PTR BILLS ADDRESS PATENTS AND GENERIC Rx HUMAN DRUG APPROVALS

The agricultural bill appropriately provides PTR for products that are essentially agricultural -- utilized in the production of food -- while the Competition-PTR bills represent a carefully crafted two-title compromise between the divergent interests of the two components -- brandname and generic -- of the human-use prescription drug industry.

2. 97th CONGRESS NEARLY ENACTED LEGISLATION CLOSELY RESEMBLING "AGRICULTURAL PATENT REFORM"

The agricultural bill's provisions closely resemble those contained in legislation (S. 255 and H.R. 6444) passed by the Senate and approved by a majority of the House in the 97th Congress. [Those more comprehensive bills covered human pharmaceuticals as well as pesticides and animal health products. Enactment was not achieved because a two-thirds majority was lacking in the House. Those bills would have allowed seven-year patent term extensions, rather than the five-year maximum permitted under the current proposals.]

3. AGRICULTURAL PTR BILL DEALS PRIMARILY WITH CHEMICALS USED IN FOOD PRODUCTION

H.R. 5529 is designed primarily to provide patent term equity for only one broad category of products, chemicals used in the production of foodstuffs.

4. MOST ANIMALS DRUGS ARE USED IN AGRICULTURE

The bulk (about 82 percent in 1983) of animal drugs are used in agricultural, food-producing animals -- cattle, swine, sheep, poultry and dairy cows.

5. LIKE PESTICIDES, DRUGS ARE USED IN FOOD ANIMALS FOR ECONOMIC REASONS; FOOD ANIMALS DO NOT RECEIVE DRUGS LIKE HUMANS

Animal drugs are used in food-producing animals almost exclusively for economic reasons. FDA's premarketing regulatory review of such an animal drug takes an average of over six years (sometimes it stretches to 10 or 11). This, of course, is the main reason Patent Term Restoration for these products is essential if the industry is to continue the R&D necessary to provide new, more effective, animal health products for America's livestock and poultry producers. A vital element of that regulatory review -- and an extremely costly and time consuming one -- is human food safety. The agency insists upon being absolutely satisfied that the animal drug, its metabolites and residues, will pose no hazard to those who consume animal-derived foods. This important consideration closely parallels those applied by EPA to pesticides used on edible food crops. For obvious reasons, there is nothing comparable to FDA's scrutiny of human-use drugs. Food animal medicine is not even remotely analogous to human medicine. Whole herds and flocks of animals and fowl are treated simultaneously to prevent, control and treat diseases and parasites, to promote growth and to enhance feed efficiency. The use of animal health products is essential to the economical production of wholesome meat, eggs and dairy products in plentiful supply at affordable prices.

6. ANIMAL AGRICULTURE ORGANIZATIONS SUPPORT H.R. 5529

The PTR provisions of the "Agricultural Patent Reform" legislation are endorsed by all of the major associations representing food animal producers and veterinarians, including:

National Cattlemen's Association
National Pork Producers Council
National Broiler Council
American Farm Bureau Federation
National Turkey Federation
National Milk Producers Federation
American Feed Manufacturers Association
American Veterinary Medical Association

7. TWO ADMINISTRATION DEPARTMENTS ENDORSE THE NON-CONTROVERSIAL AGRICULTURAL PTR BILL

The Departments of Commerce (which includes the Patent Office) and Agriculture have affirmatively endorsed H.R. 5529, the Agricultural PTR bill, to which no opposition is known.

8. SPECIFIC PROVISIONS OF PTR LEGISLATION APPLYING TO ANIMAL DRUGS & BIOLOGICALS ARE DISPARATE

Under both the Agricultural PTR bill and the Drug Competition-PTR bills, the maximum patent term restoration for an animal health product would be five years. But here the resemblance ends. There are substantial, critical differences between the two proposals' formulas for computing the amount of restoration that can be granted, and other important disparities as well.

- Credits Toward PTR -- The Agricultural bill allows the entire preliminary investigational period to count toward the allowable PTR. Under the Drug Competition-PTR bills, only one half of this period can be counted. Both proposals allow all of the time consumed by the second phase of premarketing review (from the filing of an application for approval to the formal approval of the product for marketing). When the formulas are applied to two random examples, the Agricultural PTR bill allows a full five-year extension for each, while the Drug Competition-PTR proposal would permit only four years in each case. (No two animal health products would be treated exactly alike.)

- "Caps" Make a Difference -- Under the Agricultural bill, a maximum five-year extension could be granted for an animal health product -- compensating for five of the years consumed by testing and regulatory review -- giving the product a total of 22 years under patent (although the effective patent life

could not exceed the Congressionally-mandated 17 years). Under the Drug Competition-PTR bills, the PTR extension plus the patent term remaining upon approval could not exceed 14 years, regardless of how much of the original 17-year patent term remained at the time of approval.

- "Pipeline" Products Treated Disparately -- For a product patented and not yet approved prior to enactment (a "pipeline" product), the Agricultural PTR bill limits patent term extension to three years. The Drug Competition-PTR proposal would limit such an extension to two years if the product had previously undergone any part of any phase of regulatory review.

- "Due Diligence" Provisions are Different -- The Agricultural PTR bill provides that the product's patent holder can be sued in Federal court by anyone seeking to reduce the extension term who contends the patent holder failed to exercise "due diligence" in pursuing marketing approval. Under the Drug Competition-PTR bills, the complainant (presumably a potential "me-too" marketer) would file a petition with the appropriate Federal Department. The decision as to whether to reduce the PTR extension, or perhaps to eliminate it altogether, would in the former instance come from the court; in the latter, from the authorized Department.

- Drug Competition-PTR Proposal Overturns Bolar Decision -- In a recent case [Roche Products, Inc., v. Bolar Pharmaceutical Co., Federal Circuit, April 23, 1984], an appellate court ruled that it is an infringement of the patent to manufacture a patented product for the purpose of conducting studies in order to obtain marketing approval. The Drug Competition-PTR proposal explicitly overturns the Bolar decision. As it pertains to human-use drugs, this provision is offset somewhat by provisions of the bills' Title I (ANDAs), but the bills contain no comparable compensatory provisions applicable to animal health products. The Agricultural PTR bill does not address the Bolar decision.

- Animal Drugs Do Not Belong in an ANDA Proposal -- As noted above, Title I of the Drug Competition-PTR bill sets up a system for expediting FDA approval of generic human-use prescription drugs. (Title I is commonly called the ANDA provisions; the acronym stands for Abbreviated New Drug application.) This title is the "trade-off" against brandname Rx drug PTR. It has been suggested that Title I should be expanded somehow to provide similar treatment for animal health products. Such action would be utterly inappropriate. FDA has not adopted any formal system for handling "abbreviated" new animal drug applications (NADAs), as it has for human drug NDAs. The agency has no systematic list of animal drugs that are subject to abbreviated applications, nor does it have any formal policy regarding their bioequivalency. Moreover, with human food safety as a paramount concern, tbe approval issues

for drugs used in food-producing species are significantly more complex than they are for human drugs. Such animal drugs are therefore not ordinarily amenable to an abbreviated NADA approach. As discussed below (10), there is no separate "generic" animal health products industry seeking Congressional action to hasten approval of its drugs. Neither are there any massive Federal tax-supported programs like Medicare and Medicaid to stimulate governmental interest in promoting a generic industry.

9. ANIMAL HEALTH PRODUCTS WERE NOT INVOLVED IN THE LENGTHY NEGOTIATIONS LEADING TO "COMPETITION-PTR" BILLS

The Drug Competition PTR bills represent a compromise resulting from 10 months of intensive negotiations involving Members of Congress and both components, brandname and generic, of the human-use prescription drug industry, balancing abbreviated approval concepts and patent extension terms. These negotiations and deliberations never involved AHI, and to our best knowledge they never focussed on animal drugs and biologicals.

10. ANIMAL HEALTH INDUSTRY IS A UNIQUE, UNIFIED BRANDNAME-GENERIC MIX: THERE IS NO SEPARATE GENERIC INDUSTRY

There is no separate "generic" animal health products industry. AHI is the only trade association representing that industry. AHI's 55 member firms manufacture nearly 90 percent of the animal health products marketed in the United States, many of which are unpatented ("generics").

CONCLUSION

The Animal Health Institute, supported by every major agricultural and professional organization that uses animal health products, urges prompt enactment of Patent Term Restoration legislation for animal drugs and biologicals. H.R. 5529, the "Agricultural Patent Reform Act of 1984," treats those products appropriately with other agricultural chemicals. AHI therefore urges enactment of H.R. 5529, or, alternatively, enactment of its provisions as a part of another legislative package. This will provide a long overdue, essential stimulus for the development of innovative products for use in the production of animal-derived foods.

[For further information contact AHI at (703) 684-0011.]

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June 22, 1984

MEMORANDUM

Re: Comparison of Patent Term Provisions of H.R. 5529 and S. 2748

H.R. 5529 and S. 2748 contain somewhat different methods for computing the patent restoration term that would be applicable to animal drugs. In addition, S. 2748 contains a provision that overturns the Bolar decision with respect to the scope of patent infringement without any compensating benefit for animal drugs.

Under H.R. 5529, the basic patent term extension is for a maximum of five years. In addition, no extended patent may have a term exceeding 27 years from the date of filing the earliest patent application. (The date of filing is not used as a measure of computation in S. 2748.) Subject to those two limitations, the patent extension period in H.R. 5529 comprises (a) the INAD time up to filing the NADA plus (b) the NADA pendency time. To the extent either of thse periods runs past 10 years after issuance of the patent, only half of the time after the 10-year mark is counted.

The patent holder may be sued by a person seeking to reduce the extension term based on the failure of the patent holder to exercise "due diligence" in seeking to complete INAD studies or seeking to obtain NADA approval. If the INAD period was less than four years, and the NADA pendency period was less than two years, due diligence is statutorily presumed to exist,

and no suit may be maintained. If any of those periods are exceeded, then due diligence can be tested.

S. 2748 contains a much more complex system of determining a patent extension. The starting point remains the regulatory review period, comprising INAD time to the filing of an NADA plus NADA pendency time. The basic extension is half of the INAD time plus all of the NADA pendency time. This basic period is subject to the following limitations:

1. For products patented after enactment, the total extension may not exceed five years, and the extension plus the amount of time remaining on the patent at the date of approval may not exceed 14 years.

2. For products patented prior to enactment, a five-year extesion is permissible if there was no INAD time or NADA pendency time prior to enactment. If any "regulatory review period" occurred prior to enactment, the maximum permissible extension is two years. Both of these extensions are also subject to the 14-year cap.

3. In all cases, there is a potential "due diligence" reduction. Rather than by a law suit against the patent holder, the due diligence issue is raised by filing a petition with either the Secretary of HHS (for drugs and human antibiotics and human biologicals) or with the Secretary of Agriculture (for animal biologicals). Due diligence is "litigated" before the Secretary, who decides whether there should be a reduction in the

time periods that are to be considered in calculating the permissible INAD or NADA pendency time.

The following are examples of how the systems would work. First, assume a five-year INAD period and a three-year NADA pendency time. Under H.R. 5529, the regulatory review period is eight years, of which five can be granted as a patent extension so long as that addition does not result in a violation of the 27-year limit on date of first patentfiling to the end of the extension period. Under S. 2748, only half of the INAD time is taken, so that the regulatory review period is 5½ years, which results in a maximum extension of five years, assuming that the patent was granted after enactment. If, at the point of approval, there were ten years remaining on the original patent life, an additional "extension" year would be lost, because the extension plus the remaining patent life cannot exceed 14 years. Under both H.R. 5529 and S. 2748, it would be permissible for another person to challenge the due diligence of the patent holder and seek a further reduction.

Assume as a second example a four-year INAD period and a two-year NADA pendency period. Under H.R. 5529, the total of six years would be reduced to five. Under S. 2748, only half of the INAD time would be counted, for a total patent term extension of four years, well within the maximum five allowed. Even if there were ten years remaining on the patent, a 14-year total extended life would be granted. Under H.R. 5529, no reduction

would be permitted for lack of "due diligence"; under S. 2748, a due diligence challenge would be permitted.

Under the Bolar decision, it is an infringement of the patent to manufacture the patented product for the purpose of conducting studies in order to obtain FDA approval for the drug. S. 2748 specifically overturns this decision, and permits an infringement claim to be made only if the person making the product and conducting the tests obtains an FDA approval prior to the expiration of the patent. In the case of human drugs, this provision is somewhat offset by other provisions dealing with the time when abbreviated application can be sought and obtained. No such compensating period is provided for animal drugs or veterinary biologicals. Thus, it is inequitable for this provision to be applied to non-human drug products.

July 12, 1984

THE TIME IS NOT RIPE FOR
STATUTORY ABBREVIATED
NEW ANIMAL DRUG APPLICATIONS

It has been suggested that Title I of the Hatch-Waxman Abbreviated New Drug Application - Patent Term Restoration bill, (S. 2748/H.R. 3605), be modified to incorporate comparable abbreviated application provisions for new animal drugs. Due to the administrative and scientific complexity of the issues surrounding new animal drugs, it would be wholly inappropriate to attempt for the first time to create such a structure in this pending legislation.

FDA has no experience in the routine processing of abbreviated new animal drug applications. In contrast, as the attached chronology shows, FDA has, over a 15 year period, developed a policy and procedure for handling abbreviated human new drug applications arising out of the human drug efficacy study (DESI program).

As early as February 1969, FDA announced the availability of abbreviated new drug applications for human drugs, and it published a final rule specifying the format for these applications in early 1970. After considering a possible revision of the ANDA program, FDA settled on the existing format, and has since published a list of drugs that are eligible for abbreviated new drug applications, and two supplements to that list.

None of these steps has been taken with new animal drugs. There has never been an announcement of an abbreviated new animal drug application program. There is no section in the Code of Federal Regulations specifying the content of an abbreviated new animal drug application. There is no list of drugs that are eligible for abbreviated new animal drug applications.

Moreover, there is no established animal drug bioavailability program comparable to that established for human drugs that underlies the human abbreviated new drug application program. There are no Center for Veterinary Medicine (CVM) generic drug and drug monograph staffs as there are such human drug staffs experienced in handling abbreviated new drug applications and in determining the suitability of drugs for abbreviated application handling.

In sum, the CVM has never adopted plans and policies, or enunciated them in a consistent manner, that would permit the

drafting of a statutory provision that would simply continue existing policies as the one would for human drugs.

There is, in fact, a very sound reason why CVM has not been able to adopt an abbreviated new animal drug policy: For almost all animal drugs there is a human food safety issue that has no counterpart in the case of human drugs, and that was never resolved in the DESI program. Three examples will suffice to demonstrate the complexity of this issue and why it continues to thwart both industry and government attempts to complete the implementation of the drug efficacy study, which is a necessary prelude to any generic drug program.

1. In 1977, a company submitted an NADA for a generic equivalent of a combination implant of progesterone and estrodial benzoate. FDA demanded food safety information concerning this combination that had not been provided by the original applicant, or considered as part of the DESI review of this drug. After litigation established that FDA had to treat the new applicant and the original applicant equally, in 1979, FDA proposed to revoke the existing NADA and to deny the new one, acknowledging that the new product was the generic equivalent of the already-marketed drug. Following further research and submissions, in 1981 FDA reopened the administrative record to obtain public comment on the recommendation of the then-Bureau of Veterinary Medicine that proposed revocation and denial should be withdrawn, and that the pending application should be approved, based upon a reconsideration of the test of human food safety. In November 1982, the new applicant finally received its approval. FDA has still not published a final notice resolving the food safety issue as was promised in the Federal Register notice of the new approval. Thus, human food safety concerns that have not yet finally been resolved blocked an "abbreviated" application for over five years.

2. In the Federal Register for July 5, 1984, FDA proposed to terminate interim marketing requirements for a variety of sulfa drugs, and finally, to resolve the DESI status of these drugs. One problem that had been holding up the resolution was the status of the human food safety concerns relating to these drugs.

FDA required a commitment from sulfa drug marketers to conduct food safety studies in 1974, since early 1975 has not accepted any new applications to market these drugs, and has taken off the market any persons previously marketing the drugs who had not made a commitment to conduct the required human food safety studies. As FDA makes clear in the new Federal Register notice, the submitted human food safety "data are proprietary. Sponsors of NDAs submitted in the future must either have authority to reference the appropriate master file containing the data or

submit original data." This shows the second aspect of the human food safety issue that stands in the way of "abbreviated" NADAs.

Although some of the efficacy issues may be resolved through the Drug Efficacy Study, it is FDA's position that human food safety data must be new and original. The sulfa notice indicates that in some cases actual clinical trials will be required to satisfy the human food safety requirements. Such studies are incompatible with the notion of an "abbreviated" NADA.

As noted earlier, FDA has permitted no new applicants since early 1975. Based upon this most recent Federal Register document, more than 10 years will have passed before the first "abbreviated" applicant (with its new human food safety data) will be able to come on the market.

3. An even more protracted proceeding has precluded any new interim marketers or abbreviated applications for various antibiotic drugs that are listed in 21 C.F.R. 558.15. Here again, the requirement for submitting applications and research commitments began in 1973; since that date, no new applications have been permitted pending FDA's resolution of the human food safety issues raised by many of the drugs listed in that section. As a result, there can be no abbreviated new drug applications for the products and combinations listed until the human food safety issues are resolved. This may not be for many more years, given the complexity of the issues relating to the safety of antibiotic residues in the human food chain.

The human food safety issues involving animal drugs can thus be seen to be complex, and their resolution time-consuming. These issues are an ongoing obstacle to the development of an abbreviated new animal drug application system. Unlike the human abbreviated new drug application system, where only data relating to manufacturing, good manufacturing practices and bioavailability are required, the new animal drug procedures require an independent demonstration of human food safety above and beyond efficacy and bioequivalence to the original drug product. These data are required to be original to each applicant, placing a significant economic burden on animal drug sponsors that does not exist with respect to human drugs.

The absence of any simplified system of demonstrating human food safety is a key reason why the time is not yet ripe for a statutory abbreviated new animal drug application provision.

Chronology of FDA's Development
of the Abbreviated NDA Policy

Date	Cite	Action
5/28/68	33 FR 7762	Notification that FDA would not require NDAs for human drugs that have gone through the DESI review and have been determined to be safe and effective.
2/27/69	34 FR 2673	Announced availability of ANDA procedure for certain DESI human drugs for which FDA has published an announcement in the Federal Register that an ANDA would be satisfactory.
12/31/69	34 FR 20426	Announced availability of ANDA procedure for cyclamates.
4/24/70	35 FR 6574	Final rule published specifying format for ANDAs.
6/20/75	40 FR 26156	Proposed revising the ANDA rules to make them apply only to DESI drugs which have bioavailability or special manufacturing problems, rather than all DESI drugs. For those drugs, FDA proposed to substitute general surveillance and monitoring controls in place of abbreviated NDAs.
9/22/75	40 FR 43531	Withdrew portion of June 20, 1975 proposal (see above) which would have permitted certain DESI drugs to be marketed without an approved NDA or ANDA.
9/1/78	43 FR 39126	Proposed revision of the ANDA regulations to specify that a finding that an ANDA is appropriate applies only to drug products identical to the product that was the subject of the finding.

Date	Cite	Action
1/13/82	47 FR 1765	FDA published notice that it was considering extending ANDA policy to include post-1962 drugs.
6/22/82	47 FR 26822	Redelegation to directors of divisions in the Office of New Drug Evaluation of authority to approve abbreviated new drug applications.
10/19/82	47 FR 46622, 46649-50	In proposed revision of NDA regulations, FDA included a description of the data and information required in an ANDA, and a mechanism for listing drugs for which an ANDA will be accepted by FDA.
1/21/83	47 FR 2751	FDA published amended ANDA regulation making clear that when FDA finds that a drug is suitable for an ANDA, the finding will apply only to products identical to the product that was the subject of the finding. Regulation also established a petition procedure to use in seeking FDA determination as to whether a product is suitable for an ANDA.
2/25/83	48 FR 8133	FDA annnounced the availability of a list identifying drugs for which an ANDA is acceptable.
7/1/83	48 FR 30456	FDA published a supplement to the "List of Drug Products Suitable for ANDAs."
12/16/83	48 FR 55923	FDA published a second supplement to the "List of Drug Products Suitable for ANDAs."

ANIMAL HEALTH INSTITUTE MEMBERSHIP

July 1983

Agri-Bio Corp.

A.H. Robins Company

A.L. Laboratories, Inc.

American Cyanamid Company

American Hoechst Corporation

American Home Products Corporation

American Scientific Laboratories

Bayvet Division of Miles Laboratories

Beecham Laboratories

Biologics Corporation

Brae Laboratories, Inc.

Bristol Veterinary Products

Burns-Biotec Laboratories

Burroughs Wellcome Company

CEVA Laboratories, Inc.

Ciba-Geigy Corporation

Colorado Serum Company

Duphar Nutrition, Inc.

Elanco Products Company
Division of Eli Lilly & Company

EVSCO Pharmaceutical

Fort Dodge Laboratories, Inc.

Fromm Laboratories, Inc.

Hess & Clark, Inc.

Hoffmann-La Roche, Inc.

ImmunoGenetics, Inc.

International Minerals & Chemical Corporation

International Multifoods

Intervet USA, Inc.

Medico Industries, Inc.

Merck & Company, Inc.

Monsanto Company

Norden Laboratories, Inc.

Osborn Laboratories, Inc.

Pfizer Inc.

Philips Roxane, Inc., Subsidiary of Boehringer Ingelheim, Ltd.

Pitman-Moore, Inc.

Ralston Purina Company

Ribi Immunochem Research, Inc.

Salsbury Laboratories, Inc.

Schering Veterinary

SDS Biotech Corporation

SmithKline Beckman Corporation

E.R. Squibb & Sons, Inc.

Sterwin Laboratories, Inc.

Syntex Agribusiness, Inc.

TechAmerica Group, Inc.

Tuco Products Company

United Veterinary Laboratories

The Upjohn Company

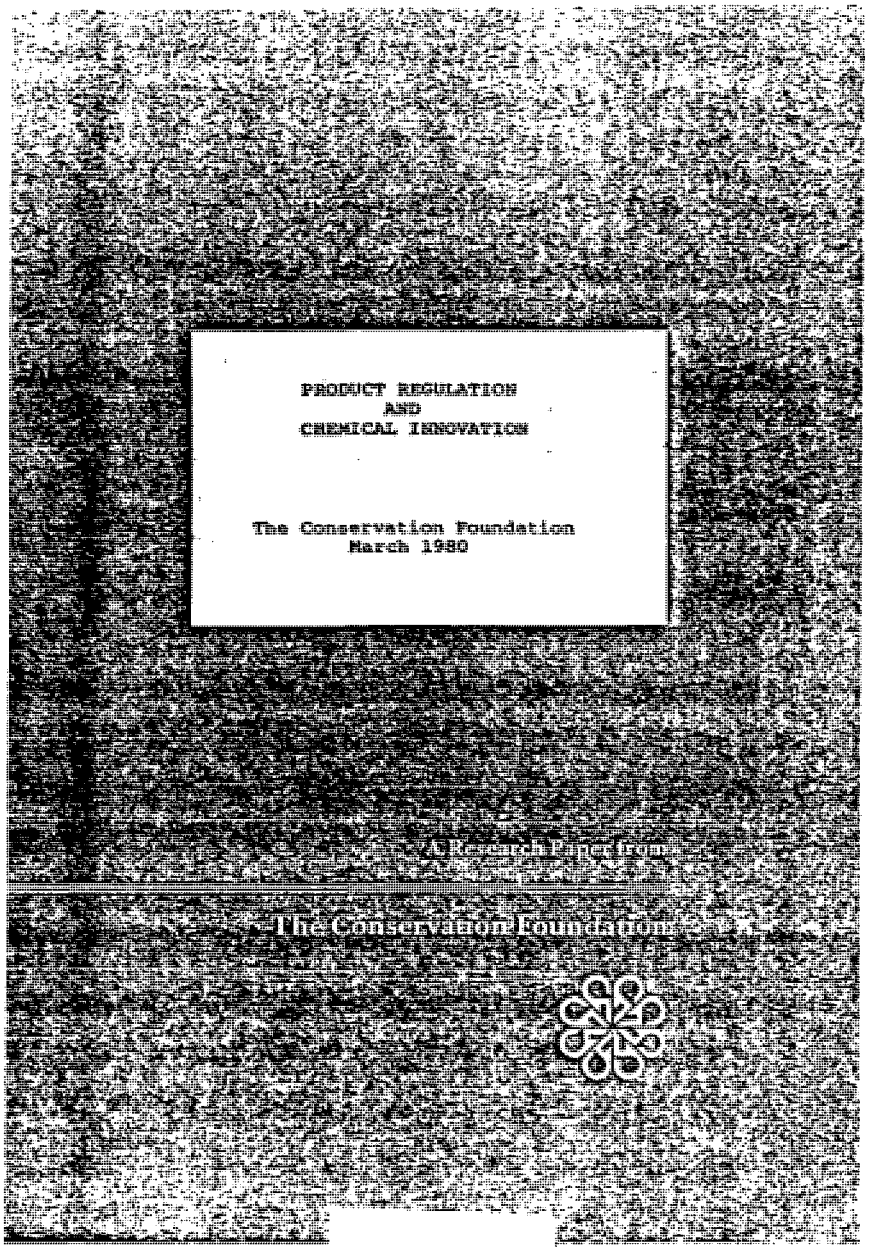
Veterinary Laboratories, Inc.

Vineland Laboratories, Inc.

Wellcome Animal Health, Inc.

Wendt Laboratories, Inc.

Zoecon Industries


PRODUCT REGULATION
AND
CHEMICAL INNOVATION
The Conservation Foundation
March 1980
A Research Paper from
The Conservation Foundation

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3. Data Confidentiality and Patents

No area of product regulation has been more controversial and troublesome than data confidentiality. The fundamental conflict is between the need for organizations and individuals outside EPA to have adequate information about a chemical to judge the risk it presents and the need of chemical producers to maintain exclusive ability to make and market a chemical.

The National Association of Manufacturers has noted that, "There are few inventions and fewer entrepreneurs (be they small or large) that will ever be commercially successful without an exclusive license." (National Association of Manufacturers, 1979) The traditional form of such a license is a patent. But the U.S. patent system has been weakened in a number of respects, and patents may be difficult to obtain and defend in other countries. Thus chemical firms have come to rely increasingly on keeping secret information about the chemical and how it is manufactured as a way of preventing potential competitors from marketing the same product.

The desire for secrecy runs counter to the need to have information to judge risk. Manufacturers may be reluctant to submit information to the government for fear that it will fall into the hands of competitors. One agency or level of government may be prevented from giving information to other agencies or governments by trade secret regulations. Citizen organizations may not be able to get sufficient data to judge the adequacy of government regulatory efforts. Scientists may be deprived of important scientific knowledge. Workers may be unable to judge the

risk of chemicals used in their place of work because the identity of the chemicals cannot be revealed.

A related but separable question is the extent to which results of health and safety studies conducted by a firm are the property of the firm. There are three general views on this matter: the results of such studies are scientific knowledge of importance to society and should not be considered private property; such studies are expensive to conduct and thus the firm which did the the study should be reimbursed by other firms that use the data, for example for registration purposes; such studies are private property in the full sense and thus may be sold to or withheld from other firms at the discretion of the owner of the property. These three views are not as contradictory to each other as they might appear. For example, there are ways in which the firm that did the studies could maintain exclusive use of the data for registration purposes while still making the data known to the general public.

3-1. Extend the 17 year patent protection for pesticides by the length of time between the date of original issuance of the patent and the date of registration approval by EPA.

There have been several extensive studies of possible reform of the patent law, and the National Agricultural Chemicals Association currently has a committee devoted exclusively to studying possible changes in patent law applicable to pesticides. We did not have the time or resources to master the intricacies of patent law and thus cannot delineate the full range of costs and benefits of proposed changes. However, it seems to us equitable to try to minimize the adverse effects on manufacturers caused by delay in

the registration process. Extension of the patent life is one way to do this.

The major benefit of extending the patent life for pesticides is that it increases the amount of time a manufacturer or formulator has to be the exclusive marketer of a product. This increases the product's profitability and thus encourages product development. The expiration of a patent threatens to reduce the manufacturer's return on investment, and return on investment is the basis on which most firms decide to market a new product. However, it should be noted that the one analysis of patent life remaining on registered pesticides showed that newly registered pesticides still had most of their patent life remaining (see Chapter IV). The proposal also would have the subsidiary benefit of reducing the pressure to use rights to health and safety data as a substitute for patents to protect exclusive rights in a product.

The major cost of the patent extension would be reduced competition. While there are costs to such a reduction (such as higher prices), they are not likely to be costs to innovation. The major losers from such reduced competition would be consumers and perhaps small formulators who will have to pay more but who do not account for any of the innovation in the industry. Thus reduced competition of this sort would not result in any loss of innovation. However, this might be less true of other industries to which the proposal might be applied, such as drugs and food additives.

Another potentially significant cost is that such an extension of patent life would reduce the incentives for pesticide

registrants to obtain speedy completion of the registration process. Thus, for example, the registrant might take a much longer time to provide additional data requested by EPA. The result would be that society might be deprived of the use of new pesticides for some period of time. However, there are economic pressures aside from patent life that encourage a firm to obtain registration as soon as possible (sunk investment in capital equipment, for example) so that it is not likely that the proposal would add to delay in registration, except in the unlikely case where an initial registration for a minor crop might be delayed to coincide with registration for the major intended crop use.

The recommendation for extending the patent life does not apply to chemicals regulated under TSCA. Because TSCA is not a registration statute there is not the same equity argument to compensate manufacturers for bureaucratic delay. If the patent life of TSCA chemicals is extended by the time between original patent issuance and date of submission of the pre-manufacturing notification, it would have the undesirable effect of encouraging manufacturers to submit the notification to EPA as close to the time of marketing as possible, thus providing the agency with as little review time as possible.

3-2. Health and safety data submitted to EPA under the provisions of Section 5 of TSCA should be considered the property of the firm that paid for the data. The firm should have exclusive use of the data for three years from the date of premanufacturing notification, and should be entitled to reimbursement for a period of ten years. Subsequent manufacturers of the chemical would also be required to submit Section 5 notifications.

This option, which would require legislative changes in TSCA, is intended to suggest a possible solution to the difficult problems discussed in the introduction to this section. It could result in a significant improvement in innovation and in removing a major obstacle to implementing regulation. It would provide a positive incentive for firms to submit test data to EPA, and eliminate some of the differences between U.S. and Common Market approaches.

The option would give the firm which paid for the data exclusive use of the data for a period of three years from the date of submission of a new chemical or significant new use notification. Other firms could not use the data without the original firm's permission. However, the data could still be made public in keeping with current TSCA provisions by requiring an affidavit regarding the origin of the data or by using some type of identification code linked to the basic data which would be known only to the firm and to EPA. This would prevent unauthorized use of the data by competing firms for a sufficient period of time to permit the first firm to establish itself in the marketplace.

Use of publicly released data by foreign competitors has been one of the major reasons why U.S. firms have been reluctant to make health and safety data public. This is a serious problem. It could be remedied if international agreement could be reached on the information to be submitted with new chemical notifications. Such information could require coding or submission of detailed information known only to the original investigator. This information would not be made public, and therefore a firm in one country

could not use health and safety data originally performed by a firm in another country without the original firm's permission. Alternatively, the international agreement could require that test data be accompanied by an affidavit that the firm submitting the data has either developed the data itself or has obtained permission to use the data from the firm that did do the testing.

Between the third and tenth year from date of the notification the original firm would be required to grant others the right to use the data providing that each such other firm paid the first firm a fee which they (or if necessary an arbitrator) agreed was equal to the cost (or some stated percentage of the cost) that would be incurred to develop the data at an efficient, competent laboratory. After ten years from the notification date no limitations would be placed on use of the data, and the substance would be placed on the inventory for manufacture by anyone without notification.

These suggested provisions are a compromise and thus are subject to criticism from widely differing viewpoints. Industry might argue that the data compensation period should be extended indefinitely, not limited to ten years. Others might argue that there should be no exclusive data rights because such rights would waste resources by encouraging duplicative testing, and would also reduce competition.

We have limited the option to TSCA because the current state of data rights under FIFRA is being litigated. The FIFRA provisions under dispute are in general ways similar to the proposal outlined in this option, although the provisions for exclusive

use of data developed after 1978 are not now being litigated. We believe that some compromise of the type we have outlined is the only kind of solution that is feasible to deal with the knotty problems of proprietary data rights.

ANIMAL HEALTH INSTITUTE*

DISCUSSION OF PATENT TERM RESTORATION

FOR ANIMAL HEALTH PRODUCTS

June 26, 1984

Introduction

Animal health products -- drugs regulated by HHS/FDA and biologicals, by USDA/APHIS -- would receive Patent Term Restoration (PTR) under two legislative proposals currently under active consideration.

Legislation

- H.R. 5529, the "Agricultural Patent Reform Act of 1984" (Glickman-DeWine), also covering pesticides (EPA/FIFRA) and precursor chemicals (EPA/TSCA).

- S. 2748 (Hatch-Kennedy) and H.R. 3605 (Waxman), the "Drug Competition and Patent Term Restoration Act of 1984," identical bills designed principally to provide PTR for human-use prescription drugs and to expedite FDA approval of "me-too" generics after brandname Rx drugs' patents expire.

Animal Health Institute Position

*The Animal Health Institute (AHI) is the national industry trade association representing the 55 firms that manufacture nearly all of the animal drugs and biologicals marketed in the United States. AHI urges enactment of PTR provisions pertaining to animal health products that conform to the legislative language of H.R. 5529, the "Agricultural Patent Reform" bill. The rationale for this position follows.

1. AGRICULTURAL BILL DEALS PRIMARILY WITH PATENTS OF AGRICULTURAL CHEMICALS; COMPETITION-PTR BILLS ADDRESS PATENTS AND GENERIC Rx HUMAN DRUG APPROVALS

The agricultural bill appropriately provides PTR for products that are essentially agricultural -- utilized in the production of food -- while the Competition-PTR bills represent a carefully crafted two-title compromise between the divergent interests of the two components -- brandname and generic -- of the human-use prescription drug industry.

2. 97th CONGRESS NEARLY ENACTED LEGISLATION CLOSELY RESEMBLING "AGRICULTURAL PATENT REFORM"

The agricultural bill's provisions closely resemble those contained in legislation (S. 255 and H.R. 6444) passed by the Senate and approved by a majority of the House in the 97th Congress. [Those more comprehensive bills covered human pharmaceuticals as well as pesticides and animal health products. Enactment was not achieved because a two-thirds majority was lacking in the House. Those bills would have allowed seven-year patent term extensions, rather than the five-year maximum permitted under the current proposals.]

3. AGRICULTURAL PTR BILL DEALS PRIMARILY WITH CHEMICALS USED IN FOOD PRODUCTION

H.R. 5529 is designed primarily to provide patent term equity for only one broad category of products, chemicals used in the production of foodstuffs.

4. MOST ANIMALS DRUGS ARE USED IN AGRICULTURE

The bulk (about 82 percent in 1983) of animal drugs are used in agricultural, food-producing animals -- cattle, swine, sheep, poultry and dairy cows.

5. LIKE PESTICIDES, DRUGS ARE USED IN FOOD ANIMALS FOR ECONOMIC REASONS; FOOD ANIMALS DO NOT RECEIVE DRUGS LIKE HUMANS

Animal drugs are used in food-producing animals almost exclusively for economic reasons. FDA's premarketing regulatory review of such an animal drug takes an average of over six years (sometimes it stretches to 10 or 11). This, of course, is the main reason Patent Term Restoration for these products is essential if the industry is to continue the R&D necessary to provide new, more effective, animal health products for America's livestock and poultry producers. A vital element of that regulatory review -- and an extremely costly and time consuming one -- is human food safety. The agency insists upon being absolutely satisfied that the animal drug, its metabolites and residues, will pose no hazard to those who consume animal-derived foods. This important consideration closely parallels those applied by EPA to pesticides used on edible food crops. For obvious reasons, there is nothing comparable in FDA's scrutiny of human-use drugs. Food animal medicine is not even remotely analogous to human medicine. Whole herds and flocks of animals and fowl are treated simultaneously to prevent, control and treat diseases and parasites, to promote growth and to enhance feed efficiency. The use of animal health products is essential to the economical production of wholesome meat, eggs and dairy products in plentiful supply at affordable prices.

6. ANIMAL AGRICULTURE ORGANIZATIONS SUPPORT H.R. 5529

The PTR provisions of the "Agricultural Patent Reform" legislation are endorsed by all of the major associations representing food animal producers and veterinarians, including:

National Cattlemen's Association
National Pork Producers Council
National Broiler Council
American Farm Bureau Federation
National Turkey Federation
National Milk Producers Federation
American Feed Manufacturers Association
American Veterinary Medical Association

7. TWO ADMINISTRATION DEPARTMENTS ENDORSE THE NON-CONTROVERSIAL AGRICULTURAL PTR BILL

The Departments of Commerce (which includes the Patent Office) and Agriculture have affirmatively endorsed H.R. 5529, the Agricultural PTR bill, to which no opposition is known.

8. SPECIFIC PROVISIONS OF PTR LEGISLATION APPLYING TO ANIMAL DRUGS & BIOLOGICALS ARE DISPARATE

Under both the Agricultural PTR bill and the Drug Competition-PTR bills, the maximum patent term restoration for an animal health product would be five years. But here the resemblance ends. There are substantial, critical differences between the two proposals' formulas for computing the amount of restoration that can be granted, and other important disparities as well.

- Credits Toward PTR -- The Agricultural bill allows the entire preliminary investigational period to count toward the allowable PTR. Under the Drug Competition-PTR bills, only one half of this period can be counted. Both proposals allow all of the time consumed by the second phase of premarketing review (from the filing of an application for approval to the formal approval of the product for marketing). When the formulas are applied to two random examples, the Agricultural PTR bill allows a full five-year extension for each, while the Drug Competition-PTR proposal would permit only four years in each case. (No two animal health products would be treated exactly alike.)

- "Caps" Make a Difference -- Under the Agricultural bill, a maximum five-year extension could be granted for an animal health product -- compensating for five of the years consumed by testing and regulatory review -- giving the product a total of 22 years under patent (although the effective patent life could not exceed the Congressionally-mandated 17 years). Under the Drug

Competition-PTR bills, the PTR extension plus the patent term remaining upon approval could not exceed 14 years, regardless of how much of the original 17-year patent term remained at the time of approval.

- "Pipeline" Products Treated Disparately -- For a product patented and not yet approved prior to enactment (a "pipeline" product), the Agricultural PTR bill limits patent term extension to three years. The Drug Competition-PTR proposal would limit such an extension to two years if the product had previously undergone any part of any phase of regulatory review.

- "Due Diligence" Provisions Are Different -- The Agricultural PTR bill provides that the product's patent holder can be sued in Federal court by anyone seeking to reduce the extension term who contends the patent holder failed to exercise "due diligence" in pursuing marketing approval. Under the Drug Competition-PTR bills, the complainant (presumably a potential "me-too" marketer) would file a petition with the appropriate Federal Department. The decision as to whether to reduce the PTR extension, or perhaps to eliminate it altogether, would in the former instance come from the court; in the latter, from the authorized Department.

- Drug Competition-PTR Proposal Overturns Bolar Decision -- In a recent case [Roche Products Inc., v. Bolar Pharmaceutical Co., Federal Circuit, April 23, 1984], an appellate court ruled that it is an infringement of the patent to manufacture a patented product for the purpose of conducting studies in order to obtain marketing approval. The Drug Competition-PTR proposal explicitly overturns that decision. As it pertains to human-use drugs, this provision is offset somewhat by provisions of the bills' Title I (ANDAs), but the bills contain no comparable compensatory provisions applicable to animal health products. The Agricultural PTR bill does not address the Bolar decision.

- Animal Drugs Do Not Belong in an ANDA Proposal -- As noted above, Title I of the Drug Competition-PTR bill sets up a system for expediting FDA approval of generic human-use prescription drugs. (Title I is commonly called the ANDA provisions; the acronym stands for Abbreviated New Drug Application.) Tbis title is the "trade-off" against brandname Rx drug PTR. It has been suggested that Title I should be expanded somehow to provide similar treatment for animal health products. Such action would be utterly inappropriate. FDA has not adopted any formal system for handling "abbreviated" new animal drug applications (NADAs), as it has for human drug NDAs. The agency has no systematic list of animal drugs that are subject to abbreviated applications, nor does it have any formal policy regarding their bioequivalency. Moreover, with human food safety as a paramount concern, the approval issues for drugs used in food-producing species are significantly more complex than they are for human drugs. Such animal drugs are therefore not ordinarily amenable to an abbreviated NADA approach. As mentioned before, there is no

separate "generic" animal health products industry seeking Congressional action to hasten approval of its drugs. Neither are there any massive Federal tax-supported programs like Medicare and Medicaid to stimulate governmental interest in promoting a generic industry.

9. **ANIMAL HEALTH PRODUCTS WERE NOT INVOLVED IN THE LENGTHTY NEGOTIATIONS LEADING TO "COMPETITION-PTR" BILLS**

The Drug Competition PTR bills represent a compromise resulting from 10 months of intensive negotiations involving Members of Congress and both components, brandname and generic, of the human-use prescription drug industry, balancing abbreviated approval concepts and patent extension terms. These negotiations and deliberations never involved AHI, and to our best knowledge they never focussed on animal drugs and biologicals.

10. **ANIMAL HEALTH INDUSTRY IS A UNIQUE, UNIFIED BRANDNAME-GENERIC MIX: THERE IS NO SEPARATE GENERIC INDUSTRY**

There is no separate "generic" animal health products industry. AHI is the only trade association representing that industry. AHI's 55 member firms manufacture nearly 90 percent of the animal health products marketed in the United States, many of which are unpatented ("generics").

CONCLUSION

The Animal Health Institute, supported by every major agricultural and professional organization that uses animal health products, urges prompt enactment of Patent Term Restoration legislation for animal drugs and biologicals. AHI believes H.R. 5529, the "Agricultural Patent Reform Act of 1984," treats those products appropriately with other agricultural chemicals. AHI therefore urges enactment of H.R. 5529, or, alternatively, enactment of its provisions as a part of another legislative package. This will provide a long overdue, essential stimulus for the development of innovative products for use in the production of animal-derived foods.

[For further information contact AHI at (703) 684-0011.]

# # #

national association of plant patent owners
1250 eye street, n.w.
suite 500
washington, d.c. 20005
202/789-2900

PROBLEM: Certain varieties of plants developed or discovered outside the U.S. are subject to a post-entry quarantine upon importation to U.S. for propagation. The purpose of the quarantine is to prevent the introduction of pests, viruses and diseases into the country. The length of the quarantine may range from one to six years depending on the variety involved (e.g. roses, ornamental shrubs, fruit trees). A patent for the new variety is sought by the owner upon importation and the time in quarantine results in a shortened patent term. A patent owner cannot market or sell the plant during the quarantine.

STATUTORY AUTHORITY: The quarantine authority of the Secretary of Agriculture was granted by the Plant Quarantine of 1912 as amended July 31, 1947 (7U.S.C.154) and regulatory authority may be found at 7C.F.R. 319.37-7.

Nursery stock subject to quarantine is defined at 7U.S.C.152 and a specific list of varieties subject to quarantine at the present time may be found at 7C.F.R.319.37-7.

PATENT LAW: All provisions of patent law, including the term of patents, apply to plant patents. However, there is a separate definition of plants eligible to be patented which may be found at 35U.S.C.161.

DRAFTING CONCERNS: Proposed legislation has generally referred to "products" and manufacturing, as included in 35U.S.C.101,therefore it would be necessary to introduce the terms "Variety of Plants" and perhaps "Asexual reproduction."

Also would need additional definition of regulatory review period to include quarantines imposed by virtue of the Plant Quarantine Act of 1912 as amended. A quarantine has clearly defined time limits and is generally a passive situation not requiring sponsor testing and data collection therefore it should not require the elaborate provisions necessary to cover regulatory reviews that require affirmative testing.

H.R. 5529

(d) As used in this section:

(1) The term 'product' means any machine, manufacture, new variety of plant, or the composition of matter for which a patent may be obtained and is limited to the following

Add new paragraph:

(d) (1) (E) Any variety of plant subject to post entry quarantine under the Plant Quarantine Act of 1912 as amended.

Add new paragraph:

(5) (D) With respect to a product which is a variety of plant, the term is the period beginning with the date of arrival at the port of entry and ending with the termination of the quarantine by the Department of Agriculture.

CHAPTER 15—PLANT PATENTS

Sec.

161. Patents for plants.
162. Description, claim.
163. Grant.
164. Assistance of Department of Agriculture.

§ 161. Patents for plants

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of title. (Amended September 3, 1954, 68 Stat. 1190.)

The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.

§ 162. Description, claim

No plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible.

The claim in the specification shall be in formal terms to the plant shown and described.

§ 163. Grant

In the case of a plant patent the grant shall be of the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced.

§ 164. Assistance of Department of Agriculture.

The President may by Executive order direct the Secretary of Agriculture, in accordance with the requests of the Commissioner, for the purpose of carrying into effect the provisions of this title with respect to plants (1) to furnish available information of the Department of Agriculture, (2) to conduct through the appropriate bureau or division of the Department research upon special problems, or (3) to detail to the Commissioner officers and employees of the Department.

§ 154. General restriction on importation of nursery stock; exceptions

It shall be unlawful for any person to import or offer for entry into the United States any nursery stock unless and until a permit shall have been issued therefor by the Secretary of Agriculture, under such conditions and regulations as the said Secretary of Agriculture may prescribe, and unless such nursery stock shall be accompanied by a certificate of inspection, in manner and form as required by the Secretary of Agriculture, of the proper official of the country from which the importation is made, to the effect that the stock has been thoroughly inspected and is believed to be free from injurious plant diseases and insect pests: Provided, That the Secretary of Agriculture shall issue the permit for any particular importation of nursery stock when the conditions and regulations as prescribed in this Act [7 USCS §§ 151 et seq.] shall have been complied with: Provided further, That nursery stock may be imported for experimental or scientific purposes by the Department of Agriculture upon such conditions and under such regulations as the said Secretary of Agriculture may prescribe: And provided further, That nursery stock imported from countries where no official system of inspection for such stock is maintained may be admitted upon such conditions and under such regulations as the Secretary of Agriculture may prescribe: And provided further, That the Secretary of Agriculture is authorized to limit entry of nursery stock from foreign countries under such rules and regulations as he may deem necessary, including the requirement, if necessary, that such nursery stock be grown under postentry quarantine by or under the supervision of the United States Department of Agriculture for the purpose of determining whether imported nursery stock may be infested or infected with plant pests not discernible by port-of-entry inspection and provided that if imported nursery stock is found to be infested or infected with plant pests, he is authorized to prescribe remedial measures as he may deem necessary to prevent the spread thereof.

(Aug. 20, 1912, c. 308, § 1, 37 Stat. 315; July 31, 1947, c. 405, 61 Stat. 680.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Effective date of section:

This section became effective Oct. 1, 1912, as provided by § 14 of Act Aug. 20, 1912, c. 308.

Amendments:

1947. Act July 31, 1947, added ": And provided further, That the Secretary of Agriculture is authorized to limit entry of nursery stock from foreign countries under such rules and regulations as he may deem necessary, including the requirement, if necessary, that such nursery stock be grown under postentry quarantine by or under the supervision of the United States Department of Agriculture for the purpose of determining whether imported nursery stock may be infested or infected with plant pests not discernible by port-of-entry inspection and provided that if imported nursery stock is found to be infested or infected with such plant pests, he is authorized to prescribe remedial measures as he may deem necessary to prevent the spread thereof".

Transfer of functions:

All functions of all officers, agencies and employees of the Department of Agriculture were transferred, with certain exceptions, to the Secretary of Agriculture by 1953 Reorg. Plan No. 2, § 1, eff. June 4, 1953. 18 Fed. Reg. 3219, 67 Stat. 633, set out as a note under 5 USCS § 903.

§ 152. "Nursery stock" defined

For the purpose of this Act [7 USCS §§ 151 et seq.] the term "nursery stock" shall include all field-grown florists' stock, trees, shrubs, vines, cuttings, grafts, scions, buds, fruit pits and other seeds of fruit and ornamental trees or shrubs, and other plants and plant products for propagation, except field, vegetable, and flower seeds, bedding plants, and other herbaceous plants, bulbs, and roots.

(Aug. 20, 1912, c. 308, § 6, 37 Stat. 317.)

§ 319.37-7 Postentry quarantine.

(a) The following restricted articles from the designated countries and localities (1) may be imported or offered for importation into the United States only after a completed postentry quarantine agreement, as provided in paragraph (c) of this section, has been submitted to the Plant Protection and Quarantine Programs, and (2) shall be grown under postentry quarantine conditions specified in paragraph (c) of this section:

Restricted Article (excluding seeds)	*Foreign Country(ies) or Locality(ies) from which imported*
Acacia spp. (acacia)	All except Australia, Canada, and Oceania.
Acer spp. (maple)	All except Bulgaria, Canada, Federal Republic of Germany (West), France, German Democratic Republic (East), Great Britain, and Japan.
Actinidia spp. (Chinese gooseberry, kiwi).	All except Australia, Canada, Japan, New Zealand, and Taiwan.
Aesculus spp. (horsechestnut)	All except Canada, Czechoslovakia, Federal Republic of Germany (West), German Democratic Republic (East), and Great Britain.
Althaea spp. (althaea, hollyhock).	All except Africa, Canada, and India.

Restricted Article (excluding seeds)	Foreign Country(ies) or Locality(ies) from which imported
Berberis spp (barberry) destined to any State except the eradication States listed in § 301 38-2a of this chapter (plants of all species and horticultural varieties designated as resistant to black stem rust in accordance with § 301 38-1 of this chapter).	All.
Bromeliaceae (bromeliads) destined to Hawaii	All.
Cedrus spp. (cedar)	All except Canada and Europe.
Chaenomeles spp (flowering quince) meeting the conditions for importation in § 319 37-5(b).	Countries listed in § 319 37-5(b) except Canada.
Chrysanthemum spp. (chrysanthemum).	Great Britain and all other countries and localities except Argentina, Brazil, Europe (other than Great Britain), Republic of South Africa, and all countries and localities located in part or entirely between 90° and 180° East longitude.
Crataegus monogyna Jacq. (hawthorne, thornapple, red haw).	Europe.
Cydonia spp (quince) meeting the conditions for importation in § 319 37-5(b).	Countries listed in § 319.37-5(b) except Canada.
Datura spp.	All except Canada, Colombia and India.
Dianthus spp (carnation, sweet william).	Great Britain, unless exempted from postentry quarantine conditions pursuant to § 319 37-5(d), and all other countries and localities except Canada.
Eucalyptus spp (eucalyptus)	All except Argentina, Canada, Europe, Sri Lanka (Ceylon), and Uruguay.
Euonymus spp (euonymus)	All except Canada, Federal Republic of Germany (West), and German Democratic Republic (East).
Fragaria spp. (strawberry)	All except Australia, Austria, Canada, Czechoslovakia, France, Great Britain, Italy, Japan, Lebanon, The Netherlands, New Zealand, Northern Ireland, Republic of Ireland, Switzerland, and Union of Soviet Socialist Republics.
Fraxinus spp (ash)	All except Canada and Europe.
Fruit and nut articles listed by common name in paragraph (b) of this section.	All except Canada.
Gladiolus spp. (gladiolus) except bulbs.	All except Africa, Canada, Italy, Malta, and Portugal.
Hibiscus spp. (hibiscus, rosemallow).	All except Africa, Canada, India, and Trinidad and Tobago.
Humulus spp. (hops)	All.
Hydrangea spp. (hydrangea)	All except Canada and Japan.
Jasminum spp (jasmine)	All except Belgium, Canada, Federal Republic of Germany (West), German Democratic Republic (East), and Great Britain.
Juniperus spp (juniper)	All except Canada and Europe.
Larix spp (larch)	All except Canada and Europe.
Ligustrum spp. (privet)	All except Canada, Federal Republic of Germany (West), and German Democratic Republic (East).
Mahoberberis spp destined to any State except the eradication States listed in § 301 38-2a of this chapter (plants of all species and horticultural varieties designated as resistant to black stem rust in accordance with § 301.38-1 of this chapter).	All.
Mahonia spp (mahonia) destined to any State except the eradication States listed in § 301 38-2a of this chapter (plants of all species and horticultural varieties designated as resistant to black stem rust in accordance with § 301 38-1 of this chapter).	All.
Malus spp (apple, crabapple) meeting the conditions for importation in § 319 37-5(b).	Countries listed in § 319.37-5(b) except Canada.
Mespilus germanica (medlar)	Countries listed in § 319 37-5(b) except Canada.
Morus spp (mulberry)	All except Canada, India, Japan, People's Republic of China, and Union of Soviet Socialist Republics.
Nut and fruit articles (see fruit and nut articles).	
Passiflora spp. (passion fruit, granadilla).	All except Canada.
Philadelphus spp. (mock orange)	All except Canada and Europe.
Picea spp (spruce)	All except Canada, Europe, Japan, and Siberia.
Pinus spp (pine) (2-or-3 leaved).	All except Canada, Europe, and Japan.
Populus spp (aspen, cottonwood, poplar).	All except Canada and Europe.
Prunus spp (almond, apricot, cherry, cherry laurel, English laurel, nectarine, peach, plum, prune) meeting the conditions for importation in § 319.37-5(b).	Countries listed in § 319.37-5(b) except Canada.
Pseudotsuga spp. (Douglas fir).	All except Canada and Europe.
Pyrus spp. (pear) meeting the conditions for importation in § 319.37-5(b).	Countries listed in § 319.37-5(b) except Canada.
Quercus spp. (oak)	All except Canada and Japan.
Ribes nigrum (black currant)	All except Australia, Canada, Europe, and New Zealand.
Rosa spp. (rose)	All except Australia, Canada, Italy, and New Zealand.

Restricted Article (excluding seeds)	Foreign Country (ies) or Locality (ies) from which imported
Rubus spp. (cloudberry, blackberry, boysenberry, dewberry, loganberry, raspberry)	All unless exempted from postentry quarantine conditions pursuant to § 319.37-5(e).
Salix spp. (willow)	Europe except Federal Republic of Germany (West), German Democratic Republic (East), Great Britain, and The Netherlands.
Sorbus spp. (mountain ash)	All except Australia, Canada, Federal Republic of Germany (West), German Democratic Republic (East), Japan, New Zealand, People's Republic of China, Philippines, and Oceania.
Syringa spp. (lilac)	All except Canada and Europe.
Ulmus spp. (elm)	All except Canada and Europe.

(b) *Fruit and Nut Articles* (common names are listed after scientific names).

Achras—(Synonym for *Manilkara*)
Annona—custard apple, cherimoya, sweetsop, sugarapple, soursop, bullock's heart, alligator apple, suncoya, ilama, guanabana, pond apple
Anacardium—cashew
Artocarpus—breadfruit, jackfruit
Averrhoa—carambola
Blighia—akee
Bouea—kundangan
Calocarpum—sapote
Carica—papaya, pawpaw
Carissa—natal plum
Carya—hickory, pecan
Castanea—chestnut
Ceratonia—St. Johnsbread
Chrysobalanus—coco plum
Chrysophyllum—starapple
Coccoloba—sea-grape, pigeon plum
Corylus—filbert, hazel, hazelnut, cobnut
Crataegus—hawthorne
Diospyros—persimmon, kaki, mabola
Durio—durian
Eriobotrya—loquat, Japanese medlar, Japanese plum
Euphoria—longan
Eugenia—roseapple, Malayapple, Curacaoapple
Feijoa—feijoa, pineapple guava
Ficus—fig
Garcinia—mangosteen, gourka
Juglans—walnut, butternut, heartnut, regranut, buartnut
Lansium—langsat
Litchi—lychee, leechee
Macadamia—macadamia nut, queensland nut
Malpighia—Barbados cherry
Mammea—mammeapple, mamey
Mangifera—mango
Manilkara—sapodilla
Melicoccus—honeyberry, mamoncilla, spanish lime, genip
Nephelium—rambutan, pulasan
Oleo—olive
Persea—avocado, alligator pear
Phoenix—date
Phyllanthus—otaheite-gooseberry
Pistacia—pistachio
Pouteria—lucuma
Psidium—guava, guayala
Punica—pomegranate, granada
Pyronia—quinpear
Rhodomyrtus—hill gooseberry, rose myrtle
Ribes (other than *Ribes nigrum*)—red currant, white currant, gooseberry
Spondias—yellow mombin, red mombin, hog plum
Syzygium—Malayapple, rose apple, java plum
Theobroma—cacao
Vaccinium—blueberry, cranberry
Ziziphus—jujube

(c) Any restricted article required to be grown under postentry quarantine conditions shall be grown under the supervision and control of a person who has signed a postentry quarantine agreement to comply with the following conditions for the period of time specified below:

(1) To grow such article or increase therefrom only on specified premises;

(2) To permit an inspector to have access to the specified premises for inspection of such article during regular business hours;

(3) To keep the article and any increase therefrom identified with a label showing the name of the article, port accession number, and date of importation;

(4) To keep the article separated from any domestic plant or plant product of the same genus by no less than 3 meters (approximately 10 feet); and from any other imported plant or plant product by the same distance;

(5) To allow or apply remedial measures (including destruction) determined by an inspector to be necessary to prevent the spread of an injurious plant disease, injurious insect pest, or other plant pest;

(6) To notify Plant Protection and Quarantine Programs if any abnormality of the article is found or if the article dies;

(7) To grow the article or increase therefrom, if an article of *Rubus* spp. (cloudberry, blackberry, boysenberry, dewberry, loganberry, raspberry) from Europe, only in a screenhouse with screening of a minimum of 16 mesh per inch;

(8) To grow the article or increase therefrom, if an article of *Chrysanthemum* spp. (chrysanthemum) or *Dianthus* spp. (carnation, sweet-william), only in a greenhouse or other enclosed building; and

(9) To comply with the above conditions for a period of 6 months after importation for an article of *Chrysanthemum* spp. (chrysanthemum), for a period of 1 year after importation for an article of *Dianthus* spp. (carnation, sweet-william), and for a period of 2 years after importation for any other such articles.

(d) A completed postentry quarantine agreement shall accompany the application for a written permit for an article required to be grown under postentry quarantine conditions.*

June 6, 1984

QUESTIONS FOR AGRICULTURAL AND CHEMICAL PANEL:

1. In testimony before this Subcommittee last Congress the National Agricultural Chemical Association (NACA) cited a Conservation Foundation report. Yet that report (at page V-26) states that patent term legislation would have at least two potential adverse consequences: (1) reduced competition; and (2) reduced incentives for the manufacturers to proceed with speed through the regulatory process. The report goes on to oppose the inclusion in a patent term bill of any substances regulated under the Toxic Substances Control Act ("tosca") because to do so would encourage the submission of data to EPA as close as possible to the time the substance will be marketed --- thereby limiting the chances of effective EPA review. How do you respond to these comments?

2. Agricultural chemicals regulated under the Federal Insecticide, Fungicide and Rodenticide Act ("fifra") are not subject to the same type of regulatory process as human pharmaceuticals. For example, the tests which must be done by the company are required to meet general federal regulatory standards, but these tests all occur before any notification to the Federal government and their timing is largely within

the control of the manufacturer. Given this diminished level of Federal regulatory delay (e.g. EPA review after submission of the data could be less than a year), wouldn't it be appropriate to reduce the period of patent term extension to guard against the possibilities of dilatory testing? One possibility would be to grant only 1/2 of the period between the commencement of the tests and the filing of an experimental use permit (EUP). An alternative would be to permit aggrieved parties to more easily file for reduction in the patent term extension claiming a lack of due diligence.

3. Assuming that only about a third of the agricultural chemical companies are U.S. based how will passage of this bill affect American innovation and/or our balance of employment and balance of payments?

4. Under FIFRA the registration data submitted to EPA may not be disclosed for a period of ten years (regardless of when the patent expires). Doesn't this create a situation similar to that found with human pharmaceuticals in that generic manufacturers may not have access to sufficient data to be able to enter the market with a generic agricultural chemical even after the expiration of the patent?

5. How do you respond to the comments of EPA on H.R. 5529? Specifically, should the regulatory review period --- for which patent term extension is granted --- begin with the filing of FIFRA or TSCA data, even though such data is incomplete?

6. What are your views about the attempt of H.R. 3605 to partially overrule the result of the decision of the Court of Appeals for the Federal Circuit in Roche v. Bohlar?

In Roche the court held that a generic drug manufacturer could not avoid liability for patent infringement by claiming that limited drug testing --- done in anticipation of patent exiration and anticipatory to seeking FDA approval --- was an "experimental use".

7. Should this legislation provide the same type of abbreviated approval process for animal drugs as obtains for human generic manufacturers under H.R. 3605

8. Why should TSCA substances be granted an extension of patent life when the government review period is only 90 or 180 days?

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION
THE MADISON BUILDING
1155 Fifteenth Street, N.W., Washington, D. C. 20005
202 • 296-1585 Cable: NAGRCHEM

June 5, 1984

Mr. David Beier
Assistant Counsel
Subcommittee on Courts, Civil Liberties
and the Administration of Justice
2137 Rayburn Building
Washington, DC 20515

Dear Mr. Beier:

Per your request, I am pleased to enclose biographies on the three NACA witnesses who will be testifying at tomorrow's hearing before your Subcommittee.

If there is any additional information you might need, please let me know.

Best wishes.

Sincerely,

L. W. Shaw

Luther W. Shaw
Vice President
Public Affairs

LWS:wps

Enclosures

VAUGHN D. BRYSON

Vaughn D. Bryson has been president of Elanco Products Company, the agricultural products division of Eli Lilly and Company, since January, 1982.

A native of Gastonia, North Carolina, Mr. Bryson received a Bachelor of Science degree from the University of North Carolina in 1960 and completed the Stanford-Sloan program at the Stanford University Graduate School of Business in 1967.

Mr. Bryson joined Eli Lilly in 1961 as a salesman in High Point, North Carolina. He served in various sales positions in North Carolina, Florida, and Georgia until June, 1965, when he was transferred to the company's headquarters in Indianapolis as a market research analyst. Later that year he became a senior personnel representative.

In July, 1967, Mr. Bryson was named a personnel manager, and a few months later he became manager of economic studies. He was named a district sales manager in Sacramento in 1968, director of distribution and materials planning early in 1970, and director of sales for the company's Great Lakes region later that year. In 1972 he became director of market research and in 1974, executive director of corporate pharmaceutical marketing planning. In August of 1975, Mr. Bryson became area director for Japan and Southeast Asia for Eli Lilly International Corporation. A year later he was named a vice president and in 1977, Canada, Australia, New Zealand and South Africa were added to his responsibilities. In 1979, he reestablished the company's European office as vice president for Europe, the Middle East, and Africa.

Mr. Bryson is a member of the Stanford Business School Association, the Board of Directors for the National Agricultural Chemicals Association, Animal Health Institute, Indiana Institute of Agriculture, Food and Nutrition, St. Francis Hospital, the Community Service Council of the United Way, and the Purdue University Ag Advisory Committee.

JOHN E. MAURER

John E. Maurer is general consulting attorney for Monsanto Company.

Mr. Maurer joined Monsanto in 1952 and has held a number of assignments in the Patent Department, including patent counsel for Monsanto Industrial Chemicals Co., an operating unit of Monsanto Company, from 1971 to 1976.

In 1976 he was appointed director, results management, for the Corporate Research and Development staff and the Environmental Policy Staff. He was on special assignment in 1978 with the Environmental Policy Staff working in the area of contract administration. He was appointed general patent counsel from 1979 to 1983 and to his present position in 1983.

Mr. Maurer is a member of the American and Missouri Bar Associations, as well as the Bar Association of Metropolitan St. Louis, of which he is past president of the Patent Section. He is past president of the Association of Corporate Patent Counsel, a vice president and member of the board of directors of Intellectual Property Owners, Inc., a member of the board of the American Patent Law Association, a member of council of the Patent, Trademark and Copyright Section of the American Bar Association, on the Advisory Board of PTC Research Foundation, a member of Licensing Executives Society, and a member of Executive Committee of the International Patent & Trademark Association.

He is also 2nd Governor of the Pacific Industrial Property Association, and a member of the Chemical Manufacturers Association (PTC Committee), the U.S. Chamber of Commerce, National Association of Manufacturers (Task Force on Intellectual Property), and the U.S. State Department Advisory Committee on International Intellectual Property.

Born in St. Louis, Mr. Maurer received a bachelor's degree in chemical engineering at Missouri School of Mines & Metallurgy in 1951. He received a J.D. degree at St. Louis University in 1958. In 1974, Mr. Maurer attended the Institute of Management of Northwestern University.

He is married to the former Margaret Ellen Riley of St. Louis. They have three children.

KLAUS A. SAEGEBARTH

Klaus A. Saegebarth, director of the Research and Development Division in Du Pont's Agricultural Chemicals Department, joined the Du Pont Company in 1957 as a research chemist in the Elastomer Chemicals Department at the Jackson Laboratory at Deepwater Point, N. J., later moving to the Elastomers Research Laboratory at the Experimental Station.

He became a development supervisor at the Elastomers plant at Beaumont, Texas in 1965 and was made a division head at the Experimental Station Laboratory in 1967. In 1969 he transferred to the Fabrics and Finishes Department as the director of their Experimental Station Laboratory, and in 1970 he was made the research and development manager of the Marshall Laboratory. In 1972 he was transferred to the sales organization as the assistant national manager of industrial finishes and then became the trade finishes national manager in 1973. In 1974 he was appointed assistant director of the Finishes Division and was named director of Research and Development of the Fabrics and Finishes Department in 1978. He was named director of the Agrichemicals Research and Development Division in the Biochemicals Department on January 1, 1980. On September 1, 1983 he became the director of Research and Development of the newly formed Agricultural Chemicals Department.

Born January 5, 1929, in Berlin, Germany, he received a Bachelor of Science degree in Chemistry in 1953 from the University of California at Berkeley and his Ph.D. degree in Organic Chemistry from the University of Washington (Seattle) in 1957. He is a member of the Sigma Xi and Phi Lambda Upsilon honor societies, the American Chemical Society and has been active in the National Paint and Color Association.

He is married to the former Mary Ann Douglass and they live at 604 Haverhill Road, Wilmington, Delaware. They have three children, Eric of northern New Jersey, Katherine of Wilmington and Margaret of New York City.

ENVIRONMENTAL POLICY INSTITUTE

August 7, 1984

TO: Members, House Judiciary Committee

FROM: H.R. 6034, The Agricultural Patent Reform Act of 1984

The Environmental Policy Institute strongly urges you to vote against full committee approval of H.R. 6034, the Agricultural Patent Reform Act of 1984, for the following reasons:

- o The need for H.R. 6034 has not been substantiated. The chemical and pharmaceutical industries have not shown why patent term extension for pesticides and veterinary products is needed. They have not produced economic data which show that product innovation or return on investment is suffering under the present system. R&D in new pesticide and veterinary products has increased in recent years rather than decrease. In the herbicide area alone, at least 22 new products are slated for registration in the 1985-1990 period.

- o Present regulatory system is not onerous. While testing and regulation of new pesticide products may consume some years of a product's exclusive marketing life, R&D costs for popular products are often recouped in one or two years, leaving 10 or more years of exclusive marketing. Moreover, experimental use permits from EPA add to a product's effective market life.

- o Agrichemical profitability at all-time high. A number of companies -- including Monsanto, W. R. Grace, Uniroyal, DuPont and American Cyanamid -- have reported very substantial, and in some cases, record-breaking second-quarter earnings for 1984 because of agrichemical sales. Monsanto's CEO, Richard J. Mahoney, recently emphasized the important role that agricultural chemicals played in helping that company to the best second quarter earnings in its history. Uniroyal too, noted that its second quarter earnings for agricultural chemicals were the strongest ever. (see enclosed article, "Agricultural Rebound Enriches Chemical Earnings", Journal of Commerce, 3 August 1984).

- o Pesticide reform and public health and safety set aside. H.R. 6034 provides an economic windfall to the agrichemical industry while Congress, for the last two years, has taken little action to protect the public's health and safety in the area of pesticide testing and regulation. Both FIFRA reform and food safety bills currently lag in Congress while H.R. 6034 is pushed ahead with unprecedented speed.

- o Patent term extension for pesticides will discourage pest-management innovation. By giving longer patent terms for pesticides and veterinary products, Congress will be encouraging further capitalization of a research infrastructure geared to produce chemical-based agricultural products. Moreover, longer patent

(over)

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terms for such products mean longer product life, and consequently, less of an incentive to innovate beyond the bounds of familiar chemistry. Thus, longer patent life will help to bias research and capital investment in one direction. With such an incentive for pesticide production, commercial investment in alternative pest control strategies and products will be discouraged.

- o H.R. 6034 may increase economic concentration in pesticide industry. In a 1981 FTC staff paper investigating 4 agricultural input industries, it was discovered that four-firm and eight-firm concentration ratios in the pesticide manufacturing industry were 57 percent and 79 percent respectively. Sub-market concentration, as in corn and soybean herbicides, as well as corn insecticides, was found to be substantially higher (see enclosed tables). The issue of potential anticompetitiveness in the pesticide industry has not been explored in the consideration of H.R. 6034, yet patent term extension in this area could figure prominantly in both farm costs and food prices.

- o H.R. 6034 includes biotechnology patents prematurely. Regulation of commercial products and processes using biotechnology and gene-splicing technologies has not been addressed by Congress. Regulatory time frames for such products, therefore, are unknown at present. EPA, for example, has yet to issue even a discussion of principles in this new area of product regulation. Legislating patent-term extension for biotechnology products at this time, therefore, is premature.

- o Biotechnology products pose new patent & environmental questions. In the area of agricultural biotechnology research, several major chemical and pharmaceutical companies are working on ways to move herbicide-resistant genes into crops such as corn, soybeans and wheat. How will these new products of agricultural biotechnology be patented? Will both the gene and crop variety be patented as one entity in this situation, or will they be patented as separate pieces of a product package? Moreover, will patent term extension for such products serve to increase the use of synthetic pesticides in the environment?

- o H.R. 6034 provides patents for food-producing substances. Congress has not explored the economic and environmental ramifications of patenting powerful substances such as genes, plant growth regulators, microbial pesticides and livestock hormones that will account for the control and cost of agricultural productivity and food production.

In sum, the Environmental Policy Institute urges you to oppose this legislation at this time, as the issues of patenting, biotechnology, food production and environmental quality are increasingly intertwined, and worthy of more scrutiny and analysis than Congress can provide in hasty, end-of-the-session legislation.

Respectfully,

Jack Doyle, Director
Agricultural Resources Project

Enclosures

[From the Journal of Commerce, Aug. 3, 1984]

Agricultural Rebound Enriches Chemical Earnings

(By Al Wyss)

A big rebound in demand this year for major agricultural chemicals, including fertilizers and pesticides, provided substantial added momentum to the general upsurge in the chemical industry's second quarter sales and earnings.

The rise in the industry's sales and net income involved a wide range of products including industrial and specialty chemicals as well as downstream products like man-made fibers and plastics. This reflected rising consumption of chemicals in a broad spectrum of industrial and consumer markets such as the housing, automotive, textile and paper industries.

But the resurgence in agricultural chemical demand, following the slump last year, made a significant contribution to sales and earnings gains for a number of major companies, including W.R. Grace & Co., Monsanto Co., Uniroyal Inc., American Cyanamid Co., Stauffer Chemical Co. and International Minerals & Chemical Corp.

This involved a number of complex factors, including the continuing farm recovery in the United States, increased acreage plantings, the elimination of last year's Payment-in-Kind program that reduced acreage plantings and good weather in major agricultural areas around the world that spurred exports of pesticides.

As a result of such factors, W.R. Grace & Co. reported that the most significant factor in its 42 percent rise in net income in the second quarter was the strong performance of its agricultural chemical operations.

This enabled the company's Agricultural Chemicals Group to earn $14 million in the second quarter—historically the strongest period for fertilizer sales—an increase of $12.4 million over 1983's second quarter.

And Uniroyal, which reported record net income for the second quarter, pointed out that its agricultural chemicals product line had the strongest quarter in the company's history.

These gains were achieved through higher sales of existing products, as well as the products developed by Uniroyal internally and products acquired within the last two years.

Richard J. Mahoney, president and chief executive officer of Monsanto Co., which had the best second quarter earnings in its history, emphasized the important role that agricultural chemicals played in this performance.

"Roundup and Lasso herbicides are on schedule for another good year," he said "with a favorable market performance for both herbicides."

He noted that demand was aided substantially by higher acreage plantings in the United States and generally good weather conditions around the world for the application of these two widely used products.

The sharp rise in agricultural chemical sales also was noted by George J. Sella Jr., chairman, president and chief executive officer of American Cyanamid.

Sales and operating earnings of the Agricultural Group were significantly higher," he said, "reflecting the continuing farm recovery in the United States. Sales of fertilizers and crop protection chemicals were well ahead of last year as farmers no longer curtailed production under the government's now-expired Payment-in-Kind program.

Like other major producers of pesticides, American Cyanamid is continuing to carry out intensive research and development that is resulting in new, significantly improved insecticides and herbicides. This has opened up new markets and boosted sales for chemical companies in the United States and in world markets.

Mr. Sella said that during the second quarter, Cyanamid received experimental use permits from the Environmental Protection Agency for Arsenal industrial herbicide; Scepter herbicide, which controls a broad spectrum of weeds in soybeans; and Assert, an herbicide for use on cereal crops. All three are members of a new class of herbicides develops by Cyanamid scientists.

Improved market conditions contributed to a marked improvement in the operating income from agricultural chemicals for Stauffer Chemical, which rose to $6.3 million in the last quarter compared to a loss of $10.3 million in the year-earlier period. Part of this improvement, however, resulted from the elimination of losses from the monosodium glutamate business that was shut down during the second quarter of fiscal 1984.

A strong demand for herbicides made a substantial contribution to the significant percentage gains of the agricultural and industrial chemicals segment of the Du Pont Co. Operating income from this segment rose 92 percent in the second quarter to $92 million that the company attributed largely to a strong demand for herbicides and titianium dioxide.

L. Stanton Williams, chairman of PPG Industries, noted that agricultural demand was high for potash for fertilizers, as well as herbicides and other biochemical products.

Significant technological advances by U.S. companies in pesticides, which have resulted in a new generation of more-effective, less-toxic and easier to apply products, has brightened prospects for a continued strong demand in the years ahead both in the United States and in world markets.

But in fertilizer, despite the rebound this year, a number of complex problems cloud the outlook. Such problems were stressed by George D. Kennedy, president of International Minerals & Chemical Corp., a company that scored a 35 percent increased in the last quarter in earnings from continuing operations. This reflected better volume in fertilizer tonnage shipped to domestic and export markets.

But Mr. Kennedy pointed out that volume recovery did not translate into appreciably higher prices for most products.

"Return to adequate pricing for potash and phosphate, IMC's principal products, is being constrained by the high value of the dollar, financial problems in less developed countries and slow recovery on farms everywhere," he said.

A rising trend in fertilizer imports also has roused major concern in the industry and already has had a negative impact upon pricing. The adverse import trend has become particularly evident in nitrogen with U.S. imports of nitrogen last year exceeding exports by more than 1.4 million tons.

This year, imports of nitrogen are rising more rapidly and a further widening of the negative trade balance is expected. With production facilities expanding and production rising in a number of foreign countries, a further surge of nitrogen and ammonia imports is considered likely.

MARKET SHARES FOR SELECTED PESTICIDES

	Top 3-4 Firms	Combined Market	Year	Source
All Herbicides	Ciba Geigy Monsanto Stauffer Dow	71%	1976	USDA-ESCS
Corn Herbicides	Monsanto Ciba Geigy Stauffer Shell	87%	1978	USDA, FTC
Soybean Herbicides	Monsanto Eli Lilly BASF	63%	1980	USDA & 1981 Farm Chemicals Handbook
Grain Sorghum Herbicides	Ciba Geigy DOW Monsanto Shell	75%	1980	USDA & Chemicals Economics Handbook
Cotton Herbicides	Eli Lilly Ciba Geigy	52%	1979	USDA & 1981 Farm Chemicals Handbook
All Insecticides	Monsanto Hercules Stauffer FMC	46%	1976	USDA-ESCS
Grain Sorghum Insecticides	FMC Monsanto Union Carbide	62%	1980	USDA & 1981 Farm Chemicals Handbook
Corn Insecticides	Am. Cyanamid FMC Stauffer	78%	1980	USDA & 1981 Farm Chemicals Handbook

Note: Data compiled by the Environmental Policy Institute, Washington, D.C.

The 1978 Pesticide Market by Use and Crop

Market	Millions of Dollars at User's Level	
Herbicides - Total		1731.9
Corn	658.0	
Soybeans	549.9	
Cotton	128.4	
Wheat	68.7	
Sorghum	50.2	
Rice	36.9	
Other	239.8	
Insecticides - Total		809.4
Corn	208.4	
Cotton	207.0	
Fruits and Nuts	125.1	
Vegetables	87.6	
Other	183.3	
Fungicides - Total		189.5
Fruits and Nuts	63.3	
Vegetables	31.7	
Peanuts	26.7	
Other	67.8	
Soil Fumigants		65.6
Defoliants and Dessicants		37.8
Other		26.4
All Pesticides		2860.6

Source: 142 Farm Chemicals (September 1979).

-Leading producers of herbicides used by farmers in 1976

Firm	Share of market (percent of all active ingredients used)
	Percent
Ciba Geigy Corporation	28
Monsanto Agricltural Products Co.	27
Stauffer Chemical Co.	10
Dow Chemical USA	6
Shell Chemical Co.	3
Eagle River Chemical Corp.	2
E.I. duPont De Nemours and Co. Inc.	2
Thompson-Hayward Chemical Co.	2
Leading 8 firms	80

-Leading producers of insecticides used by farmers in 1976

Firm	Share of market (percent of all active ingredients used)
	Percent
Monsanto Agricultural Products Co.	14
Hercules Incorporated	12
Stauffer Chemical Co.	10
FMC Corporation	10
Vertac Consolidated	9
American Cyanamid Co.	8
Union Carbide Corp.	8
Tenneco Chemicals Inc.	6
Leading 8 firms	77

Source: ESCS nationwide surveys of farm pesticide use for 1966, 1971, and 1976.

ECONOMIC CONCENTRATION IN SELECTED HERBICIDE MARKETS

90% of corn herbicides	4 firms
67% of cotton herbicides	2 firms
66% of sorghum herbicides	1 firm
76% of soybean herbicides	4 firms

SOURCE: Leibenluft, Robert F., Competition in Farm Inputs: An Examination of Four Industries (February 1981) Federal Trade Commission Policy Planning Issues Paper.

Market Shares of Leading Corn Herbicide Producers - 1978

Company	Broadleaf Herbicides		Grasses Herbicides		All Corn Herbicides	
	Millions of lbs	Market Shares	Millions of lbs	Market Shares	Millions of lbs	Market Shares
Monsanto	0.2	0.2	63.1	58.1	63.3	30.7
Ciba-Geigy	55.4	56.6	4.8	4.4	60.2	29.2
Stauffer	—	—	37.2	34.3	37.2	18.0
Shell	19.1	19.5	—	—	19.1	9.2
Vertac	7.3	7.5	0.1	0.1	7.4	3.6
Farmland	6.1	6.2	—	—	6.1	3.0
Dow	1.2	1.3	3.2	2.9	4.4	2.1
Velischol	2.0	2.0	—	—	2.0	1.0
Others	6.6	6.7	0.2	0.2	6.8	3.3
	97.9	100.0	108.6	100.0	206.5	100.0

ESTIMATED MARKET SHARES OF GRAIN SORGHUM HERBICIDES FOR 1980

Producer	Trade Name (product name)	Market Share - %	Active Ingredients (thousands of lbs.)
Ciba-Geigy	AAtrex* (atrazine)	30.6	3,613
	(propachlor)	25.0	2,945
Dow Chemical	Bexton	---	---
Monsanto	Ramrod	---	---
Ciba-Geigy	Milocep, Miloguard	10.5	1,239
Shell	Shell Atrazine*	10.2	1,204
Dow, Fallek-Lankro,	(2,4-D)	4.8	571
North Amer. Philips,	"	---	---
Rhone-Poulenc,	"	---	---
Vertac Chemical	"	---	---
Vertac Chemical	(atrazine)*	2.4	286
Ciba-Geigy	Igran	1.5	174
Monsanto	Roundup	0.9	110
Northwest Industries (Velsichol)	Banvel	0.8	92
(other)	---	13.3	1,565
Total Consumption		100.0	11,799

* Market shares for the 5.1 million pounds of atrazine products applied to the U.S. grain sorghum crop in 1980 were estimated on the basis of the atrazine production capacities given in the 1980 Chemicals Economic Handbook for Ciba-Geigy, Shell and Vertac Chemical.

SOURCE: Data was compiled by the Environmental Policy Institute from: "Pesticide Use on Grain Sorghum in the Major Producing States, 1980," U.S. Dept. of Agriculture, Economic Research Service, February 1982, Washington, D.C.; 1981 Farm Chemicals Handbook, Meister Publishing Co.; and Chemical Economics Handbook: Herbicides, SRI International, January 1980.

ESTIMATED MARKET SHARES OF GRAIN SORGHUM INSECTICIDES FOR 1980

Producer	Trade Name (product name)	Market Share - %	Active Ingredients (thousands of lbs.)
FMC	Furadan	30.9	927
Monsanto + others?	(parathion)	18.6	556
Union Carbide	Sevin	13.4	400
Boots-Hercules	(toxaphene)	9.7	291
Idacon, Vertac	"	---	---
American Cyanamid	Thimet	4.7	142
Uniroyal	Omite, Comite	4.7	140
Bayer (Mobay)	Di-Syston	2.9	87
	(methomyl)	2.4	72
Du Pont	Lannate	---	---
Shell	Nudrin	---	---
	(dimethoate)	2.0	61
American Cyanamid	Cygon, Fostion MM	---	---
BASF Wyandotte	Rebelatte	---	---
Dow Chemical	Lorsban	0.7	22
(other)	---	9.9	298
Total Consumption		100.0	2,996

SOURCE: Data was compiled by the Environmental Policy Institute from: "Pesticide Use on Grain Sorghum in the Major Producing States, 1980," U.S. Dept. of Agriculture, Economic Research Service, Washington, D.C., February 1982: and 1981 Farm Chemicals Handbook, Meister Publishing Co.

ESTIMATED MARKET SHARES OF COTTON HERBICIDES FOR 1979

Producer	Trade Name (product name)	Market Share - %	Active Ingredients (thousands of lbs.)
Eli Lilly	Treflan	34.3	6,366
Crystal Chemical,	(MSMA)	13.8	2,561
Diamond Shamrock,	"	---	---
Drexel, Vineland	"	---	---
Ciba-Geigy	Cotoran	10.6	1,969
W.A. Cleary, Crystal,	(DSMA)	9.3	1,719
Diamond Shamrock,	"	---	---
Drexel, Vineland	"	---	---
Monsanto	Roundup	7.5	1,402
Ciba-Geigy	Caparol	5.2	965
American Cyanamid	Prowl	2.3	431
Ciba-Geigy	Tolban	2.3	430
Shell	Bladex	2.1	399
Blue Spruce, Dow	(dinoseb)	1.7	310
Crystal, Vertac	"	---	---
	(diuron)	1.5	276
Du Pont	Karmex, Krovar	---	---
Hopkins Chemical	Urox "D"	---	---
Diamond Shamrock	Dacthal	0.9	175
Ciba-Geigy	Sancap	0.5	95
BASF Wyandotte	Basalin	0.4	78
(other)	---	7.5	1,400
Total Consumption		100.0	18,576

SOURCE: Data compiled by the Environmental Policy Institute from: "1979 Herbicide, Defoliant, and Dessicant Use on Cotton in the United States," U.S. Dept. of Agriculture, Economic Research Service, Washington, D.C., May 1982; and 1981 Farm Chemicals Handbook, Meister Publishing Co.

ESTIMATED MARKET SHARES OF COTTON INSECTICIDE FOR 1979

Producer	Trade Name (product name)	Market Share - %	Active Ingredients (thousands of lbs.)
	(methyl parathion)	21.4	4,689
Kerr-McGee	Metron	---	---
Monsanto	---	---	---
Pennwalt	Penncap M	---	---
Vertac Chemical	Vertac Methyl Parathion	---	---
	(sulfur)	12.9	2,837
FMC, Sandoz,	"	---	---
Los Angeles Chem.,	"	---	---
Stauffer Chem.,	"	---	---
+ others?	"	---	---
Du Pont,	(EPN)	11.9	2,617
Northwest Industries	"	---	---
Boots-Hercules,	(toxaphene)	4.7	1,037
Idacon, Vertac	"	---	---
	(chlordimeform)	4.3	935
Ciba-Geigy	Galecron	---	---
NOR-AM Ag. Products	Fundal	---	---
	(permethrin)	2.7	595
FMC	Pounce	---	---
ICI Americas	Ambush, Ectiban	---	---
Penick Corp.	Pramex	---	---
Uniroyal	Omite, Comite	2.6	576
Union Carbide	Temik	2.2	480
Rohm and Haas	FW-293	2.0	439
	(methomyl)	1.8	393
Du Pont	Lannate	---	---
Shell	Nudrin	---	---
Shell	Pydrin	1.7	383
Chevron	Orthene	1.6	357
Bayer (Mobay)	Guthion	1.5	323

COTTON INSECTICIDES (cont.)

Shell	Azodrin	1.2	261
Shell	Bidrin	1.1	250
American Cyanamid	Cygon, Fostion MM	1.0	224
Bayer (Mobay)	Di-Syston	1.0	217
Bayer (Mobay),	(methamidophos)	0.8	173
Chevron	"	---	---
Bayer (Mobay)	Bolstar	0.5	120
American Cyanamid	Thimet	0.5	113
Ciba-Geigy	Supracide	0.3	75
	(trichlorfon)	0.2	46
Upjohn	Proxol	---	---
Bayer (Mobay)	Dylox, Dipterex	---	---
(other)	---	21.9	4,814
Total Consumption		100.0	21,954

SOURCE: Data compiled by the Environmental Policy Institute from: "Insecticide Use of Cotton in the United States, 1979," U.S. Dept. of Agriculture, Economic Research Service, Washington, D.C., May 1982; and 1981 Farm Chemicals Handbook, Meister Publishing Co.

ESTIMATED MARKET SHARES OF COTTON DEFOLIANTS AND DESSICANTS FOR 1979

Producer	Trade Name (product name)	Market Share - %	Active Ingredients (thousands of lbs.)
Kerr-McGee	(sodium chlorate)	35.6	8,250
Occidental Petr.	" "	---	---
	(arsenic acid)	29.5	6,833
Pennwalt	Dessicant L-10	---	---
Commercial Chem.	---	---	---
Bayer (Mobay)	DEF	26.8	6,197
Chevron	(paraquat)	1.9	431
Pennwalt	Herbicide 273	1.1	261
Crystal Chem.	(cacodylic acid)	0.8	188
Vineland Chem.	" "	---	---
(other)	---	4.3	998
Total Consumption		100.0	23,158

SOURCE: Data compiled by the Environmental Policy Institute from: "1979 Herbicide, Defoliant, and Dessicant Use on Cotton in the United States," U.S. Dept. of Agriculture, Economic Research Service, Washington, D.C., May 1982; and 1981 Farm Chemicals Handbook, Meister Publishing Co.

U.S. Producers of Animal Health Products

	Estimated animal health sales, 1981 (millions of dollars)	Percent of corporate sales	Percent of corporate operating income	Estimated animal health sales annual growth, 1981-85
Pfizer	$ 440	13%	13%	10%
Eli Lilly	385	13%	15%	20%
American Cyanamid	265	7%	7%	11%
Merck	200	7%	7%	27%
SmithKline	155	7%	5%	17%
Upjohn	134	7%	7%	11%
Syntex	83	12%	N.A.[a]	11%

[a]N.A. = information not available.

SOURCE: S. J. Zimmer and R. B. Emmitt, "Industry Report: Animal Health Products Market" (New York: F. Eberstadt & Co., Inc., 1981).

Global Animal Health Product Markets

	Estimated sales, 1981 (millions of dollars)	Estimated annual growth, 1981-85
Nutritional products	$2,500	10-15%
Medicinal products:		
Biologics/Vaccines	1,000	20-25%
Antibacterials	2,000	10-15%
Anthelmintics	450	25-30%
Ectoparasiticides	400	10-15%
Coccidiostats	300	15-20%
Growth promotants	200	24-30%
Other	650	15-20%
Subtotal	5,000	15-20%
Total	$7,500	15-20%

SOURCE: S. J. Zimmer and R. B. Emmitt, "Industry Report: Animal Health Products Market" (New York: F. Eberstadt & Co., Inc., 1981).

SOURCE: OTA, Commercial Biotechnology: An International Analysis, January 1984.

World and U.S. Sales of Growth Promotants (millions of dollars)

Products	Sales 1979 World	1979 U.S.	1980 World	1980 U.S.	1981E[a] World	1981E[a] U.S.	1985E[a] World	1985E[a] U.S.	Compound annual growth 1981-85E[a]
Hormones:									
Synovex (Syntex)	$ 14	$ 8	$ 16	$ 8	$ 19	$ 8	$ 23	$ 8	9%
MGA (Upjohn)	12	11	12	10	12	9	12	0	No change
Ralgro (IMC)	16	15	24	22	32	29	55	45	15%
Compudose (Eli Lilly)	—	—	—	—	4	—	100	50	N.A.[b]
Other:									
Rumensin (Eli Lilly)	$ 60	$ 55	$ 65	$ 55	$ 75	$ 60	$200	$125	28%
Feed	60	55	65	55	75	60	125	100	14%
Bolus	—	—	—	—	—	—	75	25	N.A.
Avoparcin ("Avotan") (American Cyanamid)	15	—	20	—	25	—	50	10	19%
Other	33	—	38	—	43	—	75	—	15%
Total	$150	$ 29	$175	$ 95	$210	$106	$515	$246	25%

[a]E = estimated.
[b]N.A. = information not available.

SOURCE: S. J. Zimmer and R. B. Emmitt, "Industry Report: Animal Health Products Market" (New York: F. Eberstadt & Co., Inc., 1981), Modified by the Office of Technology Assessment.

Sales of Major U.S. Animal Vaccine Products, 1981 (millions of dollars)

	Sales
Cattle products:	
Clostridium	$ 16.0
Infectious bovine rhinotracheitis and bovine leukosis virus	13.0
Leptospirosis and combinations	6.0
Vibriosis and combinations	3.0
Swine products:	
Atrophic rhinitis (Bordetella)	$ 6.0
Pseudorabies	5.0
Erysipelas	3.5
Pet products:	
3-way feline virus disease	$ 4.5
Rabies	12.0
Canine parvovirus and combinations	9.0
Poultry products:	
Marek's disease	$ 12.0
Newcastle disease and combinations	9.0

SOURCE: S. J. Zimmer, "The Impacts of Applied Genetics in Animal Agriculture," contract report prepared for the Office of Technology Assessment, August 1982.

Major Producers of Animal Vaccines Sold in the United States

Company	1981 sales (millions of dollars)	Market share
Norden (SmithKline) (U.S.)	$40	27%
Philips-Roxane (Boehringer Ingelheim) (F.R.G.)	18	12
Fort Dodge (American Home Products) (U.S.)	14.5	10
Beecham (U.K.)	11	7
Jensen Salsbery (Wellcome) (U.K.)	9	6
Dellen (TechAmerica) (U.S.)	8.6	6
Pitman-Moore (Johnson & Johnson) (U.S.)	1.8	1
Syntex Agribusiness (U.S.)	1.5	1

SOURCE: S. J. Zimmer, "The Impacts of Applied Genetics in Animal Agriculture," contract report prepared for the Office of Technology Assessment, August 1982.

SOURCE: OTA, Commercial Biotechnology: An International Analysis, January 1984.

THE BOOM IN PESTICIDE REVENUES. . . AND
NEW-PRODUCT R & D

Producer	Existing Products & Annual Revenues	New Herbicides	Market	Registrat
American Cyanamid	Prowl (H) Counter 15-G (I-N) Cycocel (PGR) Cyphos (FS)	Scepter AC 293	Soybean Cereals	1986 1986
American Hoechst		Whip Runout	Soybean Soybean, corn	1986 1986
BASF Wyandotte	Basagran (H)-$160 million	Poast	Soybean, cotton	1983
Chevron		Selectone	Soybean, cotton	1983
Ciba-Geigy	Dual (H)-$40-50 million Ridomil MZ (F)	CGA 82725 CGA 84446	Soybean, cotton Wheat	NA NA
Du Pont	Glean (H)-$40 million	Allay Londax Classic Assure	Wheat, cereal Rice Soybean Soybean, cotton	1986 1988 1985 1985
Dow Chemical		Tandem Verdict	Corn Soybean, cotton	1986 1987
Eli Lilly	Treflan (H)-$300 million	EL-107	Cereals	NA
ICI Americas		Pusilade Reflex	Soybean, cotton Soybean	1983 1986
Monsanto	Lasso (H) - $400 million Roundup (H) - $500 million Avadex (H) - $125 million	Super Lasso Barness	Soybean, corn Corn, soybeans	1985 1986
PG Industries		Cobra Genate Genep Eptc PPG 10-13	Soybean Corn Corn, cotton Wheat, corn	1986 1983 1983 1987
Rohm & Haas	Blazer (H) - $65 million	Blazer analog	Soybean	1986
Stauffer Chemical	Sutan + (H) Eradicane Eptam (H) Devrinol (H) Vernam (H)	Cyclorate Racer 10-84 Eradicane Extra	Corn Wheat Soybean Corn	NA 1986 1983 1983
Uniroyal		Rescue	Soybean	1983

Source: Information compiled by the Environmental Policy Institute from corporate annual reports, Chemical Week and Chemical Business.

Key: H - herbicide I - insecticide
N - nematicide F - fungicide
PGR - plant growth regulator
LH - livestock hormone
FS - feed supplement

*Only a partial list of existing and prospective products.

ENVIRONMENTAL POLICY INSTITUTE

26 July 1984

Hon. Robert W. Kastenmeier, Chairman
House Judiciary Subcommittee on Court,
Civil Liberties, and the Administration of Justice
2232 Rayburn House Office Bldg.
Washington, D.C. 20515

Dear Rep. Kastenmeier:

The Environmental Policy Institute (EPI) respectfully urges you to delay further consideration of H.R. 5529, the Agricultural Patent Reform Act of 1984.

We believe that a number of questions need to be answered and more information needs to be provided about the purpose and intent of this bill, as well as the need for patent term extension for pesticide and veterinary products before further action is taken. Specifically, we urge that further hearings be scheduled.

Wider Hearings Needed: Lack of Information

As you know, this bill was formerly a more obscure part of the pharmaceutical patent bill, and so, more information has been provided about the patent life, research costs, and the pricing of drugs than has been provided for pesticide and veterinary products. Very little detailed information is available on the actual step-by-step cost of developing specific pesticides; how pricing would be affected over time; and how these products affect both farmers and consumers. And although a range of farm organizations have expressed support for the previous Senate bill, and now H.R. 5529, few of these organizations have actually testified on the bill in either the House or the Senate. Moreover, no environmental or consumer organizations have been asked to testify on the current measure. In fact, only 3 representatives -- those of Eli Lilly, DuPont and Monsanto -- representing the National Agricultural Chemicals Associations, the Chemical Manufacturers Association and the Animal Health Institute, have actually testified on H.R. 5529.

More striking perhaps is the absence of government agency input on this new bill, even though the issues and jurisdictional questions involve agencies such as USDA, EPA, FDA and the Department of Justice. We believe that hearings seeking a broader range of opinion and analysis should be sought.

Patents For Biotechnology Products Raises New Issue

The inclusion of language covering products made through recombinant DNA techniques is a new element in this legislation,

never before so specified in earlier bills. The fact that this legislation makes pesticides and veterinary products made by recombinant DNA technology eligible for patent term extension could be problematic given the uncertain regulatory situation now swirling around biotechnology. Writing biotechnology products into this bill could prejudice the regulatory debate yet to come. What happens, for instance, if specialized legislation is written covering only products made by recombinant DNA techniques? Moreover if these biotechnologies themselves are put on a regulatory fast tract might the argument for patent term extension then dissipate? Might the technologies also help speed up the regulatory and testing processes for pesticides, thus shortening the time needed for pre-market testing and review of pesticides and animal drugs?

Pesticide Research Investment Booming

We do not find sufficient evidence to suggest that there is currently, a lack of investment by agri-chemical companies in the development of new pesticide and veterinary products. To the contrary. In the May 9, 1984 issue of Chemical Week, for example, some 14 major companies are identified as having a total of at least 22 new herbicide products slated to come to market in the 1985-1988 period and beyond. That suggests to us that there is some considerable incentive to invest in herbicide research under the current regulatory system without patent term extension.

Regulatory Costs & Industry's Return on Investment

Industry has variously claimed that it costs between $30 million and $50 million to develop and bring to market new pesticide and veterinary products. Yet product-specific data showing exactly how those costs are derived have not been available. For example, did it cost Monsanto $30 million to develop Bronco, a hybrid herbicide made from Lasso and Roundup, two other Monsanto herbicides? Generalized, unsubstantiated figures of testing and regulatory costs do not provide the kind of sound information that the public or Congress needs to make fair and reasonable decisions.

Moreover, even if such figures are correct, they ought to be tied to specific products. For example, the Wall Street Journal notes in March 30, 1984 story that even through it took DuPont more than 6 years and $35 million to develop a new herbicide named Glean, that sales of more than $40 million occurred for Glean in its first year on the market. Other herbicide products are reaping annual returns of between $60 million and $800 million. Such figures suggest to us that there is ample return on investment in the agrichemical products market.

Claims of Consumer Benefit Need Substantiation

One of the arguments advanced by the chemical and pharmaceutical industries in favor of H.R. 5529 is that longer patent terms will continue to spur the development of new agricultural technologies that will result in abundant and

affordable foods for consumers. For example, it has been claimed that U.S. consumers pay 9% less for animal-derived foods than they would if animal drugs did not exist. Such claims need to be substantiated in further detail, and projections offered as to how new products and longer patent life will effect food prices and supply.

Patents & Farmers' Cost of Production

Still another issue is how patent term extension on pesticide and veterinary products may effect prices for farmers. A 1982 letter to members of the House Agriculture Committee from Edward Andersen of the National Grange (a farm group which is currently not supporting H.R. 5529), urging that pesticides and animal drugs be excluded from an earlier patent bill, noted: "Because pesticides and animal drugs represent a major portion of the costs of production for many commodities, we are concerned that this legislation could keep the costs of these essential products high for longer periods of time". Later in his letter, Andersen explained, "the Grange is not convinced that extending the length of the patent protection is warranted at this time. Nor are we convinced that it would eventually serve the interests of the family farmer" (1982 Grange letter attached).

We believe that in 1984 these concerns have still not been adequately addressed. The committee should specifically request testimony from USDA, industry, and the major farm groups on this topic of pesticide and animal drug prices as they relate to farmers' and ranchers' cost of production.

Patent Reform Pushed While FIFRA Reform Lags

In 1983, Congressional leaders said that reform of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) would come up in 1984 for major legislative review and reform. At issue are matters such as tighter registration procedures to prevent potentially harmful pesticides from reaching the market; speeded-up safety review of numerous pesticides being sold without adequate registration data; and the closing of loopholes which have allowed widespread "emergency use" of inadequately tested chemicals. Now, in 1984, both the Congressional leadership and the Administration have apparently put off FIFRA reform until the next Congress, and possibly until after consideration of the 1985 farm bill. Given the current status of FIFRA legislation, the increasing public outcry over pesticide misuse, and the litany of pesticide testing scandals, is it prudent to consider patent legislation that could spur major research investments for more pesticide products based on the presumption that the present, flawed regulatory system will prevail? EPI urges the committee to consider the message Congress will be sending the general public if H.R. 5529 precedes FIFRA reform.

Where's The Innovation?

It is often argued that the nation's patent system contributes to technological innovation and products of social benefit. However, there are legitimate questions about the extent to which some pesticide and animal health products actually qualify as genuine innovations as opposed to "copycat chemistry", "freshened-up" products and/or trivial improvements.

In both the chemical and pharmaceutical industries, it is not uncommon for a company to try to spread its research and development costs over as many patentable years as possible, particularly through the use of "variations-on-a-theme" chemistry.

Some pesticide makers, in fact, become very committed to one class of chemistry, and devise product spin-offs which often derive from one kind of chemical molecule. For example, Ciba-Geigy's atrazine herbicide Aatrex, started a whole line of high-performance herbicides very much like Aatrex. Monsanto's herbicide Bronco is a chemical relative of another Monsanto herbicide, Roundup. Monsanto is also devising Super-Laso, a successor to Lasso. Rohm & Hass' new herbicide Goal, is, in fact, a derivative of an existing herbicide named Blazer. "Many companies," says Chemical Week, "are virtually wedded to one class of compounds; what passes for new herbicides are often analogues of previous successes." And it appears that even the U.S. Patent Office can be fooled by some molecular twists, issuing patents for pesticides that are less than unique. For example, Ciba-Geigy's director of biological research, John F. Ellis, referring to the similarity between Ciba-Geigy's herbicide Dual and Monsanto's Lasso, admits to "copycat chemistry". "I don't know how we ever got a patent", says Ellis, "but we found a loophole."

Does this mean that the patent system contributes to trivial invention? And how much of what patenting does under the guise of useful innovation actually winds up helping protect a company's vested interest -- which is really a way of stifling innovation and competition?

In both the chemical and pharmaceutical industries -- particularly among the largest companies with the largest research labs -- there appears to be a patent-on-patent building process; where one patent on one popular product begets a new and improved version of the same product, another patent, more profitability, more research and still more patents. After crossing a certain threshhold, and after scoring with a $100 million-a-year product or two, the momentum for research and patenting appears to favor the largest companies.

In the long run, at least for some chemical and pharmaceutical companies, patents appear to encourage rear-guard

actions rather than forward-looking research and risk-taking innovation. Succesful patented products, it seems beget more of the same, or create incentives simply to protect or hold a market position rather than truly innovate.

Before Congress extends the patent term on pesticides and veterinary products with H.R. 5529, it should take a good hard look at the pace of genuine innovation in the agrichemical industry, and the extent to which the nation's patent system is really helping or retarding that process.

In sum, the Environmental Policy Institute believes that this legislation is unwarranted at the present time, and at the very least, additional hearings should be scheduled inviting a broader cross-section of government, environmental, consumer and farm organizations to comment on the bill before further action is taken.

Respectfully,

Jack Doyle, Director
Agricultural Resources
Project

Enclosure

CC: Selected Members
of Congress

national grange

[illegible] Washington, D. C. 20006 (202) 628-3507

Edward Andersen, Master

December 13, 1982

Dear Representative:

The National Grange, representing 425,000 members in 41 states, wants to alert you to some little known provisions of the Patent Restoration Act of 1982, H.R. 6444. The bill, narrowly defeated on a suspension vote on September 15th, could still come to the floor during the lame duck session.

Debate on this bill has centered around its impact on the pharmaceutical companies and their consumers, so most members do not realize that the legislation would also extend the patents of pesticides and animal drugs. Because pesticides and animal drugs represent a major portion of the costs of production for many commodities, we are concerned that this legislation could keep the costs of these essential products high for longer periods of time. Many of our members have been hurt by the recession in the farm economy, and farmers' costs have soared while prices for farm products remain low.

The National Grange supports continued research into better pesticides and animal drugs, and we feel that attention must be given to decreasing the regulatory burden surrounding testing and certification of these chemicals. We are encouraged by the progress already made in this regard, and we support further review of the registration regulatory process.

However, the Grange is not convinced that extending the length of the patent protection is warranted at this time. Nor are we convinced that it would eventually serve the interests of the family farmer. Generic brands of commonly used chemicals pose potential for cutting farm operating costs, and unless a more convincing case can be made to extend the patent life for new and existing products, we urge that pesticides and animal drugs be excluded from any patent term extension legislation.

We urge you to consider the impacts of this bill on the agricultural community, and oppose H.R. 6444 as it is currently drafted.

Sincerely,

Edward Andersen

Edward Andersen, Master
The National Grange

EA:khv

cc: House Agriculture Committee
bcc: Secretary Block
bcc: Caroline LeGette

ENVIRONMENTAL POLICY INSTITUTE

27 July 1984

Hon. Peter W. Rodino, Chairman
House Committee on the Judiciary
2462 Rayburn House Office Bldg.
Washington, D.C. 20515

Dear Rep. Rodino:

The Environmental Policy Institute (EPI) respectfully urges you to postone full committee consideration of H.R. 6034, the Agricultural Patent Reform Act of 1984. This bill was reported out of subcommittee yesterday with changes that present new problems beyond those already in the original bill.

We believe that a number of questions need to be answered and more information provided about the purpose and intent of this bill before further action is taken. Specifically, we believe that further consultation with appropriate federal agencies, consideration of jurisdictional questions concerning the Commerce and Agriculture Committees, and the possible scheduling of broader public hearings are needed before this bill is considered by the full committee.

Wider Hearings Needed; Lack of Information

As you know, this bill was formerly a more obscure part of the pharmaceutical patent bill, and so, more information has been provided about the patent life, research costs, and the pricing of drugs than has been provided for pesticide and veterinary products. Very little detailed information is available on the actual step-by-step cost of developing specific pesticides; how pricing would be affected over time; and how these products affect both farmers and consumers. And although a range of farm organizations have expressed support for the previous Senate bill, and now H.R. 5529, few of these organizations have actually testified on the bill in either the House or the Senate. Moreover, no environmental or consumer organizations have been asked to testify on the current measure. In fact, only 3 representatives -- those of Eli Lilly, DuPont and Monsanto -- representing the National Agricultural Chemicals Associations, the Chemical Manufacturers Association and the Animal Health Institute, have actually testified on H.R. 5529.

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The inclusion of language covering products made through

218 D Street, S.E. Washington, D.C. 20003 (202) 544-2600

recombinant DNA techniques is a new element in this legislation, never before so specified in earlier bills. The fact that this legislation makes pesticides and veterinary products made by recombinant DNA technology eligible for patent term extension could be problematic given the uncertain regulatory situation now swirling around biotechnology. Writing biotechnology products into this bill could prejudice the regulatory debate yet to come. What happens, for instance, if specialized legislation is written covering only products made by recombinant DNA techniques? Moreover if these biotechnologies themselves are put on a regulatory fast tract might the argument for patent term extension then dissipate? Might the technologies also help speed up the regulatory and testing processes for pesticides, thus shortening the time needed for pre-market testing and review of pesticides and animal drugs?

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Jack Doyle, Director
Agricultural Resources
Project

Enclosure

national grange

[illegible], D. C. 20006 (202) 628-3507

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Sincerely,

Edward Andersen

Edward Andersen, Master
The National Grange

EA:khv

cc: House Agriculture Committee
bcc: Secretary Block
bcc: Caroline LeGette

(Slip Opinion)

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY *v.* MONSANTO CO.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

No. 83–196. Argued February 27, 1984—Decided June 26, 1984

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes the Environmental Protection Agency (EPA) to use data submitted by an applicant for registration of a covered product (hereinafter pesticide) in evaluating the application of a subsequent applicant, and to disclose publicly some of the submitted data. Under the data-consideration provisions of § 3, as amended in 1978, applicants now are granted a 10-year period of exclusive use for data on new active ingredients contained in pesticides registered after September 30, 1978, while all other data submitted after December 31, 1969, may be cited and considered in support of another application for 15 years after the original submission if the applicant offers to compensate the original submitter. If the parties cannot agree on the amount of compensation, either may initiate a binding arbitration proceeding, and if an original submitter refuses to participate in negotiations or arbitration, he forfeits his claim for compensation. Data that do not qualify for either the 10-year period of exclusive use or the 15-year period of compensation may be considered by EPA without limitation. Section 10, as amended in 1978, authorizes, in general, public disclosure of all health, safety, and environmental data even though it may result in disclosure of trade secrets. Appellee, a company headquartered in Missouri, is an inventor, producer, and seller of pesticides, and invests substantial sums in developing active ingredients for pesticides and in producing end-use products that combine such ingredients with inert ingredients. Appellee brought suit in Federal District Court for injunctive and declaratory relief, alleging, *inter alia*, that the data-consideration and data-disclosure provisions of FIFRA effected a "taking" of property without just compensation, in violation of

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the Fifth Amendment, and that the data-consideration provisions violated the Amendment because they effected a taking of property for a private, rather than a public, purpose. The District Court held that the challenged provisions of FIFRA are unconstitutional, and permanently enjoined EPA from implementing or enforcing those provisions.

Held:

1. To the extent that appellee has an interest in its health, safety, and environmental data cognizable as a trade-secret property right under Missouri law, that property right is protected by the Taking Clause of the Fifth Amendment. Despite their intangible nature, trade secrets have many of the characteristics of more traditional forms of property. Moreover, this Court has found other kinds of intangible interests to be property for purposes of the Clause. Pp. 12–15.

2. EPA's consideration or disclosure of data submitted by appellee prior to October 22, 1972, or after September 30, 1978, does not effect a taking, but EPA's consideration or disclosure of certain health, safety, and environmental data constituting a trade secret under state law and submitted by appellee between those two dates may constitute a taking under certain conditions. Pp. 16–25.

(a) A factor for consideration in determining whether a governmental action short of acquisition or destruction of property has gone beyond proper "regulation" and effects a "taking" is whether the action interferes with reasonable investment-backed expectations. With respect to any health, safety, and environmental data that appellee submitted to EPA after the effective date of the 1978 FIFRA amendments (October 1, 1978), appellee could not have had a reasonable, investment-backed expectation that EPA would keep the data confidential beyond the limits prescribed in the amended statute itself. As long as appellee is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest, a voluntary submission of data in exchange for the economic advantages of a registration can hardly be called a taking. Pp. 17–19.

(b) Prior to its amendment in 1972 (effective October 22, 1972), FIFRA was silent with respect to EPA's authorized use and disclosure of data submitted to it in connection with an application for registration. Although the Trade Secrets Act provides a criminal penalty for a Government employee who discloses, in a manner not authorized by law, any trade secret information revealed to him during the course of his official duties, it is not a guarantee of confidentiality to submitters of data, and, absent an express promise, appellee had no reasonable, investment-backed expectation that its information submitted to EPA before October 22, 1972, would remain inviolate in the EPA's hands. The possibility was substantial that the Federal Government at some future time

would find disclosure to be in the public interest. *A fortiori*, the Trade Secrets Act, which penalizes only unauthorized disclosure, cannot be construed as any sort of assurance against internal agency use of submitted data during consideration of the application of a subsequent applicant for registration. Pp. 19–22.

(c) However, under the statutory scheme in effect between October 22, 1972, and September 30, 1978, a submitter was given an opportunity to protect its trade secrets from disclosure by designating them as trade secrets at the time of submission. The explicit governmental guarantee to registration applicants of confidentiality and exclusive use with respect to trade secrets during this period formed the basis of a reasonable investment-backed expectation. If EPA, consistent with current provisions of FIFRA, were now to disclose such trade-secret data or consider that data in evaluating the application of a subsequent applicant in a manner not authorized by the version of FIFRA in effect between 1972 and 1978, its actions would frustrate appellee's reasonable investment-backed expectation. If, however, arbitration pursuant to FIFRA were to yield just compensation for the loss in the market value of appellee's trade-secret data suffered because of EPA's consideration of the data in connection with another application (no arbitration having yet occurred), then appellee would have no claim against the Government for a taking. Pp. 22–25.

3. Any taking of private property that may occur in connection with EPA's use of data submitted to it by appellee between October 22, 1972, and September 30, 1978, is a taking for a "public use," rather than for a "private use," even though subsequent applicants may be the most direct beneficiaries. So long as a taking has a conceivable public character, the means by which it will be attained is for Congress to determine. Congress believed that the data-consideration provisions would eliminate costly duplication of research and streamline the registration process, making new end-use products available to consumers more quickly. Such a procompetitive purpose is within Congress' police power. With regard to FIFRA's data-disclosure provisions, the optimum amount of disclosure to assure the public that a product is safe and effective is to be determined by Congress, not the courts. Pp. 25–27.

4. A Tucker Act remedy is available to provide appellee with just compensation for any taking of property that may occur as a result of FIFRA's data-consideration and data-disclosure provisions, and thus the District Court erred in enjoining EPA from acting under those provisions. Neither FIFRA nor its legislative history discusses the interaction between FIFRA and the Tucker Act, and inferring a withdrawal of Tucker Act jurisdiction would amount to a disfavored partial repeal by implication of the Tucker Act. FIFRA's provision that an original

submitter of data forfeits his right to compensation from a later submitter for the use of the original submitter's data if he fails to participate in, or comply with the terms of, a negotiated or arbitrated compensation settlement merely requires a claimant to first seek satisfaction through FIFRA's procedure before asserting a Tucker Act claim. Pp. 27–30.

5. Because the Tucker Act is available as a remedy for any uncompensated taking appellee may suffer as a result of the operation of the challenged provisions of FIFRA, appellee's challenges to the constitutionality of the arbitration and compensation scheme of FIFRA are not ripe for resolution. Pp. 30–31.

564 F. Supp. 552, vacated and remanded.

BLACKMUN, J., delivered the opinion of the Court, in which BURGER, C. J., and BRENNAN, MARSHALL, POWELL, REHNQUIST, and STEVENS, JJ., joined, and in which O'CONNOR, J., joined, except for Part IV–B and a statement on p. 24. O'CONNOR, J., filed an opinion concurring in part and dissenting in part. WHITE, J., took no part in the consideration or decision of the case.

NOTICE: This opinion is subject to formal revision before publication in the preliminary print of the United States Reports. Readers are requested to notify the Reporter of Decisions, Supreme Court of the United States, Washington, D. C. 20543, of any typographical or other formal errors, in order that corrections may be made before the preliminary print goes to press.

SUPREME COURT OF THE UNITED STATES

No. 83–196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY *v.* MONSANTO COMPANY

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

[June 26, 1984]

JUSTICE BLACKMUN delivered the opinion of the Court.

In this case, we are asked to review a United States District Court's determination that several provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 61 Stat. 163, as amended, 7 U. S. C. § 136 *et seq.*, are unconstitutional. The provisions at issue authorize the Environmental Protection Agency (EPA) to use data submitted by an applicant for registration of a pesticide[1] in evaluating the application of a subsequent applicant, and to disclose publicly some of the submitted data.

I

Over the past century, the use of pesticides to control weeds and minimize crop damage caused by insects, disease, and animals has become increasingly more important for American agriculture. See S. Rep. No. 95–334, p. 32 (1977); S. Rep. No. 92–838, pp. 3–4, 6–7 (1972); H. R. Rep. No. 92–511, pp. 3–7 (1971). While pesticide use has led to improvements in productivity, it has also led to increased risk of

[1] For purposes of our discussion of FIFRA, the term "pesticides" includes herbicides, insecticides, fungicides, rodenticides, and plant regulators. See §§ 2(t) and (u) of FIFRA, as amended, 7 U. S. C. §§ 136(t) and (u).

harm to humans and the environment. See S. Rep. No. 92–838, at 3–4, 6–7; H. R. Rep. No. 92–511, at 3–7. Although the Federal Government has regulated pesticide use for nearly 75 years,[2] FIFRA was first adopted in 1947. 61 Stat. 163.

As first enacted, FIFRA was primarily a licensing and labelling statute. It required that all pesticides be registered with the Secretary of Agriculture prior to their sale in interstate or foreign commerce. §§ 3(a) and 4(a) of the 1947 Act, 61 Stat. 166–167. The 1947 legislation also contained general standards setting forth the types of information necessary for proper labelling of a registered pesticide, including directions for use; warnings to prevent harm to people, animals, and plants; and claims made about the efficacy of the product. §§ 2(u)(2) and 3(a)(3).

Upon request of the Secretary, an applicant was required to submit test data supporting the claims on the label, including the formula for the pesticide. §§ 4(a) and (b). The 1947 version of FIFRA specifically prohibited disclosure of "any information relative to formulas of products," §§ 3(c)(4) and 8(c), but was silent with respect to the disclosure of any of the health and safety data submitted with an application.[3]

In 1970, the Department of Agriculture's FIFRA responsibilities were transferred to the then newly created Envi-

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[2] The first federal legislation in this area was the Insecticide Act of 1910, 36 Stat. 331, which made it unlawful to manufacture and sell insecticides that were adulterated or misbranded. In 1947, the 1910 legislation was repealed and replaced with FIFRA. 61 Stat. 172.

Some States had undertaken to regulate pesticide use before there was federal legislation, and many more continued to do so after federal legislation was enacted. In 1946, the Council of State Governments recommended for adoption a model state statute, the uniform State Insecticide, Fungicide, and Rodenticide Act. See S. Rep. No. 92–838, p. 7 (1972); H. R. Rep. No. 313, 80th Cong., 1st Sess., 3 (1947).

[3] Appellant here concedes, however, that as a matter of practice, the Department of Agriculture did not publicly disclose the health and safety information. Brief for Appellant 5, n. 5.

ronmental Protection Agency, whose Administrator is the appellant in this case. See Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15623 (1970).

Because of mounting public concern about the safety of pesticides and their effect on the environment and because of a growing perception that the existing legislation was not equal to the task of safeguarding the public interest, see S. Rep. No. 92–838, at 3–9; S. Rep. No. 92–970, p. 9 (1972); H. R. Rep. No. 92–511, at 5–13, Congress undertook a comprehensive revision of FIFRA through the adoption of the Federal Environmental Pesticide Control Act of 1972, 86 Stat. 973. The amendments transformed FIFRA from a labelling law into a comprehensive regulatory statute. H. R. Rep. No. 92–511, at 1. As amended, FIFRA regulated the use, as well as the sale and labelling, of pesticides; regulated pesticides produced and sold in both intrastate and interstate commerce; provided for review, cancellation, and suspension of registration; and gave EPA greater enforcement authority. Congress also added a new criterion for registration: that EPA determine that the pesticide will not cause "unreasonable adverse effects on the environment." §§ 3(c)(5)(C) and (D), 86 Stat. 980–981.

For purposes of this litigation, the most significant of the 1972 amendments pertained to the pesticide-registration procedure and the public disclosure of information learned through that procedure. Congress added to FIFRA a new section governing public disclosure of data submitted in support of an application for registration. Under that section, the submitter of data could designate any portions of the submitted material it believed to be "trade secrets or commercial or financial information." § 10(a), 86 Stat. 989. Another section prohibited EPA from publicly disclosing information which, in its judgment, contained or related to "trade secrets or commercial or financial information." § 10(b). In the event that EPA disagreed with a submitter's designation of certain information as "trade secrets or commercial or finan-

cial information" and proposed to disclose that information, the original submitter could institute a declaratory judgment action in federal district court. § 10(c)..

The 1972 amendments also included a provision that allowed EPA to consider data submitted by one applicant for registration in support of another application pertaining to a similar chemical, provided the subsequent applicant offered to compensate the applicant who originally submitted the data. § 3(c)(1)(D). In effect, the provision instituted a mandatory data-licensing scheme. The amount of compensation was to be negotiated by the parties, or, in the event negotiations failed, was to be determined by EPA, subject to judicial review upon the instigation of the original data submitter. The scope of the 1972 data-consideration provision, however, was limited, for any data designated as "trade secrets or commercial or financial information" exempt from disclosure under § 10 could not be considered at all by EPA to support another registration application unless the original submitter consented. *Ibid.*

The 1972 amendments did not specify standards for the designation of submitted data as "trade secrets or commercial or financial information." In addition, Congress failed to designate an effective date for the data-consideration and disclosure schemes. In 1975, Congress amended § 3(c)(1)(D) to provide that the data-consideration and data-disclosure provisions applied only to data submitted on or after January 1, 1970, 89 Stat. 755, but left the definitional question unanswered.

Much litigation centered around the definition of "trade secrets or commercial or financial information" for the purposes of the data-consideration and data-disclosure provisions of FIFRA. EPA maintained that the exemption from consideration or disclosure applied only to a narrow range of information, principally statements of formulae and manufacturing processes. In a series of lawsuits, however, data-submitting firms challenged EPA's interpretation and

obtained several decisions to the effect that the term "trade secrets" applied to any data, including health, safety, and environmental data, that met the definition of trade secrets set forth in Restatement of Torts § 757 (1939). See, *e. g.*, *Mobay Chemical Corp.* v. *Costle*, 447 F. Supp. 811 (WD Mo. 1978); *Chevron Chemical Co.* v. *Costle*, 443 F. Supp. 1024 (ND Cal. 1978). These decisions prevented EPA from disclosing much of the data on which it based its decision to register pesticides and from considering the data submitted by one applicant in reviewing the application of a later applicant. See S. Rep. No. 95–334, at 7; H. R. Rep. No. 95–663, p. 18 (1977).

Because of these and other problems with the regulatory scheme embodied in FIFRA as amended in 1972, see S. Rep. No. 95–334, at 2–5; H. R. Rep. No. 95–663, at 15–21; see generally EPA Office of Pesticide Programs, FIFRA: Impact on the Industry (1977), reprinted in S. Rep. No. 95–334, at 34–68, Congress enacted other amendments to FIFRA in 1978. These were effected by the Federal Pesticide Act of 1978, 92 Stat. 819. The new amendments included a series of revisions in the data-consideration and data-disclosure provisions of FIFRA's §§ 3 and 10, 7 U. S. C. §§ 136a and 136h.

Under FIFRA, as amended in 1978, applicants are granted a 10-year period of exclusive use for data on new active ingredients contained in pesticides registered after September 30, 1978. § 3(c)(1)(D)(i). All other data submitted after December 31, 1969, may be cited and considered in support of another application for 15 years after the original submission if the applicant offers to compensate the original submitter. § 3(c)(1)(D)(ii).[4] If the parties cannot agree on the amount of

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[4] § 3(c)(1)(D), 7 U. S. C. § 136a(c)(1)(D), reads in relevant part:

"(D) . . .

"(i) With respect to pesticides containing active ingredients that are initially registered under this Act after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration

compensation, either may initiate a binding arbitration proceeding. The results of the arbitration proceeding are not subject to judicial review, absent fraud or misrepresentation. The same statute provides that an original submitter who

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and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide . . .

"(ii) except as otherwise provided in subparagraph (D)(i) of this paragraph, with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person . . . within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. . . . [T]he findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. . . . If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the

refuses to participate in negotiations or in the arbitration proceeding forfeits his claim for compensation. Data that do not qualify for either the 10-year period of exclusive use or the 15-year period of compensation may be considered by EPA without limitation. § 3(c)(1)(D)(iii).

Also in 1978, Congress added a new subsection, § 10(d), 7 U. S. C. § 136h(d), that provides for disclosure of all health, safety, and environmental data to qualified requesters, notwithstanding the prohibition against disclosure of trade secrets contained in § 10(b). The provision, however, does not authorize disclosure of information that would reveal "manufacturing or quality control processes" or certain details about deliberately added inert ingredients unless "the Administrator has first determined that the disclosure is necessary to protect against an unreasonable risk of injury to health or the environment." §§ 10(d)(1)(A) to (C).[5] EPA

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data in support of the application. . . . Registration action by the Administrator shall not be delayed pending the fixing of compensation;

"(iii) after expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under subparagraphs (D)(i) and (D)(ii) of this paragraph, the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data."

[5] Section 10(d) reads in relevant part:

"(1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products and any information concerning the effects of such pesticide on on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans, and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public: *Provided*, That the use of such data for any registration purpose shall be governed by section 3 of this Act: *Provided further*, That this paragraph does not authorize the disclosure of any information that—

"(A) discloses manufacturing or quality control processes,

may not disclose data to representatives of foreign or multinational pesticide companies unless the original submitter of the data consents to the disclosure. § 10(g). Another subsection establishes a criminal penalty for wrongful disclosure by a government employee or contractor of confidential or trade secret data. § 10(f).

II

Appellee Monsanto Company (Monsanto) is an inventor, developer, and producer of various kinds of chemical products, including pesticides. Monsanto, headquartered in St. Louis County, Mo., sells in both domestic and foreign markets. It is one of a relatively small group of companies that invent and develop new active ingredients for pesticides and conduct most of the research and testing with respect to those ingredients.[6]

"(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredients of a pesticide, or

"(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide,

unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

"(2) Information concerning production, distribution, sale, or inventories of a pesticide that is otherwise entitled to confidential treatment under subsection (b) of this section may be publicly disclosed in connection with a public proceeding to determine whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment, if the Administrator determines that such disclosure is necessary to the public interest."

[6] A study by the Office of Pesticide Programs of the EPA showed that in 1977 approximately 400 firms were registered to produce manufacturing-use products. S. Rep. No. 95–334, p. 34 (1977). It was estimated that the 10 largest firms account for 75% of this country's pesticide production. *Id.*, at 60. A correspondingly small number of new pesticides are marketed each year. In 1974, only 10 new pesticides were introduced. See Goring, The Costs of Commercializing Pesticides, International Conference of Entomology, Aug. 20, 1976, reprinted in Hearings on Extension of

These active ingredients are sometimes referred to as "manufacturing-use products" because they are not generally sold directly to users of pesticides. Rather, they must first be combined with "inert ingredients"—chemicals that dissolve, dilute, or stabilize the active components. The results of this process are sometimes called "end-use products," and the firms that produce end-use products are called "formulators." See the opinion of the District Court in this case, *Monsanto Co.* v. *Acting Administrator, United States Environmental Protection Agency*, 564 F. Supp. 552, 554 (ED Mo. 1983). A firm that produces an active ingredient may use it for incorporation into its own end-use products, may sell it to formulators, or may do both. Monsanto produces both active ingredients and end-use products. *Ibid.*

The District Court found that development of a potential commercial pesticide candidate typically requires the expenditure of $5 million to $15 million annually for several years. The development process may take between 14 and 22 years, and it is usually that long before a company can expect any return on its investment. *Id.*, at 555. For every manufacturing-use pesticide the average company finally markets, it will have screened and tested 20,000 others. Monsanto has a significantly better-than-average success rate; it successfully markets one out of every 10,000 chemicals tested. *Ibid.*

Monsanto, like any other applicant for registration of a pesticide, must present research and test data supporting its application. The District Court found that Monsanto had incurred costs in excess of $23.6 million in developing the health, safety, and environmental data submitted by it under FIFRA. *Id.*, at 560. The information submitted with an application usually has value to Monsanto beyond its instrumentality in gaining that particular application. Monsanto

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the Federal Insecticide, Fungicide, and Rodenticide Act Before the Subcommittee on Agriculture Research and General Legislation of the Senate Committee on Agriculture, Nutrition, and Forestry, 95th Cong., 1st Sess., 250, 254 (1977).

uses this information to develop additional end-use products and to expand the uses of its registered products. The information would also be valuable to Monsanto's competitors. For that reason, Monsanto has instituted stringent security measures to ensure the secrecy of the data. *Ibid.*

It is this health, safety, and environmental data that Monsanto sought to protect by bringing this suit. The District Court found that much of this data "contains or relates to trade secrets as defined by the Restatement of Torts and Confidential, commercial information." *Id.*, at 562.

Monsanto brought suit in District Court, seeking injunctive and declaratory relief from the operation of the data-consideration provisions of FIFRA's § 3(c)(1)(D), and the data-disclosure provisions of FIFRA's § 10 and the related § 3(c)(2)(A). Monsanto alleged that all of the challenged provisions effected a "taking" of property without just compensation, in violation of the Fifth Amendment. In addition, Monsanto alleged that the data-consideration provisions violated the Amendment because they effected a taking of property for a private, rather than a public, purpose. Finally, Monsanto alleged that the arbitration scheme provided by § 3(c)(1)(D)(ii) violates the original submitter's due process rights and constitutes an unconstitutional delegation of judicial power.

After a bench trial, the District Court concluded that Monsanto possessed property rights in its submitted data, specifically including the right to exclude others from the enjoyment of such data by preventing its unauthorized use and by prohibiting its disclosure. 564 F. Supp., at 566. The court found that the challenged data-consideration provisions "give Monsanto's competitors a free ride at Monsanto's expense." *Ibid.* The District Court reasoned that § 3(c)(1)(D) appropriated Monsanto's fundamental right to exclude, and that the effect of that appropriation is substantial. The court further found that Monsanto's property was being appropriated for a private purpose and that this interference

was much more significant than the public good that the appropriation might serve. 564 F. Supp., at 566–567.

The District Court also found that operation of the disclosure provisions of FIFRA constituted a taking of Monsanto's property. The cost incurred by Monsanto when its property is "permanently committed to the public domain and thus effectively destroyed" was viewed by the District Court as significantly outweighing any benefit to the general public from having the ability to scrutinize the data, for the court seemed to believe that the general public could derive all the assurance it needed about the safety and effectiveness of a pesticide from EPA's decision to register the product and to approve the label. *Id.*, at 567 and n. 4.

After finding that the data-consideration provisions operated to effect a taking of property, the District Court found that the compulsory binding-arbitration scheme set forth in § 3(c)(1)(D)(ii) did not adequately provide compensation for the property taken. The court found the arbitration provision to be arbitrary and vague, reasoning that the statute does not give arbitrators guidance as to the factors that enter into the concept of just compensation, and that judicial review is foreclosed except in cases of fraud. *Id.*, at 567. The District Court also found that the arbitration scheme was infirm because it did not meet the requirements of Article III of the Constitution. *Ibid.* Finally, the court found that a remedy under the Tucker Act was not available for the deprivations of property effected by §§ 3 and 10. 564 F. Supp., at 567–568.

The District Court therefore declared §§ 3(c)(1)(D), 3(c)(2)(A), 10(b), and 10(d) of FIFRA, as amended by the Federal Pesticide Act of 1978, to be unconstitutional, and permanently enjoined EPA from implementing or enforcing those sections. See Amended Judgment, App. to Juris. Statement 41a.[7]

[7] The District Court's judgment in this case is in conflict with the holdings of other federal courts. See, *e. g.*, *Petrolite Corp.* v. *United States*

We noted probable jurisdiction. —— U. S. —— (1983).

III

In deciding this case, we are faced with four questions: (1) Does Monsanto have a property interest protected by the Fifth Amendment's Taking Clause in the health, safety, and environmental data it has submitted to EPA? (2) If so, does EPA's use of the data to evaluate the applications of others or EPA's disclosure of the data to qualified members of the public effect a taking of that property interest? (3) If there is a taking, is it a taking for a public use? (4) If there is a taking for a public use, does the statute adequately provide for just compensation?

For purposes of this case, EPA has stipulated that "Monsanto has certain property rights in its information, research and test data that it has submitted under FIFRA to EPA and its predecessor agencies which may be protected by the Fifth Amendment to the Constitution of the United States." App. 36. Since the exact import of that stipulation is not clear, we address the question whether the data at issue here can be considered property for the purposes of the Taking Clause of the Fifth Amendment.

This Court never has squarely addressed the applicability of the protections of the Taking Clause of the Fifth Amendment to commercial data of the kind involved in this case. In answering the question now, we are mindful of the basic axiom that "'[p]roperty interests . . . are not created by the Constitution. Rather, they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law.'" *Webb's*

Environmental Protection Agency, 519 F. Supp. 966 (DC 1981); *Mobay Chemical Corp.* v. *Costle*, 517 F. Supp. 252, and 517 F. Supp. 254 (WD Pa. 1981), aff'd *sub nom. Mobay Chemical Co.* v. *Gorsuch*, 682 F. 2d 419 (CA3), cert. denied, 459 U. S. 988 (1982); *Chevron Chemical Co.* v. *Costle*, 499 F. Supp. 732, (Del. 1980), aff'd, 641 F. 2d 104 (CA3), cert. denied, 452 U. S. 961 (1981).

Fabulous Pharmacies, Inc. v. *Beckwith*, 449 U. S. 155, 161 (1980), quoting *Board of Regents* v. *Roth*, 408 U. S. 564, 577 (1972). Monsanto asserts that the health, safety, and environmental data it has submitted to EPA are property under Missouri law, which recognizes trade secrets, as defined in § 757, Comment *b*, of the Restatement of Torts, as property. See *Reddi-Wip, Inc.* v. *Lemay Valve Co.*, 354 S. W. 2d 913, 917 (Mo. App. 1962); *Harrington* v. *National Outdoor Advertising Co.*, 355 Mo. 524, 532, 196 S. W. 2d 786, 791 (1946); *Luckett* v. *Orange Julep Co.*, 271 Mo. 289, 302–304, 196 S. W. 740, 743 (1917). The Restatement defines a trade secret as "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." § 757, Comment *b*. And the parties have stipulated that much of the information, research, and test data that Monsanto has submitted under FIFRA to EPA "contains or relates to trade secrets as defined by the Restatement of Torts." App. 36.

Because of the intangible nature of a trade secret, the extent of the property right therein is defined by the extent to which the owner of the secret protects his interest from disclosure to others. See *Harrington*, *supra*; *Reddi-Wip*, *supra*; Restatement of Torts, *supra*; see also *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U. S. 470, 474–476 (1974). Information that is public knowledge or that is generally known in an industry cannot be a trade secret. Restatement of Torts, *supra*. If an individual discloses his trade secret to others who are under no obligation to protect the confidentiality of the information, or otherwise publicly discloses the secret, his property right is extinguished. See *Harrington*, *supra*; R. Milgrim, Trade Secrets, § 1.01[2] (1983).

Trade secrets have many of the characteristics of more tangible forms of property. A trade secret is assignable. See, *e. g.*, *Dr. Miles Medical Co.* v. *John D. Park & Sons Co.*, 220 U. S. 373, 401–402 (1911); *Painton & Co.* v. *Bourns, Inc.*,

442 F. 2d 216, 225 (CA2 1971). A trade secret can form the *res* of a trust, Restatement (Second) of Trusts § 82, Comment *e* (1959); 1 A. Scott, *Law of Trusts* § 82.5, p. 703 (3d ed. 1967), and it passes to a trustee in bankruptcy. See *In re Uniservices, Inc.*, 517 F. 2d 492, 496–497 (CA7 1975).

Even the manner in which Congress referred to trade secrets in the legislative history of FIFRA supports the general perception of their property-like nature. In discussing the 1978 amendments to FIFRA, Congress recognized that data developers like Monsanto have a "proprietary interest" in their data. S. Rep. No. 95–334, at 31. Further, Congress reasoned that submitters of data are "entitled" to "compensation" because they "have legal ownership of their data." H. R. Conf. Rep. No. 95–1560, p. 29 (1978).[8] This general perception of trade secrets as property is consonant with a notion of "property" that extends beyond land and tangible goods and includes the products of an individual's "labour and invention." 2 W. Blackstone, Commentaries, *405; see generally J. Locke, The Second Treatise of Civil Government, ch. 5 (J. Gough ed. 1947).

Although this Court never has squarely addressed the question whether a person can have a property interest in a trade secret, which is admittedly intangible, the Court has found other kinds of intangible interests to be property for purposes of the Fifth Amendment's Taking Clause. See, *e. g.*, *Armstrong* v. *United States*, 364 U. S. 40, 44, 46 (1960) (materialman's lien provided for under Maine law protected by Taking Clause); *Louisville Joint Stock Land Bank* v. *Radford*, 295 U. S. 555, 596–602 (1935) (real estate lien protected); *Lynch* v. *United States*, 292 U. S. 571, 579 (1934) (valid contracts are property within meaning of the Taking Clause). That intangible property rights protected by state

[8] Of course, it was not necessary that Congress recognize the data at issue here as property in order for it to be protected by the Taking Clause. We mention the legislative history merely as one more illustration of the general perception of the property-like nature of trade secrets.

law are deserving of the protection of the Taking Clause has long been implicit in the thinking of this Court:

> "It is conceivable that [the term "property" in the Taking Clause] was used in its vulgar and untechnical sense of the physical thing with respect to which the citizen exercises rights recognized by law. On the other hand, it may have been employed in a more accurate sense to denote the group of rights inhering in the citizen's relation to the physical thing, as the right to possess, use and dispose of it. In point of fact, the construction given the phrase has been the latter." *United States* v. *General Motors Corp.*, 323 U. S. 373, 377–378 (1945).

We therefore hold that to the extent that Monsanto has an interest in its health, safety, and environmental data cognizable as a trade-secret property right under Missouri law, that property right is protected by the Taking Clause of the Fifth Amendment.[9]

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[9] Contrary to EPA's contention, Brief for Appellant 29, Justice Holmes' dictum in *E.I. duPont de Nemours Powder Co.* v. *Masland*, 244 U. S. 100 (1917), does not undermine our holding that a trade secret is property protected by the Fifth Amendment Taking Clause. *Masland* arose from a dispute about the disclosure of trade secrets during preparation for a trial. In his opinion for the Court, the Justice stated:

"The case has been considered as presenting a conflict between a right of property and a right to make a full defense, and it is said that if the disclosure is forbidden to one who denies that there is a trade secret, the merits of his defense are adjudged against him before he has a chance to be heard or to prove his case. We approach the question somewhat differently. The word 'property' as applied to trade-marks and trade secrets is an unanalyzed expression of certain secondary consequences of the primary fact that the law makes some rudimentary requirements of good faith. Whether the plaintiffs have any valuable secret or not the defendant knows the facts, whatever they are, through a special confidence that he accepted. The property may be denied but the confidence cannot be. Therefore the starting point for the present matter is not property or due process of law, but that the defendant stood in confidential relations with the plaintiffs." *Id.*, at 102.

IV

Having determined that Monsanto has a property interest in the data it has submitted to EPA, we confront the difficult question whether a "taking" will occur when EPA discloses that data or considers the data in evaluating another application for registration. The question of what constitutes a "taking" is one with which this Court has wrestled on many occasions. It has never been the rule that only governmental acquisition or destruction of the property of an individual constitutes a taking, for

> "courts have held that the deprivation of the former owner rather than the accretion of a right or interest to the sovereign constitutes the taking. Governmental action short of acquisition of title or occupancy has been held, if its effects are so complete as to deprive the owner of all or most of his interest in the subject matter, to amount to a taking." *United States* v. *General Motors Corp.*, 323 U. S., at 378.

See also *PruneYard Shopping Center* v. *Robins*, 447 U. S. 74 (1980); *Pennsylvania Coal Co.* v. *Mahon*, 260 U. S. 393, 415 (1922).

As has been admitted on numerous occasions, "this Court has generally 'been unable to develop any "set formula" for determining when "justice and fairness" require that economic injuries caused by public action'" must be deemed a compensable taking. *Kaiser Aetna* v. *United States*, 444 U. S. 164, 175 (1979), quoting *Penn Central Transportation Co.* v. *New York City*, 438 U. S. 104, 124 (1978); accord, *Hodel* v. *Virginia Surface Mining and Recl. Assn.*, 452 U. S. 264, 295 (1981). The inquiry into whether a taking has

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Justice Holmes did not deny the existence of a property interest; he simply deemed determination of the existence of that interest irrelevant to resolution of the case. In a case decided prior to *Masland*, the Court had spoken of trade secrets in property terms. *Board of Trade* v. *Christie Grain & Stock Co.*, 198 U. S. 236, 250–253 (1905) (Holmes, J. for the Court). See generally R. Milgrim, Trade Secrets § 1.01[1] (1983).

occurred is essentially an "ad hoc, factual" inquiry. *Kaiser Aetna*, 444 U. S., at 175. The Court, however, has identified several factors that should be taken into account when determining whether a governmental action has gone beyond "regulation" and effects a "taking." Among those factors are: "the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations." *PruneYard Shopping Center* v. *Robins*, 447 U. S., at 83; see *Kaiser Aetna*, 444 U. S., at 175; *Penn Central*, 438 U. S., at 124. It is to the last of these three factors that we now direct our attention, for we find that the force of this factor is so overwhelming, at least with respect to certain of the data submitted by Monsanto to EPA, that it disposes of the taking question regarding that data.

A

A "reasonable investment-backed expectation" must be more than a "unilateral expectation or an abstract need." *Webb's Fabulous Pharmacies*, 449 U. S., at 161. We find that with respect to any health, safety, and environmental data that Monsanto submitted to EPA after the effective date of the 1978 FIFRA amendments—that is, on or after October 1, 1978[10]—Monsanto could not have had a reasonable, investment-backed expectation that EPA would keep the data confidential beyond the limits prescribed in the amended statute itself. Monsanto was on notice of the manner in which EPA was authorized to use and disclose any data turned over to it by an applicant for registration.

Thus, with respect to any data submitted to EPA on or after October 1, 1978, Monsanto knew that, for a period of 10 years from the date of submission, EPA would not consider that data in evaluating the application of another without Monsanto's permission. § 3(c)(1)(D)(i). It was also aware,

[10]The Federal Pesticide Act of 1978 was approved on September 30, 1978. 92 Stat. 842. The new data-consideration and data-disclosure provisions applied with full force to all data submitted after that date.

however, that once the 10-year period had expired, EPA could use the data without Monsanto's permission. §§ 3(c)(1)(D)(ii) and (iii). Monsanto was further aware that it was entitled to an offer of compensation from the subsequent applicant only until the end of the fifteenth year from the date of submission. § 3(c)(1)(D)(iii). In addition, Monsanto was aware that information relating to formulae of products could be revealed by EPA to "any Federal agency consulted and [could] be revealed at a public hearing or in findings of fact" issued by EPA "when necessary to carry out" EPA's duties under FIFRA. § 10(b). The statute also gave Monsanto notice that much of the health, safety, and efficacy data provided by it could be disclosed to the general public at any time. § 10(d). If, despite the data-consideration and data-disclosure provisions in the statute, Monsanto chose to submit the requisite data in order to receive a registration, it can hardly argue that its reasonable investment-backed expectations are disturbed when EPA acts to use or disclose the data in a manner that was authorized by law at the time of the submission.

Monsanto argues that the statute's requirement that a submitter give up its property interest in the data constitutes placing an unconstitutional condition on the right to a valuable government benefit. See Brief for Appellee 29. But Monsanto has not challenged the ability of the Federal Government to regulate the marketing and use of pesticides. Nor could Monsanto successfully make such a challenge, for such restrictions are the burdens we all must bear in exchange for "'the advantage of living and doing business in a civilized community.'" *Andrus* v. *Allard*, 444 U. S. 51, 67 (1979), quoting *Pennsylvania Coal Co.* v. *Mahon*, 260 U. S. 393, 422 (1922) (Brandeis, J., dissenting); see *Day-Brite Lighting, Inc.* v. *Missouri*, 342 U. S. 421, 424 (1952). This is particularly true in an area, such as pesticide sale and use, that has long been the source of public concern and the subject of government regulation. That Monsanto is willing to

bear this burden in exchange for the ability to market pesticides in this country is evidenced by the fact that it has continued to expand its research and development and to submit data to EPA despite the enactment of the 1978 amendments to FIFRA.[11] 564 F. Supp., at 561.

Thus, as long as Monsanto is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate government interest, a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking. See *Corn Products Refining Co.* v. *Eddy*, 249 U. S. 427, 431–432 (1919) ("The right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the State, in the exercise of its police power and in promotion of fair dealing, to require that the nature of the product be fairly set forth"); see also *Westinghouse Electric Corp.* v. *United States Nuclear Regulatory Commission*, 555 F. 2d 82, 95 (CA3 1977).

B

Prior to the 1972 amendments, FIFRA was silent with respect to EPA's authorized use and disclosure of data submitted to it in connection with an application for registration. Another statute, the Trade Secrets Act, 18 U. S. C. § 1905, however, arguably is relevant. That Act is a general criminal statute that provides a penalty for any employee of the United States Government who discloses, in a manner not authorized by law, any trade secret information that is revealed to him during the course of his official duties. This Court has determined that § 1905 is more than an "antileak" statute aimed at deterring government employees from profiting by information they receive in their official capacities.

[11] Because the market for Monsanto's pesticide products is an international one, Monsanto could decide to forgo registration in the United States and sell a pesticide only in foreign markets. Presumably, it will do so in those situations where it deems the data to be protected from disclosure more valuable than the right to sell in the United States.

See *Chrysler Corp.* v. *Brown*, 441 U. S. 281, 298–301 (1979). Rather, § 1905 also applies to formal agency action, *i. e.*, action approved by the agency or department head. *Ibid.*

It is true that, prior to the 1972 amendments, neither FIFRA nor any other provision of law gave EPA authority to disclose data obtained from Monsanto. But the Trade Secrets Act is not a guarantee of confidentiality to submitters of data, and, absent an express promise, Monsanto had no reasonable, investment-backed expectation that its information would remain inviolate in the hands of EPA. In an industry that long has been the focus of great public concern and significant government regulation, the possibility was substantial that the Federal Government, which had thus far taken no position on disclosure of health, safety, and environmental data concerning pesticides, upon focusing on the issue, would find disclosure to be in the public interest. Thus, with respect to data submitted to EPA in connection with an application for registration prior to October 22, 1972,[12] the Trade Secrets Act provided no basis for a reasonable investment-backed expectation that data submitted to EPA would remain confidential.

A fortiori, the Trade Secrets Act cannot be construed as any sort of assurance against internal agency use of submitted data during consideration of the application of a subsequent applicant for registration.[13] Indeed, there is some evidence that the practice of using data submitted by one company during consideration of the application of a subsequent applicant was widespread and well known.[14] Thus,

[12] The 1972 amendments to FIFRA became effective at the close of the business day on October 21, 1972. 86 Stat. 998.

[13] The Trade Secrets Act prohibits a government employee from "publish[ing], divulg[ing], disclos[ing] or mak[ing] known" confidential information received in his official capacity. 18 U. S. C. § 1905. In considering the data of one applicant in connection with the application of another, EPA does not violate any of these prohibitions.

[14] The District Court found: "During the period that USDA administered FIFRA, it was also its *policy* that the data developed and submitted by

with respect to any data that Monsanto submitted to EPA prior to the effective date of the 1972 amendments to FIFRA, we hold that Monsanto could not have had a "reasonable investment-backed expectation" that EPA would maintain that data in strictest confidence and would use it exclusively for the purpose of considering the Monsanto applica-

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companies such as [Monsanto] could not be used to support the registration of another's product without the permission of the data submitter." 564 F. Supp., at 564 (emphasis in original). The District Court apparently based this finding on the testimony of two former Directors of the Pesticide Regulation Division, who testified that they knew of no instance in which data submitted by one applicant was subsequently considered in evaluating another application. *Ibid.*

This finding is in marked conflict with the statement of the National Agricultural Chemicals Association, presented before a Senate subcommittee in 1972, which advocated that the 1972 amendments to FIFRA should contain an exclusive-use provision:

"Under the present law registration information submitted to the Administrator has not routinely been made available for public inspection. Such information has, however, as a matter of practice but without statutory authority, been considered by the Administrator to support the registration of the same or a similar product by another registrant." Federal Environmental Pesticide Control Act: Hearings Before the Subcommittee on Agricultural Research and General Legislation of the Senate Committee on Agriculture and Forestry, 92d Cong., 2d Sess., pt. II, p. 245 (1972).

In addition, EPA points to the Department of Agriculture's Interpretation with Respect to Warning, Caution and Antidote Statements Required to Appear on Labels of Economic Poisons, 27 Fed. Reg. 2267 (1962), which presents a list of pesticides that would require no additional toxicological data for registration. The clear implication from the Interpretation is that the Department determined that the data already submitted with respect to those chemicals would be sufficient for purposes of evaluating any future applications for registration of those chemicals.

Although the evidence against the District Court's finding seems overwhelming, we need not determine that the finding was clearly erroneous in order to find that a submitter had no reasonable expectation that the Department or EPA would not use the data it had submitted when evaluating the application of another. The District Court did not find that the policy of the Department was publicly known at the time or that there was any explicit guarantee of exclusive use.

tion in connection with which the data were submitted.

C

The situation may be different, however, with respect to data submitted by Monsanto to EPA during the period from October 22, 1972, through September 30, 1978. Under the statutory scheme then in effect, a submitter was given an opportunity to protect its trade secrets from disclosure by designating them as trade secrets at the time of submission. When Monsanto provided data to EPA during this period, it was with the understanding, embodied in FIFRA, that EPA was free to use any of the submitted data that were not trade secrets in considering the application of another, provided that EPA required the subsequent applicant to pay "reasonable compensation" to the original submitter. § 3(c)(1)(D), 86 Stat. 979. But the statute also gave Monsanto explicit assurance that EPA was prohibited from disclosing publicly, or considering in connection with the application of another, any data submitted by an applicant if both the applicant and EPA determined the data to constitute trade secrets. § 10, 86 Stat. 989. Thus, with respect to trade secrets submitted under the statutory regime in force between the time of the adoption of the 1972 amendments and the adoption of the 1978 amendments, the Federal Government had explicitly guaranteed to Monsanto and other registration applicants an extensive measure of confidentiality and exclusive use. This explicit governmental guarantee formed the basis of a reasonable investment-backed expectation. If EPA, consistent with the authority granted it by the 1978 FIFRA amendments, were now to disclose trade-secret data or consider that data in evaluating the application of a subsequent applicant in a manner not authorized by the version of FIFRA in effect between 1972 and 1978, EPA's actions would frustrate Monsanto's reasonable investment-backed expectation with respect to its control over the use and dissemination of the data it had submitted.

The right to exclude others is generally "one of the most essential sticks in the bundle of rights that are commonly characterized as property." *Kaiser Aetna*, 444 U. S., at 176. With respect to a trade secret, the right to exclude others is central to the very definition of the property interest. Once the data that constitutes a trade secret is disclosed to others, or others are allowed to use that data, the holder of the trade secret has lost his property interest in the data.[15] That the data retain usefulness for Monsanto even after they are disclosed—for example, as bases from which to develop new products or refine old products, as marketing and advertising tools, or as information necessary to obtain registration in foreign countries—is irrelevant to the determination of the economic impact of the EPA action on Monsanto's property right. The economic value of that property right lies in the competitive advantage over others that Monsanto enjoys by virtue of its exclusive access to the data, and disclosure or use by others of the data would destroy that competitive edge.

EPA encourages us to view the situation not as a taking of Monsanto's property interest in the trade secrets, but as a "pre-emption" of whatever property rights Monsanto may have had in those trade secrets. Brief for Appellant 27–28. The agency argues that the proper functioning of the comprehensive FIFRA registration scheme depends upon its uniform application to all data. Thus, it is said, the Supremacy

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[15] We emphasize that the value of a trade secret lies in the competitive advantage it gives its owner over competitors. Thus, it is the fact that operation of the data-consideration or data-disclosure provisions will allow a competitor to register more easily its product or to use the disclosed data to improve its own technology that may constitute a taking. If, however, a public disclosure of data reveals, for example, the harmful side effects of the submitter's product and causes the submitter to suffer a decline in the potential profits from sales of the product, that decline in profits stems from a decrease in the value of the pesticide to consumers, rather than from the destruction of an edge the submitter had over its competitors, and cannot constitute the taking of a trade secret.

Clause dictates that the scheme not vary depending on the property law of the State in which the submitter is located. *Id.*, at 28. This argument proves too much. If Congress can "pre-empt" state property law in the manner advocated by EPA, then the Taking Clause has lost all vitality. This Court has stated that a sovereign, "by *ipse dixit*, may not transform private property into public property without compensation . . . . This is the very kind of thing that the Taking Clause of the Fifth Amendment was meant to prevent." *Webb's Fabulous Pharmacies, Inc.* v. *Beckwith*, 449 U. S., at 164.

If a negotiation or arbitration pursuant to § 3(c)(1)(D)(ii) were to yield just compensation to Monsanto for the loss in the market value of its trade-secret data suffered because of EPA's consideration of the data in connection with another application, then Monsanto would have no claim against the Government for a taking. Since no arbitration has yet occurred with respect to any use of Monsanto's data, any finding that there has been an actual taking would be premature. See *infra*, at 30–31.[16]

In summary, we hold that EPA's consideration or disclosure of data submitted by Monsanto to the agency prior to October 22, 1972, or after September 30, 1978, does not effect a taking. We further hold that EPA consideration or disclosure of health, safety, and environmental data will constitute a taking if Monsanto submitted the data to EPA between Oc-

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[16] Because the record contains no findings with respect to the value of the trade-secret data at issue and because no arbitration proceeding has yet been held to detemine the amount of recovery to be paid by a subsequent applicant to Monsanto, we cannot preclude the possibility that the arbitration award will be sufficient to provide Monsanto with just compensation, thus nullifying any claim against the Government for a taking when EPA uses Monsanto's data in considering another application. The statutory arbitration scheme, of course, provides for compensation only in cases where the data are considered in connection with a subsequent application, not in cases of disclosure of the data.

tober 22, 1972, and September 30, 1978;[17] the data constituted trade secrets under Missouri law; Monsanto had designated the data as trade secrets at the time of its submission; the use or disclosure conflicts with the explicit assurance of confidentiality or exclusive use contained in the statute during that period; and the operation of the arbitration provision does not adequately compensate for the loss in market value of the data that Monsanto suffers because of EPA's use or disclosure of the trade secrets.

V

We must next consider whether any taking of private property that may occur by operation of the data-disclosure and data-consideration provisions of FIFRA is a taking for a "public use." We have recently stated that the scope of the "public use" requirement of the Taking Clause is "coterminus with the scope of a sovereign's police powers." *Hawaii Housing Authority* v. *Midkiff*, —— U. S. ——, —— (1984) (slip op. 10); see *Berman* v. *Parker*, 348 U. S. 26, 33 (1954). The role of the courts in second-guessing the legislature's judgment of what constitutes a public use is extremely narrow. *Midkiff*, *supra*; *Berman*, *supra*, at 32.

The District Court found that EPA's action pursuant to the data-consideration provisions of FIFRA would effect a taking for a private use, rather than a public use, because such action benefits subsequent applicants by forcing original submitters to share their data with later applicants. 564 F. Supp., at 566. It is true that the most direct beneficiaries of EPA actions under the data-consideration provisions of FIFRA will be the later applicants who will support their

[17] While the 1975 amendments to FIFRA purported to carry backward the protections against data consideration and data disclosure to submissions of data made on or after January 1, 1970, 89 Stat. 751, the relevant consideration for our purposes is the nature of the expectations of the submitter at the time the data were submitted. We therefore do not extend our ruling as to a possible taking to data submitted prior to October 22, 1972.

applications by citation to data submitted by Monsanto or some other original submitter. Because of the data-consideration provisions, later applicants will not have to replicate the sometimes intensive and complex research necessary to produce the requisite data. This Court, however, has rejected the notion that a use is a public use only if the property taken is put to use for the general public. *Midkiff*, —— U. S., at —— (slip op. 13); *Rindge Co.* v. *Los Angeles*, 262 U. S. 700, 707 (1923); *Block* v. *Hirsh*, 256 U. S. 135, 155 (1921).

So long as the taking has a conceivable public character, "the means by which it will be attained is . . . for Congress to determine." *Berman*, 348 U. S., at 33. Here, the public purpose behind the data-consideration provision is clear from the legislative history. Congress believed that the provisions would eliminate costly duplication of research and streamline the registration process, making new end-use products available to consumers more quickly. Allowing applicants for registration, upon payment of compensation, to use data already accumulated by others, rather than forcing them to go through the time-consuming process of repeating the research, would eliminate a significant barrier to entry into the pesticide market, thereby allowing greater competition among producers of end-use products. S. Rep. No. 95–334, at 30–31, 40–41; 124 Cong. Rec. 29756–29757 (1978) (remarks of Sen. Leahy). Such a procompetitive purpose is well within the police power of Congress. See *Midkiff*, —— U. S., at —— (slip op. 11–12).[18]

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[18] Monsanto argues that EPA and, by implication, Congress misapprehended the true "barriers to entry" in the pesticide industry and that the challenged provisions of the law create, rather than reduce, barriers to entry. Brief for Appellee 35, n. 48. Such economic arguments are better directed to Congress. The proper inquiry before this Court is not whether the provisions in fact will accomplish their stated objectives. Our review is limited to determining that the purpose is legitimate and that Congress rationally could have believed that the provisions would promote that ob-

Because the data-disclosure provisions of FIFRA provide for disclosure to the general public, the District Court did not find that those provisions constituted a taking for a private use. Instead, the court found that the data-disclosure provisions served no use. It reasoned that because EPA, before registration, must determine that a product is safe and effective, and because the label on a pesticide, by statute, must set forth the nature, contents, and purpose of the pesticide, the label provided the public with all the assurance it needed that the product is safe and effective. 564 F. Supp., at 567 and n. 4. It is enough for us to state that the optimum amount of disclosure to the public is for Congress, not the courts, to decide, and that the statute embodies Congress' judgment on that question. See 123 Cong. Rec., at 25756 (remarks of Sen. Leahy). We further observe, however, that public disclosure can provide an effective check on the decisionmaking processes of EPA and allows members of the public to determine the likelihood of individualized risks peculiar to their use of the product. See H. R. Rep. No. 95–343, at 8 (remarks of Douglas M. Costle); S. Rep. No. 95–334, at 13.

We therefore hold that any taking of private property that may occur in connection with EPA's use or disclosure of data submitted to it by Monsanto between October 22, 1972, and September 30, 1978, is a taking for a public use.

VI

Equitable relief is not available to enjoin an alleged taking of private property for a public use, duly authorized by law,[19] when a suit for compensation can be brought against the sovereign subsequent to the taking. *Larson* v. *Domestic &*

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jective. *Midkiff*, —— U. S., at —— (slip op. 12); *Western & Southern Life Ins. Co.* v. *State Bd. of Equalization*, 451 U. S. 648, 671–672 (1981).

[19] Any taking of private property that would occur as a result of EPA disclosure or consideration of data submitted by Monsanto between October 22, 1972, and September 30, 1978, is, of course, duly authorized by FIFRA as amended in 1978.

Foreign Commerce Corp., 337 U. S. 682, 697, n. 18 (1949). The Fifth Amendment does not require that compensation precede the taking. *Hurley* v. *Kincaid*, 285 U. S. 95, 104 (1932). Generally, an individual claiming that the United States has taken his property can seek just compensation under the Tucker Act, 28 U. S. C. § 1491.[20] *United States* v. *Causby*, 328 U. S. 256, 267 (1946) ("If there is a taking, the claim is 'founded upon the Constitution' and within the jurisdiction of the Court of Claims to hear and determine"); *Yearsley* v. *Ross Construction Co.*, 309 U. S. 18, 21 (1940).

In this case, however, the District Court enjoined EPA action under the data-consideration and data-disclosure provisions of FIFRA, finding that a Tucker Act remedy is not available for any taking of property that may occur as a result of the operation of those provisions. We do not agree with the District Court's assessment that no Tucker Act remedy will lie for whatever taking may occur due to EPA activity pursuant to FIFRA.

In determining whether a Tucker Act remedy is available for claims arising out of a taking pursuant to a federal statute, the proper inquiry is not whether the statute "expresses an affirmative showing of congressional intent to permit recourse to a Tucker Act remedy," but "whether Congress has in the [statute] *withdrawn* the Tucker Act grant of jurisdiction to the Court of Claims to hear a suit involving the [statute] 'founded . . . upon the Constitution.'" *Regional Rail Reorganization Act Cases*, 419 U. S. 102, 126 (1974) (emphasis in original).

Nowhere in FIFRA or in its legislative history is there discussion of the interaction between FIFRA and the Tucker

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[20] The Tucker Act, 28 U. S. C. § 1491, reads, in relevant part:

"The United States Claims Court shall have jurisdiction to render judgment upon any claim against the United States founded either upon the Constitution, or any Act of Congress, or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort."

Act. Since the Tucker Act grants what is now the Claims Court "jurisdiction to render judgment upon any claim against the United States founded . . . upon the Constitution," we would have to infer a withdrawal of jurisdiction with respect to takings under FIFRA from the structure of the statute or from its legislative history. A withdrawal of jurisdiction would amount to a partial repeal of the Tucker Act. This Court has recognized, however, that "repeals by implication are disfavored." *Regional Rail Reorganization Act Cases*, 419 U. S., at 133. See, *e. g.*, *Amell* v. *United States*, 384 U. S. 158, 165–166 (1966); *Mercantile National Bank* v. *Langdeau*, 371 U. S. 555, 565 (1963); *United States* v. *Borden Co.*, 308 U. S. 188, 198–199 (1939).

Monsanto argues that FIFRA's provision that an original submitter of data who fails to participate in a procedure for reaching an agreement or in an arbitration proceeding, or fails to comply with the terms of an agreement or arbitration decision, "shall forfeit the right to compensation for the use of the data in support of the application," §3(c)(1)(D)(ii), indicates Congress' intent that there be no Tucker Act remedy. But where two statutes are "'capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.'" *Regional Rail Reorganization Act Cases*, 419 U. S., at 133–134, quoting *Morton* v. *Mancari*, 417 U. S. 535, 551 (1974). Here, contrary to Monsanto's claim, it is entirely possible for the Tucker Act and FIFRA to co-exist. The better interpretation, therefore, of the FIFRA language on forfeiture, which gives force to both the Tucker Act and the FIFRA provision, is to read FIFRA as implementing an exhaustion requirement as a precondition to a Tucker Act claim. That is, FIFRA does not withdraw the possibility of a Tucker Act remedy, but merely requires that a claimant first seek satisfaction through the statutory procedure. Cf. *Regional Rail Reorganization Act Cases*, 419 U. S., at 154–156 (view-

ing Tucker Act remedy as covering any shortfall between statutory remedy and just compensation).[21]

With respect to data disclosure to the general public, FIFRA provides for no compensation whatsoever. Thus, Monsanto's argument that Congress intended the compensation scheme provided in FIFRA to be exclusive has no relevance to the data-disclosure provisions of § 10.

Congress in FIFRA did not address the liability of the Government to pay just compensation should a taking occur. Congress' failure specifically to mention or provide for recourse against the Government may reflect a congressional belief that use of data by EPA in the ways authorized by FIFRA effects no Fifth Amendment taking or it may reflect Congress' assumption that the general grant of jurisdiction under the Tucker Act would provide the necessary remedy for any taking that may occur. In any event, the failure cannot be construed to reflect an unambiguous intention to withdraw the Tucker Act remedy. "[W]hether or not the United States so intended," any taking claim under FIFRA is one "founded upon the Constitution," and is thus remediable under the Tucker Act. *Regional Rail Reorganization Act Cases*, 419 U. S., at 126. Therefore, where the operation of the data-consideration and data-disclosure provisions of FIFRA effect a taking of property belonging to Monsanto, an adequate remedy for the taking exists under the Tucker Act. The District Court erred in enjoining the taking.

VII

Because we hold that the Tucker Act is available as a remedy for any uncompensated taking Monsanto may suffer as a result of the operation of the challenged provisions of FIFRA, we conclude that Monsanto's challenges to the con-

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[21] Exhaustion of the statutory remedy is necessary to determine the extent of the taking that has occurred. To the extent that the operation of the statute provides compensation, no taking has occurred and the original submitter of data has no claim against the Government.

stitutionality of the arbitration and compensation scheme are not ripe for our resolution. Because of the availability of the Tucker Act, Monsanto's ability to obtain just compensation does not depend solely on the validity of the statutory compensation scheme. The operation of the arbitration procedure affects only Monsanto's ability to vindicate its statutory right to obtain compensation from a subsequent applicant whose registration application relies on data originally submitted by Monsanto, not its ability to vindicate its constitutional right to just compensation.

Monsanto did not allege or establish that it had been injured by actual arbitration under the statute. While the District Court acknowledged that Monsanto had received several offers of compensation from applicants for registration, 564 F. Supp., at 561, it did not find that EPA had considered Monsanto's data in considering another application. Further, Monsanto and any subsequent applicant may negotiate and reach agreement concerning an outstanding offer. If they do not reach agreement, then the controversy must go to arbitration. Only after EPA has considered data submitted by Monsanto in evaluating another application and an arbitrator has made an award will Monsanto's claims with respect to the constitutionality of the arbitration scheme become ripe. See *Duke Power Co.* v. *Carolina Environmental Study Group, Inc.*, 438 U. S. 59, 81 (1978); *Regional Rail Reorganization Act Cases*, 419 U. S., at 138.

VIII

We find no constitutional infirmity in the challenged provisions of FIFRA. Operation of the provisions may effect a taking with respect to certain health, safety, and environmental data constituting trade secrets under state law and designated by Monsanto as trade secrets upon submission to EPA between October 22, 1972, and September 30, 1978.[22]

[22] We emphasize that nothing in our opinion prohibits EPA's consideration or disclosure, in a manner authorized by FIFRA, of data submitted to

But whatever taking may occur is one for a public use, and a Tucker Act remedy is available to provide Monsanto with just compensation. Once a taking has occurred, the proper forum for Monsanto's claim is the Claims Court. Monsanto's challenges to the constitutionality of the arbitration procedure are not yet ripe for review. The judgment of the District Court is therefore vacated and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.

JUSTICE WHITE took no part in the consideration or decision of this case.

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it by Monsanto. Our decision merely holds that, with respect to a certain limited class of data submitted by Monsanto to EPA, EPA actions under the data-disclosure and data-consideration provisions of the statute may give Monsanto a claim for just compensation.

SUPREME COURT OF THE UNITED STATES

No. 83-196

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY *v.* MONSANTO CO.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

[June 26, 1984]

JUSTICE O'CONNOR, concurring in part and dissenting in part.

I join all of the Court's opinion except for Part IV–B and the Court's conclusion, *ante*, at 24, that "EPA's consideration or disclosure of data submitted by Monsanto to the agency prior to October 22, 1972 . . . does not effect a taking." In my view public disclosure of pre-1972 data would effect a taking. As to consideration of this information within EPA in connection with other license applications not submitted by Monsanto, I believe we should remand to the District Court for further factual findings concerning Monsanto's expectations regarding interagency uses of trade secret information prior to 1972.

It is important to distinguish at the outset public disclosure of trade secrets from use of those secrets entirely within EPA. Internal use may undermine Monsanto's competitive position within the United States, but it leaves Monsanto's position in foreign markets undisturbed. As the Court notes, *ante*, at 19, n. 11, the likely impact on foreign market position is one that Monsanto would weigh when deciding whether to submit trade secrets to EPA. Thus a submission of trade secrets to EPA that implicitly consented to further use of the information within the agency is not necessarily the same as one that implicitly consented to public disclosure.

It seems quite clear—indeed the Court scarcely disputes—that public disclosure of trade secrets submitted to the federal government before 1972 was neither permitted by law, nor customary agency practice before 1972, nor expected by applicants for pesticide registrations. The Court correctly notes that the Trade Secrets Act, 18 U. S. C. § 1905, flatly proscribed such disclosures. The Disctrict Court expressly found that until 1970 it was government "policy that the data developed and submitted by companies such as [Monsanto] be maintained confidentially by the [administrative agency] and was not to be disclosed without the permission of the data submitter." *Monsanto Co.* v. *Acting Administrator, EPA*, 564 F. Supp. 552, 564 (1983). Finally, the Court, *ante*, at 21, n. 14, quotes from a 1972 statement by the National Agricultural Chemicals Association that "registration information submitted by the Administrator has not routinely been made available for public inspection." It is hard to imagine how a pre-1972 applicant for a pesticide license would not, under these circumstances, have formed a very firm expectation that its trade secrets submitted in connection with a pesticide registration would not be disclosed to the public.

The Court's analysis of this question appears in a single sentence: an "industry that long has been the focus of great public concern and significant government regulation" can have no reasonable expectation that the government will not later find public disclosure of trade secrets to be in the public interest. *Ante*, at 20. I am frankly puzzled to read this statement in the broader context of the Court's otherwise convincing opinion. If the degree of government regulation determines the reasonableness of an expectation of confidentiality, Monsanto had as little reason to expect confidentiality *after* 1972 as before, since the 1972 amendments were not deregulatory in intent or effect. And the Court entirely fails to explain why the nondisclosure provision of the 1972 Act, § 10, 86 Stat. 989, created any greater expectation of confidentiality than the Trade Secrets Act. Section 10 prohib-

ited EPA from disclosing "trade secrets or commercial or financial information." No penalty for disclosure was prescribed, unless disclosure was with the intent to defraud. The Trade Secrets Act, 18 U. S. C. § 1905, prohibited and still prohibits government disclosure of trade secrets and other commercial or financial information revealed during the course of official duties, on pain of substantial criminal sanctions. The Court acknowledges that this prohibition has always extended to formal and official agency action. *Chrysler Corp.* v. *Brown*, 441 U. S. 281, 298–301 (1979). It seems to me that the criminal sanctions in the Trade Secrets Act therefore created at least as strong an expectation of privacy before 1972 as the precatory language of § 10 created after 1972.

The Court's tacit analysis seems to be this: an expectation of confidentiality can be grounded only on a statutory nondisclosure provision situated in close physical proximity, in the pages of the United States Code, to the provisions pursuant to which information is submitted to the government. For my part, I see no reason why Congress should not be able to give effective protection to all trade secrets submitted to the federal government by means of a single, overarching, trade secrets provision. We routinely assume that wrongdoers are put on notice of the entire contents of the Code, though in all likelihood most of them have never owned a copy or opened a single page of it. It seems strange to assume, on the other hand, that a company like Monsanto, well served by lawyers who undoubtedly do read the Code, could build an expectation of privacy in pesticide trade secrets only if the assurance of confidentiality appeared in Title 7 itself.

The question of interagency use of trade secrets before 1972 is more difficult because the Trade Secrets Act most likely does not extend to such uses. The District Court found that prior to October 1972 only two competitors' registrations were granted on the basis of data submitted by Monsanto, and that Monsanto had no knowledge of either of

these registrations prior to their being granted. 564 F. Supp., at 564. The District Court also found that before 1970 it was agency policy "that the data developed and submitted by companies such as [Monsanto] could not be used to support the registration of another's product without the permission of the data submitter." *Ibid.* This Court, however, concludes on the basis of two cited fragments of evidence that "the evidence against the District Court's finding seems overwhelming." *Ante*, at 21, n. 14. The Court nevertheless wisely declines to label the District Court's findings of fact on this matter clearly erroneous. Instead, the Court notes that the "District Court did not find that the policy of the Department [of Agriculture] was publicly known at the time [before 1970] or that there was any explicit guarantee of exclusive use." *Ibid.* This begs exactly the right question, but the Court firmly declines to answer it. The Court simply states that "there is some evidence that the practice of using data submitted by one company during consideration of the application of a subsequent applicant was widespread and well known." *Ante*, at 20 (footnote omitted). And then, without more ado, the Court declares that with respect to pre-1972 data Monsanto "could not have had a 'reasonable investment-backed expectation' that EPA would . . . use [the data] exclusively for the purpose of considering the Monsanto application in connection with which the data were submitted." *Ante*, at 21–22.

If one thing is quite clear it is that the extent of Monsanto's pre-1972 expectations, whether reasonable and investment-backed or otherwise, is a heavily factual question. It is fairly clear that the District Court found that those expectations existed as a matter of fact and were reasonable as a matter of law. But if the factual findings of the District Court on this precise question were not as explicit as they might have been, the appropriate disposition is to remand to the District Court for further fact finding. That is the

course I would follow with respect to interagency use of trade secrets submitted by Monsanto before 1972.

INNOVATION AND PATENT LAW REFORM

WEDNESDAY, JUNE 27, 1984

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

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

Present: Representatives Kastenmeier, Mazzoli, Synar, Glickman, Berman, Moorhead, DeWine and Sawyer.

Staff present: Michael J. Remington, counsel; David W. Beier, assistant counsel; Thomas E. Mooney, associate counsel; and Audrey K. Marcus, clerical staff.

OPENING TESTIMONY OF ROBERT W. KASTENMEIER

Mr. KASTENMEIER. This morning the subcommittee continues its hearings on patent law reform, innovation and the public interest. The focus of this morning's hearings are two recent bills which alter the effective terms of patents. Patent term legislation is not a new subject for this subcommittee. Last Congress, as many of my colleagues will recall, a comprehensive patent term bill was reported by this committee and failed on the suspension calendar by a margin of five votes.

This Congress we are faced with a new scenario. Beginning early this Congress the Pharmaceutical Manufacturing Association provided the opponents of patent term legislation with data about effective patent life. At the same time my colleague Henry Waxman held hearings on the subject of FDA's drug approval process. Apparently these parallel developments led the conflicting parties to a negotiated settlement of their differences. One of the bills before us today, H.R. 3605 is a product of that negotiation process. The parties are to be congratulated for their diligent and time consuming effort to accommodate each others concerns.

I have watched these negotiations with great interest. At various points in time I have been asked to actively intervene, but I have refrained from doing so. The question of whether there should or should not be linkage between any changes in the new drug approval process at FDA and patent term extension may be something best left to the authors of any bills. Thus, I felt that it was most appropriate to avoid tilting the balance in favor or against any of the competing economic interests. This reticence is based on my sense of what the role of this committee should be in the legis-

lative process. In my estimate, our job is to formulate or review policy initiatives in the areas of jurisdiction assigned to us. This process does not merely entail ratification of previously negotiated settlements between economic interests. Rather our compass must be guided by an independent view of the public interest. Our responsibility extends not just to the employees and shareholders of various companies, rather it extends not only to the specific concerns of consumers, patients and farmers but also to such notions as the need for a rational, coherent, understandable set of laws regulating conduct.

This morning's hearings should be seen as the first step in that process of analysis which is the essence of a representative Government—independent judgment. Having noted at the outset my own previous involvement with this subject, let there be no misunderstanding about my own sense of how important and urgent our task is. On the other hand it should be equally clear that the fresh, hard look we will give these bills is in the best tradition of this institution.

The Chair would like to call first this morning—Mr. Synar wishes to be heard?

Mr. SYNAR. Thank you, Mr. Chairman.

First of all, let me thank you for scheduling today's hearings. I think it is an important step forward in this landmark legislation. As a sponsor of the Patent Term Restoration Act I introduced almost a year ago, this compromise legislation is an effort on behalf of a number of colleagues and people throughout this country in an effort to try to get this legislation moved forward.

It was recently introduced by Henry Waxman, Orrin Hatch, Al Gore, Ed Madigan and myself and I cannot think of a piece of legislation that has a broader philosophical base than this upon introduction.

Listen to this group of people that have endorsed this bill: The National Council of Senior Citizens, the AFL-CIO, AFSCME, the Pharmaceutical Manufacturers Association, 23 of the 34 members of that association have endorsed it; there remain only seven companies that are opposed to it, the generic drug industries support this legislation, and I think this shows you the type of broad base of support that we have with the variety of groups throughout this country.

I might even add that I called my mother this morning and she supports this legislation. [Laughter.]

And this is the type of apple-pie legislation we need in this country, particularly in a very controversial Congress.

I introduced this bill over a year ago—you like that, do you, Mike—I introduced this legislation over a year ago and we have struggled to try to come up with a compromise that would be satisfactory to all the players, and I think that today's legislation, as we are viewing it, is that very good piece of middle-ground compromise legislation.

During the drafting of this compromise legislation, I became personally involved in the resolution of several conflicts, primarily the one on patent certification, which I am sure we are going to hear about this morning, and which I have a lot of questions about.

I want to assure my colleagues on both sides that this is a very fair and balanced compromise; it is consistent with the goals of the patent system for this country, as well as the real-world needs for competition and also getting generics on the market quicker.

I hope that this will be only a quick hearing and that we can move expeditiously to markup in order to satisfy the urgent need for this type of legislation.

I thank the chairman again for holding these hearings today.

Mr. KASTENMEIER. I note that my colleague, Mr. Synar, is a prime sponsor of the bill in the area even as, in the last Congress, I think it was Mr. Sawyer who was the prime sponsor.

I assume that your mother, however, is one of the few persons who is a mother of a Member of Congress who probably isn't a senior citizen.

Mr. SYNAR. That is correct; she is only 39 years old. [Laughter.]

I will tell you a great story about that. I got up—when I turned 30 years old—this is a great story—I went downstairs to my breakfast and mom was cooking. I said, "Hey, Mom, you know, this is a tough day for you. You know, I am turning 30 today and you have been telling everybody for 10 years you are 39. It is going to be very hard to explain how you are 39 and your son is 30." She turned around; she had the bacon in her hand; she said, "That is no problem whatsoever. I have been meaning to tell you that you were adopted when you were 15." [Laughter.]

Mr. KASTENMEIER. That explains it.

Well, apparently it also—you list all the supporters of this bill. Probably, I think editorially the New York Times and Washington Post do. I say that is notable because they have been on several sides of this bill in the last several years editorially, at least to this concept, and apparently they have now moved back around and are supporting the measure from whence they came 3 years ago.

The first witness before us today is a very distinguished member of the administration, a person who has testified many times before this committee, whose expertise and whose knowledgeability and whose long distinguished record coming out of the field of patents is a remarkable one. The committee considered him, indeed, a friend and so we would like to greet this morning the Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, the honorable Gerald Mossinghoff.

TESTIMONY OF GERALD J. MOSSINGHOFF, ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS

Mr. MOSSINGHOFF. Thank you, Mr. Chairman.

Mr. Chairman, and members of the subcommittee, we welcome this opportunity to testify on the subject of patent term extension, which we believe would greatly improve our patent system by providing an equitable approach to the effective length of patent terms.

The inequity to certain industries, whose inventions are denied a full patent term due to Federal premarket approval requirements, has been widely recognized. This Administration, across the board, also recognizes the need for remedial action to increase innovation generally.

Therefore, this Administration strongly supports enactment of legislation to restore the effective patent term to inventions subject to Federal premarket review. Two high-level bipartisan panels have studied this problem, the National Productivity Advisory Committee and the President's Commission on Industrial Competitiveness and each has strongly recommended and endorsed patent term restoration as a vehicle to promote renewed and increased innovation in these very important areas.

Mr. Chairman, in my previous testimony before this subcommittee on H.R. 1937 during the last Congress, and in my prepared statement on H.R. 3502, submitted in hearings before your subcommittee on March 28, fully explain our reasons for support of the legislation dealing with patent term restoration. Also, in his letter to you of June 20, 1984, the General Counsel of the Department of Commerce expressed the Administration's support for enactment of H.R. 5529, legislation which would provide for an extension of the patent term for patented products or patented methods for using or producing products which are subject to Federal regulatory review before commercial use.

That legislation, however, is limited to products which are agricultural and industrial chemicals and animal drugs. H.R. 3605, as amended, does not apply to agricultural and industrial chemicals, although it does extend its application to animal drugs.

Inventions in agricultural chemical technology and in the pharmaceutical field depend heavily on patent protection. Development of such inventions is extremely costly and yet their imitation is often simple and inexpensive. Many other inventions need a far greater outlay of capital to duplicate and they also may have a shorter commercial life before being overtaken by the advance of technology.

Pharmaceutical and agricultural chemical inventions, on the other hand, often are commercially attractive, even after the expiration of the patent term. This is evidenced by the large interest in the production-intensive or generic drug industry that they display in exploiting these inventions.

This interest is healthy, and open competition should clearly be encouraged. However, to the extent that a shortened effective patent term lessens the incentive for industry to continue making large commitments toward research and development, we must 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. In this regard, H.R. 3605, as amended, is intended to strike a compromise between the research-intensive and the production-intensive sectors of the pharmaceutical industry.

Title I of the bill, as amended, amends section 505 of the Federal Food, Drug, and Cosmetic Act to provide for the approval of abbreviated new drug applications, so-called ANDA's. It would also make amendments to the act to require applicants who file paper new drug applications to make the same certifications mandated in the filing of ANDA's and require the Food and Drug Administration to make approvals for paper ANDA's effective under the same conditions that apply to ANDA's.

Title II of the bill would add a new section 156 to title 35 of the United States Code to provide for an extension of the patent term for patented products or patented methods for using or producing products subject to regulatory review pursuant to Federal statutes before they are permitted to be introduced in commercial use.

Under the bill as amended, these Federal statutes would be limited to the Federal Food, Drug, and Cosmetic act, the Public Health Service Act, and the virus, serum, toxin and analogous products provisions of the Act of Congress of March 4, 1913. Title II would also amend section 271 of title 35, dealing with patent infringement and would further amend section 282 of title 35 to provide for additional defenses in an action involving infringement of a patent during the period of the extension of the term.

It is our understanding that the broad concepts of titles I and II of this bill were the subject of extensive negotiations between the two sectors of the pharmaceutical industry and represent a compromise acceptable to both the generic pharmaceutical industry, as well as to a majority of the companies in the research-intensive sector.

The overall compromise to allow the generic companies to obtain ANDA's in exchange for patent term restoration to research-intensive companies appears to be a reasonable solution, given that enactment of either concept by itself would have continued to receive strong opposition.

Our expertise does not extend to the intricacies contained in title I of the bill dealing with amendments to the Food, Drug, and Cosmetic Act. Accordingly, we defer to the judgment of the Food and Drug Administration regarding those provisions.

The provisions of title II, however, strike us as being confusingly difficult and in some cases, as unnecessary.

Title II of H.R. 3605, as amended, deals with patent term restoration and contains several rather complex provisions. Section 156(a)(4)(A) permits a patent which claims the product or method of using that product to be extended if two requirements are met. The first is that the product must not have been claimed in another patent which was either extended or which has an earlier issue date.

The second condition is that the product and the use for the product which is approved are not identically disclosed or described in another patent which had been extended or which has an earlier issue date.

This provision clearly restricts the potential for patent term extension. Section 156(a)(4)(B) does provide for an exception to the rule laid down in the earlier paragraph for certain product patents. It provides that a patent claiming a product which was also claimed in an earlier patent may be extended if the patent is not held by the same owner.

Thus, an earlier-issued patent which claims a broad genus of compounds would not block the possible extension of a later issued patent claiming a specific species of that genus, where neither patent holder had a choice to which patent to extend. The broad underlying policy reflected in these provisions appears to be that only the first patent which either claims the product or fully dis-

closes that product and its use is the one which should be rewarded with an extension.

In cases where the patent owner only holds one patent, this policy is not unreasonable. However, this policy does not necessarily encourage the owner of a product patent to invest the sums needed for research and development to find new uses for his already patented product or to try to isolate certain species of a broad chemical genus.

I understand that the approval process for a new chemical entity is much longer than that for subsequent uses or species of that entity. Nevertheless, it would seem fair to allow patent term extension for subsequent patents which disclose new inventions.

Section 156(a)(5) specifies conditions for extension applicable to process patents. For patents claiming a process which does not primarily utilize recombinant DNA in the manufacture of the product, extension is possible only if no other patent had previously been issued claiming the product or method of using that product, and no other method of manufacturing the product is claimed in a patent having an earlier issue date.

The underlying policy in this instance appears to be that the discovery of a new, nonrecombinant DNA process for making an existing product does not warrant the reward of patent term extension. This appears somewhat unfair to us, especially if a newly discovered process for making a product, although not using recombinant DNA, otherwise represents a scientific and, therefore, possibly a commercial breakthrough.

Paragraph (B) of section 156(a)(5) makes an exception for manufacturing methods using recombinant DNA technology, but limits the possibility of patent term extension only to those cases in which the holder of a patent for that method does not also own a patent for the product or for a method of using the product. Again, in our opinion, this provision appears too strict.

If these complicated provisions have been included in this bill to prevent patent owners from benefiting from protracted patent protection through the obtaining of several patents relating to the same pharmaceutical product, then, in my opinion, they are unnecessary. In my testimony last Congress on H.R. 1937, I addressed the subject of "evergreening" or "pyramiding" of patents. I stated then, and I would like to repeat now, that it is certainly possible to obtain process and use patents after a patent on the product itself. However, one should be clear exactly on what basis those patents are obtained and what kind of protection they afford.

First, any patent issued must be patentably distinct from any other patent, which is to say, it must contain a different invention. If someone first obtains a product patent and later discovers another unexpected and patentable use for this product, that invention is entitled to protection. This is not an extension of the original patent or merely an obvious variation of the original patent; it is a separate and distinct invention capable of being patented in its own right.

The same applies to a new discovery of a process for the manufacture of the originally patented product. If such a process is separately patentable, it is also a separately patentable invention and is also entitled to protection.

In such a case, the patentee of the original product has not extended the patent term of the product; he has made a new inventive contribution to the technology. The patentee is therefore entitled to protection in turn for having publicly disclosed the invention.

However, what does a patent on a new use for a product or on a new process of making a product convey to the patentee? Regulatory review aside, if the original patent on a product has expired, the public is free to manufacture that product for all the uses for which the product was originally intended, as well as for any other use, except for the newly patented one.

If a patent for a process of manufacture was also obtained, this particular new manufacture is protected, although the public is free to make the product in any other manner. As a consequence, the product itself does not enjoy continued and "evergreening" patent protection.

In two examples cited to us by the staff of the Committee on Energy and Commerce, to show how multiple patents may extend the protection of the original pharmaceutical, we found that the new use of the original products claimed in a later patent actually involved cancer treatments. The original use was only hormonal or bactericidal. We seriously question the wisdom of a policy which would not maintain the maximum incentives for investing in research to discover new possible cancer cures.

If the policy of these provisions is to allow extension only for patents claiming new chemical entities, then it clearly changes 200 years of patent law by instituting a system in which one patent is preferred over another. In our opinion, all patents should be treated equally. If a patent has lost a certain portion of its effective patent life to Federal premarket regulatory review, it should be made whole again. Only in this manner will the patent system continue to be a strong encouragement to innovation.

Last, these provisions place an unaccustomed burden on the Patent and Trademark Office. The determination which would be required by sections 156(a) (4) and (5) is not one which is now made by patent examiners who evaluate whether a particular claim in an application is patentable. These provisions would require determinations of infringement, involving such concepts as the doctrine of equivalents and file wrapper estoppel—determinations usually made by courts.

To be sure, our examiners can be trained to make these determinations, but to the extent that these provisions attempt to cure a problem which we do not think exists, we would not favor having to expend our otherwise scarce resources.

Should the Congress decide that this is an appropriate policy, the provision in section 156(e)(1), to the effect that the determination may be made solely on the basis of information contained in the application for extension, is the only practical way to carry out this task.

Mr. Chairman, in our attempt, as we discussed this bill with the people who would be charged with carrying out this task, we began to trip over ourselves in trying to understand which way we would go. So we asked Mr. Tegtmeyer, whom you know and who has testified before the Committee many times, to put together a chart, a

logic diagram, of how section 156 would be implemented in practice. I have attached to my statement one version of that chart and I have provided to the members of the subcommittee this fold-out chart which shows the determinations which would be necessary in implementing section 156.

Now, I think various witnesses before the committee will testify on either side of the desirability of section 156 as drafted, but I don't think anyone would disagree that if enacted and put into law, it would be the single, most complicated provision of the U.S. patent laws.

We think the complexity is unnecessary. One, we think it is to solve a problem which we don't think exists; namely, the problem of "evergreening"; and two, if the subcommittee is convinced that that is a problem, there is a very simple and very elegant solution which was included in the bill which the subcommittee reported during the last Congress, H.R. 6444. Under this bill you would take the date of the original application and all subsequent applications which refer back to that original date under 35 U.S.C. 120—you simply take that date, you would add the amount of pendency of a normal application, 3 years—hopefully we are getting it down closer to 2, you add the 17-year term, you had the 7-year extension, which you said that no patent can be extended beyond, in that case, 27 years from the date of the original application. This is a very simple, understandable provision which will replace most of the procedures that are included in this very complex section 156. I would suggest to the subcommittee, if they become convinced that "evergreening" is a problem—notwithstanding our analysis that it really is not—that you rely on that kind of a solution to the problem, rather than this kind of a solution.

Mr. Chairman, section 156(c) specifies the rules by which the length of the period of extension is determined. The calculation made under these rules is further limited by the requirements of section 156(g)(4). Under section 156(c), the length of the extension is based on the length of the regulatory review period in which the product was approved.

All regulatory review periods are divided into a testing phase and an agency approval phase. Each phase of the regulatory review period is first reduced by any time during which the applicant for the extension did not act with due diligence. Now, that is a determination by the Food and Drug Administration, one that I am pleased we would not have to make under this bill.

The determination of any lack of due diligence is made under section 156(d). After any reduction in the period for lack of due diligence, one-half of the time remaining in the testing phase would be added to the time remaining in the approval phase to comprise the total period eligible for extension. This period, by itself, cannot exceed 5 years, in accordance with 156(g)(4).

However, even if entitled to an extension of 5 years, this period would be further reduced in accordance with section 156(c)(3) if it exceeded the total remaining patent term by more than 14 years. This formula strikes us as somewhat arbitrary.

For example, we are at a loss to explain the reason why a patent, which is eligible for 5 years of extension and had 10 years of original patent term left at the end of its regulatory review period,

should only be entitled to an extension of 4 of those 5 years to reach the total of 14 years. We have seen no data that relate those 14 years in any way to anything that I think either side of the debate has come up with.

With respect to the 5-year cap, we supported, as you know, the 7-year cap in earlier bills, because this period was based on data tending to support the claim that, on the average, the pharmaceutical patent lost that much time to the Federal regulatory review process. We do not know why this cap has been reduced by 2 years.

To the extent, however, that such a reduction is the result of a compromise between the two different interests involved, the administration will not object to the compromise.

Section 202 of title II would add a new paragraph (e) to section 271 of title 35, dealing with patent infringement. Specifically, this section would provide that the making, using or selling of a patented invention solely for uses reasonably related to the development and submission of information needed for Federal regulatory review would not be an act of infringement. In this respect, the proposed legislation would clearly overrule the recent decision of the Court of Appeals for the Federal Circuit in *Roche Products* v. *Bolar Pharmaceutical,* decided on April 23 of this year.

In that case, the court, in announcing what really amounts to hornbook patent law, in my opinion, held that the experimental use of a drug patent prior to the expiration date of a patent claiming that product constituted patent infringement, even though the only purpose of the experiment was to seek FDA approval for commercial sale of the drug after the patent expires.

Overruling this decision would serve as an unfortunate precedent in curtailing the exclusionary rights accorded a patentee during the patent term. It has been alleged that one should be entitled to experiment with the patented product during the term of a patent to allow immediate competition the day after the patent expires.

It appears to us somewhat unfair to have the effective term of a patent begin somewhere in the middle of the 17-year term because of Federal premarket regulatory review and let others use the patented product, or to make or sell it—people actually make a profit, the ones who would sell the product to the experimenters would actually use it as a commercial profitmaking venture—to make or sell it during the patent term solely to escape any delay caused by that same Federal review.

In other words, if there is to be a policy to encourage competition immediately after the end of the patent term, it should also ensure that the patentee is accorded the full effective patent term to which patents on nonregulated inventions are entitled.

There are other specific provisions of H.R. 3605, as amended, which are either ambiguous or could lead to different interpretations, especially in those parts of the bill which require the Commissioner of Patents and Trademarks to make a determination of whether the patentee is entitled to an extension of the patent term.

I should add a caveat, Mr. Chairman, to the chart that we have provided to the committee. That was based in several instances on Mr. Tegtmeyer's assumptions of which way the provision would be interpreted. I imagine there are other charts that could also be made, based on differing assumptions.

The better solution to this bill, in our opinion, would be to maintain the overall political compromise of combining the concept of obtaining ANDA's and patent term restoration, but to substitute in place of title II of 3605, as amended, the simpler mechanism of patent term restoration along the lines of the bills on this subject in the last Congress, or as now contained in H.R. 3502.

Mr. Chairman, that completes my prepared statement. I will be pleased to respond to any questions you or the other members of the Subcommittee may have.

[The statement of Mr. Mossinghoff follows:]

STATEMENT OF GERALD J. MOSSINGHOFF, ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS

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 an equitable approach to the effective length of patent terms.

The inequity to certain industries, 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 legislation to restore the effective patent term to inventions subject to Federal premarket review. Also, two high-level bipartisan panels which have studied this problem, the National Productivity Advisory Committee and the President's Commission on Industrial Competitiveness, have strongly endorsed patent term restoration as a vehicle to promote renewed and increased innovation.

Mr. Chairman, I think it is fair to say that my previous testimony before this Subcommittee on H.R. 1937 during the last Congress and my prepared statement on H.R. 3502 submitted at hearings before your Subcommittee on March 28, 1984, fully explain the reasons for our support of legislation dealing with patent term restoration. Also, in his letter to you of June 20, 1984, the General Counsel of the Department of Commerce expressed the Administration's strong support for enactment of H.R. 5529, legislation which would provide for an extension of the patent term for patented products or patented methods for using or producing products which are subject to Federal regulatory review before commercial use. That legislation, however, is limited to products which are agricultural and industrial chemicals and animal drugs. H.R. 3605 as amended, does not apply to agricultural and industrial chemicals although it does extend its application to animal drugs.

Inventions in agricultural chemical technology and in the pharmaceutical field depend heavily on patent protection. Development of such inventions is extremely costly, and yet their imitation is ofter simple and inexpensive. Many other inventions need a far greater outlay of capital to duplicate, and they also may have a shorter commercial life before being overtaken by the advance of technology. Pharmaceutical and agricultural chemical inventions, on the other hand, often are commercially attractive even after the expiration of the patent term. This is evidenced by the large interest that the production intensive or generic drug industry displays in exploiting those inventions. This interest is healthy, and open competition should be encouraged. However, to the extent that a shortened effective patent term lessens the incentive for industry to continue making large commitments toward research and development, we must move to insure that these incentives are restored. Effective patent protection is a necessary prerequistie to pharmaceutical and chemical research, given the enormous costs and risks involved. In this regard, H.R. 3605 as amended, is intended to strike a compromise between the research intensive and the production intensive sectors of the pharmaceutical industry.

Title I of H.R. 3605 as amended, amends Section 505 of the Federal Food, Drug, and Cosmetic Act to provide for the approval of Abbreviated New Drug Applications (ANDA's). It would also make amendments to the Act to require applicants who file Paper New Drug Applications (Paper NDA's) to make the same certifications mandated in the filing of ANDAs and require the Food and Drug Administration to make approvals for Paper NDAs effective under the same conditions that apply to ANDAs.

Title II of this bill would add a new section 156 to title 35 of the United States Code to provide for an extension of the patent term for patented products or patent-

ed methods for using or producing products, subject to regulatory review pursuant to Federal statutes, before they are permitted to be introduced for commercial use.

Under H.R. 3605 as amended, these Federal statutes would be limited to the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the virus, serum, toxin, and analogous products provisions of the Act of Congress of March 4, 1913. Title II would also amend section 271 of title 35, United States Code, dealing with patent infringement and would further amend section 282 of title 35 to provide for additional defenses in an action involving infringement of a patent during the period of the extension of its term.

It is our understanding that the broad concepts of Titles I and II of this bill were the subject of extensive negotiations between the two sectors of the pharmaceutical industry and represent a compromise acceptable both to the generic pharmaceutical industry as well as to a majority of the companies in the research intensive sector. The overall compromise to allow the generic companies to obtain ANDAs in exchange for patent term restoration to research intensive companies appears to be a reasonable solution, given that enactment of either concept by itself would have continued to receive strong opposition. Our expertise does not extend to the intricacies contained in Title I of this bill dealing with amendments to the Federal Food, Drug, and Cosmetic Act. Accordingly, I defer to the judgment of the Food and Drug Administration regarding the provisions of Title I. The provisions of Title II, however, strike us as being confusingly difficult and in some instances as unnecessary.

Titlel II of H.R. 3605 as amended, deals with patent term restoration and contains several rather complex provisions. Section 156(a)(4)(A) permits a patent which claims the product or method of using that product to be extended if two requirements are met. The first is that the product must not have been claimed in another patent which was either extended or which has an earlier issue date. The second condition is that the product and the use for which it is approved are not identically disclosed or described in another patent which had been extended or which has an earlier issue date.

This provision clearly restricts the potential for patent term extension. Section 156(a)(4)(B) does provide for an exception to the rule laid down in paragraph (a)(4)(A) for certain product patents. It provides that a patent claiming a product which was also claimed in an earlier patent may be extended if the patents are not held by the same owner. Thus, an earlier issued patent which claims a broad genus of compounds would not block the possible extension of a later issued patent claiming a specific species of that genus where neither patent holder had a choice as too which patent to extend. The broad underlying policy reflected in these provisions appears to be that only the first patent which either claims the product or which fully discloses that product and its use is the one which should be rewarded with an extension. In cases where the patent owner only holds one patent this policy is not unreasonable. However, this policy does not necessarily encourage the owner of a product patent to invest the sums needed for research and development to find new uses for his already patented product, or to try to isolate certain species of a broad chemical genus. I understand that the approval process for a new chemical entity is much longer than for subsequent new uses or species of that entity. Nevertheless, it would seem fair to allow patent term extension for subsequent patents which disclose new inventions.

Section 156(a)(5) specifies conditions for extension applicable to process patents. For patents claiming a process which does not primarily utilize recombinant DNA in the manufacture of the product, extension is possible only if no other patent had previously been issued claiming the product or method of using that product, and no other method of manufacturing the product is claimed in a patent having an earlier issue date. The underlying policy in this instance appears to be that the discovery of a new, non-recombinant DNA process for making an existing product does not warrant the reward of patent term extension. This appears somewhat unfair, especially if a newly discovered process for making a product, although not using recombinant DNA, otherwise represents a scientific and, therefore, possibly a commercial breakthrough.

Paragraph (B) of section 156(a)(5) makes an exception for manufacturing methods using recombinant DNA technology, but limits the possibility of patent term extension only to those cases in which the holder of a patent for that method does not also own a patent for the product or for a method of using that product. Again, in our opinion, this provision appears too strict.

If these complicated provisions have been included in this bill to prevent patent owners from benefitting from protracted patent protection through the obtaining of several patents relating to the same pharmaceutical product, then they are unnecessary. In my testimony on H.R. 1937, I addressed the subject of "evergreening" or

"pyramiding" of patents. I stated then and repeat now that it is certainly possible to obtain process and use patents after a patent on the product itself. However, one should be clear exactly on what basis those patents are obtained and what kind of protection they afford. First, any patent issued must be patentably distinct from any other patent, which is to say, it must contain a different invention. If someone first obtains a product patent and later discovers another unexpected and patentable use for this product, that invention is entitled to protection. This is not an extension of the original patent or a merely obvious variation of the original invention; it is a separate and distinct invention, capable of being patented in its own right.

The same applies to a new discovery of a process for the manufacture of the originally patented product. If such a process is a separately patentable invention it is also entitled to protection. In such a case, the patentee of the original product has not extended the patent term of the product, he has made new inventive contributions to the technology. The patentee is therefore entitled to protection in turn for having publicly disclosed the invention.

However, what does a patent on a new use for a product or on a new process of making a product convey to the patentee? Regulatory review aside, if the original patent on the product has expired, the public is free to manufacture that product for all the uses for which the product was originally intended, as well as for any other use, except for the newly patented one. If a patent for a process or manufacture was also obtained, this particular new manufacture is protected, although the public is free to make the product in any other manner. As a consequence, the product itself does not enjoy continued and evergreening patent protection.

In two examples cited to us by the staff of the Committee on Energy and Commerce, to show how multiple patents may extend the protection of the original pharmaceutical, we found that the new use of the original products claimed in the later patents actually involved cancer treatments. The original use was only hormonal or bactericidal. We seriously question the wisdom of a policy which would not maintain the maximum incentives for investing in research to discover possible new cancer cures.

If the policy of these provisions is to allow extension only for patents claiming new chemical entities, then it changes nearly 200 years of patent law by instituting a system in which one patent is preferred over another. In our opinion, all patents should be treated equally. If a patent has lost a certain portion of its effective patent life to Federal premarket regulatory review, it should be made whole again. Only in this manner will the patent system continue to be a strong encouragement to innovation.

Lastly, these provisions place an unaccustomed burden on the Patent and Trademark Office. The determination which would be required by sections 156(a)(4) and (5) is not one which is now made by patent examiners who evaluate whether a particular claim in an application is patentable. These provisions would require determinations of infringement, involving concepts such as the doctrine of equivalents and file wrapper estoppel—determinations usually made by courts. To be sure, examiners can be trained to make these determinations. But to the extent that these provisions attempt to cure a problem which we do not think esists, we do not favor having to expend our otherwise scarce resources. Should the Congress, however, decide that this is the appropriate policy, the provision in section 156(e)(1), to the effect that the determination may be made solely on the basis of information contained in the application for extension, is the only practical way to carry out this task.

Section 156(c) specifies the rules by which the length of the period of extension is determined. The calculation made under these rules is further limited by the requirements of section 156(g)(4). Under section 156(c), the length of the extension is based on the length of the regulatory review period in which the product was approved. All requlatory review periods are divided in to a testing phase and an agency approval phase. Each phase of the regulatory review period is first reduced by any time during which the applicant for extension did not act with due diligence. The determination of any lack of due deligence is made under section 156(d). After any reduction in the period for lack of due diligence, one-half of the time remaining in the testing phase would be added to the time remaining in the approval phase to comprise the total period eligible for extension. This period by itself cannot exceed five years in accordance with section 156(g)(4). However, even if entitled to an extension of five years, this period would be further reduced in accordance with section 156(c)(3) if it exceeded the total remaining patent term by more than 14 years. This formula strikes us as being somewhat arbitrary. For example, we are at a loss to explain the reason why a patent, which is eligible for five years of extension and had ten years of the original patent term left at the end of its regulatory review

period, should only be entitled to an extension of four of those five years to reach a total of 14 years.

With respect to the five-year cap, we supported the seven-year cap in earlier bills, because this period was based on data tending to support the claim that, on the average, a pharmaceutical patent lost that much time to the Federal regulatory review process. We do not know why this cap has been reduced by two years. To the extent, however, that such a reduction is the result of a compromise between the defferent interest groups involved, the Administration will not object to such a compromise.

Section 202 of Title II of the bill would add a new paragraph (e) to section 271 of title 35, dealing with patent infringement. Specifically, this section would provide that the making, using or selling of a patented invention solely for uses reasonably related to the development and submission of infomation needed for Federal regulatory review would not be an act of infringement. In this respect, the proposed legislation would overrule the recent decision of the Court of Appeals for the Federal Circuit in *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.*,————, 221 USPQ 937 (Fed. Cir., April 23, 1984). In that case, the Court held that the experimental use of a drug product prior to the expiration date of a patent claiming that product constituted patent infringement, even though the only purpose of the experiment was to seek FDA approval for the commercial sale of the drug after the patent expires.

Overruling this decision would serve as an unfortunate precedent in curtailing the exclusionary rights accorded a patentee during the patent term. It has been alleged that one should be entitled to experiment with the patented product during the term of a patent to allow immediate competition the day after the patent term expires. It appears to us somewhat unfair to have the effective term of a patent begin somewhere in the middle of the 17-year term because of Federal premaket regulatory review and to let others use the patented product, or make or sell it during the patent term, solely to escape any delay caused by that same Federal review. In other words, if there is to be a policy to encourage competition immediately after the end of the patent term, is should also ensure that the patentee is accorded the full effective patent term to which patents on nonregulated inventions are entitled.

There are other specific provisions in H.R. 3605 as amended, which are either ambiguous, or could lead to different interpretations, especially in those parts of the bill which require the Commissioner of Patents and Trademarks to make a determination of whether a patentee is entitled to an extension of the patent term. I have not specifically addressed those issues because I believe that they could be resolved. A better solution to this bill, for instance, could be to maintain the overall compromise of combining the concept of obtaining ANDAs and patent term restoration, but to substitute in place of Title II of H.R. 3605 as anmended, the simpler mechanism of patent term restoration along the lines of the bills on this subject in the last Congress, or as now contained in H.R. 3502.

Mr. KASTENMEIER. Thank you, Commissioner Mossinghoff, for that analysis of the bills before us.

Now, not all—I suppose not all of the comments or criticisms you have of 3605, as amended, might be appropriate for that purpose, since some of your comments go to the concepts, but to the extent possible, do you have alternative language, statutory language which would back up some of your suggestions in terms of dealing with 3605?

Mr. MOSSINGHOFF. Well, the principal approach that we would take would be to incorporate provisions from H.R. 6444. There is an awful lot of thought and, we think, good work that went into the bill that was reported—well, actually came very close to passage by the House—I think it received more than a majority in the House during the last Congress, but under the procedures did not receive the necessary two-thirds. There was an awful lot of work going into H.R. 6444 in the previous Congress.

Most of those concepts are included in H.R. 3502, the patent term restoration bill in this Congress. That would be our starting point, we think, We could give the Subcommittee alternative approaches if the Subcommittee becomes convinced that an anti-"evergreen-

ing" provision is necessary in the bill to either maintain the political compromise or on its own merits, then we would recommend the provision that was included in H.R. 6444, and that simply starts off with the filing date of the original application.

That is a date which all subsequent applications refer back to for their filing date. Simply start with that date, add the periods that you think are relevant, the period of pendency in the Patent and Trademark Office, somewhere between 2 and 3 years, the 17 years that most patents enjoy, then say, a 5-year patent extension because of the regulatory review and end up saying that no patent can be extended to be effective beyond 25 years of its section 120 date.

We think that is a very workable, simple approach to solve an "evergreening" problem. With respect to the rest of the legislation, we think having put that aside, then you simply go to the wording of H.R. 3502 and substitute that for the provisions, the very complicated provisions of section 156.

On the issue of whether there should be an exception to the 200-year-old rule of what infringes a U.S. patent, an exception which would reverse the *Roche* v. *Bolar* case, that again is a decision—we don't recommend that. We think that the patent laws were intended and have, ever since the beginning of the Republic, proscribed making, using or selling the patented invention, and we don't think that there has been a case made to reverse that.

Roche v. *Bolar* merely stated the obvious. It merely said that making things which are patented and commercially selling them or using them for a commercial end was an infringement of the patent. The wording of that provision, if you are going to accept the policy behind it—again, changing 200 years of patent law—if you are going to accept the policy, then the wording in section 156 is not something we would object to. It does that very effectively, but we don't recommend that as a matter of policy.

So on the one hand, if the policy is to extend for 5 years, then we think H.R. 3502, with maybe the H.R. 6444 cutoff, would be appropriate and with respect to the changing of what would amount to an infringement, that is a decision, obviously, which the subcommittee is going to have to make.

We recommend they not make the decision, but if they do, the specific language of H.R. 3605 is adequate to do that.

Mr. KASTENMEIER. I hate to put you on the spot, but I guess I will do it.

In the event—and we are going to listen very carefully to all of the testimony, as we have to yours, and this committee will have until August 1 to act, in the event that the Congress should produce a—well, should ultimately approve H.R. 3605 as currently amended in its current form, and I do not make that prediction, but hypothetically, in view of your reservation, are you inclined to recommend the President veto such a bill?

Mr. MOSSINGHOFF. Mr. Chairman, I really think I am going to move off that spot that you just put me on. [Laughter.]

Mr. KASTENMEIER. I consider that a——

Mr. MOSSINGHOFF. I really can't say at this point. In my opinion, based on an awful lot of experience of working with Congress, that is a very different determination of whether you oppose legislation

going in or whether once Congress, in a clearly bipartisan way, decides to enact it, whether you recommend that the President veto it, I don't think it is a good piece of legislation as it is now drafted, Mr. Chairman.

I hope we can convince the subcommittee that it can be improved while maintaining the same general political balance that was obtained in the drafting of it. We were informed through the staff of this committee, and we appreciate that, of some of the steps that were taken in the compromise and some of the provisions which were, I think, fatally included in earlier drafts, were amended out.

For example, "patent" is now defined to mean a U.S. patent, rather than a worldwide—you know, you had to look at patents around the world. That was changed and so the bill has been improved, and we are hopeful that there is enough flexibility in the system that it can be improved a lot more to maintain what we very much want, what this administration strongly supports, and that is patent term restoration for these two very important industries.

Mr. KASTENMEIER. Well, believe me, your answer to my question is—even in its form, the form in which you answered it—very useful to the committee.

At least, I understand in the bill a grant of e..clusive marketing authority to the Commissioner of the FDA with respect to unpatentable substances. What rationale is there for that if that is an area in which you reviewed?

Mr. MOSSINGHOFF. This is, I guess, the 4-year provision. I would like to defer again to the FDA on that. That seems to me to be a drug policy issue, rather than a patent issue. If it is not patented——

Mr. KASTENMEIER. You don't see implications of patent policy in that?

Mr. MOSSINGHOFF. Not necessarily. I mean, there are some sort of exclusive marketing rights, but if it is not patented, my view would be that I would totally defer to the Food and Drug Administration to decide when something can or can't be marketed.

Mr. KASTENMEIER. I have other questions, but due to the hour, I think I will yield to my colleagues, however, at this point. I would like to first yield to the gentleman from California, Mr. Moorhead.

Mr. MOORHEAD. Thank you.

I think that the issue that you have discussed to the greatest extent—and that is, the validity of the patent and being able to be inviolate during its term is the key problem that many people have had with this legislation and I know people in the industry itself, but in the compromise that was worked out, I believe some of the senior groups and the generics and so forth agreed to the legislation because it has had that very point in it.

What has to be done, if we are going to change it, I would presume, in getting the bill through, would be to find some way that you could satisfy their needs and at the same time, give the extension of time to the people who developed these patents, because 2 years ago we got a bill through and the uproar that came as a result of opposition eventually defeated the bill.

Do you have any suggestions that you can make to us as to how we can get around this dilemma and still keep everyone fairly well satisfied?

Mr. MOSSINGHOFF. I guess everyone will speak for himself at these hearings. I wasn't aware that that was absolutely critical to the compromise. I thought the main elements of the compromise were some form of patent extension, in this case, less than what was in the original legislation, so that——

Mr. MOORHEAD. But also——

Mr. MOSSINGHOFF [continuing]. And in turn for the major part—I thought the major compromise was in return for statutory abbreviated new drug application procedures, which would be established——

Mr. MOORHEAD. But also——

Mr. MOSSINGHOFF [continuing]. But whether you overruled *Roche* v. *Bolar* or not, you would have the two major elements of the compromise. As I say, everyone is going to speak for himself, but I didn't view this—and it is a reversal of a long-standing U.S. patent law to say that people can make something and profit commercially during the term of a patent for some purpose——

Mr. MOORHEAD. Getting the product on the market immediately——

Mr. MOSSINGHOFF. That is right and clearly——

Mr. MOORHEAD [continuing]. Was the thing that they had in mind.

Mr. MOSSINGHOFF. That is right. Clearly, if someone has a patent on a motor, it is, again, hornbook patent law that a competitor can't build a lot of versions of the motor to be able to hit the street the day the patent expires. That is an infringement because that is making a patented device.

Mr. MOORHEAD. I agree with you. [Laughter.]

I wonder if we weaken this presumption, what effect is it going to have on all of patent law? Isn't it going to have an effect in other places as well if we start tearing down that——

Mr. MOSSINGHOFF. Well, I think it is an unfortunate precedent. I think it would be the first time—again, it is a step that should not be taken lightly by anyone—it is the first time that this would have happened and it would be an unfortunate precedent. We spend a lot of time, as you know, Mr. Moorhead, working hard trying to convince other countries that they should strengthen their protection of intellectual property and patents, and this would be a clear case of the Congress deciding to weaken the rights normally given to patentees under a system which has worked very well for an awfully long time.

Mr. MOORHEAD. That brings up my next question. We have been struggling this year to find ways that we could improve the protection for our products overseas and do away with the counterfeiting that has been going on in various parts of the world on various kinds of products that come out of the United States.

I wonder what effect this would have on the protection of patents abroad, especially those dealing with pharmaceuticals. Would the whole protective system be broken down?

Mr. MOSSINGHOFF. I don't know if it would be broken down, but it would certainly—it would not go unnoticed internationally

among those who question whether there should be protection at all for pharmaceuticals. That is an extremely complicated area and, as you know, we have been working very hard to try to convince people that they should have strong protection in this area, the area of pharmaceuticals, so this would be an example of action by the Government of the United States, which would, in effect, weaken the protection in the very areas that we are working hard trying to strengthen internationally.

Mr. MOORHEAD. We are going to have the responsibility of trying to find alternatives. If we make changes in this legislation, we are going to have to try to find alternatives that can give the desired results to the holders of patents, at the same time satisfy others that feel that it is important to get products on the market as early as possible that will be at a reasonable price.

Do you think that any kind of reasonable equity could have been achieved by an outright extension of patents in this area where, regardless of circumstances, instead of the 17 years, because we recognize it takes a certain number of years to get Food and Drug people to approve the marketing of a product—if you gave an automatic 7-year increase and made it 24 years and everyone had to fit within that now, that would do away with this big complicated table that you have and would satisfy most people, but perhaps not all——

Mr. MOSSINGHOFF. That is what is really the basis of the bill that passed the Senate during the last Congress and came very close to passing the House, actually received a majority of the votes of the House. It was a relatively straightforward extension.

This committee added to that a safeguarding provision that said you can't have patent extension beyond a certain amount because of derivative patents that might be issued for the same application. That is what we would recommend.

Now, the issue of trading that off against the abbreviated new drug application, that is something that we would have to—it is something we didn't get into when we testified on simple patent term restoration. We think that is a good idea, in and of itself. We supported it then. I believe it was supported during the previous Administration, so it is not a partisan issue at all. It was supported by the two groups, bipartisan advisory groups that looked at this, so we recommended just the extension.

We understand that politically there had to be some kind of a give and take here and we thought the give and take was going to be that kind of an extension for abbreviated new drug applications. We were unhappily surprised with what came out of that process in terms of the complexity of taking a relatively straightforward patent term restoration bill and turning it into a very elaborate, perhaps workable, but perhaps not workable solution.

Mr. MOORHEAD. I had just one other question and it is perhaps one that you just have to take a guess at. Because patent rights are property rights, the retroactive part of 202 would seem that it might be an uncompensated taking of property and a violation of the fifth amendment, as well as a violation of the due process clause of the Constitution.

Would you like to comment on that?

Mr. MOSSINGHOFF. I am aware of a memorandum—I think there will be testimony about it this morning—that discusses the constitutional implications of it. We decided not to get involved in that directly. Issues of constitutionality are better, I think, left with the Office of Legal Counsel over in the Department of Justice, so we didn't get into the constitutional issue.

It would be contrary to all the precedent I know about to have this committee or the Congress change the rights of patentees who hold issued patents. In all of the legislation having to do with maintenance fees, for example, both in the last administration and in this administration, and this Congress agreed, all the changes were made prospectively so they only applied to applications filed after the date the law was changed. They were not changed retroactively. We don't charge maintenance fees for any application not already on file when Congress passed the law requiring maintenance fees.

So, if I can step aside from the issue of constitutionality, it clearly is without precedent that I know of in terms of changing or limiting a patentee's rights retroactively.

Mr. MOORHEAD. Thank you for your good advice and for being here this morning.

Mr. MOSSINGHOFF. Thank you.

Mr. MAZZOLI [presiding]. Let me yield myself 5 minutes in lieu of the chairman.

Mr. Mossinghoff, let me ask you: How much of this Rube Goldberg machine here is based on supposition? I think you mentioned that your colleague had made some assumptions on his part in order to compile this. Do you know how much of this, percentagewise, is based on assumption and how much is pretty much down to brass tacks?

Mr. MOSSINGHOFF. I think all of it is there. I think everything that is required to be done is there, and I think that if you read the sections, we have not added things based on assumptions. I think it is the question of which branch of the tree you go up.

Mr. MAZZOLI. Yes.

Mr. MOSSINGHOFF. You assume you go up the left branch or the right branch, but if you wish—Mr. Tegtmeyer, I think, is in the hearing room; I would be pleased to ask him——

Mr. MAZZOLI. Let me ask you now, because I am not an expert in this field at all, does this mean that this process would have to be concluded, achieved in order to decide how much extension you would get under this bill before this subcommittee?

Mr. MOSSINGHOFF. This process would have to be completed before you decide: One, whether you can give any extension at all, and there are a lot of traps you can fall in on your way to getting any patent extension at all; and then once you get a patent extension, this process is used to determine how long that would be.

Mr. MAZZOLI. So this would determine whether, and then how much?

Mr. MOSSINGHOFF. That is right.

Mr. MAZZOLI. Would there be any—does your colleague estimate how long it would take to conclude such an elaborate examination?

Mr. MOSSINGHOFF. If I may, Mr. Chairman, Mr. Tegtmeyer is our Assistant Commissioner, I could ask him to come up and answer these.

Mr. MAZZOLI. Yes, if it is—yes, I think that would be fine, please, yes, sir. That seems to be kind of interesting.

He was conveniently out of sight back there until we fingered him. [Laughter.]

I am sorry; I shouldn't have asked the question the way I did.

You have heard the question, essentially, that your judgment—this elaborate chart was based on some assumption—I have asked your colleague, Mr. Mossinghoff, how much is based on assumption and how much of this is pretty much an absolute based on your examination of this bill before us.

Mr. TEGTMEYER. Most of the chart is based upon just an extraction of the provisions from the bill, putting them in an organized form on a chart where you can see the steps you have to go through.

However, we had to make some assumptions. For example, if there are elements missing, from the application for an extension, such as dates or similar kinds of information, the question arose whether this deficiency is correctable once the 60-day period expired for filing the application for extension. That is the kind of question to which we had to assume certain answers to arrive at the procedures we developed, but most of it is relatively step by step right out of the bill.

Mr. MAZZOLI. As a professional, would you have any idea how long it would take for something to navigate this course?

Mr. TEGTMEYER. It is a little difficult to predict because we don't know what kinds of materials are going to be submitted with an application for extension by the applicant, whether we are going to receive large amounts of prior patent references that we will have to wade through, and whether there will be frequent exchanges or dialogs with the party seeking the extension. This is something we don't have experience with at the present time.

Mr. MAZZOLI. In other words, the decision is whether they have a half room full of paper or a full room full of paper; is that, essentially speaking, the case?

Mr. TEGTMEYER. That is pretty close to the picture, yes, sir.

Mr. MAZZOLI. Pretty close to the case.

Well, the alternative to this, Mr. Mossinghoff, is something like we had in an earlier bill. Would you kind of refresh my memory of what might have been in an earlier bill?

Mr. MOSSINGHOFF. Yes, Mr. Chairman. The earlier bill that I referred to was—well, it is actually a bill pending in this Congress, H.R. 3502, and that has a whole host of cosponsors. It was introduced by Mr. Synar on June 30, 1983. In comparison to the bill we are testifying on, which is 50 pages long, this bill is a 10-page bill, and it talks about merely defining the kinds of things that are covered.

In other words, whether it is under various acts, the Federal Food Drug, and Cosmetic Act and so on, to obtain an extension, the owner of record shall notify the Commissioner under oath within 90 days after termination of regulatory review that the regulatory review has ended. The notification should be in writing and identi-

fy the statute, the dates, the products, the requirements of the statute. Upon receipt of that, we publish a notice in the Official Gazette. Unless the requirements are met, we issue a certificate. It is simply——

Mr. MAZZOLI. To extend for how long? Was there a limit on the——

Mr. MOSSINGHOFF. Yes, this one is for 1-for-1——

Mr. MAZZOLI. Yes.

Mr. MOSSINGHOFF [continuing]. Up to a maximum of 7 years.

Mr. MAZZOLI. An extension of 1 year for each 1 year in the processing phase——

Mr. MOSSINGHOFF. That is right.

Mr. MAZZOLI. Up to a limit of 7 years.

Mr. MOSSINGHOFF. That is right. Now, one of the compromises reached in the bill in front of us, which the administration does not object to, says that there are two phases to this regulatory review, a testing phase and the actual review phase.

On the theory that some testing would obviously have to be done by any responsible company, you would split the testing phase in half and then you would have up to a total of 5 years, rather than a total of 7 years.

Mr. MAZZOLI. But you would not count the testing phase or only half of the testing?

Mr. MOSSINGHOFF. Only half of the testing phase, all of the other phase——

Mr. MAZZOLI. The review phase.

Mr. MOSSINGHOFF. The review phase, and—but a maximum of 5 years——

Mr. MAZZOLI. Five years.

Mr. MOSSINGHOFF [continuing]. Rather than an actual 7.

Mr. MAZZOLI. So in any event——

Mr. MOSSINGHOFF. That has nothing to do with the complexity. That is——

Mr. MAZZOLI [continuing]. These other formulas sort of finesse the question of all this paperwork and exotic detail and they give you, in certain cases, 5 or 7 limited, but they give you that based on the filing of the fairly simple chart.

Mr. MOSSINGHOFF. Right.

Mr. MAZZOLI. My time is about to expire. Let me ask probably two questions. One is a policy question and you may not be able to answer it.

If the committee were to opt for a simple procedure, something along the lines that you have described, would this, in your judgment, if you can answer the question, in any way seriously defeat this compromise which has been established among the pharmaceuticals and the generics?

Mr. MOSSINGHOFF. I don't think it should.

Mr. MAZZOLI. Thank you. Let me ask you this question. You talked—maybe I misunderstood you, you said something to the effect that the patent system has worked very well over the years and, in effect, why change it? I think you had reference to the ANDA, to the abbreviated new drug application. Am I correct or incorrect?

Mr. MOSSINGHOFF. No, what I was saying, Mr. Chairman, is that the patent system, since its very beginning, said it would be an infringement of a patent to make, use or sell a patented thing. What *Roche* v. *Bolar* said is that that is true, and it is true even though the making of the patented thing—in this case a pharmaceutical—was made to enable a generic company to do the testing they needed to become poised to hit the market. They said that the patent system prevents making, using and selling.

Mr. MAZZOLI. Right.

Mr. MOSSINGHOFF. The amendment to 35 U.S.C. 271 in the bill would retroactively change that and say that the making of a pharmaceutical simply to do tests in order to be poised to move in would not be an infringement. That would change a fundamental aspect of patent law which has been in effect since the beginning of the patent system.

Mr. MAZZOLI. Apparently as a professional, you don't think that should be done, is that the idea?

Mr. MOSSINGHOFF. That is right. I do not think that should be done.

Mr. MAZZOLI. The gentleman from Michigan.

Mr. SAWYER. Thank you, Mr. Chairman.

I am really overwhelmed by this Henry Waxman art form here. [Laughter.]

I really expect to get to one of the squares and it will say, "Go back to beginning," or "Go to jail." [Laughter.]

That 6444 in the last Congress was my bill, as you may recall. A model of simplicity, I might say. [Laughter.]

It did, in fact, pass both Houses. Unfortunately—we got on the floor so late in the last Congress in the House, we had to go on suspension, which meant that it had to pass two to one, and while it passed with a significant majority, it didn't quite equal two to one, which is very difficult to do here anyway.

I wouldn't see any objection to the 5-year compromise vis-a-vis the 7-year, since while the 7-year may have had some relationship to the impact on patent terms, the whole patent term of 17 years is kind of a gerrymandered thing anyway. The fight was whether it was a period of two apprenticeships which were 7 years each or 3, and in its wisdom, the Congress compromises between 21 and 14 and made it 17, so I don't think we are locked in by that. The 5 seems perfectly reasonable.

I also think it is very reasonable to have this abbreviated application form for the generics since there really isn't much point of their going through all this expense of testing and everything for a product that has already been through most of it, but when they get to overruling Bolar, which is knocking out, as you say, 200 years of patent theory, and more or less on a kind of off-the-cuff deal between Waxman and Engman and whoever else was involved, and I say that endearingly because Henry is a good friend of mine and Lou Engman used to be a law partner of mine, so I am kind of caught between a lot of people here, but I just think that is gratuitous and ought not to be in there.

I also am upset by the impact of some of the provisions on the presumption of validity that usually surrounds a patent and the way that a challenge can be forced during the term of the patent

where the patentee has to, in effect—or the patent holder, in effect, has to come forward and bring a litigation to establish the validity of his patent by the serving of some kind of notice. It is a very complicated thing.

Do you think that there is a possibility that these people could get back to, let's say, a 5-year maximum extension? As I recall, it is 2 years for some that are in the mill, but it is 5 years in general.

Mr. MOSSINGHOFF. Right.

Mr. SAWYER. In tradeoff for a simplification and a rapid or abbreviated patent thing for the generics so they wouldn't have to go through a lot of this at the end, do you think that just limiting it to those simple things and doing away with the art form here—do you think that would be viable?

Mr. MOSSINGHOFF. I hope so, yes, sir. I think it is. I think it should be. Again, I think that you could easily substitute the provision of your bill, H.R. 6444. I obviously didn't participate with the Subcommittee, but I am sure you included that because of the fears raised about "evergreening." Well, that is very simple, straightforward and everybody understands it.

Every patent has on it the date that the applicant claims is the earlier filing date——

Mr. SAWYER. If I can understand it, almost anybody can understand it, I assure you.

Mr. MOSSINGHOFF. If "evergreening" is a problem, that is a very simple solution which would sweep away an awful lot of the underbrush of this bill. I agree totally with you on *Roche* v. *Bolar*. I don't see why that is in here at all and it seems to me that the basic elements of the compromise still exist and could be put forth in a very straightforward manner.

Mr. SAWYER. That is one thing that kind of worries me. Henry Waxman's subcommittee—and I am not a great turf protector up here since, on my side of the aisle, we don't have much turf anyway [laughter] but, you know, it is a nonlegal and nonpatent-oriented committee and while it is fine for them to handle things like the abbreviated new drug application and all that sort of thing, it seems to me they just ran roughshod over the whole patent law in the course of drawing this bill or reaching this compromise and I hope this subcommittee is going to take a good hard look at the parts that affected patent law, but I think rather violence has been done to the patent law over in that other subcommittee.

Thank you. I yield back, Mr. Chairman.

Mr. MAZZOLI. Thank you, the gentleman's time has expired.

Will the gentleman proceed, and then we can adjourn.

Mr. DEWINE. Mr. Chairman, the second bell has rung. I appreciate the Commissioner's testimony very much. I found it very interesting and instructive and I am going to stop at that point.

Mr. MAZZOLI. All right, thank you. The subcommittee will recess for 15 minutes and will return and you gentlemen are excused. Thank you very much, we appreciate it.

[Recess.]

Mr. KASTENMEIER [presiding]. The committee will come to order.

Next, the Chair is pleased to call, and indeed, to greet Mr. Robert J. Lewis, representing the Pharmaceutical Manufacturing

Association; and also Mr. William Haddad, representing the Generic Pharmaceutical Industrry Association.

Mr. Lewis, would you care to proceed.

TESTIMONY OF ROBERT J. LEWIS, REPRESENTING THE PHARMACEUTICAL MANUFACTURING ASSOCIATION; ACCOMPANIED BY ALAN D. LOURIE, VICE PRESIDENT, CORPORATE PATENTS, SMITHKLINE BECKMAN CORP., CHAIRMAN, PATENT COMMITTEE, PHARMACEUTICAL MANUFACTURING ASSOCIATION; AND WILLIAM HADDAD, REPRESENTING THE GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION; ACCOMPANIED BY ALFRED B. ENGELBERG, PARTNER, AMSTER, ROTHSTEIN & ENGELBERG; JAMES F. FLUG, COUNSEL, LOBEL, NOVINS & LAMONT; AND EUGENE M. PFEIFER, COUNSEL, BURDITT & CALKINS

Mr. LEWIS. Thank you, Mr. Chairman.

Lewis Engman, our president, is unavoidably out of the country. He has asked me to present his testimony and to respond to any questions that you and the other subcommittee members may have.

I would also like to introduce Alan Lourie, who is patent counsel for Smithkline Beckman Corp., and who is also the chairman of the PMA Patent Committee.

Mr. Chairman, the Pharmaceutical Manufacturers Association appreciates this opportunity to testify on H.R. 3605, the Drug Price Competition and Patent Term Restoration Act of 1984.

The PMA represents the research-based pharmaceutical companies that develop and produce prescription drugs in the United States and throughout the world. PMA members develop more than 90 percent of the new chemical entity pharmaceuticals introduced in the United States each year.

PMA supports H.R. 3605, which will restore patent life lost for drugs and related products subject to lengthy Government premarket clearances and will also amend existing law to expedite the approval of generic drugs by the Food and Drug Administration.

This compromise legislation is a major step forward for the American consumer. Its provisions will increase competition, lower prices, and stimulate the development of new life-saving medicines critically needed around the world. This legislation is a compromise, however, and as is often the case with compromises, a number of PMA member companies do not support some aspects of this bill, even though they may support the underlying concepts of patent term restoration and ANDA reform.

Nonetheless, a majority of PMA's board members supports the legislation and believes the bill is a reasonable compromise which should benefit the American public.

Title I of this bill, as amended by the House Energy and Commerce Committee, was first proposed in a substantially simpler format, a one page bill, by Congressman Waxman in July of 1983. Hearings were conducted by the Subcommittee on Health and the Environment and the bill was favorably reported by that subcommittee in August 1983.

Subsequently, after lengthy and continuing discussions and negotiations lasting almost a year, among the research-based pharmaceutical industry, the generic drug industry, various interest groups and Members of Congress, the bill was amended and favorably reported by the Energy and Commerce Committee on June 12, 1984.

Title I of H.R. 3605 would make important new changes in the procedures for the approval of abbreviated new drug applications. Existing law and FDA regulations generally require applications for FDA approval of generic drugs first marketed after 1962 to be supported by their own studies demonstrating safety and effectiveness.

Under this bill, generic versions of these drugs may be approved by FDA if they are exactly the same as their pioneer counterparts without independent evidence of safety and effectiveness after all pioneer patents have expired. If a generic company intends to challenge the validity of a patent, notice must be given to the patent owner when the ANDA is submitted in order to give the parties a chance to resolve that issue through litigation.

For pioneer drugs first marketed between January 1, 1982, and the effective date of the legislation, no ANDA may be granted for 10 years from the date of approval of the pioneer product. For unpatentable drugs approved after enactment of the legislation, no ANDA may be granted for 4 years after approval of the pioneer drug.

Mr. Chairman, PMA and its member companies have very carefully reviewed title I of this legislation. Like title II, the ANDA portion is a product of compromise. As such, it is a balance of conflicting priorities. We believe that when considered in light of the salutory provisions in title II, it is a fair balance worthy of your favorable consideration.

Title II, as you know, Mr. Chairman, had it origins in legislation which you supported in the last Congress. Although that legislation was narrowly defeated under suspension of the rules on the House floor in September 1982, it was supported by 250 members. It also passed the Senate by a voice vote in 1981.

Although title II of H.R. 3605 is different in several respects from its predecessor bills in the last Congress, the essential purpose of the legislation remains the same: to encourage medical innovation by restoring a portion of that part of a drug patent's life lost through the lengthy drug approval process.

H.R. 3605 provides that the term of a patent for drug products and certain other products subject to premarketing approval by FDA may be restored for up to 5 years to reflect the time required to do the necessary testing and to obtain FDA approval. For drugs, the amount of time that can be restored equals half the investigational, or IND period, plus all of the approval, or NDA period, less any time during which the applicant does not pursue FDA approval with due diligence.

The maximum amount of time that can be restored is 5 years and may not result in an effective patent life of more than 14 years. Restoration is not available for certain patents which come within one of several specific exclusions.

For drugs which have begun clinical testing and which have received a patent prior to the date of enactment but have not yet received FDA approval, up to 2 years of restoration is permitted.

The cause of the loss of patent life for pharmaceuticals is simply explained. When a firm discovers a promising new drug compound, it patents it immediately or risks losing the new technology to a competitor. Generally, a patent is issued within 2 or 3 years of patent filing, and the 17 years of protection begins immediately to expire.

But the patent clock begins ticking long before a new product is ready for production and distribution. In fact, at the time its patent issues, a new drug compound is, on average, 7 to 10 years away from the marketplace, 7 to 10 years that are needed to satisfy important statutory requirements for safety and efficacy administered by the FDA.

Although Congress never intended it, the time consumed in meeting these FDA requirements is, in effect, subtracted from the patent lives of drugs. The pharmaceutical innovator's new product typically enters the market with less than 10 of the 17 years of patent protection provided by statute, and therefore, with only a fraction of the related investment incentives provided innovators in other industries. This is neither fair nor good public policy.

It is the American consumer who is the real loser in all this. Government policies that discourage drug research postpone the consumer's access to new medicines; they deprive him of the savings new medicines make possible by making unnecessary more costly forms of treatment, such as hospitalization and surgery; and they oblige him to forego the benefits of the competition that occur when innovation is thriving. These consequences need not occur.

Title II of the bill, by restoring to new drug products up to 5 of the 7 to 10 years currently subtracted from their average patent life will 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.

Mr. Chairman, as I mentioned at the beginning of my statement, H.R. 3605 is a compromise. As such, title II includes provisions about which PMA has had some reservations. The effects of these provisions were weighed very carefully by each of our companies. But while they cause concern, we recognize that they are the very fabric of the compromise of divided views and goals.

PMA and a majority of its members recognize this and support title II as it stands.

In conclusion, the PMA supports enactment of H.R. 3605. The bill provides needed patent incentives for new drug research and creates a workable system for approving duplicate versions of pioneer products.

We believe that H.R. 3605 is a long-overdue legislative measure which will promote competition, encourage research, and provide American consumers earlier access to better medicines at lower cost.

Finally, Mr. Chairman, we request the opportunity to provide for the record comments on the other legislative issues that are the subject of today's hearing.

Thank you.
[The statement of Mr. Engman follows:]

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

Mr. Chairman, the Pharmaceutical Manufacturers Association appreciates the opportunity to testify on H.R. 3605, the "Drug Price Competition and Patent Term Restoration Act of 1984." The Pharmaceutical Manufacturers Association represents the research-based pharmaceutical companies that develop and produce prescription drugs in the United Sates and throughout the world. PMA members develop more than 90 percent of the new chemical entity pharmaceuticals introduced in the United States each year.

PMA supports H.R. 3605, which will restore patent life lost for drugs and related products subject to lengthy, government pre-market clearances, and will also amend existing law to expedite the approval of generic drugs by the Food and Drug Administration. This compromise legislation is a major step forward for the American consumer. Its provisions will increase competition, lower prices and stimulate the developoment of new life-saving medicines critically needed around the world.

This legislation is a compromise, however, and as is often the case with compromises, a number of PMA member companies do not support some aspects of this bill even though they may support the underlying concepts of patent term restoration and ANDA reform. Nonetheless, a majority of PMA's Board members supports the legislation and believes the bill is a reasonable compromise which should benefit the American public.

TITLE I—ABBREVIATED NEW DRUG APPLICATIONS

This title, as amended by the House Energy and Commerce Committee, was first proposed in a substantially simpler format by Congressman Waxman in July, 1983. Hearings were conducted by the Subcommittee on Health and the Environment and the bill was favorably reported by that subcommittee in August, 1983. Subsequently, after lengthy and continuing discussions and negotiations among the research-based pharmaceutical industry, the generic drug industry, various interest groups and Members of Congress, the bill was amended and favorably reported by the Energy and Commerce Committee June 12, 1984.

Title I of H.R. 3605 would make important new changes in the procedures for the approval of abbreviated new drug applications (ANDAs).

Existing law and FDA regulations generally require applications for FDA approval of generic drugs first marketed after 1962 to be supported by their own studies demonstrating safety and effectiveness. Under H.R. 3605, generic versions of these drugs may be approved by FDA if they are exactly "the same" without independent evidence of safety and effectiveness after all pioneer patents have expired. If a generic company intends to challenge the validity of a patent, notice must be given to the patent owner when the ANDA is submitted in order to give the parties a chance to resolve the issue through litigation. For pioneer drugs first marketed between January 1, 1982 and the effective date off the legislation, no ANDA may be granted for 10 years from the date of approval of the pioneer product. For unpatentable drugs approved after enactment of the legislation, no ANDA may be granted for four years after approval of the pioneer drug.

Mr. Chairman, PMA and its member companies have very carefully reviewed Title I of this legislation. Like Title II, the ANDA portion is a product of compromise. As such, it is a balance of conflicting priorities. We believe that when considered in light of the salutory provisions of Title II, it is a fair balance worthy of your favorable consideration.

TITLE II—PATENT TERM RESTORATION

Mr. Chairman, this title had its origins in legislation which you supported in the 97th Congress, H.R. 6444. Although that legislation was narrowly defeated under the suspension of rules on the House floor in September, 1982, it was supported by 250 Members and passed the Senate by a voice vote in 1981.

Although Title II of H.R. 3605 is different in several respects from its predecessor bill in the last Congress, the essential purpose of the legislation remains the same—to encourage medical innovation by restoring a portion of that part of a drug patent's life lost through the lengthy drug approval process.

H.R. 3605 provides that the term of a patent for drug products and certain other products subject to pre-marketing approval by FDA may be restored for up to five

years to reflect the time required to do the necessary testing and obtain FDA approval. For drugs, the amount of time that can be restored equals half the investigational (IND) period plus all of the approval (NDA) period, less any time during which the applicant does not pursue FDA approval with due diligence. The maximum amount of time that can be restored is five years, and may not result in an effective patent life of more than 14 years. Restoration is not available for certain patents which come within one of several specific exclusions.

For drugs which have begun clinical testing and which have received a patent prior to the date of enactment, but have not yet received FDA approval, up to two years of restoration is permitted.

The cause of the loss of patent life pharmaceuticals is simply explained. When a firm discovers a promising new drug compound, it patents it immediately or risks losing the new technology to a competitor. Generally, a patent is issued within two or three years of patent filing, and the 17 years of protection begins immediately to expire. But the patent clock begins ticking long before a new product is ready for production and distribution. In fact, at the time its patent issues, a new drug compound is, on average, 7 to 10 years away from the marketplace—7 to 10 years that are needed to satisfy important statutory requirements for safety and efficacy administered by the Food and Drug Administration.

Although Congress never intended it, the time consumed in meeting these FDA requirements is, in effect, substracted from the patent lives of drugs. The pharmaceutical innovator's new product typically enters the market with less than 10 of the 17 years of patent protection provided by statute and, therefore, with only a fraction of the related investment incentives provided innovators in other industries. This is neither fair nor good public policy.

It is the American consumer who is the real loser in all this. Government policies that discourage drug research postpone the consumer's access to new medicines, deprive him of the savings new medicines make possible by making unnecessary, more costly forms of treatment such as hospitalization and surgery, and oblige him to forego the benefits of the competition that occur when innovation is thriving.

These consequences need not occur. Title II of the bill, by restoring to new drug products up to five of the 7 to 10 years currently substracted from their average patent life, will reverse the decline in research inventives, 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.

Mr. Chairman, as I mentioned at the beginning of my statement, H.R. 3605 is a compromise. As such, Title II includes provisions about which PMA has had some reservations. The effects of these provisions were weighed very carefully by each of our companies. But while they cause concern, we recognize that they are the very fabric of the compromise of divided views and goals. PMA and a majority of its members recognize this and support Title II as it stands.

CONCLUSION

The Pharmaceutical Manufacturers Association supports enactment of H.R. 3605. The bill provides needed patent incentives for new drug research and creates a workable system for approving duplicate versions of pioneer products. We believe that H.R. 3605 is a long overdue legislative measure which will promote competition, encourage research and provide Amercian consumers earlier access to better medicines at lower cost.

Finally, Mr. Chairman, we request the opportunity to provide, for the record, comments on several of the other legislative issues that are the subject of today's hearing.

Mr. KASTENMEIER. Thank you, Mr. Lewis, for your statement and that of your president, Mr. Lewis Engman. And indeed, without objection, we will be pleased to receive your further comments on issues which are subject of today's hearing.

I compliment you on the brevity, conciseness of your statement, the coherence of it, and I am sure we will have some questions for you, however.

But at this point, I would like to call on Mr. William Haddad for his statement.

Mr. Haddad.

Mr. HADDAD. Thank you.

Before I begin my statement, I would like to applaud the chairman for his diligence, patience, and courtesy during these long, controversial discussions in hearings beginning several years ago. He was particularly generous with his time when we were on the other side of this issue and I appreciate the opportunity to appear here today.

Also, many, if not a majority of the members of this subcommittee, advised me in private when I was walking the halls, to seek a compromise with the PMA, to see if we can find—and I believe maybe the chairman gave me some of that sound advice as well—find some method of bringing together the forces.

Third, I would like to, at the outset, clarify an impression that seems to be developing here somewhat in the colloquy of colleagues and the good spirits that this committee likes to treat some of these issues to take the stiffness out of them. This is not a compromise between Lou Engman of the PMA and Bill Haddad of the GPIA.

GPIA was part of what I considered a public interest coalition of seniors, elderly, and consumers. Other people might have not viewed it that way.

Second, this was not our legislation. It was decided upon by independent Members of Congress, and if I heard it once, I heard it 25 times, "Mr. Haddad, that is not in the public interest, and therefore, will not be part of this legislation."

I will address some of Mr. Mossinghoff's comments as we go through——

Mr. KASTENMEIER. May I just inquire. You are talking about other interests or Members of Congress——

Mr. HADDAD. There are a number of issues that I strongly object to in this legislation, where I would have had a different point of view, and that point of view was considered not in the public interest by the people who drafted this legislation. This was drafted by Members of Congress working by themselves and resolving conflicting issues in issues at the hearing in the Jeffersonian way the various interests, and I gather in that context I am a special interest.

Mr. KASTENMEIER. In another committee.

Mr. HADDAD. In another committee, you are absolutely right, and I appreciate the jurisdiction of this committee, having been raised on the Hill.

I will address Mr. Mossinghoff's interpretations of the bill as we go along and I will submit for the record some longer answers. I don't think he has the familiarity with the legislation that might have been expected from someone who participated so intimately in its development.

My name is——

Mr. KASTENMEIER. May I interrupt at this point. I think it might be useful. There are so many present this morning. This is a very important subject, but you will note that there are interruptions and Members coming and going and not necessarily because of votes on the floor.

At this time today—I just say this parenthetically for the audience—the bankruptcy conference report is before us because this is the last day of the authority to operate the bankruptcy courts and

many members of this subcommittee are involved in the process. So that is why we are getting some subsidiary interruptions.

Important as this issue is, that is also a very important issue and so that is one of the reasons you will observe some of the comings and goings of the subcommittee this morning.

Mr. HADDAD. The analogy is well taken, too, because it is the last day of the bankruptcy legislation and it is the last hour to move this legislation through Congress.

My name is William F. Haddad. As you know, I am president of the Generic Pharmaceutical Industry Association. Our members manufacture approximately 85 percent of the low-priced generic drugs produced in America. Generic drugs are approved by the Food and Drug Administration as therapeutically equivalent to the higher priced brand name counterparts.

However, our industry only sells 20 percent of all generic drugs. Eighty percent are sold by the brand name companies: Lilly, Pfizer, Warner Lambert, SKF, American Cyanamid. GPIA members, however, manufacture generic drugs which are later sold by the brand name companies.

Our production-intensive membership tends to be closer to state of art manufacturing than research-intensive companies. The board of directors of GPIA supports H.R. 3605, which combines the abbreviated new drug application and drug extension legislation into the Drug Price Competition and Patent Restoration Act of 1984.

We believe the Congress, in its wisdom, has fashioned a delicately balanced, pragmatic workable and equitable compromise in the public interest. As a result, the size of the generic market will double; the prices of off-patent drugs will quickly be cut in half; as competition increases, some prices will drop to a fifth or a tenth of the current prices without any reduction in FDA's safety and effectiveness requirements and standards.

These are not insignificant consequences for the average American family. There is no third-party subsidy for about 80 percent of the prescriptions filled in this country. For the chronically ill, the elderly, and for families with children, the cost of medicine accounts for a sizable portion of their budget. I have previously supplied this subcommittee with unsolicited correspondence from elderly Americans who are forced to make triage decisions at the end of month: Do you buy food or medicine? Many stretch their drug doses or stop taking them.

Your approval of this legislation will make that choice unnecessary for many elderly Americans I will provide for the record, because of the time constraints, the date and information to support that conclusion. Today are a number of drugs that are off patent and available for competition yet are being sold as single source drugs at extraordinary high prices to individuals who are chronically ill, and to the elderly will be hard pressed to pay for them, unless the Congress in its wisdom, approves this legislation and permits competition for drugs which are now off patent.

SINGLE-SOURCE OFF-PATENT DRUGS

Therapeutic category	Drug product	982 sales	Patent exipration date
Diuretic	Dyazide	$176,847,000	1980.
Antiarthritic	Indocin [1]	87,841,000	December 15, 1981.
Antianxiety	Ativan	54,942,000	January 3, 1984.
Diabetes	Tolinase	49,225,000	November 13, 1979.
Insomnia	Dalmane	48,387,000	January 17, 1984.
Antibiotic	Keflin	43,101,000	November 11, 1982.
Cardiac	Norpace	38,130,000	December 21, 1982.
Antibiotic	Minocin	33,231,000	December 23, 1982.
Anti-Seizure	Tegretol	30,073,000	August 9, 1977.
Dermatitis	Lidex	24,218,000	March 24, 1981.
Gastrointestinal	Reglan	22,270,000	November 23, 1982.
Anti-Psychotic	Navane	21,832,000	March 21, 1984.
Infertility	Danocrine	21,451,000	June 24, 1981.
Antiarthritic	Meclomen	20,544,000	April 11, 1984.
Antianxiety	Serax	19,114,000	January 3, 1984.
Anticancer	Oncovin	15,889,000	September 7, 1982.
Infertility	Clomid	12,927,000	November 24, 1976.
Insomnia	Restoril	11,723,000	January 3, 1984.
Cholesterol reducer	Atromid S	11,589,000	July 26, 1983.
Total 1982 sales		743,334,000	

[1] 1st generic approved March 20, 1984.

Mr. HADDAD. But having said all of that, let me emphasize that this legislation is delicately balanced; it is a compromise of sharply conflicting views; it is finely tuned and can be easily upended if the door is opened to amendments to benefit special interests.

The dissident companies that now seek to rewrite this legislation were, at the highest levels of their corporations, involved in suggesting and implementing changes in their self interests which were accommodated by the PMA and are already included in this legislation. We disagree with some of those changes, but it was decided by the drafters of this legislation that the best interests of the public were served by their inclusion.

When the process was completed, the board of directors of the PMA decided, by a two-to-one margin, to reject the very points of view you are now hearing from the dissident companies. Their vote, of course, did not relieve this subcommittee of its responsibility to make its own independent determination of what is in the public interest.

But I am confident that the subcommittee will place heavy weight on the opinions, not only of the organizations involved, but

on the seniors, labor, and other citizen groups that have joined with us.

I must say, in all candor, that deep in my soul, I believe we are giving the brand name companies something they do not deserve in return for something I believe is our right under existing law. We continue to believe the Congress, this committee, as well as the PMA, were misled, misled by an alleged scientific study produced at an institute at the University of Rochester Medical School which improperly and inaccurately concluded patent drug life had been cut in half by Government regulation.

We have produced unrefuted and now independently verified data that reveals actual average exclusive market life to the 100 most widely used drugs is from 16 to 18.5 years. The New York Times supported Mr. Sawyer's legislation, as did the Washington Post, as did many Members of Congress. But as the information about patent life was revealed, the New York Times, the Washington Post, and others changed their viewpoint.

But in the last Congress, we were not able to convince this subcommittee to accept the implications of this data. We did, however, receive genuine expressions of concern from the members of this subcommittee, and particularly its chairman, about the catch-22 that permits the continued monopoly of off-patent drugs because the FDA has failed to develop a viable procedure for approving drugs which entered the market after 1962—the so-called post-1962 drugs.

Unfortunately, the solution to this serious impediment to competition was not within the scope of the previous legislation. The congressional resolution of this issue is vital to our industry. For drugs which entered the market prior to 1962, the FDA has an equitable and predictable procedure for approving generic drugs and assuring their safety and effectiveness.

The Good Manufacturing Practice standard is uniform for all companies manufacturing drugs. Over 3,000 drugs have been approved using the ANDA process. FDA says there are no problems in this procedure or that will develop as a result of using this procedure.

Millions of Americans every day use generics cleared by the pre-1962 procedure. For reasons which I regard as political and not scientific, the same procedure is not used for drugs entering the market after 1962. The post-1962 drugs, when they entered the market, were proved not only safe, but effective.

The safety and effectiveness of those drugs has been thoroughly confirmed by the marketplace. Several years ago, we won the right to have a procedure to approve post-1962 drugs. The Paper NDA was, at best, a Mickey Mouse procedure that has virtually excluded most post-1962 drugs from the marketplace.

I am sure PMA will tell you what this compromise means to them, and you have heard Mr. Lewis' statement, but we view this compromise as providing up to 5 years of extended patent life to take account of their complaints of delays in the approval process and certain protections to assure their fears of frivolous patent challenges.

Under this legislation, the consumer gets almost immediate access to lower priced off-patent generics. The consumer also bene-

fits from the promise of the research-intensive companies to invest their increased profits resulting from extended patent life in research that could lead to new or better cures for disease.

Finally, I heard the arguments made by the CEO's of the dissident companies; I have read their briefing documents; and I have seen the briefs prepared by their lawyers. With all due respect, their arguments are disingenuous at best and deliberately deceptive at worst.

They remind me of the wolf in "Little Red Riding Hood" who disguised as the benevolent grandmother, uses a falsetto voice in an effort to convince the innocent victim of his good intentions. I am not going to eat your legislation; I only want to amend it.

As I have noted earlier, the PMA heard that voice, but kept the door closed to the dissidents' amendments because these amendments would have destroyed dual purposes of this legislation. In cognizance of their proposed amendments, let me see if I can briefly outline what we see this legislation as achieving and what it does not do.

First, the legislation does not place an administrative burden on either the Patent Office or the FDA. Some of you sit on the Budget Committee. I looked at The Missinghoff chart—I used to make my living making charts like this when I was in Government and in business. The process is called a preemptive strike: This is a chart that GS–13 bureaucrat prepared for OMB at the start of budget negotiations.

Second [laughter] I could make a similar presentation charting the decisions you have to make coming to the Congress in the morning, and charts like that have been made by psychologists and system analysts and by children's computers.

Second, there is a clause on page 41 of the legislation which satisfied and addressed and answered Mr. Mossinghoff's complaints. It is (e)(1) on page 41 at the top: "A determination that a patent is eligible for extension may be made by the Commissioner solely," Mr. Sawyer, "solely on the basis of the information contained in the application for extension."

We happen to favor Mr. Kastenmeier's and your cap of 27, which would now be 25 years, but it would never survive a compromise.

Two, the legislation does not change the FDA standards of safety and effectiveness. As I have said, over 3,000 drugs have been approved. The Members of Congress, the military forces, private and public hospitals use generics every day.

This legislation does not encourage patent infringement. In fact, existing patent enforcement procedures are altered to provide PMA companies with advantages available to no other class of patent holders.

GPIA would favor the law as it now is. When we challenge a patent today, we take our chances within the legal system, where, as you know, the penalties can be Draconian. If we infringe a patent, we may be required to pay, not the profit that we might make, but the profit that they might have made if they had sold our product. The profits are so enormous they could require a company to divest itself of all its assets.

I might note that if the company challenging the invalid patent is proven correct, there is no compensating penalty against the patent holder.

This legislation does provide up to 5 years of patent extension, but limits extensions to prevent abuses. This legislation does not deprive any patent holder of the profit from a single day during the life of a valid patent. I repeat, this legislation does not deprive any patent owner of the profit from a single day during the life of a valid patent, despite the attempt to claim that the bill in some mysterious way deprives patent owners of constitutional property rights.

In the negotiations before Bolar was decided, we agreed to the provisions of testing a drug prior to its patent ending and making provisions that no one would go in the marketplace prior to the expiration of a patent. That was agreed to very early on and it was part of a very complex give and take.

In summary, while each of us maintains our separate identities and conflicting preferences, I am sure we will be before the Congress again as adversaries. This is one time, however, when our particular and the public interest converge. The Congress is to be applauded for leading the blind horses to this cool water.

I am accompanied by Al Engelberg, who has been patent counsel to us during this discussion; Jim Flug, who has worked on the legislation with us; and Gene Pfeifer, who brings to our organization his experience at FDA. We are prepared to answer any of the questions that might have come up during my testimony or before it.

Thank you.

[The statement of Mr. Haddad follows:]

STATEMENT OF WILLIAM F. HADDAD

My name is William F. Haddad. I am President and Chief Executive Officer of the Generic Pharmaceutical Industry Association. Our members manufacture and sell approximately 85% of this country's low priced generic drugs. Generic drugs are approved by the Food and Drug Administration as therapeutically equivalent to the higher priced brand name counterparts. However, our industry supplies only 20% of all generic drugs. Eighty percent are sold at higher prices than ours by brand name companies . . . Lilly . . . Pfizer . . . Warner Lambert . . . SKF . . . American Cyamamid. GPIA members, however, actually manufacture many of those drugs for the brand names companies. Our production-intensive membership tends to be closer to state-of-the-art manufacturing than research intensive companies.

The GPIA Board of Directors supports the combined abbreviated new drug application and drug patent extension legislation known as the Drug Price Competition Act of 1984. We believe the Congress has fashioned a delicately balanced, pragmatic, workable and equitable compromise in the public interest. As a result, the size of the generic market will double and the prices of off-patent drugs will quickly be cut in half; as competition increases, some prices will drop to one-tenth of their current prices without any reduction in FDA's safety and effectiveness standards. These are not insignificant consequences for the average American family. There is no third-party subsidy for 80% of the prescriptions filled in this country. For the chronically ill, the elderly and for families with children, the cost of medicine accounts for a sizeable portion of their budget. I have previously provided this committee with unsolicited correspondence from elderly Americans who were forced to make triage decisions at the end of each month. Do they buy food or medicine? Many stretch out their drug dosages or stop taking them. Your approval of this proposed legislation will make that choice unnecessary for many elderly Americans.

But—having said that—let me again emphasize this is a delicately balanced compromise of conflicting views. It is finely tuned and can be easily upended if the door is opened to self-serving amendments to benefit narrow special interests. Many problems and concerns were resolved during lengthy discussions on the precise con-

tents of the bill. The companies who believe they are not bound by the PMA decision were privy to all those discussions and energetically and successfully argued their viewpoints, causing many alterations of the legislation in ways which disappointed us. Deep in our soul, we believe we are giving the brand name companies *something* they do not deserve in return for *something* which we *think is* our right under existing law. But we are realistic enough to recognize that this Congress might not entirely adopt our position. We continue to believe the Congress and the PMA were misled by an alleged scientific study produced at an Institute at the University of Rochester's Medical School which improperly and inaccurately concluded drug patent life had been cut in half by government regulation. We have produced unrefuted data to this subcommittee that reveals actual exclusive market life ranges from 16 to 18.5 years. In the last Congress, we were unable to convince this Committee to accept the implications of this data. We did, however, receive expressions of genuine concern from this subcommittee and its Chairman about the Catch-22 which permits the continued monopoly of off-patent drugs because the FDA has failed to develop a viable procedure for approving drugs which entered the market after 1962—the so called post-1962 drugs. Unfortunately the solution to this serious impediment to competition was not within the scope of the previous legislation.

The Congressional resolution of this issue is vital to our industry. For drugs which entered the market prior to 1962, the FDA has an equitable and predictable procedure for approving generic drugs and ensuring their safety and efficiency. The requirements extend to the manufacturing of the drug itself. That Good Manufacturing Practices standard is uniform for all drug companies. Over 3000 drugs have been approved using this Abbreviated New Drug Application (ANDA) process. FDA reports there have been no problems with this procedure. Millions of Americans each day use generic drugs cleared by the pre-1962 process.

But for reasons which I call political and not scientific, the same procedure is not used to approve drugs entering the market after 1962. These post-1962 drugs, when they entered the market, were approved as not only safe but effective. The safety and effectiveness of these drugs have been thoroughly confirmed in the market by the time they become candidates for competition. Several years ago we won the right in the courts to have generic versions of off-patent, post-1962 drugs approved by proving their equivalence and providing the published literature to the FDA. This "paper NDA" was, at best, a "Mickey Mouse" procedure that has virtually excluded most post-1962 drugs from being approved, resulting in perpetual monopolies for off-patent drugs, and higher prices for consumers and the government. The new compromise legislation wipes out that bureaucratic distinction between pre and post 1962 drugs and assures that as soon as a drug patent expires, the generic equivalent will be approved and marketed promptly.

I am sure PMA will tell you what this compromise means to them, but we view it as providing them up to five years of extended patent life to take account of their complaints of delays in their approval process; special non-prospectivity provisions for drugs now in the pipeline and for drugs entering the market from 1982 until enactment; and certain protections to prevent frivolous patent challenges. Under this legislation the consumer gets almost immediate access to lower priced generic and branded generic drugs. The consumer also benefits from the promise of the research intensive companies to invest their increased profits resulting from extended patent life in research that could lead to new or better cures for disease.

In summary, while each of us maintains our separate identities and conflicting preferences—I am sure we will be before Congress again as adversaries—this is one time our particular interests and the public interest converge, and the Congress is to be applauded for leading the blind horses to this cool water.

Mr. KASTENMEIER. Thank you, Mr. Haddad.

I have several questions. Mr. Lewis, how would you describe the position briefly of the so-called dissident companies who will testify later? I know that may be difficult for you, but the point I am getting at is that I would like a sort of an analysis by you of what their position—of how you understand their position.

Mr. LEWIS. OK, Mr. Chairman, as you know, there are several of them in the room and they will be testifying after me——

Mr. KASTENMEIER. Of course.

Mr. LEWIS [continuing]. And obviously, they will speak for themselves.

This is——

Mr. SYNAR. I would just like to explore that, too. I want a characterization—not necessarily what they are going to say—I would like a characterization, too.

Mr. KASTENMEIER. That is right, and the purpose is to have the point of view commented on from more than a single source.

Mr. LEWIS. PMA, as we have demonstrated before, is not a monolithic entity. We are composed of 130 companies, if you included subsidiaries and other related groups, and I cannot recall any issue of importance that was controversial in the Congress when all of our members have agreed across the board.

Our policy has always been that companies, when they disagree with the PMA majority, are free to go their own way, to speak their mind, and to represent their companies as they see their own interests, and that is what I believe has happened in this case.

Mr. KASTENMEIER. Well, is it your—you are saying that their own interests, differentiated from other PMA members, indicate financially or otherwise that they ought not support this legislation?

Mr. LEWIS. I think each company, when it decided how to take its position on this bill, was looking at a whole spectrum of things, including its perception of the public interest, including its perception of what was doable in this Congress, various political considerations, as well as its obligations to its stockholders. I think it would be impossible for me to try to characterize why any one individual company would reach any particular conclusion.

Mr. KASTENMEIER. All right. You wouldn't say that—and I am not at all sure of this, but I am just asking whether this tends to represent a number of companies who have major drugs in terms of market income—have tremendous impact on the market that may have their patent expiring in the near future and would, if any accelerated attempt by generics to get a hold of these drugs represent a very serious encroachment into their market? You would not say that that would be the case with some or all of the——

Mr. LEWIS. Mr. Chairman, I see companies on both sides of this issue that have important drugs which, should this pass, would be vulnerable nearly immediately to generic competition. I see companies on both sides that are research-intensive and have drugs in the pipeline that would benefit from title II.

Mr. KASTENMEIER. Thank you.

Mr. Haddad, I was trying to understand your comment earlier to the extent that some of the views may have been imposed by the committee, but you say, nonetheless, you support this bill——

Mr. HADDAD. Yes, we do.

Mr. KASTENMEIER [continuing]. But you would say also—you would have to say also that some of it, or some of the provisions within it were—seem to have been imposed from within the committee on the parties, is that——

Mr. HADDAD. Let me characterize it this way. It is a delicately balanced compromise of conflicting interests. You know how I feel about patent extension. You have had the patience to listen to me many times. But Congress doesn't agree with me.

I think I am right; you think I am wrong, and now we have worked out a compromise that we can live with. I am sure Mr. Synar doesn't agree with my viewpoint on that, either, but it is a

compromise we can live with because it has protections; it has procedures; it has predictability; it provides rewards and benefits to our industry and the consumers, and it answers some of the PMA criticisms of the system.

I like the 14-year cap. That is a safeguard for us. I don't like some of the due diligence, procedures. This is a compromise.

Incidentally, Mr. Kastenmeier, attached to my testimony are examples of single-source off-patent drugs which are not being approved because of the lack of process. The first is one used in high blood pressure. It is Dyazide and annual sales are almost $177 million. That list will give you an example of the kinds of drugs that have been off patent for which no competition has been permitted.

Some of those go back to 1976 and 1977.

Mr. KASTENMEIER. Without objection, that statement will be——

Mr. HADDAD. And I also did include the price increases on some of those drugs because, as you know, without competition, there is no real control of prices and I included the Washington Post and the New York Times editorial and an explanation by Business Week, headed "A Drug Compromise that Benefits Everyone."

[The New York Times article follows:]

[From the New York Times, June 25, 1984]

HOW MUCH HAVEN FOR DRUG PIONEERS?

A long and stormy battle between rival groups of pharmaceutical manufacturers is near resolution in an important bill designed by Representative Henry Waxman of California. Despite objections by a break-away faction of large drug houses, the Waxman bill is just compromise that will foster invention of new drugs and lower the price of older drugs coming off patent.

The struggle pits companies that develop their own drugs against makers of "generics," drugs that are chemically identical to the original and marketable after its patent has expired. Generics end the monopoly position of the patent-holder and force down high drug prices. That's greatly in the public interest. But so is insuring profit incentives for manufacturers to invest in the research and development of new drugs.

Generic drugs have eaten into the sales of off-patent brand-name drugs, and the Pharmaceutical Manufacturers Association has advocated longer patent terms for drugs to compensate for the time consumed by Government review. Patent term "restoration" of up to seven years is needed, the association contends. Otherwise, there's not enough incentive for costly research; fewer drugs would be invented and medical costs would rise.

Congress almost passed such a seven-year bill in 1982 but balked at the last minute. It has also resisted bills to let generic drugs onto the market as soon as the originals go off patent.

From this impasse, Mr. Waxman has created a compromise serving both interests. The new-drug companies will be compensated for up to five years in patent life lost in the approval process. The generic drug makers will get faster and simpler Government review for the class of drugs now coming off patent. Both the P.M.A. and the Generic Pharmaceutical Industry Association have agreed to the deal, which is also supported by Mr. Waxman's Senate counterpart, Orrin Hatch.

A dissenting group of 10 of 32 P.M.A. companies opposes the deal; they apparently stand to profit if the bill is delayed or dies. Each has important drugs coming off patent soon. Hoffman-La Roche's tranquilizer Valium, for example, with 1983 sales of $250 million, comes off patent in 1985. The patent of American Homes Products' heart drug Inderal, with sales of $300 million, expires this year. As long as the generic equivalents are denied speedy review, these drugs will enjoy an exclusive market.

The Waxman bill is eminently fair to the drug companies' interests. The association contends the effective patent life of drugs has fallen to less than 7 years. Mr. Waxman's staff estimates from P.M.A. data that top selling drugs average more than 14 years of patent life, although the overall average is lower because it includes small-volume drugs that the companies don't rush to market.

A 14-year patent life for drugs compares favorably with that enjoyed by other kinds of inventions, which also face obstacles on the way to market. Mr. Waxman's bill restores lost patent time up to a total of 14 years. As most of the pioneer drug companies agree, that's ample incentive to invent new drugs.

Mr. KASTENMEIER. The next question I have: Without title I—now, let's assume title I was not part of this bill, Mr. Haddad, I would ask you to very briefly, if possible, compare H.R. 6444 with title II in terms of consumer or other interests.

Mr. HADDAD. Some of the experts here might do it. I think the—contrary to Mr. Sawyer's 10- and 50-page—or whoever, Mr. Moorhead's 10- and 50-page legislation, I think this tightens up some of the characterization of a——

Mr. SAWYER. Would the gentleman please repeat what he said? I had kind of turned off on you a little bit ago——

Mr. HADDAD. I know——

Mr. SAWYER [continuing]. But now I heard my name.

Mr. HADDAD. I realize that. [Laughter.]

Mr. Sawyer, I believe, when I discussed this issue with you over the years, you were turned off to my arguments about patent extension.

Mr. SAWYER. I tried not to be.

Mr. HADDAD. I know that. I appreciate your partnership with Mr. Engman as well as your interest in the ANDA arguments. I realize all of these accesses to information.

Mr. Moorhead, I believe, characterized the 10-page simplified bill and the 50-page complex bill that has now been drafted. There are a number of issues that came up during the discussion of patent extension which now seem to be clarified by this legislation, but title II alone would not be acceptable to us.

Mr. KASTENMEIER. Of course it wouldn't be acceptable. I understand that in terms of your position. I was asking you——

Mr. HADDAD. I like your cap.

Mr. KASTENMEIER [continuing]. Taking title II alone——

Mr. HADDAD. Right.

Mr. KASTENMEIER [continuing]. Versus H.R. 6444, how do you come out?

Mr. HADDAD. I think it is tightly drafted, more tightly drafted in terms of our interests and I think that it closes up some fears that may have not been more than just fears on our part about what the legislation could do. There is a difference, for example, in the cap; there is a difference in 7 and 5 years; there is a difference in the procedures; there is a difference in something that is very important to you, prospectivity, which you and I have discussed. This has the 14-year cap; it has that one period of 1982 to enactment; it has 2 years in the pipeline. It has a number of different provisions, but it does provide in the view of the PMA board an acceptable substitution for some of those points.

I think Mr. Engelberg has some comment.

Mr. KASTENMEIER. Very briefly. I have a couple of members here who are going to have to——

Mr. ENGELBERG. Very briefly, Mr. Kastenmeier, last fall, when the data was finally released, which Congressman Synar had asked for, and we first got a chance to explore the impact of subsequent-use patents on the question of what really constitutes effective

commercial life, we were put in a position where in discussing how effective patent life would be measured in this bill with respect to H.R. 6444 and the earlier bills, that extension was really only required or perhaps even necessary based on that data for patents covering new drugs which had never been marketed before for any drug use and this bill basically is based on a simple principle that says that the first patent covering the approved product can be extended once, and then defines what that means in a number of carefully drafted rules.

The earlier versions of the bill in the earlier Congresses would have permitted multiple extensions of the same patent and would have permitted the claims of a patent to be construed in a way which would cover much more than any delay caused by a regulatory review. So that really is the fundamental difference.

Mr. KASTENMEIER. Just to understand one statement you made, Mr. Haddad. You said that you produced data that revealed actual exclusive market life ranges from 16 to 18.5 years. I am just curious why the market life was so long.

Is this because of the "evergreening" effect or is it because of the difficulty in generics coming in to compete with these drugs—that is to say, the loss of time in picking up——

Mr. HADDAD. It is both, but it is disproportionate. A lot of it has to do with so-called evergreening, which is a word the PMA doesn't like, but what it does is extend exclusive market life by using the process patent and use patent.

For example, the last major drug to come off patent was Melaril which had an exclusive market life of 26 years. Valium, when it comes off next year, will have 22 years. It is also—that list that I just submitted to the committee indicates that the process that FDA now uses is keeping us off the market, which adds time to exclusive market life.

Mr. KASTENMEIER. Thank you.

Let me yield to the gentleman from——

Mr. SYNAR. Mr. Chairman, we are going to have to come back.

Mr. GLICKMAN. I would just take one question that would just take 1 second.

Mr. KASTENMEIER. The gentleman from Kansas.

Mr. GLICKMAN. Thank you very much.

I just would ask—you know, I am the sponsor, along with Mr. DeWine, of the animal side of this picture, the agricultural and chemical side of this picture. Mr. Lewis, did anyone representing the Animal Health Institute or the animal drug industry participate in your negotiations with Congressman Waxman on the content of H.R. 3605?

Mr. LEWIS. Congressman, it is my understanding—and I may have some of the particulars amiss—that all of the industries that have been involved in our bill and in your bill were involved in that process to a greater or lesser extent.

Mr. GLICKMAN. You can't tell me if the animal drug provisions were specifically assessed and discussed or whether they were included as an adjunct to the human drug provisions right now.

Mr. LEWIS. I would be surprised if they had not been specifically discussed. I know that Congressman Waxman's principal concern was with human drugs and that is where most of that focus was.

Mr. GLICKMAN. OK. Well, my understanding is that they were not and I think it is just useful information.

Thank you, Mr. Chairman.

Mr. KASTENMEIER. The gentleman from Michigan.

Mr. SAWYER. I think a picture here is worth 1,000 words, so I don't think I need to ask any more questions. Thank you. [Laughter.]

Mr. KASTENMEIER. I have at least one more question of Mr. Lewis.

You have heard what the Commissioner of Patents said. Quite apart from that, would you agree that the bill does have the effect of creating a disincentive for pursuit of subsequent-use patent by not providing for a patent term extension once the prior patent has been granted for an extension?

Do you think that is a problem?

Mr. LEWIS. Mr. Chairman, I don't believe it creates a disincentive. I believe it fails to create the same kind of incentive for use of patents as it does create for product patents and I must say, as I listened to the Commissioner and his very eloquent and elegant arguments, I heard echos in my own mind because these were precisely the arguments that I made and Alan Lourie made and others of our colleagues made during this long process and we, in fact, as the Commissioner conceded, picked up many points, but obviously, in a compromise, did not pick them all up.

Mr. KASTENMEIER. All right.

Would it be fair, then, to characterize the discussion or the debate as between those who are more or less patent purists, including the Commissioner, and those who are the realists seeking accommodation between industries? Is that what we are really dealing with here?

Mr. LEWIS. Well, I think the patent purists, if you wish to call them that, certainly have a very legitimate point. I think in taking a look at the bill in its entirety—and he was talking here principally about one exclusion which, at least one point in the process, our companies felt would affect some 15 percent of their patents. Now, subsequently—and they may wish to address this later on—some companies revised that figure upward but we were not talking about the typical case and that is just one provision of one title of this two-titled bill, an enormously complex bill, and our position, as I think I make clear in my testimony, is that on balance, we favor it.

Mr. KASTENMEIER. The PMA testified before Congressman Waxman that there were six prerequisites to an acceptable ANDA bill. Have these conditions been met in your view?

Mr. LEWIS. Mr. Chairman, as I mentioned in my testimony, the original Waxman bill was one page long. There were no standards; there were no restrictions; there was no phase in.

That portion of the bill is now 30 pages long and contains a good number of the things that we are looking for. I might also add that in reviewing the amendments which are being sought by the dissenting companies, even if they were all adopted, not everything that we were asking for last summer would be included in the bill.

I would just say once again that when we testified on that bill, we were testifying on the ANDA legislation within its four corners.

On this particular piece of legislation, obviously many of our concerns about that have been balanced by what we believe are the net gains in title II of the bill.

Mr. KASTENMEIER. Mr. Haddad, of course you—this is, I think, my last question—represent the Generic Pharmaceutical Industry Association, and I think you have said that this does not necessarily mean that you represent the public interest, but that it may be part of a coalition of others, including consumers and elderly. Do you see the consumers and elderly—consumers of therapies—as being—is there any dissent within that community that you are aware of, as to——

Mr. HADDAD. The letters that——

Mr. KASTENMEIER [continuing]. The value of this bill to that particular community?

Mr. HADDAD. That is a well-put question. The letters to the members of the committee that I have seen, subcommittee and Members of Congress, stress, as Mr. Lewis has, that this is a delicately balanced compromise, that there are portions of——

Mr. KASTENMEIER. The question is, is it delicately balanced among or between whom?

Mr. HADDAD. Between the need to get generic to the market quickly and the patent restoration arguments that you raised over the years, that this seems to be an equitable compromise; that if you tinker with it, the whole house could fall down. It hasn't been an easy compromise to reach. For example, the elderly will say, "If you are giving patent extension, you are making us pay more money in the future." So it is delicately balanced and there is—there was dissension, but, like at the PMA, it was resolved, however it was resolved, without dissenting opinions.

Mr. KASTENMEIER. You are not aware of any—you tell the committee you are not aware of any consumer group or group of elderly citizens or other public group that has something to do with either the industries that they are now in position to——

Mr. HADDAD. I do not—the coalition included two senior citizen groups, the American Association of Retired Persons and the National Council of Senior Citizens. Both have addressed themselves in writing to this.

The AFL-CIO and component members were part of the coalition and they have addressed themselves to it. The Nader groups have not yet addressed themselves to this compromise. They remain silent at the moment.

Mr. SAWYER. Mr. Chairman.

Mr. KASTENMEIER. Yes.

Mr. SAWYER. I was just going to say, in the 8 years that I have been here, I have never seen a compromise that wasn't a delicately balanced compromise, which is code for "Keep your damn hands off it."

Mr. HADDAD. Well put. Well put. [Laughter.]

But I understand the turf problems as well.

Mr. KASTENMEIER. I want to thank you both. I would also like to say that I would hope that in the days ahead that your offices would be available to respond to further questions that may develop on this legislation.

I am sure that we have not explored all the questions that we would like to today, but in any event, you both have been very helpful and I appreciate your appearance.

I regret having to say that we will have to recess. The hour is now 12:25, nearly 12:30, and I would hope we could recess until 1:15. It is clear that members who will be available later are not now available to us.

I regret that because there are many people in this room who are busy people and who have other schedules, but the Chair has no—really no option but to recess until 1:15.

Accordingly, the committee stands in recess.

[Whereupon, at 12:30 p.m., the subcommittee was recessed, to reconvene at 1:15 p.m., this same day.]

AFTERNOON SESSION

Mr. KASTENMEIER. The committee will come to order. We expect to be joined momentarily by other members.

Our second panel today consists of three individuals representing a group of pharmaceutical manufacturers who are opposed to the legislation in its present form.

The first member of the panel is Mr. John R. Stafford, president of American Home Products. The second witness is Prof. Norman Dorsen, a very well known teacher of law at New York University. He has been before us in other capacities in the past. The last witness is also a person who has been before this committee in the capacity of Commissioner of Patents. He is the honorable William Schuyler, Jr.

We have received a copy of your written statements so, without objection, they and other statements given earlier will be made a part of the record and you may proceed as you wish.

Mr. Stafford, did you wish to proceed first?

TESTIMONY OF JOHN R. STAFFORD, PRESIDENT, AMERICAN HOME PRODUCTS, ACCOMPANIED BY CHARLES F. HAGAN, VICE PRESIDENT AND GENERAL COUNSEL OF AMERICAN HOME PRODUCTS CORP.; AND JEFFREY DELLENBAUGH, PATENT COUNSEL WITH JOHNSON & JOHNSON; NORMAN DORSEN, PROFESSOR OF LAW, NEW YORK UNIVERSITY SCHOOL OF LAW; AND WILLIAM E. SCHUYLER, JR., FORMER COMMISSIONER OF THE PATENT AND TRADEMARK OFFICE

Mr. STAFFORD. Thank you, Mr. Chairman.

We appreciate the opportunity to appear before the subcommittee to discuss H.R. 3605. As you have indicated, my name is John Stafford. I am president of American Home Products. With me today are Prof. Norman Dorsen, professor of constitutional law at NYU Law School; Mr. William Schuyler, former Commissioner of Patent and Trademark Office.

I am also accompanied by Charles Hagan, vice president and general counsel of American Home and Jeffrey Dellenbaugh, patent counsel with the Johnson & Johnson Co.

We have a comprehensive statement which I ask be included in the record. I would like to briefly summarize our views.

Other companies in our group are Bristol-Myers, Carter-Wallace, Hoffmann-La Roche, Johnson & Johnson, Merck & Co., Norwich Eaton, a Procter & Gamble company, Schering-Plough, Squibb and Stuart Pharmaceuticals, a division of ICI Americas.

All of these companies are committed to original pharmaceutical research and development. We represent about half of the private pharmaceutical research and development investment in this country, an investment which over the years has propelled our country into the world technological leadership position.

In today's costly health care environment, prescription drugs, to quote a recent study, are the "least expensive form of medical therapy and greatly reduce health care costs by cutting back the need for surgery and hospitalization."

The medicines we develop in our laboratories are absolutely essential to continued medical progress in this century and beyond. In human terms, the saving of lives and suffering is immeasurable.

Our companies have been responsible for some of the most significant pharmaceutical breakthroughs of the last several decades. We recognize that each time we begin to develop a new drug, we are taking a multimillion dollar gamble. A large amount of our research never culminates in a marketed product.

On average, the cost of developing a new medicine in this country is now in the $70–$85 million range, taking an average of 7 to 10 years to complete, all of the rigorous scientific protocols and secure FDA approval.

Integrity of the patent system and research incentives are the cornerstone of pharmaceutical research and development. The key to this research commitment is the knowledge that our multimillion dollar investments lead to a patent and the right to market the results of that research exclusively for a certain period of time.

Sales of our products not only permit us to recover research and development costs, but more importantly, give us funds to invest in further research to develop future generations of medicines.

Mr. Chairman, as you are aware the patent system does not work as it was intended for our industry. By the time new drugs are cleared by FDA, they have far less than 17 years of patent life. For example, FDA reported that of 205 drug products approved between 1962 and 1978, 51 had no or little patent life at the time of approval. We have long believed that this is a situation that merits remedy by the Congress and, indeed, efforts in this direction have been made in past years.

At the same time, there is a public need to resolve the question of how FDA approves generic versions of post-1962 drugs. Congress should establish a workable system for approving these generics and for assuring their safety, effectiveness and quality, and the legislation must not have the effect of discouraging original research.

We support fully the objectives of this legislation. However, Mr. Chairman, we believe that this bill in its current form does not accomplish its objectives. A proper balance has not been achieved. The legislation before you provides an inadequate system for approval of safe and effective post-1962 generics and weakens the existing patent system. We believe that efforts to stimulate research leading to new drug therapies is at least as important as accelerating the approval process for generic copies.

Moreover, the bill raises many difficult patent issues, including serious constitutional questions about the elimination of patent rights for already patented products. Thus, any incentives provided are more than outweighed by the limitations which the bill would mandate.

Quite frankly, we do not believe there has been enough time since the bill was introduced 2 weeks ago to examine fully all of its ramifications. The legislation was reported out by the Energy and Commerce Committee the same day it was introduced without benefit of hearings on the particular bill that they acted on.

The issues are complex and merit careful consideration, and hence we welcome this opportunity to appear before you today.

We have developed seven amendments in support of the bill's objectives. Our amendments are not merely technical. They do not involve just language changes. Our amendments are designed to remedy some very fundamental and far-reaching deficiencies in this legislation.

If these deficiencies are left unchanged, the constituent we all want to serve, the American consumer, will be the true loser. While this bill will facilitate the availability of generic drugs, it should not be done at the expense of undermining the development of original drugs.

As drafted, a number of provisions would shrink existing patent protection and restore patent terms only under limited circumstances. On the other side, it would create a number of new regulatory problems and would have the effect of reorienting FDA priorities toward approval of generic drugs in answering freedom of information requests, rather than focusing, as we believe it should, on bringing important new therapies to American patients.

Our written testimony describes fully the specific amendments we are seeking. In keeping with the subcommittee's jurisdiction, I will focus primarily on patent problems raised by the legislation. First, this bill illogically restricts patent term restoration. Many new drug products will, in fact, not be eligible for restoration. These specific exclusions were covered by the Commissioner of Patents this morning and in the interest of time, I will move on to the next point in my statement.

Not only does this bill impose significant limitations on patent restoration, it also reduces existing patent protection. It is a long-accepted tenet of patent law that the unauthorized use, sale or manufacture of a patented product during the life of the patent constitutes infringement. A recent court of appeals case underscored this in *Roche* v. *Bolar.*

The legislation under consideration today would overturn *Bolar* and permit commercial competitors to test a drug during its patent life. The bill eliminates this important patent right for patents already in existence. This provision raises serious constitutional questions which will be addressed by Professor Dorsen. If *Bolar* is to be overruled at all, it should be prospective only.

We believe this is a simple matter of fairness. Drugs approved before enactment of this bill are ineligible for patent extension, yet these drugs would lose an important element of existing patent protection. We believe this needs to be remedied.

Our third concern is that this legislation will encourage patent infringement and patent litigation. Under present law, a patent has a statutory presumption of validity. Under this legislation, however, a competing drug manufacturer may call into question the validity of a patent merely by submitting an abbreviated application to FDA and notifying the patent holder. Eighteen months later, that product must be allowed on the market, even though the patent still is presumed valid.

Patents should continue to be presumed valid and manufacturers should not be allowed to market a drug until a court has fully decided the patent's validity.

Our fourth major concern relates to the public disclosure by FDA of safety and effectiveness data contained in new drug applications for pioneer drugs. These data represent millions of dollars of investment and retain great commercial value, especially against competition in foreign countries that do not recognize U.S. patents.

The release of these data would erode our technological competitiveness and adversely affect our Nation's pharmaceutical leadership. It is difficult to see how giving millions of dollars of commercial information to competitors for use abroad at the mere cost of photocopying promotes the health of Americans or the competitiveness of our industry.

Finally, we are concerned about the many new burdens that this bill imposes on FDA, which, among other things, would also involve the agency in patent matters. For example, it would require FDA to hold due diligence hearings on the length of patent term restoration. These requirements and those related to the ANDA provisions of the bill would impose a heavy new burden on an already overloaded FDA. As a result, FDA's limited staff would be reviewing applications to market generic copies of drugs rather than applications for important breakthrough drugs. The public would thus be deprived of the benefits of important new therapies.

To conclude, Mr. Chairman, our 10 companies support the legislative objectives of H.R. 3605, but the problems we have raised here today and in our more detailed written comments must be resolved to afford maximum public health protection, as well as to continue research incentives for the pharmaceutical industry.

I will complete my remarks, Mr. Chairman, and request Professor Dorsen to comment on the constitutional issues, unless you would prefer to stop for questions, of course, that would be fine, too. I thought you might want us all to give our remarks and then be available for questions.

[The statement of Mr. Stafford follows:]

JA 179035-1 E

STATEMENT

ON BEHALF OF

American Home Products Corporation
Bristol-Myers Company
Carter-Wallace, Inc.
Hoffmann-La Roche Inc.
Johnson & Johnson
Merck & Co., Inc.
Norwich Eaton Pharmaceuticals, Inc.
(A Procter and Gamble Company)
Schering-Plough Corporation
Squibb Corporation
Stuart Pharmaceuticals
(Div. of ICI Americas Inc.)

BEFORE THE SUBCOMMITTEE
ON COURTS, CIVIL LIBERTIES, AND THE
ADMINISTRATION OF JUSTICE
OF THE COMMITTEE ON THE JUDICIARY
UNITED STATES HOUSE OF REPRESENTATIVES

HEARING ON H.R. 3605

June 27, 1984

INTRODUCTORY REMARKS

Mr. Chairman and Members of the Committee:

My name is Jack Stafford and I am the President of American Home Products Corporation. We are here today to speak on behalf of 10 of the nation's leading research-based pharmaceutical companies: American Home Products Corporation; Bristol-Myers Company; Carter-Wallace, Inc.; Hoffmann-La Roche Inc.; Johnson & Johnson; Merck & Co., Inc.; Norwich Eaton Pharmaceuticals, Inc., a Procter and Gamble Company; Schering-Plough Corporation; Squibb Corporation; and Stuart Pharmaceuticals, a Division of ICI Americas Inc.

Together our companies account for approximately 50% of the pharmaceutical research dollars spent in the United States by private industry. Let there be no mistake about the public benefit of this pioneering work. Our companies have been responsible for some of the most significant pharmaceutical breakthroughs of the last several decades. Not only have we developed new drug therapies for many previously untreatable conditions, but drug innovations often provide the least expensive, most cost-effective form of medical therapy. Several recent studies establish that pharmaceuticals can lead the way in the effort to curtail health-care costs by cutting back the need for more expensive surgery and hospitalization. (Appendix A.) Moreover, the pharmaceutical industry is undeniably important to our national economy. Our group of com-

panies employ approximately three-quarters of a million workers in the United States. In 1983, the U.S. exported over $2.5 billion worth of pharmaceutical products that accounted for a net favorable trade surplus in excess of $1.2 billion. These health and economic benefits make it imperative for Congress to encourage adequate future research by restoring the effectiveness of America's patent system while maintaining our commitment to providing the world's safest and most dependable drug products.

Therefore, at the outset Mr. Chairman, we would like to commend the Congress for considering this important piece of legislation. We support its objectives. Specifically, our group favors legislation which would (1) restore some of the patent life lost to the regulatory review process for innovative drug products, and (2) accelerate the availability of safe and effective generic drug products. Although we support the goals and purposes of H.R. 3605, we believe that certain changes are essential in order to produce a bill which achieves its objectives fairly and equitably. This complex legislation must receive careful and thorough consideration.

We applaud your efforts, and those of the entire Committee to tackle these problems and we appreciate the opportunity to appear before the Subcommittee today.

As you know, this bill raises many difficult patent issues including serious constitutional questions about the elimination of patent rights for already-patented products.

In the past Representative Henry Waxman, who introduced this legislation, has said, "On first glance the proposal to restore patent term appears to be a simple and straight-forward issue of equity. But, ... it is really a complex and difficult public policy decision which requires a careful balancing of the need for incentives for pharmaceutical innovation and the societal impact of those incentives." H.R. 3605 is by far the most intricate measure of its type ever introduced, and some of its effects of pharmaceutical patent issues are not immediately clear. On careful examination, though, several flaws relating to the patent provisions become clear.

Most important, it would limit unduly the kinds of drugs and patents that would benefit from patent term restoration under the bill: products with multiple patents, significant improvements to existing products, and other worthwhile uses of the pharmaceutical research dollar all would be ineligible for restoration under H.R. 3605. The bill will encourage needless patent infringement and premature patent litigation. H.R. 3605 would also provide for the retroactive taking of important patent ownership rights without just compensation and would require the FDA to disclose valuable proprietary data to competitors both here and abroad. The bill's proposed restrictions on existing patent rights and the lengthy litany of the types of patents not eligible for patent term restoration could have far ranging adverse effects on the development of new technology in this country, including serious implica-

tions for the future of university-based research and the emerging and vitally important field of biotechnology. In addition, the bill contains narrow transition provisions that would penalize companies that invested in research in areas such as new indications, new dosage forms, and new delivery systems. We hope to be able to assist the Committee in understanding the impact this bill will have on innovation in our industry.

H.R. 3605 also raises significant public health concerns which need to be addressed before final consideration of this legislation. Our group believes and the FDA agrees that the bill restricts FDA's authority to insure that all drugs are safe and effective.

The FDA, in fact, raises a number of additional points that our group has not asserted. The FDA's "Technical Comments" on the legislation identify several of the health and safety problems which could arise if this legislation is enacted in its present form. For example, the bill would impose a number of severe administrative burdens on the FDA which could have the unintended consequence of actually thwarting the statutory objective of speedy approval of safe and effective innovative drugs. (Technical Comments, Appendix D.)

Some may have represented to you that our group, by seeking careful consideration of this legislation and its complex issues, is really trying to defeat the bill. I assure

you that this is not the case. We believe that the issues embodied in the bill deserve far more consideration than they received before the House Energy and Commerce Committee where this complex 45-page bill was entered as an amendment to a 1 1/2-page bill, and the amended bill was reported out of the Committee on the very same day it was introduced.

Today, in keeping with the Committee's expertise and jurisdiction over patent issues, we would like to use our limited time to focus the Committee's attention on several issues affecting patent rights and innovation which are raised by the legislation.

I. THE NEED FOR REAL PATENT TERM RESTORATION IS COMPELLING

The 98th Congress must deal with many difficult and controversial problems, but none are more challenging nor more crucial than the need to reverse the decline in U.S. innovation and productivity. Congress must not only be concerned with how to reverse this trend, but also must avoid unintentionally stifling U.S. technology.

- The U.S. share of world pharmaceutical R&D expenditures has fallen from greater than 60 percent during the 1950s to less than 30 percent now.
- The U.S. share of world pharmaceutical exports has fallen from greater than 30 percent before 1960 to less than 15 percent today.
- The number of new drugs entering clinical trials and owned by U.S. firms has steadily dropped from a yearly average of 60 in the mid-1960s to about 25 a year now. In contrast, the number of compa-

rable foreign-owned new drugs has remained almost constant at about 20 a year.

- The percentage of world pharmaceutical production occurring in the United States has fallen from 50 percent in 1962, to 38 percent in 1968, to 27 percent in 1978.

- Smaller U.S. pharmaceutical firms self-originate fewer new drugs than before 1960 and are increasingly dependent on foreign firms for licensing new products, though licensed products still make up less than half of drug introductions by small firms.

By any measure the pace of America's drug innovation is slowing. Unless Congress and the public are willing to provide meaningful incentives for pioneering research while insuring the safety and effectiveness of all drug products, then investment in private pharmaceutical research is likely to decline and will no longer provide the kind of products that have brought such an improvement in public health over the past 30 years.

One big step in the right direction would be to restore the diminishing effectiveness of the U.S. patent system for certain products, such as pharmaceuticals, that are subject to elaborate pre-market approval requirements by the Federal Government. Under current law, the Government grants a 17-year patent and then prohibits the pharmaceuticals from being marketed until all FDA-required tests are completed, reviewed, and approval is obtained. During this time, the life of the patent is ticking away, often for many years. For example, FDA reported that of 205 drug products approved between

1962 and 1978, 51, or 25%, had no or comparatively little, effective patent life at the time of approval. (Appendix B.)

Gradually, the time needed to complete and clear the regulatory review process has grown longer, as products and tests have become more sophisticated and the regulatory resources of agencies like the FDA have become stretched to their limit. In 1962, for example, it took approximately 2 years and $6 million to bring a new medicine from the laboratory to the marketplace. It now takes an average 7 to 10 years and about $70-85 million to complete this testing period. Thus, it is not uncommon for a drug product to have lost up to one-half of its patent life without having yet been marketed. (Appendix B.)

This phenomenon, coupled with the inability of many new products to recover their investment, discourages innovation. For example, from 1955 through 1962, an average of 46 drugs were introduced annually in the United States; today, undoubtedly for a variety of reasons, that average is only 17 drugs a year, a decline of 63 percent.

This reduction in the number of drug innovations strongly indicates that the public is being deprived of new therapies. A decline in pharmaceutical patent lives -- the result of inadvertence rather than Congressional intent -- could erode the investment research incentive provided by the traditional 17 year statutory patent term. No one could have anticipated that a testing and approval process that took

about two years in the early 1960s would take seven to ten years by 1980. Our group of companies urges that it is time to rebuild the incentives originally provided by the patent system.

We realize how difficult it is to draft a bill that accommodates all the multiple objectives touched by H.R. 3605. This is a bill that purports both to accomplish patent restoration and to promote the availability of generic drug products. But, amendments are needed to achieve these objectives.

On one hand, the patent term restoration provided by the bill is, in many cases, iillusory because H.R. 3605 contains restrictions on the eligibility of patents for extensions. In fact, at least one provision would actually shrink existing patent protection. That provision, section 202, would reverse the decision recently rendered in Roche Products, Inc. v. Bolar Pharmaceutical Co., No. 84-560 (Fed. Cir. April 23, 1984), by the Court of Appeals for the Federal Circuit, which has appellate jurisdiction over all patent cases. The reversal of Bolar with respect to existing patents is clearly inequitable. On the ANDA side, the bill would create a number of new regulatory problems. Overall, we are concerned that it would reorient FDA's priorities toward approval of ANDAs and release of proprietary safety and effectiveness data and away from approval of important new drug therapies.

This result would be bad policy and could create public health problems.

We submit that encouraging research leading to new drug therapies is at least as important as streamlining the approval process for generic copies of drugs. H.R. 3605 has been described by its proponents as a politically attractive bill because, as a compromise, it has something for everyone: patent term restoration for the research-oriented pharmaceutical industry and increased availability of generic drugs from "me-too" manufacturers. However, as currently drafted, it is not a successful compromise because it severely restricts patents eligible for extension and undermines the basic principles of established patent law. Nonetheless, we firmly believe that the concept underlying this legislation is indeed attractive because both patent term restoration and safe and effective generic products serve the best interests of the consumer. Consumers benefit not only from price competition among the finite number of existing approved drug therapies, but also from the development of new cures and treatments. Obviously, unless a new drug is developed there can never be a generic copy of that drug.

U.S. pharmaceutical companies have been pre-eminent in developing and disseminating health-care products in this country and throughout the world. But this country's continued leadership in this field and its international competitiveness are in jeopardy. The bill under consideration today

could result in a decline in scientific research and innovation.

II. ANALYSIS OF H.R. 3605

A. Unfulfilled Commitment -- Discouraging Innovation by Limiting Drugs Eligible for Restoration

This bill purports to be a fair balancing between the need for swift FDA market approval for products whose patents have expired and the need to restore the portion of patent life lost to regulatory delay. However, patent term restoration as offered in the bill is, in many cases, illusory and the ANDA provisions go far beyond what is necessary to provide prompt approval for generic drug products after the expiration of valid patents. In reality, the bill effectively denies patent term restoration for a variety of new drug products. This result is accomplished through detailed and complicated restrictions on the types of patents eligible for restoration. If the objective of the bill is to restore incentives for pharmaceutical innovation, then patent term restoration must reflect the reality of pharmaceutical research and development, and apply to a broader range of drug patents.

- The Species v. Genus Patent Problem.

Section 201(a) (proposed 35 U.S.C. 156(a)(4)) of the bill prohibits patent term extension for cases in which the applicant holds, or will hold, more than one patent claim-

ing the drug in question. Many new pharmaceutical innovations will thus be ineligible for restoration because they will, in fact, be covered by more than one patent held by the same owner or exclusive licensee. As an example, many drugs are claimed both by a patent with claims of broad scope, the genus, and also by a subsequent patent claiming a specific compound, or species within the genus.

After the initial discovery leading to the genus, pharmaceutical research is ordinarily continued on families of compounds sharing similar chemical structural features and often similar biological characteristics. The objective is to study the entire family and to identify new compounds within the family that appear to provide more of a likelihood of therapeutic promise than other compounds within the genus. The R&D expenses to take a new medicine from discovery to market approval range from $70-80 million. Section 201(a) would prohibit patent term restoration on the species patent if the holder of the genus patent conducts this species research, and would allow it only if the two patents are forever held by separate owners.

For example, the Squibb Corporation obtained a patent on the genus of 9-halosteroids and later was able to develop two popular topical steroids from this genus: Kenalog (triamcinolone acetonide) and Halog (halcinonide). Wyeth Laboratories obtained a patent on a genus of anti-anxiety agents, which has led to the development of four specific drugs--

oxazepam (marketed as Serax), lorazepam (marketed as Ativan), pemazepam, and lormetazepam. Had H.R. 3605 been in effect when these patents were issued, none of these products would have qualified for restoration because each was covered under a species patent and belonged to a family identified in an earlier genus patent. This destroys much of the incentive to develop new compounds under the genus patent.

° The Split Application Problem

Another way in which a compound becomes covered by more than one patent is through division of the patent claims within the Patent Office itself. Under present law, the Patent Office can require that claims in a patent application be divided and prosecuted in separate patents. Over 80% of patent applications for chemical compounds are prosecuted in severed applications. This requirement is met as part of the patent prosecution or by the Patent Office itself upon examination of the application. At this early stage of drug development, the patent applicant is forced under this bill to choose which compound to prosecute first. Under section 201(a) of H.R. 3605 (proposed 35 U.S.C. 156(a)(4)(A)), the first-issued patent of the series would be the only patent entitled to restoration. Subsequently issued patents of the series would be precluded from restoration.

This restrictive provision is ill-advised because it unrealistically and unfairly requires manufacturers to determine in advance of FDA approval and marketing which patent in

a series will cover the valuable products and therefore be worthy of extension. Because only the first-approved application would be eligible for extension, and patent applicants rarely know at the early stages of development -- when patent applications are made -- which aspects of a new product will become most valuable at a later date, patent term restoration becomes a game of chance. Moreover, even if the future commercial success of a new chemical compound was predictable, the patent applicant cannot assure that the patent claiming the potential successful product will be issued before the others, which is what the bill currently requires to ensure eligibility for patent term restoration. H.R. 3605 would thereby fail to provide the certainty requisite for investment and long-term research planning that will stimulate making discoveries available to the public.

° The Overlapping Patent-Product Problem.

Another exception to patent term restoration embodied in section 201(a) of the bill, proposed section 35 U.S.C. 156(a)(8), would apply where a substance is covered by multiple patents, each claiming a different use for that substance, or where a single patent covers two or more FDA-approved drugs. The term of claims in the patent covering the second FDA-approved drug could not be restored.

In the pharmaceutical industry, it is common for additional research on a patented drug product to lead to

the development of new delivery systems, therapeutic indications, or dosage forms of the original product. These later innovations contribute significantly to the safety and effectiveness of drug therapy, and the later-discovered products deserve restoration to the same extent as the initial products of a patent. Yet the bill would provide only one restoration per patent, even when a company has expended considerable resources in developing the subsequent FDA approved products. For instance, in 1972 Merck and Company, Inc. was issued a patent on a beta blocker which resulted in a product called Blocadren, a highly effective cardiovascular drug which is used in the prevention of a second heart attack, the heart attack most likely to cause death. Though widely used in Europe, it was not approved in the United States until 1981 and therefore had only eight years left on the patent once it was brought to the U.S. market.

Merck continued its research on this compound long after it was marketed in Europe as a cardiovascular drug and in 1978 received approval from FDA to market the product for a new use. Merck had discovered that the same compound which was useful in the treatment of cardiovascular disease would also decrease intraocular pressure on the eye when used as eyedrops, making it a useful drug in the treatment of glaucoma. Merck obtained a patent for the glaucoma indication in 1980 and manufactured the drug under the brand name Timoptic. Timoptic, a breakthrough drug which in many cases eliminates

the need for surgery, costs only 22 cents per dose and replaces a surgical procedure which costs approximately $800 per procedure and approximately $200 per day in hospitalization costs.

Under this proposed bill, the Timoptic active ingredient was claimed in the earlier issued patent for Blocadren, it would not be entitled to patent term restoration under subparagraph (4)(A) of section 201 of the bill. On the other hand, Blocadren was not approved in this country until 1981 while Timoptic was approved in 1978. Therefore, subparagraph (7)(A) of section 201 prevents the discoverer from getting restoration on Blocadren because Timoptic was approved first.

Schering-Plough has developed both Valisone (betamethasone valerate) and Diprosone (betamethasone dipropionate) from a single patent, and has turned the Diprosone formula into another form marketed as Diprolene, which has an improved delivery vehicle and allows lower dosages. None of the later improvements to these topical steroids would qualify for extension if H.R. 3605 were law, because they all arise under a single patent.

Just as one patent may cover two drugs, one drug or a family of drugs frequently is covered by more than one patent. Subsequent innovations to an existing drug may result in one product being covered by multiple patents. For example, the drug propranolol (Inderal) was patented in 1967 and is currently indicated for seven indications. Research continued

on the agent and a patent was obtained for the new product, Inderal LA, in 1979. The new form of the drug is considered an improved therapy for four indications, largely because it requires less frequent doses and thereby stabilizes serum levels of the drug and raises patient compliance through less frequent doses. Yet since Inderal LA is covered by both the 1967 and the 1979 patents, the drug would be ineligible for patent term restoration under section 201(a) of H.R. 3605, proposed section 35 U.S.C. 156(a)(4).

Similarly, the compound Cyclapen-W (cyclacillin) received patent protection in 1965 as an antibiotic, and the product was later improved by formulating an anhydrous version that has a longer and more stable shelf life and was patented separately in 1971. Wyeth Laboratories, which now sells only the improved anhydrous version of the drug, would be ineligible for restoration of either patent's term if H.R. 3605 had been law at the time of Cyclapen-W's discovery. These examples show how H.R. 3605 unfairly restricts the products for which patent term restoration may be available, and would deny restoration for the very kinds of new inventions and innovations it purports to encourage.

° The Manufacturing Patent Problem.

Section 201(a) of the bill (proposed 35 U.S.C. 156(a)(5)(A)) limits availability of patent term restoration for patents covering a method of manufacturing (not using rDNA

technology), including the limitation that no other type of patent has been or "may be issued for any known therapeutic purposes" claiming the method of using the product. New advances in pharmacological manufacturing techniques can contribute greatly to reducing the cost of drug therapy, and these innovations should be encouraged by providing for appropriate patent terms.

Furthermore, the bill contains special provisions for biotechnology and rDNA manufacturing techniques. Under proposed 35 U.S.C. 156 (a)(5)(B), the term of a process patent utilizing rDNA technology can be extended only if two tests are met: the patent holder of the method of manufacture is not the exclusive licensee or holder of the patent on the product itself (i.e., different ownership), and no other method of manufacturing the product primarily using rDNA technology is claimed in a patent having an earlier issue date. This second test would eliminate patent term restoration for much of the rDNA work being conducted, because a previously-issued dominating patent claiming rDNA technologies would exclude subsequently-issued "method of manufacture" patents from patent term restoration. This provision is overly broad, particularly where the dominating patent belongs to another party. One example of a dominating patent is the "Cohen-Boyer" patent developed at Stanford University, which covers basic rDNA manufacturing technologies. It would not take many of these broad-coverage, dominating patents to exclude almost

all future rDNA innovations from restoration of term. The existence of these dominating patents will turn the patent term extension promised in proposed 35 U.S.C. 156(a)(5)(B) into a mere illusion.

B. Encouraging Patent Infringements And Premature Patent Litigation

Under present law, a patent has a statutory presumption of validity. Under section 101 of H.R. 3605 (proposed 21 U.S.C. 505(j)(4)(B)(iii)), a competing drug manufacturer, a so-called "second-comer," can submit an ANDA on a patented drug, and give appropriate notice of this submission to the patent holder, who then has 45 days to institute a patent infringement action. Assuming such an action is brought, the second-comer is allowed to market the drug after the expiration of an 18-month period following the notice unless a court declares the patent valid within this period. This provision would institutionalize and provide incentive for a system of attacks on presumptively valid patents. It does serious damage to a patent system that generally -- apart from the regulatory system's inadvertent erosion of effective patent life -- has long served this nation well by fostering and promoting research, invention, and innovation.

Under section 101, the ANDA applicant can also force the patent holder to litigate the validity of the patent within 45 days of the initial submission of an ANDA, whether complete or not. This is in contrast to the current law which

provides that a full NDA must be complete before it is considered filed. ANDAs are often incomplete and require revision and additional work before they are accepted for filing by the FDA. The bill does not require that the ANDA submission be complete, even though there is presently a comparable requirement of "due diligence" in prosecuting an NDA imposed under the patent term restoration side of the bill upon a patent owner seeking an extension of the patent. If a patent suit can be triggered even before a complete ANDA is filed, then some companies and groups of companies will be encouraged to attack unexpired drug patents. Their risk is slight because they will not have to invest in the research required for a complete NDA.

Presumably, section 101's 18-month delay in the ANDA effective date once an infringement suit is filed is intended to permit a court to adjudicate a patent's validity before the ANDA becomes effective. However, this provision is grossly deficient. As the Subcommittee is well aware, the trial of a complex civil suit such as patent litigation is almost never completed within 18 months. Congestion in the courts and the low priority assigned to civil relative to criminal cases can stretch patent litigation out for five years or more. In fact, it has been recently reported that the completion of trials of patent actions (calendar waiting time plus trial time) average 35 months, not counting the time spent in discovery or pre-trial motions. Report of Proceedings of the Ju-

dicial Conference of the U.S., March 16-17, 1983 and September 21-22, 1983, Annual Report of the Director of the Office of U.S. Courts, table C54 (1983).

If enacted in its present form, the bill is certain to generate increased patent litigation. Owners of unexpired patents will need to respond to virtually every second-comer's notice of an ANDA submission with a suit for patent infringement. First, failure of the holder of a valid patent to litigate would permit the FDA to approve the "me-too" company's or companies' ANDAs and permit infringing commercial sales. Profits from the infringing sales could permit the initial and subsequent generic manufacturers to finance patent litigation. Second, failure of the patent owner to respond may support an estoppel or laches defense in subsequent litigation. Patent issues rarely lend themselves easily to quick summary judgment or other prompt resolution. This could result in extended and terribly costly patent litigation to the patent owner during the early stages of a patent -- precisely when unencumbered patent protection is most useful.

If the infringement occurs close to the end of the patent term, a court might eventually issue a final ruling in favor of the patent owner but mandate only payment of monetary damages, rather than also ordering the infringing product off the market. This would further encourage patent infringement and litigation, by allowing a second-comer to market competing

products before expiration of the patent term, merely by paying the equivalent of a licensing fee ordered by the court.

Since patents are presumed valid, an ANDA applicant should not get a free ride on the pioneer's original efforts to obtain an NDA and market a "me-too" drug until a court has fully and properly decided the patent's validity. Further, the bill should be amended to require, at minimum, a complete ANDA filing to trigger the initial steps that could lead to serious patent infringement.

C. Commercial Testing During Patent Term

It is a long-accepted tenet of patent law that the unauthorized use, sale, or manufacture of a patented product during the life of the patent constitutes infringement. This aspect of the rights accruing to the patent owner was underscored recently in the case of Roche Products, Inc. v. Bolar Pharmaceutical Co., No. 84-560 (Fed. Cir. Apr. 23, 1984). The United States Court of Appeals for the Federal Circuit held, consistent with prior rulings, that a generic drug manufacturer may not use another company's patented discoveries for purposes of obtaining FDA approval until expiration of the patent term. This decision is sound law and necessary to prevent damaging, commercially competitive work on a patented substance while the patent owner is still entitled to exclusive rights.

The legislation under consideration today, however, goes further than merely overruling Bolar. It would permit a commercial competitor to engage in acts which would now constitute blatant patent infringement. It is surprising that this restriction on patent rights should be contained in a bill intended to restore patent life and encourage innovation. The competition in today's market for innovative drug products is extremely intense. In order to encourage this research while respecting the rights of the patent owner, adequate patent protection such as was reaffirmed in the Bolar decision is critical.

The bill would eliminate this important patent right not only for patents issued in the future but also for patents already in existence. This provision of the bill raises serious constitutional concerns. By overruling Bolar retroactively, the bill deprives current patent holders of valuable property rights and constitutes a "taking" without due process. Even if Congress wishes to overrule the Bolar decision, it should do so only prospectively and only for those patents eligible for patent extension under the bill.

We believe the provisions of the bill permitting a competitor to conduct commercial testing of an invention covered by a valid patent should be amended. It is one thing to overrule Bolar for drugs that will benefit from the patent restoration provisions of the bill; however it is clearly unfair to remove existing patent rights from drugs

that are ineligible for any benefit under the bill. In any event, the attempt to apply such changes to already-issued patents raises serious constitutional concerns and must be remedied.

D. Government Disclosure to Foreign Competitors Of Valuable Proprietary Information

For over 45 years the FDA has not publicly disclosed, or allowed the release for any purpose not explicitly authorized by an NDA holder, any safety or effectiveness data contained in a pioneer NDA, while these data retain any commercial value. 21 C.F.R. 20.61, 314.11, 314.14. See 37 Fed. Reg. 9128, 9130-31 (May 5, 1972); 39 Fed. Reg. 44602, 44612-14, 44633-38 (Dec. 24, 1974); 40 Fed. Reg. 26142, 26148, 26168-7 (June 20, 1975); 43 Fed. Reg. 12869, 12870 (March 28, 1978). This interpretation of the FDC Act has consistently been upheld in court. E.g., Johnson v. DHEW, 462 F. Supp. 336 (D.D.C. 1978); Webb v. DHHS, Food, Drug, Cosm. L. Rep. ¶ 38,138 (D.D.C. 1981). See also, Pharmaceutical Mfrs. Ass'n v. Weinberger, 401 F. Supp. 444 (D.D.C. 1975); Syntex Corp. v. Califano, Food, Drug, Cosm. L. Rep. ¶ 38,221 (D.D.C. 1979). Cf. Public Citizen Health Research Group v. FDA, 704 F.2d 1280 (D.C. Cir. 1983).

Section 104 of H.R. 3605 would provide for a dramatic and ill-conceived reversal of this long-standing policy, although the bill's sponsors apparently maintain it would merely codify current FDA disclosure policy regarding drugs

subject to ANDAs. It has indeed been FDA policy to allow for limited disclosure of material contained in NDAs. This policy, however, applies to pre-1962 drugs, and since adoption the regulation has applied only to data generated before 1962. The regulation was adopted before any serious consideration had been given to ANDAs for post-1962 drugs. It does not follow that a policy which may be appropriate for data which are at least 22 years old is sound for data developed relatively recently and which are of far greater commercial value. Moreover, in the course of its ongoing rewrite of the NDA regulation, FDA itself intends to revise this regulation to reflect the continuing proprietary nature of these data. The bill would negate this effort.

The bill would permit the public disclosure of all of the extensive and costly research data generated by research-based pharmaceutical companies, at least as soon as FDA approval of a generic version of the new drug could become effective, even though the data may be of significant value to foreign competitors or may retain proprietary value in the United States. Also, it is not clear in section 104 that the term "information" is limited to safety and effectiveness information as distinguished from other confidential data such as manufacturing methods and processes.

The data that would be released can retain commercial value, even though FDA would no longer require another applicant to submit the data to obtain approval for sale in

the United States. These data would be commercially valuable because they could be used to obtain approval to market the drugs in foreign countries.

Senator Orrin Hatch earlier this year drove home the value of U.S.-produced technical data during efforts to tighten the Freedom of Information Act. Senator Hatch said:

> Foreign governments and foreign competitors of U.S. companies are able to obtain very valuable unclassified technical information simply by submitting a FOIA request to the Federal agencies that have paid to have the data developed. In fact, cottage industries have sprung up to systematically obtain and catalog such technical data, which they then market throughout the world.

The data disclosable under section 104 are particularly valuable in those countries which do not recognize U.S. patents. Thus, by providing for the release of these data, the bill hands foreign competitors of U.S. drug firms information which costs many millions of dollars to obtain and which can be used to obtain approval to market drugs in competition with the U. S. owner and generator of the data. This is hardly the way for this legislation to reverse the decline in pharmaceutical innovation and maintain the competitiveness of American industry.

Under section 104, trade secret data that now cost, on average, $70-85 million to generate per new drug would be freely released to anyone requesting them, including the innovating firm's foreign competitors. Competitors will copy the data and submit them to foreign drug regulatory agencies when

they request permission to sell the drug abroad. Unlike FDA, most foreign drug approval agencies give preference in their approval decisions to firms of their own nationality. American firms can expect to lose market shares in these nations and, in some instances, watch a foreign firm get marketing approval instead of themselves.

Section 104, as presently drafted, may jeopardize U.S. pharmaceutical exports and numerous American jobs. The exports at stake are to nations that (a) require data in the application for market approval that, but for section 104, would not be publicly available, and yet (b) do not recognize product patents. (Appendix C).

In effect, under section 104 our government would give foreign firms, for merely the cost of photocopying, private U.S. commercial information needed by the foreign firms to go on the market in their home countries. It would be ironic if such a provision were enacted now, when the U.S. government is vigorously negotiating against international efforts to impose compulsory licensing requirements on U.S. patent holders.

As FDA noted, in its Technical Comments (Appendix D), this provision of H.R. 3605 also has significant resource implications for FDA. Under the FOIA, FDA is obligated to respond to requests for documents in its files, including the voluminous safety and effectiveness data, ordinarily within ten days and in special cases, within twenty days. Since the

enactment of FOIA, FDA has consistently received more requests for documents than virtually any other Federal agency. In 1983, FDA received over 39,000 FOIA requests. One hundred twenty-five "full time equivalents," many of whom are highly trained scientists and doctors, were required to process these requests. Under H.R. 3605, over twenty years of safety and effectiveness data and information for off-patent drugs will be available for disclosure immediately upon enactment. If FDA were to receive requests for even a modest part of those data, the workload and resource burdens would be staggering. It is difficult to see how the public benefits by the FDA being forced to divert scarce resources to processing FOIA requests and ANDAs at the expense of new drug applications.

Despite the toll in jobs and balance of trade, Section 104 is unrelated to the goals of the bill, namely to expedite approval of generic drugs and to restore some of the time lost on patent during regulatory review of human and animal drugs and medical devices. Mandating disclosure of trade secrets would not affect the availability or pricing of generic substitutes, nor does it relate to the type or amount of information necessary for FDA approval of generics. In the United States, generic competitors do not need access to the raw data because the bill authorizes FDA to rely upon the innovator's data in making its decisions on the approvability of the generics rather than require that the generic firm duplicate the data.

Section 104 should be amended to require FDA to make available a detailed summary of safety and effectiveness data, but not the complete raw data. Also section 104 should be clarified so that the term "information" relates only to information on safety and effectiveness.

E. Burdens On The FDA And Its Unnecessary Involvement in Patent Issues

The bill imposes a number of new administrative burdens on the FDA. While many of these bear upon FDA's traditional functions, many others involve FDA for the first time in the administration of the patent system. Contrary to the implication in the Report on H.R. 3605 of the Energy and Commerce Committee, these complex procedures and their effects on FDA have not been considered at any time. They deserve full and careful evaluation. We understand that FDA representatives are making their views known independently on some of these features of the bill and therefore we will leave it to the FDA to address important aspects of these new responsibilities. (Appendix D.)

III. CONCLUSION

In conclusion, our group supports the legislative objectives of this important bill, but we believe that there are changes which must be made to improve and clarify the legislation. We have specific amendments that we believe will improve and clarify this important legislation. Moreover, we

wish to impress upon this Subcommittee the need for careful consideration of the complex and controversial public policy questions raised by the legislation. We stand ready to work with the Committee and its staff so that a meaningful and fair bill can be enacted this session of Congress.

Thank you very much for the opportunity to address this Subcommittee.

APPENDIX A

STUDIES DEMONSTRATING THE COST-EFFECTIVENESS OF PHARMACEUTICALS

Arthur D. Little, Inc., Report 7: Beta-Blocker Reduction of Mortality and Reinfarction Rate in Survivors of Myocardial Infarction: A Cost-Benefit Study (PMA Cost-Effectiveness of Pharmaceuticals Report Series, April 1984).

Arthur D. Little, Inc., Report 8: Use of a Beta Blocker in the Treatment of Glaucoma: A Cost-Benefit Study (PMA Cost-Effectiveness of Pharmaceuticals Report Series, April 1984).

Arthur D. Little, Inc., Report 9: Use of Beta Blockers in the Treatment of Angina: A Cost-Benefit Study (PMA Cost-Effectiveness of Pharmaceuticals Report Series, April 1984).

J. Adams, Report 1: The Societal Impact of Pharmaceuticals: An Overview (PMA Cost-Effectiveness of Pharmaceuticals Report Series, Feb. 1984).

T. Dao, Report 5: Cost-Benefit and Cost-Effectiveness Analysis of Pharmaceutical Intervention (PMA Cost-Effectiveness of Pharmaceuticals Report Series, March 1983).

J. Haaga, Report 3: Cost Effectiveness and Cost-Benefit Analysis of Immunization Programs in Developing Countries: A Review of the Literature (PMA Cost-Effectiveness of Pharmaceuticals Report Series, Sept. 1982).

A. Vinokur, C. Cannell, S. Braker, F.T. Juster, J. Lepkowski & N. Mathiovetz, Report 6: The Role of Survey Research in the Assessment of Health and Quality-Of-Life Outcomes of Pharmaceutical Interventions (PMA Cost-Effectiveness of Pharmaceuticals Report Series, June 1983).

J. Wagner, Report 4: Economic Evaluations of Medicines: A Review of the Literature (PMA Cost-Effectiveness of Pharmaceuticals Report Series, October 1982).

B. Weisbrod & J. Huston, Report 2: Benefits and Costs of Human Vaccines in Developed Countries: An Evaluative Survey (PMA Cost-Effectiveness of Pharmaceuticals Report Series, July 1983).

COST-EFFECTIVENESS OF PHARMACEUTICALS

A Summary Report

April 1984

Pharmaceutical Manufacturers Association

FOREWORD

This paper summarizes the results of studies sponsored by the Pharmaceutical Manufacturers Association to determine the cost-effectiveness of pharmaceutical products. The studies prove what has long been assumed: that drugs are an economical form of medical therapy and that they can substantially reduce overall health-care costs. For a cost-conscious age, the value of pharmaceuticals cannot be over-emphasized.

This paper is a summary of nine reports:

- The first presents an overview of the social benefits of pharmaceuticals;
- three evaluate the literature on the cost-effectiveness of drugs and vaccines;
- three study the cost-effectiveness of beta blockers in preventing second heart attacks and in treating glaucoma and angina;
- one discusses a model developed for determining the cost-effectiveness of pharmaceuticals, and
- the final report examines ways to measure how drugs improve the quality of life.

Each report was prepared by an independent researcher, except the ones written by Thi D. Dao, Ph.D., Deputy Director of PMA's Office of Policy Analysis, on Cost Benefit and Cost-Effectiveness Analysis of Pharmaceutical Intervention and by John G. Adams, Ph.D., former PMA Vice President for Scientific and Professional Relations on The Societal Impact of Pharmaceuticals: An Overview. Drafts of each primary report were reviewed by experts in economics, medicine and health policy whose names are listed at the end of this document. We are grateful for their advice and assistance in preparing the reports for publication.

Lewis A. Engman

President

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The Nine Primary Reports

Project Advisory Panel

PMA Cost-Effectiveness Project Staff

Project Outside Reviewers

EXECUTIVE SUMMARY

In competitive markets, demand gravitates towards those products and services that work best and work cheaply. So it is in the market for medical services where rival therapies compete. Thus, it should come as no surprise to anyone familiar with the costs and benefits of medicines that for decades drugs have been steadily assuming work previously done by other therapies — increasing their contribution to the nation's health, and doing so as an ever-declining share of health-care spending.

Were one required to define "cost-effectiveness" by example, one would be hard put, even in the hypothetical, to construct a more apt illustration than drugs.

Although scientists and medical academicians have long recognized that medicines are cost-effective, relatively little has been done to document this seemingly self-evident fact.

This paper summarizes nine reports which in the aggregate make this proposition both obvious and unavoidable.

Cost-Effectiveness of Vaccines

In one report in this series, the use of vaccines in developed countries is shown to be cost-effective against measles, mumps, rubella, pneumococcal pneumonia in high-risk groups, pertussis, adenoviral respiratory infections, polio and influenza in the elderly.

One study of measles vaccine, for example, found that benefits were more than 10 times the costs over a nine-year period (that is, the benefit-cost ratio was 10.4:1). The benefit-cost ratio for mumps vaccine ranged from 3.6:1 to 7.4:1, and for rubella vaccine the ratio ranged from 8:1 to 27:1 for girls from 2 to 12 years of age.

Vaccines were also shown to be cost-effective in developing countries. Thus, a study found that benefits were 33 times the costs for measles immunization in Yaounde, Cameroon (a benefit-cost ratio of 33:1). Other studies showed ratios of 2:1 for tuberculosis vaccine in India, 3.3:1 for tuberculosis and DPT prevention in Indonesia and 9:1 for tetanus in Haiti.

Cost-Effectiveness of Drugs

Another report in this series, a literature review, shows that antibiotics, anti-tuberculosis drugs, anti-ulcer medicines, anti-psychotics and anti-hypertensive agents are all cost-effective.

In a study of the preventive use of an antibiotic, for example, the average annual cost of preventing urinary tract infections was found to be $85 per patient, compared to $126 for treating the infection--a saving of 33 percent. In another study, Medicaid expenditures were determined to be approximately 70 percent less for persons using a new anti-ulcer drug than for those not receiving the medicine. And a third study concluded that treating mental patients with an anti-psychotic drug was the least costly of five forms of therapy--lower by 26.1 percent to 62 percent—and was one of the most effective methods.

Cost-Effectiveness of Beta Blockers

Three other reports in this series examine for the first time the cost-effectivenes of beta blockers—a new class of cardiovascular drugs. These studies show that the benefits of these drugs far exceed their costs in preventing second heart attacks and in treating glaucoma and angina. In preventing second heart attacks, the net annual benefits of using a beta blocker were estimated to range from $1.6 billion to $3.0 billion. In treating glaucoma, the net annual benefits of using such a drug instead of surgery were estimated to range from $746 million to more than $1 billion. And in treating angina, the net annual benefits of using a beta blocker were estimated to be as high as $237 million—without even considering the improvement in health associated with a 40 percent reduction in the incidence of the disease.

Social Benefits of Drugs

The economic benefits of drugs do not necessarily include social benefits that cannot be quantified. These benefits are also summarized in the first of the nine reports.

Many contagious diseases that once were the leading causes of death in this country have been controlled through the development in recent years of anti-infective agents. These medicines have cut death rates from such diseases as tuberculosis, influenza, pneumonia, cholera, puerperal sepsis, scarlet fever, meningococcal meningitis, typhoid fever, dysentery, syphilis, smallpox and polio.

During the last 10 years, new medicines have helped reduce the death rate for what had become the leading killer throughout the industrialized world--cardiovascular disease. Medicines also have become increasingly effective against the disease Americans fear most—cancer. By late 1983, the five-year survival rate for cancer had risen to more than 50 percent. Modern medicines have helped to treat a wide range of other diseases--including mental illnesses, epilepsy, diabetes, arthritis, Parkinson's disease and glaucoma.

As the reports summarized in this paper make plain, medicines are cost-effective. They not only save lives, they save money.

INTRODUCTION

Pharmaceuticals are among the least expensive of health-care products and services Americans use when they are seriously ill, particularly when they are hospitalized. At the same time, prescription drugs often are the most effective treatment for many acute and chronic diseases.

These two factors—the relatively low cost of drugs and their obvious effectiveness--support the widespread view within the scientific and medical professions that drugs are cost-effective. Heretofore, only a limited number of studies have been undertaken to establish what has appeared to be self-evident.

For years, health-care studies focused on questions of equity and access — on the availability of health care to different people, rich and poor, black and white, urban and rural. But, recently, as expenditures for health care have risen to 10 percent of the Gross National Product, there has been increasing concern—by government, industry and the general public—about the cost of such care.

The studies summarized in this report respond to that cost concern by demonstrating what has previously been widely assumed--namely that drugs and vaccines are cost-effective medical therapy.

As used in this paper, the terms "cost-effectiveness" and "cost-benefit" analyses refer to systematic economic analytical techniques that compare the negative consequences (costs) and positive outcomes (effectiveness, benefits) resulting from drug therapy. A drug is cost-effective when it achieves the same result as another form of therapy at a lower cost. A drug is cost-beneficial when it confers benefits that exceed costs.

Studies of vaccines (Reports 2 and 3) show that they are cost-effective because they prevent diseases at lower costs than the diseases can be treated. Studies of cimetidine demonstrate that it is extremely cost-effective because it averts the need for more expensive duodenal ulcer surgery. The importance of other drugs as lower-cost substitutes for hospital or other institutional care is shown by the studies of anti-microbial and anti-psychotic drug therapy (Report 4).

The studies reviewed in these reports, however, contain methodological limitations — some inherent in the analysis but others avoidable if the proper methodology had been used. In Report 4, Judith L. Wagner, Director of Technology Research Associates, stated:

"Consistent definitions and methods of measuring the direct and indirect costs of illness do not exist....Perhaps the greatest shortcoming of the literature is the inadequacy of attempts to deal with the psychological benefits and costs that cannot be captured as indirect costs."

In response to this criticism, a model was developed for cost-effectiveness analysis of pharmaceuticals (Report 5). In addition, the feasibility of applying survey research techniques to measuring the psychological benefits and costs associated with drug therapy was analyzed (Report 6).

In applying this cost-effectiveness model to beta-blocker drugs (Reports 7, 8 and 9), it was found that their benefits far outweighed their costs in preventing second heart attacks and in treating glaucoma and angina. The benefit-cost ratio was estimated to be as high as 14:1, even without the inclusion of psychological benefits.

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SOCIAL BENEFITS OF PHARMACEUTICALS

(Report 1)

The development of safe and effective medicines is of relatively recent origin, as explained by John G. Adams, former PMA Vice President for Scientific and Professional Relations, in Report 1.

As late as 1930, drug companies in this country were still essentially simple manufacturing enterprises that undertook little research and development. At that time, there were no antibiotics, no corticoids, no tranquilizers, no anti-hypertensives, no anti-histamines and no vaccines against polio, measles, mumps and whooping cough. More than three-quarters of the prescriptions written by physicians were compounded by pharmacists.

New Therapeutic Age

It was the development of sulfanilamide in 1935 and of penicillin in 1941, combined with needs brought about by World War II, that produced the modern drug industry in the United States—and ushered in a new therapeutic age. A number of drug companies launched crash programs during the war to develop methods to mass-produce penicillin. Thereafter, the companies increasingly engaged in other research efforts that transformed the industry into a high-technology business based on scientific progress.

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During 1948-1958, pharmaceutical companies introduced 4,829 new products and 3,686 new compounds. According to a recent study, 150 of the 200 most frequently prescribed drugs in 1982 were developed since 1950.

As a result of this pharmaceutical research, enormous progress has been made in conquering disease. The value of modern medicines has perhaps been most succinctly stated by Victor Fuchs in his examination of health-economic issues, Who Shall Live? (Basic Books, 1974):

"Surgery, radiotherapy, and diagnostic tests are all important, but the ability of health care providers to alter health outcome...depends primarily on drugs....Our age has been given many names--atomic, electronic, space, and the like—but measured by impact on people's lives it might just as well be called the drug age."

Anti-Infective Agents

Many contagious diseases that once were leading causes of death in the United States have been controlled through the development of anti-infective drugs. The use of medicines, particularly antibiotics and other antibacterial agents, also has led to a reduction in surgery for such conditions as osteomyelitis, mastoid infection and brain and lung abcess.

diseases—tuberculosis, influenza and pneumonia—accounted for more than 25 percent of all deaths in the United States. Since that time, the death rate from tuberculosis has been dramatically reduced in this country partly as a result of the development of effective medicines. Some 10 pharmaceuticals—including several antibiotics—developed since the 1940s have helped to control the disease. In 1980, there were 27,749 tuberculosis cases and only 1,770 deaths caused by the disease in the United States compared to 84,304 cases and 19,707 deaths in 1953—a 91 percent reduction in deaths.

Vaccines

Similarly, anti-infective medicines and vaccines have helped to cut the death rates in this country from influenza, pneumonia and such other serious diseases as cholera, puerperal sepsis, scarlet fever, meningococcal meningitis, typhoid fever, dysentery and syphilis.

Dramatic successes have been achieved against smallpox and polio. During the 1920s, there were more than 530,000 cases of smallpox reported in the United States. Because of widespread vaccination, not one confirmed case of smallpox has been reported in this country in more than 25 years—not one throughout the world since 1977.

As recently as 1952, 57,879 cases of polio were reported in the United States. The Salk vaccine was introduced in 1955, followed by the Sabin vaccine six years later. The result: only eight cases of polio reported in 1983.

Vaccines also have provided immunity against infectious diseases such as measles, diphtheria, whooping cough, tetanus, rubella, mumps, pneumoccal pneumonia, hepatitis B and rabies.

Analgesics

Aspirin—introduced just after the turn of the century—was the first safe and effective non-narcotic analgesic, but its potency was limited. Although analgesics do not cure or appreciably alter the course of a disease, they can relieve pain and bring a sense of well-being in the presence of disease. The first non-opiate drug to match the opium alkaloids in analgesic potency was meperidine, synthesized in 1939. Some of the recently-discovered non-steroidal anti-inflammatory drugs also have excellent analgesic properties.

Cardiovascular Drugs

During the last 25 years, new medicines helped produce a substantial reduction in the death rate for what had become the leading killer in the United States and throughout the industrialized world—cardiovascular disease. In just the last 10 years, deaths from strokes declined by 43 percent, while deaths from heart attacks decreased by 25 percent. New medicines, including the thiazide class of diuretic hypotensives, beta blockers and calcium antagonists, were partly responsible for the improvement.

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Anti-Cancer Drugs

Medicines also have become increasingly effective in treating the disease Americans fear the most—cancer. The first anti-cancer drugs, the nitrogen mustards, were introduced in 1942. Since that time, more than 50 other anti-cancer drugs have been developed. In late 1983, the National Cancer Institute reported that more than 50 percent of all cancer patients are surviving for at least five years—up from 33 percent in the mid 1950s—and that most of this group are cured of the disease.

Medicines have helped treat a wide range of other diseases—including mental illnesses, epilepsy, diabetes, glaucoma and Parkinson's disease—and, in all, have helped prolong and greatly improve the quality of life for millions of people throughout the world.

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REVIEW OF LITERATURE ON COST-EFFECTIVENESS OF VACCINES

(Reports 2 and 3)

Reviews of the literature on vaccines and vaccination programs both in developed and developing countries result in the same conclusion: their benefits generally exceed their costs, despite differences in evaluative approaches and in the data used.

Vaccines in Developed Countries

In Report 2, Burton A. Weisbrod and John H. Huston of the University of Wisconsin reviewed cost-effectiveness studies of 10 vaccines and vaccination programs in developed countries. The results of their review follow.

Measles: All seven studies of measles vaccine showed that its benefits far exceeded its costs. The unanimity of results was found even though the studies were conducted over many years—from 1963 to 1975—and in many regions of several countries—Austria, Finland and the United States. Of the two studies reporting results that can be expressed in benefit-cost ratios, one found that benefits were more than 10 times costs over a nine-year period (a benefit-cost ratio of 10.4:1), the other that benefits were almost five times costs over a six-year period (a benefit-cost ratio of 4.9:1). And in another study, benefits were shown to exceed costs by $1.3 billion from 1963 to 1972.

Mumps: Four evaluations of mumps vaccine found benefit-cost ratios ranging from 3.6:1 to 7.4:1 as well as significant net benefits. One study, for example, calculated a net benefit of $5 million for each cohort of 1 million children, while another found a net benefit of about $50 per immunization.

Rubella: Three studies found that benefits greatly exceeded costs when rubella vaccine was routinely given to children. For females from 2 to 12 years old, benefits ranged from eight to 27 times costs (that is, benefit-cost ratios ranged from 8:1 to 27:1).

Pneumococcal Pneumonia: Four studies of pneumococcal vaccine concluded that benefits exceeded costs for persons in high-risk groups, such as the elderly and chronically ill. This conclusion was reached even though no attempt was made to include the value of lives saved by the vaccine. The benefits from immunizing low-risk groups were less clear.

Pertussis: There is only one evaluation of pertussis vaccine, and it found that benefits exceeded costs by more than 150 percent.

The vaccine is given as part of the DPT (diphtheria, pertussis and tetanus) trivalent vaccine, so the costs of patient and physician time for administering the vaccine are minimal. The major costs arise from the infrequent side effects of the vaccine, which can include convulsions and encephalitis.

Adenovirus: A study of military recruits found that the benefits of adenovirus vaccine exceeded costs by 1.56:1.

Tuberculosis: The results of the studies of the BCG (bacille Calmette-Guerin) vaccination for tuberculosis are contradictory. One study, using Austrian data, found that the benefits of the vaccine substantially exceeded costs regardless of the age of those vaccinated. Another study, using British data, found that costs exceeded benefits using a wide range of vaccine costs and many methods of treating tuberculosis. More than anything, the different findings of the two studies probably reflect disparities in methodology.

Polio: Two studies of polio vaccine found it cost-beneficial by a ratio as great as 10:1, with net benefits estimated to be about $1 billion a year in the United States. As with most vaccine studies (and, in fact, all evaluations of medical technology), however, the social benefits were understated because the better health of people for whom the disease was prevented was not taken into account. This is especially significant in the case of polio because of the crippling effects of the disease and the youth of its victims.

Influenza: The evaluations of flu vaccine have focused on the benefits and costs of vaccinating people in various age groups. That is because the consequences of contracting influenza appear to be related to age and to a person's health immediately before infection.

One study—which examined the immunization of persons 25 to 65 years of age—found benefit-cost ratios ranging from 2:1 to 5:1 for two types of workers over a five-year period. A study by the Congressional Office of Technology Assessment found that vaccination of persons at high risk was more cost effective than vaccination of the general populations.

Hepatitis B: Cost-effectiveness analyses for hepatitis B vaccine—which only became available in June 1982—have been undertaken for different vaccination strategies in different population groups. The results are quite speculative, however, because the vaccine is so new. One study found that for a "medium-risk" population--surgical residents in hospitals—the least costly approach was to vaccinate the entire target group.

Vaccines in Developing Countries

In Report 3, John G. Haaga of Cornell University reviewed the literature of some 20 cost-effectiveness studies of immunization programs in developing countries and concluded that the programs substantially improved public health and economic welfare.

One study showed that benefits were 33 times costs for measles immunization in Yaounde, Cameroon (a benefit-cost ratio of 33:1). Other results found benefit-cost ratios of 2:1 for tuberculosis in India, 3.3:1 for tuberculosis and DPT prevention in Indonesia and 9:1 for tetanus in Haiti.

The cost of vaccines, Haaga emphasized, constituted only a small part of total costs. Delivery costs were the largest. The cost per immunization ranged from a few cents to more than $20, with much of the variation attributable to differences in the number of persons immunized and in health-care infrastructures.

Generally, the studies were limited by lack of complete data showing the extent to which immunization programs succeeded in reducing the incidence of disease and mortality. As Haaga reported, however, the available data demonstrate that immunization programs substantially improved the health of people in developing countries.

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REVIEW OF LITERATURE ON COST-EFFECTIVENESS OF PHARMACEUTICALS

(Report 4)

In Report 4, Judith L. Wagner, Director of Technology Research Associates, reviewed the literature on the cost-effectiveness of major classes of drugs for which such analyses had been done. A summary of her findings follows.

Anti-Microbial Therapy

Two kinds of studies were reviewed in this drug class: (1) studies evaluating the prophylactic use of antibiotic therapy in higher-risk groups, and (2) those considering the cost-effectiveness of alternative settings for antibiotic therapy.

Antibiotics in Prophylaxis: The prophylactic use of antibiotics shortly before or after surgery is a particularly appropriate subject for cost-effectiveness evaluation. That is because of the potential for savings in hospital costs and physician office visits, and because of the potential for reducing a patient's pain and possibly saving the patient's life. Clinical evidence clearly demonstrated that there is a significant reduction in surgery-related infections with the prophylactic use of antibiotics, but more economic evaluations are needed. The limited economic data also suggested that post-surgery antibiotics saved costs in some situations.

For patients with uncomplicated but recurrent urinary tract infections, the prophylactic use of antibiotics may well save more than the costs of such use. In one study of the prophylactic use of antibiotics, for example, the average annual cost of preventing urinary tract infections was found to be $85 per patient, compared to $126 for treating infections—a saving of 33 percent.

Alternative Settings of Care: Some serious bacterial infections require extended antibiotic therapy administered intravenously. Because of the difficulty of administration, the therapy often is given in a hospital and may be the only reason a patient is hospitalized. Two small uncontrolled studies of home antibiotic programs suggested that third-party reimbursement for such programs would be cost-effective. These small programs, moreover, probably understated the potential savings from home intravenous therapy because savings likely would increase as the number of participating patients rises.

Anti-Tuberculosis Drugs

Pulmonary tuberculosis—once a major killer in the United States—is a relatively rare and curable infectious disease in this country. As late as 1950, the death rate from tuberculosis in the United States was 22.5 per 100,000 people. By 1980, the rate had declined to less than 1 per 100,000.

This dramatic improvement is due at least in part to the development of effective preventive and therapeutic drugs. A succession of chemotherapeutic agents has proven effective against tuberculosis since 1948, when the efficacy of combined anti-microbial chemotherapy was demonstrated in Great Britain.

This success provides strong evidence that tuberculosis chemotherapy in patients with the disease is well worth its costs. Drug therapy is an undisputed bargain when the low cost of most anti-microbial drugs is compared to the cost of other therapeutic approaches, such as long-term hospitalization.

Anti-Ulcer Drugs

The introduction of a new medicine to treat peptic ulcer disease—a relatively common illness—shows dramatically how health-care costs can be reduced by the development of a single drug. In 1976, peptic ulcers accounted for the hospitalization of 620,000 Americans—which is about 175 such cases per 100,000 people. More than 25 percent of the patients who were hospitalized required surgery, the treatment of last resort for ulcer disease. In 1975, the total cost of this disease in the United States was about $2 billion.

In August 1977, a new drug—cimetidine—was approved for use in the United States for the short-term treatment of duodenal ulcers. Clinical evidence has demonstrated that cimetidine helps heal ulcers. The major

question for economic evaluation, however, is whether these clinical effects are translated into net direct, indirect and psychological benefits.

Studies here and abroad have shown that, immediately following the introduction of cimetidine, surgery rates declined. One study also found that cimetidine helped working patients—who previously missed work because of duodenal ulcer problems--return to their jobs more quickly.

A recent analysis of the impact of cimetidine on the costs of ulcer disease in Rhode Island found that surgery rates dropped after the drug was introduced. The authors estimated that this reduction in surgery in 1978 led to state-wide savings of $185,000 to $450,000.

Another study examined the impact of the introduction of cimetidine on health-care expenditures for Michigan Medicaid patients with ulcer disease. The result: Medicaid expenditures were approximately 70 percent less for persons on cimetidine than for those who did not receive the drug.

Most of the economic evaluations of cimetidine did not, however, consider its psychological benefits. Regardless of whether the drug reduces direct health-care costs or improves worker productivity, it may well be worth its cost just because patients suffer less than they would with other therapy.

The evidence on cimetidine, therefore, clearly demonstrates the effect that a single drug can have in reducing health-care costs.

Anti-Psychotic Drugs

The introduction of anti-psychotic drugs in the mid 1950s brought about a revolution in the care of patients with serious mental problems. The use of these drugs radically changed the prevailing view about the way to care for these patients, and the drugs were at least partially responsible for a rapid reduction in the number of patients in long-term mental hospitals in the 1960s. The social implications of the shift from institutions to community-care settings have been debated, but the importance of anti-psychotic drugs in making the move possible is undisputed.

The patients most affected by the development of anti-psychotic drugs are those with schizophrenia, which is characterized by a range of dysfunctional behaviors. In 1968, patients with schizophrenia accounted for an estimated 50 percent of all inpatient treatment for mental illness, and 10 percent of all outpatient visits. The direct and indirect costs of schizophrenia were estimated at about $10 billion nationally in 1973.

Most clinical studies have found that anti-psychotic drugs—such as the phenothiazines for the treatment of schizophrenia—are effective in preventing rehospitalization, although there are few economic evaluations of such drugs.

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Not only have anti-psychotic drugs helped schizophrenic patients remain out of the hospital, they also have increased the cost-effectiveness of hospital treatment. A randomized study of 228 first-admission patients in a California state hospital found that drug therapy alone was one of the two most effective treatments--and the least costly--compared to alternatives that included psychotherapy only, a combination of psychotherapy and drug therapy, electric shock treatment and care in a supporting environment. The drug therapy was lower in cost than the other forms of treatment by 26.1 percent to 62 percent.

None of the studies, however, considered the effects of adverse reactions to the phenothiazines. These reactions are dose-related, and have been estimated to occur in approximately 10 to 20 percent of the patients.

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A MODEL FOR COST-EFFECTIVENESS ANALYSIS OF PHARMACEUTICALS

(Report 5)

In Report 5, Thi D. Dao of the PMA's Office of Policy Analysis prepared a model for cost-effectiveness analysis of pharmaceuticals. The report describes research activities required to identify treatment protocols, alternative therapies and their respective outcomes, and resource utilization. In addition, it discusses quantification of benefits and costs; expertise requirements; and inherent strengths and weaknesses of cost-effectiveness methodology.

This model was the basis for the cost-effectiveness analyses of beta-blocker drugs in Reports 7, 8 and 9.

ASSESSMENT OF THE CONTRIBUTIONS OF PHARMACEUTICALS TO QUALITY OF LIFE

(Report 6)

In Report 6, Amiram Vinokur and his colleagues at the Institute of Social Research at the University of Michigan reviewed the application of survey research techniques to measuring improvements in the quality of life produced by drug therapy.

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THE USE OF BETA BLOCKERS:
NEW DATA ON THE COSTS AND BENEFITS OF PHARMACEUTICALS
(Reports 7, 8, and 9)

A.D. Little, Inc. conducted three cost-benefit studies of the use of beta blockers--a new class of cardiovascular drugs--to prevent second heart attacks and to treat glaucoma and angina. These studies compared the use of beta blockers to non-drug therapy--such as surgery--and to treatment without beta blockers. The results: the use of beta blockers produced benefits that greatly exceeded their costs.

Cost-Benefit of a Beta Blocker in Preventing Second Heart Attacks

In Report 7, in which the use of the beta blocker timolol to prevent second heart attacks was studied, the net annual benefits for the entire potentially eligible population were estimated to range from $1.6 billion to $3.0 billion. (The $1.6 billion benefit is based on a 10 percent discount rate that was used to convert future costs and benefits into their present values, while the $3.0 billion benefit is based on a 2.5 percent rate.) Benefits exceeded costs by a factor ranging from 8 to 14. These results were confirmed by sensitivity analyses, which are statistical techniques used to test the validity of research findings.

Other important findings about the beta blocker have shown that:

—The drug potentially is able to prevent death due to second heart attacks for 27.5 percent of all patients surviving an initial heart attack—approximately 10,000 persons a year.

—It is able to reduce the incidence of non-fatal second heart attacks by 16.0 percent.

—The use of the drug slightly increases the direct cost of treatment, but this is more than offset by a gain in productivity. The net result is a savings ranging from $4000 to $7500 per patient per year.

Cost-Benefit of a Beta Blocker in the Treatment of Glaucoma

In Report 8, the beta blocker timolol was found to be significantly more cost-effective than surgery in treating glaucoma. The net recurring annual benefits of using the drug for the entire potentially eligible population was estimated to range from $0.746 billion to $1.057 billion, based on 10 percent and 2.5 percent discount rates, respectively.

Further, the net recurring annual benefits of the beta blocker exceeded its net annual costs by a factor ranging from 8 to 13. The validity of these results also was confirmed by sensitivity analyses.