APPLICATIONS FOR PROCESS PATENTS

HEARING

BEFORE THE

SUBCOMMITTEE ON INTELLECTUAL PROPERTY AND JUDICIAL ADMINISTRATION

OF THE

COMMITTEE ON THE JUDICIARY HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

ON

H.R. 4307

APPLICATIONS FOR PROCESS PATENTS

MAY 5, 1994

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THURSDAY, MAY 5, 1994

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON INTELLECTUAL PROPERTY
AND JUDICIAL ADMINISTRATION,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:03 a.m., in room 2237, Rayburn House Office Building, Hon. William J. Hughes (chairman of the subcommittee) presiding.

Present: Representatives William J. Hughes, Don Edwards, Barney Frank, Carlos J. Moorhead, and Howard Coble.

Also present: Hayden Gregory, counsel; Jarilyn Dupont, assistant counsel; Veronica Eligan, secretary; and Thomas Mooney, minority counsel.

OPENING STATEMENT OF CHAIRMAN HUGHES

Mr. HUGHES. The Subcommittee on Intellectual Property and Judicial Administration will come to order.

The Chair has received a request to cover this hearing in whole or in part by television broadcast, radio broadcast, or still photography or by any or such methods of coverage in accordance with committee rule 5(a). Permission will be granted, unless there is objection.

Hearing none, such coverage will be permitted.

Today, the subcommittee is conducting a hearing on H.R. 4307 introduced by myself, my distinguished friend from California, Mr. Moorhead, and several of our colleagues. H.R. 4307 is intended to resolve a longstanding process patent issue which has been the subject of numerous hearings over several Congresses.

H.R. 4307 is a statutory solution to the longstanding problem. The legislation provides for a narrowly drawn change in patent law which will be applicable to all process patent applications which meet specific conditions. It will resolve the issue faced by certain process patent applicants without harm to the basic principles of patentability.

The problem addressed by H.R. 4307 involves the application of two different court rulings by the Patent and Trademark Office in the examination of process patent applications. The court holdings have created a situation in which process patent applications have been denied on the grounds that they are unjustified and inconsistent with other examinations. The biotechnology industry seems to be the most significantly affected by the contradictory practices of the patent examiners.

After extensive review and reexamination of the criticism of previously introduced broad changes, H.R. 1417, in the 101st Congress, I, like the administration, have concluded that the industry-specific approach is not the best solution and the approach taken by H.R. 4307 is perhaps better policy.

At the last hearing, I expressed the desire that this matter be resolved by the PTO administratively. There was also an expectation that the U.S. Court of Appeals for the Federal Circuit would act soon on two cases before it that might resolve the conflicts created by its previous rulings.

I am sorry to say that the court has failed to issue any opinions despite the lengthy period of time the case has been before it, now over 17 months. The PTO has concluded that it cannot resolve the problem administratively. Accordingly, a statutory solution is, in my judgment, in order.

[The bill, H.R. 4307, follows:]

I

103D CONGRESS
2D SESSION

H. R. 4307

To amend title 35, United States Code, with respect to applications for process patents.

IN THE HOUSE OF REPRESENTATIVES

APRIL 28, 1994

Mr. HUGHES (for himself, Mr. MOORHEAD, Mr. FRANK of Massachusetts, Mr. BOUCHER, Mr. SENSENBRENNER, Mr. FISH, and Mr. COBLE) 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, with respect to applications for process patents.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. EXAMINATION OF PROCESS PATENT APPLICATIONS FOR OBVIOUSNESS.

Section 103 of title 35, United States Code, is amended—

(1) by designating the first paragraph as subsection (a);

(2) by designating the second paragraph as subsection (c); and

(3) by inserting after the first paragraph the following:

"(b)(1) Notwithstanding subsection (a), a process using or resulting in a product that is novel under section 102 and nonobvious under subsection (a) of this section, shall be considered nonobvious if—

"(A) claims to the process and the product are contained in either the same application for patent or in separate applications having the same effective filing date; and

"(B) the product, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.

"(2) A patent issued on a process under paragraph (1)—

"(A) shall also contain the claims to the product used in or made by that process, or

"(B) shall, if such product is claimed in another patent, be set to expire on the same date as such other patent.".

SEC. 2. EFFECTIVE DATE.

The amendments made by section 1 shall apply to any application for patent filed on or after the date of the enactment of this Act and to any application for pat-

ent pending on such date of enactment, including (in either case) an application for the reissuance of a patent.

Mr. HUGHES. The Chair recognizes the gentleman from California.

Mr. MOORHEAD. Thank you, Mr. Chairman.

I very much appreciate you scheduling these hearings. I know the chairman's schedule has been busy as well as that of the full committee's and I do appreciate all of the effort that he has made in redrafting this legislation. I would also like to commend the gentleman from Virginia for all of his hard work on this important legislation.

From an economic point of view, the U.S. biotech industry has gone from zero jobs 15 years ago to $6 billion and 70,000 jobs today. The White House Council on Competitiveness Projects a $30 billion to $50 billion market for biotech products by the year 2000, and many in the industry believe this estimate is conservative.

Companies that depend heavily on research and development are especially vulnerable to foreign competitors who copy and sell their products without permission. The reason that high-tech companies are so vulnerable is that for them the cost of innovation, rather than the cost of production, is the key cost incurred in bringing a product to market.

In addition to the ability to obtain and enforce a patent, small companies in particular must be concerned about obtaining a patent in a timely fashion. In 1992, the pendency of a biotech patent application was 27 months with the backlog of applications increasing from 17,000 in 1990 to almost 20,000 in 1992. The Patent Office has taken steps to improve the situation by reorganizing its biotechnology examination group and increasing the number of new examiners. The PTO has also implemented special pay rates for their biotechnology examiners. As a result, biotech patent application pendency has been reduced from 27 months to 21 months, and the backlog in applications has been reduced from 20,000 in 1992 to 17,000 in 1994.

Although this is a slow progress, it is a substantial improvement. However, we must continue to reduce these delays because this industry is so dependent on patents in order to raise capital for reinvestment in manufacturing plants and new product development. And even more so for an industry targeted by Japan for major and concerted competition.

This subcommittee took the first step in 1988 in the omnibus trade bill, when the Congress enacted two bills which I introduced relating to the process patents and reform of the International Trade Commission. However, our work will not be complete until we enact H.R. 4307. This bill modifies the test for obtaining a process patent. It overrules *In re Durden* (1985), a case frequently criticized that has been cited by the Patent Office as grounds for the denial of biotech patents, as well as chemical and other process patent cases.

Because so many of the biotech inventions are protected by patents, the future of that industry depends greatly on what Congress does to protect U.S. patents from unfair foreign competition. America's foreign competitors, most of whom have invested comparably little in biotechnology research, have targeted the biotech industry for change and concerted action. According to the Biotechnology Association in Japan, the Ministry of International Trade and

Industry (MITI) and the Japanese biotechnology industry have joined forces and established a central plan to turn Japanese biotechnology into a 127 billion yen industry by the year 2000. If we fail to enact this legislation, the Congress may contribute to the fulfillment of that projection.

We will be told this morning by those who do the research, by those who take the risks and by those who do the manufacturing that there is a real problem out there that needs to be corrected. This is the fourth hearing on this type of legislation. We know there is a problem. Let's devise a solution and move this legislation to the floor of the House.

Thank you, Mr. Chairman.

Mr. HUGHES. I thank the gentleman.

I want to echo the sentiments of the gentleman from California when he praises Rick Boucher of Virginia who cannot be with us but who has submitted a statement which, without objection, will be made a part of the record. Rick Boucher has been in the forefront of the effort to basically address the conflict that has developed in process patents. And I want to congratulate him on his work.

[The prepared statement of Mr. Boucher follows:]

PREPARED STATEMENT OF HON. RICK BOUCHER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF VIRGINIA

Thank you, Mr. Chairman, for inviting me to speak to the issue of process patents addressed in H.R. 4307. This bill promises necessary patent protection to American inventors, and I commend you for introducing it. I am pleased to be an original cosponsor of this excellent measure, and I urge the subcommittee to give it every favorable consideration.

Mr. Chairman, we are all familiar with the purposes of this important legislation, but let me briefly review its history and background. When Congress amended our patent law in 1988, it provided that unauthorized use of a patented process by someone inside or outside the U.S. comprised an act of patent infringement. The purpose was to prevent the unfair use of American innovation. These amendments, unfortunately, did not address the unique needs of the biotechnology industry.

The biotechnology industry employs highly trained scientists and engineers throughout the country. Our biotech industry is a clear leader in world trade.

Intellectual property protection is key to maintaining that lead. But traditional product

patent concepts of obviousness and novelty can block intellectual property protection for biotechnology, despite the millions of research and development dollars and hard work that American companies and their scientist put into vital innovations in this area. These innovations may well provide new treatments and cures for breast cancer, AIDS, and Alzheimer's disease.

Despite these impressive goals, deficiencies in our patent law grant unfair advantages to foreign competitors and threaten the long term viability of the industry. We are seeking to put American companies on an even footing with their Japanese and European competitors by providing patent protection for the production process, so long as the starting material is novel.

This problem arises when biotechnological processes are used for new drug development. If we continue to deny such process patent protection, we will dampen American invention and initiative, jeopardizing future drug development and the economic and medical benefits that accompany it.

The U.S. Patent Office has taken the position that it is barred from granting appropriate patent protection for the processes used to make biotechnology products because of an aberrant court case, the rule of which the Patent Office agrees should be reversed. This situation is particularly unfair because our trading partners in Japan and Europe can obtain such security from their patent office counterparts.

In modern biotechnology, an inventor often may develop a novel, patentable starting material, such as a host cell, DNA sequence or vector, and use a process previously used in another context to create a non-patentable final product. The final product cannot be patented because it naturally occurs in minute quantities. In these cases, the U.S. does not grant process patent protection, while other countries will. Foreign competitors are then free to take the novel starting material out of the country, use an identical process to produce the biotechnology product, and then re-import the product into the U.S., circumventing the U.S. inventor's patent on the starting material. In these circumstances, it is our goal to make the process patentable.

In last week's Washington Post, I read an article about laboratory-grown anti-bodies which show promise as "magic bullets" to fight infection, cancer, organ rejection, and chronic diseases such as rheumatoid arthritis. Biotechnology offers great promise for the future health of all Americans. Mr. Chairman, if such "magic bullets" exist, let us promote innovation by clarifying the rules by which the PTO issues process patents, as H.R. 4307 does.

The legislation under discussion today will address patent law uncertainty by clarifying the issue of obviousness in process patent claims. It has been pending, in one form or another, for several years. I hope that with your leadership, Mr. Chairman, we will see it enacted this year. In passing legislation, we will allow the United States to keep its global lead in a uniquely American industry, generating billions of dollars for our economy.

Mr. HUGHES. Barney Frank of Massachusetts has also been in the forefront of the effort to resolve this issue, and I want to thank Barney for his work on process patents.

Now the Chair would recognize the gentleman from California.

Mr. EDWARDS. I have no statement.

Mr. HUGHES. The gentleman from Massachusetts.

Mr. FRANK. Mr. Chairman, thank you for your words and also for the leadership you have shown in addressing this issue.

I hope we will enact legislation. We have a very important industry which has been unsettled by a decision, and I think it is our responsibility to resolve that issue.

To those who have problems with it, I would address the plea that they respond not with don't do anything, but with specifics. If they think there are particular aspects of it that could do them damage, let us know.

I am especially unimpressed with references to 200 years of patent law. If I had more sense that the people in 1790 knew a lot about biotechnology, I would be impressed with the immutability of the law in this regard. But given the fact that we are dealing here with something which did not exist in the 18th century, I am loath to credit the Founding Fathers with that degree of prescience. Albeit, I am greatly respectful of them, citing them with regard to biotechnology, does not seem to be helpful.

The notion that Congress has no role and that there should not be statutes is not a serious argument. Those of you who from time to time tell us never to change the patent law, from time to time tell us to change it, and rather than have these kinds of, frankly, ritualistic acts of obeisance to the unchanged law, I would welcome specifics.

And there is no question, there are questions. And we have gone back and forth among ourselves. Should this be industry specific? Are there particular safeguards we can put in? I would be pleased to listen to this.

But one of the important industries like biotechnology, which is important both for the good it will do in terms of the products developed and as a source of economic activity, and it is important, one, not only for my State but for this Nation as we look at what the United States' role will be in the world and what kinds of things we can look to in terms of our own economic activity.

Biotechnology is the kind of extremely high value-added, intellectually based activity that we have to count on for much of our wealth generation in the future. Simply to ignore this industry's very legitimate concerns would be in error.

And so I appreciate you giving us this chance, and I look forward to people being constructive and telling us if they have a problem with this or that aspect and going forward.

Mr. Chairman, I think you have done a very good job. I think we have a bill that I can vote for, but I would be willing to listen to anyone who has any specific changes that they would propose.

Mr. HUGHES. I thank the gentleman for his usual, insightful analysis of where we are. We have really agonized over this issue for the better part of a year and a half. And it is my hope that all the witnesses today will attempt to be constructive and suggest how we can improve it.

I looked, specifically, at the industry-specific remedy, and I had hoped that the courts would resolve it. I had hoped that the PTO would resolve it, but they haven't. We are trying to set good policy. And so I hope that the witnesses will heed the constructive suggestions of the gentleman from Massachusetts. Tell us how we can do it better.

Michael Kirk, our first witness, is presently the Administrator for Legislative and International Affairs for the Patent and Trademark Office. He has also been designated as the Deputy Commissioner of Patents and Trademarks. He has had a long and illustrious career at the Patent and Trademark Office. He has been a principal U.S. negotiator for trade-related intellectual property rights issues in the Uruguay Round of GATT talks.

He received his bachelor of science in electrical engineering from the Citadel in 1959, and his juris doctor in 1965 from the Georgetown University Law Center. And in 1969, he added a master of public administration from Indiana University.

He has testified several times before us, and it is a pleasure to welcome him back. We have your written testimony, which, without objection, will be made a part of the hearing record.

Please summarize so that we can get right to questions.

STATEMENT OF MICHAEL KIRK, ADMINISTRATOR FOR LEGISLATIVE AND INTERNATIONAL AFFAIRS, U.S. PATENT AND TRADEMARK OFFICE, U.S. DEPARTMENT OF COMMERCE, ACCOMPANIED BY CHARLES VAN HORN, DEPUTY ASSISTANT COMMISSIONER FOR PATENT POLICY AND PROJECTS

Mr. KIRK. Thank you, Mr. Chairman. With me is Charles Van Horn, the Deputy Assistant Commissioner for Patent Policy and Projects.

We are pleased to testify on H.R. 4307, a bill that would amend our patent law to afford needed additional protection for inventions, including those in the field of biotechnology.

We believe our industry needs encouragement to expand its research and development efforts to continue its growth and competitiveness without falling victim to unfair competition.

Mr. Chairman, the administration supports this bill. We strongly support this bill.

Under present law, inventors cannot prevent importation of a product made abroad by a process which uses a material patented in the United States, unless they have patent protection for that process. Although not unique, the biotechnology industry is particularly susceptible to this problem.

We previously discussed before this subcommittee the example of the inventor who invents a patentable "host cell" that is used to produce a product, such as a new protein pharmaceutical. The engineered host cell receives a patent but the same cannot be said for the process of making the protein or indeed even the protein itself. This means, then, that someone can take this patented host cell offshore and produce it and import it back in, and the patent holder is totally without remedy to prevent this.

The judicial interpretations of patentability of processes based on patentable starting materials or resulting in patentable end products are in conflict, as we have discussed here before. And, we in

the Patent and Trademark Office, do not believe that we can craft a way through the judicial precedents without running afoul and putting in danger any patents that we might issue as a result of this.

As you have pointed out, the Court of Appeals for the Federal Circuit has yet to hand down its decision, notwithstanding having heard the *Ochiai* case in November 1992.

Thus, we are forced to determine on a case-by-case basis whether a process is obvious in view of the prior art, despite the fact that it starts with a patentable material or results in a specific patentable end product that is not part of the prior art.

As a consequence, we believe that without legislative guidance, patent applicants will continue to be unable to predict with certainty whether they can obtain process patent protections in situations where we believe it logically should be provided.

The amendment proposed by H.R. 4307 would simplify and provide certainty in the determination of patentability of processes of making or using novel and nonobvious products for applicants who comply with its requirements. This would make our patent law consistent with the patent examination standards now practiced in the European and Japanese patent offices.

However, because the proposed legislation applies to only one criterion of patentability, namely nonobviousness under 35 U.S.C. 103, it doesn't necessarily ensure the patentability of a process claim, even if the process claimed uses or makes a patentable product. That process could well be unpatentable because it does not satisfy the requirement of utility or because it is not sufficiently described to enable someone skilled in the art to use the process, thus failing to comply with 35 U.S.C., section 112.

Lastly, H.R. 4307 would provide an effective means of protecting technology patented in the United States from what we consider to be unfair foreign competition. It would not unduly burden the retail industry and consuming public because under section 271(g) of title 35, no infringement remedies against unauthorized retail sellers and noncommercial users of the product made by the patented process can be obtained, unless there is no adequate remedy available upstream against importers or wholesalers of that product.

Further, no remedy is available if the product was materially changed by subsequent processes or if it becomes a trivial and nonessential component of another product.

And, generally speaking, remedies for infringement are not available before the person subject to liability had notice of infringement with respect to that product.

When I testified before this committee last June on H.R. 760, the predecessor bill, I stated that the administration could accept legislation providing relief only for the biotechnology industry because a more comprehensive solution proposed by the predecessor bills of H.R. 760 had met with considerable opposition.

I also expressed, however, the administration's preference for a nonindustry-specific amendment to 35 U.S.C. 103 to address the legal uncertainties that continue to exist regarding the patentability of processes generally that make use of patentable materials. We continue to favor this approach, despite continuing opposition from some quarters because we do not agree with arguments that

this legislation would lower the standards for obtaining patent protection in this country.

Rather, if protection of a patented product is to be meaningful, it must enable the patent owner to prevent the harm in this country stemming from unauthorized activity, regardless of whether that activity is carried out here or abroad.

Enactment of H.R. 4307 would prevent competitors from unfairly circumventing the rights of a patent owner simply by shifting the location of their infringing activities. It would close a loophole in U.S. law providing an unfair advantage to our foreign competitors; a loophole that doesn't exist in the laws of Japan and Europe.

I would be pleased to answer any questions. Thank you.

Mr. HUGHES. Thank you, Mr. Kirk.

[The prepared statement of Mr. Kirk follows:]

PREPARED STATEMENT OF MICHAEL K. KIRK, ADMINISTRATOR FOR LEGISLATIVE AND INTERNATIONAL AFFAIRS, U.S. PATENT AND TRADEMARK OFFICE, U.S. DEPARTMENT OF COMMERCE

Mr. Chairman and Members of the Subcommittee;

I am pleased to testify on H.R. 4307, a bill that would amend our patent law to afford needed additional protection for inventions, including those in the field of biotechnology. The Administration supports the intent of this bill to improve U.S. patent law to stimulate the development of new products and processes. Our industry needs encouragement to expand its research and development efforts to continue its growth and competitiveness, without falling victim to unfair foreign competition.

Section 1 of H.R. 4307 would amend section 103 of title 35, United States Code, to ensure that under certain circumstances a process would not be considered obvious if it either makes or uses a product that itself is novel and nonobvious. To obtain this determination, the process and product claims must be sought to be

patented in the same application, or in separate applications having the same effective filing date. In addition, the product and the process must be owned by the same person and the claims to the product and the process must be issued either in the same patent, or in different patents expiring on the same date.

Under present law, inventors cannot prevent importation of a product made abroad by a process which uses a material patented in the United States, unless they have patent protection for that process. Although not unique, the biotechnology industry is particularly susceptible to this problem. Take the common example of an inventor who develops through genetic engineering a "host cell" that will be used to produce a product, such as a new protein pharmaceutical. The engineered host cell is likely to receive patent protection. The same cannot be said for the processes used to make or use the host cell, and even the protein pharmaceutical itself. This may be because the processes are conventional combinations of well known procedures, or that the protein was known, even if only in trace quantities, before the inventor developed a way of producing it on a commercial scale. The result in both instances is that the inventor can take action only against a party that uses the host cell within the United States. A third party can, therefore, use the patented host cell outside of the United States, import the resulting product, and effectively circumvent liability for patent infringement. See, e.g., Amgen Inc. v. United States International Trade Commission, 902 F.2d 1532, 14 USPQ2d 1734 (Fed. Cir. 1990). Foreign piracy of U.S. technology through exploitation of a legal loophole such as this should not be tolerated.

The problem has been aggravated by two factors: (1) the present state of court precedent interpreting the statutory law governing the patentability of processes using patentable "starting" materials, and (2) the rapidly evolving state of the art

in genetic engineering of proteins. Current law interpreting the patentability of processes based on patentable starting materials, or resulting in patentable end products, stems from two holdings by the U.S. Court of Appeals for the Federal Circuit. In In re Durden, 763 F.2d 1406, 226 USPQ 359 (Fed. Cir. 1985), the Federal Circuit held, on the facts before it, that a process of using a patentable "starting compound" to make a patentable "end product" was not patentable. The court reasoned that because the process itself was well known for compounds similar to the patentable starting compound, applying the process to this compound would be obvious. The Federal Circuit was careful to indicate in its opinion that the patentability of each process must be evaluated on a case-by-case basis. Thus, in following the interpretation of the law by the Court in Durden, the Patent and Trademark Office cannot interpret 35 U.S.C. §103 to find a process based on patentable starting materials and yielding a patentable end product nonobvious, as a matter of course. Rather, the Patent and Trademark Office has been forced to determine, on a case-by-case basis, whether a process is obvious in view of the prior art, despite the fact that it is specifically based on a patentable starting material or results in a specific patentable end product.

The Federal Circuit had an opportunity to reconsider the Durden holding in In re Pleuddemann, 910 F.2d 823, 15 USPQ.2d 1738 (Fed. Cir. 1990). Pleuddemann invented a patentable starting material which he used in a process to make a patentable final product. Apart from the use of the patented starting material, the method of making the final product was conventional. The Federal Circuit held, on the facts of that case, that it was not obvious to use the patented starting material to make the patentable final product.

The Patent and Trademark Office believes that the result reached in Pleuddemann is correct from the standpoint of policy. Notwithstanding attempts by the Federal

Circuit in Pleuddemann to distinguish Durden, however, it is difficult, if not impossible, to reconcile these two cases, as well as an earlier decision by the Court of Customs and Patent Appeals in In re Albertson, 332 F.2d 379, 141 USPQ 730 (CCPA 1964). The legal standard governing the obviousness of processes that make or use patentable materials is again before the Federal Circuit, (In re Ochiai (Appeal No. 92-1446)). This appeal, raising as an issue the conflict between Durden, Albertson and Pleuddemann, has been under advisement since November 2, 1992.

Regrettably, we cannot be sure that the inconsistencies between Durden, Albertson and Pleuddemann will be resolved by the Federal Circuit in Ochiai. We fear, therefore, that without legislative guidance patent applicants will continue to be unable to predict with reasonable certainty whether they can obtain process patent protection in situations where logically it should be provided.

In this respect, the amendment proposed by H.R. 4307 would simplify and provide certainty in the determination of patentability of processes using or making novel and nonobvious products, for applicants who comply with its requirements. These processes would, of course, be deemed nonobvious only to the extent that they specifically recited using or making a particular patentable product. This would make our patent law consistent with the patent examination standards now practiced in the European and Japanese Patent Offices. However, because the proposed legislation applies only to one criterion of patentability, i.e., nonobviousness under 35 U.S.C. 103, it does not necessarily ensure the patentability of a process claim even if such process uses or makes a patentable product. That process could well be unpatentable because it does not meet the requirement of utility under 35 U.S.C. 101, or because it is not sufficiently described to enable someone skilled in the art to use the process, thus failing the

requirements of 35 U.S.C. 112. In sum, to be considered patentable, a process must meet a number of statutory requirements besides nonobviousness.

Lastly, H.R. 4307 would provide an effective means of protecting technology patented in the United States from unfair foreign competitors. At the same time, it would endeavor not to burden the retail industry and the consuming public because under section 271(g) of title 35, no infringement remedies against unauthorized retail sellers and noncommercial users of the product made by the patented process can be obtained, unless there was no adequate remedy available "upstream" against importers or wholesalers of that product. Further, no remedy is available if that product was materially changed by subsequent processes or if it became a trivial and nonessential component of another product. And, generally, remedies for infringement are not available before the person subject to liability had notice of infringement with respect to that product.

When I testified last June before this Subcommittee on H.R. 760, the predecessor bill of H.R. 4307 in this Congress, I stated that the Administration could accept legislation providing relief for only the biotechnology industry because a more comprehensive solution proposed by other predecessor bills had met considerable opposition. However, I also expressed the Administration's preference for a non-industry-specific amendment to 35 U.S.C. 103 to address the legal uncertainties that continue to exist regarding the patentability of processes making or using patentable materials. We continue to favor this approach, despite continuing opposition from some quarters, because we do not agree with arguments that this legislation would lower the standards for obtaining patent protection in this country. Rather, if protection of a patented product is to be meaningful, it must enable the patent owner to prevent the harm in this country stemming from unauthorized activity, regardless whether that activity is carried out here or

abroad. Enactment of H.R. 4307 would prevent unfair competitors from circumventing the rights of a patent owner simply by shifting the location of their infringing activities.

Section 2 of H.R. 4307 provides for the effective date of the amendment proposed by this bill. We favor the generally prospective application of the bill's provision, although it should be pointed out that it does permit a certain amount of retroactivity, because all patent applications pending on the date of enactment of this bill, including applications for reissue of patents, would be subject to its provisions. In accordance with section 251 of title 35, any patent granted no more than two years prior to the filing of a reissue application may be reissued, enlarging the scope of its claims. Thus, if the original patent disclosed a process of using a host cell claimed in that patent, a reissue application could be filed and would benefit from the new law. Of course, the enlarged scope of any reissued patent would be subject to the intervening rights provisions of 35 U.S.C. 252, and, therefore, the rights of persons who relied on present law regarding their business decisions would not be adversely affected.

H.R. 4307 would provide the means that could be used by applicants who desire greater certainty in obtaining protection for processes that make or use patentable products. As part of our patent laws this would close another loophole that so far has provided an unfair advantage to unauthorized users abroad of technology patented in the United States. I would be pleased to try to answer any questions you may have on H.R. 4307.

Mr. HUGHES. Is it accurate to say that the Patent Office has acknowledged that there is inconsistent application by the PTO examiners of the *Durden* and *Pleuddemann* holdings in the processing of patent applications?

Mr. KIRK. Yes, Mr. Chairman, we do acknowledge that. Our examiners, some 2,000-strong, are looking at a mixed 30-year history of whether or not such processes are or are not patentable, and we are simply not able to glean the necessary guidance from the case law to provide that guidance to our examiners. So, yes, there is inconsistent application.

Mr. HUGHES. Testimony will be given later in this hearing concerning the potential negative impact H.R. 4307 would have on the computer industry, in particular.

Let me go over the issue with you in detail and ask you for your response. If you are a company that receives a patent on a microprocessor, the company at the same time files a process claim claiming a use of this patentable microprocessor with a process which has long been in the public domain such as the process for performing direct memory access, under the present state of patent law, is it possible for the company to obtain a process patent?

Mr. KIRK. Under the present state of patent law, we think the answer would be uncertain; maybe, maybe not, depending on the way the examiner interpreted the case law. That is the problem that brings us here.

Mr. HUGHES. Do you have any specific examples of patents which have been granted under similar facts for the computer industry?

Mr. KIRK. I do not have any with me, no, sir.

Mr. HUGHES. Would there be a different result under H.R. 4307?

Mr. KIRK. Yes, there would be. Under H.R. 4307, the holder of the patent to the patented microprocessor could obtain a claim for using that microprocessor in terms of carrying out a particular program.

Mr. HUGHES. Do you anticipate any increase in computer process patent applications or patents granted for the computer industry under similar facts if this bill is enacted?

Mr. KIRK. Mr. Chairman, we do not. There might be arguments by some that computer manufacturers would file patent applications loaded up with process claims, claiming the use of their patented microprocessors with particular programs, particular software. But this is not going to increase the number of patent applications filed.

There may be circumstances where, due to considerations of whether a process and a product constituted a single invention or not, there might be a restriction requirement. But for the most part, we don't see that there would be any great additional number of applications filed.

Furthermore, from the standpoint of just commercial reality, we don't believe that this is likely to be a phenomenon that we would see—to see a microprocessor patentee obtain claims for the use of that processor with a particular program.

The marketplace reality speaks against this. What would the microprocessor patent owner do with those process claims? Certainly he would not try to enforce these claims against users in the United States. If a user walked into a computer store and knew

that one particular brand of microprocessor had all sorts of restrictions due to process claims on a patent, he simply would walk to the next aisle and buy a competitor's product where he could freely use any public domain software.

Second, we believe that it has been the history of the industry that when someone comes up with a new microprocessor, the last thing he wants to do is to impose restrictions. Inventors of new microprocessors usually encourage people to modify existing software so it can be used and to develop new software so it can be used. So restrictions of this type, we think were one to choose to do this, would be quickly self-correcting in the marketplace.

Mr. HUGHES. Did you read the testimony that is to be produced by a subsequent panelist, Richard Waterman of Dow Chemical Co.?

Mr. KIRK. Yes, Mr. Chairman.

Mr. HUGHES. The concern that he raises is something that I want to talk to you about. He provides an example in his testimony of a modified catalyst for making polyethylene, which is no different from any other polyethylene. Under present law, would the process that uses the catalyst that produces polyethylene possibly be patentable?

Mr. KIRK. Well, in the testimony, as I recall, he posited two different situations. One situation, the catalyst, when used in the process, produced a superior quality of polyethylene. And I think he suggested that the process for producing this superior quality of polyethylene using the patentable catalyst would probably be patentable.

He then suggested that the process of using the catalyst to produce polyethylene, that differed in no other way from polyethylene produced by any other catalyst, would not be patentable. This is what concerns us. We are right back into the situation of conflict between *Durden, Pleuddemann* and all of its predecessors.

One of the cases that we did find, after reading the testimony, the case of *In re Kuehl*, which is a case decided a number of years ago—let's see, in 1973 by the Court of Customs and Patent Appeals, the predecessor of the CAFC.

The court considered the patentability of a process claim for a basic cracking process for turning crude oil into gasoline and other products. That claim was very brief and it called for use of a patentable catalyst.

You had a patentable catalyst applied in a conventional cracking process. The claim read: "A hydrocarbon conversion process which comprises contacting a hydrocarbon charge under catalytic cracking conditions with the composition of claim six," that being the patentable catalyst.

The only thing that was different in this process from any other process of cracking was the new, patented catalyst.

The Patent and Trademark Office took the view that that was not patentable because you had a conventional process and the availability of the new patentable catalyst should not lend patentability to that claim.

The CCPA reversed and said, no, that is not right; you cannot consider that the patented catalyst was part of the prior art and, therefore, you can't consider that in making your determination of obviousness. So you wind up with a situation very analogous to the

situation in the testimony. You start with crude oil and wind up with some type of petroleum product—the same petroleum product that you wind up with in any cracking process, the only difference being that you have a patented catalyst, and the court said the process was patentable.

So if you applied this case to the example that Mr. Waterman cited, indeed that second process, where the polyethylene was——

Mr. HUGHES. So the bottom line is the result would be no different under this particular law?

Mr. KIRK. Under this case, yes, sir.

Mr. HUGHES. The gentleman from California.

Mr. MOORHEAD. Thank you, Mr. Chairman. I also want to welcome you this morning, Mr. Kirk.

Mr. KIRK. Thank you.

Mr. MOORHEAD. You have been very helpful to us many times in the past. There are members of the private bar who say there is no problem that we have to deal with here. On the other hand, the biotech firms say that there is a big problem. Which is it?

Mr. KIRK. Well, we think that the biotech firms have identified a problem. We do know, indeed, that there was one specific problem that existed and we believe that there still is a problem out there. We would, however, defer to the biotech industry to highlight all the specific problems that they run into, in a commercial sense.

Mr. MOORHEAD. Our chairman gave you an example in which you responded that if they filed a certain kind of a process claim, even if uncertain, it would be possible to get a patent under some circumstances.

Does this legislation that we are working with make it more clear and more certain when to grant such a patent?

Mr. KIRK. It would, Mr. Moorhead. It would make the situation clear and certain, which we believe would be promotive of more research and development, particularly in biotechnology.

Mr. MOORHEAD. When so much money is being spent on research and development of both products and processes under which they are to be manufactured, isn't it rather important that the law be specific enough so that people know what they are doing and what the probable result will be?

Mr. KIRK. Well, we would think that it would. The rallying cry for the creation of the Court of Appeals for the Federal Circuit was to bring certainty to the law. And we believe that the creation of the CAFC has fostered respect for the patent laws. So we think this would be very positive.

Mr. MOORHEAD. As you know, there is opposition to this legislation from patent lawyers who say that this bill creates a per se rule of patentability for process patent application. Is this really true?

Mr. KIRK. We do not believe it is true because we would still examine process claims, as I indicated earlier, for questions of utility, for questions of enablement, best mode, has it been adequately described to enable one skilled in the art to make and use the invention, et cetera. So it is not simply a per se rule of patentability, in our opinion.

Mr. MOORHEAD. Does the *Pleuddemann* case, which related to methods of using, solve all the problems created by the *Durden* case? Can you reconcile the two cases?

Mr. KIRK. Mr. Moorhead, this is the crux of our difficulty. In both *Durden* and *Pleuddemann*, we start with a patentable product. We then, through a process, create another patentable product. In one case, it was characterized as a process of "making" the second product. And the second case, *Pleuddemann*, it was characterized as a process for "using" the first product. So it seems to have some bearing upon whether you semantically call it "making" or "using." This, to us, is not the clear guidance that we need.

Mr. MOORHEAD. Thank you.

Mr. HUGHES. The gentleman from California. The gentleman from Massachusetts.

Mr. FRANK. Just one set of questions, and I appreciate very much what Mr. Kirk has told us.

On the question of industry-specific versus nonindustry-specific, the administration's preference is for the broader bill, as I understand it. Elaborate a little bit on why.

Mr. KIRK. Yes, Mr. Frank, we believe that this is an issue that is broader than just biotechnology. And we believe that it should not be possible for our foreign competitors to take advantage of the research efforts of American firms simply because our law denies them a use claim here in the United States, which the patent offices in their counties grant our competitors to keep our products out of their countries. So we think that having it across the board for all industries levels the playing field, and that is why we favor the broader approach.

Mr. FRANK. Is it the sense of the administration that if we don't do this, there would be some targeting? That you would have foreign competitors looking, in fact, to exploit the loophole that the *Durden* case may have left open?

Mr. KIRK. There has already been one case where there was an example with, I believe, the EPO host cell which has been cited. The host cell, patented in the United States was taken offshore where it was not patented, and the manufacturer then used that host cell to produce an unpatented product and was in the process of importing it into the United States. There was no remedy for this.

Mr. FRANK. With regard to the dangers that some of the people who have expressed opposition to the bill have articulated, you said you think that they are very unlikely to result. Would there be ways that we might develop language to reassure them?

Mr. KIRK. We have offered to meet with the opponents of the bill at any time to discuss their concerns to try to sharpen the bill. Our door remains open.

Mr. FRANK. There might be ways to make explicit the interpretations that you are talking about?

Mr. KIRK. Yes.

Mr. FRANK. Thank you. Thank you, Mr. Chairman.

Mr. HUGHES. The gentleman from North Carolina.

Mr. COBLE. Three questions. Are you aware of any problems encountered either by the Japanese or European patent offices in granting process patents without examining for obviousness?

Mr. KIRK. No, Mr. Coble, we are not.

Mr. COBLE. I thought that was the answer, but I wanted it on the record.

Does the Patent Office have any method for determining how many process patents directly relating to biotechnology have been denied on the basis of *In re Durden?*

Mr. KIRK. We do not, Mr. Coble. We simply have not been able to get a handle on a figure that would give us that information short of going through massive numbers—case after case after case. That is not a research project that we have undertaken.

Mr. COBLE. Timewise, it would be prohibitive?

Mr. KIRK. Yes.

Mr. COBLE. So you would not have even a ballpark figure?

Mr. KIRK. No.

Mr. COBLE. The proponents argue that the biotechnology industry is unique and that the problems with the *Durden* decision impact more than any other industry. Would the PTO agree with this conclusion?

Mr. KIRK. We believe that the impact today is certainly most pronounced in the biotechnology industry. There is no question about that. But, for example, the *Durden* case came out of a nonbiotech field, as I recall. So the problem is broader than just biotech.

Mr. COBLE. Thank you, Mr. Kirk. No further questions.

Mr. HUGHES. Just one more question and then I may have some that I want to submit to you and ask if you would respond to within 10 days.

Does the PTO foresee difficulties in issuing patents examined under the terms of this bill so that there would be no delays between the issuance of the process patent and the product patent?

Mr. KIRK. Mr. Chairman, we do not for the reason that if we assume that the product claim would be examined first and would issue first, and the process claim were to follow, we would require a terminal disclaimer to ensure that the process patent would expire on the same day. Next year when, hopefully, we will see the TRIPS Uruguay Round commitments implemented into our law, that problem will substantially disappear because the term would run from the date of filing rather than the date of grant.

Mr. HUGHES. Thank you very much. You have been very helpful to us today. We appreciate it.

Mr. Van Horn, thanks for joining us.

Mr. HUGHES. Our next panel consists of Gerald Mossinghoff, the current president of the Pharmaceutical Research and Manufacturers of America, formerly the Pharmaceutical Manufacturers Association, which represents over 100 research-based pharmaceutical companies.

Mr. Mossinghoff is a former Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, and he also has served as a U.S. Ambassador to the Diplomatic Conference on the Revision of the Paris Convention and the Chairman of the General Assembly of the United Nations World Intellectual Property Organization.

The public career of Mr. Mossinghoff also includes service as the Deputy General Counsel and Director of the Congressional Liaison Office for NASA.

In 1957, he graduated with a bachelor of science degree in electrical engineering from St. Louis University, and a juris doctor degree from George Washington University in 1961.

He is testifying on behalf of the Pharmaceutical Research and Manufacturers of America.

We welcome you today. You are certainly no stranger to the subcommittee and we are glad to have you with us today. We have your written testimony, which we have read, and we hope that you can summarize for us.

Mr. FRANK. Mr. Chairman, I think we should note that this is the first time Mr. Mossinghoff will be testifying before Congress with a new name. This is a very auspicious occasion. Specifically, since we are the Intellectual Property Subcommittee, we ought to take account of trademark changes or whatever.

Mr. MOSSINGHOFF. Thank you, Mr. Chairman. And in response to Congressman Frank, we have our application on file at the U.S. Patent and Trademark Office for the new name and acronym and logo that appeared in the Washington Post this morning. So we are using intellectual property to the fullest.

Mr. HUGHES. And I would like to introduce also Lisa Raines, the vice president for government relations for Genzyme Corp., a biotechnology company headquartered in Massachusetts, in which Mr. Frank has a passing interest.

From 1986 to 1993, Ms. Raines worked for the Industrial Technology Association, which is now the Biotechnology Industry Organization on whose behalf she is testifying today.

Ms. Raines previously worked for the Congressional Office of Technology Assessment. She received her bachelor's degree in economics from the State University of New York at Stony Brook in 1979, and her juris doctor in 1982 from the Georgetown University Law Center.

We welcome you. Also, Ms. Raines, we have your testimony which, without objection, will be made a part of the record in full. We hope both of you can summarize so that we can get right to our questions.

You may proceed, Mr. Mossinghoff.

STATEMENT OF GERALD J. MOSSINGHOFF, PRESIDENT, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)

Mr. MOSSINGHOFF. Thank you, Mr. Chairman.

This month the membership of the Pharmaceutical Manufacturers Association added the word "research" to our name to make sure that the public knows that we represent the biotechnology industry, the startup industries and the established pharmaceutical companies that do most of the research in the United States that results in virtually all the new drugs and biologics that are invented.

In the established pharmaceutical industry, the Boston consulting group determined that one-third of the projects in the bigger companies, a full one-third of their projects now involve biotechnology. It is really the wave of the future.

PhRMA strongly supports H.R. 4307 to amend section 103 so that a claim directed to a process using a patentable product would

be considered nonobvious and therefore patentable. This legislation will enable patent applicants to obtain claims directed to the use of starting materials or intermediates to produce end products that result in greater protection for such end products.

The availability of improved process protection in this country will enable the patentee to address the currently unfair situation in which a competitor can go offshore and take advantage of the research done by the U.S. companies.

Under current U.S. patent law, the patent owner has an effective remedy if the competitor's activities occur in the United States. The current law forces infringers offshore, taking not only the fruits of the research, but also jobs and economic activity offshore. So we fully support your bill, sir, and we hope that it is enacted soon.

Thank you Mr. Chairman.

Mr. HUGHES. Thank you very much.

[The prepared statement of Mr. Mossinghoff follows:]

PREPARED STATEMENT OF GERALD J. MOSSINGHOFF, PRESIDENT, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA)

Mr. Chairman and Members of the Subcommittee:

I appreciate the opportunity to appear before the Subcommittee today to express the support of the research-based pharmaceutical industry for H.R. 4307. The Pharmaceutical Research and Manufacturers of America or "PhRMA" (formerly the Pharmaceutical Manufacturers Association) represents more than 100 research-based pharmaceutical companies -- including more than 40 of this country's leading biotechnology companies -- that discover, develop and produce most of the prescription drugs used in the United States and a substantial portion of the medicines used abroad. PhRMA companies will invest over $13.8 billion in research and development this year, and rely heavily on the incentives and protections of the patent laws in their R&D endeavors. The legislation before this Subcommittee provides for a limited but needed change to section 103 of the patent code.

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H.R. 4307 will amend section 103 so that a claim directed to a process using a patentable product would be considered nonobvious and therefore patentable. Process claims would therefore not be subjected to a higher standard of patentability than are other inventions. This legislation, when enacted, will enable patent applicants to obtain claims directed to the use of starting materials or intermediates to produce end products and result in greater protection for such end products. The availability of improved process protection in this country will enable a patentee to address the unfair situation which is now occurring, particularly in the biotechnology industry, in which a competitor can make and use a patented intermediate in a foreign country and import into this country the final but unpatented product. Under current U.S. patent law, the patent owner has an effective remedy if the competitor's activities occur in the United States. The bill being considered by the Subcommittee today would effectively provide the U.S. inventor with a remedy under U.S. law if that same activity occurred in a foreign country rather than here.

The inventor's ability to obtain process protection under current law has been brought into question by decisions of the Court of Appeals for the Federal Circuit and the Patent and Trademark Office's implementation of those decisions. The

amendment to section 103 provides a needed, clear signal to both the Office in its implementation of the law and to the judiciary.

Earlier versions of this legislation would have restricted the scope of the legislation to the biotechnology industry. While the biotechnology industry presents a compelling case for the need for this legislation, the legislation obviously has application to other technologies as well, including traditional pharmaceuticals. The legislation being considered by this Subcommittee is also prospective in its application, and we support that approach.

Mr. Chairman, it is my privilege to appear here today to place PhRMA on record in support of H.R. 4307. I would be pleased to respond to any questions you or Subcommittee members may have.

Mr. HUGHES. Ms. Raines.

STATEMENT OF LISA J. RAINES, VICE PRESIDENT, GOVERNMENT RELATIONS, GENZYME CORP., ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

Ms. RAINES. Thank you, Mr. Chairman.

I am Lisa Raines. I am with Genzyme Corp., which is the largest biotechnology company in the State of Massachusetts and the fourth largest in the country with 1,800 employees. It gives you a sense of the scale of our industry. And yet there are over 500 companies, universities, and other organizations, that are members of the Biotechnology Industry Organization, which I am pleased to represent today.

Mr. Chairman, we are very happy to support your bill and to urge the subcommittee to act quickly on its enactment. I want to say just a couple of words about the biotech industry, rather than the legislation in particular, to focus on why it is so important to our industry that this legislation be enacted.

The biotech industry is an important new source of economic vitality for the United States. American scientists invented genetic engineering and American investors are providing the funding for developing these important new products.

We have gone from an industry that didn't exist 15 years ago to an industry that directly employs more than 100,000 people. We believe that our industry may employ more than a million within the next 10 years. The ability of our industry to grow and build, and to sell products not only here but overseas, depends on our ability to protect those inventions from piracy.

Under current law, we have got adequate protection against domestic competitors but not foreign competitors. Because of the interpretation of the *Durden* case by the PTO, we are left in a situation where a foreign competitor can take a U.S. patented invention overseas, use it to make an end product that is shipped back to the United States, and the American company, the patent holder, has no recourse.

Thanks to its early lead, the U.S. biotech industry should be able to claim a large share of the world market. Today we do. The question is whether we will in the future.

It would be unfortunate if our products came to be labeled "invented in America, made in Japan." Without adequate legal protection for our innovations, our industry's early investment and progress will be worth little in global competition. The patent system, which should reward innovators in biotechnology for their achievements, currently allows foreign-based piracy without penalty.

We feel that the threat of domestic or foreign piracy undermines investment in our industry and that only statutory changes such as those proposed in the pending bill would address our concerns.

Thank you very much, Mr. Chairman. I would be happy to answer any questions.

Mr. HUGHES. Thank you.

[The prepared statement of Ms. Raines follows:]

PREPARED STATEMENT OF LISA J. RAINES, VICE PRESIDENT, GOVERNMENT RELATIONS, GENZYME CORP., ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

SUMMARY

The American engine of innovation stands poised and ready to lead our economy into the next century. The fuel for that engine is a strong and vibrant intellectual property system. As a leader in research and development, a creator of breakthrough products, and a pioneer industry, the biotechnology industry relies heavily on protection against piracy and unfair competition. The Biotechnology Industry Organization supports H.R. 4307 because it clarifies the rules for issuing process patents. By enacting this bill, Congress will materially aid in developing incentives for discovering and marketing new, socially useful products in biotechnology.

BACKGROUND

This Subcommittee has conducted several earlier hearings on the subject of process patent protection. It is not necessary to repeat in detail material that has been included in earlier hearing records. It is, however, important to underline several fundamental points.

First, this Subcommittee has played an important, pivotal role in shaping intellectual property policy in the United States. This bill is no exception. The choices presented by

this bill are similar to those faced by the Subcommittee for other intellectual property bills. These questions include:

* Is this question appropriately before the Congress?

* Will the public interest be advanced by enacting the bill?

* Will enacting the bill serve the economic needs of the country?

The bill before this Subcommittee is clearly ripe for consideration; legislation addressing these issues has been pending in Congress for over four years. Congressional consideration is appropriate because, despite claims made four years ago by the same opponents as today that the courts would resolve this issue, that has not happened.

The bill will further the public interest in ensuring that inventors are commensurately rewarded for their contribution to the useful arts and science. This bill makes clear that, but for the underlying invention, there would have been no process to patent. Thus, the bill allows carefully crafted patents whose scope matches the nature and extent of the invention.

Finally, the bill would advance American economic interests because it would assist the American biotechnology industry in securing rights that are already granted to its international competitors in their home countries. It is important to recognize that the principal effect of the bill would be to prevent an inventor's foreign competitors from doing what his domestic competitors are already prohibited from doing under the claims of the product patent that must issue in order for process claims to issue under the bill.

WHY IS LEGISLATION NECESSARY

First, existing Federal statutory law, 35 U.S.C. section 103, requires that patent applications be examined as a whole. To the extent that court cases (In re Durden) and administrative practice within the Patent Office separate out the process part of an invention from the intertwined product claims, there is a conflict between the statute and case law that requires a resolution.

Second, as the evidence before the Subcommittee (e.g., surveys in 1990, questionnaire results in 1993, and testimony and staff interviews and letters in 1993) demonstrates, there is no consistent pattern of applying the existing law to process patent applications in the biotechnology area. Failure to clarify the

policy and the law in this area will continue to leave patent applicants with a "Tower of Babel" to interpret. This confusion, in turn, undermines investment confidence and can distort research priorities.

Third, adoption of this change in the law is consistent with the "analogy process" laws of our trading partners. The only clear winners from the perpetuation of the existing confusing state of the law are our foreign competitors.

Finally, the bill before the Subcommittee provides patent protection only to the specific process that an inventor applies to his own invention. It is consistent with the principle that patent claims should be no broader than the invention enabled by the inventor.

ARGUMENTS AGAINST THE BILL SHOULD BE REJECTED

Opponents of the bill have alternated in their objections between concerns about a biotechnology-specific bill (when legislation has been specific) and about a general bill (when legislation has been general). They cannot have it both ways.

Opponents of the bill have apparently conceded that there is a problem facing the biotechnology industry, but their solutions

are either self serving or wishful thinking. On the one hand, they have argued that more litigation by members of the patent bar will solve this issue. On the other hand, they have continually claimed that the judicial solution is just around the corner. They cannot have it both ways.

Opponents of the bill have argued that the legislation would permit the issuance of unexamined patents. This is not true. If enacted, this bill would continue to require the examination of all patent applications. In the narrow set of circumstances described in the bill (where there is a patentable starting material or end product), the examination would not look at the question of whether a method of using or making the patentable product is obvious. It is reasonable and appropriate for the bill to find, as a matter of law, that it can never be obvious how to make or use an invention that never existed before the patentee invented it.

Opponents of the bill have argued that this bill is inconsistent with the laws of other nations. This is not true. As the Patent and Trademark Office has testified, and as other materials in the record demonstrate, our European and Japanese trading partners do not face the same impediments to process patent protection as does the United States biotechnology industry.

Opponents of the bill have argued that there will be major problems with respect to computer software and hardware patents. If this is so, and the opponents recognize that the biotechnology industry has specific problems, how can they in good conscience object to an industry-specific solution? Do these same opponents object to other industry-specific intellectual property laws and regulations, including the semiconductor chip act or the rules for depositing program code with the Copyright Office?[1]

Opponents of this bill have argued that enacting a measure that serves to protect the inventions of a preeminent American industry will erode the strength of the patent system. This is not true. When the Court of Appeals invited Congress to correct a clear gap in the patent law in the Amgen (EPO) case, it did so because the patent law can always be improved.

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[1] "A foolish consistency is the hobgoblin of little minds, adored by little statesmen and philosophers and divines. With consistency a great soul has simply nothing to do. He may as well concern himself with his shadow on the wall. Speak what you think now in hard words and tomorrow speak what tomorrow thinks in hard words again, though it contradict everything you said today,--"Ah, so you shall be sure to be misunderstood."--Is it so bad then to be misunderstood? Pythagoras was misunderstood, and Socrates, and Jesus, and Luther, and Copernicus, and Galileo, and Newton, and every pure and wise spirit that ever took flesh. To be great is to be misunderstood." Ralph Waldo Emerson (1803-1882); American essayist, poet and philosopher; "Self-Reliance," Essay, First Series, 1841 (9-262).

Title 35 of the United States Code is not a holy writ handed down from on high. It was not even written by Thomas Jefferson. It was largely the product of a single Congress that happened to act in 1952. It is not now -- nor was it ever -- perfect.

The tragedy today is that an American inventor of a remarkable new biotechnology process can face unfair foreign competition without redress. That situation undermines confidence in the patent law and ultimately in the role of Congress to redress legitimate grievances.

CONCLUSION

The biotechnology industry urges the Subcommittee to act quickly to markup, report, pass in the House, and enact into law the pending measure. We fully support the Chairman in his efforts to bring to a close the often tortured process of legislative review. The time to act is now. The benefits will be real.

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LISA J. RAINES

Protecting Biotechnology's Pioneers

Patent laws must be amended to provide adequate protection for advances in genetic engineering.

The biotechnology industry is an important new source of economic vitality for the United States. American scientists invented genetic engineering and American investors have funded the research and development (R&D) that enables the biotechnology industry to translate cutting-edge science into economic growth. As a result, the United States leads the world in the research, development, and manufacture of biotechnology products. In 1991, sales totaled $5.8 billion, an 18 percent increase over 1990, and net exports exceeded $600 million. The White House Council on Competitiveness projects that by the year 2000, biotechnology will be a $50-billion industry.

Thanks to its early lead, the U.S. biotechnology industry should claim a large share of that market. But without adequate legal protection for its innovations, the U.S. industry's early investment and progress will be worth little in global competition. The patent system, which should reward the achievements of biotechnology pioneers, is allowing intellectual pirates to copy innovative biotechnology products without penalty. Under current law, inventors cannot obtain effective patent protection for the products themselves, the processes by which they are created, or even the original materials used in these processes. The threat of domestic or foreign piracy undermines continued investment in R&D. Only statutory changes can protect the U.S. competitive edge in biotechnology.

Endangered investments

One of the distinguishing characteristics of the biotechnology industry is the extraordinarily high level of investment in R&D. Since the inception of the biotechnology industry in the late 1970s, biotechnology companies have plowed at least $10 billion into long-term R&D programs; in 1991 alone, they spent $3.2 billion. They reinvested in R&D an average of 47 percent of the 1991 income generated by product sales—an average of $81,000 per employee. By comparison, pharmaceutical companies, traditionally considered the nation's most research-intensive, spent 14 percent of their 1991 income on R&D.

In such a research-intensive industry, the need to protect innovation is particularly urgent. Clearly, a

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pioneer company that commonly invests $100 million to $200 million to develop a new biopharmaceutical product must be assured that a competing company cannot pirate its intellectual achievements. And precisely because it is so expensive to innovate, other firms are highly motivated to find ways to short-cut the process.

Piracy is fairly easy to accomplish in biotechnology. For one thing, most scientific breakthroughs are routinely published in scientific journals, rather than being maintained as trade secrets. This aids research progress but makes it difficult to protect intellectual property. Once a journal has published an important scientific discovery, such as the genetic sequence that codes for a potentially important therapeutic protein, it is a fairly simple matter for other scientists to copy the product from this "recipe."

Biotechnology researchers can also use the equivalent of "reverse engineering" to reproduce competitors' inventions. When a company isolates or synthesizes a purified protein that appears to have therapeutic significance, it will begin preclinical and clinical trials of the substance to determine its usefulness in treating diseases. Once these studies begin, a competitor may obtain a sample of the material from a third party, such as a university where the trial is being conducted. It is then relatively easy to sequence the protein to determine its precise amino acid composition. This, in turn, enables the competitor to determine the gene sequence needed to synthesize the protein.

The tremendous cost of developing a new biotechnology product stands in stark contrast to the ease with which the product can be copied. Under these circumstances, clear and meaningful patent protection is essential.

Unpatentable products

Modern biotechnology began with the first recombinant DNA experiment in 1973. But it was not until 1980—when the U.S. Supreme Court held that a genetically engineered microorganism was patentable—that biotechnology companies formed to commercialize recombinant DNA technology. This decision suggested that "everything under the sun made by man," including biotechnological inventions, was patentable.

Though genetically engineered microorganisms that produce useful proteins and enzymes are clearly patentable, the resulting biopharmaceutical products often are not. To be patentable, an invention must be *novel*, *non-obvious*, and *useful*. For instance, traditional pharmaceutical products are synthetic molecules, which easily meet the principal criteria of patentability. By contrast, a genetically engineered protein can be considered novel only if it was never known before it was isolated and purified. For example, tissue plasminogen activator, a naturally occurring protein that dissolves the coronary blood clots that cause heart attacks, was totally unknown before it was isolated by researchers using biotechnology techniques; it has been patented.

However, if the scientific literature reveals that the protein has previously been purified to some extent, even if it has not been definitively characterized, it may be ruled unpatentable for lack of novelty. The fact that previously available methods did not allow scientists to isolate enough of the protein for any practical use is considered irrelevant.

The case of insulin demonstrates the drawbacks inherent in trying to patent biotechnology products. Insulin was discovered in 1921, when scientists first removed a dog's pancreas, making the animal diabetic. By extracting canine insulin from the excised pancreas, they were able to treat the dog's diabetes. Several years later, other scientists isolated human insulin from human cadaver pancreases. All that these scientists knew was that they had a test tube containing a trace amount of human insulin. They didn't know what the chemical structure was or how to manufacture it.

As a result, for more than 50 years after its discovery, human insulin was not available to treat diabetes. Instead, diabetics were forced to rely on animal insulin from the pancreases of slaughtered pigs and cows. This treatment was not always effective, since the immune system of some diabetics rejected the animal insulin as a foreign substance.

Nevertheless, the fact that human insulin had been isolated in the 1920s effectively barred the researchers who later made it possible to manufacture human insulin from obtaining a product patent. In 1951, Frederick Sanger succeeded in identifying the chemical structure and precise molecular weight of human insulin. This discovery won him the Nobel Prize, but it couldn't win him a patent. In 1979, David Goeddel synthesized recombinant human insulin, enabling patients the world over to gain access to the product they

desperately needed. He couldn't get a product patent either.

Protecting the process

In the absence of *product* patent protection, scientists can seek patent protection for the *process* used in making the product. Since genetic engineering is the only commercially feasible method for manufacturing human proteins, a patent on the recombinant manufacturing process can be tantamount to a product patent for biotechnology products, and many process patents have been granted. However, the ability of the biotechnology industry to obtain process-patent protection has been drastically circumscribed by the erroneous and inconsistent application of a recent Federal Circuit Court ruling.

The U.S. patent system is allowing intellectual pirates to copy innovative biotechnology products without penalty.

In a 1985 decision, *In re Durden*, the U.S. Court of Appeals for the Federal Circuit (CAFC) denied a process patent. The appellants in *Durden* sought to patent a chemical process for making novel carbamate products from novel oxime starting materials. The applicants acknowledged that carbamates had previously been produced by reactions involving oxime compounds, but argued that the specific oximes used in the process as well as the carbamates produced were original.

The CAFC summarized the problem as follows: "The issue to be decided is whether a chemical process, otherwise obvious, is patentable because either or both the specific starting material employed and the product obtained are novel and non-obvious."

The court decided that the process could not be patented. It argued that the use of a different reaction material in an otherwise familiar process does not constitute a new reaction process. Even the applicants admitted that the results of this particular process were predictable. The court cautioned against applying *Durden* to processes involving other disciplines, but did not explicitly restrict its scope.

In the six years since the *Durden* decision was issued, it has had a chilling effect on process-patent protection for the U.S. biotechnology industry. The U.S. Patent and Trademark Office (PTO) frequently cites *Durden* in denying patents to genetic engineering processes. A survey of the impact of *Durden*, commissioned by Genentech, a biotechnology company, shows that at least 60 percent of biotechnology product patents that do not have corresponding process patents can be directly linked to a *Durden* rejection.

The reasoning used in applying *Durden* to genetic engineering runs as follows: The basic process of genetic engineering is known. It consists of inserting a DNA molecule into a living cell so that the cellular machinery produces the specific protein encoded by the DNA molecule. Therefore, once a new DNA molecule has been invented, it is obvious that it can and should be used in a recombinant DNA process. Since non-obviousness is one of the three criteria for patentability, the process is not patentable.

The denial of process-claim protection is routine even if the starting materials are found by the patent examiner to be patentable in their own right. The *Durden* decision says, in effect, that it is obvious how to use an invention that never existed before.

In many cases, one can obtain a biotechnology process patent only if one can demonstrate that "unexpected results" occurred during the use of the otherwise "obvious" process. When unexpected results cannot be shown, process-patent protection cannot be obtained. Fully two-thirds of biotechnology process patents are issued only after a *Durden* rejection is made and later overcome with evidence of unexpected results.

Demonstrating unexpected results often requires additional scientific experimentation and extensive negotiations with the PTO, both of which add substantially to the expense of obtaining a process patent. Inventors with limited budgets, such as small companies and universities, are placed at a distinct disadvantage. The Genentech study found that all of the universities surveyed had forfeited the process-patent protection to which they appear to be entitled.

Other precedents

To complicate the situation further, the application of the *Durden* decision to biotechnology process patents

is completely inconsistent. Experience shows that some patent examiners are more likely than others to use *Durden* as grounds for rejecting patent applications; the luck of the draw often determines whether an inventor will obtain process-patent protection.

In fact, there are other legal precedents directly in conflict with *Durden* that are far more readily applicable to biotechnology processes. The most significant of these is *In re Mancy*, a case involving a process using traditional culture techniques on a new bacterial strain to prepare an antibiotic. Even though the same basic culture techniques had been used on other strains to produce the antibiotic using, the process patent was upheld because of the patentability of the new strain.

It seems logical that *Mancy*, rather than *Durden*, should be applied to biotechnology cases. The process described in *Mancy* is analogous to the preparation of a desired protein by culturing a previously unknown, genetically engineered cell. Indeed, the reasoning in *Mancy* underlies the law for inventions in Europe and Japan, both of which have a long tradition of patenting process inventions that use patentable starting materials.

Why, then, does the PTO apply *Durden* rather than *Mancy* to genetic engineering cases? The reason appears to be that *Durden* and *Mancy* are characterized as two different kinds of process inventions. *Durden* deals with a *process of making* an end product, whereas *Mancy* refers to a *process of using* starting materials. Indeed, a more recent case, *In re Pleuddeman*, stated that "there is a real difference between a process of making and a process of using and the cases dealing with one involve different problems from cases dealing with the other."

Genetic engineering *uses* starting materials to *make* an end product, so that it may fairly be characterized as either a method of making or a method of using. By electing—for reasons that are unclear—to consider all biotechnology processes as method-of-making cases, the PTO has ruled that they should be governed by *Durden*. But the fundamental question is not whether they are making or using processes, but why these processes receive different treatment from the patent office.

A Long Wait at the Patent Office

The growth of the biotechnology industry is mirrored by the growth of U.S. biotechnology patent filings. Between 1985 and 1990, the number of biotechnology patent applications filed grew at an annual rate of 15 percent, double the average rate for all technologies. In 1990 alone, 9,385 new biotechnology patent applications were filed.

Since the mid-1980s, the biotechnology industry has faced significant delays in the issuance of new patents. Despite efforts to correct the problem, these delays continue to increase. In the absence of a more timely process, it has been difficult for firms to attract the investment capital they need to refine and test their discoveries. This obstacle is a particularly serious one for small startup firms, which often have no assets other than their proprietary technology.

In 1987, representatives of the biotechnology industry proposed a series of patent-office reforms designed to improve the speed of patent issuance as well as the quality of the process. These reforms included increasing the number of biotechnology patent examiners, providing them with computers and adequate support staff, and establishing a cooperative effort between the patent office and the biotechnology industry to provide advanced training seminars for biotechnology patent examiners.

The PTO embraced these suggestions in a plan it developed to address the biotechnology patent backlog. Between 1988 and 1990, the biotechnology examining corps grew from 80 to 136 examiners. PTO also established the Biotechnology Institute, co-chaired by PTO staff and representatives from the biotechnology industry, to provide specialized technical and legal training.

Nonetheless, a recent report by the U.S. General Accounting Office (GAO) found that patent applicants from the biotechnology industry are facing even longer delays than before. The average biotechnology patent application languishes for 13 months before a patent examiner

Starting materials patents: An alternative?

If an end product is not patentable because it lacks novelty (as in the case of insulin) and the genetic en-

even begins the review. It routinely takes 48 months for the PTO to issue genetic engineering patents, compared to 18 months for patents in other areas. A simple lack of resources appears to be the culprit. For instance, plans to increase the number of biotechnology patent examiners to 200 by the end of 1991 have been put on hold by the PTO because of an office-wide hiring freeze precipitated by budgetary constraints. The lack of adequate staff is compounded by the high annual turnover rate within the biotechnology examining corps—a rate that sometimes exceeds 30 percent, roughly twice that for examiners working with other technologies. The high turnover rate is largely due to the substantial gap between public- and private-sector salaries for biotechnology patent lawyers.

High turnover rates result in greater inefficiency in a variety of ways. For example, in order to meet its staffing goals in 1990 and 1991, the patent office had to hire two new examiners for every new slot. Furthermore, since new examiners go through a training program that takes two years to complete, they cannot work independently until they have several years of apprenticeship. As experienced biotechnology patent examiners leave and are replaced by inexperienced examiners, there are fewer examiners available who can work independently. And the remaining experienced examiners must spend more of their time training new examiners and less of their time examining patent applications.

It would cost perhaps $5 million per year to hire new biotechnology patent examiners and to increase the pay rates of senior biotechnology examiners to a competitive level. Accordingly, the patent office has asked Congress to appropriate additional resources. The biotechnology industry strongly endorses the PTO's request and has expressed its willingness to shoulder an increase of 10 to 15 percent in patent fees toward this end. By supporting the innovation undertaken by small firms, the investment of such a modest sum could contribute substantial returns.
- L.J.R.

gineering process is not patentable because it is considered obvious under *Durden*, the inventor may nevertheless patent the starting materials. Obtaining a patent on a new DNA molecule or on the genetically engineered cell containing the inserted cell is relatively simple. However, unlike patents on products or processes, patents on starting materials fail to provide adequate protection from foreign competition.

A U.S. patent grants the right to prevent unauthorized parties from "making, using, or selling" the invention in the United States. If the patent is on an end product, then not only can the product not be "made" in this country without the patentee's permission, it cannot be "sold" in this country, even if it is manufactured overseas and subsequently imported into the United States. Legislation enacted in 1988 extended this principle to process patents: It prohibits not only unauthorized domestic use of the process but also the import of foreign-manufactured products if a U.S.-patented process was used in making them.

But current law does not give starting-material patents the same enforcement rights. The rulings in two cases involving the California-based biotechnology company Amgen show that, although unauthorized domestic use of U.S.-patented starting materials constitutes patent infringement, the patent does not give a company the right to prevent other companies from using these starting materials overseas and then exporting the finished product to the United States.

Amgen pioneered the development of erythropoeitin (EPO), a hormone produced in the kidney that stimulates the production of red blood cells. Amgen holds a patent covering the gene that codes for EPO and the genetically engineered host cell into which the gene was inserted. Its patent on the EPO gene and host cell effectively prevents anyone else from making EPO in the United States, since these starting materials are essential for the production of EPO using genetic engineering techniques and genetic engineering is the only known way to make EPO in commercial quantities.

However, a Japanese company, Chugai Pharmaceutical, obtained the starting materials from a U.S. company, Genetics Institute. Genetics Institute's own use of these materials was held to be an act of infringement, and the company is now enjoined from further manufacture. The use of U.S.-patented starting

materials by Genetic Institute's Japanese partner was *not* ruled to constitute infringement, even though the product is being manufactured for export to the United States.

In 1987, patent lawyers working for the biotechnology industry sought to strengthen the protection offered by biological starting-materials patents by making them enforceable at the border. The biotechnology Patent Protection Act, introduced in early 1990 by Representative Rick Boucher (D.-Va.) and Senator Dennis DeConcini (D.-Ariz.), contained provisions to overrule the *Durden* decision and to extend existing principles of process-patent law to patents on biological starting materials.

When the House Judiciary Committee's Subcommittee on Intellectual Property and the Administration of Justice held hearings on the bill in September 1990, substantial opposition focused on the provision prohibiting the import of products made with biological starting materials patented in the United States. Patent purists objected on principle to having a patent-law provision that applied to only one industry; at the same time, several chemical companies insisted that universal application would wreak havoc for the chemical industry, presumably because it would affect the import of chemical intermediates. There was no satisfying both sides.

Furthermore, by granting the U.S. International Trade Commission (ITC) authority to bar importation in cases like Amgen's, the legislation would have created diplomatic problems for our government, then (and now) in the midst of negotiations on the General Agreement on Tariffs and Trade. The U.S. Trade Representative had already conceded that the ITC violates GATT's prohibition against discrimination. (Domestic companies can go to the ITC and seek an exclusionary order to block products at the U.S. border if "unfair trade practices" are involved; foreign companies cannot.)

Finally, some legislators did not want to make the provision retroactive, which would have allowed Amgen to enforce its patent against Chugai. They felt that it would be unfair to undermine the investment made by Chugai and its U.S. partners, which was based on current patent law. Congress generally frowns on retroactive legislation and often "grandfathers" parties by exempting actions taken before a law is passed.

New strategy

Instead of taking this "belt-and-suspenders" approach, combining the legislative overruling of *Durden* with measures to expand the enforcement of patents on biological starting materials, the biotechnology industry is now focusing all its efforts on persuading the Congress to overrule the application of *Durden* to biological process patents. In March 1991, Representative Boucher and Senator DeConcini introduced a revised version of the biotechnology Patent Protection Act, which omits the controversial provision for prohibiting imports of products made with U.S.-patented starting materials. Although not as comprehensive as the earlier bill, it will nonetheless provide the necessary protection for an estimated 90 to 95 percent of worthy biotechnology inventions.

Because the bill requires the legislature to override a decision of the Federal Circuit Court and changes patent law dramatically, it might be expected to provoke considerable controversy. Nonetheless, a number of industries and dozens of universities have shown substantial support for overruling *Durden*. Even Harry Manbeck, the Commissioner of Patents and Trademarks, conceded in his October 1990 testimony before the House Intellectual Property Subcommittee that the PTO finds *Durden* to be confusing and inconsistent with other cases, so that overruling it would greatly clarify the law.

The Senate Judiciary Committee's Patent, Trademarks, and Copyrights Subcommittee held hearings on the biotechnology Patent Protection Act in June 1991. In July, the seven subcommittee members voted unanimously to support the legislation, and in November, the full Senate Judiciary Committee also approved it unanimously. It will go to the full Senate in early 1992. Hearings before the House Judiciary Committee's Subcommittee on Intellectual Property and the Administration of Justice were held in November 1991. The bill has earned bipartisan support in the House and Senate and has been endorsed by the Bush administration.

Opposition to the bill has been expressed by several groups, however, making enactment uncertain. The National Association of Pharmaceutical Manufacturers, which represents the generic drug industry, opposes the legislation because it would prevent foreign companies from exporting to the United States generic drugs that are manufactured overseas

using U.S.-patented chemical intermediates. The research-based pharmaceutical industry, on the other hand, believes that foreign companies should be prohibited from this practice. Our guiding principle is that if an activity is infringing if it is performed in the United States, then it should be infringing if it is performed overseas for the purpose of making a product for sale in the United States. A company should not be permitted to export its infringing activities so as to circumvent U.S. patent law.

In addition, many private-practice patent lawyers—and their associations such as the American Bar Association and the American Intellectual Property Law Association—object on grounds that the legislation would lead to "automatic" process patents, which would increase uncertainty in the law. Of course, these same lawyers benefit financially from the extended patent prosecutions that result from the current *Durden* problem.

The phenomenal growth and competitive strength of the biotechnology industry can be directly attributed to the willingness of scientists and investors to devote their lives and savings to the discovery and implementation of scientific advances. By extending the scope of patent protection for their endeavors, the United States can reward their efforts and ensure the continued advancement of the biotechnology industry.

Recommended reading

In re Durden, 763 F.2d 1406 (Federal Circuit Court 1985).

In re Mancy, 499 f.2d 1289 (Court of Claims and Patent Appeals 1974).

Isabelle McAndrews, "Removing the Burden of Durden Through Legislation: H.R. 3957 and H.R. 5664," *Journal of the Patent and Trademark Office Society*, vol. 72 (1990): 1188.

David Beier and Robert H. Benson, "Biotechnology Patent Protection Act," *University of Denver Law Review*, vol. 68 (1991): 173.

G. Steven Burrill and Kenneth B. Lee, Jr., *Biotech '92: Promise to Reality*. Washington, D.C.: Ernst & Young, 1991.

Mr. HUGHES. Mr. Mossinghoff, the opponents of the bill contend that these patents will be unexamined patents thus bringing into question the validity of the entire patent process in this country.

Do you perceive any problem with the validity of H.R. 4307, if enacted?

Mr. MOSSINGHOFF. I disagree with that. I agree fully with Assistant Commissioner Kirk that these will clearly be examined claims against all the standards that the examiners examine other claims against. It is simply removing what I believe is an artificial impediment to getting valid process claims.

I was an examiner for 4 years while I went to George Washington Law School, in the electronics area. The *Durden* case didn't exist and I think we would have done exactly what this bill would permit doing during those 4 years.

Mr. HUGHES. Do you think that H.R. 4307 will lead to the filing of process claims that are broader than those claims filed today?

Ms. RAINES. No, I don't think they will be any broader.

I think one of the misconceptions that some of the opponents of the legislation have suggested is that somehow processes will be taken out of the public domain and assigned to an individual. The thing to keep in mind is that the process claims to which this legislation would entitle an inventor are only the uses of the patented material in a corresponding process. That is to say, allowable claims would be limited to the process on using something the applicant invented. And since the applicant invented the product, nobody has ever used that product in a process before. So we are looking at very specific, narrow process claims strictly corresponding with the extent of the contribution of the inventor in that particular field.

Mr. HUGHES. Thank you. The gentleman from California.

Mr. MOORHEAD. Thank you, Mr. Chairman.

These questions are to either one or both of you, but I want to welcome each one of you here this morning.

Can you explain to the subcommittee why end product patent protection is especially weak for biotechnology products, and why strong process patent protection is so important to the biotech industry?

Ms. RAINES. Yes, Mr. Moorhead, I think an example is the easiest way to illustrate this. Unlike the traditional pharmaceutical industry which has come up with novel molecules that have never existed before, and, therefore, are easily patentable, in biotechnology often what we are trying to do is identify a substance that is in a healthy human body and try to find a way to make it for an unhealthy person who is not making it on his or her own.

Human insulin was first identified in 1930 from a cadaver in such minute quantities that you couldn't have treated a single individual. And there was no way to treat a single individual, let alone enough to run a clinical trial or get involved in commercial marketing. Forty years later, a biotechnology company identified the human gene that codes for insulin and developed a process for making that product by inserting a human gene into a single celled organism.

Although it was the first time that product was made in commercial quantities, the product was not patentable because of what a

scientist did 40 years ago. It is not novel, which is one of the criteria for patentability. So we have a number of biotech products that are proteins in our bodies. We knew they existed, but we couldn't make them before in any significant quantity and, because we had isolated them in the past, they are not patentable.

Mr. MOORHEAD. Do the large and small biotech companies agree with you that this legislation is needed if they are going to protect the industry in the future?

Ms. RAINES. Yes, Mr. Moorhead, there is very broad, I would say virtually universal support for this legislation, and there has been for legislation of this type for the last 5 years.

Mr. MOSSINGHOFF. I would respond, also, Mr. Moorhead, not only the large biotech companies, but also the large pharmaceutical companies support this because it is broader than just what is referred to as biotechnology. It would apply to antibiotics and to vaccines. There is strong and unanimous support within PhRMA for this legislation.

Mr. MOORHEAD. What would be the effect on the biotech industry if, instead of passing legislation to strengthen process patent protection, we waited for the courts to resolve the issue?

Ms. RAINES. I think we would be waiting for a very long time. The opponents of this legislation have been asking us to wait for that resolution for 4 years. Even if a pending case that could resolve this issue, which was argued a year and a half ago, was decided tomorrow, because the *Durden* case was another three-judge panel, it would ultimately have to go to an en banc review by the full court and that would take at least another year.

I think realistically it would take years for judicial resolution to occur. In the meantime, companies are vulnerable to the kind of foreign-based infringement that the current law exposes them to.

Mr. MOORHEAD. Thank you both.

Mr. HUGHES. The gentleman from Massachusetts.

Mr. FRANK. Thank you.

To some extent, we have a problem here, which we often have. There is professed agreement on goals, but differences in interpretation, and this is a particularly difficult subject for many of us who are not, unfortunately, technically trained. And so the question I have, you are familiar with the objections that we are going to hear from later and we have heard from other people. Some of the objections, it seems to me, go to differences over interpretations that were not intended.

Do either of you think that there are ways that we might add some extra language? I have thought that one of the things that we should have is a key that we could hit on the legislative bill drafting machine saying that this bill does not do what this bill does not do. Now, that doesn't resolve all the problems, but are there ways that we might be able to make some of these things explicit, allay some of the fears of opponents, which are understandable if in fact any of them happen, without undercutting the kind of protections that are important for the process situation? Ms. Raines.

Ms. RAINES. I would say, frankly, this is a very artfully, carefully drafted bill. And that it is very difficult to see how some of the kinds of effects that the opponents project would actually occur.

To the extent that the committee issues a report which makes its intentions clear, I think that this would be helpful. And we certainly would not oppose any clarification. It is just that the individuals and organizations that object to these effects because of the fact that the bill is generic and not specific to the biotechnology industry, are the same individuals who objected to the Senate-based bill, which is specific to the industry. It is very hard to address an objection to both at the same time.

Mr. FRANK. I agree with that. And that is why my preference would be in situations like this to say to those who have been objecting, if you think this is a problem and if you think this would lead to something that no one here intends, I will look at language that you bring forward. I don't think it is incumbent on you to do that. But people who do think this might have some unintended consequences, sometimes that is hard to do or impossible to do, but I would be willing to look at language that is specifically aimed at. Sometimes that is not what people want.

One other question, that is to do with the obviousness issue. One of the suggestions that you have obviated "obviousness" in your bill. Would you address that?

Mr. MOSSINGHOFF. I would respond to that. I think it is absolutely clear that the intermediate or the starting material used in the process has to satisfy sections 102 and 193, and 103 is the nonobviousness test. In Europe, they use a different phrase, inventive height, and they don't have that problem in interpreting this. I don't think that is a valid objection.

I would say in terms of amending this bill, I agree with Ms. Raines totally. It was actually a pleasure getting ready for this hearing because of a very real identified problem. It is real and crisp, the legislation is mature, and it is ready to be enacted.

I spent the last year testifying on health care reform. I wish that was as simple as this problem is. I think the bill is very well done, and I urge its adoption as written, perhaps with report language, as Ms. Raines suggested.

Mr. FRANK. The example in the testimony that IBM gives is that the problem could be that a process patent, in and of itself unobjectionable, could be used in conjunction with software or with some other product and that might become excessively restrictive. Does that seem to you a real danger?

Ms. RAINES. I don't think so. As Mr. Kirk mentioned, it runs counter to the entire marketing approach of the computer industry. And I would suggest, as well, that if there is misuse of the patent, that there are remedies under our antitrust laws to address those kinds of concerns. I don't think that it is a realistic concern.

There has never been any evidence these kinds of problems would occur and they haven't occurred in Europe, where these kinds of claims are available.

Mr. MOSSINGHOFF. I would add that early on in my career as a patent examiner in the Military Electronics Division at the Patent Office, I granted patents routinely where you have an improved radar system, and I would grant a patent that had that system and it also had the method of using that system to intercept incoming aircraft. So it doesn't seem like that is a conceptual problem at all.

Mr. HUGHES. The gentleman from North Carolina.

Mr. COBLE. Thank you, Mr. Chairman.

It is good to have you all with us. I was going to put this question to Mr. Kirk but I failed to do so.

If this bill is enacted, tell me your opinion as to this question: Would it have any change or impact on the intellectual property provisions provided in NAFTA or other international trade agreements under negotiation? I am shifting the focus to the arena of trade now. Would it have any impact as far as you all could tell?

Mr. MOSSINGHOFF. I believe it would have the beneficial impact, particularly with respect to NAFTA in the Canadian law and the new Mexican law, and I would expect them to follow this for the benefit of their own inventors and any other activity that is done by U.S. citizens in those countries. It follows the precedent of Europe and Japan, and indeed we would welcome it being set as a universal provision in patent law.

Mr. COBLE. Ms. Raines, do you want to be heard on that? Do you concur?

Ms. RAINES. I concur.

Mr. COBLE. Thank you. That is the only question that I have, Mr. Chairman.

Mr. HUGHES. Is there any country in the world that has this kind of loophole dealing with process patents, to your knowledge?

Mr. MOSSINGHOFF. I really don't know the answer to that. I would be pleased to have someone look at that and provide that for the record—whether there are. I suspect there are, because obviously the mature patent laws are in industrialized Western Europe, Asia, and the United States. So I suspect there are patent laws in less developed areas that might have no coverage or decisions.

[The information follows:]

PhRMA is not aware of any country where the patent law is such that an applicant is unable to obtain process patent claims in the type of situation addressed by H.R. 4307. In many less developed countries, adequate product and process patent protection is not even available and therefore the loophole you refer to would not exist.

Mr. HUGHES. What about the industrialized world?

Mr. MOSSINGHOFF. I wouldn't think so.

Mr. HUGHES. Thank you very much. You have been very helpful to us and we appreciate your testimony very much.

Our next panel consists of Roger Smith, the assistant general counsel for the IBM Corp. He is responsible for all international property matters for the company throughout the world. He has been employed by IBM since 1958 when he joined the company as a patent attorney.

He received a bachelor of science degree in electrical engineering from Gonzaga University in Spokane, WA, in 1954, and a juris doctor degree in 1958.

Mr. Smith is currently the president of the Intellectual Property Owners, Inc., and is a vice president of the American Intellectual Property Law Association.

He served as a member of the Secretary of Commerce's 1992 Advisory Commission on Patent Law Reform and was a member of the U.S. delegation to the WIPO Diplomatic Conference on World Patent Law Harmonization in July 1991.

Mr. Waterman is a general patent counsel for the Dow Chemical Co., and has held that position for the past 17 years.

Mr. Waterman has a B.S. and a Ph.D. degree in chemical engineering and a juris doctor degree. He has been involved with patent work for over 36 years.

He was also a member of the Advisory Committee on Patent Law Reform and has served as president of the Association of Corporate Patent Counsel. He is a member of the board and the executive committee of the Intellectual Property Owners, Inc., and is past chairman of the Intellectual Property Committee of the Chemical Manufacturers Association.

We are delighted to have both of you with us today. We have read your statements, and they will be made a part of the record in full. As you know, we would like you to summarize. Mr. Smith.

STATEMENT OF ROGER S. SMITH, ASSISTANT GENERAL COUNSEL, INTERNATIONAL BUSINESS MACHINES CORP. (IBM)

Mr. SMITH. Thank you, Mr. Chairman. We appreciate the opportunity to testify and appreciate the fact that you have indeed read our statement. As you know, we oppose this bill.

IBM is a developer and provider of a wide range of devices, processes and services in the information handling area. We spent, in 1993, about $5.6 billion on R&D and we use patents to protect the fruits of that activity. We do have a stake in the patent system. Indeed, we were the largest single patent receiver in the United States in 1993, the first time that any American company has achieved that status in 8 years.

We believe that a strong, equitable, and fair patent law is essential to industry and indeed to all of the American public. The law must provide protection to inventions but it must also assure that technology already in the public domain remains free for everyone to use.

We believe that H.R. 4307 should not be enacted into law. If enacted, we believe it will do substantial injury to our industry and in fact to the American public at large.

According to this bill, various process claims are made patentable by statute without the benefit of examination if they are associated with patentable products, either in the manufacture of those products, but in our view more importantly, in the use of those products.

That has the potential, in our view, for allowing a patent owner, the owner of a new product, to recapture vast areas of technology formerly free for the American public to use, and we believe that is wrong.

Potential infringers of unexamined claims will have no ability to attack the validity of those claims for obviousness, and the U.S. court system will be constrained to enforce those claims without review for obviousness.

It is apparent, Chairman Hughes, from your identification of my example using direct memory access, that you are familiar with that example. IBM once owned the patent to the direct memory access technique. That patent has long expired. If this bill is passed into law, the owner of a new patentable microprocessor, let's assume that it is the next microprocessor of choice in the computer

industry, the owner of the patent to that new microprocessor would be perfectly capable of copying all of the specification and claims of our expired patent into a patent that includes his novel microprocessor claim or indeed into a second patent which is coterminous with that patent.

Mr. Kirk pointed out, and I believe others, that this claim would not be unexamined in fact. That is true to the extent that it would be examined for compliance with other aspects of the patent law than obviousness. It would be examined with respect to section 112 of the law. But if, indeed, the direct memory access process passed that test when it was first patented, it certainly can pass that test when it is included in the new patent. So I am not satisfied that this examination is going to resolve very many problems.

Now, what happens in the case of this direct memory access patent is that the owner of the novel microprocessor has the right to charge a separate royalty to those people who want to use the microprocessor with the direct memory access technique. Those may be downstream ultimate users or other computer manufacturers. Indeed, it seems clear to me that the owner of the patent might prevent other computer manufacturers from practicing that process altogether, which would be a terribly severe thing.

There is another set of claims that the computer manufacturer might include, and those are claims to known programs—known application programs for using the microprocessor. In the event that such program claims are included, and again assuming that they can pass the test of section 112, it would be perfectly appropriate for the owner of the novel microprocessor claim, to include claims to as many application programs as that owner cared to put into his patent.

Conceivably, there could be hundreds of such claims, and the reality of that is that the owner of this novel microprocessor patent now has the ability to shift the focus of his patent from purchasers of his novel microprocessor, which he is appropriately entitled to address, to users of the programs that the processor runs or vendors of the programs that the processor runs.

Mr. Kirk says that this is not a problem because people will just not use that microprocessor. That is not an adequate answer, in our view. If, indeed, the novel microprocessor is a step forward in the art, people ought to be able to use it. They ought not to be forced to go to less attractive answers just to avoid this problem.

I believe that passage of this bill will do enormous harm to the data processing industry. There will be substantial economic distortion and there will be dire consequences to my industry. To allow a computer product patent owner to charge a toll on all processes used with his novel computer product and to determine which software will be permitted to run on that product simply is wrong.

As written, this is not a good bill in our view. It was originally proposed to resolve problems said to exist in the biotechnology community, but as currently written it applies to all technologies.

The need in biotechnology has been questioned in some quarters but certainly beyond the biotechnology community, this bill is not only not needed, it is extremely dangerous.

If the bill becomes law, Americans are going to have to pay a heavy price not only in tribute to patent owners who have recaptured technology formerly available, but in the added uncertainty and confusion that will result when a large number of process claims unexamined for obviousness are inflicted on the public.

I believe that Mr. Kirk testified that computer owners would not write such claims. I wish that that were true, but I am not convinced that it is true. I am not convinced that owners of novel products would not attempt to broaden the sweep of their patents to cover additional activity. Indeed, there is substantial evidence that that activity occurs in our industry today.

I would cite to you, though not specifically on point, a case in the Eastern District of Texas, Sherman Division, *Cyrex* v. *Intel*, which had to do with a claim to a novel microprocessor that included not only that microprocessor but additional known memory elements that the microprocessor would interact with in a computer system.

That claim was struck by the district court on the basis that the purchaser of the microprocessor should have an implied license to use the microprocessor to infringe the additional elements of the claim. That is very helpful law, but it is not clear that that implied license or the exhaustion doctrine would protect in the cases we are worried about.

In the cases that we are concerned with, the novel computer element might have uses beyond those which individual claims of the patent are applied to. And the exhaustion doctrine, or the doctrine of implied license may not apply.

Mr. HUGHES. Let me interrupt you there. We have a vote in progress, and I want to give you ample time to basically articulate your position. We are going to recess for about 10 minutes so we can catch that vote and come back, but Mr. Moorhead cannot come back and he would like to direct a question to you.

Mr. MOORHEAD. The question I have is that it has been stated that Japan and other industrialized countries of Europe have protection in this particular area. Are they suffering so badly and paying a high price for their law? And isn't it unfair to our companies if we are not giving our people the same protection that the Japanese are giving to their companies and the people in Europe are giving to theirs?

I can't stay for the answer, but I hope that when I return, perhaps both of you can respond. The chairman will be here, and it is something that I would like to see in the record.

Mr. SMITH. I am eager to respond to that.

Mr. HUGHES. We will recess for about 10 minutes. We will be right back after this vote.

[Recess.]

Mr. HUGHES. The subcommittee will come to order.

Mr. Smith, I apologize for the interruption, but I think we are good for a while now. We shouldn't have any more votes for a little while. You may proceed.

Mr. SMITH. Thank you very much. I have about concluded my remarks. I do want to make a couple of remarks and then answer Mr. Moorhead's question.

With respect to the application of this bill to the computer industry, and your question to Mr. Kirk concerning the direct memory

access example, Mr. Kirk indicated that he was not certain whether that claim would or would not be valid. I must say that as I read the proposed statute, the claim would be valid. But even assuming that he is correct and there is only uncertainty, it seems to me unfair to inflict that kind of uncertainty on our industry and on the American public, requiring that that uncertainty be resolved on a case-by-case, claim-by-claim basis in the courts. As you know, court proceedings are very expensive.

With respect to Mr. Moorhead's question, I do not believe that the laws of Europe or Japan, as they apply to the electronic industry, provide the result that has been testified to today. I am not aware of any rule in the European Economic Community or in Japan, which provides for the automatic issuance of unexamined process claims if there is a valid product. It is my understanding that there is a practice in these offices that is limited to the biotechnology areas that may result in the issuance of such claims. But it does not occur in the data processing industry. So we don't have the problem because we don't see the claims.

[The prepared statement of Mr. Smith follows:]

PREPARED STATEMENT OF ROGER S. SMITH, ASSISTANT GENERAL COUNSEL, INTERNATIONAL BUSINESS MACHINES CORP. (IBM)

Mr. Hughes, members of the subcommittee, my name is Roger Smith and I am the Assistant General Counsel of the IBM Corporation. As you may know, IBM is a developer and provider of a large variety of products and services in the information handling business. In 1993 IBM spent approximately 5.6 billion dollars on research and development in the technologies associated with information handling. Patents are important to IBM to protect the fruits of this activity. We are a substantial user of the U.S. patent system. Indeed we were the single largest receiver of patents issued in the U.S. during 1993. IBM uses its patents through licensing to assure freedom to market its products and services, and to see that others who wish to benefit from our R&D pay their fair share of that expense through royalties.

A strong, fair and equitable patent law is essential to protect the interests of all Americans, inventors and the general public. The law must provide protection to new and useful creations, but it must also assure that technology already in the fund of public knowledge remains free for all to exploit. The law must provide reasonable clarity so that users of the system and the general

public are able to operate without uncertainty or undue litigation.

We believe that H.R. 4307 should not be enacted into law. Its provisions run counter to the sound economic and patent legal principles that have served the United States so well. If enacted, it would do substantial damage to industry, including the information handling industry, and to the American public. The concepts contained within the bill are revolutionary, they are contrary to established legal principles[1], and they threaten to do untold mischief. Under current law a patent may contain multiple claims, including both product and process claims, but each claim must differ substantially from the other claims. Each claim gives rise to separate rights. The Patent and Trademark Office examines each claim separately for compliance with the criteria for patentability including non-obviousness. The patent code says every claim of a patent shall be presumed valid independently of the validity of other claims. This bill would make various process

[1] Being mindful that a great deal has been said and written about the bill in earlier testimony and knowing that members of this Subcommittee are knowledgeable about the principles of patent law affected by the bill, I believe it unnecessary to provide a detailed discussion of the current law.

claims patentable by statute without the benefit of the rigorous examination for obviousness that all other patent claims receive in the United States Patent and Trademark Office. According to the bill, processes which may be perfectly obvious, well documented in the prior art and notoriously old and well-known, would become patentable if they are associated with a patentable product, either in its manufacture or in its use.

This extraordinary provision fundamentally changes the nature of legal rights that have existed through more than 200 years of statutory and case law in this country. Potential infringers of these unexamined claims would have no ability to contest their validity and the United States courts would be required to enforce them without review. Potentially vast areas of process technology formerly free and available for use by the public, either because those areas had never been patented or because patents relating to them had expired, would be recaptured by patent owners of patentable products when the process is used with those products.

To illustrate the enormity of the problem that the bill would create consider the following example: an inventor employed by the HAL

Computer Company invents a new microprocessor which is faster, more powerful and less expensive than the microprocessors currently in use in today's personal computers. It is, in fact, the next microprocessor of choice for the computer industry. A patent is awarded to HAL for the novel microprocessor and the company is properly entitled to exclude its competitors from manufacturing or using the device. Or it may appropriately charge those competitors a royalty for such manufacture or use. If HR 4307 were to become law however, HAL would be able to include in the microprocessor patent, or for that matter in a different patent which is coterminous with the microprocessor patent, claims to old software processes for using the novel microprocessor in day-to-day activities. A computer software-related invention is one example of an invention that can be claimed as a process; a process for causing the elements of the computer to coact to bring about a certain result. One process claim that HAL might include would be a claim covering a technique known as Direct Memory Access, a technique which, although not essential to facilitate every use of a computer, provides such significant benefits that it is used in most modern day computers from mainframes to personal computers. IBM once owned a patent covering the technique. That patent has

been expired for some years. If H.R. 4307 were to become law, HAL, however, would be perfectly within its rights to make a claim to the process for performing direct memory access with the novel microprocessor. The claim would not be examined for obviousness notwithstanding the existence of the technique in the prior art. Persons wishing to use the new microprocessor, purchased from HAL or from its licensee, would be required to apply for a separate license from HAL in order to use this well known and important process in computer systems using the novel microprocessor. The exhaustion doctrine[2] that extinguishes a patentee's right to control the use or disposition of an article once he has sold it, would not necessarily reach to the process claim. Arguably, HAL might decide not to license the process claim at all but, instead, reserve this particular technique for practice with its microprocessor in computer systems that it sells.

Should HAL decide to license the process, it would be entitled to charge a royalty for the use of this claim in addition to the royalty it might charge for the practice of the claim to the microprocessor itself. HAL might decide to sell the unexamined

[2] See, e.g. United States v. Univis Lens Co., 316 US 241 (1942).

process patent claim to a third party. Thus persons wishing to practice modern day computer technology would be faced with the need to deal with two patent owners, HAL, who owns the patent to the microprocessor, and HAL's assignee, who holds the patent to the resuscitated direct memory access process.

Consider now another claim that HAL might put in its patent or in a coterminous patent. Word processing programs are widely sold. You can go to a computer store and buy such a program today. Should H.R. 4307 become law, HAL could obtain another unexamined claim to the use of key elements of word processing with its microprocessor. That claim would be by statute, perfectly valid, notwithstanding that the process is notoriously old and well known. Then, anyone who wants to practice word processing has to see HAL for a license before he can do so, if he wants to do so on a computer including HAL's novel microprocessor. Moreover, HAL would be within its rights to charge a royalty to users of the process based on the number of documents they prepared or the value of the documents or the number of words processed, for there is an infringement each time the process is practiced in a computer using HAL's microprocessor. The scenarios can go on and on.

Having invented the next commercially valuable microprocessor, HAL would be in a position to selectively capture any program process that can be performed in that computer. Moreover, HAL would have the ability to change the focus of its patent right from the direct purchasers of its processor to the users of the programs its processor ultimately performs. Software vendors who wished to create for the new microprocessor programs that include old and well-known process techniques would be required to seek licenses to do so. There is thus enormous economic distortion consequent to this bill.

The potential for a patent owner to establish control over processes which it did not invent has dire consequences in the information handling industry. To allow a product patent owner to charge a toll on all processes used with the product, and to determine which software will be permitted to run on the product is simply wrong.

Mr. Chairman and members of the subcommittee, this is not a good bill. It is not a necessary bill. It was originally proposed to resolve problems said to exist in the biotechnology industry. I refer you to testimony of Intellectual Property Owners and the American

Intellectual Property Law Association at the June 9, 1993 hearing before this subcommittee that this bill is not needed in the biotechnology community. I am not a biotechnology expert, but I believe that testimony is compelling. As now written, the bill applies to all technologies. Certainly beyond the biotechnology community this bill not only is not needed, but it is extremely dangerous. I have cited two examples of how the inventor of a product could use the proposed law to recapture technology long available to the public and extend the sweep of his patent far beyond his invention. There are untold others. I believe I can say with great confidence that patent attorneys, being the creative individuals that we are, will find many creative applications for the law.

If this bill becomes law, Americans are going to have to pay a heavy price, not only in tribute to patent owners for recaptured technology, but in the added uncertainty and confusion a large number of unexamined patent claims would bring. And there would be large numbers of such claims! No Patent and Trademark Office examination would be present to limit creative inventors and their attorneys.

Litigation would increase sharply as the proper metes and bounds of these claims are, inevitably, tested. And issues such as those raised under Section 112 of the patent code which requires patent applicants to "particularly point out and distinctly claim" will abound. Questions such as those concerning the status of unexamined claims if the underlying product claims are found invalid, will add to the confusion and expense.

Mr. Chairman and members of the subcommittee, this bill does a great disservice to the American public and to industry. I respectfully submit that it should not be enacted into law.
Thank you.

Mr. HUGHES. Let me just, if I might interrupt you there, the European Patent Office is using an examination procedure similar to that proposed in H.R. 4307. Let me cite to you one provision in the European Patent Office Guidelines for Examination used in Europe, and I am quoting:

If an independent claim is new and nonobvious, there is no need to investigate the obviousness of any claims dependent thereon. And, similarly, if a claim to a product is new and nonobvious, there is no need to investigate the obviousness of any claim for a process which inevitably results in the manufacture of that product or any claims for use of that product.

Mr. SMITH. Well, you have me at a disadvantage, Mr. Hughes, because I am not aware of——

Mr. HUGHES. That is in their guidelines.

Mr. SMITH. That may be the guidelines and perhaps that is the way the European office deals with the claims in the biotechnology area, but——

Mr. HUGHES. That is every claim, not just biotechnology. That is every claim.

Mr. WATERMAN. That is an administrative procedure. And what we are saying is, why can't the Patent Office here do the same thing?

We know that about 3 weeks ago, the Commissioner of Patents, by administrative edict, told the examining core to ignore the decision of *In re Baird* and that there was a better line of decisions.

Mr. HUGHES. Well, we will get into that when we take all the testimony. I apologize, and I will be happy to respond to that, because that would have been my preferential way to deal with it.

Mr. SMITH. There is a difference between a guideline and a statute. In one case, I don't think the courts are as required or constrained to follow the guidelines as they are to follow statutory law.

Finally, I would like to say that my industry is certainly sympathetic to the problems of the biotech industry and we are certainly not interested in seeing foreign pirates invade that industry any more than we would be in our industry, but the sweep of this legislation is simply too broad.

We would be happy, though we are not biotechnology experts, to meet with the Office and members of the first panel, and see whether there is some narrow application or some narrow drafting of a law that could be accomplished to solve their problems without providing what we consider to be the great injury that this law provides. Thank you.

Mr. HUGHES. Thank you, Mr. Smith.

Mr. Waterman, we welcome you.

STATEMENT OF RICHARD G. WATERMAN, PH.D., GENERAL PATENT COUNSEL, DOW CHEMICAL CO.

Mr. WATERMAN. Thank you, Mr. Chairman.

My testimony today, of course, is in opposition to H.R. 4307. And we oppose this bill because we feel that it would change significantly the way the Patent Office would examine applications using a zero standard approach for patentability because it seems to ordain something to be patentable, and under today's law, nothing is ordained patentable; everything has to pass the title 35 test of patentability and nonobviousness.

And we think that the uncertainty faced by the biotechnology industry leading to the legislation has evaporated. And the biotechnology industry is no worse off in obtaining process claims than the rest of the industry, and the rest of the industry is not complaining.

We should not tarnish the whole patent system to solve a problem arising from a single incident which has since gone away. Dow, too, has a stake in the biotechnology industry but we do not see the current bill as providing a significant benefit when all the tradeoffs are taken into consideration.

If we look at what the bill is intended to accomplish, and that is to the granting of process claims that really could be enforced against imports, and these process claims would be enforced under 35 U.S.C. 271(g) under the product of the process.

And the question I would ask is, do these unexamined claims—and I think they would be unexamined—should they be given the benefit of such force?

And to answer that question, I included an example in my written statement showing how under the bill an invention for an improved drill bit for drilling oil could be used to sue for infringement against anyone importing, using, or selling the oil imported into the United States. And I would ask, does the process of using the drill bit, which has no other use, really rise to the level of invention and should the patentee have the right to exclude the oil imported? And I believe most would say it does not.

My written statement includes some additional examples also that show the false rewards and paper tigers that may be issued in the form of process claimed through the enactment of this bill.

The examples I gave merely reflect the standard commonly encountered in the practice of obtaining U.S. patents. And this is expressed by the Court of Appeals for the Federal Circuit in *In re Dillon,* which is cited in my written statement, which commented on the *Durden* case, and I refer you to that quote there which discusses the criteria to be used in determining obviousness of process claims.

That standard has served the inventive community well, and in my opinion, the biotechnology industry will be allowed to obtain the desired process claims following that decision. Anything else would erode the recognition and prestige that flows from an inventor joining the ranks of a patentee.

The problem that we see with the bill is that it would permit an infinite member of process claims, particularly claims to cover schemes on how the product could be used.

At first blush, that sounds great. My company could develop a war chest of these process claims to harass our competitors. But what goes around comes around. To follow the indiscriminate granting of process claims under the bill would surely lead to considerable uncertainty and a proliferation of harassing litigation. Such attempts to enforce unexamined process claims would generate contempt and distrust for the U.S. patent system.

Additionally, it would come at a time when there is already heightened concern for the increased cost of litigation and, in effect, we will have exchanged examination by the PTO for examination by the courts and this will confound and delay the ability to enforce

other meritorious patents and thus impede competitiveness. And in the fight to bring some balance to our litigious society, Congress needs to assure itself in drafting legislation that it is not creating unnecessary litigation.

We all know the goal of the PTO is to complete examination within 18 months. But with all the additional process claims that would be added, there is no way the Patent Office could maintain this pace unless they do what the bill permits them to do and that is not to examine process claims. There would be no prosecution history available on the process claims. And I question whether or not they really would be examined under section 112, as Mr. Kirk says, because examiners are human and if Congress says, this claim can be allowed, I think they would allow it.

While this practice of not examining process claims may be of benefit to the Patent Office, it is of no value to my company. We would rather pay a higher fee and have a thorough examination and obtain an enforceable patent. To paraphrase an old saying, you pay now or you pay a lot more later.

This bill also, I feel, would introduce a new concept, the concept of having examined claims, and unexamined claims. Then how does a competent attorney counsel his or her clients as to the enforceability of the claims? One might say no problem. One size fits all because 35 U.S.C. 282 provides each claim shall be presumed valid independently of the validity of all other claims. But section 282 was obviously drafted under the assumption that all claims would be examined.

Therefore, I would be inclined to counsel my client that the presumption of validity would not apply to the unexamined claims issuing under the bill, and I think most courts would agree with me, and we would be right back here for another quick fix.

This bill would provide some basic unfairness. Section 282 goes on to say the burden of establishing invalidity of a claim will rest on the party asserting such invalidity. To impose this burden on an unexamined claim would certainly not carry the fairness and equity we strive for in our judicial system. We would also need to look at the impact the bill would have on the marketplace with the broad right under the bill to obtain process claims for the use of a patented product, the purchaser may have restrictions he never dreamed of as to what he can do with what we bought. He could be an infringer or a contributory infringer if he resold the product to someone who used it for one of the claimed uses. And I think the point is clear, confusion in the marketplace would be created.

Mr. Kirk said there would not be any problem because of 271(d) which says there will be no enforcement against resale at a retailer level; however, companies like mine and others, we sell intermediates to other companies to convert them into other products.

We feel this bill would not enhance innovation nor science. Declaring something to be patentable because it relates to something else patentable has nothing to do with inventing and shouldn't be rewarded under the patent system.

The only innovation this legislation would create of necessity is that of patent attorneys. These people would extend themselves to create process claims on any patentable machine, composition of

matter or manufacturer. They would be compelled to do so. They have the duty to their client to seek as broad a patent coverage as the law will allow. Claims of this nature would expand the right to exclude under the patent system far beyond the inventive contribution of the patent.

Again, the focus needs to come back to the problem that this legislation is trying to solve. And, frankly, I can't find it.

There is nothing wrong with the current standards for patentability. They are well-recognized and understood. The problem to be solved, if one truly exists, may be the practice followed by the U.S. PTO.

Thank you very much.

[The prepared statement of Mr. Waterman follows:]

PREPARED STATEMENT OF RICHARD G. WATERMAN, PH.D., GENERAL PATENT COUNSEL, DOW CHEMICAL CO.

My name is Richard Waterman. I have been in the patent profession for over 36 years, and for the past 17 years have been General Patent Counsel for The Dow Chemical Company.

My background includes being: past President of the Association of Corporate Patent Counsel, an organization of heads of patent departments of about 180 of the largest U.S. corporations; past Chairman of the Intellectual Property Committee of the Chemical Manufacturers Association; a member of the Board and Executive Committee of Intellectual Property Owners; a member of the 1990-92 Advisory Commission on Patent Law Reform; a member of the former Advisory Committee to the USPTO on patent harmonization;

Dow's corporate headquarters are located in Midland, Michigan. Dow manufactures and supplies more than 2,000 products and services, including chemicals and performance products, plastics, hydrocarbons and energy, and consumer specialties - which include agricultural products, pharmaceuticals and consumer products. The company operates 181 manufacturing sites in 32 countries, and employs 56,000 people around the world.

In 1993, Dow's consolidated statement showed it spent $1.25 billion for research and development. Dow relies

heavily on the U.S. patent system to protect much of this investment. Consequently, Dow is a large user of the patent system. In 1993 the U.S. Patent and Trademark Office (PTO) granted Dow 410 patents. Dow ranks 21st in all corporations receiving U.S. patents, and ranks 10th among U.S. companies receiving U.S. patents. Approximately 50% of these patents include process claims.

Because of its reliability, the U.S. patent system is currently well respected by the innovation and investment communities, as well as the international community. The basis for this reliability stems from the fact that all independent claims are examined by the examining corps of the PTO and therefore carry with them a presumption of validity.

H.R. 4307 would change the way the PTO would examine claims for patentability by creating a new standard...a zero standard approach for patentability because it ordains something to be patentable. Nothing under current law is ordained patentable! Everything has to pass the Title 35 patentability tests of novelty (Section 102) and nonobviousness (Section 103). This bill would change Section 103 by, in effect, inserting an asterisk denoting that one of the two cornerstones will no longer apply where process claims are included with product claims.

We understand the uncertainty faced by those in the biotechnology field when this legislation first made its entry into the House and Senate Subcommittees a few years ago. However, we think that uncertainty has evaporated and the biotechnology field is no worse off when it comes to obtaining process claims than any other industry. We should not tarnish the whole patent system to solve a problem arising from a single incident which has since gone away. Dow, too, has a stake in biotechnology, but we do not see the current Bill as providing any significant benefit when all the tradeoffs are taken into consideration. The existing system can be used to provide adequate protection.

First, let us look at what H.R. 4307 is intended to accomplish, and that is to allow the granting of process claims which would be enforced almost exclusively against imports. This is because if one obtains a claim to a machine, manufacture, or composition of matter, the patentee can enforce those claims against anyone making, using or selling them in the U.S.A. It would be claims to the process of using the machine, manufacture or composition of matter that would be enforced against imports. They would be enforced under 35 USC 271(g) against the products made by the process. The question is, should unexamined claims be given the benefit of such force?

To answer that question, let's look at an example. Let us presume we have an invention which involves an improvement on a drilling bit for drilling oil (the improved bit lasts longer). If someone uses that bit in the U.S., the patentee can sue for infringement on the claim covering the bit. Presume the patentee received a claim under H.R. 4307 for "a process of drilling for oil using the improved drilling bit", and the bit is used outside the U.S. Then the patentee, under Section 271(g), could sue for infringement against anyone importing, using, or selling the oil produced using the drill bit., i.e., the product of the process. There is no change whatever in the oil produced and there is no other use for the improved patented drill bit. Does the use of the improved drilling bit to drill for oil really rise to the level of invention, and should a patentee have the right to exclude the importation of the oil produced? I believe most would say it does not.

Another example. Supposing we have a metal composition that is stamped into parts by a particular machine, but the parts rust easily. Then a different metal composition is invented that has better corrosion resistance and is patented. The new metal composition is substituted for the old and is inserted into the same machine in the same fashion to produce the same part. Under H.R. 4307 the process for making that same part is now automatically

patentable. The situation begs the question - should that be given the dignity of a patentable invention. I do not think many inventors would take much pride in such a process claim.

Let's take yet another example, an invention for a modified catalyst for making polyethylene. The catalyst that was modified was a known catalyst for making polyethylene and had no other known use. The modified catalyst meets the test for patentability, and continually produces a polyethylene with a uniform molecular weight never before achieved. Would a process claim to the use of this catalyst to make polyethylene be a patentable invention in itself? I think most would agree yes, in view of the unique properties of the product made using the improved catalyst.

Now, suppose the modified catalyst above meets the test for patentability but there is nothing to distinguish the polyethylene manufactured by it or the process of using it. Is it inventive to use this catalyst to make polyethylene? I believe most would say it is not.

The above examples merely reflect a standard commonly encountered in the practice of obtaining U.S. patents. This is expressed by the Court of Appeals for the Federal Circuit in the case of In re Dillon, on rehearing En banc, 16 USPQ 1897 (1990).

> "Suffice it to say that we do not regard Durden as authority to reject as obvious every method claim reading on an old type of process, such as mixing, reacting, reducing, etc. The materials used in a claimed process as well as the result obtained therefrom, must be considered along with the specific nature of the process, and the fact that new or old, obvious or nonobvious, materials that are used or result from the process are only factors to be considered, rather than conclusive indicators of the obviousness or nonobviousness of a claimed process. When any applicant properly presents and argues suitable method claims, they should be examined in light of all these relevant factors, free from any presumed controlling effect of Durden."

The above standard serves the inventive community well. Anything less would erode the recognition and prestige that flows from joining the ranks of a patentee.

The problem with H.R. 4307 is that it would permit almost an infinite number of process claims because it makes

no distinction between a process of making and a process of using. For example, if one had a claim to a composition of matter, probably there would be only a limited number of ways (and claims) of making that composition. On the other hand, conceivably there would be numerous and expansive ways to draft claims to cover schemes on how it could be used. These claims are in a class by themselves. They are scooped into a patent merely because they have a relationship to something else that is patentable. At first blush that sounds great; my company could obtain a war chest of these process claims with which to harass competitors. The problem is - what goes around, comes around.

To follow the indiscriminate granting of process claims under H.R. 4307 would surely lead to considerable uncertainty and a proliferation of harassing litigation. Such attempts to enforce unexamined process claims would generate contempt and distrust for the U.S. patent system. This would indeed be lamentable, coming at a time when the patent system is most respected by the innovation and investment communities.

It would also come at a time when there is already heightened concern about the increase in the cost and complexity of litigation. This was one of the principal concerns of the Advisory Commission on Patent Law Reform.

Much of this concern is directed at the unavailability of District Courts to handle civil trials. But proliferation of litigation caused by uncertainty of rights will only compound the frustration already present. In the fight to bring some balance to our litigious society, Congress needs to assure itself in drafting legislation that it is not creating unnecessary litigation.

We all know the USPTO operates under a quota system and attempts to complete its examination of an application within 18 months. With all the additional process claims that would be added to applications, there is no way the Patent Office could maintain this pace unless they do what the bill permits them to do, and that is to not examine any of the process claims. No prosecution history would be generated concerning the process claims. And what about meeting the requirements of Section 112 for enablement and best mode? H.R. 4307, by automatically mandating a finding of nonobviousness of these claims, would encourage the PTO to not examine all the other requirements for patentability which must be met for all other patentable inventions.

While this practice of not examining process claims may be of benefit to the Patent Office, it is of no value to my company. We would rather pay a higher fee for a quality

examination and obtain an enforceable patent. To paraphrase an old saying, you pay now, or you pay a lot more later.

H.R. 4307 would introduce into the U.S. patent system a new concept, a concept of having two types of process claims - "examined" claims, and "unexamined" claims. How does a competent attorney counsel his or her client as to the enforceability of the unexamined claims? One might say the answer is simple, one size fits all, since Section 282 provides that "each claim of a patent...shall be presumed valid independently of the validity of other claims...". But Section 282 obviously was drafted under the assumption that all claims would be examined. Therefore, I would be inclined to counsel my client that the presumption of validity would not apply to unexamined claims. And I think most courts would agree with me, and then we would be right back to Congress for another quick fix.

Also, I think this Bill would provide some basic unfairness. Section 282 goes on to say "The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity". To impose this burden on an unexamined claim would certainly not carry the fairness and equity we strive for in our judicial system.

We also need to look at the impact this Bill would have on the market place. Once a patented product is legitimately put on the market, a purchaser is free to sell and use that product unless there are patent claims covering a use (if there is more than one use). With the broad right under H.R. 4307 to obtain process claims for the use of a patented product, the purchaser may have restrictions he never dreamed of on what he can do with what he bought. He could very well be an infringer or a contributory infringer if he resold the product to someone who used it in one of the claimed uses. I think the point is clear, confusion would be created.

This bill would not benefit the public because of the reasons stated above. Nor would it enhance innovation. It would not advance science. Declaring something to be patentable only because it relates to something else patentable has absolutely nothing whatever to do with inventing, and should not be rewarded under the patent system.

The only innovation this legislation would stimulate, of necessity, is that of patent attorneys. These people would extend themselves to create process claims on any patentable machine, manufacture or composition of matter. They would be compelled to do so. They have a duty to their

client to seek as broad patent coverage as the law will allow. Not only that, they would be compelled to do it in order to avoid claims for malpractice, for if they failed to include process claims covering as many uses of the machine, manufacture, or composition of matter as can be dreamed up, then surely they would expose themselves to suit. Claims of this nature would expand the right to exclude under the patent system far beyond the inventive contribution behind the patent.

To be dealt with in the final analysis, is the increase in lawsuits filed to determine the rights for each and every patent which includes process claims along with their attendant product claims granted pursuant to H.R. 4307. In effect, we will have exchanged examination by the PTO for examination by the courts. This will confound and delay the ability to enforce other meritorious patents, and thus impede competitiveness, including the competitiveness of the biotechnology field.

Again, the focus needs to come back to the problem that this legislation is trying to solve. There is nothing wrong with the current standards for patentability. They are well recognized and understood. The problem to be solved (if one truly exists) appears to be a practice followed by the USPTO.

I respectfully urge this Subcommittee to not recommend passage of H.R. 4307 and to encourage other alternatives or resources to solve the apparent concern of the biotechnology industry.

Mr. HUGHES. That seems to be part of the problem. Your suggestion is there is not a problem. How do you explain the dilemma over *Pleuddemann* and *In re Durden*? The courts have been attempting to resolve that conflict now for the better part of 17 months. I think it was argued about a year and a half ago. PTO has been wrestling with that issue and could not administratively deal with it as indicated as the Europeans have done by their guidelines.

Mr. WATERMAN. Well, as I said earlier——

Mr. HUGHES. How can you say there is no problem? We have that conflict that has not been resolved.

Mr. WATERMAN. I think we saw the recent example with the Commissioner passing down the edict to ignore the *In re Baird* case. Seems to me, they could do the same thing in this situation.

Mr. HUGHES. PTO has indicated they cannot. I have asked them for the better part of a year to do just that.

Mr. WATERMAN. Perhaps they have changed their ways since they just did it 3 weeks ago. Maybe we can be hopeful.

Mr. HUGHES. It is almost as if what you are saying is that there is not a problem for us. There is not a problem for us, therefore, there is no problem. I realize you didn't say it in those terms, but I suspect that if it was your industry that found themselves in the predicament that the biotech industry finds themselves in, you would be in here seeking relief.

Mr. WATERMAN. In that respect, my company is a chemical company and very related to the type of biotech claims, and we have not found any real difference in our ability to obtain process claims before or after *Durden*.

Mr. HUGHES. But see, both you and Mr. Smith have testified that basically you are dealing with a statute which would automatically provide without examination, patent protection, but the fact of the matter is that you have to have a patentable material, a new product that is patentable, which is nonobvious, which otherwise complies with the statute, and if you don't have that, then you don't have a claim basically for process patent. Isn't that true?

And what is so wrong with encouraging inventors to create new products? Isn't that what it is all about? Isn't that one of the things that we are trying to encourage is creativity?

Mr. SMITH. Congressman Hughes, I am certainly sympathetic to the desire and the need for people to obtain patents on new products. The concern that we have is the increased sweep of the patent when it goes beyond the new product and potentially makes patentable all uses of the new product. All uses.

Mr. HUGHES. Well, Mr. Smith, let me ask you, do you think it is fair for one of America's inventors who has spent years developing a particular product, rating that product, and receives protection in this country, but finds that somebody else, some pirate, can take it offshore and basically use that process and that product, basically, and ship it back into this country and deny that creator of property in this country their rightful due?

Mr. SMITH. No, sir, I don't think that is fair. And as I indicated at the end of my testimony, to the extent that a solution to that problem can be discovered, I would be happy to see it.

Mr. HUGHES. But, Mr. Smith, your association is opposed to an industry-specific fix and you are opposed to a generic fix. That suggests to me that you are opposed to any fix. And, you know, we have wrestled with this for the better part of a year and a half. I happen to disagree with you. I think that there is a problem. I don't know that there is a perfect solution.

But, you know, we live in a different world, as my good colleague from Massachusetts has said, who has a way of articulating these issues. We didn't contemplate that we would have a biotech industry 200 years ago. And the patent law, like the copyright law, doesn't fit into any nice niches and we have to continue to wrestle with how to make it relevant to today's technologies. And we have a problem.

Now, it is no answer, Mr. Smith, you are a distinguished lawyer, to suggest that there is a big difference because in Europe they don't have the problem because they have it in their guidelines, but that is different than creating a statute. What is the difference if the net effect is the same? If in fact the Patent Office is smart enough in Europe to protect Europeans against that kind of piracy, how do we argue that basically trying to create a statutory fix in some way is different if the net effect is the same? What is the difference?

Mr. SMITH. Mr. Hughes, I don't believe that the net effect is the same. I believe that the statute carries a great deal more weight than a guideline, and I would be delighted to see the Office adopt guidelines which would solve the biotechnology industry's problem. I understand that you say that they can't. I submit to you that it is that they won't, not that they can't.

Mr. HUGHES. They can't; they won't. What is the difference? I can't order the Patent and Trademark Office to administratively deal with this problem. They tell me they can't do it. They can't do it. They won't do it. It hasn't been done. And we have been very patient. We are looking for the answers. You have not offered anything constructive yet.

What you are basically saying is, we are opposed to it, it doesn't impact us, and we are opposed to it; we think it is overly broad.

Tell us how can we narrow it so that it doesn't have unintended results.

Mr. SMITH. I would be much happier, Congressman Hughes, to see legislation which is industry specific than legislation which crosses all industries.

Mr. HUGHES. But your association opposes that, Mr. Smith.

Mr. SMITH. That is correct. I am speaking now as a representative of the IBM company.

I will tell you as a representative of the Intellectual Property Owners, while we are not eager to see industry-specific legislation, until we see a demonstrated problem, if there is a demonstrated problem, we certainly would be much more interested in seeing industry-specific legislation to resolve it than broad legislation.

Mr. HUGHES. If IBM had a problem, you can be sure you would be telling us about the problem. It happens to be that some other sector, important sector of our economy has a problem. Now when another important sector of our economy has a problem, that is a problem for all of us, IBM too, because we are all in this together.

But let me suggest to you that I don't think that industry-specific fixes are good policy. Believe it or not, I am interested in good policy. And, frankly, if one industry has a problem today, it is very likely that IBM could have that problem tomorrow or Dow Chemical tomorrow. And that is why it is important to look at what represents good policy.

If you could persuade me that an industry-specific fix would be better policy, I would take it. But I am not persuaded and I haven't heard any arguments yet that would persuade me that what we are doing is not good policy. But don't come in here and tell me that we don't have a problem, because we do have a problem.

The gentleman from Massachusetts.

Mr. FRANK. Mr. Smith, do you think *Durden* was correctly decided?

Mr. SMITH. I am afraid that I am not particularly familiar with that industry.

Mr. FRANK. Mr. Waterman, how about you?

Mr. WATERMAN. I think it had been clarified in *In re Dillon.*

Mr. FRANK. That was not the question. If you answer a question that I didn't ask you, it will confuse me. Do you think that *Durden* was correctly decided, in your judgment?

Mr. WATERMAN. Correctly decided? I would say no.

Mr. FRANK. No, it was not. So some action to undo the effects of *Durden* is appropriate?

I think that is helpful because I think it establishes that we do have something to deal with.

Is *Dillon* enough or, as you both suggested, a regulation by the Patent Office—and I agree with Mr. Hughes, and we were hoping they would do that, but I do understand the one concern they might have, which is trying to deal with potentially inconsistent, or in fact inconsistent, decisions by regulation which is less suitable than a statute.

And I guess, Mr. Smith, I am a little curious when you say that the problem with the statute as opposed to the regulation, because I gather you said that if this same policy was carried out by regulation you would be in favor of it. So the difference, then, becomes whether it should be done by statute or regulation. You say, well, if it was done by statute, the judges would take it too seriously. How do we get a regulation that gets judges to take it seriously enough? If the regulation is not statutory, then it is not binding on the judges, is it? Or will it be?

Mr. SMITH. My answer to that, sir, is if it is done by regulation, it is probably only going to be accomplished in those areas where it really makes sense.

Mr. FRANK. Mr. Waterman thinks that the judges made a mistake in *Durden*. How do we make sure that they don't make another mistake?

Mr. SMITH. I think we cannot assure that they don't make a mistake but at least we would have the opportunity to challenge.

Mr. FRANK. We could by making a statute. We lessen it.

Mr. WATERMAN. I think what Mr. Smith and I would like to reemphasize is that when you do it by statute, then——

Mr. FRANK. It is real.

Mr. WATERMAN [continuing]. It is real and it is almost mandated.

Mr. FRANK. Not almost. It is mandated.

Mr. WATERMAN. When it is done by an administrative procedure, they are at least applying standards of patentability that they apply to everything else and you have something that is of some value.

Mr. FRANK. Then maybe you could write in some language that would do that. But it seems to me that you are saying whether we have it taken seriously or not.

Mr. Waterman, I am puzzled. On page 9, you say that one of the problems is that the bill would result in an unexamined claim and you say that this would not be presumed valid and, therefore, that would cause complications and confusion; is that correct?

I mean, on page 9 you say, "Section 282 obviously was drafted under the assumption that all claims would be examined, therefore, I would be inclined to counsel my client that the presumption of validity would not apply to unexamined claims." In other words, you object that this bill would create claims which would grant patents, but they would not be presumed valid.

Mr. WATERMAN. There would be two classes of claims.

Mr. FRANK. What puzzled me is that the next paragraph complains that the bill would say they were valid. So I don't know which one you pick.

The next paragraph says, the problem is that the bill goes on to say, "the burden of establishing invalidity of a patent shall rest on the party asserting such invalidity."

So in the first paragraph you say the problem is this would create claims that weren't presumed valid. In the second paragraph, you say an additional problem is this bill would presume them valid. Is seems that you can plead in the alternative in court, but I don't think you can testify in the alternative. But I think that is what you have done on page 9.

Mr. WATERMAN. I think you have done a nice job for me in putting forth the example of the problems that we are going to be facing. We are going to have confusion.

Mr. FRANK. No, the problem, Mr. Waterman, is that you have made two exactly opposite policy arguments, and if I were you, I would have put a paragraph in the middle, frankly. Maybe I would not have caught it.

In paragraph one, you say that you are going to have patents and they are not going to be presumed valid and in paragraph two you say the problem is that you are going to have patents that are going to be presumed valid.

Which do you object to? You cannot object to both. Which is good policy or which isn't?

Mr. WATERMAN. I object to the inconsistency that the bill would produce for us.

Mr. FRANK. You don't say that.

Mr. WATERMAN. That is my intended message.

Mr. FRANK. Oh, Mr. Waterman, you are a much better draftsman than that. I think what you said was, let's think of everything bad about this bill and throw it in here. Because you don't say inconsistency. You say—the last paragraph on page 9, you have it in

front of you, "also, I think this bill would provide some basic unfairness. To impose this burden, the burden of establishing invalidity, on an unexamined claim would certainly not carry the fairness and equity that we strive for in our judicial system."

But the previous paragraph complained that there is inconsistency. You can mean one or the other; there would be too much volatility. But I don't see how you can make both claims as a statement of policy that they should or shouldn't be——

Mr. WATERMAN. What I am saying is that I would counsel my client that I wouldn't give as much faith to those unexamined claims as I would to an examined claim but when you get into court you have to follow the procedures that are statutorily put in your face that they are presumed valid. And, therefore, you have the burden of proof.

Mr. FRANK. Why would you tell the client that? In other words, you would say to the client, listen, if I were you I wouldn't treat this as valid, but by the way, when we get into court, we have the burden of proof. That is some advice, Mr. Waterman.

Mr. WATERMAN. I think that is the problem that we have facing us with this legislation.

Mr. FRANK. Again, you agree that *Durden* was incorrectly decided. You think that the policy we are talking about here should be adopted by regulation. You don't like the statute.

I will tell you, as I would read it then, the burden is on you to come in with a better statute. But if I choose between this statute or nothing, I choose this statute. And I am skeptical that you are trying to give us the effects. The notion that we should do it by regulation and not by statute when we are trying to deal with a court interpretation of a statute makes me nervous.

One other question, though, I apologize if I misunderstand this, your example of the drill bit and oil.

Mr. WATERMAN. Yes.

Mr. FRANK. I am getting confused as between process patents and then the use patent. I mean, the drill bit thing is not the invention of the bit, you are talking then about the use; right?

Mr. WATERMAN. That is right. That is what the legislation would provide that you—any patent which is using a patented product, whether the process for making that product or the process of using that product, are both deemed unobvious. So this would be a use product.

Mr. FRANK. And your saying this would change in result from *Pleuddemann*, the bill would change the *Pleuddemann* case? Because I thought that was what would be the case that would govern in this situation.

Mr. WATERMAN. Well, the *Pleuddemann* case and *Durden*—one is the process of making and the other is the process of using.

Mr. FRANK. The question was whether the statute would change *Pleuddemann* as well.

Mr. WATERMAN. I think it just endorses it.

Mr. FRANK. But since that affects the question of use, then I don't understand your hypothetical. I thought the purpose of your hypothetical was to say that this would make a tremendous change with regard to use, but it is *Pleuddemann* that governs use and you

are saying this endorsed *Pleuddemann*. I find it hard to believe what kind of change we are making, then.

Mr. WATERMAN. *Pleuddemann* is a chemical case also, but the point to be made there was look at what is going to happen in the future with all these process claims and what we are going to have to deal with in combating the enforcement of all these use inventions that are ordained patentable.

Mr. FRANK. I understand, but I say again the statute endorses *Pleuddemann* and that is already the law. So you can't blame that on the statute, the proposed statute, if that is what the *Pleuddemann* case says.

Mr. WATERMAN. No, except *Pleuddemann* applies standards of patentability and it is examined, whereas the bill would not——

Mr. FRANK. Let me ask Mr. Smith one last question.

With your example with HAL where you say this would allow you not simply to charge people for the process but an additional amount for using the software with the process, here I have a disagreement with you based on my economic understanding of the situation. If you have the market power to do that, why wouldn't you do that anyway? If you have the market power to charge a premium because you have got the patent, it seems to me that you are going to charge the maximum premium, that is what you are supposed to do, for that entity.

Mr. SMITH. On the product.

Mr. FRANK. Yes, and it is hard for me to understand the economic theory by which you say, I am going to charge you X to use my product but if you use my product and something else that is essential to make my product work, I am going to charge you more. I don't see where any additional market power comes in. It seems whatever you could force them to pay for using the product with regard to the software, that is the market power that allows you to charge that premium. Period.

Mr. SMITH. Sir, there are two different people that you are charging in this case. The purchasers of the hardware product will pay royalty for the use of that up to some economic point of diminishing returns. The people that you are going to charge for using the separate claim to the software used on that product are a different group of people, not the purchasers of the product.

Mr. FRANK. I am missing something. I thought it would be the owner of the hardware that would be using the software. I thought you were talking about charging me not just for the hardware I was using, but for the software I would be using on the hardware. Who is the different person?

Mr. SMITH. In that case it would be the same, but it is not required that you charge the user for the software. You can charge the developer of the software.

Mr. FRANK. If I make software, and somebody else buys it, you can't charge me for how he uses it. If I am the software developer and somebody who has bought the process patented hardware then buys my software and uses it there, there is no way you can charge me. How can you charge me? All I did was sell the guy the software. How can you charge me?

Mr. SMITH. I believe I can charge you a royalty if you wrote that software to run on that particular hardware.

Mr. FRANK. Oh, yes, if it was specifically to run on that or was just general and could be run on that as well as other stuff.

Mr. SMITH. Software typically does require some modifications to fit the hardware that it is going to run on. There are links that are necessary.

Mr. FRANK. And it would be a question of who did that. But if I designed it specifically for that hardware, then there is an issue.

Mr. SMITH. Correct. And I submit that in most cases that would be the situation.

When you write WordPerfect for Windows, you write it differently than if you write it for DOS.

Mr. HUGHES. Would the gentleman yield to me?

Mr. FRANK. Yes.

Mr. HUGHES. That is precisely the point. It is a new process, and patentable. And that is precisely the existing law.

Mr. SMITH. It is a new process, Congressman Hughes, but it is not an unobvious process. And the tribute that is being paid is for use of the process, not for use of the product. And as I understand the biotechnology examples, the problem that exists is principally where the process is used to make another product, whether that product be unpatentable or whether it be the product that is patentable.

In the data processing industry, the process that is involved is not one that is confined to the manufacture of the product. It is any process that the patented product can employ. I think there is a much greater danger in the case of the use of the patented product in that situation than there might be in the use of the obvious process to make a product, or the use of the process to make the patented product, if I have made myself clear.

Mr. HUGHES. Does the gentleman have anything further?

Mr. FRANK. No, thank you, Mr. Chairman.

Mr. HUGHES. You lost me in another area. Would you agree that under present law a product patentor can impose restrictions on his patent? Any question about that under existing patent law?

Mr. SMITH. What sort of restrictions?

Mr. HUGHES. Limitations. Restrictions on a patented product.

Mr. SMITH. There is a law that says once he has parted with that patented product, through the first sale doctrine he can no longer impose those restrictions on the further use or disposition.

Mr. WATERMAN. Unless they have another use claim.

Mr. HUGHES. Unless there is another claim.

Well, we thank you for your testimony. I think I understand it. I think I understand the position of the association. I have for some time. And I wish there was a perfect solution, but we very seldom ever find perfect solutions to anything. The perfect solution is usually the enemy of progress because we never find it.

But let me extend an invitation to you if you see some area where we can tighten it so that we don't unintentionally do damage to any other industry, I would be happy to look at it.

Mr. SMITH. We would be delighted to take you up on that offer.

Mr. HUGHES. We have extended that invitation before. We have extended that invitation for the better part of a year and a half while we have debated and-agonized over this issue. It is an important issue and we are going to move the bill expeditiously, so my

suggestion is if you have constructive suggestions, you might want to communicate them to us in the next 10 days or so.

Mr. FRANK. Mr. Chairman, I want to thank you. This has been a very useful hearing. Could we amend the House rules to add the concept of nonobviousness as a requirement for debate?

Mr. HUGHES. I think we could probably do that. That concludes the hearing for the day on that note, and the hearing stands adjourned.

[Whereupon, at 12:08 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

APPENDIX

STATEMENT OF HON. DENNIS DECONCINI, A SENATOR IN CONGRESS FROM THE STATE OF ARIZONA

CHAIRMAN HUGHES, RANKING MEMBER MOORHEAD, AND MEMBERS OF THE SUBCOMMITTEE, THANK YOU FOR INVITING ME TO SPEAK TODAY REGARDING H.R. 4307.

I WELCOME THIS OPPORTUNITY TO TESTIFY BECAUSE I BELIEVE THAT IT IS VITALLY IMPORTANT THAT CONGRESS ESTABLISH PROCESS PATENT PROTECTION FOR AMERICAN INDUSTRIES, SO THAT WE CAN CONTINUE TO LEAD THE WORLD IN MANY VERY IMPORTANT FIELDS. I APPLAUD THE CHAIRMAN FOR CRAFTING HIS LEGISLATION, AND ALTHOUGH IT IS A DIFFERENT APPROACH THAN THE SENATE BILL, IT CREATES A COMMON GROUND UPON WHICH WE CAN WORK TOGETHER AND PROVIDE THE NECESSARY PROTECTIONS.

AS THE CHAIRMAN KNOWS, THE SENATE HAS, ON TWO OCCASIONS, PASSED LEGISLATION WHICH IS SIMILAR, ALBEIT MORE NARROW, THAN THE BILL BEING CONSIDERED TODAY. THE SENATE BILL, S. 298, WHICH PASSED THE SENATE ON JULY 15, 1993 ESTABLISHES PROCESS PROTECTIONS FOR THE BIOTECH INDUSTRY.

WHILE I BELIEVE THAT THE NEED FOR THIS PROTECTION IS PARTICULARLY NECESSARY IN THE BIOTECH FIELD, THE UNDERLYING LEGAL PRINCIPLES FOR ESTABLISHING THE PROTECTION ARE VALID AND APPLICABLE REGARDLESS OF THE INDUSTRY IN QUESTION. THEREFORE, WHILE THE SENATE BILL AND THE HOUSE BILL DIFFER IN TERMS OF SCOPE, I BELIEVE THAT PROTECTIONS ARE NECESSARY TO ALLOW CERTAIN INDUSTRIES, SUCH AS BIOTECHNOLOGY, TO ATTAIN THEIR FULL POTENTIAL.

IT IS VITAL THAT THE HOUSE AND THE SENATE CAPITALIZE ON THESE BILLS AND WORK TOWARD A SUITABLE RESOLUTION. WE CAN ALL AGREE THAT AMERICAN LAW LAGS FAR BEHIND AND THREATENS THIS NATION'S SUPERIORITY IN MANY EMERGING TECHNOLOGIES.

THE REASONS FOR RESOLVING THIS ISSUE ARE SELF-EVIDENT. IT IS CLEAR, IN LIGHT OF IN RE DURDEN, THAT A SEVERE INCONSISTENCY EXISTS IN REGARD TO PROCESS PATENTS. IT IS ALSO CLEAR THAT CONGRESS, AND NOT THE COURTS, WILL ULTIMATELY HAVE TO RESOLVE THE INCONSISTENCY. WE HAVE BEEN WAITING FOR SOME TIME NOW, AND THE COURTS HAVE NOT CLARIFIED THE LAW ON THIS POINT. NO ONE IS BENEFITTING FROM THE PROTRACTED UNCERTAINTY IN THIS AREA OF PATENT LAW.

IN FACT, THE SURVIVAL OF BIOTECH DEPENDS UPON THE CERTAINTY CREATED BY EFFECTIVE AND ENFORCEABLE INTELLECTUAL PROPERTY LAWS. U.S. PATENT LAW NEEDS TO DETER FOREIGN PIRACY OF U.S. INVENTIONS

IF U.S. COMPANIES ARE TO SURVIVE IN INTENSELY COMPETITIVE INDUSTRIES. STRONG PROCESS PATENT PROTECTION WOULD PROVIDE THE SORT OF DETERRENCE TO FOREIGN PIRACY NECESSARY FOR COMPANIES TO RESEARCH AND DEVELOP AREAS OF EMERGING TECHNOLOGY.

WE SHOULD NOT PASS UP AN OPPORTUNITY TO PROVIDE AMERICAN COMPANIES WITH THE PROTECTION THEY NEED AND DESERVE. I KNOW THAT WE CAN REACH A SOLUTION TO THIS PROBLEM GIVEN THE COMMON GROUND BETWEEN THE HOUSE AND SENATE VERSIONS OF THIS LEGISLATION. I LOOK FORWARD TO WORKING WITH THE CHAIRMAN AND THE OTHER MEMBERS OF THIS SUBCOMMITTEE ON A FINAL RESOLUTION OF THIS MATTER.

THANK YOU FOR THE OPPORTUNITY TO TESTIFY ON LEGISLATION THAT THIS SENATOR BELIEVES IS NECESSARY FOR THE U.S. TO MAINTAIN ITS ROLE AS THE WORLD'S LEADER IN TECHNOLOGY.

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