AMENDING TITLE 35, UNITED STATES CODE, WITH RESPECT TO PATENTS ON CERTAIN PROCESSES

HEARING

BEFORE THE

SUBCOMMITTEE ON INTELLECTUAL PROPERTY AND JUDICIAL ADMINISTRATION

OF THE

COMMITTEE ON THE JUDICIARY HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

ON

H.R. 760

AMENDING TITLE 35, UNITED STATES CODE, WITH RESPECT TO PATENTS ON CERTAIN PROCESSES

JUNE 9, 1993

Serial No. 32

Printed for the use of the Committee on the Judiciary

U.S. GOVERNMENT PRINTING OFFICE

77-796 CC WASHINGTON : 1994

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402

ISBN 0-16-044440-3

COMMITTEE ON THE JUDICIARY

JACK BROOKS, Texas, *Chairman*

DON EDWARDS, California
JOHN CONYERS, JR., Michigan
ROMANO L. MAZZOLI, Kentucky
WILLIAM J. HUGHES, New Jersey
MIKE SYNAR, Oklahoma
PATRICIA SCHROEDER, Colorado
DAN GLICKMAN, Kansas
BARNEY FRANK, Massachusetts
CHARLES E. SCHUMER, New York
HOWARD L. BERMAN, California
RICK BOUCHER, Virginia
JOHN BRYANT, Texas
GEORGE E. SANGMEISTER, Illinois
CRAIG A. WASHINGTON, Texas
JACK REED, Rhode Island
JERROLD NADLER, New York
ROBERT C. SCOTT, Virginia
DAVID MANN, Ohio
MELVIN L. WATT, North Carolina
XAVIER BECERRA, California

HAMILTON FISH, JR., New York
CARLOS J. MOORHEAD, California
HENRY J. HYDE, Illinois
F. JAMES SENSENBRENNER, JR., Wisconsin
BILL MCCOLLUM, Florida
GEORGE W. GEKAS, Pennsylvania
HOWARD COBLE, North Carolina
LAMAR S. SMITH, Texas
STEVEN SCHIFF, New Mexico
JIM RAMSTAD, Minnesota
ELTON GALLEGLY, California
CHARLES T. CANADY, Florida
BOB INGLIS, South Carolina
BOB GOODLATTE, Virginia

JONATHAN R. YAROWSKY, *General Counsel*
ROBERT H. BRINK, *Deputy General Counsel*
ALAN F. COFFEY, JR., *Minority Chief Counsel*

SUBCOMMITTEE ON INTELLECTUAL PROPERTY AND JUDICIAL ADMINISTRATION

WILLIAM J. HUGHES, New Jersey, *Chairman*

DON EDWARDS, California
JOHN CONYERS, JR., Michigan
ROMANO L. MAZZOLI, Kentucky
MIKE SYNAR, Oklahoma
BARNEY FRANK, Massachusetts
HOWARD L. BERMAN, California
JACK REED, Rhode Island
XAVIER BECERRA, California

CARLOS J. MOORHEAD, California
HOWARD COBLE, North Carolina
HAMILTON FISH, JR., New York
F. JAMES SENSENBRENNER, JR., Wisconsin
BILL MCCOLLUM, Florida
STEVEN SCHIFF, New Mexico

HAYDEN W. GREGORY, *Counsel*
EDWARD O'CONNELL, *Assistant Counsel*
WILLIAM F. PATRY, *Assistant Counsel*
JARILYN DUPONT, *Assistant Counsel*
THOMAS E. MOONEY, *Minority Counsel*
JOSEPH V. WOLFE, *Minority Counsel*

CONTENTS

HEARING DATE

TEXT OF BILL

OPENING STATEMENT

WITNESSES

LETTERS, STATEMENTS, ETC., SUBMITTED FOR THE HEARING

Page

APPENDIXES

AMENDING TITLE 35, UNITED STATES CODE, WITH RESPECT TO PATENTS ON CERTAIN PROCESSES

WEDNESDAY, JUNE 9, 1993

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

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

Present: Representative William J. Hughes, Don Edwards, Howard L. Berman, Jack Reed, Carlos J. Moorhead, Howard Coble, and Bill McCollum.

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

OPENING STATEMENT OF CHAIRMAN HUGHES

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

Good morning and welcome to today's hearing. Today the subcommittee is conducting a hearing on legislation introduced by our distinguished colleague, Rick Boucher, who served ably on this subcommittee in past Congresses, and Carlos Moorhead, the ranking minority member of the subcommittee.

The subject of this hearing has been considered by this subcommittee in the past two Congresses, I might say, although the scope of the legislation has been somewhat modified. The primary issue under consideration is the extent to which the patent system provides adequate protection for biotechnological developments.

The proponents of the legislation maintain that unfriendly court decisions block them from getting necessary and appropriate patent protection. As a result, predatory foreign competitors are attempting to exploit the deficiencies in U.S. law by making our firms' products overseas and importing them back into the United States with impunity.

There is no question that the biotechnology industry plays a very significant role in our economy. Witnesses today will testify to that fact and also will emphasize the heavy investment of capital required to bring new biotechnology products to the marketplace.

Many of the biotechnological products being developed result in drugs needed to treat a wide array of illnesses and conditions ranging from common medical problems to life-threatening diseases such as AIDS.

The legislation mandates a change in patent law exclusively for biotechnology products. Industry-specific legislation is an approach we try to avoid as much as possible in patent law.

However, the various generic proposals we have seen in the past few years attracted a lot of criticism and opposition. Proponents turned to, or perhaps I should say returned to, solutions which are limited to changes in the law affecting only biotechnology.

While that may be unusual in the history of U.S. patent law, it may prove to be the best solution. In any event, it is necessary to examine the matter carefully to determine if the legislation is necessary and if this is the right legislation.

[The bill, H.R. 760, follows:]

I

103D CONGRESS
1ST SESSION

H. R. 760

To amend title 35, United States Code, with respect to patents on certain processes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 3, 1993

Mr. BOUCHER (for himself, Mr. MOORHEAD, Mr. COBLE, Mr. KOPETSKI, Mr. MCDERMOTT, Mr. DICKS, Mr. BLILEY, Mr. GALLEGLY, and Mr. MCCOLLUM) introduced the following bill; which was referred to the Committee on the Judiciary

---

A BILL

To amend title 35, United States Code, with respect to patents on certain processes.

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

TITLE I—BIOTECHNOLOGICAL PROCESS PATENTS

SEC. 101. CONDITIONS FOR PATENTABILITY; NONOBVIOUS SUBJECT MATTER.

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

(1) in the first unnumbered paragraph by inserting "(a)" before "A patent";

(2) in the second unnumbered paragraph by inserting "(b)" before "Subject matter"; and

(3) by adding at the end thereof the following new subsections:

"(c) Notwithstanding any other provision of this section, a claimed process of making or using a machine, manufacture, or composition of matter is not obvious under this section if—

"(1) the machine, manufacture, or composition of matter is novel under section 102 of this title and nonobvious under this section;

"(2) the claimed process is a biotechnological process as defined in subsection (d); and

"(3)(A) the machine, manufacture, or composition of matter, and the claimed process invention at the time it was made, were owned by the same person or subject to an obligation of assignment to the same person; and

"(B) claims to the process and to the machine, manufacture, or composition of matter—

"(i) are entitled to the same effective filing date; and

"(ii) appear in the same patent application, different patent applications, or patent which is owned by the same person and which expires or is set to expire on the same date.

"(d) For purposes of this section, the term 'biotechnological process' means any method of making or using living organisms, or parts thereof, for the purpose of making or modifying products. Such term includes recombinant DNA, recombinant RNA, cell fusion including hybridoma techniques, and other processes involving site specific manipulation of genetic material.".

SEC. 102. NO PRESUMPTION OF INVALIDITY.

The first unnumbered paragraph of section 282 of title 35, United States Code, is amended by inserting after the second sentence "A claim issued under the provisions of section 103(c) of this title on a process of making or using a machine, manufacture, or composition of matter shall not be held invalid under section 103 of this title solely because the machine, manufacture, or composition of matter is determined to lack novelty under section 102 of this title or to be obvious under section 103 of this title.".

SEC. 103. EFFECTIVE DATE.

The amendments made by this title shall apply to all United States patents granted on or after the date of the

enactment of this Act and to all applications for United States patents pending on or filed after such date of enactment, including any application for the reissuance of a patent.

TITLE II—BIOTECHNOLOGICAL MATERIAL PATENTS

SEC. 201. INFRINGEMENT BY IMPORTATION, SALE OR USE.

(a) INFRINGEMENT.—Section 271 of title 35, United States Code, is amended by adding at the end the following new subsection:

"(h) Whoever without authority imports into the United States or sells or uses within the United States a product which is made by using a biotechnological material (as defined under section 154(b)) which is patented in the United States shall be liable as an infringer if the importation, sale, or use of the product occurs during the term of such patent.".

(b) CONTENTS AND TERM PATENT.—Section 154 of title 35, United States Code, is amended—

(1) by inserting "(a)" before "Every";

(2) by striking out "in this title," and inserting in lieu thereof "in this title (1)";

(3) by striking out "and, if the invention" and inserting "(2) if the invention";

(4) by inserting after "products made by that process," the following: "and (3) if the invention is a biotechnological material used in making a product, of the right to exclude others from using or selling throughout the United States, or importing into the United States the product made or using such biotechnological material,"; and

(5) by adding at the end thereof the following: "(b) For purposes of this section, the term 'biotechnological material' is defined as any material (including a host cell, DNA sequence, or vector) that is used in a biotechnological process as defined under section 103(d).".

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendment made by this section shall take effect six months after the date of enactment of this Act and, subject to paragraph (2), shall apply only with respect to products made or imported after the effective date of the amendments made by this section.

(2) EXCEPTIONS.—The amendments made by this section shall not abridge or affect the right of any person, or any successor to the business of such person—

(A) to continue to use, sell, or import products in substantial and continuous sale or use by such person in the United States on the date of enactment of this Act; or

(B) to continue to use, sell, or import products for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investment made or business commenced in the United States before such date.

O

Mr. HUGHES. The Chair recognizes the distinguished ranking Republican member, Mr. Moorhead.

Mr. MOORHEAD. Thank you, Mr. Chairman.

I very much appreciate the scheduling of these hearings. I know the chairman's schedule has been full and that the subcommittee schedule has also been full, and I do appreciate all of his efforts in making these hearings possible. I would like to certainly commend our friend and lead sponsor of this bill, Rick Boucher of Virginia, for his work on this legislation and welcome Senator DeConcini here this morning. We are honored to have you here, Senator.

From an economic point of view, the U.S. biotech industry has gone from zero revenues and zero jobs 15 years ago, to $6 billion and 70,000 jobs today. The White House Council on Competitiveness projects a $30 to $50 billion market for biotech products by the year 2000, and many of the industry believe this estimate to be 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 technology companies are so vulnerable is that for them the cost of innovation, rather than the cost of production, is the key cost that is incurred in bringing the 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. Last year 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. I am concerned that with the cut in the PTO budget that they will not be able to reduce this backlog.

Delays of this type are unacceptable, particularly for an industry that is so dependent upon patents to raise capital for reinvestment in manufacturing plants and in new product development, and even more so for an industry targeted by Japan for major and concerted competition. The Patent Office has taken steps to improve the situation, reorganizing its biotechnology examination group and increasing the number of new examiners it intends to hire over the next year. The PTO is also implementing special pay rates for their biotech examiners and creating new expert biotech examiners.

This subcommittee made the first step in 1988 in the omnibus trade bill, when the Congress enacted two bills I introduced relating to process patents and reform of the International Trade Commission. However, our work will not be complete until we enact H.R. 760, which has been introduced by Rick Boucher and Howard Coble, Bill McCollum and others, myself included.

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 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 comparatively little in biotechnology research, have targeted the biotech industry for major and concerted action. According to the Biotechnology As-

sociation 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 per year industry by the year 2000. If we fail to enact this legislation, the Congress may contribute to 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 third hearing on this type of legislation. We know there is a problem. Let's devise a solution and move this legislation to the House floor.

Welcome again to our guests this morning.

Mr. HUGHES. The gentleman from Florida.

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

As a cosponsor of this legislation as well, I certainly commend Mr. Boucher and welcome him and Senator DeConcini.

I would like to make a brief comment or two, but I would not wish to read an entire statement. I would like to ask unanimous consent, if I could, to put my complete statement in the record?

Mr. HUGHES. Without objection.

Mr. MCCOLLUM. Thank you.

In 1981, more than 100 million people were treated with products derived from biotechnology. Today more than 100 new products are in clinical trials, including therapies for diseases such as Alzheimer's, AIDS, cancers, cystic fibrosis, septic shock, and others.

The United States leads the world in biotechnology research and manufacture. However, the prominence of this breakthrough industry, Mr. Chairman, I believe is endangered.

A typical biotechnology company will spend $230 to $350 million to bring a drug from the stage of discovery to that of marketing. On average, it takes 12 years before FDA approval is granted.

This time-consuming and costly process forces biotechnology companies to rely on patent protection for adequate return on their investment. The threat of imitators who manufacture duplicate drugs is enough to ward some companies away from developing drugs.

Common sense tells us to reward innovation and punish imitators. Yet the opposite is true in our present patent law.

Foreign competitors are legally permitted to use a patented host cell, DNA sequence, or vector offshore to manufacture a drug, and then import the finished product for sale in the United States. The biotechnology industry's survival will be threatened if foreign competitors are allowed to continue to circumvent patent laws. Yet this piracy is rewarded in the present law and encourages businesses to go overseas to evade U.S. law.

There are two basic reasons why this piracy must be halted: Most importantly, the economic drawbacks are insurmountable for companies. Promising therapies may not be pursued as a result of the drying up of venture capital investments by those unsure of financial security and chance at profit.

In deciding whether to proceed with the development of a product, biotechnology companies must look at the market potential of the drug. The company must be assured that another company cannot pirate the original company's research.

Yet this is simple, as most breakthroughs are published in scientific journals. Without adequate patent protection, companies will not be giving the go-ahead to proceed, as their early investment would be worth little in the global market. High costs associated with prosecution and litigation regarding patent disputes also drain research funds for companies.

Second, the lack of straightforward patent laws leads to inconsistent results by patent examiners. And then as was discussed, the case of *In re Durden* is a real problem, and I think that it was erroneous and we need to do something about that, Mr. Chairman.

In short, as I said, I am not going to read the complete statement in the record. I simply think we have got a major problem and I am looking forward to hearing the witnesses.

Mr. HUGHES. I thank the gentleman.

[The prepared statement of Mr. McCollum follows:]

PREPARED STATEMENT OF HON. BILL MCCOLLUM, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

I want to begin by thanking the chairman for scheduling this legislative hearing on H.R. 760, the Biotechnology Patent Protection Act. As an original cosponsor of H.R. 760, I am very pleased that the subcommittee is considering this important legislation.

In 1991, more than 100 million people were treated with products derived from biotechnology. Today, more than 100 new products are in clinical trials including therapies for diseases such as Alzheimer's, AIDS, cancers, cystic fibrosis, septic shock, and others. The United States leads the world in biotechnology research and manufacture. However, today the prominence of this breakthrough industry is endangered.

A typical biotechnology company will spend $230 to $350 million dollars to bring a drug from the stage of discovery to that of marketing. On average, it takes twelve years before FDA approval is granted. This time-consuming and costly process forces biotechnology companies to rely on patent protection for adequate return on their investment. The threat of imitators who manufacture duplicate drugs is enough to ward some companies away from developing drugs.

Common sense tells us to reward innovation and punish imitators. Yet the opposite is true in our present patent law. Foreign competitors are legally permitted to use a patented host cell, DNA sequence, or vector offshore to manufacture a drug, and then import the finished product for sale in the United States. The biotechnology industry's survival will be threatened if foreign competitors are allowed to continue to circumvent patent laws. Yet this piracy is rewarded in the present law and encourages businesses to go overseas to evade U.S. law.

There are two basic reasons why this piracy must be halted. Most importantly, the economic drawbacks are insurmountable for companies. Promising therapies may not be pursued as a result of the drying up of venture capital investments by those unsure of financial security and chance at profit. In deciding whether to proceed with the development of a product, biotechnology companies must look at the market potential of the drug. The company must be assured that another company cannot pirate the original company's research. Yet this is simple as most breakthroughs are published in scientific journals. Without adequate patent protection, companies will not give the go-ahead to proceed as their early investment would be worth little in the global market. High costs associated with prosecution and litigation regarding patent disputes also drain research funds for companies.

Secondly, the lack of straightforward patent laws leads to inconsistent results by patent examiners. The application of *In re Durden*, a non-biotech patent case, to the biotechnology industry is erroneous. Some examiners refer to *In re Mancy* as more applicable, which is indeed the case. The PTO has recommended to Congress that unless legislation is enacted in this area, the uncertainly here will continue and worsen. The time-consuming and expensive process of patent litigation as a result of this confusion would be obviated by a clearer law.

The proposed Biotechnology Patent Protection Act would solve these problems. The act closes a loophole that allows unfair imports of biotechnology-derived products to be sold in the United States. Under this bill, the federal court's jurisdiction will be extended to exclude foreign products that are made through the use of a pat-

ented U.S. product. Our bill addresses this deficiency directly by extending process patent protection to cover the inventor's process of making the product. Process patents permit the manufacturer to exclude imitators from manufacturing, using or selling an invention for 17 years on the method of producing a product. These patents are routinely issued overseas in Western Europe and Japan.

Our current law grants foreign competitors unnecessary and unfair advantages. It leaves our inventors legally powerless to protect their ingenuity. Its revision would reward high risk and innovation and consequently benefit the public interest by stimulating the development of drugs to treat diseases. This bill will promote competitiveness and fairness by producing an international patent standard that provides equality with foreign competitors. To rid the market of unfair advantages is not discriminatory—but will restore parity. It will update our patent laws to allow biotechnology inventions to obtain the same kind of protection as already exists for other types of inventions both here and abroad.

This bill is prospective in that only actions which take place after the effective date are prohibited. It is supported by the pharmaceutical and biotechnology industries as well as the university community. It enjoys wide bipartisan support. Former President Bush's administration supported the bill, and President Clinton has also indicated his support of rectifying current shortcomings in the law.

Present U.S. patent laws governing process patents are inadequate. Unless adequate patent protection is granted for biotechnology-derived products, patients will be denied cutting-edge therapies, and the U.S. will lose a strong and viable industry which currently contributes millions of dollars worth of exports to the U.S. balance of trade. The enactment of this bill will remove a court-imposed obstacle to the progress of an industry we should be promoting—not impeding. This bill benefits the biotechnology industry, the public, and the United States. It provides a legislative remedy for current inadequacies in the law and promotes an industry which focuses on significant, unmet needs. In order for these needs to continue to be met, the biotechnology industry must be protected.

Mr. HUGHES. We have a most distinguished first panel. Rick Boucher is our colleague from the Ninth District of Virginia. He has served in Congress since 1983.

He is presently a member of the Committee on the Judiciary, the Committee on Energy and Commerce, and chairs the Subcommittee on Science, Space and Technology. He has served on this particular committee in past Congresses and contributed immensely to the work of this particular subcommittee. We welcome him to the Subcommittee on Intellectual Property and Judicial Administration.

Senator DeConcini is a cosponsor of the Senate counterpart to H.R. 760 in the Senate, S. 298. Senator DeConcini has served in the Senate since 1977. He is the senior Senator from Arizona.

He serves on the Senate Judiciary Committee and is the chairman of the Subcommittee on Patents, Copyrights and Trademarks. He also serves on the Committee on Appropriations, the Committee on Rules and Administration, the Committee on Veterans' Affairs, and is chairman of the Select Committee on Intelligence.

Maybe you can share with us what you do in your spare time.

He is a most distinguished Member of the Senate. I might say, we have had an excellent working relationship on intellectual property issues.

He does an outstanding job, and we are just delighted to have you with us also, Dennis.

Your statements, without objection, will be made a part of the record.

We hope you can summarize, but you may proceed as you see fit.

Who would like to go first?

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

Mr. DECONCINI. Mr. Chairman, I thank my colleague, Mr. Boucher.

I am chairing an Appropriations Subcommittee that starts at 10:15, and it is now 10:30, so I appreciate the opportunity and thank you, Congressman, very much.

Mr. Chairman and Ranking Member Moorhead, Mr. McCollum, I first want to truly thank you for an opportunity to be permitted to come over here to the House and to testify on H.R. 760. This is an important piece of legislation, the Biotechnology Patent Protection Act of 1993, and indeed, I can't think of anything more important from the standpoint of our country's capability to be competitive and move forward.

I wanted to testify here primarily, if I can, to leave the impression with this committee of the strong, strong support that H.R. 760 has in the Senate. The Senate companion measure, S. 298, passed the Judiciary Committee in March of this year by unanimous consent. Identical legislation also passed the Senate near the end of the last Congress.

The United States is the world leader in biotech inventions and presently biotechnology is a $2 billion a year industry. However, it is expected to increase to $50 billion by the year 2000. More important than the billions of dollars that this industry generates for our economy, biotechnology offers potential solutions to seemingly hopeless problems. And currently, biotechnology researchers are developing new energy sources, cures for cancer, heart disease and healthier food products.

Unfortunately, because of the rapid growth of this dynamic area, our laws have failed to keep up with the advances of biotechnology. And unlike some other industries, biotechnology is highly dependent on patent protection.

Without process patent protection, not only does investment dwindle but U.S. firms remain vulnerable to the unauthorized use of these patents abroad.

Mr. Chairman, I am not going to go into my full statement because of your time, I would ask that it be included in the record, which you have already agreed to.

I do want to say this legislation provides no more protection to the biotechnology industry than what current law was intended to provide. Even the opponents of this legislation will concede today that the protection should be provided. We only disagree on the means.

We often hear the common refrain from opponents to wait for another decision from the Federal courts. Well, Mr. Chairman, it has been 8 years since *In re Durden* was decided.

Case after case has come down from the courts on the issue, yet the Patent Office continues to reject biotech process claims because of the *Durden* decision. It is time to provide some certainty in the area of the law.

Mr. Chairman, the U.S. biotech companies invest enormous amounts of capital and many years of research in producing their products. In return, they need to be provided adequate intellectual property rights and protection against unfair foreign competition.

So in closing, Mr. Chairman, I hope if I can leave any impression here at all with this distinguished committee, and the distinguished chairman, we look forward to working with you on this legislation as well as other legislation.

Mr. Boucher and Mr. Moorhead, and others who have put this legislation forward for several years, should be commended. We have worked on this with them.

I want to just also comment, Mr. Chairman, that working with you and the ranking member and the other members of this committee is a joy. And, you know, between our two Houses, we don't always have joys because of the nature of the beast. But though we have disagreements, we are able to sit down and time and time again, year after year, and even when the chairman of this committee was chairman of the Criminal Law Subcommittee in the House Judiciary Committee—you are a gifted person because you know that legislation needs to happen in the spirit of finding what is best for the particular problem and working it out. And I commend you for that, Mr. Chairman.

I look forward to working with you and this Congress on a number of issues.

Mr. HUGHES. Thank you very much, Senator.

[The prepared statement of Mr. DeConcini follows:]

PREPARED 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 permitting me to speak today on H.R. 760, the Biotechnology Patent Protection Act of 1993.

I wanted to testify before your subcommittee because I thought it was important for you to know of the strong support that H.R. 760 has in the Senate. The Senate companion measure, S. 298, passed the Judiciary Committee on March 16 by unanimous consent. Identical legislation also passed the Senate near the end of the last Congress.

The United States is the world leader in biotech inventions. Presently, biotechnology is a $2 billion a year domestic industry. However, it is expected to increase to $50 billion by the year 2000.

More important than the billions of dollars that this industry generates for our economy, biotechnology offers potential solutions to seemingly hopeless problems. Currently, biotechnology researchers are developing new energy sources, cures for cancer and heart disease, and healthier food products.

Unfortunately, because of the rapid growth of this dynamic area, our laws have failed to keep up with the advances in biotechnology. Unlike some other industries, biotechnology is highly dependent on patent protection. But the ability to obtain the needed patent protection to spur research and development in this field has been seriously lacking.

Without process patent protection, not only does investment dwindle but U.S. firms remain vulnerable to the unauthorized use of their patents abroad.

The United States has a bad habit of creating obstacles for cutting edge technologies just when our global competitors are gearing up.

Time and time again we hear of a U.S. industry losing its global lead to a country that is willing to provide that industry with the tools to succeed. S. 298 is an essential tool to ensure the continued success of the U.S. biotechnology industry. By enacting this legislation—now—we will not have to witness—tomorrow—the loss of another leading technology to a foreign competitor.

No one denies that the biotech industry has had a patent problem. It has been going on for some time. We only differ on the solution.

This legislation provides no more protection to the biotechnology industry than what current law was intended to provide. Even the opponents of this legislation concede that this protection should be provided. We only disagree on the means.

We often hear the common refrain from opponents to wait for another decision from the Federal circuit. Mr. Chairman, it has been 8 years since *Durden* was decided. Case after case has come down from the circuit on this issue. Yet, the Patent

Office continues to reject biotech process claims because of *Durden*. It is time to provide some certainty in this area of the law.

This legislation would also close the loophole that permits foreign piracy of patented biotech material. I and many others worked very hard to pass the Process Patent Act of 1988. However, the biotech industry is now facing the same problem that led us to pass the 1988 act.

The Biotechnology Patent Protection Act prevents competitors from using a patented invention overseas and then shipping the resulting product into the United States. This is merely an issue of fairness. Why should a competitor be permitted to ship into the United States a product—that if made here—would be a patent infringement?

Mr. Chairman, United States biotech companies invest enormous amounts of capital and many years of research to produce their products. In return, they need to be provided adequate intellectual property rights and protected against unfair foreign competition.

In closing, I want to thank Representatives Boucher and Moorhead and the other cosponsors for their work on this legislation. I want to especially thank you, Mr. Chairman, for moving forward on H.R. 760. your leadership is essential for its progress.

Once again, I appreciate the opportunity to present my views to the subcommittee.

Mr. HUGHES. Speaking of joys, we just sent you one of our joys a week ago. The economic package.

Mr. DECONCINI. As I said, Mr. Chairman, there will be changes made.

Mr. HUGHES. What a delightful experience. Anyway, thank you very much.

Is floor action scheduled on S. 298?

Mr. DECONCINI. It is not yet, but will soon be, I believe. We are still leaving the record open for the report.

It is at the printer and should be through sometime in month. I hope to get that bill passed without a big debate or any big problem.

I don't know what will happen to it in our body, as you know, it is subject to anything coming up on it. But I am optimistic that we can pass it again as we did last year.

Mr. HUGHES. Thank you.

Well, I don't have any questions because your excellent statement is very comprehensive. We appreciate you appearing this morning to testify on behalf of this legislation.

Do the members have any questions of the Senator?

If not, I am going to excuse the Senator since he has a hearing he has to chair.

Mr. MOORHEAD. Mr. Chairman, we really appreciate him coming over. I agree with your statement, I think it was great.

Mr. DECONCINI. Thank you, Mr. Chairman.

Mr. HUGHES. Rick, we welcome you. We have your statement which also is a part of the record, and you may proceed as you see fit.

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

Mr. BOUCHER. Thank you, Mr. Chairman.

I am going to summarize the written statement. I am very pleased to appear this morning to testify in support of H.R. 760; in which I am also pleased to be joined in cosponsorship by the distinguished ranking Republican member of this subcommittee, the

gentleman from California, Mr. Moorhead, and by a number of other members of the subcommittee.

I want to thank you, Mr. Chairman, for directing the subcommittee's attention to a very important matter and for taking the time to schedule today's hearing.

The biotech industry is an industry with a bright promise for the success of the Nation in the global markets of the future. It is a uniquely American enterprise, which as Mr. Moorhead indicated, employs more than 70,000 people, and these are all new jobs. They are high-wage jobs and they are high-skill jobs.

Biotechnology firms are making major contributions to our social needs, as well, in areas such as health care and agriculture. On the market today are products derived from biotechnology for the treatment of cancer, diabetes and heart attacks. And, as Mr. McCollum indicated, a number of promising new products are on the way for the treatment or possible cure of diseases such as AIDS, Alzheimer's, cystic fibrosis and Lou Gehrig's disease.

Yet, Mr. Chairman, the promise of the biotechnology industry is seriously challenged by a simple and obvious defect in our patent law. That inadequacy opens the door for foreign firms to expropriate American inventions and compete in this country, directly with the firm in this country that originated and invented the product.

In essence, the patent law confers an advantage on foreign companies that is not conferred on U.S. firms. It actually encourages a pilfering of U.S. creativity, and we have examples of that conduct occurring.

It is to that defect in the patent law that H.R. 760 is addressed. In most cases, biotechnology products are genetically engineered forms of chemicals which naturally occur. They naturally occur in very small quantities. And what the biotechnology companies do is manufacture those naturally occurring products in larger commercially viable quantities. To do that, companies engineer a host cell to produce the product.

The firm then treats the host cell with a frequently straightforward and otherwise known process to create that product in commercially viable quantities. The company can't patent the end product because it naturally occurs in nature. All the company is doing is creating that natural product in larger quantities.

The company can patent the host cell, but under current law, the use of a patented host cell abroad to manufacture a product for importation back into the United States is not an infringement of the host cell patent. And under the 1985 ruling in *In re Durden,* the process that is used by the firm cannot be patented. H.R. 760 is the effort that Mr. Moorhead and I have put before the subcommittee to address the problem.

In title I of the bill, the process that is used by biotechnology firms would become patentable. If the process receives a patent, then under 35 U.S.C., section 271(g), the importation into the United States of a product made by the use of that process would then be an infringement of the patent and the product could then be excluded.

In title II of the bill, the use abroad of a host cell that is patented in the United States would constitute a patent infringement when the product is imported back into this country.

I would suggest, Mr. Chairman, that a comprehensive solution to the problem would be the enactment of both titles I and II of the bill. But an effective solution of the problem would be the enactment of either title I or title II. Either path that the subcommittee chooses would solve the problem and do so in an effective manner.

Mr. Chairman, this is a serious problem. It threatens a very important industry, an industry that is important to us both commercially and for social reasons. I think it is a problem that requires a legislative solution.

We have heard since the bill was first introduce in 1989, that if we simply provided more time, the courts on their own would solve this problem. Here we are 4 years later, additional court decisions, as Senator DeConcini indicated, have been handed down but the problem remains.

I would respectfully suggest that the problem is not going to be solved by additional litigation. That will only be costly. It will serve to deter investment in biotechnology research, and the time truly has come for a legislative solution.

So I thank the subcommittee for its attention to this concern and very much hope that during the course of this 103d Congress, we will see a legislative solution for the problem. The Senate has acted through the Judiciary Committee, and is expected to act soon on the Senate floor, and I would hope that this committee will join the Senate in that favorable consideration.

Thank you, Mr. Chairman.

Mr. HUGHES. Well, thank you.

[The prepared statement of Mr. Boucher follows:]

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

Mr. Chairman, I am pleased to appear before the Subcommittee to testify in support of H.R. 760, the Biotechnology Patent Protection Act of 1993.

The American biotechnology industry is one of the crown jewels of our internationally competitive economic future. In the past ten years, this uniquely American enterprise has created nearly 100,000 new high skill and high wage jobs.

Biotechnology firms are addressing pressing social needs in the areas of human health care and agriculture. Currently on the market are products for the treatment of cancer, diabetes and heart attacks. In development are potential cures and treatments for AIDS, Alzheimer's disease, cystic fibrosis and Lou Gehrig's disease.

Biotechnology is a shining example of the successful transfer of technology from the federally supported biomedical infrastructure of the NIH to the private sector. Yet, the promise of this exciting growth industry is being challenged by a simple and obvious inadequacy in our patent law.

In most cases, biotechnology products are genetically engineered forms of chemicals which occur in nature. To create them, a biotech firm genetically engineers a host cell to produce a particular hormone or protein. The firm then treats it according to a frequently straightforward process, which causes the cell to begin producing that hormone or protein. The result is a unique starting product used to create a unique end product. Given that these end products already exist in nature, they are essentially unpatentable. Biotech firms, therefore, count on patenting the process they use to produce the protein in order to protect their R&D investment and the innovations that investment produces.

A 1974 decision, *In re Mancy,* allowed process patents when the novel starting material was combined with a previously known process to yield an unexpected result.

In 1985, however, a case called *In re Durden,* dealing with a science unrelated to biotechnology, found the opposite. Regardless of whether a firm has invented a new end product, the Patent Office must examine the process in isolation from its starting material and final result in order to issue a process patent.

The net result of this inconsistency is a real world risk that American inventions—such as Amgen's EPO—could be unfairly copied by foreign rivals and used to produce a freely importable end product. As the Chairman said during our hearing on November 21, 1991, "You have to concede there is a problem. There is a problem."

The reason there is a problem could be, as most commentators and the industry suggest, that *Durden* was incorrectly decided. Or there is a problem because—as former Patent Commissioner Man beck and Solicitor McElvey have said in testimony and in pending litigation—the *Durden* case cannot be reconciled with other appellate precedents. Or there is a problem because with the current application of the *Durden* case by the patent examiners that no rational, predictable result is possible when filing for process claims.

Regardless of the reasons, there is a consensus that a problem exists. The disagreement arises from how best to solve it.

Some of the witnesses before you today will argue that continued litigation is the best answer. I disagree. That argument was first made in 1989 when this legislation was first discussed. In the intervening four years, the industry has invested over $7 billion in new R&D and still there is no solution to the patent issue in sight. Congress has frequently rejected a call for patience and judicial resolution when there was a demonstrable harm. There is no question that there is demonstrable harm in this case. The cost of litigating these process claims may be good for lawyers, but it is not useful to society.

Nor is it useful for our patent law deficiencies to encourage the use of American inventions off-shore to create unfair foreign competition.

The fact that Amgen came close to running aground over this problem should be evidence enough of the problem. Yet as the record from the hearing in the last Congress in which two additional cases were described demonstrates and testimony before this Congress underscores, this continued uncertainty is creating a real risk for American inventors.

It is up to the Congress to act to set a fair and complete patent policy when the courts have failed. It is very clear to me that such a failure has occurred here.

I urge my colleagues to listen carefully to the testimony here today and see if you can understand why the biotechnology industry is so concerned about this legislation.

This is the fourth hearing on legislation to address the patent problems of the biotechnology industry held in the last four years. Currently, the hearing record is over 625 pages long, and I hope that by the end of this hearing the need for the legislation will be recognized and the Subcommittee will move to a mark-up soon.

Thank you, Mr. Chairman, for allowing me this opportunity to express my views on this important bill.

Mr. HUGHES. I want to congratulate the gentleman from Virginia because he has worked very diligently on this issue for as many years as I can remember. I know that he has gone through the throes of a number of different proposals, generic, industry specific, in attempting to deal with what is or could potentially be a very serious problem for one of our very, very important industries. I congratulate the gentleman for his yeoman's work in that area.

I have no questions, I think your statement is extremely comprehensive and very helpful.

The gentleman from California.

Mr. MOORHEAD. I certainly agree that you have a very fine statement and I want to congratulate you also. I think it is important when we talk about delays, so many of these companies, in the biotech industry aren't huge companies that have lots of money to spare.

Some of them only have one or two products that they are working on and long delays can bankrupt them, in many instances, and some of the companies have had difficulties along that line. It is easy to talk about waiting until the courts come up with a solution, but for some that may be too late.

For a growing industry, it is very important that they have a playing field that they can understand, regardless of what the play-

ing field is, one that is comprehensible, so that they can plan for their future in such a way that they can make good judgments, and I don't think that they can under the present state of the law. I think it has to be changed.

Mr. HUGHES. Thank you.

Any members have any questions?

The gentleman from Florida.

Mr. MCCOLLUM. I do, Rick, if I could, because the critics of this legislation would suggest several things that are wrong with it. And I just wanted to very briefly give you an opportunity to respond to some of that.

They suggest that there has not been a single case cited of actual commercial harm to any U.S. company from foreign competition. They suggest that none of the major first-generation products to emerge in the industry has lacked effective patent protection. They suggest that the *Pleuddemann* and *Dillon* cases sufficiently modify *Durden,* that there is no need for us to be concerned about *Durden* any longer. And they suggest it would be a terrible blow to the patent law, from the standpoint of precedent, to give some special treatment, as they see it, to biotechnology and by changing definitions or codifying them.

Do you have any responses to those?

I know you were taking copious notes on what I said, which I rarely get anyone to do, let alone a Congressman.

Mr. BOUCHER. I have responses to each of those, and I will be brief about it.

Some of the other witnesses will testify and talk somewhat more directly about the particular harm that has arisen to individual companies as a consequence of these inadequacies. Amgen had a problem which existed several years ago, which, as I recall, was resolved through a settlement eventually, but the course of litigation and the uncertainties arising from that litigation proved to be quite costly to the company, and it was the classic case of the kind of problem that we are addressing with this bill.

In the *Amgen* case, a Japanese company appropriated that technology, made the product in Japan and then imported that product back into the United States. Amgen had a patent on its starting material and host cell.

But those patents did not protect Amgen from the imports of the product manufactured abroad, because it is not viewed under the current condition of U.S. patent law to be a violation of the U.S. host cell patent to use the patented host cell overseas, manufacture the product and then ship it back into the United States.

Title II of our bill would make it a violation of the host cell patent to import the product from that host cell and that would be a very discrete and straightforward way of solving this particular problem. I think you will hear about the *Amgen* case in more detail later, but that is certainly one example of real harm occurring.

The second question raised was whether or not biotech companies really have effective patent protection, and then I would go back to that same example, they really don't. The only things they can patent today are the starting material and the host cell. *In re Durden* says they frequently can't patent the process; they often can't patent the final product because it has been previously puri-

fied, and in any event, the biotechnology process simply creates that in commercially viable and pure quantities.

So the only point in the process where they can reliably get any kind of patent is on the starting material and the host cell. And under current law, that starting material patent doesn't protect them from the manufacturer of the product offshore, so clearly they don't have an effective patent.

The case of *In re Pleuddemann* didn't clarify the *Durden* problem. In fact, it is muddying the waters. In preparation for the hearing today, I was reading the transcript of the hearing we had several years ago in which Commissioner Manbeck, who at the time was the head of the PTO, was asked that precise question.

In fact, I asked him that question. And he said that *In re Pleuddemann* actually made the law more muddled than it was before and certainly doesn't offer any great protection to biotechnology firms. And in the wake of *In re Pleuddemann,* the confusion exists, and the PTO has not been consistently awarding process patents, so we certainly don't get any relief on that.

Then the question of special treatment, I would say all we are really trying to do for biotechnology is what has already been done for other industries. We are not asking for anything special for biotechnology. We simply want to protect this American industry from unfair foreign expropriation of its creativeness.

Mr. MCCOLLUM. Thank you.

You have done a very good job of taking notes as always.

Mr. HUGHES. The gentleman from California, any questions?

Mr. EDWARDS. I want to thank you, Mr. Boucher, for a very valuable description. This is of great interest in Silicon Valley, where I come from. It is an important part of the high tech industry.

Mr. HUGHES. The gentleman from North Carolina.

Mr. COBLE. Thank you, Mr. Chairman. I will be very brief.

I want to put a question to the gentleman from Virginia, perhaps, to extend what you said, Rick, in response to the gentleman from Florida's question.

I am a cosponsor of this legislation, you perhaps know. And not unlike other issues, Mr. Chairman, that come before us, we have convincing arguments submitted on the one hand and then 5 minutes later we hear equally convincing arguments on the other hand.

In a simplified way, Rick, let me ask you this: The members of the private patent bar who insist that there is indeed no problem, conversely there are spokespersons from different biotech firms who insist, in an equally convincing manner, that there is indeed a problem.

Perhaps other witnesses might, can elaborate in more detail on it, but I would be glad to hear from you on this, about this conflict.

Mr. BOUCHER. Well, there clearly is a problem as the *Amgen* case adequately demonstrates. I think the greater problem may not be to simply count up the number of active circumstances where products have been manufactured offshore and then shipped back into the United States, but to look at what the potential for that to happen has done or may be doing today to the willingness of biotech firms to make the major investments in research that are necessary to create new products.

This is an enormously research-intensive industry, and while the research investments accumulate something like $2 to $3 billion annually, if you aggregate all of what the industry is doing, I rather suspect that number would be higher if the patent law were clearer. So if we can provide stability by remedying this defect, instead of seeing $2 to $3 billion in research on an annual basis, I think, we will experience far greater investment, and instead of bringing a hundred products to market, we will increase that figure as well. And I think that the real value of this effort is that it will provide stability and a solid foundation that would encourage research investment by the industry.

Mr. COBLE. Thank you.

Thank you, Mr. Chairman.

Mr. HUGHES. Does the gentleman from Rhode Island have any questions?

Mr. REED. Mr. Chairman, I just want to commend Mr. Boucher for his efforts in this regard and for his mastery of the subject.

Mr. HUGHES. Before the gentleman leaves, I want to say we are going to hear from the Patent Office. I understand they have been accepting the process patents, it just depends on how it is worded. Which is kind of an unusual quirk in the law, but if it is framed in terms of use under *Pleuddemann,* it has a far better chance of being accepted and making it. So we will hear from the Patent Office as to what the state of the law is.

Mr. BOUCHER. Mr. Chairman, if I could comment on that. It may be that there is a way to contort a patent application to frame the process in terms of use instead of manufacturing. Under *Pleuddemann,* the manufacturing process claims are not allowed.

Yet it is rather clear to me that what is actually involved here is a manufacturing process taking a host cell, applying a process to it to create a final product. That is classic manufacturing.

Mr. HUGHES. There, obviously, is some confusion, and your point is well taken in that regard. But I just thought I would clarify the record. We will hear from the PTO that they are accepting process patents.

Mr. BOUCHER. And endorsing title II of the bill?

Mr. HUGHES. Yes. Which is an interesting revelation.

Thank you very much.

Mr. BOUCHER. Thank you very much.

Mr. HUGHES. Our next witness is Michael Kirk, who is presently the Acting Assistant Secretary and Acting Commissioner of Patents and Trademarks, and has been since February 15, 1993, and is accompanied by Charles Van Horn of the PTO.

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 is also the Assistant Commissioner for External Affairs at the PTO. In this position, he has been responsible for legislative matters.

Michael Kirk received his bachelor of science in electrical engineering from the Citadel in 1959, and his doctor of law degree in 1965 from the Georgetown University Law Center. In 1969, he added a master of public administration from Indiana University.

We welcome you once again to the subcommittee, Mr. Kirk.

We have your statement which, without objection, will be made a part of the record in full. We would like you to summarize for us because we have read your statement and it would be very helpful to us if you do.

You may proceed as you see fit.

STATEMENT OF MICHAEL K. KIRK, ACTING ASSISTANT SECRETARY AND ACTING COMMISSIONER OF PATENTS AND TRADEMARKS, U.S. PATENT AND TRADEMARK OFFICE, U.S. DEPARTMENT OF COMMERCE, ACCOMPANIED BY CHARLES E. VAN HORN, PATENT POLICY AND PROJECTS ADMINISTRATOR, OFFICE OF ASSISTANT COMMISSIONER OF PATENTS, U.S. PATENT AND TRADEMARK OFFICE

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

Members of the subcommittee, I am pleased to appear here today to testify on H.R. 760, a bill that would provide added protection for the owners of patented biotechnological materials. The administration supports the intent of this bill to strengthen patent protection for biotechnological inventions. Such protection is important for the continued growth and competitiveness in the biotechnology industry in the United States.

With continuing advances in the field of biotechnology and through the evolution of the patent law, biotechnology companies have encountered a problem in adequately protecting certain types of biotechnology inventions. This problem stems from difficulties in obtaining effective patent protection for biotechnological end products or for processes for making biotechnological end products.

Without such protection, a competitor can take a biotechnological starting material, such as genetically engineered host cells, offshore, produce the end product and then import it back into the United States without restriction. Such actions within the United States could be stopped by the holder of a U.S. patent to the biotechnological starting material, as the use of the patented biotechnological material in the United States would be an infringement under our law. The result is that foreign piracy goes unpunished while similar activity in this country would be precluded.

In previous sessions of Congress, bills have been introduced to address this problem, as we have heard. Provisions in some of these bills would have addressed the problem for all industries. Others would have created a product-by-product form of protection to enable holders of U.S. patents to block importation of products made using biotechnological starting materials. The present bill would provide an industry-specific amendment to the obviousness standard of section 103 and would create a product-by-product infringement remedy.

The administration believes that it would be desirable to clarify the uncertainties regarding the patentability of processes that make or use patentable products. This clarification should be made for all industries, not just the biotechnology industry.

Accordingly, we would support an amendment to 35 U.S.C. 103 that would provide that a process of making or using any product would not be considered obvious if the product itself is novel and

not obvious. However, we recognize that such an approach may not be feasible in view of the opposition that continues to be expressed by some of the witnesses here this morning.

In view of this, the administration could accept a tightly crafted amendment along the lines of title II of H.R. 760, that would address the problems facing the biotechnology industry. Such an approach would eliminate the need for the relief specified in title I and would be less likely to disrupt established legal precedent on the standard of obviousness. It should also reduce the opposition that previous bills have faced.

Furthermore, the Federal circuit is presently considering an appeal that may resolve the uncertainty regarding the patentability of processes that make or use patentable products and thereby render unnecessary the changes proposed in title I of H.R. 760. Of course, should the court resolve this uncertainty, the need for title II would also diminish to a great extent.

In order to provide the same degree of downstream protection for innocent purchasers that exists in Section 271(g) of title 35 for process patents, the subcommittee may wish to consider adding certain limitations to the scope of infringement contemplated by proposed section 271(h). Specifically, we would suggest that a provision be included that limits the remedy for infringement of a product involved in retail sales or noncommercial use.

We also have certain technical comments to offer regarding title II, particularly the definition of biotechnological material. We appreciate the difficulty of defining such terms, given the rapidly evolving nature of this field of technology. However, we believe the present definition in section 201(b)(5), building on the definition of biotechnological processes in section 101, is too broad.

We believe that an appropriate definition would allow the owner of patented biotechnological material, such as genetically engineered host cells, transgenic animals and plants, cell fusion products or nucleotide sequences, to block importation of products produced using those materials. However, the definition should not allow protection to be extended to any patented material that is used in any stage of any process that uses a living organism or parts thereof.

With these amendments, we believe that title II would provide a very extensive remedy to the problem that has been raised by the biotechnology industry.

We would be pleased to try to answer any questions that you may have.

Thank you.

Mr. HUGHES. Thank you very much, Mr. Kirk.

[The prepared statement of Mr. Kirk follows:]

PREPARED STATEMENT OF MICHAEL K. KIRK, ACTING ASSISTANT SECRETARY AND ACTING COMMISSIONER OF PATENTS AND TRADEMARKS, U.S. PATENT AND TRADEMARK OFFICE, U.S. DEPARTMENT OF COMMERCE

Mr. Chairman and Members of the Subcommittee:

I am pleased to appear today to testify on H.R. 760, a bill that would provide added protection for the owners of patented biotechnological materials. The Administration supports the intent of this bill to strengthen patent protection for biotechnology inventions. Such protection is important for the continued growth and competitiveness of the biotechnology industry in the United States.

H.R. 760 addresses a problem facing the biotechnology industry in two ways. The first approach, outlined in Title I of the bill, would amend section 103 of title 35, United States Code, to ensure that a biotechnological process claimed to make or use a product would not be considered obvious if that product itself is novel and nonobvious. Section 282 of title 35 would also be amended to ensure that its presumption of validity extends to claims for such processes. Such an approach mainly addresses the problem of importation of a product produced outside the United States using patented materials, by providing patent holders recourse to the remedies of 35 U.S.C. 271(g) and section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337). Those remedies allow the holder of a U.S. process patent to preclude the importation of a product produced offshore using the patented process.

The second approach, outlined in Title II of the bill, would more directly address the problem of foreign importation of a product produced outside the United States using a biotechnological material patented in the United States. This change would make importation of a product so produced an infringement directly actionable under section 271 of title 35, and correspondingly, under section 337 of the 1930 Tariff Act. Title II would thus create a "product-by-product" analog of the existing product-by-process remedy under section 271(g) of title 35.

The biotechnology industry has proven to be particularly dependent upon effective patent protection. There are several reasons for this. First, as is the case with other research intensive industries, such as pharmaceuticals and agricultural products, biotechnology product development requires a tremendous commitment of time, money and resources. Such commitments are necessary not only to discover commercially applicable new technologies, but also to absorb the risks associated with developing new products and to clear regulatory hurdles before a new product can reach the market. Second, research in biotechnology has traditionally been very open, with a strong impetus for early publication of scientific advances and extensive scientific cooperation. This openness has proven crucial to the rapid growth of the biotechnology industry and must not be deterred. Third, unlike other research intensive industries, once a company has successfully developed a commercially viable biotechnology product, it is relatively easy for a competitor to copy and thereby exploit the innovator's investment and efforts. Possession of only a small amount of a biotechnogical starting material allows one to produce the end product through routine techniques. Thus, without adequate patent protection, a competitor can easily and cheaply take advantage of the investments and efforts that the innovator expended to develop the biotechnological starting material. Such "free riding" seriously undermines the economic viability of developing new biotechnology products by deterring investment and new product development.

Biotechnological inventions have been patented at a rapid pace since the early 1980s. One impetus for this increased rate of patenting was the holding of the Supreme Court in *Diamond* v. *Chakrabarty*, 447 U.S. 303 (1980), that genetically altered microorganisms are patentable subject matter. Since then, a wide range of non-naturally occurring biotechnology products, including DNA sequences, genetically engineered cell lines and therapeutically useful proteins, have received patent protection.

Patented biotechnological processes received additional protection in 1988, when Congress passed the Omnibus Trade and Competitiveness Act (Pub. Law 100-419). This Act added section 271(g) to the patent code, and amended section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). Section 271(g) of title 35 makes importation of a product produced offshore using a process patented in the United States an infringement of the process patent. The amendments to § 337 of the Tariff Act of 1930 made it easier for a U.S. patent holder to obtain relief through the International Trade Commission against importation of a product produced using a process patented in the United States.

With continuing advances in the field of biotechnology and through evolution of the patent law, however, biotechnology companies have encountered a problem in adequately protecting certain types of biotechnology inventions. The problem stems not only from questions regarding the patentability of biotechnological products and processes, but also from the unique characteristics of biotechnological "starting materials" and the biotechnology product development cycle.

A common biotechnological initiative involves genetically altering a cell to produce a useful protein (the "end product"). The "starting materials" in such a case include not only the genetically altered cell line, (a "host cell"), but also nucleotide sequences used to alter the cell genetically. While an inventor may be able to obtain a patent for these "starting materials," he can face difficulties in obtaining patent protection for the process of using the host cell to produce the end product, and for the end product itself. For example, the object of many biotechnological initiatives is to produce a product that is identical in structure and function to a product that

occurs in nature. The more successful the inventor is in replicating nature, however, the less likely is the prospect of obtaining effective product patent protection for the final product. Thus, protection that would enable an inventor to preclude the importation of an infringing end product may not be available to the same degree as it is for products in other technologies, such as pharmaceuticals based on new chemical entities.

Moreover, as techniques for engineering cells genetically becomes more refined, the predictability increases in applying those techniques to successfully yield new end products. This, in turn, can decrease the likelihood of obtaining effective patent protection for processes that use a biotechnological starting material, such as a DNA sequence or a genetically engineered cell line, to yield a specific end product.

Also, biotechnological "starting materials" tend to have a different relationship to commercially significant "end products" than starting materials in other fields of technology, including chemical disciplines. In many cases, biotechnological starting materials do not have a function other than the production of a specific end product. Examples include hybridomas that produce monoclonal antibodies, genetically engineered host cells that produce specific proteins, and even nucleotide constructs used to modify specific cell lines to produce useful host cells. Therefore, possession of the patented biotechnological starting material makes it easy to produce through routine effort a specific, valuable commercial end product.

Thus, if an inventor cannot obtain either patent protection for the end product or for processes for making the end product, a competitor can take the patented starting material offshore, produce the end product, and import it back into the United States without restriction. This despite the fact that the patent owner could preclude the same activities if they occurred within the United States (i.e., even though the end product and the process of using the patented starting materials are not patented, the *use* of the host cell in the United States would be an infringement under our law). Thus, foreign piracy is rewarded while similar activity *within* this country would be precluded.

The problem has been aggravated by two factors: (1) the present state of court precedent interpreting the statutory law governing the patentability of processes of making products using patentable starting materials, and (2) the advances in the state of the art of genetic engineering of proteins that make certain processes of producing "end products" from biotechnological starting materials more or less routine. The problem has been compounded by the holding of the U.S. Court of Appeals for the Federal Circuit in *In re Durden,* 763 F.2d 1406, 226 U.S.P.Q. 359 (Fed. Cir. 1985). In *Durden,* 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 could not interpret 35 U.S.C. § 103 to find a process patentable merely because a patentable material was either used or made by that process.

The Federal Circuit had an opportunity to reconsider the *Durden* holding in *In re Pleuddemann,* 910 F.2d 823, 15 U.S.P.Q. 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 U.S.P.Q. 730 (CCPA 1964). The legal standard governing the obviousness of processes that make or use patentable materials is again before the Federal Circuit. An appeal which has been orally argued is now under advisement, *In re Ochiai* (Appeal No. 92-1446). The appeal raises as an issue the conflict between the *Durden, Albertson* and *Pleuddemann* cases.

In the last Congress, the previous Administration supported a legislative change to 35 U.S.C. § 103 to provide that a process of making or using a product would not be considered obvious if the product itself is novel and nonobvious. Such a change would provide a mechanism for all applicants who comply with its requirements to avoid a conclusion along the lines of *Durden* that a claimed process of making or using a patentable product was obvious under 35 U.S.C. § 103. Thus, in the 102d

Congress, the previous Administration supported in principle H.R. 1417, which would have changed 35 U.S.C. § 103 in a non-industry-specific manner, because it believed that reaching inventors in all fields of technology would lead to a more consistent application of the law.

The previous Administration, however, did oppose measures introduced in previous sessions of Congress that would have provided "dual relief" or would have amended the obviousness standard in an industry-specific fashion. In the 101st Congress, the previous Administration opposed as unnecessary provisions of H.R. 3957, a predecessor bill to H.R. 760, that would have created a product-by-product form of infringement remedy *in addition to* changing the standard of obviousness for process claims based on a patentable product.

Despite the previous Administration's support for legislation along the lines of H.R. 1417 in the 102d Congress, there has been substantial opposition to legislative efforts to amend 35 U.S.C. § 103. Concerns were expressed that the changes proposed in bills in previous sessions of Congress would create a "per se" standard of patentability for claims to processes that make or use a patentable material. Such a standard, it was feared, would call into question the presumption of validity of process claims, as such claims would not have been examined under the obviousness standard of 35 U.S.C. § 103. Others testified that legislative action was not necessary, arguing that the problems of rote application of the *Durden* standard were exaggerated and that judicial holdings existed that distinguished the *Durden* decision. Still others testified that the problems cited by the biotechnology industry in obtaining process patent protection were not shared by other industries.

The Clinton Administration believes that a non-industry-specific amendment to 35 U.S.C. § 103 is desirable to address the present uncertainties regarding the patentability of processes that make or use a patentable material. However, we are aware that such an approach may not be feasible in view of the opposition to previous bills. Accordingly, this Administration could accept a tightly crafted amendment along the lines of Title II of H.R. 760 that would address the problems facing the biotechnology industry. In order to provide the same degree of downstream protection for innocent purchasers that exists in section 271(g) of title 35, the Subcommittee may consider adding certain limitations to the scope of the infringement contemplated by proposed section 271(h). Specifically, we would suggest that a provision be included that limits the remedy for infringement of a product involved in retail sales or noncommercial use.

Such an approach would eliminate the need for the relief specified in Title I of the bill, would be less likely to disrupt established legal precedent on the standard of obviousness, and could avoid opposition that previous bills have faced. Also, the Federal Circuit is presently considering an appeal that may resolve the concerns surrounding the *Durden* decision and render unnecessary the changes proposed in Title I of H.R. 760. Of course, should the Court overturn *Durden*, the need for Title II of H.R. 760 may also diminish to a great extent.

We have a technical comment to offer regarding the definition of "biotechnological material." We appreciate the difficulty of accurately defining such material, given the rapidly evolving nature of this field of technology. However, we believe that the present definition in section 201(b)(5), as modified by section 101, is too broad.

As defined in the bill, biotechnological material would include any material used in "any method of...using living organisms, or parts thereof, for the purpose of making or modifying products." Many processes use parts of living organisms but are not generally viewed as "biotechnological" processes. Examples include milling, weaving, paper production, and food preparation. The bill might also be construed to view as "biotechnological material" patented items such as laboratory equipment and inorganic compounds used in a biotechnological process. We do not believe this is the intent of the bill.

Potential problems could be avoided by limiting the definition of biotechnological materials to living organisms, or parts thereof, that are used to make products. Such a definition would not permit the holder of a patented laboratory instrument or inorganic compound mentioned above to block importation of any product produced using those materials. It would, however, allow owners of patented biotechnological materials, such as genetically engineered host cells, transgenic animals and plants, cell fusion products or nucleotide sequences, to block importation of products produced using those materials.

Another technical comment concerns the proposed amendment to section 154 of title 35 that includes a typographical error which changes its intended meaning. Instead of providing exclusion for imported products "made *or* using such biotechnological material," the provision should read "made *by* using such biotechnological material."

I would be pleased to try to answer any questions you may have on H.R. 760.

Mr. HUGHES. In past discussions with the PTO and from past testimony, it has been suggested that the matter can be resolved by simply applying the totality of case law and not focusing primarily on the holding of *In re Durden.* What is the problem with that type of administrative solution, Mr. Kirk?

Mr. KIRK. Mr. Chairman, as was commented earlier this morning by Congressman Boucher, we believe the problem is that the case law is confusing. The cases going back to in *In re Albertson,* and coming forward, leave a trail of inconsistent judicial interpretation.

For us to choose a path through that, we believe would leave applicants and patentees with a very uncertain status as to the possible validity of any claims that they might obtain. We would far prefer to see the path clarified by Congress, I would say, than by the court's decision.

But unfortunately, we have not even seen that coming forward and are still awaiting the most recent two cases. But it is our view that the existing case law simply does not provide the degree of certainty that our examiners would need to consistently and adequately apply the patent law to these processes.

Mr. HUGHES. Could there be any more confusion than there is now? It seems to me, when the waters are so muddied, and they are muddied, that is the time for leadership, administrative leadership.

Mr. KIRK. We would certainly not disagree with that statement, Mr. Chairman. The problem is we are not certain that we are in the position to provide that leadership.

We can adopt an administrative fiat that would direct our examiners to do something. That does not control what the courts would do.

Mr. HUGHES. We do it all the time. And I have a feeling that the courts would uphold you, if it is done for a reason and the basis for the reason—I think it is inexcusable that we have let this drift all these years. *Durden* was decided 8 years ago.

Mr. KIRK. Well, we have——

Mr. HUGHES. Nothing in life is certain and it seems to me that it has cried out for leadership. I am not faulting you, you haven't been the head of the PTO, but that to me is where it should be resolved.

Mr. KIRK. I think, Mr. Chairman, that at this stage it is the collective wisdom of the Patent and Trademark Office that we do not see a route that we could take with an administrative directive to our examiners that would provide the type of certainty that both you and we would like to see.

We would very much like to have certainty come into play into this area. We are not convinced we see it.

Mr. HUGHES. Don't *Pleuddemann* and *Dillon* basically give you a roadmap of where you could go? I mean it seems to me that those subsequent decisions have given you every reason to chart a course.

Mr. KIRK. *Pleuddemann,* which was decided only by a panel, we believe, is directly in conflict with *Durden* once you get past the semantics of "making" or "using." The language in *Dillon* was dicta and not really controlling on this issue.

One must go back to the Court of Customs and Patent Appeals cases which were precedent for the CAFC. And when one goes back to those cases, the same type of confusion exists with respect to the *Albertson* and *Mancy* cases.

The law in this area has been confused for a number of years. We certainly recognize that.

Now, one would hope if no action is taken otherwise, that the opinion that would come down from the Court of Appeals for the Federal Circuit in the *Ochiai* case might provide a sufficient direction or at least give the Office the opportunity to go forward with the direction, but we are not certain that will be the case.

Mr. HUGHES. I want to tell you, frankly, I have recognized, as my ranking Republican and others on this subcommittee, Bill McCollum, that there is a serious problem that needs fixing. I have some difficulty with industry-specific approaches.

I am not sure that is good policy for all the reasons that are fairly well articulated, and I haven't really seen a lot of abuses. We will ask industry today what abuses have occurred.

Amgen was pointed to, but that was fixed. That was compromised a few years ago. The potential for harm is there and this is a very important industry, and I acknowledge that.

We have waited very patiently for the courts to resolve it. It has been briefed and argued and yet we still see no relief forthcoming, and that is why, frankly, your Office is making decisions. You are awarding process patents. You are doing it on the basis of how it is worded.

I mean, I have one before me that further is an obvious example of just the use of words to try to get around basically *Durden,* and so you are basically awarding process patents, and it seems to me that you could really do this country a great service by utilizing your administrative powers and making a decision. You don't like industry-specific because of all the reasons that have been articulated.

While you have articulated the administration's support for title II. That, at best, is less than a satisfactory fix. I mean, the right way to do it would be for you to bite the bullet, make a decision, let the chips fall where they may.

Mr. KIRK. I think, Mr. Chairman, that if we were looking at a blank slate and did not have a history of cases in this area, much like the European Patent Office did when it adopted its rule in this area, that we very well would likely have—certainly this current administration would favor a rule like that in place. But, unfortunately, we do have the baggage of our past judicial precedents; the EPO did not.

Mr. HUGHES. Let me ask you another way. Given your testimony as to the uniqueness of biotechnological materials and limited function of the host cell, don't these factors play a part in justifying a departure from the strict standards of *In re Durden* and the application of other case law?

Mr. KIRK. We believe the policy does justify a fix in the direction of the testimony that we have given, and even more preferably, the nonindustry-specific change to section 103. We would like to see that policy adopted.

Unfortunately, when one looks at the case law, we don't see the clear path that you would like us to follow. We simply don't see that, Mr. Chairman.

Mr. HUGHES. The gentleman from California.

Mr. MOORHEAD. Thank you, Mr. Chairman.

Welcome, Mr. Kirk. Good to have you here.

Mr. KIRK. Thank you.

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 applications; is this true?

Mr. KIRK. Mr. Moorhead, we do not believe that it creates a per se rule of patentability. Assuming that if one were to, for example, adopt the amendment to section 103, the examiners would continue to examine those claims for compliance with section 112 and the other requirements of the patent law.

What the bill would do in title I, it would simply say that as long as the product which the process was making or using, as long as that product was novel and nonobvious, then the process would be considered nonobvious, but only nonobvious.

Mr. MOORHEAD. My next question is one that has been approached from a little different angle, perhaps, by our chairman. One of the claims made by opponents of this bill is everything can be done by the Patent Office to resolve the so-called *Durden* problem. Is this true, and if not, why not?

Mr. KIRK. Again, Mr. Moorhead, we believe that the judicial precedent that exists precludes us from adopting a rule that would not have the potential to be found in conflict with existing law by the court at some later stage. We do not see a clear path to discern between the conflicting decisions that have been handed down, so we simply do not believe that there is that path out there today.

Perhaps with the court's decision in the *Ochiai* and *Brouwer* cases, sufficient additional guideposts will be provided that we might be in a position to move forward with such an administrative guideline, but we do not see it today.

Mr. MOORHEAD. Does the *Pleuddemann* case solve all the problems created by the *Durden* case? Can you reconcile the two cases?

Mr. KIRK. No, sir, we cannot. We simply cannot. The question of whether you are using a patented process to make a patentable product, and the question of whether you are starting with a patentable product and making another patentable product, begin to trip over each other in an area of semantics. We do not believe that there is sufficient clarity, when you look at *Pleuddemann,* you look at *Durden,* and you look at the previous cases, to find *Pleuddemann* to be a solution.

Mr. MOORHEAD. Thank you.

Mr. HUGHES. The gentleman from Rhode Island.

Mr. REED. Mr. Kirk, as I understand it, most of our major competitors, the Europeans and Japanese, don't insist upon a nonobviousness test; is that a fair assumption?

Mr. KIRK. That is correct, Mr. Reed. Both Japan and the European Patent Office, once they determine that there is a patentable product, do not examine the process of using or making that product. They don't have this problem.

77-796 O – 94 – 2

They provide better protection in that regard for biotechnology than does the United States.

Mr. REED. As a competitive measure, is your Office taking the position that we should reach some type of similar accommodation in our patent law to reach equal footing with the Japanese and the Germans?

Mr. KIRK. That has been the position of the Patent and Trademark Office under the last two administrations, Mr. Reed. We believe that a nonindustry-specific, a generic approach, if you will, that would essentially end up putting the United States in the same position as our major foreign competitors, would be the approach to take.

Mr. REED. I am getting to your specific testimony today. You seem to be endorsing title II of the bill, but rejecting title I, could you explain the logic for accepting one part of this provision and rejecting the other part?

Mr. KIRK. Well, in the past, Mr. Reed, we have never supported both approaches. It is, in our view, something like belts and suspenders. If one amends section 103, one doesn't need the latter approach and vice versa. Therefore, given the degree of opposition which appears in our observation to be more intense, if you will, against amendments to section 103, we believe that a tightly crafted, narrowly focused provision that would address the problems that have been raised by the biotech industry would be an appropriate way to go.

Mr. REED. So can I infer from that, that your opposition is more a response to the perceived opposition to the bill rather than the result of a logical defect in the legislation itself or any type of legal problem or contradiction in terms of the two sections?

What you seem to be saying is that you get a lot more protection in the Boucher bill than perhaps might be necessary. But what is wrong with more protection sometimes, I guess would be my response?

Mr. KIRK. Well, when we testified in previous years in support of a general approach to modifying section 103, we had, at that time, suggested that the equivalent provision which is now in title II, was not necessary. It is simply our view that you don't need both, that is all.

Mr. REED. Thank you, Mr. Chairman.

Thank you, Mr. Kirk.

Mr. HUGHES. The gentleman from Florida.

Mr. MCCOLLUM. Thank you, Mr. Chairman.

Mr. Kirk, one of the more interesting cases, I guess the one used for illustration, is the *Amgen* situation, and we are going to hear from them shortly, obviously that is after you have testified. I am just curious, in terms of their application for a patent on their process, they say that they have not yet received that, but yet the issue has been resolved with them. Is there something pending, are they going to be receiving a patent for their process?

Mr. KIRK. Mr. McCollum, the situation is that the interference that they had been involved in has been settled, and process claims of the type that they would need to protect themselves have been allowed. So that even though a patent has not yet been technically issued, a patent will be issued which will contain the process

claims that would allow them to protect against the reimportation of products produced by the host cell.

But, I would make one comment in that regard, sir, and I would refer to the recording industry as an example. We have seen in the past where once a problem is allowed to grow—and I have reference, for example, to the problem that our recording companies have had with the record rental shops in Japan or even in this country. The problem arose when another new technology, namely, tape recording, was widely introduced in the United States and made possible the home taping on analog tape recorders of copyrighted music. Once these industries get established and once there is a constituency for it, it is exceedingly difficult to stop the problem.

Therefore, relief would be appropriate—we know the potential for the problem is there, and we would hope that the industry panel participants could shed additional light on that. But our concern is that if we wait for the problem to reach such proportions that it is truly causing pain, it will be that much more difficult to fix.

Mr. MCCOLLUM. I think your point is well made.

Mr. Boucher, Congressman Boucher, in responding to my throwing out several things to him, and then I think the chairman with a couple of comments said that he thought there was a need now, in order to get a process patent, to use the language that involved use as opposed to manufacture, could you discuss the distinctions between this, and maybe tell us what—I didn't get a chance to ask him what he really meant by that.

I am not sure I understand that. Maybe I do, but at least I think the record should reflect it.

Mr. KIRK. Mr. McCollum, I would like to ask Mr. Van Horn, who is responsible for interpreting these laws for our examining operation, to comment on your question.

Mr. MCCOLLUM. I will be happy to let anybody do it who can.

Thank you.

Mr. VAN HORN. The *Pleuddemann* case does suggest to some, if you couch a process in terms of a "use" of a starting material as opposed to a process of "making" the final product, that it would constitute patentable subject matter. We submit that this is primarily a semantic distinction, in many cases, and really exalts form over substance.

It is much like describing this pitcher as being a pitcher partially full of water or a pitcher partially empty. In each case, the pitcher doesn't change. So, too, in a process of making a final product, or process of using the starting material, the invention is not altered by this description of the particular process.

Mr. MCCOLLUM. That is why *Pleuddemann* just doesn't make a whole lot of sense.

Mr. VAN HORN. I think that is a good summary, yes.

Mr. MCCOLLUM. You didn't write the opinion, obviously. If you had written it, you would have written a different opinion, I can tell already.

The bottom line is we do need some legislation. The question still remains which alternative. You suggest, Mr. Kirk, and incidentally, what you are saying is that we don't need to do both, then you are urging us to do the title in the provisions?

Mr. KIRK. Yes.
Mr. MCCOLLUM. Thank you very much.
Thank you, Mr. Chairman.
Mr. HUGHES. The gentleman from California.
Mr. Edwards.
Mr. EDWARDS. No questions.
Mr. HUGHES. The gentlemen from California, Mr. Berman.
Mr. BERMAN. No questions.
Mr. HUGHES. I have a couple more questions.
Are you granting process patents in biotechnology?
Mr. KIRK. Yes, we are, Mr. Chairman.
Mr. HUGHES. I am looking at an application that was submitted in 1990, that basically was couched in terms of making for manufacturing, which was rejected, then resubmitted, using the terms, "a method of using a DNA sequence" which was approved. Are you saying that is not happening?
Mr. KIRK. No, Mr. Chairman, we are not saying that is not happening. But we are saying that it has been called to our attention that in the group involved there, group 180, that the particular technique that was successful in that case, has been tried in others and has been unsuccessful. So the situation is that you wind up with uncertainty, and this is what this legislation would address and solve.
Mr. HUGHES. Your testimony indicates that the PTO could support a change in section 103 as long as it was a generic change and not an industry-specific change. I mean, that is the bottom line.
Would the change result in an examination system for a process patent similar to that under the European or Japanese Patent Office?
Mr. KIRK. Yes.
Mr. HUGHES. I understand you would look at the totality, the host cell and the process in making a decision?
Mr. KIRK. In the European and Japanese Patent Offices, they would look at the product. If the product were determined to be patentable, then the processes for making and using would not be examined.
Now we would go further than that, because we would examine the process claims to ensure they comply with section 112. But in terms of the nonobviousness of the process claims, we would adopt a somewhat similar attitude to those two offices.
Mr. HUGHES. Why wouldn't that fix it, if we basically looked at the totality? You conceded that in your testimony—and it is rather clear that biotechnology is unique.
Mr. KIRK. Well, if one were to look at the totality, and you were to consider the *Durden* decision, and you have a host cell, or let's say you have any kind of a patentable starting material, and let's say there is a technique that becomes quite common in the biotech field—and this problem could well grow as the biotech field matures, because processes would become more predictable—one would know that one could take an old process, apply it to a new starting material, and wind up with some desirable result. In that old process it would be obvious to take any material of this category and apply it, so you are looking at the totality of it and saying: Here is an obvious process and why should we grant it?

Mr. HUGHES. Do we know of any problems encountered by either the European or Japanese Patent Office in granting patents without examining for obviousness?

Mr. KIRK. Mr. Chairman, we are not aware that they have had any problems.

Mr. HUGHES. As you know, the generic changes to section 103 were criticized heavily in the last Congress by industry representatives representing electronics, chemicals and others. They are still opposed today, as you know.

Why does the PTO think such a change will not lead to such dire consequences as predicted by the opponents of the change?

Mr. KIRK. Mr. Chairman, we do not believe that it would lead to these consequences because a similar practice basically to a generic section 103 fix has been followed in Europe and Japan for many years, and the dire consequences do not appear to have surfaced there, so we see no reason why they would here.

Mr. HUGHES. Does the Patent Office have any method for determining how many process patents are directly related to the biotechnology industry that have been denied on the basis of *In re Durden?*

Mr. KIRK. We do not have statistics on that, Mr. Chairman.

Mr. HUGHES. Your written testimony indicates the administration would support a change in section 271, as I indicated, and eliminate the import problem experienced by the biotechnology industry, or the potential problem that might be experienced, that is more to the point. But will such a change have any impact on the intellectual property provisions provided in the NAFTA or other international agreements under negotiation, in particular the provisions dealing with discrimination among industries?

Mr. KIRK. Mr. Chairman, I am aware that this charge has been made by the opponents of this legislation. There is language that exists both in the GATT TRIPS agreement and in the NAFTA intellectual property chapter that have been cited in this regard. This language, in essence, says that patents shall be available and patent rights enjoyable, without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced.

Having been a participant in the GATT TRIPS negotiations, I think I could make a few comments about that which might serve to quiet some of the concern.

First of all, the nondiscrimination provision with respect to the place of invention was specifically targeted at U.S. patent law, section 104. The second phrase that refers to nondiscrimination with respect to the field of technology was specifically targeted at the Canadian compulsory licensing provisions for pharmaceuticals, and other countries that singled out pharmaceuticals for compulsory licensing, granting special regimes that did not apply to all patented technologies.

Third, the nondiscrimination language with respect to whether products are imported or locally produced is an indirect way of getting at compulsory licenses granted for failure to work. So, this language specifically targeted certain things, and the negotiators knew it at the time. And I would say that basically what the nondiscrimination was getting at was to say that a country could not

have a given level of protection and then single out some technology and discriminate against it by lowering the level of protection; that was certainly the case with respect to the Canadian compulsory license provisions for pharmaceuticals.

We would submit that this language does not preclude a country from raising the level of protection, from discriminating in a positive fashion in favor of a particular type of technology. And in that regard, I would simply point out that at the time this was negotiated, the Japanese and the United States, both had provisions in their laws granting special added protection to pharmaceuticals, namely, patent term extension, and the Europeans were considering and have adopted patent term extension since then.

No one thought, no one ever contemplated, and it has never been anybody's concern that patent term extension to make up for the regulatory review process would, in any way, be inconsistent with this provision.

Mr. HUGHES. The American Intellectual Property Law Association, they will be testifying shortly, make a point that in NAFTA that two provisions had to be read together. The first, and I am quoting: "Make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application..." and second, "patents shall be available and patent rights enjoyable without discrimination as to the field of technology." That is what you just recited.

They argue that those provisions had to be read together. And they raise the question: Has the country made patents available on a nondiscrimination basis, that applies the nonobviousness criteria for patent ability on a discriminatory basis? That is the question.

Mr. KIRK. Mr. Chairman, I would respond to the comments, first of all, that the two sentences in this regard are separate, each from the other. The first sentence really was to focus on the fact that patents were to be made available in all fields of technology, a fundamental statement, and then the exceptions which primarily occur in paragraph two——

Mr. HUGHES. You say it should not be read together?

Mr. KIRK. They should not be read together, no, sir.

Mr. HUGHES. Anybody have any further questions?

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

Mr. HUGHES. Our second panel is G. Kirk Raab and Steven Odre.

Mr. Raab is the president and chief executive officer of Genentech, Inc. This morning he is speaking on behalf of the Biotechnology Industry Organization, which is the successor to the Industrial Biotechnology Association and the Association of Biotechnology Companies.

Mr. Raab has been with Genentech since 1985, previously having worked for Abbott Laboratories, Pfizer, and Beecham. He holds a bachelor's degree from Colgate University. He presently serves on the board of directors of several biotechnology-related companies.

Steven Odre joined Amgen, Inc., in 1986, and presently serves as the vice president of intellectual property and associate general counsel. He previously worked for Searle Pharmaceuticals, Abbott Diagnostics, Ross Laboratories and Monsanto Agricultural Co. Mr.

Odre received his bachelor's degree in chemistry in 1971 from Union College in New York, a masters in analytical biochemistry from Purdue University and doctor of law degree from the Chicago Kent School of Law in 1977.

We welcome both of you to today's hearing.

We have your statements, which we have read and which will be made a part of the record in full.

We hope you can summarize for us because then we can get right to questions, but you may proceed as you see fit.

Mr. Raab, would you like to start?

STATEMENT OF G. KIRK RAAB, PRESIDENT AND CHIEF EXECUTIVE OFFICER, GENENTECH, INC., ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION

Mr. RAAB. Yes, Mr. Chairman. I just have a few brief comments.

I am president, and as I like to say, chief decisionmaker at Genentech. I am also about to become chairman of the Biotechnology Industry Organization, as you mentioned, which will represent over 500 companies, many of them very small and some of them large, but most without any revenues from the sales of products.

We support this legislation. We support it for economic reasons, for patient health care reasons and for employment in the U.S. reasons.

Mr. Chairman, we met during the last Congress and talked about this, and I think your decision to examine this legislation carefully and thoughtfully, as you are, and as represented by this hearing, is very important.

I am here to ask your help. This is a 4-year-old situation. It is a Gordian knot, and we need help having this knot cut, and that is what I am here to request from you today.

The amount our industry spends on research and development has been addressed by others this morning. Our industry has lost $9 billion in the last 5 years, and that money is going into research and development. We do the riskiest kind of research and development, in some of the most important types of medical problems, and others as well.

Yet, we have the poorest patent protection of any industry of our type in this country. Our exposure is against foreign production, things happening outside of the United States, and we wonder why this is good for Americans and America.

I would just like to mention how I and others in my position make decisions, because I think it is relevant. When we are looking at new products, I talk to scientists, I talk to physicians, I talk to accountants, and they give me a fair, clear, understanding of the risks, which are very significant as I am going to take as we move ahead and spend close to $350 million in developing our products, if we are successful. And I understand those risks.

Then my patent attorney comes in and I ask him about the risks, and he says, "I don't know." I try to get him to explain to me in lay terms that I can understand these risks, and when we finish the conversation, he says, "I don't know." Yet, I need to make the decision. So I try to—I feel like I am sort of Lewis Carroll in "Alice in Wonderland" sometimes, and I have to make the decisions. And

I look at what has happened to Amgen and, yes, they settled, but they settled after spending millions of dollars. We look upon what Amgen has gone through with horror.

I would point out, I was on the Amgen board of directors for many years before I joined Genentech. When I look at what they faced, I see their situation as sort of an automobile accident, and the possibility of Genentech's or other company's blood on the road in a similar situation. This moves me to become conservative.

For example, we are working on a very exciting product, but I don't know what is going to happen with it. And yet I know a very large pharmaceutical company is considering right now producing this product outside the United States. It so happens that there is an American company producing it outside the United States, so they can use the uncertainty on patents to come in and compete against Genentech who took the risk and made the discovery.

I have difficulty understanding why that is good for American health care, for American employment and this technology and industry that is so fundamentally important to our country and our future. And for that reason, I petition your assistance and understanding and look forward to answering your questions.

Mr. HUGHES. Thank you, Mr. Raab.

[The prepared statement of Mr. Raab follows:]

PREPARED STATEMENT OF G. KIRK RAAB, PRESIDENT AND CHIEF EXECUTIVE OFFICER, GENENTECH, INC., ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION

My name is Kirk Raab. I am the President and Chief Executive Officer of Genentech, Inc. In addition, I am the incoming Chairman of the Board of Directors of the new trade association the Biotechnology Industry Organization. BIO represents over 800 biotechnology companies in the United States and throughout the world. We strongly support enactment of the pending legislation, H.R. 760 by Congressman Boucher, Moor head and others.

Mr. Chairman, when I visited you in your office last Congress in support of legislation in this area I appreciated your commitment to carefully examine the issues raised by this legislation. I know that you expect to fully examine the important legal issues that this legislation appears to pose.

As a non-lawyer who has to make decisions about products for unmet medical needs, I can only offer a practical/businessman's perspective on this legislation. I can tell you without any equivocation that the continued uncertainty in the patent law with respect to the existence of clear rules for obtaining process patents and/or remedies for our existing patents is: (1) eroding our competitiveness; (2) frustrating the underlying purposes of the patent laws to reward and stimulate innovation; and (3) skewing the research and development decision making process. Let me explain why.

When a biotechnology company makes a decision to go forward with a research and development project. It is making a gamble—or more accurately a series of gambles. Unlike the roulette player who can quickly determine whether she won or lost, we must wait. If our initial gamble pays off, then we merely get to make a series of other gambles at escalating levels. The final bet we make is, *on average,*—according to the Congressional Office of Technology Assessment—$359 million per new product. Moreover, the decisions I make today will affect products to be launched after the year 2000.

No other industry spends as much on R&D as biotechnoloay. In the past 5 years, as an industry, we have lost $9 billion because our R&D far exceeds any sales.

No other industry is as R&D intensive. As an industry, we spend more on R&D as a percentage of revenue or assets than any other industry. We also spend more on R&D per employee than any other industry.

Yet we have the weakest patent protection of any of the seven critical technologies for the future of American competitiveness.

This patent weakness is adversely affecting our industry today. For example, my own company faces a situation today where we have an invention which was conceived and reduced to practice in 1982 and we only this year received the first al-

lowed claims (to starting materials and a host cell) and that our process patent application has been rejected and resubmitted.

This means that a potentially commercial product that is in clinical trials could go all the way through the FDA process and still face unfair foreign imports (from a large pharmaceutical company) who is using our inventions to make the end product overseas. This is not a fanciful hypothetical case but a real world problem.

We have all watched with horror the tortured path that Amgen has endured to vindicate protection of its breakthrough invention. Without this legislation we—and others in our industry—are likely to find ourselves in the same jeopardy.

Let me take a few minutes to address some of the "objections" to this legislation. First, it is claimed that the courts will resolve this issue. After tens of millions of dollars to pay for patent litigation, which could have increased efforts on AIDS, breast cancer and Alzheimer's, I must seriously contest this "legal fiction." When this argument was first raised in 1989 to the first bill on this subject the argument had superficial appeal—but four years later, I think not.

Second, it is claimed that there is not enough evidence of a problem. Here I can speak with certainty. The collective experience of our industry—including the studies we have submitted to the Committee of *Durden* problems—clearly demonstrates the truth that we are being tormented by an incorrectly decided case, that the Patent Office says is irreconcilable with other precedents, and that the Patent Office examining process produces *delays. inconsistent results, and uncertainty.*

When I ask our patent attorneys whether we will have process patent protection for an invention that we plan to put hundreds of millions of dollars into—I think it is reasonable to expect a more clear answer than: "...I don't know. I can't tell. It depends on which examiner we get. It could issue in a few years, but I can't be certain."

Faced with that level of uncertainty, it is possible that in the competition for scarce R&D money otherwise worthy projects will be passed over in favor of projects of arguably less importance to the public health merely because of the strength of the patent position of the competing project. When the two projects each are based on breakthrough science (ergo the issuance of patents on the DNA sequence, vector and/or host cell) why should the whim of the examination process or esoteric distinctions between *Durden* and *Pleuddemann* (methods of making or methods of using) dictate what our R&D priorities should be?

The subcommittee has expressed an interest in the difference between the legislation currently pending and the bills that were before the subcommittee last Congress. Attached to my testimony is a copy of the testimony from my colleague, George Ebright, presented to the subcommittee last year. That testimony addresses in greater detail the need for a legislative solution to the problems we face as a result of uncertainty caused by the *Durden* case. The legislation that passed the Senate last Congress unanimously and the legislation, H.R. 760, currently before the subcommittee differ in two important respects from the bill pending last Congress.

First, the legislation overrules *In re Durden* only with respect to biotechnology related processes. This change was made solely to meet objections from patent lawyers who argued that no problems had been proven with respect to the application of section 103 of title 35 to non-biotechnology inventions. We continue to believe that *Durden* was incorrectly decided and should the subcommittee so desire support legislation that would overrule *Durden* generally.

Second, the legislation before the subcommittee creates new remedies for the holders of patents on DNA sequences, vectors and host cells to prevent the unfair importation of products made through the use of these patented intermediates. The rationale for this amendment was comprehensively addressed in the two hearings before the subcommittee in earlier congresses by representatives of Amgen and I refer you to their testimony.

I understand from your staff that you have concerns about the consistency of this legislation with the proposed North American Free Trade Agreement (NAFTA). As a supporter of NAFTA, I do not denigrate its importance even though it is not currently United States law. On the contrary, I believe that this bill is fully consistent. The provisions of the NAFTA (and the pending GATT agreement from which they are derived) are designed exclusively to bar discrimination *against* forms of technology. Thus, the agreement bars signatory countries from preventing the issuance of patents to classes of technologies (e.g., pharmaceuticals or chemical inventions). The agreement does not prevent the *extension* of protection to specific invention categories—otherwise we would be forced to repeal all of the provisions of the patent law relating to plants and biological materials and pharmaceutical products that recognize distinctions in terms of patentability standards, length of term and other matters.

The most specious argument against the bill is that it will create a *per se* rule of patentability. This is not true. Under the bill, inventors would merely be entitled to obtain the same scope of patent protection as inventors of similar inventions get in Europe and Japan. If our scientists have not created a novel, non-obvious starting material and/or end product, there will be no process to protect. Thus, logic should tell you that the structure upon which the process patent is based will be an examined patented invention. In addition, the process itself will continue to have to be examined to meet with other requirements of patentability—novelty and utility, as well as the specification requirements of the patent law. This objection has been dismissed by the Patent Office and should be rejected by the Committee.

Finally, our friends in the patent bar argue that Congress should not enact industry specific legislation. This argument would be consistent if they also argued that we should repeal all the industry specific statutes (including the Plant Patent Act, the Plant Variety Protection Act, the deposit rules for biotechnological materials, and patent term extensions for pharmaceutical products). Sadly, I am afraid that the only foolish consistency in their position is that they would rather see the innovation of an American inventor face unfair foreign competition a few more years until the "courts solve this vexing, temporary problem."

In the past ten years, the Congress and this Committee has seen fit to correct problems created by at least seven patent cases through the enactment of legislation. I respectfully submit we have met our burden of demonstrating a problem with serious financial consequences that merits a legislative response.

The biotechnology industry cannot afford to wait. We urge you to conclude the hearing process and move this legislation to mark-up and enactment.

PREPARED STATEMENT OF GEORGE W. EBRIGHT, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, CYTOGEN CORP., PRINCETON, NJ, ON BEHALF OF THE INDUSTRIAL BIOTECHNOLOGY ASSOCIATION, BEFORE THE SUBCOMMITTEE ON INTELLECTUAL PROPERTY AND JUDICIAL ADMINISTRATION, HOUSE COMMITTEE ON THE JUDICIARY, NOVEMBER 21, 1991

Good morning, my name is George Ebright and I am the Chairman and Chief Executive Officer of Cytogen Corporation, a biotechnology company located in Princeton, New Jersey. Cytogen is a diversified health care products company whose 170 employees focus on the discovery, development, manufacture, and marketing of biopharmaceutical and medical diagnostic products for cancer.

I also serve as a Board member of the Industrial Biotechnology Association (IBA), a trade association that represents over 100 companies. IDA member companies are engaged in biotechnology research and development in the fields of health care, agriculture, food and industrial enzymes, and toxic waste degradation. Collectively, IBA represents more than 80% of all biotechnology R&D investment in the United States. I am here today on behalf of IDA and am accompanied by Lisa Raines, IBA's staff intellectual property expert.

The U.S. biotechnology industry believes that the patent system should reward the achievements of biotechnology pioneers, but that instead it allows intellectual pirates to copy innovative biotechnology products without penalty. The system is failing, and statutory changes are vital to our Nations ability to retain the competitive edge it currently has in biotechnology. *IBA urges the Congress to remedy this problem by expeditiously enacting H.R. 1417.*

The remainder of my testimony elaborates on these themes. I begin by profiling the U.S. biotechnology industry, describing what it does and how it is improving both our economy and quality of life. I continue with a discussion of the fact that, as our Nation's most research-intensive industry, biotechnology innovation must receive the same kind of intellectual property protection as innovation by other industries. (An appendix provides national statistics on these points.)

I then explain in some detail why many biotechnology inventions are *not* receiving the necessary patent protection, and point out that the U.S. failure to issue biotechnology process patents conflicts with patent law in both Europe and Japan. It is indeed ironic that many foreign counties provide superior biotechnology process patent proection to our own country, which pioneered this technology.

Finally, I describe how the biotechnology industry arrived at H.R. 1417 (with some minor amendments) as the most reasonable and appropriate soiution to the problem.

PROFILE OF THE BIOTECHNOLOGY INDUSTRY

Bioetechnology is the applicaton of engineering and technological principles to living organisms or their components to produce new inventions or processes. An important branch of biotechnology is genetic engineering, or recombinant DNA tech-

nology, which concerns the analysis and alteration of genes and proteins. These sciences are of vital importance to U.S. and world progress in innumerable fields. In fact, the National Academy of Engineering characterizes genetic engineering as one of the ten outstanding engineering achievements in the past quarter century.[1]

On the medical side, genetically engineered drugs and vaccines are now available to treat a number of diseases, including diabetes, dwarfism, hepatitis, heart attacks, anemia, leukemia, and organ transplant rejection. Medical products in development have the potential to eradicate hundreds of diseases, including such intractable diseases as cancer, arthritis, AIDS, and Alzheimers. Biotechnology has also vastly improved our ability to diagnose medical conditions.

On the agricultural side, biotechnology promises to improve the nutritional and aesthetic quality of our food supply while lowering farm input costs and offering environmental benefits over existing agricultural technologies. In addition to benefitting American consumers, farmers, and the environment, advances in agricultural biotechnology (such as development of drought- and disease-resistant crops) offer perhaps the only hope for agricultural self-sufficiency and economic stability in developing countries.

Other applications of biotechnology include fine chemical manufacture and bioremediation, which consists of using microorganisms to convert toxic pollutants into harmless substances. Bioremediation is increasingly being used to treat coastal oil spills and toxic waste dumps, and to treat industrial waste prior to disposal.

In addition to these remarkable new products, biotechnology is an important new source of economic vitality for America. American scientists invented genetic engineering and American investors have funded the research and development that is enabling our industry to translate cutting-edge science into economic growth.

As a result, the U.S. is the world leader in the research, development, and manufacture of biotechnology products. In 1991, the U.S. biotech industry produced sales of $4 billion, a 38% increase over 1990, and net exports in excess of $600 million. The White House Council on Competitiveness projects that biotechnology will be a $50 billion industry by the year 2000.

Clearly, biotechnology is an industry that can contribute mightily to U.S. economic growth and improved quality of life. Indeed, two major reports released this year label led biotechnology one of several "critical technologies" that will drive U.S. productivity, economic growth, and competitiveness over the next ten years and perhaps over the next century.[2]

PROTECTING INVESTMENT IN BIOTECHNOLOGY R&D

One of the distinguishing characteristics of the biotechnology industry is the extraordinarily high level of investment made in research and development (R&D). Since the biotechnology industry's inception in the late 1970s, biotechnology companies have ploughed at least $10 billion into long-term R&D programs. In 1991, U.S. biotech industry R&D totalled $3.2 billion, an 18% increase over 1990. A single biopharmaceutical product typically costs $100 to 200 million to develop.

Industrywide, R&D accounts for 30% of all costs incurred by biotechnology companies. Although the research-intensive pharmaceutical industry is often used as a benchmark for investment in innovation, biotech industry research intensity surpasses that for the traditional pharmaceutical industry. While no studies directly compare the R&D intensity of all industries, recent studies by Ernst & Young[3] and *Businessweek*[4] suggest that the biotechnology industry is probably this country's most R&D intensive industry.

R&D as a percentage of revenue is a measure routinely used in established industries to gauge the proportion of today's product sales being reinvested in research towards tomorrow's products. According to Ernst & Young, the to ten pharmaceutical companies averaged 14% reinvestment in 1991, whereas biotech companies reinvested an average of 47%. *BusinessWeek* reports that the top five U.S. companies in R&D spending per dollar of revenue are all biotechnology companies.

Another way of measuring investment in innovation is to examine R&D expense per employee. In 1991, biotech companies averaged $81,000, as compared with $23,000 for the top ten pharmaceutical companies. Five of this country's top ten R&D spenders in dollars per employee are biotechnology companies.

---

[1] National Academy of Engineering, *Engineering and the Advancement of Human Welfare: 10 Outstanding Achievements 1964-1989* (1989).

[2] Council on Competitiveness, *Gaining New Ground: Technology Priorities for America's Future* (1991); White House Office of Science and Technology Policy, *Report of the National Critical Technologies Panel* (1991).

[3] Ernst & Young, *Biotech 92: Promise to Reality, An Industry Annual Report* (1991).

[4] *BusinessWeek*, Special issue on *Innovation in America* (July 1, 1991).

In deciding whether to fund an R&D program, biotech companies examine whether the expected product life, market potential, and competitive situation warrant the investment. Clearly, if a pioneer company is to invest $100 to $200 million to develop a new biopharmaceutical, it must be assured that a competing company cannot pirate the pioneer's intellectual achievements.

INTELLECTUAL PIRACY IN BIOTECHNOLOGY

Piracy is fairly easy to accomplish in biotechnology. For one thing, most scientific breakthroughs are routinely published in scientific journals, rather than maintained as trade secrets. Liberal publication policies, which are consistent with the academic scientific tradition from which the biotechnology industry springs, have four major benefits. First, it enables other scientists to review and verify the accuracy of our scientists' research results. Second, it advances science and technology by enabling other scientists to learn from and build on the work of other scientists. Third, it conserves our Nation's research resources by enabling scientists to avoid unnecessarily duplicating the work of others. Finally, it increases the morale and dedication of industry scientists by allowing them to obtain the recognition of their academic colleagues for their achievements.

Once an important scientific breakthrough is published, such as the genetic sequence that codes for a potentially important therapeutic protein, it is a fairly simple matter for a trained scientist to copy the product from the "recipe" routinely published in the scientific journal.

This is not the only way to pirate a pioneering biotechnology invention. 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 and samples of the purified protein are used outside of the four walls of the innovator, a competitor may obtain a sample of the material from a university at which the clinical trial is being conducted or from some other source. It is then relatively easy to sequence the protein so as to determine its precise amino acid composition. This, in turn, enables the competitor to determine the gene sequence needed to synthesize the protein. The process just described is the biotechnology equivalent of "reverse engineering."

As has been demonstrated, the great cost of developing a new biotechnology product stands in stark contrast to the ease with which the product can be copied. Under these circumstances, the only incentive to make such investments is the availability of clear and meaningful patent protection. Without such protection, there is simply no incentive to invest, and without investment, there can be no new products, no new jobs, no new exports, and no new economic growth.

AVAILABILITY OF PATENTS FOR BIOTECHNOLOGY INVENTIONS

While modern biotechnology is generally considered to shave begun with the first recombinant DNA experiment in 1973, it was not until 1980—when the U.S. Supreme Court held that a genetically engineered microorganism was patentable—that biotechnology companies began forming to commercialize recombinant DNA technology. This decision suggested that "everything under the sun made by man," including biotechnological inventions, was patentable.[5]

But while genetically engineered microorganisms are clearly patentable, the biopharmaceutical products they produce often are not. This compares unfavorably with traditional pharmaceutical chemicals, which are almost always patentable new molecules.

The reason for the difference relates to the difference in scientific approach. Traditional pharmaceutical chemistry involves randomly generating thousands of new molecules and screening them for biological activity. Since these randomly generated molecules are entirely synthetic, they easily meet the principal criteria of patentability: novelty, utility, and nonobviousness.

But biotechnology does not involve randomly generating new molecules. Instead, genetic engineering technology is used to identify and synthesize naturally occurring human proteins and enzymes. Our bodies produce at least 50,000 different proteins and enzymes, each with a different function, such as stimulating our immune system, telling wounds to heal, and instructing our bodies to make more blood cells.

To be patentable, an invention must be *novel, nonobvious, and useful.* When these criteria are applied to a genetically engineered protein, patent will generally be granted if the protein was never known before it was isolated and purified using genetic engineering techniques. For example, tissue plasminogen activator, a natu-

[5] *Diamond* v. *Chaklbarty*, 447 U.S. 303 (1980).

rally occurring protein that dissolves the coronary blood clots that cause heart attacks, was totally unknown before it was isolated using biotechnology techniques and has been patented.

However, if the scientific literature reveals that the protein has previously heen purified to some extent, even if it has not been definitively characterized, it may be deemed unpatentable for lack of novelty. This may occur even when the amount of the natural product that has been isolated is insufficient for any practical use and the method employed cannot provide practical quantities of the material.

For example, insulin was first 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 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 fifty 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. Unfortunately, since porcine and bovine insulin are slightly different from human insulin, some diabetics found that their bodies rejected the animal insulin as a foreign entity.

Nevertheless, this 1920s research effectively barred anyone who later identified human insulin's chemical structure or invented a way to manufacture it from obtaining a product patent. Frederick Sangers success in identifying the chemical structure and precise molecular weight of human insulin (1951) won him the Nobel Prize but couldn't win him a patent. And David Goeddel's success in synthesizing recombinant human insulin (1979) enabled patients the world over to finally have access to the product, but he couldn't get a product patent either. Yet it is only because of the work of these men that diabetics finally have access to this drug.

In the absence of *product* patent protection, what incentive is there for scientists and investors to devote their lives and their savings to identifying a proteins molecular structure and devising genetic engineering methods for its manufacture? In biotechnology, the answer is to obtain patent protection on the *process* for making the product. Since genetic engineering is the only commercially feasible method for manufacturing these human proteins, a patent on the recombinant manufacturing process can be tantamount to a product patent.

LIMITED AVAILABILITY OF PROCESS PATENTS

However, the biotechnology industry's ability to obtain process patent protection has been circumscribed since a recent Federal Circuit Court ruling. And without process patents, the industry simply does not have the means whereby to prevent piracy of genetic engineering inventions by foreign companies that want to sell to U.S. markets.

The problem is the erroneous and inconsistent application of *In re Durden*,[6] a nonbiotech patent case, to important biotechnology processes. During the six years since the U.S. Court of Appeals for the Federal Circuit (CAFC) decided this case, it has become increasingly difficult to obtain process patent protection in the United States for genetic engineering inventions.

Durden involved the process of making novel carbamate products from novel oxime starting materials. The patent applicants made the following admission:

> Generally speaking, it is known that heterocyclic Oxime compounds (which appellants' oximes are conceded to be) can be reacted with known carbamoyl halide compounds, as evidenced by Punja U.S. Patent No. 3,843,669.

The CAFC adopted the applicants' statement of the issue in this case, 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 nonobvious. [Emphasis added.]

The court regarded the reaction process to be unpatentable, irrespective of the patentability of the reactants and of the reaction products, on the ground that no new reaction process is invented merely because a different reaction material is used in an otherwise old process. The results of using an old process was predictable, this being aamitted by the applicants.

Part of the uncertainty of *Durden* lies in determining its scope of application. While the CAFC cautioned against universally applying *Durden,* there is no reason

[6] 763 F. 2d 1406 (Fed. Cir. 1985).

to deduce from the court's cautionary note that *Durden* is not similarly applicable to nonchemical disciplines. As a result, it has frequently been cited by the PTO in denying patents to genetic engineering processes. This 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. A survey of the impact of *Durden* commissioned by Genentech shows that at least 60% of biotechnology patents lacking process claims can be directly linked to a *Durden* rejection.

Basically, *Durden's* application to genetic engineering, as applied by PTO to hundreds of biotechnology cases, is 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 that particular DNA molecule. Therefore, once you have invented a new DNA molecule, it is obvious that it can and should be used in a recombinant DNA process. Since nonobviousness is one of the three criteria for patentability, an obvious process is not patentable.

Durden says, in effect, that it is obvious how to use an invention that never existed before. As a result, in many cases, one can only obtain a biotech process patent 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.

Demonstrating "unexpected results" will likely require additional scientific experimentation and extensive negotiations with the PTO, both of which substantially add to the expense of obtaining a process patent. This means that inventors with limited budgets, such as small companies and universities, are placed at a distinct disadvantage. In the Genentech study, all of the universities surveyed forfeited the process patent protection to which they appear to be entitled.

A majority of biotechnology process patents—almost two-thirds, in fact—are issued only after a *Durden* rejection is made and later overcome with evidence of "unexpected results." However, even when "unexpected results" can be demonstrated, some processes are still rejected as "obvious." A recent case, *Ex carte Orser* illustrates how the PTO cites *Durden* to reject biotechnology process claims even when the applicant shows unexpected and superior results due to how the biological materials affected the claimed process.[7]

Even those who are lucky enough to overcome *Durden* rejections may have issuance of their patents needlessly delayed for six or eight months. This delay can jeopardize a company's ability to raise the capital necessary, for example, to conduct animal and human studies of a new drug's safety and effectiveness.

Furthermore, experience shows that whether a *Durden* rejection is made in the first place varies from patent examiner to patent examiner, so that the luck of the draw—that is, which patent examiner is assigned their case—is a significant factor in determining whether an inventor will obtain process patent protection.

These findings are consistent with the biotechnology industry's belief that *Durden* has had a chilling effect on process patent protection for the U.S. biotechnology industry.

APPLYING DURDEN CONFLICTS WITH OTHER CASES AND OTHER COUNTRIES

The application of *Durden* to biotechnology cases, which involve microorganisms, is in direct conflict with *In re Mancy*[8] and other cases.[9] *Mancy* involved a process of using traditional culture techniques on a new bacterial strain to prepare an antibiotic. Even though other strains were already known to produce the antibiotic using basically the same culture techniques, the process patent was upheld. The facts in *Mancy* are analogous to the preparation of a desired protein by culturing a previously unknown, genetically engineered cell and to the preparation of antibodies by culturing a previously unknown hybridoma or other immortalized cell.

It therefore seems a matter of logic that *Mancy,* not *Durden,* should be applied to biotechnoloqy cases. And, indeed, the reasoning in *Mancy* is the law for inventions in Europe and Japan, both of which have a long tradition of patenting process inventions that use patentable starting materials. Policymakers should not overlook the fact hat our foreign competitors are already providing their inventors with the kind of process patent protection that we seek.

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

[7] 14 USPQ 2d 1987 (Bd. of Pat. App. and Inter. 1990).
[8] 499 F.2d 1289 (C.C.P.A. 1974).
[9] *E.g., In re Kuehl,* 475 F.2d 658 (C.C.P.A. 1973).

more recent case, *In re Pleuddeman,*[10] 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 to consider such cases as method of making cases, the PTO has ruled that they should therefore be governed by *Durden*. Although there may be times when using differs from making, it is not clear why the two modes of reciting a process should yield diametrically opposite results.

It appears that virtually all commentators and legal practitioners believe that *Durden* is applied in a fashion that wrongly denies process patent protection to biotechnology inventions. In the last three years, five law review articles have been written on this subject. All of them support overruling *Durden*.[11]

STARTING MATERIALS PATENTS: AN ALTERNATIVE

If an end product is not patentable because it lacks novelty (as in the insulin example) and the genetic engineering process is not patentable because it is considered obvious under *Durden,* the inventor may nevertheless patent the *starting materials.* It is a relatively simple matter for an inventor to obtain a patent on a new DNA molecule or on the cell into which that DNA is inserted for the purpose of genetically engineering the cell to produce a protein.

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 U.S. Legislation enacted in 1988 extended this principle to process patents: not only is unauthorized domestic "making" of the process prohibited, but importation of foreign-manufactured products is also prohibited if a U.S.-patented process was used. In both cases, the principle is that if an activity constitutes infringement of a U.S. patent if performed within the United States, then it is also an act of infringement to do it overseas and import the end product.

But current law does not give starting material patents these same enforcement rights. The rulings in two cases involving the biotechnology company Amgen[12] show that, while unauthorized domestic use of U.S.-patented starting materials constitutes patent infringement, the patent does not give a company the right to prevent the use of these starting materials overseas followed by importation of the finished product.

Amgen is a California biotechnology company that as a pioneer in the development of erythropoietin (EPO), a hormone produced in the kidney that stimulates red blood cell production. Amgen holds a patent covering the gene that codes for EPO and the genetically engineered host cell into which the gene was inserted.

Amgen's patent on the EPO gene and host cell effectively prevents anyone else from making EPO in the U.S., 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. While 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, use of these starting materials by its Japanese partner is *not* infringement, even though the product is being manufactured for export to the U.S. because the starting materials are being used outside the U.S., there is technically no infringement of the U.S. patent, notwithstanding subsequent importation of the end product.

---

[10] 15 USPQ 2d 1738 (1991).

[11] Murashige, "Section 102/103 Issues in Biotechnology Patent Prosecution," 16 *AIPLA Quart. Jour.* 294 (1988-89); Wegner, "Much Ado About Durden," 71 *Jour. Pat. & Trademark Off. Soc'y.* 785 (1989); Comment, "The Elimination of Process: Will the Biotechnology Patent Protection Act Revive Process Patents?," 24 *John Marshall Law Review* 263 (1990); McAndrews, "Removing the Burden of Durden Through Legislation: H.R. 3957 and H.R. 5651," 72 *Jour. Pat. & Trademark Off. Soc'y.* 1188 (1990), Beier and Benson, "Biotechnology Patent Protection Act," 68 *University of Denver Law Review* 173 (1991).

[12] *Amgen* v. *U.S. International Trade Commission,* 902 F.2d 1532 (Fed. Cir. 1990) and *Amgen* v. *Genetics Institute and Chugai Pharmaceutical,* 927 F.2d 1200 (Fed.Cir. 1991), *cert. denied,* ——— *U.S.* ——— *(1991).*

Since process patents are enforceable against foreign-based infringement while starting material patents are not, the latter is not an adequate substitute for the former.

THE SOLUTION

When the biotechnology industry began working on a solution in 1987, our patent lawyers came up with a two-pronged approach to amending the patent statute: (1) make biological starting material patents enforceable at the border and (2) overrule the *Durden* case. Either of the two prongs would solve the problem for the large majority of biotechnology inventions; together they would solve the entire problem.

The original version of the Biotechnology Patent Protection Act, encompassing this essentially belt-and-suspenders approach, was introduced in the 101st Congress by Representatives Rick Boucher (D-VA) and Carlos Moorhead (R-CA) in the House, and by Senator Dennis DeConcini (D-AZ) in the Senate. Hearings were held by this Subcommittee in September 1990, shortly before the 101st Congress adjourned *sine die*.

When the industry drafted the belt-and-suspenders bill, we anticipated that the first prong—making biological starting material patents enforceable at the border—would be fairly noncontroversial, since it merely extended existing process patent law principles to biological starting materials. Similarly, we anticipated that legislatively overruling a federal circuit court case would provoke considerable controversy because it would dramatically change patent law. We were wrong on both counts.

To our surprise, substantial opposition arose to making biological material patents enforceable at the border. While many "patent purists" objected on principle to having a patent law provision apply to only one industry, several chemical companies insisted that universal application would wreak havoc for the chemical industry. 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 during the midst or the GATT negotiations, because the U.S. Trade Representative had already conceded that the ITC violates GATT's prohibition against discrimination. (Domestic companies, but not foreign 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.)

Objections were also raised to the provision's effective date, which some viewed as retroactive, because it would have enabled Amgen to enforce its patent against Chugai. Those holding this view believe it would be unfair to undermine the investment made by Chugai and its U.S. partners, whose currently noninfringing importation would become infringing.

Also to our surprise, substantial support for overruling *Durden* was shown by other industries—including the National Association of Manufacturers and the Pharmaceutical Manufacturers Association, and large portions of the chemical industry—as well as by dozens of universities. Even the Commissioner of Patents and Trademarks conceded, in his October 1990 testimony before this Subcommittee, that the PTO finds *Durden* to be confusing and inconsistent with other cases, so that overruling it would greatly clarify the law.

In the 102nd Congress, Representatives Boucher and Moorhead, and Sen. DeConcini, introduced a revised version of the Biotechnology Patent Protection Act (H.R. 117/S.654). The new bill overrules *Durden* but does not expand enforcement for biological material patents. While not as comprehensive as the earlier bill, it would, in IBA's opinion, provide the necessary patent protection for an estimated 90-95% of worthy biotechnology inventions.

CONCLUSION

Biotechnology is one of the few high technology industries where the U.S. remains the world leader, but our continued preeminence is jeopardized by deficiencies in our Nation's patent law. If uncorrected, these deficiencies could lead to other countries pirating U.S.-developed technologies to make products for export to the U.S., unfairly competing with the American innovator.

The Biotechnology Patent Protection Act (H.R. 1417 and S. 654) would correct this problem. It ensures that innovative biotechnology processes that are eligible for patent protection in major industrialized countries overseas are eligible for patent protection here at home.

This legislation is not protectionist. The bill will benefit innovators over copycats, not domestic companies over foreign companies. Indeed, foreign inventors—who receive 15% of all U.S.-issued patents—will benefit along with American inventors.

However, as U.S. biotechnology companies have a commanding technological lead over Japanese and European companies, we anticipate receiving a substantial share of the process patents issued as a result of this legislation. To document the comparative technology competitiveness of the U.S. biotechnology industry, one needs only to consider that U.S. companies developed *every one* of approximately twenty biopharmaceuticals sold throughout the world today.

Those who oppose enactment of this legislation in the misguided belief that it will create new uncertainties or lead to new litigation underestimate the sensitivity of the biotechnology industry to these issues. For the past fifteen years, our industry has been breaking new ground not only in science, but in the field of intellectual property law. Our industry has absolutely no interest in adding to the uncertainty that permeates much of biotechnology intellectual property law. We all recognize that patent litigation is a tremendous drain on a small company's limited resources and should only be resorted to when no reasonable alternative exists.

After lengthy consideration we have concluded that this legislation will lead to greater certainty and predictability, that it will decrease unnecessary litigation, and—most importantly—that it will enable innovators to obtain the patent protection which they have fairly earned.

This bill has broad bipartisan support in the House and Senate, and has been endorsed by the Bush Administration. Its speedy enactment is a major priority for the biotechnology industry.

The Senate Judiciary Committee's Patents, Trademarks, and Copyrights Subcommittee held hearings on the bill in June; in July, the seven Subcommittee members voted unanimously to support the legislation. The biotechnology industry would be exceedingly grateful for similarly favorable and expeditious consideration by this Subcommittee.

APPENDIX: 1991 U.S. BIOTECHNOLOGY INDUSTRY STATISTICS

Number of Companies and Employees.—Total number of companies: 1,100, same number as 1990. Total number of employees: 70,000, a 6% increase over 1990.

Revenues, Sales, Income, Market Capitalization, and Assets.—Total revenues (including collaborative research agreements): $5.8 billion, a 23% increase over 1990. Total product sales: $4.0 billion, a 38% increase over 1990. Total product sales to foreign customers: $640 million, or 16% of total. Total market capitalization: $35 billion, a 75% increase over 1990. Total assets: $12.5 billion, a 25% increase over 1990

Research and Develonent.—Total industry R&D: $3.2 billion, an 18% increase over 1990. R&D expenditures as a percentage of revenue: 47% (compare with 14% for top ten pharmaceutical companies). R&D expenditures as a percentage of total expenditures: 30% (compare with 19% for top ten pharmaceutical companies). Average R&D expenditures per employee: $81,000 (compare with $23,000 for top ten pharmaceutical companies). Total federal biotech R&D: $3.8 billion, an 8% increase over 1990.

Profile by Market Segment.—Therapeutic: 35%, diagnostic: 28%, supplier: 18%, agbio: 8%, and other: 11%.

Profile by Size.—Small (1-50 employees): 76%, mid size (51-135 employees): 15%, large (136-299 employees): 6%, and top tier (300-plus employees): 3%.

Source: *Biotech '92: Promise to Reality: An Industry Annual Report,* published by Ernst & Young. Except where otherwise indicated, data are estimated 1991 figures.

Mr. HUGHES. Mr. Odre, welcome.

STATEMENT OF STEVEN M. ODRE, VICE PRESIDENT FOR INTELLECTUAL PROPERTY, AMGEN INC.

Mr. ODRE. Mr. Chairman and members of the subcommittee, I greatly appreciate the opportunity to appear before you this morning to share with you some of the experiences of Amgen and impress upon you the need for patent reform to ensure that America's innovative biotechnology industry can maintain its leadership position in the world economy.

I have direct personal experience with the very problem that is being addressed by H.R. 760, and I have seen first hand just how the biotechnology industry in the United States has been disadvantaged by the refusal of the Patent Office to grant process patent

claims because of its interpretation of CAFC's decision *In re Durden.*

The high level of investment in research and development required to bring to market the remarkable new products made available for the first time by biotechnology requires effective, enforceable patent protection. Although present patent laws provide some degree of protection, a significant problem currently exists which gives our foreign competitors a decided advantage over domestic companies.

Mr. Chairman, my written statement describes the details of Amgen's experience following 6 years of litigation, which may help convince this committee that the patent laws must be updated to protect biotechnology inventions.

Amgen has a patent to a host cell, the only known way to produce recombinant erythropoeitin, that has been litigated, relitigated, and upheld at the CAFC, yet today it is valid and enforceable only against domestic manufacturers. Although protected from U.S. competitors under its patent rights, Amgen was unable to deal with a Japanese competitor under the very same patent rights in the United States.

This problem was caused by a lack of effective patent protection, namely, a lack of a process claim and has resulted in clear and definite harm. Moreover, present U.S. patent law provides a patent owner the right to exclude other companies in the United States from making, using or selling a patented material, but fails to provide adequate protection for the use of such patented material outside the United States for making a product and importing the product into the United States.

Today, if one obtains a patent claiming only a recombinant host cell, it does not automatically follow that one would also receive patent protection for the process of producing a product by means of that patented host cell. Therefore, it is not possible to prevent the importation of the product made abroad using the patented host cell.

Consequently, a foreign manufacturer is allowed to do what no domestic manufacturer is permitted to do; market in the United States a product made from the patented host cell. U.S. patent law must allow domestic and foreign manufacturers to complete on a level playing field, one on which U.S. companies are not placed at a competitive disadvantage by U.S. law.

Unless Congress closes this loophole, the consequences will be a continued shift to offshore manufacture of recombinant products and a loss of jobs and investment in the U.S. biotechnology industry.

It is Amgen's belief that changes must be made in the U.S. patent laws to protect our biotechnology industry and provide effective remedies from unfair competition. The CAFC has made it clear that this is a task for the Congress, which can explore its impact and side effects.

Mr. Chairman, Amgen's experience reveals a weakness in the U.S. patent laws that were drafted prior to the dawn of biotechnology. The legislation before this committee will remove unintentional barriers to award of biotechnology process patents and provide long overdue protection against unfair competition.

H.R. 760 will create a level playing field by allowing a patent owner to enforce a patent claiming a host cell against a foreign manufacturer. It makes no sense that we apply our patents only against ourselves.

No one here today would suggest that a host cell patent should not be enforced against a domestic manufacturer. Why then should the same patent not be enforced against a foreign manufacturer who is doing exactly what the domestic manufacturer cannot do?

Unless this loophole is closed, the law today gives every manufacturer, domestic and foreign, the incentive to manufacture overseas and thereby avoid the scope of U.S. patents protecting host cell claims. Amgen spent 6 years and millions of dollars trying to protect its investment in what was, at the time, its only product, from what all but the most biased would agree is an unfair act.

A foreign competitor, using Amgen's patented technology overseas can avoid Amgen's U.S. patent on the technology and enter the U.S. market even though the same conduct would infringe on Amgen's U.S. patent if conducted in the United States. Unintended loopholes in laws designed to protect American business against unfair acts must be closed when shown to be exploited by foreign competitors.

This is especially true when these acts exploit U.S. technology, results in the export of U.S. jobs and a threat to the U.S. leadership in biotechnology, one of the few industries where America continues to hold the leadership position.

Amgen seeks a level playing field, nothing more, nothing less, thereby allowing all United States and foreign manufacturers to compete equally in the United States. We thus support H.R. 760 and urge its prompt enactment.

If one other U.S. based company must face the same problem, the delays and expenses encountered by Amgen, it is one too many.

Thank you for the opportunity to present Amgen's views on this critical issue.

Mr. HUGHES. Thank you, Mr. Odre.

[The prepared statement of Mr. Odre follows:]

PREPARED STATEMENT OF STEVEN M. ODRE, VICE PRESIDENT AND ASSOCIATE GENERAL COUNSEL, AMGEN INC.

Mr. Chairman and Members of the Committee, I am Steven M. Odre, Vice President and Associate General Counsel of Amgen Inc., a biotechnology company headquartered in Thousand Oaks, California. I am here today to share with you the experience of one of this country's largest biotechnology companies under current United States patent law. As you know, Amgen has encountered about every possible pitfall in the patent arena. Our company has, in effect, served as a microcosm for problems with patent laws that plague the biotechnology industry.

Patents are the life-blood of the emerging biotechnology industry. Without meaningful, enforceable patent protection, startup biotechnology companies would not be able to attract the venture capital which is necessary to finance research and development on new, innovative health care products. Enforceable patent protection laws are essential to the success of the biotechnology industry.

Current patent law provides the biotechnology industry with only limited patent protection for its inventions. Two principal problems exist. First, the decision of the Court of Appeals for the Federal Circuit ("CAFC"), *In re Durden*, has made it difficult for biotechnology companies to secure process patent protection. Second, the law itself creates an unlevel playing field for biotechnology companies. Foreign competitors have taken advantage of a loophole in the patent laws which allows a foreign company to do what no U.S. competitor can do—use the technology patented

in the U.S. offshore to make products and compete in this country against the U.S. patent owner.

Amgen is the acknowledged pioneer in the development and production of recombinant erythropoietin (or rEPO). Amgen was the first to clone the gene and produce rEPO and has obtained patents throughout the world. EPOGEN was AMGEN's first product approved for sale after eight years of costly investment in research and development.[1] However, a foreign competitor sought to exploit a loophole in United States patent laws that would allow it to manufacture a rEPO product in Japan using the same recombinant host cell for which Amgen holds a U.S. patent, then import and market the product in this country. This loophole in the patent and trade laws allows foreign companies to use technology protected by a U.S. patent—technology that no company could legally use in the United States—to make a product overseas and sell it in the United States. When Amgen asked the International Trade Commission ("ITC") and subsequently the CAFC to enforce its rights under its patent by stopping the importation of foreign produced rEPO, it was told by the CAFC that only Congress could affect such a change in the law. The ITC and CAFC held that current law does not protect innovative companies such as Amgen from this type of unfair foreign competition. Amgen continues to strongly believe that changes must be made in the United States patent laws to protect our biotechnology industry from misuse of this country's technology.

BACKGROUND

Amgen Inc.

Since its founding in 1980, Amgen has been dedicated to the development of innovative human therapeutic products, using advances in recombinant DNA technology and molecular biology. Amgen spent eight years and over $100 million to develop its rEPO product, pioneering a genetically-engineered therapeutic product of enormous medical value to many thousands of patients suffering from anemia caused by kidney failure.

When Amgen was formed in 1980, the primary treatment for severe anemia in kidney dialysis patients was to administer repeated blood transfusions. Needless to say, such treatment presented hazards (i.e., exposure to AIDS and hepatitis), and provides only a partial and temporary increase in the patient's red blood cell level. What clearly was needed was a replacement of the missing vital protein, erythropoietin. However, the naturally occurring human protein itself was at best difficult to obtain. Previously a form of the protein was found only in minute quantities in urine, and to this day this urinary derived product cannot be effectively used for human testing or treatment. Using recombinant DNA technology and molecular biology, Amgen's scientists were able for the first time, to produce an erythropoietin product for therapeutic uses.

Patent and Regulatory Status

Clinical trials began in 1985. In June 1989, the Food and Drug Administration ("FDA") approved Amgen's Product License Application for EPOGEN. Amgen's rEPO has been designated by FDA as an orphan drug, and thus was granted seven years of exclusive marketing approval in the United States for the use of the drug for treatment of anemia associated with chronic renal failure.

In late 1983 Amgen applied for patent protection for the gene encoding rEPO and host cell necessary to manufacture rEPO as well as for the process for making rEPO and the recombinant erythropoietin product itself. In October 1987, the U.S. Patent and Trademark Office ("USPTO") granted Amgen a patent which includes claims to the gene encoding erythropoietin and recombinant host cells containing this gene. However, because of *In re Durden*[2] the USPTO refused at that time to allow claims to the process for making rEPO using the patented host cells.

With knowledge of Amgen's successful development of rEPO, Genetics Institute ultimately replicated Amgen's success. Because the USPTO refused to award Amgen a patent containing process claims, the President of Genetics Institute publicly stated on November 1, 1987 that his company's Japanese partner Chugai would simply avoid Amgen's patent by manufacturing rEPO overseas and then import the product into the United States. The recombinant host cell needed to make rEPO[3] was

[1] Amgen received FDA approval in Feb. 1991 for its second product, a Granulocyte-Colony Stimulating Factor, NEUPOGEN.

[2] 763 F.2d 1406 (Fed. Cir., 1985) says, in effect, that a process using a patentable "starting material" to make a patentable "final product" is not patentable unless it can be demonstrated that "unexpected results" occur during the use of the full process.

[3] Amgen's patented technology is the only means of producing rEPO.

shipped to Japan by Genetics Institute, thus allowing Chugai to conduct manufacturing activities in Japan that would constitute patent infringement if conducted in the United States.

In 1988, Chugai formed Chugai-Upjohn, a partnership with the Upjohn Company to market Chugai's rEPO and imported rEPO for clinical trials in the United States. Because Amgen's rEPO enjoys orphan drug exclusivity for the chronic renal failure indication,[4] Chugai's rEPO cannot be approved by FDA for chronic renal failure. However, Chugai can file an application with FDA for other uses of rEPO. Upon approval of such an application, Chugai could commence importing rEPO from Japan and sell it in the United States.

Delays Resulting from In re Durden

Since 1983, when it first filed a patent application claiming its pioneering recombinant erythropoietin technology, Amgen has had patent applications pending that would protect not only the end product of its enormous research and development effort, but the manufacturing process as well. Significant delays in the issuance of a process patent were encountered as a result of the USPTO's initial reliance upon the holdings of *In re Durden*. Amgen estimates that at least a five year delay in issuance of enforceable process patent protection was engendered by *In re Durden*.

A little more than a year following the grant of Amgen's patent claiming the host cell required to produce rEPO, Amgen finally overcame the Patent Office's initial rejection of its application in view of *In re Durden* only by restricting the scope of the process claims when compared with the process claims allowed on Amgen's patent application in foreign countries. However, as of this date, no U.S. patent has issued having such process claims.

The ITC Dilemma

To protect itself from unfair acts of a foreign competitor, on January 4, 1988, Amgen filed a complaint before the International Trade Commission alleging unfair acts of Chugai regarding importation to the United States of rEPO manufactured in Japan using the recombinant technology for which Amgen has obtained a United States patent.

The issue before the ITC dealt with the meaning of relevant provisions of the Tariff Act of 1930, which, in pertinent part, defines an "unfair act" as

> [t]he importation for use...of a product made...by means of process covered by the claims of any unexpired valid United States letters patent.[5]

Although the host cells claimed by the Amgen patent and utilized by Chugai to manufacture rEPO in Japan are the only known way to produce rEPO, Chugai took the position that no "unfair act" occurred because the Amgen patent lacks a "traditional" process claim.

In 1988, as part of its revisions to the trade law,[6] Congress changed the authority of the ITC to make it easier for American innovators to obtain protection from unfair acts. Senator Lautenberg, one of the drafters and sponsors of these changes, explained in no uncertain terms during the debate on the 1988 legislation than it was Congress' intent in enacting the reforms to protect U.S. genetic engineering technology against actions such as Chugai's. As stated by Senator Lautenberg:

> Section 337(a)(1) (a reenactment of section 337(a)) will provide the assistance necessary for emerging U.S. industries such as the biotechnology industry, to compete in a marketplace without interference due to unfair acts of foreign competitors. The continued broad jurisdiction of the International Trade Commission will help U.S. industry address the unfair activity of foreign competitors who, for example, import products manufactured using patented genetic engineering technology. *Merely moving manufacture offshore does not absolve the wrongdoer from the requirement to compete fairly.* The Trade Act protection prohibits the foreign enterprise from taking jobs

[4] The Orphan Drug Act authorizes the award by the Food and Drug Administration of marketing exclusivity for a drug designated for a rare disease or condition. Once a drug is so designated and approved, the FDA is prohibited from approving another application requesting approval of the same drug for the same disease or condition until seven years after approval of the pioneer product. The law's definition of rare disease or condition includes one which affects less than 200,000 people in the United States. See Section 525(a)(2) of the Federal Food, Drug and Cosmetic Act. EPOGEN, approved for the treatment of anemia associated with chronic renal failure, is a drug that meets such definition.

[5] Section 337(a)(1)(A)(ii) of the Tariff Act of 1930.

[6] Omnibus Trade and Competitiveness Act of 1988, Pub. L. 100-418. The provisions of Section 337(a)(1)(A)(ii) quoted above were not modified by the 1988 law.

from American workers by doing offshore that which they could not lawfully do in the United States.

134 Cong. Rec. S10714 (daily ed. Aug. 3, 1988) (statement of Sen. Lautenberg) (emphasis added).

In January, 1989, ITC Administrative Law Judge Sydney Harris found that Amgen was the first to clone the gene encoding rEPO and held that Chugai's use of the patented host cell to manufacture rEPO, if practiced in the United States, would constitute infringement of Amgen's patent. Judge Harris, however, also held that despite Senator Lautenberg's floor statement, the legislative history of the predecessor statute to Section 337(a) compelled the conclusion that, since Amgen's patent does not "cover" the process for producing rEPO (but, instead claims the EPO gene and host cells which produce rEPO), there is no violation of Section 337(a).

In April 1989 the ITC dismissed Amgen's initial complaint, concluding that the ITC lacked jurisdiction under Section 337(a) since Amgen did not have a traditional process patent claim. This decision was appealed to the CAFC, which reversed the ITC's finding that it lacked jurisdiction, but affirmed the decision of Judge Harris that there was no violation of Section 337(a). The opinion included a clear statement that the remedy "is a task for the Congress" and not the courts.

Litigation in the District Courts

In October 1987, Amgen sued Chugai and Genetics Institute for patent infringement and brought a declaratory judgment action for non-infringement and invalidity of the Genetics Institute patent. In December 1989, a United States District Court in Massachusetts determined that certain claims of both Amgen's and Genetics Institute's patents were valid and others were invalid.[7] However, the court categorically stated that Amgen was first to invent the gene and host cell that lead to the development of rEPO. The District Court's decision was appealed to the CAFC which in March 1991 unanimously held that Amgen's patent is valid and enforceable, but held Genetic Institute's patent to be invalid. This decision became final when certiorari was denied by the U.S. Supreme Court in October 1991.

EFFECT OF AMGEN'S EXPERIENCE WITH THE PATENT AND TRADE LAWS

Both an Administrative Law Judge and a Federal Magistrate—finders of fact—have determined that Amgen performed the pioneering work that led to the invention of rEPO. Following the March, 1991 CAFC decision, the litigation to date has the following effect:

Amgen holds a valid and enforceable U.S. patent on the gene and recombinant host cells which produce rEPO. This prevents United States based manufacturers from using this patented technology to produce an rEPO product in this country.

Neither Genetics Institute nor any other company can legally manufacture rEPO in the United States without infringing Amgen's host cell patent. However, a foreign manufacturer such as Chugai can continue to escape the applicability of the U.S. patent laws by manufacturing rEPO overseas and importing it into the United States.

Since 1983 Amgen has had pending a process patent application, and, to date, in spite of overcoming the rejection of the claims in view of *In re Durden* in the USPTO, a patent having process claims has not issued.

Because the ITC and the CAFC have held that Section 337(a) applies only to traditional Process claims, and not claims on the biological materials essential for the production of rEPO, Chugai remains free from Amgen's U.S. patent to produce rEPO abroad by using Amgen's patented technology, and import the rEPO product into the United States.

COMMENTS ON H.R. 760 AND THE NEED FOR ADDITIONAL PROTECTIONS

Amgen's experience reveals a significant weakness in U.S. patent and trade laws that were drafted prior to the dawn of biotechnology. In our opinion, the legislation before this Committee forms the basis for a long overdue updating of the law to overcome unintentional barriers to the award of biotechnology process patents and protection against the unfair competition resulting from the use of U.S. patented technology by foreign competitors overseas.

H.R. 760 is designed to counter the effect of the *In re Durden* decision for biotechnology patents to the extent that *In re Durden* may prohibit pioneers from obtaining process patent protection on a process using recombinant host cells. As

[7] *Amgen Inc.* v. *Chugai Pharmaceutical Co.. Ltd.*, 13 U.S.P.Q2d 1737 (D. Mass., 1990).

noted earlier, although Amgen has overcome a rejection under *In re Durden*, obtained allowed process claims with respect to rEPO, and expects to receive a U.S. patent having such claims, Amgen has no desire to see other members of the biotechnology industry experience similar delays in obtaining enforceable protection. Strengthening the patent laws to protect pioneering innovators is critical to the United States biotechnology industry—and clearly is in the national interest.

Nothing has changed since similar bills were first introduced in 1989 that alleviates the need for remedies provided in the legislation introduced this year.[8]

Congress should update the law to protect against foreign competitors using technology claimed by U.S. biotechnology patents and competing in the U.S. market. H.R. 760 closes unintended loopholes that allow competitors to unfairly reap the benefit of inventiveness, initiative, and entrepreneurship which the United States has invested—loopholes which, if not properly remedied, will have a negative impact on the United States economy by discouraging revolutionary breakthroughs in the development of important new medical therapies.

In Amgen's view, the thesis that merely overturning *In re Durden* is by itself sufficient to protect the biotechnology industry is incorrect. There are several instances of biotechnology companies and universities having patents with claims to host cells without claims to a process for making a product using a host cell. When faced with rejections of process claims because of *In re Durden*, many applicants, due to cost or other reasons, may accept claims limited only to host cells and abandon process claims. For these companies and universities in such instances the overturning of *In re Durden* is insufficient.

H.R. 760 would amend Title 35, U.S. Code, to render persons who import, sell or use in the United States products made overseas by "infringing" claims to biotechnological material from which such products are made, i.e., host cells liable as infringers, and thus subject to actions in U.S. District Court. This would provide a "level playing field" which would permit domestic and foreign manufacturers to compete on equal footing in the U.S. market.

NAFTA

I understand that the Committee has asked for comment regarding the impact of H.R. 760 on the provisions of NAFTA. The NAFTA chapter on intellectual property rights requires each party—the U.S., Mexico, and Canada—to set up certain minimum protections. These requirements establish a floor for the protection of such rights, not a ceiling. The purpose of these protections is to "foster creativity and innovation, and promote trade in goods and services that are the subject of intellectual property rights."[9] Thus NAFTA requires the parties, "at a minimum," to follow the NAFTA chapter and certain other conventions protecting intellectual property rights.[10] Throughout the chapter, the NAFTA requires protections, while it permits derogations from those protections.[11] The NAFTA thus does not prohibit a country from strengthening an existing law of intellectual property protection. H.R. 760, which is designed to protect biotechnology inventions, is totally consistent with those provisions of the NAFTA.

In fact, the NAFTA affirmatively requires effective patent protection for pharmaceutical products.[12] Such patent rights include both product and process claims.[13] Not only is H.R. 760 consistent with these provisions, it can be said to implement them.

CONCLUSION

H.R. 760 would increase the certainty regarding the intellectual property rights for the biotechnology industry. In addition, there is little question that H.R. 760 will provide a "level playing field" between domestic and foreign biotechnology competi-

---

[8] It has been asserted by some that the courts will eventually resolve the issue addressed by H.R. 760. It has been over four years since this argument first surfaced and we are still awaiting judicial resolution. Opponents of the bill continue to disregard the uncertainty regarding the scope of any court decision and the resulting confusion it may produce.

It has also been argued that Congress should not enact H.R. 760 because it is industry specific legislation. If H.R. 760 is to be criticized because it is industry specific, then statutes such as 35 U.S.C. 271(e), which exempts from infringement activities solely for uses reasonably related to the development and submission of information to obtain regulatory approval of a product, should never have been enacted.

[9] NAFTA Art. 1702.

[10] *Id.* Art. 1701, 1 ¶2.

[11] *Compare. e.g.. id.* Art. 1709, ¶¶ 1, 4, 6 *with* ¶¶ 2, 3, 6.

[12] *Id.* Art. 1708 ¶4 ("product patent protection for pharmaceutical[s]").

[13] *Id.* Art. 1709, ¶5.

tors. H.R. 760 will provide a clear message that foreign competitors must compete fairly with the U.S. biotechnology industry.

Amgen, America's leading independent biotechnology company, spent six years and millions of dollars trying to protect its interest in what was at the time its only product from what all but the most biased would agree is an unfair act. In contrast, a foreign competitor, by using Amgen's patented technology overseas can avoid Amgen's U.S. patent on the technology and enter the United States market notwithstanding the fact that the same conduct would infringe Amgen's U.S. patent if conducted in the United States. When unintended loopholes in laws designed to protect American business against unfair acts are exploited by foreign competitors to perpetuate such unfair acts should the loopholes remain unclosed? No, especially when the result is the unfair exploitation of United States technology, the export of United States jobs and a threat to United States leadership in biotechnology, one of the few industries where America continues to hold a leadership position. We believe that upon reflection the Congress will agree.

Mr. HUGHES. Do you have any specific instances of foreign companies taking advantage of the U.S. firms' inability to obtain patent process protection?

Mr. RAAB. I think that other than the example cited by Amgen, the most revealing way to look at it is we surveyed, in view of my appearing before you, the 21 companies who make up our associations patent committee, as to whether they had problems. Nineteen of them said they were facing problems and 15 of them said they had immediate problems. So I think this is a sword that is hanging over all of our heads and is potentially a very real one in our deciding what we work on and how much we invest it.

Mr. HUGHES. Are you at liberty to share with us those potential problems?

Mr. RAAB. Yes. I think we can provide that to the committee, yes.

Mr. HUGHES. That would be very helpful.

[The information appears in appendix 1.]

Mr. HUGHES. There are no specific problems right now that you are aware of but there are potential problems?

Mr. RAAB. That is correct; that I can personally cite, but we will share that with the committee.

Mr. HUGHES. The record will remain open for the committee to receive that information.

Mr. RAAB. We will do that promptly.

Mr. HUGHES. If Congress predetermines that protection under title I and title II of the bill is unnecessary and rather duplicative, which title would you prefer and why?

Mr. ODRE. Amgen would prefer title II. And I think although we prefer both titles, we feel there is nothing wrong with having belts and suspenders, but if given a choice——

Mr. HUGHES. Suspenders may not work.

Mr. ODRE. In California, at Amgen, we don't wear suspenders or ties.

Mr. RAAB. I would just comment that we also feel that way but that we support whichever way the chairman and the committee feel is appropriate.

Mr. HUGHES. Have you considered politics, Mr. Raab?

Mr. RAAB. If you work at Genentech or Amgen, you are in politics one way or the other.

Mr. HUGHES. I know that to be the case. Sometimes the politics of corporate hierarchy are more intense than we experience up here.

If Congress provides protection for biotechnology, wouldn't other industries ask to be included in any industry-specific legislation?

Mr. RAAB. Would you repeat that, please.

Mr. HUGHES. Aren't other industries going to ask for the same protection; they already have. If we go industry specific, aren't other industries going to ask for the same protection?

Mr. RAAB. I suppose there is a potential for that. I have no reason to deny it. But I think those that I know of, if you look at the unique circumstances of our industry, both from the point of view of the fact that the product is so often a natural one. I have sort of a, quote, clever way I describe our industry. Our products are, "created by God and discovered by the industry." The reason I say this is that they are things that generally are already in our body, and we are working on providing those to people who don't have any or enough of those. So I don't think that I can come up with, very readily, such a unique situation where the products provide such significant potential or actual benefit for humankind.

Mr. HUGHES. Mr. Odre, the PTO testified, and the opponents will also testify subsequently, that the section contained in title II is overly broad. In fact, the limitations found in the 1988 process patent amendments not permitting infringement of a product manufactured where the patented process is trivial or a nonessential component of another product are not in H.R. 760. Would you agree that these limitations need to be included if, in fact, H.R. 760 becomes the law?

Mr. ODRE. I would have to take a look at specifically the limitations. From what I heard today, I don't think that would present a major problem.

Mr. HUGHES. Finally, for each of your companies, how many process patent applications directly related to biotechnological products have been filed with the PTO, any idea?

Mr. RAAB. I don't know. We would supply that to you. We can certainly do that.

Mr. HUGHES. So received.

[The information appears in appendix 1.]

Mr. HUGHES. How many of these process patents directly related to biotechnology have been ultimately granted or denied? I request you provide that to us, also.

Mr. RAAB. We would supply that, yes.

Mr. HUGHES. That would be very helpful.

[The information appears in appendix 1.]

Mr. HUGHES. How long has the approval process for patent process taken at the PTO?

Mr. RAAB. I would use the example of—I didn't cite the product that this concerned, that we are working on. I mean, we have been working on this, we identified this over 11 years ago, this potential product, and we still do not have a process patent. It is still going on.

Mr. HUGHES. You indicate in your testimony, Mr. Raab, that two-thirds of biotechnology process patents are issued only after a *Durden* rejection is made and later overcome with evidence of an unexpected result. I have one such example here.

I wonder if you can for the record also explain how that figure was arrived at? I know you probably don't have it today, but if you would supply that, we would appreciate it.

Mr. RAAB. Certainly.

[The information appears in appendix 1.]

Mr. HUGHES. Mr. Odre, in your testimony and previous testimony on behalf of Amgen, you indicate that Amgen received a patent in 1985 for its host cell, a gene for EPO. At that time, however, a process claim was denied. What was the exact reason given for the denial of the process patent?

Mr. ODRE. I believe, it was July 1987, Amgen received the rejection under *In re Durden*, and we made the election at that time to cancel the claim, the process claims, make them the subject of a separate patent application. Our patent was issued in October 1987, and but for the *Durden* rejection, the process claims would have been issued in the October 1987 patent.

Mr. HUGHES. So the basis was *In re Durden*?

Mr. ODRE. Yes.

Mr. HUGHES. In Amgen, was a process patent protection granted, or I understand that you will receive it?

Mr. ODRE. At least, I hope so.

Mr. HUGHES. I hope so, too. Isn't it correct that its problems with respect to any foreign competition are largely solved?

Mr. ODRE. I believe if Amgen does obtain patent protection, it would go a long way towards solving our problems. There are two points to make on it: One, as we have noted, we don't have process protection today. Second, the claim that has been allowed by the U.S. Patent Office is somewhat limited compared to the claim that has been allowed by the European Patent Office.

Adequate enough to give us the protection, yes. But not protection of the same scope.

Mr. HUGHES. Won't that always be the case? Even if we deal with the *Durden* problem, the patent process, like all process patents, basically, they can be problematical, that is obvious. We can solve *Durden*, but we are never going to resolve all the uncertainties.

Mr. ODRE. I think that is, perhaps, why title II may be important. Title II provides a remedy. It doesn't grant patentability, and host cell claims have been litigated. Fortunately, or unfortunately, Amgen participated in that, and they have been held valid. People understand the scope of those claims.

Mr. HUGHES. The gentleman from Florida.

Mr. MCCOLLUM. Thank you very much.

In light of the fact that we have a very big hit movie coming out this weekend called Jurassic Park, I wonder if either of you two gentlemen wanted to disclaim any dinosaur research in your companies?

Mr. RAAB. I would point out that Genentech was mentioned in the book, but our understanding is we are not in the movie.

Mr. MCCOLLUM. I did read the book.

Mr. RAAB. I think it should be a wonderful movie and about as far from the truth and reality as any science fiction movie is.

Mr. MCCOLLUM. I just couldn't resist, Mr. Chairman, a little deviation from the subject matter here. I don't think that is the *Durden* case.

In the discussions we have had up to this point in time—on a serious note, it seems we narrow this focus down to title I and title II, and you said, Mr. Odre, that you think title II would be adequate to do this job. But could you explain for the record for me—you know, I am a cosponsor of this, and I think I understand it, but I don't think that everybody here probably has been through this.

What would be added by title I? If we just went with title II, what are we missing?

Would title—you say if you had to pick between the two, you would pick title II. You would like to have the whole thing. Why would you like to have the whole thing, is really what I am asking?

If we shelve it, throw title I out, what are we throwing out, that we are going to miss?

Mr. ODRE. If we throw out title I and relied solely only on title II, then we would have one exclusive remedy. What title I would allow is not—there may be circumstances where we would not want to litigate the host cell patent or host cell claim, and we can rely on process protection. Again, they both cover the invention. And under the U.S. law, they are both entitled to patent protection.

Mr. MCCOLLUM. Would you save money for companies by not having to get to the point where you use title II, if title I was around? In other words, is there a real dollar and cents practical reason why title I would be beneficial?

Mr. ODRE. I don't know of any dollar and cents reason why title I would be beneficial. Depending on the facts and the circumstances of the particular case, title I would cover a process to an invention.

The invention can be described in various ways, whether it is a final product, whether it is a host cell, again a sequence or a process. Those are all provided under current U.S. law. And we believe that protection is available, it should be provided.

Mr. RAAB. I think the other thing of interest of which my associate just reminded me is that title I enables you to bring under the ITC, International Trade Commission, a procedure which is a potentially very efficient and effective procedure that we have available to us.

Mr. MCCOLLUM. And which you wouldn't have if we didn't have title I, obviously?

Mr. RAAB. That is correct.

Mr. MCCOLLUM. I just wanted to make sure before we throw some baby out with this bath water, that we don't throw the wrong baby out.

I have no other questions, Mr. Chairman, thank you.

Mr. HUGHES. The gentleman from Rhode Island.

Mr. REED. We have been talking about domestic market potential and your protections within the market. I am just curious, this might be somewhat peripheral, what has your experience in foreign markets been?

Mr. RAAB. I think Mr. Odre knows the specifics much better than I. But, fundamentally, we can get much more significant protection

overseas because of their having a system similar to that which we hope comes about as a result of this legislation.

Mr. REED. If this legislation passed, would you agree with Mr. Odre's testimony, that foreign competitors and U.S. companies would be competing on a level playing field, is that fair?

Mr. RAAB. That is correct. I think one of the things that is important to focus on is the science behind our manufacturing. In our manufacturing organization we have over 60 Ph.D.'s and the thought of there being an incentive to have that kind of activity outside of the United States rather than inside the United States, is such a powerful negative, not just from a competitive point of view, but for keeping the technology in the country, for advancing the technology and, obviously, providing the employment.

Mr. REED. Mr. Odre, do you have any comments?

Mr. ODRE. I believe with respect to Europe, as we have seen, they do provide effective patent protection. Amgen's erythropoeitin patent has been especially held in at least two European countries now, and recently by the European Patent Office, against infringers. With respect to other countries, such as Japan, I think we are still working on that situation.

Mr. REED. The final question goes to something the chairman alluded to. If you had the process patent, you really wouldn't have the same degree of problems that you have today in the United States. Is there any credibility to the argument that the real problem is that companies don't aggressively or persistently pursue the process patent, and that really should be the remedy, or is the problem that these patent applications fail because they are not well documented or well presented?

Mr. ODRE. I can tell you, at least from Amgen's personal experience on erythropoeitin, we did pursue the patent process continuously. The only time we did cancel the claim was in July 1987, when we got the *In re Durden* rejection, and we had to do that.

It became a business decision. In order to enforce our patent rights at the time, it was necessary to get patent protection. We immediately filed a continuation application.

It was made special by the Patent Office and prosecution was pursued immediately until we had allowed claims. When the interference proceeding was declared, again the Patent Office made that proceeding special and it was fast-tracked through the Patent Office. And from Amgen's standpoint, the original application was filed in 1983, although we had allowed process claims in December 1988, we are sitting here today in June 1993, and still do not have process claims issued.

Mr. REED. Mr. Raab.

Mr. RAAB. I would like to just comment, really not from Genentech's point of view, but from that of the Biotechnology Industry Association. As I mentioned earlier, there are many, very, very small companies and these companies do not always file perfect applications and claims, but they all do put a tremendous amount of, under the present circumstances, energy, expense and science in trying to mold and design them as adequately as possible under the circumstances.

That time and energy invested by scientists in the smallest companies is very costly, and I think they do their very best.

But when you have 17 employees and you are struggling to survive, your survival is going to come first from the products you discover, the dilution of that kind of energy is very complex. I think it is again relevant to not just Amgen and Genentech, but more importantly to these wonderful companies of the future that our industry association represents.

Mr. REED. Thank you, gentlemen.

Thank you, Mr. Chairman.

Mr. HUGHES. I thank you, Mr. Raab and Mr. Odre, for your excellent statements.

Your statements, which are part of the record, are very comprehensive, and we appreciate that.

The record will remain open for 10 days; is that sufficient time.

Mr. RAAB. I think so, yes.

Mr. HUGHES. Thank you very much, you have been very helpful to us today.

Our final panel today consists of William LaFuze and Robert Armitage.

William LaFuze appears today on behalf of the American Intellectual Property Association of which he is the 85th president. He is a partner in the law firm of Vinson & Elkins in Houston, TX.

He received a bachelor of science degree in physics and a law degree from the University of Texas. He received his masters degree in physics from Southern Methodist University.

Robert, Bob, Armitage is appearing today on behalf of the Intellectual Property Owners, Inc., and the National Association of Manufacturers. He has been a practicing patent attorney for 19 years.

He presently serves on the board and executive committee of the Intellectual Property Owners, Inc., and is the chairman of the Intellectual Property Committee of the National Association of Manufacturers.

We welcome both of you to today's hearing.

As I advised the previous witnesses, we have read your statements, which are excellent, very comprehensive, and will be made a part of the record in full.

We would like you to summarize so we can get right to questions.

Who would like to go first?

Mr. LAFUZE. Mr. Chairman, I will.

Mr. HUGHES. Welcome.

STATEMENT OF WILLIAM L. LaFUZE, PRESIDENT, AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

Mr. LAFUZE. Thank you.

Mr. Chairman and distinguished members of this subcommittee, I am very pleased to be able to testify today on behalf of the American Intellectual Property Law Association.

As you know, the AIPLA takes a proactive interest with respect to legislative changes which are necessary to improve our intellectual property laws generally, and particularly, our patent laws which implement the mandate of the Constitution to encourage the development of new technology by offering in exchange the incentive of a limited monopoly. Although we favor legislative improvement where needed and justified to carry out the constitutional ob-

jectives of the patent system, we appear here today to oppose and comment on H.R. 760.

In opposing H.R. 760, I should say that should be distinguished from—we support the biotechnology industry. We support the American industry, generally. We support the full use of the patent system to protect new technology.

The AIPLA has considered H.R. 760 in light of the several predecessor bills considered in the 101st and 102d Congresses. The principles upon which we oppose H.R. 760 today, are the same principles on which we opposed the prior bills. There are several reasons for opposition for the bill.

First, and fundamentally, there is no compelling need and justification for the proposed amendments. Proponents of the bill continue to cite *In re Durden* as a need for legislative change, because *Durden* is alleged to have caused the confusion in the PTO with regard to examination of biotech clients.

The AIPLA believes that *Durden* does not justify a need for legislative change. Except in specific limited circumstances, *Durden* is not the controlling precedent for rejecting process claims.

Mr. McCollum mentioned a moment ago, "Jurassic Park." We believe *In re Durden* belongs in "Jurassic Park." It is a dinosaur that you should never see except in extremely limited circumstances, perhaps only in the movies.

The cases since, decided since *Durden*, have clarified *Durden* and largely put *Durden* to rest.

To the extent that there are any lingering questions remaining because of *Durden*, other cases are pending before the Federal circuit involving the *Durden* issues. Those cases have been argued and submitted, and decisions are expected soon which should remove any such problems associated with *Durden*.

The bottom line is this: The PTO is currently examining and issuing process patents on biotechnology processes. Title 35, as interpreted by the court, provides fair and balanced standards to obtain patent protection for processes, including processes involving biotech materials.

Lastly, the proponents claim that the bill is needed to protect the U.S. biotech industry from unfair foreign competition. However, the AIPLA doesn't see evidence of commercial harm resulting from current law, nor does it believe that such harm is likely to occur.

Our question is, where is the evidence that supports the conclusions we hear from the proponents?

There are several undesirable and objectionable features of the bill, which I would like to point out. The AIPLA opposes any proposal that provides greater rights in one field of technology and lesser rights in other fields because of the existence of competing circumstances. This bill would specifically grant broader rights to biotechnology than any other field of technology.

The AIPLA opposes the grant of patents without examination. H.R. 760 would permit the PTO to issue process claims without examining them under the nonobvious standard, which is the linchpin standard for determining invention.

The bill would extend the reach of the patent laws to unpatentable articles of commerce made by biotechnological materials so that consumers and retailers would be liable for patent in-

fringement. Consider a few examples of products who use the same process or importation may be an infringement.

Suppose you have water that has been produced by a process which uses genetically altered bacteria. How can you explain a bill which would make taking a shower with such water an act of patent infringement?

Consider milk produced by a genetically modified cow or a shirt made from cotton harvested from a plant modified by the addition of a patented gene; consider bread made from a genetically modified yeast. The act of importing, selling or using any such products is an act of patent infringement under this bill.

The bill would add provisions to our patent statutes that do not exist in the laws of other countries, including Japan and Europe. The implementation of such changes may run afoul of our obligations under GATT and NAFTA to provide for patent rights which are enjoyable, without discrimination as to the field of technology.

If such changes which favor a specific industry in our country do not violate GATT or NAFTA, then there are other dire consequences. That type of interpretation would encourage each major country to favor industry in its technology which is strong and disfavor those technologies which are weak.

Should we start the battle in which biotechnology is given extra broad protection in the United States, prompting other countries to broaden their laws in areas in which they are ahead or limiting where they are weak? Either result is highly undesirable.

The result is chaos and nonuniformity in patent laws of the world, with each country likely to adopt domestic protectionist amendments to their laws.

In this respect, the bill is a dramatic step away from harmonization of world patent laws, which AIPLA supports as a general proposition and which we believe is in the best interests of American industry. H.R. 760 imposes certain requirements on process invention which, under certain circumstances, effectively denies patent protection to many process inventions which are patentable under current law, and reduces the term of protection for process patents provisions, perhaps inadvertently, that actually harm the biotech industry and are inconsistent with the stated objectives of the bill. So although the bill would broaden the law in certain respects, it would actually narrow it in other harmful respects.

I make my living in the courthouse. And it seems to me that most of the emphasis placed on the bill, most of the testimony given, and most of the evidence, to the extent that there has been some, is with regard to the issuance of patents.

Little attention has been devoted to the problems that will arise when these patents are enforced through litigation. Patents do not give the owner the right to practice the invention. They only give the patent owner the right to exclude others from practicing the invention.

In other words, they only give you the right to sue. There are two possible consequences of litigating process claims of patents issued pursuant to this bill, and both are seriously adverse.

The patent examination process is shifted from the PTO, the Government agency responsible for examining and issuing valid patents, to the courts. I assure you, in a time in which our civil

justice system has ground to a halt because of lack of funding, that this is a terribly adverse result.

There is another possibility. If the courts are faced with process patents issued under this bill, they may elect not to be the examiner, in the first instance, and after trials or partial trials, may send these patents back to the Patent Office to examine them, in the first instance. This would provide an inefficient, duplicitous and expensive waste of the judicial and human resources.

I would like to say that I think the biggest problem that we face as we try to analyze the reasons given by the proponents of the bill, is the simple lack of evidence to support that there really is a problem here. We believe the problem is not *In re Durden*.

In re Durden, in our judgment, should not be used by the Patent Office to reject claims except in extremely limited and bizarre cases. For these reasons and for the other reasons set forth in our prepared statement, which you have, AIPLA opposes the bill.

Thank you very much for the opportunity.

[The prepared statement of Mr. LaFuze follows:]

PREPARED STATEMENT OF WILLIAM L. LAFUZE, PRESIDENT, AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

The American Intellectual Property Law Association (AIPLA) is a national bar association of 8,000 members, primarily lawyers engaged in the practice of patent, trademark, copyright, licensing and related fields of law affecting intellectual property rights. AIPLA membership includes lawyers in private, corporate and government practice; lawyers associated with universities, small businesses, and large businesses; and lawyers active in both domestic and international transfer of technology.

The AIPLA appreciates the opportunity to appear today to comment on H.R. 760.

H.R. 760 addresses whether Congress should bestow on the owners of patents covering "biotechnological" inventions more favorable and extensive patent rights than the law currently allows. This Subcommittee has previously held public hearings on this question in the 101st and 102nd Congresses.

There is no precedent in U.S. patent law or foreign patent laws for the expanded patent rights being petitioned for by segments of the biotechnology industry. Therefore, during this period, a number of different approaches to amending the law have been proposed and considered. The first bill of the series, H.R. 3957, was introduced on February 6, 1990. It provided for an amendment to 35 USC 103, 271, and 19 USC 1337(a)(1)(B). Later that year, H.R. 5664 which would have only amended 35 USC 103, was introduced. In the next Congress, a bill, H.R. 1417, which was identical to H.R. 5664 was introduced. The current bill, H.R. 760, resembles the first bill H.R. 3957. Title I is a refined version of the Section 103 amendment, although its effect is limited to "biotechnological processes." Title II provides, as did H.R. 3957, for a new basis for infringement of patented "biotechnological materials," although the scope of Title II is significantly broader than the comparable provision of H.R. 3957.

The AIPLA has carefully considered the issue of special patent law treatment for biotechnological inventions and processes, as well as the various proposals to provide such treatment. The AIPLA believes that the current statute, as interpreted by the courts, provides a fair and balanced framework within which process inventions, including biotechnology related processes, are evaluated for non obviousness. With the enactment of the Process Patent Act of 1988 (P.L. 10008) Congress provided comparable enforcement rights for patented processes as are provided in foreign countries. Given those two facts, the AIPLA opposes the provisions of H.R. 760 on the same grounds as we have opposed its predecessors. Longstanding basic provisions of law should not be amended without a clearly established compelling need to do so. In our opinion, there is no need to legislate extraordinary benefits for biotechnology patent owners.

A more complete listing of the reasons why we believe that extraordinary patent rights for biotechnology are neither needed nor in the interest of maintaining an equitable and workable patent system follow:

First: The primary stated purpose for the enactment of H.R. 760 and like remedial legislation is the need to protect the U.S. biotechnology industry from "unfair" for-

eign competition. Yet as this debate enters its fourth year, the industry has not cited a single case of actual commercial harm to any U.S. company from unfair foreign competition. Nor, to our knowledge, has there been any explanation of how or why this threat may materialize in the future. On the other hand, by all accounts the biotechnology industry is flourishing. By its own estimates, industry sales of $5.8 billion will reach $50 billion by the year 2000. We do not believe the current state of the patent law poses any danger or threat to the industry from enemies from within or abroad.

Second: Thousands of biotechnology related patents are issued each year, and each year application filings are increasing. As this Subcommittee well knows the PTO is having difficulty coping with burgeoning biotech patent business. Also, virtually none of the major first-generation products to emerge from the industry has lacked effective patent protection, including method claims, including human growth hormone, Factor VIII, Erythropoietin, the inter ferons, human insulin, colony stimulating factors, inter lukens, plasminogen activators, and a host of others.

Yet, the proponents of this legislation still cite as justification for remedial legislation the 1985 *Durden* [1] decision of the Federal Circuit. To the extent that this decision of the Federal Circuit may at one time have been over zealously applied by patent examiners, this justification no longer applies. Subsequent appeals decided by the Federal Circuit in cases such as *Pleuddemann* [2] and *Dillon* [3] have established that *Durden* is not a basis for the automatic or categorical rejection of all process claims, especially those incorporating the use of patentable starting materials, including biotechnological materials. In practice, biotechnology process claim are being examined and patents are being issued by the PTO just as any other claims would be.

Third: The precedent which would be set by changing the law on non-obviousness for a particular type of invention in a particular industry would undermine the credibility of the patent system. AIPLA continues to believe that the patent statute should not imply, much less explicitly state, that certain classes of patent claims somehow escape full scrutiny by the Patent and Trademark Office or are subject to a different, weaker, or more cursory patent standard. Technology-specific rules of patentability represent a long and winding legislative road: today the biotechnology industry, tomorrow the semiconductor industry, later still the computer software developers, thereafter the pharmaceutical companies. AIPLA can see no end to the special interests that may attempt to take advantage of a "designer" patent system, with technology-by-technology definitions of the rules of patentability.

A second natural effect of special interest patent laws is that it will inevitably lead to demands from those industries not receiving the special benefits to be included. We cannot understand how Congress, after providing benefits for the successful biotechnology industry, could deny those same benefits to other industry sectors particularly those demonstrably suffering from strong foreign competition.

The precedent this bill represents would be especially tragic given the masterful job which the judicial system has done and continues to do in adapting *general principles of patentability* to all technologies in a dynamic way. This Congress simply must resist the special interest temptation to ornament the patent laws with special interest provisions that would disrupt 200 years of uninterrupted continuity in patent laws which are nondiscriminatory to all inventions.

Fourth: The AIPLA is not opposed to changes in the patent law, and in fact the opposite is true. The U.S. patent system has been under active evaluation and analysis for the past several years by both government and the bar. The AIPLA strongly supported "The Patent Harmonization Act of 1992," introduced by the chair and ranking minority member of this subcommittee. That bill included a number of significant reforms to U.S. patent laws. We hope that a patent harmonization bill will be introduced in this Congress so the public debate over patent law reform can continue. This will greatly assist our government prepare for the final session of the diplomatic conference on the draft Patent Law Treaty.

For a variety of reasons, we believe that cooperating with other countries to harmonize, to the extent possible, is in the best interest of U.S. inventors and industry. Enacting unique and unprecedented provisions such as H.R. 760 into U.S. law, particularly when the stated reason is to "protect" against "unfair" foreign acts, works against that American interest.

Fifth: The provisions of H.R. 760 are particularly sensitive because patent protection for methods of using a patented material as part of process to make unpatented products can affect commerce in common or staple goods. Downstream buyers, sell-

[1] *In re Durden*, 763 F.2d 1406, 226 USPQ 359 (Fed. Cir. 1985).
[2] *In re Pleuddemann*, 910 F.2d 823, 15 USPQ2d 1738 (Fed. Cir. 1990).
[3] *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990).

ers, and users of these articles of commerce rarely know how they were manufactured or produced; yet they could become liable for patent infringement.

Potential patent infringement liability in broad classes of persons engaged in buying, selling or using commonplace articles made by patented processes was first established in the United States by the "Process Patent Act of 1988." P.L 100–408. Congressional proceedings which led to the enactment of this new law were highly controversial because of these concerns, even though this law corresponds to the patent law in foreign countries. And, of course, the patent rights could only arise out of a process that was deemed to be patentable after full application of existing patent law standards to establish that an invention was made by the PTO. Also, limitations on liability were included.

H.R. 760 would expand current law by providing automatic coverage for any and all unpatented products made by using a patented product deemed to be a "biotechnological material:" a $10.00 cotton/polyester shirt made from cotton harvested from a plant modified by addition of a patented gene, a $1.00 loaf of French bread made using genetically modified yeast, a $0.50 glass of milk obtained from a genetically modified cow, and a $50,000 luxury sedan with leather seats derived from cattle containing a patented genetic modification. Extending patent protection to extremes and blurring the connection between an inventive act and patent rights threatens to undermine public confidence and support for the patent system.

Technology-specific legislation raises a further consideration not discussed in our 1991 testimony, namely the impact of this precedent under either the GATT or NAFTA. For the purpose of exploring this issue in the simplest and most tangible way, we would call this subcommittee's attention to the language in Article 1709 of the North American Free Trade Agreement, in which the United States, Canada and Mexico commit themselves to:

> ...make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application....

and further stipulate:

> ...patents shall be available and patent rights enjoyable without discrimination as to the field of technology...."

These two provisions must be read together: although patents *must* be available, they only need be provided where an invention is non-obvious (or evidences an "inventive step" in the words of NAFTA), and—where available—must be non-discriminatory as to field of technology. When read together, the following question requires exploration: Has a country made patents available on a non-discriminatory basis if it applies the non-obviousness criterion for patentability on a discriminatory basis? Put in more technical terms under the patent laws: Does non-discrimination only relate to the *subject matter considered eligible for a patent* or does it extend to the *conditions for patentability*, e.g., novelty, utility and non-obviousness?

Title I of H.R. 760 provides that biotechnology process inventions—and *only* biotechnology process inventions—will be *conclusively* presumed to be non-obvious whenever the process involves making or using a patentable product. In other fields of technology, no such conclusive presumption with respect to non-obviousness would exist; the normal rules of patentability would apply. Such discrimination in the non-obviousness determination, under NAFTA, could be viewed as "discrimination as to the field of technology," given the broadest interpretation of the language in the agreement. Alternatively, such a discrimination could be considered to be sanctioned under NAFTA on the grounds non-discrimination applies only to whether the invention relates to patent-eligible subject matter, not other issues of patentability. Specifically, patents are "available" for biotechnology inventions on a non-discriminatory basis, with the technology-specific rules on non-obviousness being irrelevant to the question of the narrowest interpretation of "availability."

Taking the most narrow interpretation of "availability," such that no NAFTA-prohibited discrimination would exist, leads to some troubling conclusions about the effectiveness of this language. Assuming that providing such a presumption (here, conclusive presumption) of non-obviousness is NAFTA-compatible for this *one* field of technology, would a presumption of *obviousness* rather than *non-obviousness* be equally NAFTA-compatible? For example, would NAFTA allow Canada or Mexico to amend its patent laws as they apply to biotechnology process inventions to provide a presumption of *obviousness* (or unpatentability) where the biotechnology process involved the using of an old, unpatentable product? If the answer is "yes" to all manner of adverse presumptions to patentability, then all the benefits of NAFTA for U.S. inventors could be spoiled.

These possibilities are certain to be unsettling ones to those in U.S. industry who look to trade agreements to improve the international competitiveness of high technology industries in this country. If technology-specific presumptions of non-obviousness are not discriminatory, then it may be difficult to conclude that technology-specific presumptions of obviousness are somehow discriminatory. In other words, it may be impossible to have our NAFTA cake and eat it too? If this country must have biotechnology-specific legislation, must we argue that the NAFTA-style non-discrimination clause deals only with subject matter eligibility, not substantive patentability standards such as non-obviousness. In doing so, we run the risk of reducing the expected benefits of NAFTA to a few crumbs—as foreign countries enact polar-opposite presumptions on non-obviousness into their patent laws.

Moreover, if technology-specific legislation can be sanctioned under the non-discrimination provision of NAFTA, they can equally be sanctioned under the GATT. The provision in NAFTA is basically a clone from Article 27 of the current "Dunkel text" for a TRIPS agreement in the Uruguay Round of GATT negotiations. What is to prevent a country from taking "target practice" at selected U.S. industries: high temperature superconductor patents one year; advanced computer memory technologies the next?

While AIPLA has not had yet completed a definitive analysis of the impact of possible trade agreement obligations upon H.R. 760, the tentative observations we have discussed here today do again emphasize the troubling side of any technology-specific foray into the patent laws. They again emphasize the need for the proponents to provide an overwhelming and compelling justification for such a foray. Those supposed benefits, especially when limited to a single industry, must overwhelmingly justify all disadvantages—actual and potential—that may result from even the most carefully crafted legislation.

Although H.R. 760 is directed primarily to the granting of patents to protect biotechnology processes, it leaves many questions unanswered as to enforcement of such patents. Consider the hypothetical in which suit is premised on a process claim which is linked to a patentable biotechnology material. Since the process claim in issue has never been examined for non-obviousness, presumably the first test regarding validity of the process claim would be to determine the validity of the linked product claim. Assuming the linked product claim to be invalid, then under Section 282, as amended by the bill, the process claim at issue would not be presumed invalid. In a litigation context, the district court, after finding the linked product claim invalid, would be faced with at least two alternatives. First, the Court could examine the process claim, a claim never before examined for obviousness because of the per se rule of the bill, under traditional 103 standards. The question arises—is it a good use of judicial resources to transfer the examination burden from the administrative agency responsible for issuing patents to the courts? Second, the court, having found the linked product patent invalid, could decide that judicial resources would be better spent by sending the case back to the PTO for a first time examination of the process claims. This process could result in multiple trials at great expense to litigants, and a substantial waste of judicial and human resources. Both of these alternatives are undesirable. Another alternative solution would be to create of statutory presumption of invalidity of the process claim linked to the product claim held invalid. This solution may result in an adjudication of invalidity of claim that had never been examined, and perhaps, under current law, would have been an allowable and valid claim. Consequently, all of the above alternatives which are presented as possibilities as a result of H.R. 760 have substantial disadvantages to the patent holder and to the judicial system.

Moving to a more technical level, Title I of H.R. 760 represents an apparent attempt at refinement of earlier versions of bills dealing with this subject before prior Congresses. As the proposed statutory language is subjected to careful scrutiny, it continues to suffer from vagueness that may prove problematic as both the Patent and Trademark Office and the courts seek to apply it. The amendment seeks to link certain process claims to corresponding product claims and declare such linked process claims to be non-obvious, without further need for the Patent and Trademark Office undertake the usual examination for non-obviousness. However, in applying this law, the PTO must ascertain when the statutorily prescribed link exists.

H.R. 760 poses several conditions that, when met, establish the required link between the product and linked process claims:

First, the ownership of the product and linked process inventions are in the same person at the time the process invention is made. This requirement is similar in substance the requirement for disqualifying certain prior art arising under 35 USC §§ 102(f) and (g) for non-obviousness purposes under § 103. This earlier statutory language was enacted as part of the 1984 amendments to the patent law.

Second, the product and linked process claims must be in patents expiring on the same date. This means that these two types of claims must be in the same patent, or, if in two or more patents, must issue on the same date have so-called "terminal disclaimers" in effect. Where terminal disclaimers apply, the patent holder must surrender a part of the seventeen year patent term in the later-issuing patent so that it expires as of the date of expiration of an earlier-issued patent.

Third, the product and linked process claims must be "entitled to the same effective filing date."

In its current form, Title I imposes untenable requirements on process inventors, *which may effectively deny patentability to many process inventions which are patentable under current law and which may reduce the duration of protection for patentable process inventions compared to the duration available under current law.* This absurd result from supposedly remedial legislation is the consequence of continuing imprecise statutory draftsmanship and the imposition of unnecessary and unprecedented legal impediments to patentability of process claims. Even if the principle of automatic non-obviousness for process claims linked to patentable product claims is supported, the proposed language in this bill is an inappropriate and unacceptable vehicle for accomplishing this result.

Under existing Federal Circuit precedent the non-obviousness of process claims for using[4] a patentable product can be established whenever both the product and process claims are presented in the same application and the claimed process is first disclosed as of an effective filing date on which the product claim is determined to be patentable.[5] By imposing new and different statutory criteria for linking the non-obviousness of process claims to patentable product claims, existing precedent will be superseded. The new and different patentability criteria will result in a diminution of process patent protection whenever:

First, the process claims and the product claim cannot meet the "common assignment" test. If, for example, one of two engineers working for different universities in the course of a collaboration invents a patentable device and subsequently and independently the second engineer invents methods for using the device, Title I of the bill would deny automatic non-obviousness to the process invention, even if the two inventors elected to file a joint, jointly-owned patent application in the name of both inventors. Under existing precedent, the process invention would qualify under the *Pleuddemann* criteria for non-obviousness. Title I of the bill would deny the benefits of the legislation to other similarly situated university and small business inventors who lack the sophistication to preemptively and prospectively assign inventions to a common entity before engaging in collaborative activities.

Second, the product and process claims cannot meet the hypetechnical test of being entitled to the "same effective filing date." In the above example, had both inventors elected initially to file separate applications, but filed even one day apart (which might happen, for example, if one application were mailed in a separate envelope containing a defective express mailing certificate), then none of the benefits of the legislation would be available unless, once the defect in filing date identity became manifest, both inventors were willing and able to abandon their pending applications and refile to obtain a later, common "effective filing date." In contrast, under existing precedent, the two inventors could file a continuation-in-part application claiming the benefit of both prior-filed applications and thereby meet all the *Pleuddemann* criteria for non-obviousness.

The lack of identity of effective filing dates as between product and process claims is even more complex in any situation where continuation-in-part applications have been filed to supplement both the original scope of the product claims and the dis-

---

[4] Processes for "making," as opposed to "using," a patentable product are treated differently and have different commercial implications. Since the grant of a product patent includes the grant of the right to prevent others from "making" the product by *any and every* means, the grant of additional patent claims to methods of making an already patented product provides only redundant protection. Process of use claims do, however, provide significant additional protection to the patent holder above and beyond the exclusivity afforded to the product itself. This protection comes in the form of 1988 amendments to 35 USC § 271 extending certain protection to the further products of processes for use (e.g., protein end-products made by patented processes for using patented rDNA materials) and the ability to bring a cause of action under § 337 of the Trade Act for importation of products obtained by use of patented processes.

[5] In the course of deciding *In re Pleuddemann*, 15 USPQ2d 1738 (Fed. Cir. 1990), the court noted:

> [T]he compounds and their use are but different aspects of, or ways of looking at, the same invention and consequently that invention is capable of being claimed both as new compounds or as a new method of bonding/priming. On the other hand, a process or method of making the compounds is a quite different thing; they may have been made by a process which was new or old, obvious or non-obvious.

closed methods for use. Further, particularly in the biotechnological field, a requirement of this type is very complex to apply. For example, decisions of the Federal Circuit has held that a recombinant DNA product may not be considered completely defined, that is entitled to an effective filing date, until it has been characterized in a substantially complete manner.[6] No one can predict with any certainty that biotechnology *process* claims will be assigned effective filing dates in precisely the same technical manner as the linked product claims. Equally importantly, both process and product claims come in a wide variety of sizes: small, medium and large or, in the language of the patent profession, species, sub-generic, and generic claims. Patent draftsman, in order to qualify for the conditions set forth in the bill, must assume that as of the relevant filing date process and product claims are set forth in exactly the same size and scope: small with small, medium with medium, and large with large.

For example, where both a second method for use and broadened product claims were added to a continuation-in-part application, the second method of use would have the same effective filing date as the broadened product claim, but a different effective filing date from sub-generic product claims supported in the originally-filed application. Does H.R. 760 intend that only the more generic process claims will be deemed non-obvious? Would sub-generic claims directed to the second process of use be deemed obvious because corresponding product claim would be entitled to the effective filing date of the parent application?

Third, the terminal disclaimer provision denies the inventor a substantial portion of the patent term because the Patent and Trademark Office "requires restriction" of the process claims into a separate application, but allows the issuance of these restricted claims in a divisional application only after extended delay. Under Patent and Trademark Office practice, the patent examiner may declare that product and process inventions are independent and distinct inventions are demand that the inventor present claims to one of the distinct inventions in a separate divisional patent applications. Under current law an applicant is not subject to a terminal disclaimer requirement, limiting the patent term of such a divisional application to the term of the issued parent patent, where the divisional application was filed pursuant to this type of requirement for restriction (assuming the claims in the divisional application are all consonant with the restriction requirement). The bill would remove this protection which all patent applicants currently enjoy and in its place reverse[7] the longstanding precedent in the application of terminal disclaimers. Where the Patent and Trademark Office made a restriction requirement between the product and linked process claims, the applicant filed divisional directed to the process claims pursuant to the requirement for restriction, and the Patent and Trademark Office thereafter required extended prosecution to establish patentability, the applicant could be subject to the loss of a substantial portion of the patent term for the process invention.

Indeed, instead of the current law's guarantee of a full seventeen year term following a restriction requirement, most or even all of the patent term could be denied.[8] Moreover, the legislation provides a further anomaly in the situation where the applicant seeks first to issue the *process* claims (e.g., where an ITC action were contemplated and process claims were necessary for ITC jurisdiction) and elects the process claims pursuant to a requirement for restriction. After the process claims issued, would a divisional patent application claiming the *product* require a terminal disclaimer? While the bill would suggest that the terminal disclaimer is necessary as a condition of patentability of the issued process claims, what authority

---

[6] *Amgen, Inc.* v. *Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), *Fiers* v. *Sugano*, F.2d, 25 USPQ2d 1601 (Fed. Cir. 1993), and *In re Bell*, 984 F.2d 1164, 25 USPQ2d 1529 (Fed. Cir. 1993).

[7] Terminal disclaimers heretofore have been appropriate only in the opposite situation from that in mandated by the subcommittee draft, i.e., where a divisional application is filed *voluntarily* and where the PTO subsequently determines that no patentable distinctiveness is present. Although the law on terminal disclaimers is all judge-made, uncodified law, the attempt here to codify a requirement for a terminal disclaimer *in a situation diametrically opposite to and totally inconsistent with the current judge-made law* makes no sense on patent policy grounds.

[8] Under the legislation, claims to the product and the process must appear in the same patent or in patents expiring on the same date. Presumably, the later provision would allow a patentee to terminally disclaim in any situation where a later-issuing patent would otherwise have a longer patent term. However, the legislation does not give much guidance as to when a "product" is considered to have been claimed in a prior-issuing patent. Again, the genus-species problem emerges as a prominent consideration. If a species product claim has issued in one patent while the generic claim has issued in a later patent, can the later patent claim properly a linked generic process absent filing a terminal disclaimer? In other words, is the species product claim a claim to the product not in the same patent as a claim to the process?

would the Patent and Trademark Office have to impose the requirement with respect to the pending product claims?

AIPLA would conclude its analysis of Title I by noting that the bill imposes a final indignity on the patent law, by adding to 35 USC § 282, a provision that a linked process "claim... shall not be held invalid... solely because the [product] is determined to [be unpatentable]..." A uniform judicial doctrine of claim construction is that each claim is independently presumed to be valid and that the invalidity of any one claim does not affect the validity of the remaining claims. Accordingly, no additional legislation is needed to achieve what the language quoted above purports to achieve.[9]

However, if enacted into law, the language of Section 103 of Title I might—by negative implication—be construed to suggest that the further codification is the *exception* not the *rule*. Accordingly, this language is highly objectionable. Other types of claims may be held invalid solely because they are linked to an invalid claim in some manner. Since the general principle of patent law is already codified, there would seem to be no reason to codify further.

The biotechnology industry is an important strategic asset for this country. AIPLA fully recognizes that the patent system must function effectively for this industry. Of course we believe that is also true for American industry as a whole. Our Association has long worked with the Congress and directly with the Patent and Trademark Office to assure that this industry's needs are being addressed. We have worked to eliminate delays in examining biotechnology patent applications, we have addressed problems at the Board of Patent Appeals and Interferences that have compounded the problem of delay, we have followed and continue to follow the Office's progress with its automation programs and other efforts tied to improving the overall effectiveness of the patent examining process, we have supported adequate funding of the Office so that talented patent examiners can be properly trained and retained in the examining corps, and, finally, we have supported progressive legislation (including the Process Patent Amendments of 1988) when needed to make the U.S. patent laws meet the competitive needs of U.S. businesses. Today is simply not a day when AIPLA can—or this Congress should—support tinkering with the most central and sensitive elements of our patent laws on behalf of that portion of the biotechnology industry supporting this legislation.

Mr. HUGHES. Mr. Armitage, welcome to you.

STATEMENT OF ROBERT A. ARMITAGE, ATTORNEY, ON BEHALF OF THE INTELLECTUAL PROPERTY OWNERS, INC., AND THE NATIONAL ASSOCIATION OF MANUFACTURERS

Mr. ARMITAGE. Thank you.

Because Mr. LaFuze's statement was so comprehensive, I am only going to make a very few remarks.

The biggest issues between opponents and proponents of this legislation seems to be the reality of the need for more process patent protection. I brought with me today the full text of all the genetic engineering patents that have been issued in the United States through April 1992. They are on this CD–ROM.

I spent some time yesterday looking at the patents that have been issued to Amgen. I discovered on the CD–ROM, which contains about 2,400 genetic engineering patents, that Amgen has been issued 20 patents. Of those 20 patents issued to Amgen, 13 of them, two-thirds of them, contain process claims.

I have a listing of these process claims here, if the committee would be interested. They include processes for making all the com-

[9] The current patent statute provides:

§ 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

mercially important products manufactured by Amgen, including colony stimulating factors and erythropoeitin.

I further took a look at the process and other claims that have been issued to Genentech. Genentech has 78 genetic engineering patents on this CD–ROM. And of those 78 patents, 50 of them contain process claims.

I have with me today copies of these process claims. They read like an encyclopedia of all the great discoveries of Genentech—in fact, there is even a process patent for the preparation of cheese.

I submit to you that these two companies are getting process claims, lots and lots of process claims. There is no evidence that I can find, from what the Patent Office has done in examining patent applications for these two companies, that they in any sense are lacking process protection.

I went one step further with this CD–ROM. There are exactly 2,398 genetic engineering patents on this CD–ROM, covering the entire genetic engineering patent output in this country.

It turns out 1,718 patents, over 77 percent of all patents in the genetic engineering field, contain process claims. If, indeed, there is a problem in the way the Patent Office deals with the *Durden* decision, it hasn't been a problem that has resulted in biotechnology companies failing to get process claims.

Now, we had today in the panel before this one, an assertion by Amgen that its problems with the Patent Office stemmed from *Durden.* That appears to be a very tiny part of the story. As Mr. Odre stated at the very end of his testimony, the major part of the story stemmed from the patent interference system in this country.

Amgen would have had an EPO process patent, according to Mr. Odre, in 1988, and avoided all of their problems which the Genetics Institute, and all of their foreign importation problems, if we had a patent system in this country based on the first-to-file principle.

We heard from Mr. Raab, that he has been waiting 11 years to get a patent on an important piece of biotechnology. We know from recent decisions of the Federal circuit, that there have been companies in this field waiting 10 years, 13 years, or even longer to get patents because of the patent interference system.

When we look at *Durden*, we are looking at a problem that may be only a little small bite out of a great big apple of problems. Patent interferences appear to be a bigger problem that, in my view, needs to be addressed by this committee and, hopefully, will.

Like Mr. LaFuze, we are not here to criticize the biotechnology industry. In fact, NAM and IPO support the industry. We support patent reform. We support major changes to the patent laws. But the conclusion that is urged that somehow there has been a real case of commercial need demonstrated here, in such a way as to justify industry-specific legislation, is unfounded. We are particularly concerned, for example, with title II; it is a totally unprecedented remedy. Nowhere else in the patent world does a similar remedy exist.

It is very difficult to determine what the reach of title II will be, because we are writing on a totally blank piece of paper: Bread, milk, water, and in my testimony I even suggest perhaps we will be creating under title II, human beings who, because they were

treated with patented genetic material, will somehow need a patent license to be able to go to school or get a job.

Now, as ludicrous as that sounds, one must remember when you are writing new law on a blank piece of paper, we won't know for perhaps a generation whether or not the words were well crafted.

Again, if there is some overwhelming case of need from this industry, IPO and NAM will be more than open for a legislative policy solution. Frankly, we need to see the problem much more quantitatively and graphically than an example in one company, in one instance, that we think is more attributable to other problems with our patent system than *Durden*.

Thank you.

[The prepared statement of Mr. Armitage follows:]

PREPARED STATEMENT OF ROBERT A. ARMITAGE, ON BEHALF OF THE INTELLECTUAL PROPERTY OWNERS, INC., AND THE NATIONAL ASSOCIATION OF MANUFACTURERS

Mr. Chairman and Members of the Subcommittee:

Thank you for this opportunity to present the views of Intellectual Property Owners (IPO) and the National Association of Manufacturers on H.R. 760.

IPO is a non-profit association representing companies, universities, and individuals who own patents, trademarks, copyrights, and trade secrets. IPO has members in most technology-based industries, including biotechnology, chemicals, pharmaceuticals, computers, electronics, and mechanical manufacturing. I am a member of IPO's Board of Directors and its Executive Committee. Representatives of IPO have testified before this subcommittee in the last two Congresses in opposition to bills similar to H.R. 760. IPO continues to oppose such legislation.

NAM is a voluntary business association of more than 12,000 member companies and subsidiaries, large and small, located in every state. Members range in size from the very large to more than 9,000 smaller manufacturing fining with fewer than 500 employees. NAM is affiliated with an additional 158,000 businesses through its Associations Council and the National Industrial Council. I am the current chair of the Intellectual Property Subcommittee, which is a subcommittee under NAM's Technology Policy Committee. NAM took a position two years ago supporting the need for biotechnology patent legislation. However, after reevaluating the need for this legislation, NAM no longer supports legislation and opposes enactment of H.R. 760.

In order to place the opposition of both organizations to biotechnology patent legislation in its proper context, I would like to begin by emphasizing a few things these two organizations strongly support.

First, we support the recognition of the U.S. biotechnology industry as a strategic national asset. Maintaining the dominance of an innovative, research-based, and globally competitive biotechnology industry is aid should be a cornerstone of this country's economic policy. It has implications ranging from national security to the creation of highly skilled domestic jobs. NAM and IPO are not anti-biotechnology.

Second, we support all manner of initiatives to assure that the patent protection available to the biotechnology industry is adequate and effective. Both NAM and IPO support the efforts of the USTR and the Commerce Department to improve foreign patent laws. We support the preservation of effective border controls to exclude infringing biotechnology derived imports. We support further efforts to improve the funding flexibility, organizational flexibility, and operational flexibility of the Patent and Trademark Office, to enable it to more promptly and completely examine biotechnology patent applications. We support international patent harmonization efforts that, among other things, will provide the United States with a reformed patent system that will be simpler, more certain, and more rapid in establishing patent rights—*features of critical importance to the contentious, fast-moving biotechnology industry.*

Third, we strongly support the past Congressional initiatives that have enhanced our domestic patent laws in areas where foreign patent systems provided more effective protection for inventors. The Process Patents Amendments Act of 1988 is an example of the Congress intervening to correct a detect or "loophole" in U.S. patent protection and to provide a level playing field with other industrialized countries.

Fourth, we support the full availability, on non-discriminatory terms, of process patents. For many discoveries, process patents must be readily and fully available in order to assure that an innovation can be fairly and effectively protected. If the

Patent and Trademark Office or the courts were to place unreasonable restrictions or impediments in the way of obtaining process patents, NAM and IPO would be here today to argue for legislative redress.

Fifth, we support the result in the *Pleuddemann* decision of the Federal Circuit and categorically oppose any reflexive and overzealous application of the *Durden* decision to delay or deny patents where *Pleuddemann*-style patentable processes are claimed. Likewise, we support the clarifying language in the *Dillon* decision of the Federal Circuit to the effect that "*Durden* did not hold that all methods involving old process steps are obvious." In other words, NAM and IPO are not here today to be pro-*Durden* and anti-non-obviousness for processes involving the use of patentable biotechnological materials.

These five premises upon which our testimony is based today leaves us with only a single issue on which we disagree with those urging enactment of H.R. 760. We disagree that, in light of current circumstances, the Congress must act to protect some important interest of the biotechnology industry. IPO and NAM would strongly urge that the best interests of the biotechnology industry, the patent system, and the country require that Congress not act: *not at this time, not with unprecedented remedies, not with retroactive effect, and—most emphatically—not with the prospect of inducing more patent controversies into an industry already overburdened with litigation.*

NOT AT THIS TIME

Two years ago, in assessing the need for legislation in light of the case presented by the biotechnology, NAM took the position that the Congress should act to clarify the law regarding the patentability of process patents. In reviewing this position after H.R. 760 was introduced, NAM concluded that the biotechnology industry's case for legislation was no longer sufficient to support Congressional action. IPO has always questioned the need for the legislation. Both IPO and NAM now agree that the lack of need for legislative action is virtually overwhelming.

Why do NAM and IPO conclude that legislation is simply not needed? The biotechnology industry has long relied on the Amgen/Genetics Institute litigation involving erythropoietin, or EPO, as the principal justification for Congressional action. The biotechnology industry's claim was that the *Durden* decision prevented Amgen from obtaining process claims relating to the recombinant DNA technology used to produce EPO and, without such claims had no remedy to prevent the importation of EPO by Genetics Institute's licensees. Within the past month Amgen has announced the settlement of the patent dispute with Genetics Institute and has indicated that this settlement will allow its process patent claims to issue in the near future. From Amgen's statements, it appears that *patent interferences,* not the *Durden* decision, were responsible for the long delay in the issuance of its process patents. In particular, it appears as though *Amgen's* process claims were found non-obvious and allowable by the Patent and Trademark Office *years ago.*

Besides the Amgen/Genetics Institute dispute, the proponents of H.R. 760 have cited no example of actual or potential commercial harm for any U.S. company because of the overzealous application or misapplication of the *Durden* decision. The present lack of documentation of actual commercial harm contrasts with the detailed evidence offered by the U.S. pharmaceutical industry in arguing for restoration of patent terms eroded by expanded FDA requirements for establishing safety and efficacy.

Hand-in-hand with the lack of commercial need is the lack of legal need. The combined effect of the *Pleuddemann* and *Dillon* decisions has been to provide more than sufficient justification to *successfully* argue against any effort by Patent and Trademark Office examiners to inflexibly, overzealously, and improperly deny process claims using novel and non-obvious materials. NAM and IPO are aware of additional appeals pending before the Federal Circuit that may eliminate any remaining rationale for the misapplication of *Durden. Congressional action is not necessary and most untimely.*

The Patent and Trademark Office is today, as this hearing is taking place, examining and allowing process claims on biotechnology inventions without any need for legislation. The Federal Circuit has interpreted the patent laws so as to require that such process claims be permitted. Whatever may have been a supposed justification four years ago or even two years ago for Congressional intervention is no longer present.

NOT WITH UNPRECEDENTED REMEDIES

The remedy for patent infringement in H.R. 760 does no less than extend the reach of the patent laws into all manner of unpatented commodities in an *unprece-*

dented manner. Patent law is founded on a simple premise: a patent on something should prevent unauthorized persons from making, using or selling *the very thing patented.* The sole exception relates to process patents, where the inventor's rights in almost every industrialized country extend to *unpatented* products directly obtained from patented process. *Nowhere do patents extend broadly to all manner of unpatented products made simply by "using" a patented product.* No country in the world provides that use of a patented tool, a patented catalyst or an enzyme, or a patented microbe in the manufacture of an unpatented commodity, however distantly related, provides a basis for according patented exclusivity to the commodity itself.

The unprecedented legal nature of the infringement remedy set forth in H.R. 760 must be considered in conjunction with the unprecedented technologies that will be covered. Biotechnological materials over the course of the next several decades will be used in all manner of unpatented materials. Medicinal research will create patentable recombinant genes for treating all manner of human maladies. These genes, and vectors for incorporating these genes into human cells, will undoubtedly be patented. Human embryos will be "treated" using these patented genes to cure otherwise fatal or life-compromising genetic defects.

Does the Congress intend that these human embryos treated using patented biotechnological materials will come under the scope of Title II? Will it become an act of patent infringement to use the human embryo which has been altered "using the biotechnological material"? Can Congress intend that the fertilized embryo not be implanted into the mother from which the human ova was obtained, *without a license from the patent holder?* Indeed, *must the mother then obtain a license to enjoy any child produced from the treated embryo,* again because the child itself will be considered under Title II's having been made "using" a patented biotechnological material?

I cannot tell you today what manner of unintended, unpredictable results will be generated should H.R. 760 become law. The proponents of this legislation are asking for unprecedented relief without having provided any cogent analysis of its future impact. They seek to cure a "loophole" in our patent law that is absent *for good and compelling reasons* from patent laws outside this country.

NOT WITH RETROACTIVE EFFECT

One particularly objectionable feature of H.R. 760 is its retroactive application. While we are aware of precedents for expanding rights under existing patents. Title II of H.R. 760 represents a particularly dangerous odyssey into retroactivity. NAM and IPO have a heightened concern over H.R. 760 because of the unprecedented rights being afforded to holders of patents on biotechnological materials.

Many basic patents relating to biotechnological constructs have been issued, and, some at least, bought and sold, licensed or not licensed, on assumptions that will be changed under Title II. Many persons in the biotechnology industry and other industries would be forced to take licenses under basic biotechnological patents—granted years ago—or be kept away from promising new applications. It simply cannot be good public policy for the Congress at this late date to greatly and uncertainly expand the effect of all biotechnological materials patents.

NOT WITH THE PROSPECT OF INCREASING BIOTECHNOLOGY PATENT CONTROVERSIES

Perhaps the most ironic characteristic of an industry complaining that patents for its technological innovations are too hard to obtain is the large and seemingly endless number of patent controversies that have erupted to date. Almost every major biotechnological discovery has been accompanied by bitter and prolonged litigation over patents. The nation cannot afford to have this Congress bestow on this industry any more opportunities to fight over patents. It cannot be in the national interest for an increased number of process patents to issue, and in turn cover all manner of unpatented products and commodities made from those processes. Likewise, the public interest cannot be served if patents on biotechnological materials will hereafter be granted to cover all manner of unpatented products and commodities made from those materials.

The intrusion of the patent system into unpatented commodities must end somewhere. More process patents and/or more rights under existing "materials" patents can only increase litigation in an industry that needs no more such controversies.

NAM and IPO have specific objections to both titles of H.R. 760. Because both are objectionable, and either could be enacted independently of the other, I will discuss them separately.

TITLE I: BIOTECHNOLOGY PROCESS PATENTS

Title I amends section 103 of Title 35, United States Code, to require the Patent and Trademark Office and the courts to treat certain biotechnological processes as "non-obvious." Title I declares such processes to be non-obvious, and therefore patentable, whenever several highly technical requirements are met—requirements totally unrelated to the historic tests for non-obviousness. These new unrelated requirements will totally replace the traditional factual inquiries for determining non-obviousness that have been developed by the courts over the past 40 years. Title I gives the concept of "non-obviousness" for these claims a highly specialized twist that has essentially nothing to do with whether a person have ordinary skill in the relevant technology would consider the process not to be "obvious" within the everyday meaning of the term. *This is a major change in the meaning of what—since 1952—has been the most if important concept in all of the patent statutes.*

LACK OF NEED

Proponents of H.R. 760 have long contended that Title I is needed in order to overturn the 1985 decision of the Court of Appeals for the Federal Circuit in *In re Durden.* The *Durden* case, the proponents claim, has been applied inflexibly and overzealously to deny patent claims needed by the biotechnology industry to protect against infringers, especially persons manufacturing offshore and importing the products of these processes.

The need argument fails because the industry seems incapable of citing any statistical, anecdotal, or other justification. There is no-pattern of denial under *Durden* of essential biotechnological process claims. There are no examples of losses suffered by the domestic biotechnology industry because of foreign importation. As indicated earlier, the one case cited by the industry, the controversy between Amgen and Genetics Institute, was not triggered by *Durden*, but by a slow, archaic patent interference system.

The Patent and Trademark Office has no continuing justification for reflexively applying *Durden* to reject process claims for using patentable materials, such as a patentable host cell or patented DNA. Between the decision in *Pleuddemann* and a subsequent decision, *Dillon,* the Patent and Trademark Office cannot simply reject process claims containing simple or conventional process steps, such as mixing, reacting, or fermenting. The Patent and Trademark Office, under existing law, must consider the nonobviousness of the materials used in the process to determine the non-obviousness of the process claimed.

If examiners are not considering all the relevant legal precedents of the Federal Circuit in their examination of patent applications, the remedy is not for the Congress to intervene with new legislation. It is rather for the Patent and Trademark Office officials to issue more precise guidance to members of the examining corps. A directive from the Office of the Commissioner that explains *Pleuddemann* and instructs the patent examiners to apply it would seem to us to be capable of ending this controversy forthwith.

Heretofore, the Patent and Trademark Office, as well as some of the proponents of this legislation, have argued that "method of using" claims cannot be distinguished from "method of making" claims. *Pleuddemann* provided express justification for the patentability of "methods for using" patentable products; it did not provide a similar holding for "methods of making" patentable products. Generally, applicants have little concern over claims to methods for making patentable products. If the product being made is patented, the patent holder can prevent anyone from making the patented product by any means whatsoever—*a separate process patent is simply redundant.* In contrast, a "method of using" a patentable material is just that; such claims should be easily identifiable by the Patent and Trademark Office without the need for the Congress to legislate.

Finally, appeals now pending at the Federal Circuit probably will provide further judicial clarification of *Durden.* These opinions are likely to answer any remaining uncertainties.

UNANSWERED QUESTIONS

If Title I is enacted, a great deal of additional litigation and legal expense will follow for patent owners and their competitors. Title I leaves unanswered several questions about specific fact situations. For instance, how will the PTO and the courts apply the requirement that the product and the claimed process invention must have been owned by the same party at the time the process invention was made? Will this requirement be used to penalize unwary inventors who fail to obtain sophisticated legal advice at an early date?

What are the implications of the requirement that the claims to the process and the product must be "entitled to the same effective filing date"? Will this be a fertile ground for litigation, for example, in cases where the inventor has several process claims and several product claims?

What are the implications of the special rule that the process and product claims, if in different patents, must "expire on the same date"? Does this remove protection that is available to patent applicants under existing law? What effect does it have on the existing judge-made doctrine that patent owners must disclaim the terminal portion of certain patents in order to make patents expire on the same date?

What about the effective date provision for Title I that makes the title applicable to "any application for the reissuance of a patent"? Does this allow patent owners to enlarge the scope of their existing patents without regard to the requirement in existing law that claims which enlarge the scope of protection must be applied for within two years? Litigation will be required to answer these and other questions raised by Title I.

UNEXAMINED PROCESS CLAIMS

We are also concerned about the uncertainty that will be created by the requirement for PTO examiners to allow the process claims automatically once they have determined that the product claims are allowed. Ever since 1836, when our patent laws were converted from a system of registering patents without examination to a system for examining each claim, the U.S. patent system has emphasized a careful examination of patent applications to ensure that inventors receive the full measure of their invention without taking rights from the public or clouding the rights of other parties to utilize technology outside the boundaries of the patent.

A primary purpose of patent examination in the PTO is to create a presumption of validity of patent claims and help avoid patent litigation. Under H.R. 760, if a product claim issued by the PTO turns out to be invalid because of prior art that was not known to the PTO during examination. an unexamined process claim later might or might not be held invalid. Title I does not make clear the status of the unexamined process claim. It states that "the process claim shall not be held invalid...solely..." because the product claim is invalid. Does this mean that the process claim is still presumed valid? How can it make sense to presume that a claim is valid that has never been examined? Is a court faced with a question of invalidity of a process claim supposed to make its own examination of the claim for the first time? Should the court send the claim back to the PTO for further examination? Title I is opening the door to expensive and time-consuming litigation that will have an inhibiting effect on research and development in U.S. industry.

In testimony on one of the predecessor bills, PTO officials cited cost savings from having to examine fewer claims as a reason for supporting the bill. This is too narrow a viewpoint. Unexamined claims will cast a chilling shadow on U.S. industry. The expense of litigating questionable process claims will make such claims effective barriers to research and production by others in the field. Uncertainty will exist not only over the validity of the unexamined process claims, but over the scope of coverage of the claims, in the absence of any prosecution history developed during PTO examination.

Enactment of Title I will cause a proliferation of unexamined process claims. Attorneys advising clients should be concerned about the difficulty that will be encountered in answering questions of validity and infringement of larger numbers of process claims than are being issued today.

Another concern about Title I is that it might create incentives for patent applicants to obtain process claims encompassing large numbers of manipulative steps covering more subject matter than the concept originated by the inventor. In the absence of any examination by the PTO, patent applicants may try to add extra subject matter to claims. This could lead to more litigation over the statutory requirement of 35 USC 112 to "particularly point out and distinctly claim" the invention.

INDUSTRY-SPECIFIC LEGISLATION

The coverage of Title I is limited to "biotechnological processes." This limitation has appeal from the viewpoint of sparing other industries the litigation burden that Title I will inflict on the biotechnology industry, but we must oppose the limitation. It is poor public policy to legislate special rules of intellectual property protection for particular industries in the absence of a clear showing that unique problems face those industries.

The proponents of H.R. 760 have not shown that the need for process claims is any different in the biotechnology industry than it is in the chemical industry or other industries where inventions frequently are claimed as processes. Indeed, the

invention in the *Durden* case was not a biotechnology invention. It was a chemical invention. The real party in interest in *Durden*—Union Carbide Corporation—wrote to this Subcommittee in the last Congress recommending against legislation even though the company failed to obtain the process claims it sought in the *Durden* case. Claims for a process of using or making a patentable product certainly are not unique to the biotechnology industry. IPO conducted a survey in 1992 of more than 100 companies and grouped the responses in four broad categories: biotechnology, chemical, electrical/computer, and general manufacturing. The survey showed that biotechnology and chemical respondents frequently seek claims for processes of using or making a patentable product. A majority of electrical/computer and general manufacturing respondents said they do not seek such claims, but even in those industries several respondents seek such claims.

Special rules of patentability for particular industries will add to the complexity of patent law and higher costs to patent owners. Litigation over the definitions of technologies included and excluded is inevitable. The term "biological process" in Title I is given a very broad meaning, extending beyond processes of making or using genetically-altered material. Whether the definition is broad or narrow, however, it will be litigated.

A further concern with industry-specific rules for determining obviousness is the effect on the North American Free Trade Agreement (NAFTA), and the proposed Uruguay Round GATT Agreement. Article 1709 of NAFTA contains a provision stating, in part, that "...patents shall be available and patent rights enjoyable without discrimination as to the field of technology...." H.R. 760 can be viewed as discriminating as to fields of technology, because it establishes a different rule for making patents "available" in the field of biotechnology. We do not know whether Canada and Mexico will raise any objection. If our trading partners do not object, however, we would still be concerned. H.R. 760 could open the way for trading partners of the U.S. to adopt their own special rules of patentability for individual technologies. Enactment of H.R. 760 for the biotechnology industry could be a first step toward each country enacting rules making it easier to obtain patents in technologies in which that country's local industry has a strong research capability, and making it harder to obtain patents in industries that are weak in that country. For example, Japan could have obviousness rules favoring electronics patents, and Germany could favor chemicals.

TITLE II: BIOTECHNOLOGICAL MATERIAL PATENTS

IPO and NAM oppose Title II of H.R. 760. which amends section 271 of Title 35, United States Code, to make it constitute infringement to import a product manufactured by using a patented biotechnological material.

LACK OF NEED

There is no more showing of need for Title II than for Title I. The Amgen and Genetics Institute dispute over patent rights in EPO does not demonstrate a need for Title II. Amgen's problems in that case appear to be attributable to the interference proceedings used in the U.S. PTO to determine which party made the invention first. If there is a lesson to be learned from the EPO case, it may be that interference proceedings cause unreasonable delays in issuance of patents. Under the first-to-file system that IPO and NAM support as part of the proposed Patent Law Harmonization Treaty, Amgen probably could have saved a large amount of time and money.

LITIGATION EXPENSES

Title II, like Title I, will burden U.S. industry with added litigation and legal costs. While Title II avoids the problem of uncertainty caused by unexamined process claims issued by the PTO, it raises a host of additional questions that will make it difficult for U.S. manufacturers to assess potential liability for patent infringement.

Title II defines a new category of acts of patent infringement. Title II's acts of infringement at first glance resemble the acts that are defined as infringement by the Process Patent Amendments Act of 1988, except that Title II addresses the situation where the patent covers a starting material instead of a process. Since existing law as interpreted by Federal Circuit in the *Pleuddemann* case gives the owner of a patent on a starting material the right to also obtain a claim to the process for using the starting material, at first review it may be unclear what Title II adds to the Process Patent Amendments Act of 1988. In fact, Title II is much broader than the 1988 act. The 1988 act provides safeguards for non-commercial users and retail

sellers that are absent from Title II of H.R. 760. Title II also omits limitations in the 1988 act that prevent lawsuits when a product is "materially changed by subsequent processes" or "becomes a trivial and non-essential component of another product." Patent owners will base infringement claims on the broad, vague Title II whenever possible instead of on the narrower 1988 act.

INDUSTRY-SPECIFIC LEGISLATION

Title II is limited to "biotechnological materials." We recommend against industry-specific legislation for Title II for essentially the same reasons I have explained in connection with Title I. No showing has been made that patent protection for biotechnology products is unique or not equivalent to patent protection for traditional pharmaceutical or chemicals. Biotechnology products today already are surrounded by patent claims, often in great profusion. Multiple developers of the same biotechnological entities often come armed in litigation each with their own patent portfolios. While biotechnology patents may have been slower to issue from the PTO in the past for administrative reasons, this has been a temporary phenomenon which does not justify permanent legislation giving special treatment for biotechnology.

Title II will create litigation over the scope of the sweeping term "biotechnological material." Literally, the words in Title II defining "biotechnological material," which refer back to "biotechnological process" in Title I, cover any product that is made by using a part of any living organism. Title II will extend the reach of this nation's patent laws into the most commonplace, everyday commodities. A bakery selling bread made using a genetically modified yeast could be liable for patent infringement. A child consuming a glass of milk produced from a transgenic cow could also come within the unprecedented reach of Title II. Does the Congress want bread, milk and all other manner of everyday commodities to come within the patent laws simply because a patented biotechnology material was involved in their production?

For the same reasons as Title I, Title II arguably is inconsistent with anti-discrimination clauses in NAFTA and the GATT Uruguay Round agreement. Title II might be viewed as a special rule for "enjoyment" of patent rights. See NAFTA Article 1709. Title II could tempt other nations to create stronger or weaker rules for infringement depending upon the industry involved.

On the other hand, a Title II not restricted to biotechnology will affect not only chemicals and pharmaceutical, but the electronics/computer and general manufacturing industries as well. 35 USC 100 and 101 define patentable processes and products in broad terms without any industry limitation. The ramifications of extending Title II into areas such as computers and electronics are totally unexplored. With or without a limitation to biotechnological materials, we oppose Title II because of its uncertain scope and the potential for litigation.

CONCLUSION

IPO and NAM urge the Subcommittee to take no action on H.R. 760. The law on patentability of processes for using or making a patented product will benefit from more case-by-case development before any attempt is made at statutory codification. Further elaboration of the law by the Federal Circuit is imminent.

If the Subcommittee should decide to go ahead with legislation, IPO and NAM would like to work with the Subcommittee to correct the numerous technical problems. Since no need for legislation has been demonstrated, however, we earnestly recommend that H.R. 760 not be enacted in any form.

We appreciate the opportunity to appear here today. I will be pleased to answer any questions.

Mr. HUGHES. Both of you indicate there really is not a problem. *Durden* is not a problem.

You heard my colloquy with the Acting Commissioner of the PTO today. There obviously is a problem.

I mean, there is a problem. They basically have not made a decision. I have taken them to task every time they have been in here, because they take the view that *In re Durden* is still the law.

Mr. LAFUZE. *In re Durden* is not the law in the sense for which it is used to support or reject process claims.

Mr. HUGHES. The law is what PTO says.

Mr. LAFUZE. Well, I would say that the law is what the Federal circuit says.

Mr. HUGHES. But I have been waiting for the Federal circuit to tell us what the law is for a long time. In the meantime, the PTO is telling us what the law is.

Mr. LAFUZE. We think that PTO has misinterpreted the law.

Mr. HUGHES. That may be. But the fact of the matter is that the waters are muddied and the PTO has not been very helpful in the process. But they have been making the decisions on the basis of *In re Durden*; isn't that so?

Mr. ARMITAGE. They have been making rejections.

I think the answer is for the PTO to do precisely what you suggested they do, and that is provide the examiners informed guidance on the relationship between *Durden, Pleuddemann* and other cases.

Mr. HUGHES. I think I have about as much chance of doing that as I have of persuading my constituents that the BTU tax is an excellent idea. I decided after 3 days to give up that effort last week.

Mr. ARMITAGE. There was in *Durden* one of the most bizarre approaches to appealing a case we have ever seen. The appellants basically admitted to the court they were not entitled a patent and they didn't get one. They admitted their invention was obvious, so the court said: If you admit your invention is obvious, basically you are done, you lose.

The Patent Office is not using *Durden* in that limited way. That is why they have gone wrong, in my view.

Mr. HUGHES. That might be, but that happens to be the case.

Mr. ARMITAGE. But what happens when the Patent Office goes wrong is what is happening now, that is, additional appeals will go to the Federal circuit, and the law will be set right, as it was in *Pleuddemann,* and as I expect it will be again in *Ochiai,* eventually.

Mr. HUGHES. Mr. Armitage, your recitation of how many applications Genentech and Amgen received is helpful. How many have they filed?

Mr. ARMITAGE. It would seem to me a most interesting statistic that the biotechnology industry should lay out for this committee. Quantitatively, what is wrong with the way their applications are being examined. I don't see that evidence.

NAM, in fact, asked the Biotechnology Industry Organization to provide us with documentation, if they could, as to what the problem was.

Mr. HUGHES. Well, they were going to provide some data. I have kept the record open so we can receive that information.

I have the same question, you know. Where have you been harmed?

But that is not the only consideration if, in fact, there is a potential real harm. We shouldn't have to wait until the sky falls in before we do something if there is a problem. And to suggest that Genentech has received 78 applications, therefore, everything is peaches and cream, is not really telling the whole story. Because I don't know how many they filed and have not received, by way of patent protection.

Mr. ARMITAGE. Precisely, and its this information on genetic engineering patents, it should provide members of the committee.

Mr. HUGHES. Well, I agree with you. And you have been very helpful in supporting our efforts of harmonization, attempting to basically look at what is happening and attempting to harmonize our laws.

The European and Japanese patent systems do not examine for the obviousness of the process claim, if the patent used to produce is patentable, as you know.

The PTO is on record to support a generic change to section 103. If AIPLA, IPO and NAM strongly support patent harmonization, what is the danger of implementing legislation basically similar to the European and Japanese systems for all industries, not just the biotechnology industry?

Mr. ARMITAGE. What we suggest at IPO—and what IPO has been working with the PTO to do is to do precisely what the Europeans do. Title I is not expressly part of the European Patent Convention; it is simply the way the European Patent Office interprets it and instructs examiners.

Mr. HUGHES. But they have a process where they look at the totality of both the patentable item as well as the process, and they look at it as a total application. What is so wrong with that?

Mr. ARMITAGE. That is precisely what our law requires the Patent Office to do in section 103.

Mr. HUGHES. You say they are not following the law as it is?

Mr. ARMITAGE. The Patent Office seems to have selective amnesia, from time to time, is what I am suggesting. As for *Durden*, they are saying something that it doesn't say, and as for *Pleuddemann,* which to me appears to be clear on its face, they don't want to accord it the effect that I think the court intended it to have.

Mr. HUGHES. If title II, Mr. LaFuze, is narrowly drawn and protects against the downstream products being affected, similar to the limitations found in the 1988 process patent amendments, would you support it?

Mr. LAFUZE. No, sir, I don't believe so.

Mr. HUGHES. Why?

Mr. LAFUZE. For all the reasons that I gave. The end product and the retailer and the consumer objections still remain. There are also some retroactivity issues that are raised by the fact that it——

Mr. HUGHES. How do we deal with retroactivity? Can we take care of the downstream problems?

What other problems do you have with it?

Mr. LAFUZE. Well, we simply think that there is no compelling need for——

Mr. HUGHES. Now, you have got to give me specific reasons. That is not going to wash around here. What are the other objections?

Mr. LAFUZE. It is our view that in order to go in and make industry-specific amendments, there needs to be a need in the first place. We simply don't see that.

Mr. ARMITAGE. There is another problem that arises whenever you make a patent law apply to something that is not patented. We fought this issue out through three Congresses with process patent

legislation. Upjohn, for example, the company I work for, probably produces or purchases a thousand different manufacturing inputs, they come from all over the world.

Now, most of those major inputs we screen for patents. We see if key chemical intermediates are patented and the like. What we can't do easily is go upstream and ask our suppliers how exactly each input was made, two steps, or three steps upstream. Did a supplier use a patented genetic tool three steps before? Was a catalyst used somewhere that was patented?

By making the reach of the patent law go beyond its natural extent, it covers more than what is patented. You create problems for people faithfully trying not to be infringers. That is why if there is a compelling need for legislation and a need to keep jobs in this country, legislation will be supported by industry broadly. But if legislation is more an ornamentation, then we have to look at other costs of trying to have everybody comply with these new infringement rules.

Mr. HUGHES. Well, I will tell you I have listened to NAM, and many of your other members, they would be fine as long as they get the same treatment.

Mr. ARMITAGE. Well, one of the——

Mr. HUGHES. Other industries, if they get the same treatment as the biotechnology industry, count them in.

Mr. ARMITAGE. For NAM, we are precisely on the opposite pole with regard to title II. There are many situations, for example, in the electronics industry, where you may have a patented machine or tool for making a semiconductor chip, and you are buying chips in quantities of thousands, not knowing with what tools they were made. You don't want patent infringement risks because somebody patented a tool that happened to be used in one batch of chips and not in another batch.

Mr. HUGHES. Well, I can understand, frankly, if I were in another sector of the economy, if one other sector was not required to demonstrate nonobviousness, I would want the same thing.

Mr. ARMITAGE. You can rest assured if the biotechnology industry gets special treatment here, there may be other industries knocking at your door with other sections of patent law in mind.

Mr. HUGHES. Yes, I understand that fully. That is why we have taken a lot of time to look at a very troubling issue. In the meantime, we continue to drift.

All right. Well, thank you.

It has been a very, very interesting hearing. We appreciate your contribution today, as always. Good to see both of you.

Thank you very much. Thank you for coming such a long distance to be with us today.

That concludes the hearing for today and the subcommittee stands adjourned.

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

APPENDIXES

APPENDIX 1.—LETTER FROM G. KIRK RAAB, PRESIDENT AND CHIEF EXECUTIVE OFFICER, GENENTECH, INC. (WITH ATTACHMENTS), TO HON. WILLIAM J. HUGHES, CHAIRMAN, SUBCOMMITTEE ON INTELLECTUAL PROPERTY AND JUDICIAL ADMINISTRATION, JUNE 23, 1993

Genentech, Inc.

June 23, 1993

The Honorable William J. Hughes
Chairman, Subcommittee on Intellectual
Property and Judicial Administration
241 Cannon House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you again for permitting me to participate in your hearing on the intellectual property problems facing the biotechnology industry. Your diligence in clarifying the record concerning the nature of the problem and in finding the best solution. Your detailed approach to addressing our problems will make this a far better bill when it goes to mark-up.

You requested that I provide some detailed answers for the hearing record. Before providing this data, let me take the opportunity to provide a context for the data.

When a biotechnology-derived invention is made by one of our firms (or frequently by a university researcher) we promptly file complete applications. These applications frequently involve claims directed at an:

- end product (a purified protein),
- a process for making the product,
- a DNA sequence, vector and host cell, and
- a process for using sequences, vectors and host cells.

It is not usual for product claims to be pursued first, in part, because of their greater importance. Prosecution of these claims often is handled separately, and are resolved only after substantial delay. The disposition of process claims also frequently follow resolution of claims to DNA sequence, vector and host cell claims. As detailed in our testimony, we frequently are denied purified protein product claims. More

frequently, we receive patents on starting materials and host cells.

The resolution of process claims has been inconsistent since the confusion created by In re Durden. This case either delays issuance of patent claims, produces inconsistent results, or sometimes results in the total denial of claims. Thus, there is not a clear picture of how Durden is applied, either generally or in specific hypothetical cases.

In an attempt to measure the impact of Durden, Genentech had a prestigious patent firm conduct a limited survey of issued claims. A copy of this study has been submitted to the staff. The reference in the 1991 testimony of George Ebright to this study is found on page 6 of his testimony. In candor, the reference to 2/3 of all claims found in the last paragraph of that page should have made it more clear that the calculation was derived from that limited study.

In anticipation of your hearing we surveyed the membership of our patent committee in a very preliminary manner as to the nature and extent of Durden problems. In a two day time frame we received a limited response to our facsimile survey (see attached). As I indicated, 19 out of 21 respondents said that they had experienced Durden problems, and 15 were currently having Durden problems. We would be delighted to work with the Subcommittee staff to collect additional information from the biotechnology patent bar.

During the hearing you requested data on the number of patent applications we have filed and the number of process claims that have been granted. Genentech has an extensive patent portfolio with hundreds/tens of patents directed to all types of inventions. An extensive, expensive and time consuming analysis of all of our patents would be required to provide the number of relevant patents granted. An even more difficult task would be to provide the number of process patents we have obtained by overcoming Durden rejections or resulted because no Durden rejection was asserted. We estimate that this search would take hundreds of hours of professional time. Problems would arise, because first, some cases never have the process claims separated from other types of claims and, thus, are not solely process cases. Second, some cases may be rejected -- in part -- for reasons other than Durden type rejections. Third, process patents may issue over Durden type rejections, but the added years necessary to overcome Durden in obtaining the allowance may severely prejudice the patent holder. Genentech would be delighted to have one of our senior patent attorneys travel to

Washington to meet with you and your staff to discuss our experience with Durden problems.

Our real world experience is that there are substantial problems with the Durden case. We have provided the staff with a set of examples of how "esoteric" differences in claim language can produce totally different results. This experience underlines the point made repeatedly by the Patent Office that it is not possible to reconcile the conflicting precedents in the area of the law. Therefore, we continue to believe that enactment of legislation in this area is in the public interest.

Thank you again for your keen interest in and understanding of the concerns of the biotechnology industry.

Sincerely,

G. Kirk Raab
President & Chief Executive Officer

GKR/saw

CONFIDENTIAL SURVEY: PROCESS PATENT EXPERIENCES

1. Have you ever received a rejection of a process claim for obviousness under the Patent Office's interpretation of the Durden decision?

   _____ Yes

   _____ No

2. Do you have any currently pending applications to which the Patent Office has made Durden objections?

   _____ Yes

   _____ No

3. Does your company have a patent containing claims covering host cells or other intermediate products without a corresponding process claim?

   _____ Yes

   _____ No

Examples: _____
_____
_____
_____
_____
_____
_____
_____
_____

ALL RESPONSES WILL BE KEPT CONFIDENTIAL

PLEASE RETURN BY 3 P.M., MONDAY JUNE 7TH TO:
MARY BETH BIERUT (FAX -- 202/857-0244)

RESULTS OF IBA SURVEY ON MEMBER COMPANIES' PROCESS PATENT EXPERIENCES -- MAJORITY REPORT DURDEN REJECTIONS

Over a brief two and a half day period during the week of June 1st, the IBA surveyed the member companies which serve on the association's Patent Committee about their process patent experiences. A copy of the survey form and of the Patent Committee membership list is attached.

Following is a summary of the survey results:

Number of surveys sent	117
Number of surveys returned	21
Number of companies which have had a process claim rejected under Durden	19
Number of companies which have pending applications to which the PTO has made Durden objections	12
Number of companies which have patents containing claims on host cells but no corresponding process claims	15

June 8, 1993

Industrial Biotechnology Association
PATENT COMMITTEE 06/28/93

Mary M. Allen, Esq.
Patent Attorney
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(908)-524-2796 ext.
(908)-524-2808 (Fax #)

Ms. Vanessa Appleby
Patent Agent
W.R. Grace & Company
Washington Research Center
7379 Route 32
Columbia, Maryland 21044
(410)-531-4515 ext.
(410)-531-4195 (Fax #)

Beth Arnold, Esq.
Patent Attorney
Genzyme Corporation
One Kendall Square
Cambridge, Massachusetts 02139
(617)-252-7500 ext.
(617)-252-7700 (Fax #)

Dr. Richard B. Bailey
Vice President, R & D
ZeaGen, Inc.
6204 South College Avenue
Ft. Collins, Colorado 80525
(303)-226-6777 ext.
(303)-226-6929 (Fax #)

Dr. Michael Baird
Director, Forensic Science
Lifecodes Corporation
550 West Avenue
Stamford, Connecticut 06902
(203)-328-9500 ext.
(203)-328-9598 (Fax #)

Dr. Sol J. Barer
Sr. Vice President of Science and
Technology,
Celgene Corporation
7 Powder Horn Drive
Warren, New Jersey 07059
(908)-271-4153 ext.
(908)-271-4184 (Fax #)

Mr. David Beier
Vice President of Government Affairs
Genentech, Inc.
1747 Pennsylvania Avenue, N. W.
Suite 1223
Washington, D. C. 20006
(202)-296-7272 ext.
(202)-296-7290 (Fax #)

Mr. Robert P. Blackburn
Director of Intellectual Property
and Chief Patent Counsel
Chiron Corporation
4560 Horton Street
Emeryville, California 94062
(510)-601-2702 ext. 4430
(510)-655-3542 (Fax #)

Allen Bloom, Esq.
Vice President & General Counsel
The Liposome Company, Inc.
1 Research Way
Princeton, N.J. 08540
(609)-452-7060 ext.
(609)-734-0882 (Fax #)

Dr. Robert Bratzler
Vice President
Commercial Development
Sepracor Inc.
33 Locke Drive
Marlborough, Massachusetts 01752
(508)-481-6700 ext.
(508)-481-7683 (Fax #)

Paul W. Busse, Esq.
Intellectual Property Counsel
3M Bioapplications
Office of Intellectual Property
P.O. Box 33427
St. Paul, Minnesota 55133-3427
(612)-736-5971 ext.
(612)-736-3833 (Fax #)

Dr. Greg Butler
Director, Patent Law
Cambridge NeuroScience, Inc.
One Kendall Square
Building 700
Cambridge, Massachusetts 02139
(617)-225-0600 ext.
(617)-225-2741 (Fax #)

Ms. Martha J. Carter
Senior Director, Regulatory Affairs
ImmuLogic Pharmaceutical Corporation
610 Lincoln Street
Waltham, Massachusetts 02154
(617)-466-6000 ext.
(617)-466-6010 (Fax #)

John A. Caruso, Esq.
Corporate Counsel & Vice President
Enzon, Inc.
40 Kingsbridge Road
Piscataway, New Jersey 08854
(908)-980-4500 ext.
(908)-980-5911 (Fax #)

Carol Cech, Ph.D
Vice President, Intellectual Prop.
Somatogen, Inc.
5797 Central Avenue
Boulder, Colorado 80301
(303)-541-3321 ext.
(303)-443-7343 (Fax #)

Stacey L. Channing, Esq.
Patent Counsel
ImmuLogic Pharmaceutical Corporation
610 Lincoln Street
Waltham, Massachusetts 02154
(617)-466-6000 ext.
(617)-466-6010 (Fax #)

77-796 O – 94 – 4

Barbara Conta, Esq.
Patent Administrator
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
(914)-347-7000 ext.
(914)-347-5045 (Fax #)

Daniel Cuoco, Esq.
Vice President General Counsel
Biogen
14 Cambridge Center
Cambridge, MA 02142
(617)-252-9200 ext.
(617)-252-9617 (Fax #)

Hugh A. D'Andrade, Esq.
Executive V.P., Administration
Schering-Plough Corporation
One Giralda Farms
P. O. Box 1000
Madison, New Jersey 07940-1000
(201)-822-7430 ext.
(201)-822-7484 (Fax #)

James H. Davis, Esq.
General Counsel and V.P., R & D
Crop Genetics International
10150 Old Columbia Road
Columbia, Maryland 21046-1704
(410)-381-3800 ext.
(410)-381-3840 (Fax #)

Audrey L. Dickason
Director of Corporate Development
Telios Pharmaceuticals, Inc.
4757 Nexus Centre Drive
San Diego, California 92121
(619)-622-2600 ext.
(619)-535-8269 (Fax #)

Dr. Bob Diener
Senior Advisor - Licensing and Safety
CIBA-Geigy Corporation
Pharmaceutical Division
556 Morris Avenue
Summit, New Jersey 07908
(908)-277-5430 ext.
(908)-277-3872 (Fax #)

William H. Epstein, Esq.
Associate Patent Counsel
Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110
(201)-235-3723 ext.
(201)-235-3500 (Fax #)

Shawn Foley, Esq.
Patent Attorney, Agricultural Biotechnology Research Unit
CIBA-GEIGY Corporation
P. O. Box 12257
Res.Triangle Pk, N.C. 27709-2257
(919)-541-8614 ext.
(919)-541-8689 (Fax #)

Mr. Gary Friedman
Agouron Pharmaceuticals, Inc.
3565 General Atomics Court
San Diego, California 92121
(619)-622-3000 ext.
(619)-622-3298 (Fax #)

Tom Gallegos, Esq.
Patent Counsel, Legal Department
E.I. du Pont de Nemours & Co.
Barley Mill Plaza
Wilmington, Delaware 19880-0036
(302)-892-7342 ext.
(302)-892-7949 (Fax #)

Dr. Robert T. Garvin
Vice President Research
Cangene Corporation
3403 American Drive
Units 1 & 2
Mississauga, Ont. Canada L4V IT4
(416)-673-0200 ext.
(416)-673-5123 (Fax #)

Dr. Paul H. Ginsberg
Assistant General Patent Counsel,
Legal Division
Pfizer Inc.
235 East 42nd Street
New York, New York 10017-5755
(212)-573-2369 ext.
(212)-573-1939 (Fax #)

Michael W. Glynn, Esq.
Corporate Patent Counsel
Patent Department
CIBA-GEIGY Corporation
7 Skyline Drive
Hawthorne, New York 10532
(914)-785-7138 ext.
(914)-347-5769 (Fax #)

Edward H. Gorman, Esq.
Associate General Counsel, Patents
and Trademarks
Abbott Laboratories
Dept. 377, AP6D
Abbott Park, Illinois 60064-3500
(708)-937-6364 ext.
(708)-937-9556 (Fax #)

William G. Gosz
Attorney
Genzyme Corporation
One Kendall Square
Cambridge, Massachusetts 02139
(617)-252-7583 ext.
(617)-252-7600 (Fax #)

George M. Gould, Esq.
Vice President and
Chief Patent Counsel
Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110
(201)-235-3741 ext.
(201)-235-3500 (Fax #)

Mr. Milton B. Graff
Patent Counsel
The Proctor & Gamble Company
Patent Division
Miami Valley Laboratories
Cincinnati, Ohio 45239-8707
(513)-627-2659 ext.
(513)-627-0260 (Fax #)

Richard Grochala, Esq.
Patent Attorney
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
(908)-524-2819 ext.
(908)-524-2808 (Fax #)

Judith A. Hautala, Ph.D
Vice President, Corporate
Development
Alpha 1 Biomedicals, Inc.
Two Democracy Center
6903 Rockledge Drive
Bethesda, MD 20817
(301)-564-4400 ext.
(301)-564-4424 (Fax #)

Ms. Jennifer Hawtof
Director of Human Resources
Berlex Biosciences
15049 San Pablo Avenue
P.O. Box 4099
Richmond, California 94804-0099
(510)-262-5000 ext.
(510)-669-4242 (Fax #)

Pamela A. Hay
Senior Corporate Attorney
T Cell Sciences, Inc.
38 Sidney Street
Cambridge, MA 02139-4135
(617)-621-1400 ext.
(617)-621-1420 (Fax #)

Ms. Frances Heller
Intellectual Property and Licensing
Specialist
Celtrix Pharmaceuticals, Inc.
3055 Patrick Henry Drive
Santa Clara, California 95054-1815
(408)-988-2500 ext.
(408)-450-4700 (Fax #)

George D. Hobbs, Esq.
Patent Counsel
Centocor, Inc.
244 Great Valley Parkway
Malvern, Pennsylvania 19355
(215)-296-4488 ext.
(215)-651-6100 (Fax #)

Mark A. Hofer, Esq.
Sr. Vice President, General Counsel
Genzyme Corporation
One Kendall Square
Cambridge, Massachusetts 02139
(617)-252-7500 ext.
(617)-252-7700 (Fax #)

Mr. Steven H. Holtzman
Executive Vice President
DNX
303B College Road East
Princeton Forrestal Center
Princeton, New Jersey 08540
(609)-520-0300 ext.
(609)-520-9864 (Fax #)

Margaret Horn, Esq.
Patent Counsel
Genencor International, Inc.
180 Kimball Way
S.San Francisco, California 94080
(415)-742-7536 ext.
(415)-583-8269 (Fax #)

Mr. Eric James
Chairman & CEO
Cangene Corporation
3403 American Drive
Units 1 & 2
Mississauga, Ontario, CANADA L4V IT4
(416)-673-0200 ext.
(416)-673-5123 (Fax #)

Herbert Jervis, Esq.
Senior Patent Attorney
SmithKline Beecham
709 Swedeland Road
P.O. Box 1539
King of Prussia, PA 19406
(215)-270-5019 ext.
(215)-270-5090 (Fax #)

Dr. Jack B. Jiang
Vice President, Chemical Research
Sphinx Pharmaceuticals Corporation
2 University Place
P.O. Box 52330
Durham, North Carolina 27717
(919)-489-0909 ext.
(919)-489-9093 (Fax #)

George W. Johnston, Esq.
Assistant Patent Counsel
Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110
(201)-235-3656 ext.
(201)-235-3500 (Fax #)

Ms. Karen G. Kaiser
Patent Agent
CIBA-GEIGY Corporation
556 Morris Avenue
Building A-3024
Summit, New Jersey 07901
(908)-277-3318 ext.
(908)-277-4306 (Fax #)

Mr. Steinar V. Kanstad
Staff Vice President, Patents and Licensing
Schering-Plough Corporation
One Giralda Farms
Madison, New Jersey 07940-1000
(201)-822-7373 ext.
(201)-822-7039 (Fax #)

Kevin Kaster, Esq.
Senior Patent Counsel
Affymax, N.V.
4001 Miranda Avenue
Palo Alto, California 94304
(415)-496-2300 ext.
(415)-424-0832 (Fax #)

Ms. Bronwen A. Kaye
Director, Federal Relations
American Home Products
1726 M Street, N.W.
Suite 1001
Washington, D.C. 20036
(202)-659-8320 ext.
(202)-659-2158 (Fax #)

Gail Kempler, Esq.
Patent Counsel
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
(914)-347-7000 ext.
(914)-347-2113 (Fax #)

Mr. Richard Koenig
Director, Corporate Communications
Centocor, Inc.
200 Great Valley Parkway
Malvern, Pennsylvania 19355-1307
(215)-651-6122 ext.
(215)-889-4701 (Fax #)

Paul Koivuniemi, Esq.
General Counsel
Synergen, Inc.
1885 33rd Street
Boulder, CO 80301
(303)-441-5543 ext.
(303)-441-5535 (Fax #)

Ronald Kullick, Esq.
V.P. Legal Counsel & Secretary
Ribi ImmunoChem Research, Inc.
553 Old Corvallis Road
Hamilton, MT 59840
(406)-363-6214 ext.
(406)-363-6129 (Fax #)

Catherine Kurtz-Gowen, Esq.
Patent Counsel
The Liposome Company, Inc.
1 Research Way
Princeton, N.J. 08540
(609)-452-7060 ext.
(609)-452-1890 (Fax #)

Elizabeth Lassen, Esq.
Director
Patents and Licensing
Calgene, Inc.
1920 Fifth Street
Suite F
Davis, California 95616
(916)-753-6313 ext.
(916)-753-1510 (Fax #)

Dr. Paul Leibowitz
Sr. Vice President, Research and Development
TSI Corporation
365 Plantation Street
Worcester, Massachusetts 01605
(508)-791-0931 ext.
(508)-754-3519 (Fax #)

Edward T. Lentz, Esq.
Patent Attorney
SmithKline Beecham
P. O. Box 7929
One Franklin Plaza
Philadelphia, Pennsylvania 19101
(215)-270-5065 ext.
(215)-270-5090 (Fax #)

Mr. Edward A. Leshchiner, Ph.D
Director of Research
Biomatrix, Inc.
65 Railroad Avenue
Ridgefield, New Jersey 07657
(201)-945-9550 ext.
(201)-945-0363 (Fax #)

Julian Levitt, Esq.
Director of Patents
Patent Department
Merck and Co., Inc.
126 Lincoln Avenue
P. O. Box 2000
Rahway, New Jersey 07065-0900
(908)-594-4119 ext.
(908)-594-4720 (Fax #)

Ron Levy, Esq.
Associate General Counsel
Amgen
Amgen Center
1840 Dehavilland Drive
Thousand Oaks, California 91320
(805)-499-5725 ext. 2205
(805)-499-8011 (Fax #)

Paul Lubetkin, Esq.
General Counsel & Secretary
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
(914)-347-7000 ext.
(914)-347-2113 (Fax #)

Thomas A. Marcoux, Esq.
Senior Patent Counsel
Kraft General Foods
250 North Street
RA-6N
White Plains, NY 10625
(914)-335-9220 ext.
(914)-335-9644 (Fax #)

Lynn Marcus-Wyner, Esq.
Patent Attorney
ICI Americas Inc.
Intellectual Property Section
1200 South 47th Street
Richmond, California 94804
(510)-231-1202 ext.
(510)-231-1112 (Fax #)

Paul Matukaitis, Esq.
Associate General Counsel
G. D. Searle & Company
5200 Old Orchard Road
Skokie, Illinois 60077
(708)-470-6300 ext.
(708)-470-6881 (Fax #)

Dr. Robert McBurney
Vice President, Research
Cambridge NeuroScience, Inc.
One Kendall Square
Building 700
Cambridge, Massachusetts 02139
(617)-226-0600 ext.
(617)-225-2741 (Fax #)

John J. McDonnell, Esq.
Patent Attorney
Allegretti & Witcoff Ltd.
British Bio-Technology Group plc
10 South Wacker Drive
Chicago, Illinois 60606
(312)-715-1000 ext.
(312)-715-1234 (Fax #)

Richard P. McGuire, Esq.
Senior Counsel, MSDRL
Merck Research Laboratories
P. O. Box 2000
R80A-1
Rahway, New Jersey 07065-0900
(908)-594-6874 ext.
(908)-594-3391 (Fax #)

James D. McNeil, Esq.
Division Counsel
Abbott Laboratories
Department 377
1 Abbott Park Road
Abbott Park, Illinois 60064
(708)-937-8360 ext.
(708)-937-9556 (Fax #)

Mr. David Miller
Vice President, Research and
Development
EcoScience
Three Biotech Park
One Innovation Drive
Worcester, Massachusetts 01605
(508)-754-0300 ext.
(508)-754-1134 (Fax #)

Bruce W. Morrissey, Esq.
Patent Counsel, Legal Department
E. I. du Pont de Nemours & Company
Barley Mill Plaza
Bld. 36, Room 2154
Wilmington, Delaware 19880-0036
(302)-992-4927 ext.
(302)-892-7949 (Fax #)

Mr. David Mugford
Schering-Plough Corporation
c/o Bower & Gardner
110 East 59th Street
New York, New York 10022
(212)-303-7021 ext.
(212)-752-3148 (Fax #)

William E. Murray, Esq
Senior Patent Attorney
Amoco Corporation
200 East Randolph Drive
Mail Code 1904
Chicago, Illinois 60601
(312)-856-5990 ext.
(312)-856-4972 (Fax #)

Dr. Bob Navratil
Mgr. of Research Administration &
Intellectual Property Protection
CIBA-GEIGY Seed Division
P.O. Box 18300
Greensboro, North Carolina 27419
(919)-547-1047 ext.
(919)-547-1030 (Fax #)

Clinton H. Neagley, Esq.
Secretary, Chief Patent & Director
of Licensing
DNA Plant Technology Corporation
6701 San Pablo Avenue
Oakland, California 94608
(510)-547-2395 ext.
(510)-547-2817 (Fax #)

A. R. Noe, Esq.
Manager, Patent Law Department
Patent Law Division
American Cyanamid Company
1937 West Main Street
P.O. Box 60
Stamford, Connecticut 06904-0060
(203)-321-2605 ext.
(203)-321-2971 (Fax #)

Mr. Allen E. Norris
Manager, Patents
Sandoz Agro, Inc.
975 California Avenue
Palo Alto, California 94304
(415)-354-3592 ext.
(415)-857-1125 (Fax #)

Henry P. Nowak, Esq.
Somatogen, Inc.
5797 Central Avenue
Boulder, Colorado 80301
(303)-440-9988 ext.
(303)-443-7343 (Fax #)

Mr. Lawrence P. O'Brien
Manager, Public Policy
CIBA-GEIGY Corporation
556 Morris Avenue, A-2068
Summit, New Jersey 07901
(908)-277-4973 ext.
(908)-277-4680 (Fax #)

Steven M. Odre, Esq.
Vice President, Intellectual
Property
Amgen
Amgen Center
1840 DeHavilland Drive
Thousand Oaks, California 91320-1789
(805)-499-5725 ext. 3047
(805)-499-8011 (Fax #)

Mr. David L. Olson
Director of Regulatory Affairs
Ecogen, Inc.
2005 Cabot Boulevard West
Langhorne, Pennsylvania 19047-1810
(215)-757-1590 ext.
(215)-752-2461 (Fax #)

Mr. Bruce A. Peacock
Executive Vice President & CFO
Cephalon, Inc.
145 Brandywine Parkway
West Chester, Pennsylvania 19380
(215)-344-0200 ext.
(215)-344-0065 (Fax #)

Mr. Harry Hamilton Penner, Jr.
President
Novo Nordisk of North America, Inc.
405 Lexington Avenue
Suite 6200
New York, New York 10174
(212)-867-0123 ext.
(212)-867-0298 (Fax #)

Donald W. Peterson, Esq.
Leydig, Voit, and Mayer
Mycogen Corporation
8182 Maryland, Suite 400
St. Louis, Missouri 63105
(314)-721-5868 ext. x223
(314)-854-8530 (Fax #)

Dr. Joe Petolino
Senior Scientist
DowElanco
P.O. Box 4011
Champaign, Illinois 61824-4011
(217)-373-5308 ext.
(217)-356-5300 (Fax #)

Amy Porter, Esq.
Director, Technology Management & Licensing
ARIAD Pharmaceuticals, Inc.
26 Landsdowne Street
Cambridge, MA 02139-8144
(617)-494-0400 ext.
(617)-494-8144 (Fax #)

Ms. Lisa J. Raines
Vice President, Government Relations
Genzyme Corporation
1020 19th Street, N.W.
Suite 550
Washington, D.C. 20036
(202)-296-3280 ext.
(202)-296-3411 (Fax #)

Dr. Stephen Raines
V.P., Intellectual Property
Genentech, Inc.
460 Point San Bruno Boulevard
S.San Francisco, California 94080
(415)-266-1705 ext.
(415)-952-9881 (Fax #)

Dr. Edward W. Raleigh
Manager, Biotech Regulatory Affairs
E. I. du Pont de Nemours & Company
P.O. Box 80038
Wilmington, Delaware 19880-0253
(302)-992-6158 ext.
(302)-992-2576 (Fax #)

Mr. J. Thomas Ranken
Manager, Public Affairs
Immunex Corporation
51 University Street
Seattle, Washington 98101
(206)-587-0430 ext.
(206)-587-0606 (Fax #)

George B. Rathmann, Ph.D
Chairman, President & CEO
ICOS Corporation
22021 20th Avenue, S.E.
Bothell, Washington 98021
(206)-485-1900 ext.
(206)-485-1911 (Fax #)

Dr. Edward Roberts
Division Patent Counsel
CIBA-GEIGY Corporation
7 Skyline Drive
Hawthorne, New York 10532
(914)-785-7126 ext. 7126
(914)-347-5769 (Fax #)

Mr. T. Roberts
Intellectual Property Manager
ICI Seeds
Jealott's Research Station
England, RG12 6EY
(034)-442-4701 ext.
(034)-445-5629 (Fax #)

Mr. Howard Rosen
Director, Corporate Development
GenPharm International
297 North Bernardo Avenue
Mountain View, California 94043
(415)-964-1519 ext.
(415)-964-3537 (Fax #)

Michael Roth, Esq.
Patent Counsel
Legal Department
Pioneer Hi-Bred International, Inc.
700 Capital Square
400 Locust Street
Des Moines, Iowa 50309
(515)-245-3594 ext.
(515)-245-3634 (Fax #)

Mr. Nicholas L. Ruggieri
Vice President, Government Affairs
Ares-Serono Inc.
1667 K Street, N.W.
Suite 410
Washington, D.C. 20006
(202)-828-8371 ext.
(202)-828-8375 (Fax #)

Mr. Vincent Sabiano
Director of Legal Affairs
Sphinx Pharmaceuticals Corporation
2 University Place
P.O. Box 52330
Durham, North Carolina 27717
(919)-489-0909 ext.
(919)-493-5016 (Fax #)

Mr. George Sausen
Cephalon, Inc.
145 Brandywine Parkway
West Chester, Pennsylvania 19380
(215)-344-0020 ext. 192
(215)-344-0065 (Fax #)

Dr. Hollis G. Schoepke
Senior V.P., Research & Development
Anaquest, Inc.
A BOC Healthcare Company
110 Allen Road
Liberty Corner, New Jersey 07938
(908)-604-7607 ext.
(908)-604-7650 (Fax #)

Dr. Saied Seyedin
Vice President, R & D
Metra Biosystems, Inc.
3181 Porter Drive
Palo Alto, California 94304-1213
(415)-494-9114 ext.
(415)-494-9138 (Fax #)

Gerald D. Sharkin, Esq.
Vice President
Patent & Trademark Affairs
Sandoz Pharmaceuticals Corp.
59 Route 10
East Hanover, New Jersey 07936
(201)-503-8483 ext.
(201)-503-8807 (Fax #)

Dr. Richard J. Sharpe, M.D.
Sr. V.P., Research, Development and
Regulatory Committee
Arcturus Pharmaceutical Corporation
260 West Cummings Park
Woburn, Massachusetts 01801
(617)-938-1686 ext.
(617)-868-7794 (Fax #)

Leonard Slootmaker, Esq.
General Counsel
Berlex Biosciences
15049 San Pablo Avenue
P.O. Box 4099
Richmond, California 94814-0099
(510)-262-5407 ext.
(510)-262-7095 (Fax #)

Mr. John Spear
Government Relations
Merck and Co., Inc.
601 Pennsylvania Avenue, N.W.
North Building - Suite 1200
Washington, D.C. 20004
(202)-638-4170 ext.
(202)-638-3670 (Fax #)

Howard C. Stanley, Esq.
Group Patent Counsel
Monsanto Agricultural Company
800 N. Lindbergh Boulevard
A35 B
St. Louis, Missouri 63167
(314)-694-3291 ext.
(314)-694-9009 (Fax #)

Mr. James G. Timmins
Director, Product Development
& Regulatory Affairs
Agracetus Inc.
8520 University Green
Middleton, Wisconsin 53562
(608)-836-7300 ext.
(608)-836-9710 (Fax #)

Mr. Bill Tindall
Communications Manager
American Cyanamid Company
Agricultural Research Division
P.O. Box 400
Princeton, New Jersey 08543-0400
(609)-799-0400 ext. 2551
(609)-275-3502 (Fax #)

Mr. Jack L. Tribble
Senior Patent Attorney
Merck Research Laboratories
126 E. Lincoln Avenue
Rahway, New Jersey 07065
(908)-594-5321 ext.
(908)-594-4720 (Fax #)

Dr. Estelle J. Tsevdos
Manager, Biotechnology Section
Patent Law Department
American Cyanamid Company
1937 West Main Street
P. O. Box 60
Stamford, Connecticut 06904-0060
(203)-321-2756 ext.
(203)-321-2971 (Fax #)

Dr. Bill Tyrrell
Patent Attorney
SmithKline Beecham PLC
Great Burgh
Yew Tree Bottom Road
England, KT185XQ
ext.
(Fax #)

Richard E. Vila, Esq.
Director of Patent
and Trademark Affairs
Sandoz Pharmaceuticals Corp.
59 Route 10
East Hanover, New Jersey 07936
(201)-503-8420 ext.
(201)-503-8807 (Fax #)

Judith A. Woods
Patent Counsel
ICOS Corporation
22021 20th Avenue, S.E.
Bothell, Washington 98021
(206)-485-1900 ext. 270
(206)-489-0356 (Fax #)

Thomas E. Workman, Jr., Esq.
Acting General Counsel
Amgen
Law Dept - 10-2-E-400
1840 Dehavilland Drive
Thousand Oaks, California 91320
(805)-499-5725 ext. 4955
(805)-499-8011 (Fax #)

Debbie Kay Wright, Esq.
Patent Counsel
Kraft General Foods
Three Lakes Drive, N4F
Northfield, Illinois 60093-2753
(708)-646-2852 ext.
(708)-646-4431 (Fax #)

Leon R. Yankwich, Esq.
Patent Counsel
Patent Department
Biogen Inc.
Fourteen Cambridge Center
Cambridge, Massachusetts 02142
(617)-252-9200 ext.
(617)-252-9617 (Fax #)

Mr. Steve T. Zelson
Director of Intellectual Property &
Chief Patent Counsel - U.S.
Novo Nordisk of North America, Inc.
405 Lexington Avenue
Suite 6200
New York, New York 10017
(212)-867-0123 ext.
(212)-867-0298 (Fax #)

Thomas D. Zindrick
Patent Counsel
DowElanco
1790 Building
Midland, MI 48674
(517)-636-1869 ext.
(517)-638-9786 (Fax #)

Total Membership: 117

APPENDIX 2.—LETTER FROM ROBERT A. ARMITAGE (WITH ATTACHMENTS), TO HON. WILLIAM J. HUGHES, JUNE 16, 1993

THE UPJOHN COMPANY

Upjohn

Corporate Intellectual Property Law
301 Henrietta Street
Kalamazoo, MI 49001
TELEPHONE: 616-385-7345
TELEFAX: 616-385-6897

Office of
ROBERT A. ARMITAGE
Vice President and
Corporate Assistant Secretary

16 June 1993

The Honorable William J. Hughes
Chairman, Subcommittee on Intellectual Property and the Administration of Justice
United States House of Representatives
Cannon House Office Building
1st Street & Independence Avenue, S.E.
Washington, D. C. 20515

Re: Hearings on H.R. 760 on June 9, 1993

Dear Mr. Chairman:

As I indicated to the subcommittee, in preparation for my testimony on June 9, I took the opportunity to review the "genetic engineering" patents issued in the United States through April of 1992, via a PTO-supplied CD-ROM. From the PTO database I have obtained the following information that the committee may find of interest:

I found that a total of 20 "genetic engineering" patents had issued to Amgen. *I have attached a listing of these 20 patents.* Several patents within this group of 20 relate to the medical marvels that have made this company successful and famous, including erythropoietin and colony stimulating factors.

Two-thirds of these Amgen patents contain ***process claims:*** 13 of 20 patents. Given that for at least one of these patents, Amgen testified that it *deliberately removed* patentable process claims so the patent would issue only with product claims, the percentage of Amgen patents that *could* have issued with process claims is undoubtedly higher. *I have attached a listing of all the process claims that Amgen has been awarded by the PTO, based on the information contained in the PTO's CD-ROM.*

Genentech has similarly obtained through April of last year 78 "genetic engineering" patents that read like an encyclopedia of biotechnology innovations (listing attached). In just over ***three-quarters*** of these 78 patents, Genentech was awarded *process* claims; *50 of the 78 Genentech patents in the genetic engineering field have been issued containing process claims.*

Attached is a listing of the process claims contained in each of these 50 patents. They include processes for making tissue plasminogen activator, growth factors, blood factors,

and even one process claim directed to a method for making cheese. (U.S. patent 4,961,938)

Altogether the PTO's genetic engineering CD-ROM collection contains almost 2400 patents. Of these, patents with *process* claims number 1,718 or over 77% of all U.S. genetic engineering patents that were issued. Attached is a 127 page listing of these 1,718 patents. This data leads us to single query that should be directed to the biotechnology industry in this country: ***Since it appears as though process patents are plentiful for biotechnology inventions, where is the evidence that more such patents are needed?*** With three-quarters of each of the industry's genetic engineering patents containing process claims, it is difficult for NAM and IPO to understand how biotechnology companies—without many more details than they have so far shared with this subcommittee—can claim that biotechnology industry needs biotechnology patent process legislation.

* * *

Both IPO and NAM are concerned that the biotechnology industry in making its case before this subcommittee has confused the need for administrative reforms in the PTO and harmonizing reforms to the patent laws with the need for an industry-specific remedy.

Patent interferences, and patent interferences alone, prevented the issuance of a process patent to Amgen, covering the manufacture of EPO, in 1988. Genentech testified that it had experienced a similar delay of 10 years in obtaining key patents for an important research project. Again, to what extent has such an extraordinary delay been *solely attributable* to *Durden*, rather that our current invention date-based patent system?

Similarly, the PTO continues to have unacceptably long average pendency for biotechnology patent applications. While many administrative initiatives have been undertaken to improve the situation, legislation in the narrow area of process claims is not substitute for an overall improvement in the examination of biotechnology inventions.

* * *

Finally, IPO has worked with the PTO over the past year to develop administrative guidance for patent examiners. Both NAM and IPO express support for the ready availability of process claims in accordance with the Federal Circuit's *Pleuddemann* decision. We believe, for example, that a simple statement along the following lines would permanently settle this issue within the PTO and influence future decisions of the Federal Circuit:

Examination of Process Claims
Guidelines for Patent Examiners

While process claims are not rendered non-obvious *solely because* they

involve the use of novel and non-obvious materials or produce novel and non-obvious end products, the requirement under 35 USC 103 that "the subject matter of a whole" of a process invention be given due consideration in determining its non-obviousness mandates that the examiner consider *the use of patentable materials* in assessing the overall non-obviousness of such an invention. Absent other considerations, the recitation in a process claim of the use of a novel and non-obvious material is an adequate basis for rebutting an inference of obviousness based on consideration of the conventionality of the individual process steps recited in the claim. Where the substance of a claim recites the use of a novel and non-obvious material, the precise form of the claim (e.g., "method of using" versus "method of making") is *not* controlling with respect to non-obviousness. The public policy of encouraging inventors to make prompt and complete disclosures of uses for the patentable materials they invent is fully consistent with the foregoing practice of assessing non-obviousness for processes that recite such uses.

With respect to claims that in substance do not recite the use of a novel and non-obvious material, the examiner need not regard the production of a novel and non-obvious end product, standing alone, as a sufficient basis for rebutting an inference of obviousness arising, *inter alia*, from the conventionality of the process steps recited in the claims. Since a claim to the patented end product is effective to prevent the manufacture of the end product by each and every possible means, a claim to any particular such process, absent an independent basis for inferring non-obviousness, would constitute the grant of a claim merely redundant in view of the claim to the patented product.

The following example describes the application of the foregoing concepts:

An inventor creates novel and non-obvious genetic material that is incorporated into a host cell. The inventor describes the use of the genetic material and/or host cell to produce a polypeptide end product by the conventional steps of culturing the host cell and isolating the end product from the culture. Given that the criteria for patentability in an application for patent are otherwise met, the inventor would be entitled to claim both the genetic material and the host cell. Additionally, any inference of obviousness with respect to the process of using the host cell to produce the end product would be overcome in view of the use of the novel and non-obvious host cell in the process. The applicant would have the option of formally describing this non-obvious subject matter either in terms of a process for using the host cell to make the end product or a process for making the end product by using the host cell.

We are open to receiving from the biotechnology industry further, specific justification for the need for legislation in this area and look forward to working with your subcommittee as it continues its consideration of the case being made by the biotechnology industry.

Yours very truly,

Robert A. Armitage

RAA/sp

Amgen

20 patents
Class 935
Class 435,
sub-class 172.3

U.S. Patent No.: 4520103
Title: Microbial production of indigo

U.S. Patent No.: 4558006
Title: A.T.C.C. HB8209 and its monoclonal antibody to erythropoietin

U.S. Patent No.: 4599306
Title: Monoclonal antibodies which specifically bind to human immune interferon

U.S. Patent No.: 4652639
Title: Manufacture and expression of structural genes

U.S. Patent No.: 4666839
Title: Methods and materials for obtaining microbial expression of polypeptides including bovine prolactin

U.S. Patent No.: 4667016
Title: Erythropoietin purification

U.S. Patent No.: 4689406
Title: Enhancement of microbial expression of polypeptides

U.S. Patent No.: 4703008
Title: DNA sequences encoding erythropoietin

U.S. Patent No.: 4710473
Title: DNA plasmids

U.S. Patent No.: 4751177
Title: Methods and kits for performing nucleic acid hybridization assays

U.S. Patent No.: 4797355
Title: Methods for attaching polynucleotides to supports

U.S. Patent No.: 4810643
Title: Production of pluripotent granulocyte colony-stimulating factor

U.S. Patent No.: 4894331
Title: Partial marker cassette mutagenesis of xylose isomerase

U.S. Patent No.: 4914031
Title: Subtilisin analogs

U.S. Patent No.: 4935350
Title: Materials and methods for controlling plasmid copy number and stability

U.S. Patent No.: 4977092
Title: Expression of exogenous polypeptides and polypeptide products including hepatitis B surface antigen in yeast cells

U.S. Patent No.: 4999291
Title: Production of human pluripotent granulocyte colony-stimulating factor

U.S. Patent No.: 5017495
Title: Plasmid encoding the Pseudomonas mendocina toluene monooxygenase gene

U.S. Patent No.: 5079166
Title: Microbial degradation of trichloroethylene

U.S. Patent No.: 5106760
Title: ATCC HB8209, its monoclonal antibody to erythropoietin and assay using same

Genentech 78 patents

U.S. Patent No.: 4310662
Title: Nucleosidic phosphorylating agent and methods

U.S. Patent No.: 4342832
Title: Method of constructing a replicable cloning vehicle having quasi-synthetic genes

U.S. Patent No.: 4356270
Title: Recombinant DNA cloning vehicle

U.S. Patent No.: 4366246
Title: Method for microbial polypeptide expression

U.S. Patent No.: 4393010
Title: Nucleosidic phosphorylating agent and methods

U.S. Patent No.: 4414150
Title: Hybrid human leukocyte interferons

U.S. Patent No.: 4425437
Title: Microbial polypeptide expression vehicle

U.S. Patent No.: 4431739
Title: Transformant bacterial culture capable of expressing heterologous protein

U.S. Patent No.: 4446235
Title: Method for cloning human growth hormone varient genes

U.S. Patent No.: 4456748
Title: Hybrid human leukocyte interferons

U.S. Patent No.: 4511502
Title: Purification and activity assurance of precipitated heterologous proteins

U.S. Patent No.: 4511503
Title: Purification and activity assurance of precipitated heterologous proteins

U.S. Patent No.: 4512922
Title: Purification and activity assurance of precipitated heterologous proteins

U.S. Patent No.: 4517294
Title: Human antithrombin III

U.S. Patent No.: 4518526
Title: Purification and activity assurance of precipitated heterologous proteins

U.S. Patent No.: 4563424
Title: Method and means for somatostatin protein conjugate expression

U.S. Patent No.: 4571421
Title: Mammalian gene for microbial expression

U.S. Patent No.: 4601980
Title: Microbial expression of a gene for human growth hormone

U.S. Patent No.: 4604359
Title: Microbial expression of a gene for human growth hormone

U.S. Patent No.: 4632981
Title: Human antithrombin III

U.S. Patent No.: 4634677
Title: Plasmid capable of expressing human growth hormone

U.S. Patent No.: 4658021
Title: Methionyl human growth hormone

U.S. Patent No.: 4659669
Title: Microbial expression of human influenza hemagglutinin proteins

U.S. Patent No.: 4663283
Title: Method of altering double-stranded DNA

U.S. Patent No.: 4670393
Title: DNA vectors encoding a novel human growth hormone-variant protein

U.S. Patent No.: 4678751
Title: Hybrid human leukocyte interferons

U.S. Patent No.: 4680262
Title: Periplasmic protein recovery

U.S. Patent No.: 4704362
Title: Recombinant cloning vehicle microbial polypeptide expression

U.S. Patent No.: 4713339
Title: Polycistronic expression vector construction

U.S. Patent No.: 4714674
Title: Chemotactic assay for immunogenicity

U.S. Patent No.: 4727138
Title: Human immune interferon

U.S. Patent No.: 4741901
Title: Preparation of polypeptides in vertebrate cell culture

U.S. Patent No.: 4742003
Title: Human transforming growth factor

U.S. Patent No.: 4755465
Title: Secretion of correctly processed human growth hormone in E. coli and Pseudomonas

U.S. Patent No.: 4757012
Title: Ascorbic acid intermediates and process enzymes

U.S. Patent No.: 4758514
Title: Ascorbic acid intermediates and process enzymes

U.S. Patent No.: 4761371
Title: Insulin receptor

U.S. Patent No.: 4762791
Title: Human immune interferon

U.S. Patent No.: 4766075
Title: Human tissue plasminogen activator

U.S. Patent No.: 4772555
Title: Dedicated ribosomes and their use

U.S. Patent No.: 4775622
Title: Expression, processing and secretion of heterologous protein by yeast

U.S. Patent No.: 4803164
Title: Preparation of hepatitis b surface antigen in yeast

U.S. Patent No.: 4810645
Title: Microbial production of mature human leukocyte interferon K and L

U.S. Patent No.: 4812554
Title: Somatostatin peptide conjugate

U.S. Patent No.: 4816567
Title: Recombinant immunoglobin preparations

U.S. Patent No.: 4853330
Title: Human tissue plasminogen activator

U.S. Patent No.: 4855224
Title: Molecularly cloned diagnostic product and method of use

U.S. Patent No.: 4855238
Title: Recombinant gamma interferons having enhanced stability and methods therefor

U.S. Patent No.: 4859600
Title: Recombinant procaryotic cell containing correctly processed human growth hormone

U.S. Patent No.: 4859609
Title: Novel receptors for efficient determination of ligands and their antagonists or agonists

U.S. Patent No.: 4886747
Title: Nucleic acid encoding TGF-.beta. and its uses

U.S. Patent No.: 4898830
Title: Human growth hormone DNA

U.S. Patent No.: 4912046
Title: Portable inducible control system

U.S. Patent No.: 4923808
Title: Method for identifying mutants secreting high levels of heterologous proteins

U.S. Patent No.: 4925793
Title: Human immune interferon

U.S. Patent No.: 4935237
Title: Processes for the preparation of t-PA mutants

U.S. Patent No.: 4935354
Title: Rennin from recombinant microbial cells for preparation of cheese

U.S. Patent No.: 4940661
Title: Metallothionein transcription control sequences and use thereof

U.S. Patent No.: 4959457
Title: Anti-lymphotoxin

U.S. Patent No.: 4960700
Title: Compositions and methods for the synthesis and assay of a mammalian enkephalinase

U.S. Patent No.: 4961938
Title: Preparation of cheese with rennin from recombinant microbial cells

U.S. Patent No.: 4963495
Title: Secretion of heterologous proteins

U.S. Patent No.: 4965196
Title: Polycistronic expression vector construction

U.S. Patent No.: 4965199
Title: Preparation of functional human factor VIII in mammalian cells using methotrexate based selection

U.S. Patent No.: 5008193
Title: Ascorbic acid intermediates and process enzymes

U.S. Patent No.: 5010002
Title: Human t-PA production using vectors coding DHFR protein

U.S. Patent No.: 5010003
Title: Use of yeast homologous signals to secrete heterologous proteins

U.S. Patent No.: 5011795
Title: Human tPA production using vectors coding for DHFR protein

U.S. Patent No.: 5024939
Title: Transient expression system for producing recombinant protein

U.S. Patent No.: 5032514
Title: Metabolic pathway engineering to increase production of ascorbic acid intermediates

U.S. Patent No.: 5037646
Title: Processes for the treatment of vascular disease

U.S. Patent No.: 5039488
Title: Devices for amino acid sequence determination

U.S. Patent No.: 5049488
Title: Method and nucleic acid for the preparation of lecithin:cholesterol acyltransferase

U.S. Patent No.: 5057417
Title: Compositions and methods for the synthesis of growth hormone receptor and growth hormone binding protein

U.S. Patent No.: 5075224
Title: Prepro-LHRH C-terminal peptide DNA

U.S. Patent No.: 5089396
Title: Nucleic acid encoding .beta. chain prodomains of inhibin and method for synthesizing polypeptides using such nucleic acid

U.S. Patent No.: 5094953
Title: Human tissue plasminogen activator variants

U.S. Patent No.: 5108919
Title: DNA sequences encoding yeast ubiquitin hydrolase

APPENDIX 3.—LETTER FROM CARL B. FELDBAUM, PRESIDENT, INDUSTRIAL BIOTECHNOLOGY ASSOCIATION, TO HON. WILLIAM J. HUGHES, JUNE 7, 1993

IBA Industrial Biotechnology Association

1625 K Street, N.W., Suite 1100
Washington, D.C. 20006-1604
(202) 857-0244
FAX: (202) 857-0237

Carl B. Feldbaum
President

BY HAND

June 7, 1993

The Honorable William J. Hughes
Chairman
Intellectual Property and Judicial
Administration Subcommittee
House Judiciary Committee
207 Cannon House Office Bldg.
Washington, D. C. 20515-3002

SUBJECT: INTELLECTUAL PROPERTY SUBCOMMITTEE HEARING ON THE BIOTECHNOLOGY PATENT PROTECTION ACT (H. 760)

Dear Chairman Hughes:

I understand that the Intellectual Property Subcommittee of the House Judiciary Committee will be holding a hearing on H. 760, the Biotechnology Patent Protection Act, this Wednesday, June 9th. You will be hearing from a representative of our industry on Wednesday. But I also wanted, on behalf of the Association of Biotechnology Companies and the Industrial Biotechnology Association -- and our 500 member companies, which collectively account for more than 90% of all private biotechnology research and development investment in the United States -- to urge you to support this bill.

The Biotechnology Patent Protection Act is critical to the continued success of the U.S. biotechnology industry. The industry spent nearly $5 billion in R&D last year, more than any other industry. But these costs pale in contrast to the ease with which biotech products can be "reverse engineered." Present U.S. patent laws do not adequately protect the industry's innovations in these circumstances, thus diminishing incentives to discover and commercialize the scientific breakthroughs from which the biotech industry draws its lifeblood.

There are two problems. The U.S. Patent and Trademark Office refuses to issue process patents for many biotechnology inventions as a result of its interpretation of In re Durden (763 F.2d 1406 (CAFC 1985)), a much criticized and inconsistently applied Federal Circuit decision.

In addition, U.S. law provides no recourse to the holder of a U.S. patent on a genetically engineered host cell which is used overseas by a foreign company, who then exports the product to the U.S. to compete with the original patentee's product.

The Biotechnology Patent Protection Act redresses both of these problems. It modifies the test for obtaining a biotechnology process patent by overruling the application of In re Durden to biotechnology process patent applications. It also makes it an act of infringement for foreign manufacturers to use U.S.-patented microorganisms overseas to make a product for export to the U.S.

This legislation, which passed the Senate in the last Congress, will help the U.S. maintain its commanding lead in biotechnology and ensure that the industry is able to continue to develop important breakthrough products to treat disease, enhance agricultural production, and treat toxic waste. I urge your support.

Thank you.

Sincerely,

Paul B. Feldban