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BIOTECHNOLOGY PATENT PROTECTION ACT OF 1991

HEARING

BEFORE THE

SUBCOMMITTEE ON INTELLECTUAL PROPERTY AND JUDICIAL ADMINISTRATION

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

ONE HUNDRED SECOND CONGRESS

FIRST SESSION

ON

H.R. 1417

BIOTECHNOLOGY PATENT LAW PROTECTION ACT OF 1991

NOVEMBER 21, 1991

Serial No. 101

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BIOTECHNOLOGY PATENT PROTECTION ACT OF 1991

THURSDAY, NOVEMBER 21, 1991

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

The subcommittee met, pursuant to notice, at 11 a.m., in room 2237, Rayburn House Office Building, Hon. William J. Hughes (chairman of the subcommittee) presiding.

Present: Representatives William J. Hughes, Rick Boucher, Carlos J. Moorhead, Hamilton Fish, Jr., Howard Coble, and Craig T. James.

Also present: Hayden W. Gregory, counsel; Michael J. Remington, assistant counsel; Elizabeth R. Fine, assistant counsel; Edward O'Connell, assistant counsel; Phyllis Henderson, secretary; Thomas E. Mooney, minority counsel; and Joseph V. Wolfe, minority counsel.

OPENING STATEMENT OF CHAIRMAN HUGHES

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

The Chair has received a request to cover this hearing in whole or in part by television broadcast, radio broadcast, still photography, or by any other similar method. And, in accordance with committee rule 5(a), permission will be granted, unless there is objection.

Is there objection?

[No response.]

Mr. HUGHES. Hearing none, permission will be granted.

Good morning and welcome to today's hearing. Today, the subcommittee is conducting a second day of hearings on biotechnology. Yesterday, we learned a great deal about the exciting research taking place at the National Institutes of Health and around the world in this important and burgeoning field. We also learned about the fundamental role that patent protection plays in promoting the research and development of biotechnology products.

The United States leads the world in biotechnology. We want to assure that our biotechnology industry continues its remarkable progress. Today, we will address the question of whether our patent laws provide adequate protection for biotechnology inventions. H.R. 1417, the Biotechnology Patent Protection Act of 1991, introduced by Representative Rick Boucher, is intended to address a

problem that has arisen in the patent protection afforded to the process of making recombinant products. Absent process patent protection, foreign companies are able to manufacture abroad and import into the U.S. products that are made using technology developed in this country. Of particular concern to the biotechnology industry is the fact that a patented host cell can be taken oversees and used to produce a recombinant protein abroad, and then the recombinant product can be imported back into this country.

Today we hope to learn more about the experience that the biotechnology industry has had with respect to the importation of recombinant products and whether it is one that demands a legislative solution. A number of witnesses this morning will suggest that Congress allow the courts and the administration the opportunity to resolve any ambiguity in the patent law within the context of the existing legal framework.

Assuming that a legislative solution is necessary, we must assess H.R. 1417, the Biotechnology Patent Protection Act of 1991, to determine whether the proposal sets forth an appropriate solution. H.R. 1417 amends the patent law to revise the patentability of all processes. The subcommittee must take special care to examine what the impact of the proposed legislation would be both in the biotechnology industry, as well as other industries that might be affected by such a change.

It promises to be again another interesting hearing

[The bill, H.R. 1417, follows:]

I

102D CONGRESS
1ST SESSION

H. R. 1417

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 13, 1991

Mr. BOUCHER (for himself, Mr. MOORHEAD, Mr. DWYER of New Jersey, Mr. COBLE, Ms. KAPTUR, Mr. GALLEGLY, Mr. MILLER of Washington, Mr. DELUGO, Mr. STENHOLM, Mr. TOWNS, Mrs. MORELLA, Mr. FISH, Mr. CAMPBELL of California, Mr. ANDREWS of Texas, Mr. LAGOMARSINO, Mr. BRUCE, Mr. MCCLOSKEY, Mr. DICKS, Mr. LIPINSKI, Mr. MCCOLLUM, and Mr. JEFFERSON) 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,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Biotechnology Patent Protection Act of 1991".

1 **SEC. 2. PATENTABILITY OF CERTAIN PROCESSES.**

2 Section 103 of title 35, United States Code, is
3 amended by adding at the end the following new para-
4 graph:

5 "When a process of making or using a machine, man-
6 ufacture, or composition of matter is sought to be pat-
7 ented in the same application as such machine, manufac-
8 ture, or composition of matter, such process shall not be
9 considered as obvious under this section if such machine,
10 manufacture, or composition of matter is novel under sec-
11 tion 102 and nonobvious under this section. If the patent-
12 ability of such process depends upon such machine, manu-
13 facture, or composition of matter, then a single patent
14 shall issue on the application.".

15 **SEC. 3. EFFECTIVE DATE.**

16 The amendment made by section 2 shall apply to all
17 United States patents granted on or after the date of the
18 enactment of this Act and to all applications for United
19 States patents pending on or filed after such date of enact-
20 ment, including any application for the reissuance of a
21 patent.

O

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

Mr. MOORHEAD. Well, thank you, Mr. Chairman. I very much appreciate the scheduling of these hearings. I know the chairman's schedule has been full, as well as that of the subcommittee. I do appreciate all of his efforts in making these hearings possible.

I would also like to commend the gentleman from Virginia, Rick Boucher, our lead sponsor of the bill, for all of his hard work in bringing about these hearings.

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 in 1991. The U.S. Department of Commerce projects a $30 billion market for biotech products by the year 2000, and many in 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 incurred in bringing a product to market.

In addition to their ability to obtain and enforce a patent, small companies in particular must be concerned about obtaining a patent in a timely fashion. As a result, the Patent Office reports that the backlog in biotechnology patent applications have been increased from 17,400 at the end of fiscal year 1990 to 19,500 at the end of June of this year. According to the testimony of the Patent Commissioner, the average biotechnology patent takes 27 months to issue, while other patents take about 18 months. I am concerned that despite the cut in the PTO budget request that the PTO will be able to continue to reduce this backlog.

Delays of this type are unacceptable, particularly for an industry that is so dependent on patents to raise capital and reinvestment in manufacturing plants and new product development, and even more so for an industry targeted by Japan for major and considered competition. The Patent Office is taking 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 biotechnology 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. 1417, the Biotechnology Patent Protection Act of 1991, which has been introduced by Rick Boucher and myself. 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 Association, in Japan the Ministry of International Trade and Industry 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 needed legislation, the Congress may contribute to the fulfillment of that projection.

Mr. Chairman, I hope we can move this legislation as fast as we can through the subcommittee.

Mr. HUGHES. I thank the gentleman.

I would like to welcome this morning as our opening witness our distinguished colleague, Representative Tom McMillen, who represents——

Mr. BOUCHER. Mr. Chairman, I have a statement. In deference to the interest of the committee in moving rapidly, I would just ask unanimous consent that it be placed in the record.

Mr. HUGHES. Without objection, so ordered. In fact, any members who have a statement might offer their statement for the record.

[The prepared statement of Mr. Boucher follows:]

RICK BOUCHER
9TH DISTRICT, VIRGINIA

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SCIENCE, SPACE, AND TECHNOLOGY
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REMARKS OF CONGRESSMAN RICK BOUCHER
HOUSE SUBCOMMITTEE ON INTELLECTUAL PROPERTY

NOVEMBER 21, 1991

Good morning. I thank the Chairman very much for holding this hearing today on the Biotechnology Patent Protection Act. I also thank this distinguished panel for agreeing to appear here today, and I look forward to hearing your testimony.

The biotech industry is immensely important for our country's economic future. Its annual sales are now about $4 billion, and experts predict that this figure may reach $30 billion within the next decade. The American biotech industry conducts up to $3.2 billion worth of research and development every year, and over the past seven years, it has won approval to market about twenty new products.

This work holds great promise for millions of Americans. Through recombinant processes, biotechnology industries create new products which benefit agricultural industries and assist in environmental cleanups. They also invent medicines which allow patients to receive new kinds of treatment for life-threatening diseases and previously incurable conditions.

America's biotechnology companies lead the world. American firms conduct the most R&D, use the most sophisticated technologies, and invent the most new products. And if their inventions receive the legal protection against piracy and unfair competition which they have earned, American firms will continue to lead the world.

Today, however, biotech inventions do not receive this strong protection. And as a result, the biotech industry's position, in fact, is under threat--not from unfair trade practices abroad, nor from our economic problems at home. The problem which the biotechnology industry has encountered stems from 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, and that many have been previously isolated and purified--although in such small quantities as to be medically and commercially useless--they are essentially unpatentable. Biotech firms, therefore, count on patenting the process they use to produce the protein to protect their R&D investment and the innovations that investment produces.

Under the 1974 decision, In re Mancey, this should be a simple procedure. That case found, as it should, that the presence of a novel starting material justified granting a process patent 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--that regardless of whether a firm 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. In practice, that standard frequently makes it extraordinarily difficult for biotech firms to patent anything other than their starting materials.

Rather than examining the totality of the invention to decide whether it is new, innovative and valuable, the Patent Office focuses on the narrow issue of whether the process used to get from a novel starting material to a novel end product differs from the processes used to create totally unrelated biotech products. The result is that the Patent Office frequently denies process patents for innovative products and leaves them wide open to foreign exploitation. And because of this, a foreign firm can take the starting material abroad, duplicate the American firm's process, produce an identical end product and export it back to the U.S. without violating any law.

Some argue that a recent decision, In re Pleuddemann, will solve the problem that In re Durden created. They are incorrect. In re Pleuddemann confuses the issue rather than settling it. This case creates an arcane distinction between patenting the "use" of a novel starting material and the process of "making" the end product. As the Patent and Trademark Office itself states, the decision "has not clarified the law and leaves patent applicants, including applicants in the biotechnology field, unable to predict with reasonable certainty whether they can obtain process patents."

Clearly, Pleuddemann is not good enough. And there is no reason to allow an obvious, legislatively correctable flaw in our patent law to continue damaging the competitiveness of American

firms, slowing rasearch and delaying the invention of life-saving medicine. We understand tha problem, we know what the solution is, and the legislation to implement that solution is before us today.

In effect, our current patent law encourages foreign firms to copy American intellactual products and discourages American firms from doing the expensive R&D necessary to invent it in the first place. This is tha opposite of the goal of the patent law--to ancouraga rasaarch, davelopment and invention.

H.R. 1417 specifies that, as states in In re Mancey, that when a firm combines a novel starting material with a known process to yiald a novel end product, it can claim a patent over the procass. This will eliminate the flaw in patent law that weakens our compatitiveness and gives foreign companies an unfair advantage over Amarican firms. It will have no ramifications on our trade negotiations--in fact, it will simply give our biotech rasaarchers tha functionally equivalent patent rights that their Japanese and European compatitors already have. It has wide support in tha American biotach industry and the academic community. The Administration has endorsed it, and I hope we will act soon to pass it.

Thank you again, Mr. Chairman, and I look forward to this hearing.

Mr. HUGHES. We have a lot of witnesses today, and, frankly, I just hope that all of the witnesses can summarize their remarks so that we can move through what promises to be a very interesting hearing. But there are a lot of questions to be asked, and I hope that we can summarize so that we can get right to questions. All of us have read the statements.

I would like to welcome this morning, as I indicated, our opening witness, our distinguished colleague Representative Tom McMillen, who represents the Fourth Congressional District of Maryland. Representative McMillen is a founder and cochairman of the Congressional Biotechnology Caucus. We really welcome him this morning. I know he is one of the leaders in the area of biotechnology in the Congress.

Tom, we have your statement which, without objection, will be made a part of the record, and you may proceed as you see fit.

STATEMENT OF HON. THOMAS C. McMILLEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MARYLAND

Mr. MCMILLEN. Thank you, Mr. Chairman, and members of the committee. I am certainly pleased to be here on behalf of the Congressional Biotechnology Caucus and its 68 members. A lot of people ask me why I am so interested in biotechnology, and I tell them that I am proof that that growth hormone works very well. So I am pleased to be here as cochair with Congressman Bliley and Senators Lautenberg and Brown.

And I just want to say, Mr. Chairman, this is the only piece of legislation that the caucus has endorsed, H.R. 1417. We think it is very, very important.

You enumerated, as well as Mr. Moorhead, what biotechnology means to this country: In the last 15 years, 70,000 new jobs, $5.8 billion in new revenues, $600 million in adding to our annual trade balance. It has been vital in the areas of health, the environment, and agriculture. I think when you focus on the health areas I think it is very, very interesting that last week Dr. Tony Fauci, who directs AIDS research at NIH, told Senator Lautenberg and myself that our Nation is extremely fortunate that this terrible AIDS epidemic began after the advent of biotechnology. He said that if AIDS had occurred before biotechnology existed, we wouldn't have known what a human retrovirus was or how it works, we wouldn't be able to diagnose the disease or ensure the safety of our blood supply, and quite frankly, we would have no hope for a cure for this disease.

I think one of the things that I want to stress to the subcommittee is that biotechnology is very, very important for our country, and the research does not come cheap. In fact, the industry has invested $3.2 billion in research and development this year. That is an 18-percent increase over the last year. And the companies in biotechnology spend an average of $81,000 per employee, which is very, very high. So I want to stress that I think this industry has promise. I think it is very, very important that it has the regulatory framework to encourage that promise.

I am very concerned about the patent protection that is vital to this industry. Without protecting this industry from foreign piracy,

I don't think American companies can maintain this edge that they have had to date.

We often in the Congress criticize American companies for being shortsighted. That they only invest for today and they can never invest for tomorrow. That is not the case in the biotechnology industry. As you know, Mr. Chairman, an average biotech company may take 10 to 12 years of huge, enormous investments, high-risk research and development investments in the neighborhood of $100 to $200 million of risk capital before they can even bring a product to the market. It is a long product cycle, and I don't think anybody can accuse the biotechnology industry of being impatient. But I think what is required is adequate patent protection. And I say that it is very, very wrong and it would be a tragedy if future biotechnology products were stamped "Invented in America; made in Japan," simply because Congress failed to staunch the hemorrhage of intellectual property rights which are permitted under the current law. Foreign companies can do things that our domestic companies cannot do.

So, Mr. Chairman, without getting into the specifics of the bill, other witnesses will do so, let me just say that I believe that the caucus wants this legislation to move as expeditiously as possible, and it will remedy a problem that I think is a hurdle for this industry to reap the great rewards that it can for our future.

Thank you.

Mr. HUGHES. Well, thank you very much, Tom, for an excellent statement. I don't have any questions.

The gentleman from California.

Mr. MOORHEAD. I just want to congratulate our colleague for the work he is doing in the caucus. It is a very important area and it is one that needs more attention, and it is far more important that it gets the attention of the Members of Congress. You are doing a great work there.

Mr. MCMILLEN. Thank you.

Mr. HUGHES. The gentleman from Virginia, the author of H.R. 1417 and a very valued member of the subcommittee?

Mr. BOUCHER. I don't have any question, Mr. Chairman.

Mr. HUGHES. The gentleman from Florida.

Mr. JAMES. No questions at this time. Thank you so much for your enlightening testimony.

Mr. MCMILLEN. Thank you.

Mr. HUGHES. The gentleman from North Carolina.

Mr. COBLE. No questions, Mr. Chairman.

Mr. MCMILLEN. I saw him come in with that one sneaker. I was very impressed. I hope you are using biotechnology to repair that sore ankle.

Mr. COBLE. Don't challenge me today.

[Laughter]

Mr. HUGHES. Thank you, Tom.

[The prepared statement of Mr. McMillen follows:]

Statement of Representative Tom McMillen

Mr. Chairman and Members of the Subcommittee, thank you for giving me this opportunity to appear before you on behalf of the Congressional Biotechnology Caucus and its 68 members to testify in support of the Biotechnology Patent Protection Act (H.R. 1417). I have the privilege of serving as co-chairman of the biotechnology caucus, along with Representative Bliley and Senators Lautenberg and Brown.

The purpose of the caucus is to help Members of Congress become aware of the problems facing the U.S. biotechnology industry and to support legislation that addresses these problems. Thus far, the only piece of legislation that has been endorsed by the caucus is the bill that is the subject of your hearing today.

Biotechnology is one of our Nation's most exciting new industries. In less than fifteen years, this industry has created 70,000 new jobs -- high paying, high tech jobs in new, nonpolluting facilities. It has created $5.8 billion in annual revenues, contributing more than $600 million to our annual trade balance. It has given doctors new tools for diagnosing and curing some of the most serious diseases known to man. Its potential in agriculture and environmental cleanup is only now being realized.

The promise of biotechnology has already been realized in health care, where virtually every biopharmaceutical approved for marketing has been deemed a "major therapeutic breakthrough" by the

FDA. Dozens of serious and life-threatening diseases are now diagnosable and treatable because of biotechnology.

Just last week, Dr. Tony Fauci, who directs AIDS research at the National Institutes of Health, told Senator Lautenberg and I that our Nation is incredibly fortunate that this terrible epidemic began after the advent of biotechnology. He said that if AIDS had occurred before biotechnology existed, we wouldn't have known what a human retrovirus was or how it works. We wouldn't be able to diagnose the disease or ensure the safety of our blood supply. We would have had no hope at all of ever developing a cure or a vaccine. He also noted that the most promising AIDS research -- and cancer research and cystic fibrosis research -- is being done by biotechnology researchers in our universities and our companies.

One thing that has become clear to me in the short time that I have co-chaired the caucus is that the enormous contributions made by this industry -- both for our Nation's health and our economy -- do not come cheap. Biotechnology is the most research-intensive industry in this country. The industry has invested $3.2 billion in R&D this year alone, an 18% increase over 1990. Biotechnology companies spend almost half of their revenue -- an incredible of $81,000 per employee -- on R&D.

This is the price for the U.S. achieving and maintaining its world leadership position in this technology. And this is the reason that improved patent protection is vital to the biotechnology industry. Without the ability to protect their

inventions from foreign piracy, American biotechnology companies simply cannot sustain this level of investment in innovation.

We in Congress often berate American industries for being too short-sighted, too oriented towards the next quarterly report, not investing in the future. This is certainly not the case for biotech companies. It takes the average biotech company ten to twelve years of huge, high risk R&D investments -- generally $100 - 200 million -- before it brings its first product to market. As far as I can tell, no other industry has such a long product cycle. Clearly, biotech companies are not impatient.

But inadequate patent protection means that a foreign company can copy an innovative product, and unfairly compete with the American pioneer. I say "foreign companies" because it is relatively easy for a U.S. inventor to obtain a gene patent that prevents domestic competition. It is ironic that current law allows foreign companies to do that which is prohibited for domestic companies. And it would be a tragedy if future biotechnology products were stamped "Invented in America; made in Japan" simply because Congress failed to staunch the hemorrage of intellectual property permitted under current law.

Mr. Chairman, the Congressional Biotechnology Caucus believes that the Biotechnology Patent Protection Act will remedy the problem and we urge the subcommittee to support it. I thank you for giving me the opportunity to present the caucus' views.

Mr. HUGHES. I would like to welcome our second witness this morning, Mr. Harry Manbeck, Commissioner of the Patent and Trademark Office. Commissioner Manbeck is accompanied this morning by Dieter Hoinkes and Charles Van Horn, of the Office of Legislation and International Affairs, and Fred McKelvey, the Patent and Trademark Office Solicitor.

Commissioner Manbeck, thank you once again for providing the subcommittee with advice, sage advice, and comments on pending legislation. We are grateful for your continued input, and we value your views very highly.

As I indicated, we have received your statement and, without objection, it will be made a part of the record in full. We hope you can summarize for us so we can get right to questions; you may proceed as you see fit. Welcome.

STATEMENT OF HARRY F. MANBECK, COMMISSIONER, U.S. PATENT AND TRADEMARK OFFICE, ACCOMPANIED BY DIETER HOINKES AND CHARLES VAN HORN, OFFICE OF LEGISLATION AND INTERNATIONAL AFFAIRS, AND FRED McKELVEY, SOLICITOR

Mr. MANBECK. Thank you, Mr. Hughes. I will present an abbreviated statement this morning, since you have our full statement for the record, I believe.

Mr. Chairman, and members of the subcommittee, I am pleased to testify on H.R. 1417, the Biotechnology Patent Protection Act of 1991. This bill would amend our patent law to afford needed additional protection for inventions, including those in the field of biotechnology. We are in full agreement with the bill's intent to improve the U.S. patent law to stimulate the development of new products and processes by discouraging unfair foreign competition.

Under present law, many inventors and patent owners have a problem. They cannot prevent importation of a product made abroad by a process which uses a material patented in the United States unless they have patent protection for the process. Although not unique, the field of biotechnology is particularly susceptible to this problem. For example, some biotechnological processes of using patented host cells to produce certain proteins are typically conventional and therefore not patentable. Thus our law currently provides an unfair advantage to unauthorized users abroad of technology patented in the United States.

H.R. 1417 would provide an effective means of protecting technology patented in the United States from unfair foreign competition because it would permit an inventor to obtain patent protection on a method of using or making a product if that product itself is patentable. Thus, a patent to the method of using a patentable material to make a product would produce a basis for filing an infringement action under section 271(g) of title 35 of the United States Code. The patentee could also petition the International Trade Commission to issue an exclusion order under section 337 of the Tariff Act of 1930. At the same time, H.R. 1417 would not grant a patentee any greater rights vis-a-vis purely domestic infringers, because under section 154 of title 35 of the United States Code the holder of a patent to an invention, such as a host cell,

may already exclude others from using that cell in the United States.

H.R. 1417 would amend section 103 of title 35 of the United States Code to ensure that under certain circumstances a process would not be considered obvious if it either makes or uses a machine, manufacture, or composition of matter that itself is novel or nonobvious. The amendment to section 103 would thus provide a mechanism for applicants who comply with its requirements to avoid a conclusion that a claim directed to a process of making or using a patentable material was obvious under this section, along the lines of the decision of the U.S. Court of Appeals for the Federal Circuit in *In re Durden.*

In following *Durden,* the Patent and Trademark Office cannot interpret the present section 103 to require that a process be held patentable merely because a patentable material was either used or made by that process.

In August of last year, the Federal circuit revisited the issue of the patentability of processes in *In re Pleuddemann,* but did not clarify the law, thus leaving patent applicants unable to predict with any reasonable certainty whether they can obtain process patents of this nature. Similarly, the Patent and Trademark Office will continue to have difficulty during examination of patent applications relating to processes in resolving the seemingly unnecessary issue of whether a process is one for making or one for using a patentable machine, manufacture, or composition.

In this respect, the amendment proposed by H.R. 1417 would simplify and provide certainty in the determination of patentability of processes using or making novel and unobvious products for applicants who comply with its requirements. The bill would also eliminate any need to resolve whether a particular process was one of making or of using a specific patentable machine, manufacture, or composition of matter.

H.R. 1417 also recognizes that a process patent might extend the period of exclusivity of a product patent or could be sought by parties other than the holder of the product patent if process claims were permitted to be patented independently of the product patent. For this reason, the bill provides that the process of making or using a patentable product will be considered nonobvious per se only if sought to be patented in the same application as the patentable product and requires that it issue as a single patent. While we completely agree that the patent term of such process claims should expire at the same time as the patent claims to the product, the bill's language may unnecessarily constrain the applicant's ability to obtain adequate protection for his invention.

In order to remedy this potential problem, we proposed an amendment to S. 654, the companion bill of H.R. 1417, when Senator DeConcini requested our views on this legislation. Since making this proposal, we have had some further thoughts on how to improve its formulation, and my prepared statement contains the specific language of our suggestions.

Legislation along the line of H.R. 1417 would provide the means that could be used by applicants who desire greater certainty in obtaining protection for processes that make or use patentable products. As part of our patent laws, this would close another loophole

that has so far provided an unfair advantage to unauthorized users abroad of technology patented in the United States.

We would be pleased to provide any assistance that the subcommittee might deem helpful to secure early enactment. Thank you.

Mr. HUGHES. Thank you, Commissioner.

[The prepared statement of Mr. Manbeck follows:]

STATEMENT OF HARRY F. MANBECK, JR.

ASSISTANT SECRETARY AND

COMMISSIONER OF PATENTS AND TRADEMARKS

BEFORE THE

SUBCOMMITTEE ON COURTS, INTELLECTUAL PROPERTY

AND THE ADMINISTRATION OF JUSTICE

OF THE

COMMITTEE ON THE JUDICIARY

U.S. HOUSE OF REPRESENTATIVES

NOVEMBER 21, 1991

Mr. Chairman and Members of the Subcommittee;

I am pleased to testify on H.R. 1417, the "Biotechnology Patent Protection Act of 1991." This bill would amend our patent law to afford needed additional protection for inventions, including those in the field of biotechnology. We are in full agreement with the bill's intent to improve U.S. patent law to stimulate the development of new products and processes. Our industry needs encouragement to expand its research and development efforts if we are to remain on the cutting edge of technology. In this respect, the United States can ill afford to let any leading, technically oriented, industry fall victim to unfair foreign competition.

Under present law, many inventors have a problem. They cannot prevent importation of a product made abroad by a process which uses a material patented in the United States, unless they have patent protection for the process. Although not unique, the field of biotechnology is particularly susceptible to this problem. Take the common example of an inventor who develops a "host cell" through genetic engineering. Such a cell can be used in a biotechnological process to produce a protein which may or may not be patentable. The inventor may obtain a patent for the host cell. However, the steps of the biotechnological process may be, and typically are, conventional apart from the use of that patentable host cell and, under current law, may or may not be patentable.

Under present U.S. patent law, the holder of a patent to the host cell would be able to preclude another from using that cell <u>in the United States</u> to make the protein. However, without patent protection for the process, the inventor has no effective remedy against someone who takes the patented host cell to another country, uses it to produce the protein, and imports the protein back into the United States. See, e.g., <u>Amgen, Inc. v. United States International Trade Commission</u>, 902 F.2d 1532, 14 USPQ2d 1734 (Fed.Cir. 1990). Thus, our law currently provides an unfair advantage to unauthorized users abroad of technology patented in the United States.

H.R. 1417 would provide an effective means of protecting technology patented in the United States from unfair foreign competition, because it would permit an inventor to obtain patent protection on a method of using or making a product, if that product is itself patentable. Thus, a patent to the method of using a patentable host cell would produce a basis for filing an infringement action under section 271(g) of title 35, United States Code. The patentee could also petition the International Trade Commission to issue an exclusion order under Section 337 of the Tariff Act of 1930. At the same time, H.R. 1417 would not grant a patentee any greater rights vis-a-vis purely domestic infringers, because under section 154 of title 35, the holder of a patent to an invention such as a host cell, may already exclude others from using that cell in the United States.

Section 2 of H.R. 1417 would amend section 103 of title 35, United States Code, to ensure that under certain circumstances a process would not be considered obvious if it either makes or uses a machine, manufacture, or composition of matter that itself is novel and nonobvious. To obtain this determination, the process and product claims must be sought to be patented in the same application. Section 2 also provides that a single patent be issued on an application containing such process and product claims.

The amendment to section 103 would thus provide a mechanism for applicants, who comply with its requirements, to avoid a conclusion that a claim directed to a process of making or using a patentable product was obvious under this section, along the lines of the decision of the U.S. Court of Appeals for the Federal Circuit in In re Durden, 763 F.2d 1406, 226 USPQ 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 "final compound" was not patentable. The Federal Circuit indicated in its opinion, however, that the patentability of each process must be evaluated on a case by case basis. In following Durden, the Patent and Trademark Office cannot interpret present section 103 to require that a process be held patentable merely because a patentable material was either used or made by that process.

The Federal Circuit revisited the issue of the patentability of processes in In re Pleuddemann, 910 F.2d 823, 15 USPQ 2d 1738 (Fed. Cir. 1990). Pleuddemann had a patent to a 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 that the method of using the patented starting material to make the patentable final product was patentable in this particular case. However, notwithstanding an attempt by the Federal Circuit to distinguish Pleuddemann from

Durden, it is difficult, if not impossible, to reconcile these two cases, as well as an earlier decision by the Court of Customs and Patent Appeals in In re Albertson, 332 F.2d 379, 141 USPQ 730 (CCPA 1964). In all three cases, a patentable starting material was used in an otherwise conventional process to make a patentable final product. Durden and Albertson characterize the process sought to be patented as a method of "making" the final product, while Pleuddemann characterizes it as a method of "using" the starting material. The distinction between Pleuddemann, on the one hand, and Durden and Albertson, on the other hand, is esoteric at best.

In our opinion, Pleuddemann has not clarified the law and leaves patent applicants unable to predict with any reasonable certainty whether they can obtain process patents of this nature. Similarly, the Patent and Trademark Office will continue to have difficulty during examination of patent applications relating to processes in resolving the seemingly unnecessary issue of whether a process is one for "making" or "using" a patentable machine, manufacture, or composition.

In this respect, the amendment proposed by H.R. 1417 would simplify and provide certainty in the determination of patentability of processes using or making novel and nonobvious products, for applicants who comply with its requirements. The bill would also eliminate any need to resolve whether a

particular process was one of making or of using a specific patentable machine, manufacture or composition of matter in those cases where patentability of such product and the process of making or using it is sought in the same application. Moreover, enactment of H.R. 1417 would make our patent law consistent with the patent granting process now practiced in the European and Japanese Patent Offices.

H.R. 1417 also recognizes that a process patent might extend the period of exclusivity of a product patent, or could be sought by parties other than the holder of the product patent, if process claims were permitted to be patented independently of the product patent. For this reason, Section 2 of the bill provides that the process of making or using a patentable product will be considered nonobvious per se only if sought to be patented in the same application as the patentable product. While we completely agree that the patent term of such process claims should expire at the same time as the patent claims to the product, the language of Section 2 may unnecessarily constrain the applicant's ability to obtain adequate protection for his invention.

For example, if a particular product can be made by a process other than that claimed in the application, or if there are several claimed processes for using the product, a patent examiner could correctly require that the product and the claimed processes be the subject of separate applications, despite the

second sentence in Section 2 of H.R. 1417. Similar results may typically occur in applications containing claims to products that could either be used in ways other than those claimed in the application, or where the claimed uses are patentably distinct from each other. Although such actions by a patent examiner would be proper, they could well defeat the intent of H.R. 1417.

In order to remedy this potential problem, as well as the possibly overly restrictive requirement that only one patent be granted on the product and processes in question, we proposed an amendment to S. 654, the companion bill of H.R. 1417, when Senator DeConcini requested our views on this legislation.

Our proposal would also add an additional paragraph to section 103 of title 35, but would further clarify the circumstances under which claims to processes of making or using a patentable product and claims to that product could appear either in the same patent or in different patents. Instead of Section 2 of S. 654 or H.R. 1417, our proposal would add the following paragraph to section 103:

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

(2) claims to the process and to the machine, manufacture, or composition of matter are entitled to the same effective filing date, and appear in the same patent or in different patents which are owned by the same person and are set to expire on the same date."

Since making this proposal, it was called to our attention that the language "... appear in the same patent or in different patents ..." might be misinterpreted to deny patentability to process claims, because they appear in a patent application rather than a patent at the time that a patent examiner determines their nonobviousness. As a consequence, we would suggest that this requirement be clarified to read "... are issued in the same patent or in different patents ..." It should also be noted that our proposal would not preclude the filing of separate patent applications for the process and the product as long as its other requirements are met.

We also proposed an amendment to section 282 of title 35 to ensure that process claims patented under the above provision would not be held invalid per se just because the product used or made by the process was determined to lack novelty or be obvious. In other words, we wanted to ensure that a determination of validity of the process claims was made independently of the product claims in the event the product claims were found to be invalid. The amendment proposed to Senator DeConcini would insert the following sentence immediately before the last sentence of section 282:

> "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."

Upon reflection, the wording of this proposal might also be improved to emphasize the intended independence of judicial review of the validity of a process claim issued under the provisions of a new third paragraph of section 103. We would, therefore, suggest that our previous proposal be reworded as follows:

> "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 entitled to the benefit of section 103(c) of this title if 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."

Section 3 of H.R. 1417 provides for the effective date of the amendment proposed by this bill. We favor the generally prospective application of the bill's provision, although it should be pointed out that it does permit a certain amount of retroactivity. First, all patent applications pending on the date of enactment of this bill would be subject to its provisions. Further, in accordance with section 251 of title 35, any patent granted no more than two years prior to enactment of the bill could be the subject of a reissue application enlarging the scope of its claims. Thus, if the original patent disclosed a process of using a host cell claimed in that patent, a reissue

application would be in order and would benefit from the new law. Of course, the enlarged scope of any reissued patent would be subject to the intervening rights provisions of 35 U.S.C. 251. Accordingly, the effective date provisions of H.R. 1417 would not adversely affect the rights of persons who relied on present law regarding their business decisions.

Legislation along the lines of H.R. 1417 would provide the means that could be used by applicants who desire greater certainty in obtaining protection for processes that make or use patentable products. As part of our patent laws this would close another loophole that so far has provided an unfair advantage to unauthorized users abroad of technology patented in the United States. We would be pleased to provide any assistance that the Subcommittee may deem helpful to secure early enactment.

* * * *

Mr. HUGHES. Commissioner, I don't know whether you have had an opportunity to read the statement submitted by the American Intellectual Property Law Association. They will be testifying on one of the subsequent panels. Have you?

Mr. MANBECK. No, sir, I have not.

Mr. HUGHES. Well, among other things they make the following observations, and I would like your response. They say, first of all, the "bill would impact all fields of technology and would benefit many foreign research-based corporations at the expense of American enterprises and consumers. In fact, since foreign corporations are granted more utility patents than American corporations, the benefit bestowed to foreign corporations is likely to outweigh the benefit to U.S. interests."

What do you have to say about that?

Mr. MANBECK. Well, I have considerable difficulty in following that argument. We are talking about granting a patent for a process based on he existence of a patentable product. Now, the foreign corporation can get its patent on the patentable product here and can assert that patent against U.S. manufacturers. We are talking the absolute converse of that of our people being able to get a patent here on the product and also being able to get a process claim so that they can enforce their—let me say enforce their invention, if I may, against imports made with the use of that product. That is not a correct term of art. But so that they can have an enforceable right to prevent the importation of a product that was made overseas with the use of technology patented in the United States.

Also, I might point out, although I do not have the exact statistics with me today, the proportion of applications filed in the United States by domestic applicants, as contrasted to those filed by foreign applicants, has gone up again last year. This is a 3-year trend now. Not a large trend, but the proportion filed by U.S. applicants is going up, rather than down.

Mr. HUGHES. Thank you. AIPLA also makes the following observations, and let me just tick them off. Maybe you can briefly respond to them.

The bill proposes an amendment to 35 U.S.C. 103 that is not needed. Its primary purpose is to protect the U.S. biotechnology industry from unfair competition, but its proponents cite no case of commercial harm to a U.S. company that this bill would have prevented, and we do not believe that a threat of such harm exists. That is the first one.

Second, the bill would implicitly repudiate one possible interpretation of a single appeals court decision in *In re Durden,* by codifying an earlier decision in *In re Mancy.* If the Patent and Trademark Office examiners are currently apply *Durden* overzealously, such erroneous applications can be promptly corrected by appropriate appellate procedures and should be immediately corrected by the PTO as a matter of administrative policy.

Third, the bill sets an unfortunate precedent and damages the patent system's credibility by implying that certain classes of patent claims escape full PTO examination and are subject to a different, weaker patentability standard.

Fourth, the bill would jeopardize existing patent rights and increase the number of persons potentially liable as patent infringers.

And, fifth, the bill would add a provision to our patent statutes that does not exist in the European Patent Convention, the Japanese patent statutes, nor, to our knowledge, in the patent laws of any other country.

I wonder if you could respond to each of those comments.

Mr. MANBECK. Mr. Hughes, I would like to respond—thank you.

Mr. HUGHES. Just start with "the bill proposes an amendment basically to protect the biotechnology industry from unfair competition when there is no indication that any has suffered harm or will suffer harm."

Mr. MANBECK. Well, I believe they say the proponents cite no case of commercial harm to a U.S. company that this bill would have prevented. It has been my understanding that there was quite a grievous case of harm involving the Amgen Corp., who has a patent to a product, does not have a process claim, and as a result has been unable to prevent the use of its product overseas to produce products which are brought back into the United States. So I do not believe that first statement is correct.

Now, as for the second statement, which talks about repudiating one possible interpretation of a single appeals court decision, *In re Durden*, and then says—indicates that Patent and Trademark examiners are currently applying *Durden* overzealously and that this could be corrected by appropriate appellate procedures and should be immediately corrected by the PTO.

Mr. HUGHES. They say if, it is being applied overzealously.

Mr. MANBECK. Well, in the first place, we do not believe that the examiners are applying the *Durden* decision overzealously. In the second place, we must follow the decisions of the court of appeals, and once a decision is issued by the court, if we don't follow it, all that will happen is those affected by it will appeal to the court, the Patent and Trademark Office Appeals Board will be overturned, and we will have to issue the patent anyway. And I do not see how the PTO can correct this problem simply through a matter of administrative policy. The court has said the law is this, and just as we are bound to follow the statutes enacted by the Congress, we are bound to follow the decisions of the court.

Mr. HUGHES. Can you reconcile the *Durden* decision and *Mancy* decision?

Mr. MANBECK. May I have just a minute?

Mr. HUGHES. Sure.

[Pause.]

Mr. MANBECK. No, sir, we cannot reconcile them. The *In re Mancy* decision, I am advised by Mr. McKelvey, is sort of like *Pleuddemann*, and we regard these decisions to be in conflict and irreconcilable.

Do you wish me to go ahead with the third question?

Mr. HUGHES. Just to follow up on that, and then we will go on to the third one. Isn't it possible to basically file a test case at this point?

Mr. MANBECK. Well, we really regarded *Pleuddemann* as a test case and hoped the court would straighten it out, and they didn't.

Mr. HUGHES. I understand.

Mr. MANBECK. And, if we take a case up on the issue of making, any panel is bound to follow the decision of the prior panel unless they would convene the whole court.

Mr. HUGHES. OK. Thanks. The third point he makes is the precedent.

Mr. MANBECK. Well, first of all, I don't agree that the bill would set an unfortunate precedent, and I do not believe it would damage the patent system's credibility. It does not imply that certain classes of patent claims would escape full examination or are subject to different, weaker patentability standards. All the bill says is that as to obviousness, section 103, that would not be taken into account in examining the process claim if there is a novel product made or used.

Now, if the product is shown in an infringement suit to be unpatentable, in other words, the patent is invalid as to the product, the effect of the bill will disappear. In other words, the process claim will be judged totally on its own merits. So I don't see how it weakens the credibility of the system. Either you have an invention or you don't have an invention. The process claim is an alternate way of stating it, in effect, so that the patent statute will reach people abroad who otherwise will have an unfair advantage.

Mr. HUGHES. I understand. The fourth one was the possibility of jeopardizing existing patent rights and increasing the potential liability as patent infringers.

Mr. MANBECK. Well, how can it—I wish somebody could explain—I am sure they will explain how it will jeopardize existing patent rights.

Mr. HUGHES. Well, we will get a chance to ask them.

Mr. MANBECK. But I don't understand how it would. And, as far as increasing the number of persons potentially liable as patent infringers, yes, sir, it will. It will.

Mr. HUGHES. I guess that is the idea. That is the idea of the whole thing.

Mr. MANBECK. Yes, of course.

Mr. HUGHES. That occurred to me. How about the fifth one? That there are no parallel statutes in Europe or in Japan?

Mr. MANBECK. It is technically correct that the EPC and the Japanese patent statutes do not contain this language. But it is our understanding that the EPC and Japanese practice is similar to that which is proposed by H.R. 1417. They don't need a statute because they don't have to follow *Durden*.

Mr. HUGHES. Or other things for that matter.

The gentleman from California.

Mr. MOORHEAD. Well, thank you, Mr. Chairman.

As you know, I have a letter from Mr. Sweet, of the University of California, supporting H.R. 1417. However, they have requested an amendment that reads as follows: "A product may not be patented when the only description of the product is by the process by which it was made and the product is merely speculative."

According to the University of California, some commercial firms are trying to use biological materials, mechanisms associated with biological materials, and kits associated with biological materials to claim rights to a university's invention, when the tool is merely one

part of an experimental procedure worked out independently by the university researcher.

According to the university, such an overreaching demand of patent rights can create obstacles to obtaining research funding and can limit the ability of the university to transfer any inventions resulting from the research.

Would the administration have any objection to this amendment?

Mr. MANBECK. Mr. Moorhead, I saw this only this week for the first time, and therefore would like an opportunity to study it further.

Mr. MOORHEAD. We will be glad to give you a copy of the letter and would appreciate a written response.

Mr. MANBECK. I have an immediate reaction, if you would be interested in that. But, as I say, this is only an immediate reaction and we do appreciate your willingness to let us study it.

Mr. HUGHES. The record will remain open for you to submit a response.

Mr. MANBECK. Well, perhaps it is better not to state the immediate reaction and be sure.

Mr. MOORHEAD. Well, I think probably that is a good idea, because it will be better if we have a chance to study the issue.

[The information follows:]

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SEP 10 1991

September 11, 1991

The Honorable William Hughes
United States House of Representatives
341 Cannon House Office Building
Washington, D.C. 20515

Dear Representative Hughes:

As Senior Vice President Brady has written to you in his letter of August 6, 1991, the University of California supports H.R. 1417, the Biotechnology Patent Protection Act. We would, however, like to request an amendment that addresses an issue of particular interest to research universities.

The language we propose would add a new section to the end of 35 USC 101, as follows:

> A product many not be patented when the only description of the product is by the process by which it was made and the product is merely speculative.

The University of California and other nonprofit institutions are experiencing increasing attempts by some originators of biological research "tools" to claim rights in the recipient's inventions merely because a particular research tool was used in the recipient's research where the originator of the tool has not further contact with the research. Specifically, some commercial firms are trying to use biological materials, mechanisms associated with biological materials, and kits associated with biological materials to claim rights in a University's inventions when the tool is merely one part of the experimental procedure worked out independently by the University researcher. The tool originator is in no way a coinventor under the patent law or otherwise a collaborator in the research.

Such an overreaching demand of patent rights can create obstacles to obtaining research funding and can limit the ability of the University to transfer any inventions resulting from the research.

Another difficulty is that much of University research is conducted under federal funding. The Federal policy contained in 35 USC 200,

et seq. is that a University interested in commercializing an invention arising in the course of its federally funded research is the best party to seek out responsible licenses to carry out the commercialization. The contractual burden of allowing an originator of a research tool to have some form of first right to such an invention without evidencing any commitment or capability in the area of the invention substantially subverts the Federal policy of facilitating technology transfer.

The law change we propose would make it clear that originators of research tools without further contribution to another's research are not entitled to patent protection for the intellectual achievements of those others.

Please let me know if you would like further information on this proposal, and thank you for considering our views.

Sincerely,

Paul E. Sweet
Director, Federal
Governmental Relations

cc: President Gardner
Senior Vice President Frazer
Senior Vice President Brady
Vice President Baker
Director Wootten

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

17 DEC 1991

Honorable William J. Hughes
Chairman
Subcommittee on Intellectual
Property and Judicial Administration
Committee on the Judiciary
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

During the recent hearing before your Subcommittee on H.R. 1417, the Biotechnology Patent Protection Act of 1991, Mr. Moorhead informed the Subcommittee of a proposed amendment received from the University of California.

Specifically, the University of California proposes to add the following sentence to section 101 of title 35, United States Code:

> "A product may not be patented when the only description of the product is by the process by which it was made and the product is merely speculative."

It is our understanding that this request springs from the concern by the University of California and other nonprofit institutions that the owners of patented biological research "tools" are somehow attempting to claim rights on inventions derived with the use of such tools, although the inventors of the research tools have had no connection or contact with the persons who made the inventions with the help of such tools.

We do not believe that the proposed amendment is necessary. Under present law, the inventor of a research tool who obtains patent protection for the tool itself may exclude others from making, using and selling that tool. However, if the patentee places the tool in the marketplace and it is bought by somebody for research purposes, there is an implied license that the tool may be used without fear of patent infringement for the purpose for which it was intended and marketed. Therefore, the owner of a patent on a tool cannot claim any rights in the inventive results derived from the very use for which that tool was sold. For example, the owner of a patent on a mechanical pencil does not have any rights in the drawings created with the use of that pencil.

Products may be patented even though they are only described by the process by which they are made. However, the patent specification must contain a description of that process in such full, clear, concise and exact terms as to enable any person skilled in the art to which that invention pertains to practice that process without undue experimentation. Accordingly, it is not possible to obtain patent protection on a product that cannot be described or which is alleged to be made by a process that also cannot be described.

I hope that my comments are helpful in explaining why the amendment proposed by the University of California is not necessary.

Sincerely,

Harry F. Manbeck, Jr.
Assistant Secretary and Commissioner
of Patents and Trademarks

Mr. HUGHES. Mr. Moorhead would not know what your immediate reaction would be, so.

Mr. MANBECK. Thank you.

Mr. MOORHEAD. Amgen is recommending an amendment to H.R. 1417 that would deal directly with what they see as an emerging problem for the biotech industry, and that is the need to prevent the importation of products of patented host cells. Would you comment on their amendment?

Mr. MANBECK. Well, of course, that is what H.R. 1417 is all about, is to prevent the importation of the products of the patented host cells, and we believe that it provides a very effective mechanism for doing it as the bill is now worded.

We have a problem with their amendment, which, in effect, creates a product-by-product claim. The Congress some years ago took up this problem in a general sense of protecting products which are made overseas by processes that would be infringing if those processes were practiced in the United States. And the bill as it emerged and is now in our law provides certain protections. Specifically, it is section 271(g) of title 35, and it provides two limitations which, if the Amgen amendment were enacted as such, would not apply to product-by-product claims as it now applies in the case of a process patent.

I think we are looking at the same thing here. The idea is to protect the U.S. patentee if somebody abroad uses his product. Your bill would accomplish this with process claims.

And specifically, 271(g) provides the following two limitations. In an action for infringement no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use or sale of the product. In other words, this is trying to protect the retailer and make sure that if the process is practiced overseas the patent owner will first proceed against the importer or the major distributor.

The second point is that a product which is made by a patented process will for purposes of this title not be considered to be so made after (1) it is materially changed by subsequent processes or (2) it becomes a trivial and nonessential component of another product.

Now, perhaps the Congress wishes to change this, I don't know. But, if the Amgen amendment were enacted as such it, in effect, would just wipe those out.

Another point is that there is confusion created by the Amgen amendment itself due to the wording of the statute, and we can go into that, but it deals with the use of an essential material and then a further definition that some things are outside the definition of an essential material, and we think it would create quite a bit of confusion.

Mr. MOORHEAD. I have some other questions, but I think my time has expired.

Mr. HUGHES. The gentleman from Virginia.

Mr. BOUCHER. Thank you very much, Mr. Chairman. Mr. Manbeck, I would like to thank the Patent and Trademark Office for its comments this morning in support of our legislation.

A couple of questions will be raised in testimony from some of the other witnesses. I would like to get you to respond to them.

The suggestion has been made that the legal uncertainty created by the *Durden* decision has been clarified in the *Pleuddemann* case. I would like your comment on whether in your view *Pleuddemann* was helpful in this process or simply served further to muddy the water. As I read it, it basically says that any time that the claim relates to manufacture, as opposed merely to use, the process patent claims still cannot go forward.

Is that your reading? And, if it is, how could that possibly help the biotech industry?

Mr. MANBECK. Well, it is our belief, sir, that *Pleuddemann* doesn't help the biotech industry. That, as you pointed out, *Pleuddemann* says it can be patentable if it is used. *Durden* says not patentable if made. We think they are irreconcilable and we do feel that legislation is necessary to resolve the conflict.

Mr. BOUCHER. Of course, in the biotech example what they are doing is manufacturing. They are making something. And so under the direct statement of *Pleuddemann,* their process patent claim could not go forward. That is pretty clear, and I take it you agree with that.

Mr. MANBECK. Excuse me, sir. I have had advice from both sides. Could you repeat it again, please?

Mr. BOUCHER. Yes. In the case of the biotech industry, the process is used on a novel starting material to manufacture a product. And, as we read *Pleuddemann,* or certainly as I read *Pleuddemann,* as long as the process for which the patent is claimed is one that is involved in manufacturing, making something as opposed merely to using something, then the process patent claim would fall. Is that your interpretation as well?

Mr. MANBECK. Yes, sir. We get to a use of semantics. And maybe a clever attorney somehow can craft a claim for using something instead of making, but we shouldn't let valuable patent rights be avoided by overseas manufacturers based on semantics.

Mr. BOUCHER. So, at the very least you would certainly agree that the *Pleuddemann* case does nothing to clarify the situation. At worst, it could make the situation more difficult from the standpoint of biotech companies that are involved in manufacture and need this patent protection?

Mr. MANBECK. Yes, sir. That is our opinion.

Mr. BOUCHER. Now, given that muddled state of the law, and the confusion that currently exists, and the fact that claims from biotech companies are in fact being denied today as a result of that muddled state of the law, what do you have to say of the suggestions of some witnesses who will come before us today and suggest that Congress do nothing, that we simply sit back and wait until the courts clarify this, that we simply sit back and hope that the Patent and Trademark Office through its able lawyers can figure out some way to disregard the current state of the law and award these process patent claims anyway? Does that not in your view, perhaps, misconceive the role of the Congress? Is there any state of facts under which we should sit back and simply wait until the courts or the PTO through a period of, perhaps, years more of liti-

gation have resolved this uncertainty? Or would it be better for us to move forward at the present time?

Mr. MANBECK. I think the best thing I can say, Mr. Boucher, is that not just the PTO but the administration recommends legislation in this circumstance. It believes it is necessary.

Mr. BOUCHER. And, if we relied on the courts to do this that could take years.

Mr. MANBECK. Yes.

Mr. BOUCHER. And we are not guaranteed that a proper result would be forthcoming in any event.

Mr. MANBECK. Yes, sir. It will take a while and you can't be sure how it is going to come out.

Mr. BOUCHER. And, in the meantime, a lot of claims that could be awarded if this bill passed would be denied?

Mr. MANBECK. That is correct.

Mr. BOUCHER. All right. Thank you very much, Mr. Manbeck.

Mr. Chairman, that is all I have.

Mr. HUGHES. The gentleman from North Carolina.

Mr. COBLE. Thank you, Mr. Chairman. Commissioner, good to have you all here.

Commissioner, there is more about the law of patents and trademarks that is unknown to me than is known. So having said that, let me plunge into this question.

As I understand the current law, an offshore company is permitted to use host cells with U.S. patents to make unpatented end products and sell them in the United States; whereas, domestic companies are prohibited from such practice. Now, this seems to me to be inconsistent at best and flawed at worst. Furthermore, I think it would open the door to permit companies to compete with those who actually invented the product.

First of all, is my interpretation correct? And, if so, is this an area where the Congress should correct it?

Mr. MANBECK. Sir, I think your impression is generally correct, and I do think it is a situation in which the Congress should act to correct it.

Mr. COBLE. One more question, Commissioner. Do you have any suggestions along those corrective courses that we should follow?

Mr. MANBECK. Yes, sir. We have reviewed the bills, this bill and the companion bill in the Senate, very carefully. We have already made some suggestions which have been incorporated in the bill, and there is what I hope will be a final suggestion in my prepared full statement.

Mr. COBLE. OK. Thank you.

Mr. MANBECK. We think the bill is really in very good shape now, but we do think there is one more clarification which would be desirable.

Mr. COBLE. Gentlemen, as you know, the National Association of Manufacturers, which is the largest trade association representing generic drug manufacturers, has expressed opposition to this bill because it is not limited in application to biotech patents. Should the bill be so limited?

Mr. MANBECK. The administration's position is that it should not be so limited. We feel the problem can exist in other areas and that

as a solution is being crafted this is a good time to take care of possible future problems in other industries too.

Mr. COBLE. Thank you, gentlemen. Thank you, Mr. Chairman.

Mr. HUGHES. Commissioner, one of the suggestions that has been made is that instead of pursuing the approach taken in H.R. 1417 Congress should amend 35 U.S.C. 271(g) to prevent the importation of a direct product made using a patented composition of matter. What are your views on that score?

Mr. MANBECK. Well, sir, I would have to study it. But, just off the top of my head, composition of matter, that would have to be a new composition of matter. Is that which comes out of the host cell a new composition of matter or not, I don't know. I think that—or is the host cell a composition of matter? So, I just don't know.

It seems to me that the drafters of this bill have provided a good solution to the problem created by the *Durden* case, and that is simply to remove the nonobviousness rejection, and I think we might be better to go forward on that than continue to search for still other ways to do it.

Mr. HUGHES. Well, the record will remain open. If you would like to give that some additional thought and talk, basically, to those in your shop that would have that expertise, we would be very happy to receive your comments.

The gentleman from Virginia, I yield to you.

Mr. BOUCHER. Let me just ask one additional question, Mr. Chairman.

If we accepted that recommendation and simply said that an item made in another country using a starting material that was patented in the United States could not be imported back to the United States, we would forego the opportunity that we have in this bill to award process patent protection here in the United States itself.

Mr. MANBECK. Yes.

Mr. BOUCHER. Now, is it not true that in Japan and in Europe there is a regimen of process patent protection in the circumstances contemplated by this bill already in force which we would then not have in the United States if this bill and its approach were not enacted?

Mr. MANBECK. I believe so. Yes, sir. I remember in my own experience when I was in industry being able to go after a company in France because of what they did in Italy because of the opportunities available under the French process patent.

Mr. BOUCHER. Under the process patent?

Mr. MANBECK. Yes.

Mr. BOUCHER. So, even if the other solution might solve one set of problems, it still would forgo the opportunity to modernize our biotechnology patent protection law—well, our general patent protection law, by giving inventors in the United States who appropriately use these processes the same kinds of protection that already exist in Japan and Europe and other places?

Mr. MANBECK. I think so, sir.

Mr. BOUCHER. OK. Thank you so much.

Mr. HUGHES. Well, you can, obviously, consider those particular problems as well as any others that you might have with that par-

ticular approach, and we would be very happy to receive your formal response to the question.

Mr. MANBECK. Thank you.

[The information was not supplied.]

Mr. HUGHES. Given recent grants on patents on processes using computer software technology, what is the impact of the proposed legislation on software process patents?

Mr. MANBECK. Well, first of all, a process claim will not be rejected for obviousness if there is a novel product. So you have to start out in the first place with the patentable product. In the United States today, if you have a patent on the product, be it in the computer world or anyplace else, you can prevent an infringer from proceeding and using your patented product. I think this bill would apply in the computer world just as it applies everyplace else, if you have the product patented. And somehow, I don't know quite what that product would be, but if you have that product, someone takes it overseas and uses it overseas in a process to make something else, this bill would enable you to reach that ultimate product as it comes back into the United States. And, again, it seems to me there is some desirability to protect the people in the United States who spend tons of money in that endeavor. In that area, I should say.

Mr. HUGHES. Has there been any indication we have had a similar problem in the software process patent area?

Mr. MANBECK. If we have, it has not been brought to my attention.

Mr. HUGHES. I see. Could PTO resolve the current problem by treating all applications for a process for making a recombinant product through use of a host cell as a method of using as defined in *Pleuddemann,* as well as relying on *In re Durden?* And, in the alternative, would applicants identify in their claims the method of using claims and overcome *Durden* in that way?

Mr. MANBECK. The attorney can come in and say he is using it, and, perhaps, our examiners would be able to go along with it. But the problem is that you are ultimately going to get in that circumstance to a court test, not only in the granting of the patent, but in an infringement action, where somebody is going to say:

"This isn't a method of using, this is a method of making." Under *Durden,* the court of appeals has set the law. They must follow the law. Therefore, your patent is invalid."

I think we are asking for a situation where ultimately there will be litigation to settle the law, which is unnecessary if the bill passes.

Mr. HUGHES. What is the Patent and Trademark Office policy on patenting biotechnology processes, specifically the process of using a host cell to produce a recombinant final product?

Mr. MANBECK. If the process itself is novel, that is, irrespective of the host cell, a patent will be granted on the process. If the process, however, is not novel in its own right, then the Patent Office will not grant a patent.

But I would like to point out to you, Mr. Hughes, and to the other members of the subcommittee that this bill will not take anything away from the applicant whose process is patentable in its own right. He can get a separate patent for that and that patent

need not be coextensive with the product patent, and if the product patent should, unfortunately, fall, it would not fall with it.

Mr. HUGHES. I just have one further question. With respect to chemical and electrical technologies that have been developed in recent decades, specifically the processes, haven't our patent laws been sufficiently flexible enough to basically accommodate those developments? In your view, is biotechnology somewhat unique?

Mr. MANBECK. I am not sure. It has been presented here for the first time as a major problem in the biotech area, but foreign competition is ever increasing. Our industry is dealing more and more in a worldwide economy and problems which may have been minor in other areas in the past may become major. So I don't want to give an absolute answer, Mr. Hughes, to that.

Mr. HUGHES. Well, maybe you can give some thought to that, because that is a question that occurs to me, you know, what is it about biotechnology basically that has given rise to the problem, when we have had other industries that have evolved remarkably, other technologies that are evolving that we never contemplated. But we have had the particular problem in biotechnology. I am not aware of any other areas, but maybe there are.

Are there any other areas, to your knowledge, that have had similar problems?

Mr. MANBECK. Not that have been brought to my attention. Although as Mr. Hoinkes points out to me, *In re Durden* does not deal with the biotech area. Every era has a precursor, and I am not sure that that is not what we have here.

Mr. HUGHES. Does the gentleman from North Carolina have any further questions?

Mr. COBLE. Just one final question, Mr. Chairman.

Mr. HUGHES. The gentleman from North Carolina.

Mr. COBLE. I was going to ask this earlier, Commissioner, and forgot to. And I am not interrogating, I am asking. I want to know, if you can tell me, what is the average charge that a patent attorney would impose for the research and filing of a patent application, number one? You may not be able to tell me that right now.

And, number two, is there anything that we can do that would result in a decrease of costs of patent prosecutions and litigation to the benefit of the clients involved?

Mr. MANBECK. Sir, I am very hesitant to state the average cost for a patent application because they vary so in complexity, particularly as the subject matter itself becomes more difficult to deal with.

Mr. COBLE. Yes. I realized that would be difficult.

Mr. MANBECK. But, you know, you have to feel—you have to believe that in most cases a patent lawyer will charge some thousands of dollars to prepare and prosecute a patent application. It is a complex job and it needs to be done very carefully, because the patent document, after all, has to last and survive possible attack for 17 years after it is issued.

Now, as you know, the Secretary of Commerce has created a commission to study the laws and possibly make recommendations to the Congress. Two of the items that are being studied are, first of all, the cost and complexity of litigation. I don't know that anything will come of that. A lot of people have looked at that. Every-

body feels it would be desirable to cut it down and make it cheaper, but nobody has been able to come up with really concrete suggestions which would allow each side to present its case properly and believe it had had a fair chance.

The other item as part of our deliberations is that, say we are looking at the possibility of enabling people to enter the system, just as an initial document, with a less formal document than they have today. Under the statute today, the patent applicant must submit a full and complete disclosure of his application, including the best mode, and he must include claims in his application as to what his invention is. This is very desirable, so that the world knows not only what the invention is, but the metes and bounds of it.

But some countries have what is known as an internal priority document which allows people to file a first, less complete document, sort of a provisional specification. This can be prepared for less money, and the Patent Office need not charge as much since it really is never processed. But at least it allows you to establish a date. Prove up your invention, as it were, as of a certain date. And it may be that—and I don't say that it will, it may be that the commission will wish to present something along that line to the Congress.

Mr. COBLE. Thank you. Thank you, Mr. Chairman.

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

Mr. BOUCHER. Nothing further, Mr. Chairman.

Mr. HUGHES. Commissioner, thank you. Once again, you have been very helpful to us. I do appreciate your contribution today.

Mr. HUGHES. Our next witnesses are Mr. Dennis D. Allegretti, Ms. Lita L. Nelsen, and Mr. George W. Ebright.

Mr. Allegretti is an attorney with the law firm of Allegretti & Witcoff, and he has a special expertise in patent law and biotechnology. Ms. Nelsen is the associate director of the Technology Licensing Office at M.I.T. And Mr. Ebright is chairman and chief executive officer of the Cytogen Corp. in Princeton, NJ, and is here today testifying on behalf of the Industrial Biotechnology Association.

I commend each of you for the special and important contributions that you have made to promoting biotechnology research and innovation and welcome you here today. We have each of your statements, which we have read, which, without objection, will be made a part of the record. We hope you can summarize for us, so we can get right to questions, but you may proceed as you see fit.

Why don't we begin with you, Mr. Allegretti? Welcome.

STATEMENT OF DENNIS D. ALLEGRETTI, PARTNER IN THE LAW FIRM OF ALLEGRETTI & WITCOFF, CHICAGO, IL, AND BOSTON, MA

Mr. ALLEGRETTI. Thank you, Mr. Chairman, members of the subcommittee. I would like to make it clear at the outset that I am here as a private citizen. I am not here testifying on behalf of any of the many clients I represent in the biotechnology field. I am here, in proof of that, at my own expense.

I have a personal viewpoint. It is a viewpoint that I hold strongly. I feel a duty to express it, and I hope that it will be considered by the subcommittee.

I have direct personal litigation experience with respect to the very problem that is being addressed by this bill. I represented Amgen in its litigation against two defendants: One a U.S. company, the other a Japanese company. The action was based on the same patent, a patent covering a host cell which produces recombinant erythropoietin, called EPO, a natural human substance which cannot be successfully separated from human sources in any significant quantity, but which can now, as a result of Amgen's patented efforts, be produced in unlimited quantities for human therapeutic use.

In that litigation the host cell patent was held to be valid, enforceable, and infringed by the U.S. company, who used the host cell to make erythropoietin in the United States. The same patent and claim was held to be not infringed by a Japanese company in the use of the same patented host cell and technology in Japan to make the same recombinant erythropoietin product and to then import it into the United States. This is precisely inequitable difference that the subcommittee is addressing and which the bill is intended to solve.

The harm to Amgen, in being able to deal with a U.S. competitor under its valid patent rights but being unable to deal with a Japanese competitor under those same patent rights, was a clear and definite harm, and it was caused by the lack of a process claim. Relief was sought under the Tariff Act and was denied because Amgen's patent to the host cell did not include a so-called classic process claim. Its relief against the Japanese defendant similarly is unavailable for the importation of the recombinant EPO product.

One of the members asked, What is the difference between the recombinant product and the natural product so far as the PTO is concerned, and might it be solved by permitting patentability of the recombinant product as such, even though it may be identical to the human product? The position of the PTO has been to deny, thus far, the patenting of any recombinant product which is identical to the human product or substantially the same, and I know of no court decision that has addressed that and indicated that it should be patentable. There is no solution in that direction is what I am suggesting.

The loophole that exists now in the patent law and under the Tariff Act, I think very strongly, needs to be plugged to cure the unfairness in competition between the U.S. inventor and an American competitor acting in the United States, on the one hand, and a foreign competitor acting in a foreign country and then importing into the United States, on the other hand.

I am concerned that there is one problem that the bill does not presently address. I have no specific proposal for it, although as a lawyer I can conceive of drafting language that would address the problem, and that is, those patents which already exist to important biotechnology inventions and which contain claims only to such substances and materials that are used to make an end product, as the DNA sequence and the host cells, patents which have resulted by reason of rejections under *In re Durden* of process claims and which have resulted in the acquiescence by the applicant for one reason or another, usually lack of cost capability, and

patents have therefore issued without process claims because of the existing practice in the Patent Office in obedience to *In re Durden.*

Those patents which lack the process claims can address very important invention subject matter, and later inventors will be able to solve their problems under this bill, whereas those prior inventors and prior patentees were unable to solve the problem. The kind of inventors that would be affected, I believe, are universities, small research institutions, and smaller startup biotechnology companies whose efforts require the earliest possible issuance of patents at the lowest possible cost. And it wasn't possible to take the avenues that have been suggested by opposers of the bill, to take appeals and keep carrying the matter upward, higher and higher, in an effort to finally get that to which they were entitled. They simply succumb to it.

One suggestion I have made in my paper is that a corresponding amendment to the patent law, to section 271, to provide that the use of these materials in a foreign country to make the end product would in itself be an act of infringement when the product is imported into the United States. So that there would be no requirement for a process claim. Even though the bill permits such process claims to be obtained, and it should, and I strongly support that, there is a way to also give relief to those present patentees who lack process claims in their patents but who have made important inventions and have patented the materials used to make the final recombinant product.

Thank you for the opportunity to address the subcommittee.

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

[The prepared statement of Mr. Allegretti follows:]

Prepared Statement of D. Dennis Allegretti, Partner in the Law Firm of Allegretti & Witcoff, Ltd., Chicago, IL, and Boston, MA

Mr. Chairman and Members of the Committee, I am Dennis Allegretti. I am a partner in the law firm of Allegretti and Witcoff. I am a patent trial attorney. For the past 38 years, I have represented companies ranging in size from fledgling biotechnology start-up companies, which have some of this country's brightest scientists and the patent rights produced by them as essentially their only assets, to multibillion dollar "Fortune 100" companies. I have served as lead trial counsel in the successful enforcement of such biotechnology patents as those relative to Amgen's recombinant erythropoietin and Genentech's tissue plasminogen activator. In my trial practice and advisory work related to litigation matters, I have seen first hand just how industry in the United States has been disadvantaged by the denial by the United States Patent and Trademark Office ("PTO") of effective process patent claims because of its interpretation of the United States Court of Appeals for the Federal Circuit ("CAFC") decision of *In re Durden*[1]. Nowhere is that disadvantage more evident than in biotechnology, the present crown jewel of American technology.

BACKGROUND

International Trade Commission

Section 337(a)(1)(A)(ii) of the Tariff Act of 1930 defines an "unfair act" as:

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

The Omnibus Trade and Competitiveness Act of 1988, Pub.L.100-418 reenacted but did not modify that important section.

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[1] 763 F.2d 1406.

The ITC (U.S. International Trade Commission) and the Federal Circuit have made it abundantly clear that the language of §337 requires so-called classic process claims[2]. In the Amgen case involving recombinant erythropoietin or "EPO", Amgen had obtained patent claims to genetically engineered host cells and DNA sequences essential to the bioengineering of EPO. The PTO, under the authority of *In re Durden*, refused to grant claims to the use of the host cells to make recombinant EPO. Thus, Amgen was unable to utilize §337 to prevent the importation of recombinant EPO made by using Amgen's patented host cells, the only way to produce that product.

While the Amgen case has perhaps served to particularly focus the issue for biotechnology, it also serves to illustrate the far more general problem confronted by U.S. business. For example, the use of a patented catalyst or a patented computerized machine outside United States to make products for importation into the United States is also unprotected in the absence of the classic process claim required by the ITC and the CAFC.

The Durden Problem

The problem finds its bad seed in the application of *In re Durden* by the PTO. During the six years since that case was decided by the CAFC, it has become increasingly difficult to obtain from the PTO usefully effective process patent protection in the United States. This has been especially true for genetic engineering inventions.

The PTO frequently if not regularly cites *In re Durden* in denying patents to such processes. This denial of process claim protection is routine even where the starting materials used by the process are found by the patent examiner to be separately patentable in their own right.

Qualified commentators[3] and legal practitioners have strongly urged that *In re Durden* is applied by the PTO in a fashion that wrongly denies process patent coverage essential to the full protection of U.S. business from competitive imports which would otherwise infringe if made in this country.

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[2] *In re Certain Recombinant Erythropoietin*, 10 USPQ2d 1906 (US ITC 1989), 37 PTCJ 647; *Amgen Inc. v. ITC*, 14 USPQ2d 1734 (CAFC 1990), 40 PTCJ 3.

[3] 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?,"; Beier and Benson, "Biotechnology Patent Protection Act," 68 University of Denver Law Review, 173 (1991).

In re Durden says, in effect, that despite the use of separately patentable starting materials in the making of a product one cannot also obtain a classic process claim unless it can be demonstrated that "unexpected results" occur during the use of the full process. When "unexpected results" cannot be shown, such process patent protection cannot be obtained. Indeed, even when "unexpected results" can in fact be demonstrated during use of the process, some applications are nevertheless still rejected as "obvious" by the PTO.[4]

The application by the PTO of *In re Durden* to biotechnology cases, which involve the use of living microorganisms, is in direct conflict with *In re Mancy*[5] and other cases[6]. *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.

Indeed, the reasoning in *Mancy* is the law for inventions in Europe and Japan, both of which have a long tradition of allowing the patenting of process inventions that use patentable starting materials.

35 U.S.C. 271(g)

The Patent Code was amended in 1988 to make process activities performed outside the U.S. acts of patent infringement for which relief can be obtained in a Federal District Court. §271(g) provides:

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[4] A recent case, *Ex parte Orser*, 14 USPQ2d 1987 (Bd. of Pat. App. and Inter. 1990), illustrates how 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.

[5] 499 F.2d 1289 (C.C.P.A. 1974)

[6] *E.g., In re Kuehl*, 475 F.2d 658 (C.C.P.A. 1973).

> "Whoever without authority imports into the United States or sells or uses within the United States a product which is made by a process patented in the United States shall be an infringer...."

§271(g) also requires a process claim subject to rejection by the PTO under *In re Durden*.

Under present law, an inventor is helpless to prevent the importation of a product that was made abroad, despite the use in its making of a critically essential material which is itself patented in the United States, unless the U.S. inventor is also able to obtain patent protection for the process of using such a patented material. The field of biotechnology is particularly susceptible to this problem.

The net result of the present law is to create an uneven playing field for U.S. business against foreign competition. The U.S. patent law provides the patent owner with the right to exclude U.S. companies from making, using, or selling patented articles, such as (for example) genetically-engineered host cells, catalysts, or machines, in the United States. The U.S. patent law provides no uniform protection, however, for the use of such vital and patented materials outside the United States for making an important product and importing that product into the U.S. I urge that it is fundamentally unfair that a foreign company can use patented U.S. technology overseas to make products for importation into the U.S., while a competing U.S. company cannot lawfully use that technology in the U.S. to make the same product. Foreign companies can compete against the U.S. patentee with impunity, but U.S. competitors cannot.

H.R. 1417

H.R. 1417 legislatively overrules *In re Durden*. The enactment of H.R. 1417 will allow the PTO to issue classic process claims which involve the use of novel and unobvious starting materials in the making of final products. These process claims provide the enabling vehicle both for seeking relief from unfair trade practices by barring importation under §337 of the Tariff Act, and for actions to enjoin infringement under 35 U.S.C. 271(g) of the Patent Code. There is little question in my mind that H.R. 1417 will substantially level the playing field between domestic and foreign high technology enterprises. H.R. 1417 provides patent litigation counsel, such as myself, with

the tools needed. Perhaps even more importantly, H.R. 1417 also delivers s clear message to foreign enterprises that they must compete fairly with the domestic U.S. biotechnology industry.

In reviewing H.R. 1417 I have noticed that the last sentence of Section 2 reads as follows: "If the patentability of such process depends upon such machine manufacture or composition of matter a single patent shall issue on the application." I believe that this provision unfortunately suggests that if respective product and process claims should issue separately, then the process claims are not entitled to the benefits of this legislation. I strongly recommend that this sentence be deleted in order to avoid any such misinterpretation and the risk of future complex and burdensome litigation to clarify what certainly cannot have been intended.

While I believe that H.R. 1417 will correct most of the problems associated with the unfortunate PTO application of the *In re Durden* decision, I also believe that the vitally important U.S. biotechnology industry needs and deserves still further and specific protection. What presently remains unclear is the scope of the process claims that will be granted by the PTO under H.R. 1417. If the PTO administratively chooses to allow only very narrow and specific claims, which recite such innumerable details as temperature, time, proportions, reagents and the like that are normally disclosed by the spplicant to describe the modes of representatively carrying out the invention, it will be difficult if not impossible to establish infringement and to secure a reasonable scope of protection. Indeed, unduly narrow claims may well be easily eroded and thereby not literally and directly infringed by foreign competitors. The patentee would then be faced with the dilemma of accepting such narrow claims as may be grudgingly svailable from the PTO or, alternatively, incurring the cost and delay of administrative appeal and litigation to secure s full and fair scope of patent coverage for the real inventive contribution made.

In order to more fully protect the inventive efforts of the still emerging U.S. biotechnology industry, I recommend that H.R. 1417 also provide for an express amendment to Section 271 of the Patent Code. Such an added amendment to 271 would provide that it is an act of patent infringement to use patented biological materials such as genetically engineered host cells and DNA sequences to make products outside the U.S. for importation into the U.S. The right provided would be independent of process patent claims. The present exclusive reliance on process claims for the enforcement of domestic biotechnology patent rights against unfair foreign competition would be eliminated.

I believe that it is unfair to allow foreign companies to utilize patented host cells and DNA sequences outside of the U.S. to make recombinant products for importation into the U.S. when U.S. companies cannot lawfully use the same material within the U.S. The patented host cells are, in essence, novel living means to make complex biological products that can be made in no other way. These unique, genetically-engineered host cells deserve some particularized protection for the continued advancement of the biotechnology industry in this country and to overcome unfair foreign competition.

H.R. 1417 together with the further amendment that I have suggested will provide litigation counsel with the tools to insure the fairness of a level playing field for U.S. business, and especially for the emerging and yet vulnerable domestic biotechnology industry.

Thank you for the opportunity to express my views on this matter.

Mr. HUGHES. Ms. Nelsen, welcome.

STATEMENT OF LITA L. NELSEN, ASSOCIATE DIRECTOR, TECHNOLOGY LICENSING OFFICE, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, CAMBRIDGE, MA

Ms. NELSEN. I appreciate the opportunity to be here, and, before I start, I would like to thank the chairman, Mr. Hughes, for his support in preserving the small entity, not-for-profit lower patent fees. It made a big difference to us and to the members of the Association of University Technology Managers and our ability to keep doing the work we are doing.

Mr. HUGHES. Well, thank you, Ms. Nelsen. I might say that my ranking Republican, Carlos Moorhead of California, was very, very instrumental also in ensuring a small entity fee. Thank you.

Ms. NELSEN. Universities mostly are doing their patents at risk; that is, they are filing very, very early, when the technology is embryonic, and they don't have licensees. It is coming right out of our pockets, and every saving in patent cost is important to us.

Based on the same issue, that we generally are doing our technology transfer at the stage when the technology is very new, when the patents are pending, and most of us are not making money on the process. We are doing it in order to induce development in this early stage science. Particularly, in biotechnology this is important because the amount of development that is required both in time and money is of the order of many years and tens of millions of dollars. When they start the process, with pending, not issued patents, it is all at very high risk; there is no guarantee that any product will come out of the technology.

Because we are using patents as a mechanism for inducing the investment, and because we are trying to do it at the point where the science first comes out of the university, so patents may be pending for up to 3 to 6 years; and we do not see the average issuance at 27 months that was mentioned here. It is more like 3½ years for the basic biotechnology patents, sometimes up to 5 or 6. It is therefore very important that the patenting process be predictable. It is the consistency of the process that is necessary to us. The consistency of what claims will be issued and which ones can be enforced. Otherwise, the potential licensees are not going to take the risk.

One of the primary objectives of the Biotechnology Patent Protection Act, as we understand it, is to clear up the confusion arising from the *Durden* decision. We believe that the types of claims covered by the act should be patentable, and that a clear ruling either by the courts or through the act will reduce the uncertainty arising from *Durden* in a beneficial way. We believe that the Process Patent Amendment Act of 1988 gave important and legitimate protection to the American biotechnology industry and that this protection should be extended to conventional processes using unique patentable starting material; again, either through change in what is patentable or through further amendment of the trade law.

Thank you.

Mr. HUGHES. Thank you very much, Ms. Nelsen.

[The prepared statement of Ms. Nelsen follows:]

Prepared Statement of Lita L. Nelsen, Associate Director, Technology Licensing Office, Massachusetts Institute of Technology, Cambridge, MA

My name is Lita Nelsen. I am the Associate Director in the Technology Licensing Office of the Massachusetts Institute of Technology. I am also the President-Elect of the Association of University Technology Managers. I appreciate the opportunity to be here and to comment on this important legislation. I would also, parenthetically, like to take the time to extend the thanks of our office and of the university community as a whole to the Chairman, Mr. Hughes, for his support in preserving the small entity exemption on patent fees. The savings were very important in enabling us to continue our work in technology transfer.

Now back to the subject at hand: M.I.T. has one of the most active patenting and licensing offices among American universities. In 1990, we had 112 U.S. patents issue to us--almost twice as many as any other university. And we signed more than 75 license agreements, six of them with new companies started up around our technology. The great preponderance of these licenses were with American companies. While our technology transfer work ranges in fields from aeronautical engineering to biology, over a third is in the biotechnology and medical fields.

Our primary objective in patenting and licensing the technology arising from our research is to induce development of this technology for the public benefit. Most of the technology coming out of our research is in a very early stage of development. It requires substantial investment, both in time and money, to bring it from an embryonic "university stage" invention through product development and testing to a product ready for the marketplace. In the case of biotechnology products, this time may be eight to ten years (or more) and the money will be tens of millions of dollars--all at high risk, since, when the invention first leaves the university, there is no guarantee that a product will ever be successfully developed from it.

We use patents as a mechanism for inducing this investment: in return for the risk of development, licensees are granted a period of exclusivity in the marketplace through exclusive licenses to our patents. Most frequently, the patents are licensed while they are still pending, giving us a substantial headstart in the development cycle.

This system to induce development is highly dependent on the consistency of the patenting process. The licensee must have reasonable confidence in the types of claims likely to issue to a pending patent and, after issuance, in the ability to enforce the patent claims against infringers both within and outside the United States. Uncertainty in the types of claims that may issue or which can be enforced will substantially decrease the incentive for early licensing and investment in development.

One primary objective of the Biotechnology Patent Protection Act appears to be to clear up the confusion arising from the Durden decision about whether certain types of process claims are allowable. We believe that the type of claims covered by the Act should be patentable and that a clear ruling either by the courts or through the Act will reduce the uncertainty arising from Durden in a beneficial way. We further believe that the Process Patent Amendments Act of 1988 gave important and legitimate protection to the American biotechnology industry, and that this protection should be extended to conventional processes using unique, patentable starting materials--either through change in the patentability of certain claims or through a further amendment of the trade law. Thank you.

Mr. HUGHES. Mr. Ebright, welcome.

STATEMENT OF GEORGE W. EBRIGHT, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, CYTOGEN CORP., PRINCETON, NJ, ON BEHALF OF THE INDUSTRIAL BIOTECHNOLOGY ASSOCIATION

Mr. EBRIGHT. Chairman Hughes, thank you for the opportunity to address the subcommittee. I am chairman and chief executive officer of Cytogen Corp., a biotechnology company located in Princeton, NJ. I also serve as a board member of the Industrial Biotechnology Association, a trade association that represents over 100 biotechnology companies in the U.S.A. Collectively, IBA represents more than 80 percent of all of the biotechnology research and development investment in the United States. I am here today on behalf of the IBA, and I am accompanied by Lisa Raines, our staff intellectual property expert.

Biotechnology, as has been said, is an important source of economic vitality for America. The United States is the world leader in research, development and manufacture of biotechnology products. In 1991, as has also been said, the U.S. biotechnology reached $4 billion in sales, a 38-percent increase over 1990, with exports in excess of $600 million.

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

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 invest in research and development is the availability of clear and meaningful patent protection. Without such protection there is simply no incentive for investment.

Unfortunately, biopharmaceutical products are often unpatentable. This compares unfavorably with traditional pharmaceutical chemicals, which are almost always patentable new molecules. Traditional pharmaceutical chemistry involves generating thousands of new molecules and screening them for biological activity. Since those generated molecules are entirely synthetic, they generally meet the principal criteria of patentability: novelty, utility, nonobviousness.

But biotechnology does not involve randomly generated new molecules; instead, it involves genetically engineering technology that is used to identify and synthesize naturally occurring human proteins and enzymes.

Now, when the criteria for patentability are applied to a genetically engineered protein, a patent can be granted if the protein was never known before. However, if the scientific literature reveals that that protein has previously been purified, even if only to a very minor extent, even if it has not been definitely characterized, it could be deemed unpatentable for lack of novelty. In the absence, then, of a product patent, process patent protection constitutes the only meaningful incentive.

However, the biotechnology industry's ability to obtain a process patent protection has been circumscribed since the recent Federal court ruling in *Durden*. 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 in the U.S. market. The problem, of course, as has been stated, is the erroneous and inconsistent application of *In re Durden,* a nonbiotechnology patent case, to important biotechnology processes.

I will not explain the process by which *Durden* is applied to process claims because we have heard that several times. But it does, indeed, seem a matter of logic that *Mancy,* not *Durden,* should be applied to biotechnology 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.

As has also been stated, so I won't elaborate, the difference between *Durden* and *Mancy* is that *Durden* refers to a method of making and *Mancy* a method of using. That has now been well documented.

H.R. 1417, the Biotechnology Patent Protection Act, would correct this problem. After lengthy consideration, IBA has concluded that this legislation will lead to greater certainty and predictability. It will decrease unnecessary litigation, and most importantly, it will enable inventors to obtain the patent protection that we have fairly earned.

In conclusion, let me restate that the U.S. biotechnology industry believes that the patent system should reward the achievement of pioneers. But instead, it allows intellectual pirates to copy innovative biotechnology products without penalty. The system as it is is failing and statutory changes are vital to our Nation's ability to retain the competitive edge that we currently have in biotechnology. We urge the Congress to remedy this problem by expeditiously enacting H.R. 1417.

Thank you.

Mr. HUGHES. Thank you, Mr. Ebright.

[The prepared statement of Mr. Ebright follows:]

Prepared Statement of George W. Ebright, Chairman and Chief Executive Officer, Cytogen Corp., Princeton, NJ, on Behalf of the Industrial Biotechnology Association

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. IBA 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 IBA 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 Nation's 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 countries provide superior biotechnology process patent protection 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 solution to the problem.

Profile of the Biotechnology Industry

Biotechnology is the application 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 technology, 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.

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

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 labelled 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 top 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

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[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).

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.

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 have 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, a patent will generally be granted if the

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

protein was never known before it was isolated and purified using genetic engineering techniques. For example, tissue plasminogen activator, a naturally occurring protein that dissolves the coronary blood clots that cause heart attacks, was totally unknown before it was isolated using biotechnology techniques and has been patented.

However, if the scientific literature reveals that the protein has previously been purified to some extent, even if it has not been definitively characterized, it may be 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 Sanger's 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 <u>product</u> patent protection, what incentive is there for scientists and investors to devote their lives and their savings to identifying a protein's molecular structure and devising genetic engineering methods for its manufacture? In biotechnology, the answer is to obtain patent protection on the <u>process</u> 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 admitted 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 to deduce from

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

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 parte 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

[7] 14 USPQ 2d 1987 (Bd. of Pat. App. and Inter. 1990).

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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 biotechnology 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 that 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

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[8] 499 F.2d 1289 (C.C.P.A. 1974).

[9] E.g., In re Huehl, 475 F.2d 658 (C.C.P.A. 1973).

materials. Indeed, a 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

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[10] 15 USPQ2d 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. 5664," 72 Jour. Pat. & Trademark Off. Soc'y. 1188 (1990), Beier and Benson, "Biotechnology Patent Protection Act," 68 University of Denver Law Review 173 (1991).

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 was 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 <u>not</u> 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.

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.

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

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 of 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. 1417/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 also 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 45% 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 unnecssary 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: 1100, 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 Development

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		Profile by Size	
Therapeutic:	35%	Small (1-50 employees):	76%
Diagnostic:	28%	Mid size (51-135 employees):	15%
Supplier:	18%	Large (136-299 employees):	6%
Ag-bio:	8%	Top tier (300+ employees):	3%
Other:	11%		

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. Ebright, do you make Princeton your home?

Mr. EBRIGHT. Actually, my primary residence is in Rosemont, PA. But having retired from the pharmaceutical industry at Smith-Kline and then, as a second career, working with the young folks at Cytogen, I maintain a condominium there.

Mr. HUGHES. It is a beautiful part of the State.

I wonder if you can identify specific investment decisions that biotechnology companies, including the Cytogen Corp., have made either to pursue certain biotechnology research or not to develop a particular product because of the protection or lack of protection afforded under our law.

Mr. EBRIGHT. I would suggest to you that the industry and many of those decisions are relatively new, and I think that few of the biotechnology companies considered the difficulties in the patent law when they first began to pursue the projects that they are pursuing. Therefore, I would be hard put to suggest to you that there is a lot of work that would have been done in the past that hasn't been done because of this state of confusion in patentability. But I can almost surely predict that it will have an impact on the decisions of where research and development money are assigned in the future.

Mr. HUGHES. Ms. Nelsen, have MIT scientists had trouble obtaining process patents for biotechnology processes?

Ms. NELSEN. I can't speak to any situation where we were unable to get the patent issued. I did speak with a number of patent attorneys with respect to *Durden* before I came here, and each of them said, "Well, I haven't had that much trouble because I can always find some way that the process itself is novel." So what we are saying is the actual weight of the *Durden* problems has not yet been that great, but it is always contingent on an uncertain ability to find something novel about the process itself. And, in our view, that is being legalistic rather than clear on what is and is not patentable.

Mr. HUGHES. I appreciate your candor.

We know how H.R. 1417 would impact upon biotechnology processes. How will H.R. 1417 affect the patenting of chemical, computer and other processes in areas outside of biotechnology?

Mr. Allegretti.

Mr. ALLEGRETTI. I heard you raise the question earlier with Mr. Manbeck and one example immediately sprung to mind for me, and that would be a catalyst. A catalyst would be new, inventive, patentable. Use of the catalyst in the United States to produce an end product which itself is not patentable would infringe a patent on the catalyst. Use of a catalyst in a foreign country to make the same product and import it into the United States would present the identical problem that we are dealing with here concerning biotechnology.

Mr. HUGHES. How about some of the so-called side effects that have been argued? For instance, one of the things that impressed me when I read the statements last night was some of the things that American Intellectual Property Law Association presented and some examples. Let me just recite one example.

Have any of you read any of the testimony?

Mr. ALLEGRETTI. I have not, Mr. Chairman.

Mr. HUGHES. I understand. OK. Well, let me just give you one of several examples cited in the testimony.

The Smith Co., is in the business of harvesting trees, cutting the trees and selling the lumber. As a part of that business, Smith manufactures high-speed saws. Over many years, Smith has improved the saws and has obtained patents on each of the improved machines. However, there is no difference from the first to the last patented saw in applying the cutting blade to the tree nor in the resulting lumber. It may be that the patent on the first Smith saw could contain a claim for a method of using the saw to cut wood.

But, over the years Smith's own saw patents and the patents of Smith's competitors are added to the prior art. Soon the claim for a method of using this type of saw to cut wood becomes obvious over the prior art even though patents may issue on the improved saws themselves. If H.R. 1417 were enacted, so it goes, and every patentable saw, including Smith's, will contain a method of using it to cut the wood, no matter how obvious it may be to use a saw to cut wood. If one of Smith's competitors begin to manufacture and use a patented saw, under current law Smith could bring an action for patent infringement against the competitor.

But now that Smith's patent on that saw includes a method of use claim, which would not have been granted but for H.R. 1417, those liable for patent infringement now will include every person who buys, sells or uses lumber cut by the saws which infringes Smith's patented saw. Also, an infringing Smith saw could be used outside of the United States by a foreign competitor of Smith to cut trees and import the resulting lumber into this country. Again, Smith could take action against the direct infringer of the patent in this case by bringing an action in the International Trade Commission to prevent the importation of lumber. But, if damages and preventing domestic trade in that lumber is what Smith seeks, Smith will now have a cause of action for patent infringement against every person who buys, sells or uses the lumber.

What is your response to that?

Mr. ALLEGRETTI. I have not heard the argument before. I think it is generally absurd, a very specious argument. One can choose analogies and carry them to their extreme limits for an argumentative purpose. I think the key point that needs to be made here is that the materials that we are speaking of are essential to the making of the recombinant biotechnology product that is to be imported. There is no other way to make the product. There are a lot of ways to chop down a tree.

I think that these kinds of arguments have been raised by administrative bodies. I know it has been raised to me, personally, by the staff counsel at the International Trade Commission. It is the "let's not open the floodgates" argument. Let's not treat biotechnology as a special exception, and if we make it a general rule for biotechnology and all other fields of technology, then there will be so many patent processes for the use of a particular patented instrumentality that we will be overwhelmed. I think that overlooks the basic problem, which is let's have fairness in the way American technology is treated for patentability and enforced against conduct that affects American business in this country.

Mr. HUGHES. Thank you. A number of organizations have suggested, as you may have heard from my questioning of Commissioner Manbeck, that instead of pursuing a remedy under H.R. 1417 Congress should amend 35 U.S.C. 271(g) to prevent the importation of a direct product made using a patented composition of matter of any kind. What is your response to that?

Mr. ALLEGRETTI. I favor some parallel provision in the Patent Act for that purpose, and my concern was what I expressed in my summary statement at the outset, which is that there are a lot of patents out there that have been accepted and taken without process claims. Those who invent later, after the passage of this bill, will be able to secure the necessary process claims. Without those process claims there is no relief available under the Tariff Act. There is no relief available under 271(g). And subject to provisions for exception and effective enactment date, as were present in the amendment to the patent statute, 271(g), further provision with respect to infringement which is based on the use of a patented biological material, such as the genetically engineered host cells and DNA sequences, would be important to those existing patents.

It is a hole in the remedy. The remedy goes 90 percent of the way, perhaps, but it doesn't cross the end zone. And I think that last 10 percent, although it may not be a large number of patents that exist out there, they can be of very critical importance to the people who procured them and those enforcement rights should be protected.

Mr. HUGHES. Mr. Ebright, would you like to comment on that?

Mr. EBRIGHT. Yes, sir. In fact, our association previously went on record as supporting both that sort of an approach along with the present bill. As a practical matter, we discovered that there was a great deal of resistance to that part of that bill, and as has been stated, we think the present bill covers 90 to 95 percent of what we need to cover. And, as a very practical matter, therefore, we are in full support of the present bill.

Mr. HUGHES. Ms. Nelsen, do you have any comment?

Ms. NELSEN. We had some problem with the bill in its previous incarnation because it was perceived to have a retroactivity provision that would wipe out major investments based on people's understanding of the law prior to this new act. To the extent that amending 271 would have that same retroactivity provision, we have at least a theoretical problem with it.

Mr. HUGHES. Mr. Allegretti, in your view, should a recombinant product, as distinct from a purified natural protein, be patentable?

Mr. ALLEGRETTI. I think I have to address that in point of time. There may have existed a point in time in the evolution of the biotechnology industry when the techniques available for purification, and hence isolation and identification, of a human protein were so primitive that the achievement of that result was a very significant and important advance. I think the state of the technology now is such that subjects of that kind should not be patentable. And I think this can be dealt with easily by the Patent Office in proper application of the statutory requirement for nonobviousness.

Mr. HUGHES. What is the status of the law in that regard? What is the PTO doing, do you know?

Mr. ALLEGRETTI. No, I don't know, sir.

Mr. HUGHES. I see. Any member of the panel know?

Ms. NELSEN. No. But it does cause us a great deal of problems, because we tend to be filing at the stage where the first clue that such a protein may exist because the inventor is going to publish his paper next Monday. And so the unpredictability does cause a problem particularly because of the evolution of obviousness in this area.

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

Mr. BOUCHER. Thank you very much, Mr. Chairman. First, I would like to report that the Senate Judiciary Committee this morning by unanimous vote reported the Senate companion to this bill sponsored by Senator DeConcini. That was S. 654. That is now on its way to the Senate floor. Hopefully, our bill will match its progress in our House.

Second, with the consent of the chairman, without objection, the record will include the series of letters that I have received from a number of universities throughout the United States that endorse H.R. 1417 and urge its adoption, so we will have that as a matter of our permanent record.

[The letters appear in the appendixes.]

Mr. BOUCHER. Mr. Allegretti, you have suggested that we adopt an amendment that would say that if a product is manufactured in some other country using a host cell or DNA sequence or other starting material that is patented here in the United States that that product, if it is shipped back into the United States, having been made overseas with the starting material that is patented here, could not enter the United States. That, of course, is not the law today. Those items are not excludable, and Amgen has had that problem with EPO.

Are you making that recommendation in the alternative to the provisions of H.R. 1417 or as an additional recommendation for the remedy that H.R. 1417 provides?

Mr. ALLEGRETTI. Clearly, as an additional recommendation. I fully support the bill as it is now cast. I am just suggesting that there is an area that is left unresolved by this. And, as to retroactive effect, as to investments made in this country, I think that can be dealt with in the same fashion as bills having a similar looking backward effect have been dealt with in the past. It is a matter of the draftsmanship of the amendment.

Mr. BOUCHER. Give us just some practical sense, if you will, of how that proposal generally is going to be received. Tell us the organizations that endorse your proposal. Give us some sense of those that oppose it. And, if you don't have that information, we will get it from some other source. But, if you know, give us that information, please.

Mr. ALLEGRETTI. I do not know. But I have one example off the top of my head. An American company that is unable to manufacture a recombinant product in the United States because of existing patents of a prior inventor would very often make a business commitment with a foreign company, such as a Japanese company, export the host cells and have the material made in the foreign country. Now, that U.S. company may have made a very substantial investment in that business relationship with the foreign com-

pany and might be disposed to be very opposed to the suggestion I am making.

Mr. BOUCHER. All right. Would it have retroactive application?

Mr. ALLEGRETTI. No. It would affect the future importation of the product.

Mr. BOUCHER. From that same company?

Mr. ALLEGRETTI. Yes, sir.

Mr. BOUCHER. They might define that as retroactive application.

Mr. ALLEGRETTI. Yes, they might, and the bill might provide for a relief where there has been a substantial investment made by an American company.

Mr. BOUCHER. Would you support that provision if we made it truly prospective only, saying that it would not apply to any circumstance where that kind of importation is taking place today?

Mr. ALLEGRETTI. If I understand you, Congressman Boucher, that would mean that if the product has been imported in the past in whatever small quantity it could continue to be imported in the future in unlimited quantities. I would not support that.

Mr. BOUCHER. Well you, I think, are making a proposal that taken in isolation, perhaps, would solve a range of problems. My sense is that it is not broadly supported. In fact, I am told that the administration opposes that addition. And I am wondering, that being the case, given the fact that the IBA tells us that H.R. 1417, if enacted, would solve roughly 90 to 95 percent of all the problems that exist today, whether it would make sense to burden that bill with something that is quite controversial, such as the recommendation that you are making?

Mr. ALLEGRETTI. I would not suggest killing the baby because it is not as beautiful as I would like it to be. I would still support the bill.

Mr. BOUCHER. That is helpful. Thank you very much.

Mr. Ebright, in the prepared testimony of the IBA, which you are representing today, it is indicated that in Europe and in Japan, I think in Germany specifically and in Japan, the regime of intellectual property laws offers a process patent protection that is similar to what is recommended for the United States in H.R. 1417. Now, a witness will appear on the next panel who will dispute that.

So I would like for you, if you would in the next few minutes, to give the subcommittee the basis on which you make the claim that that in fact is the law of Japan and Germany, in particular.

Mr. EBRIGHT. Congressman Boucher, thank you for that opportunity. I, in fact, have put down a few notes in that regard expecting this discussion.

IBA has consulted with a number of sources, and I would just like to list a few of them. First, Hal Wegner, director of the patent law program at George Washington University Law School and an internationally renowned expert in German and Japanese patent law, has expressed his opinion that what is proposed in your bill is the law in both Germany and Japan.

Second, we have also consulted with Koici Ono, chief patent counsel to Kyowa Hakka Co., in Tokyo and former president of the Japan Patent Association. In his opinion, this is the law in Japan.

Third, an article by a British patent lawyer, Stephen Crespi, specifically states that these processes are patentable in Europe, al-

though there is difficulty obtaining such patents in the United States. Fourth, a law review article published by the University of Denver Law School states that this is the law in Europe and Japan.

I have copies of those articles which I will be happy to submit to the subcommittee.

Mr. BOUCHER. That would be helpful, if you would.

Are you aware of any assertion to the contrary, other than, perhaps, the statement of the witness who will appear later today?

Mr. EBRIGHT. No, sir.

Mr. BOUCHER. And a fairly thorough review of the literature, I suppose, was made by the IBA; is that correct?

Mr. EBRIGHT. Indeed.

Mr. BOUCHER. Well, that is very helpful.

Let me give you an opportunity—they say a good lawyer doesn't ask a question unless he knows the answer. I am not sure I know what your answer is going to be to this, but I am going to give you an opportunity to answer it anyway.

The chairman posed a hypothetical dealing with a novel saw, chopping down trees, and suggesting that if this bill were to pass that the trees could not be imported into the United States if that saw were used abroad to chop them down. And I guess there might be some patent infringement even if trees were chopped down in the United States using a saw. I would like to have your answer to that, if you would.

What can you say that would give us comfort that if this bill passes we would not have to confront that kind of problem?

Mr. EBRIGHT. My first observation is that was a rather circuitous piece of reasoning and I am not sure I totally understood what was being proposed.

Mr. HUGHES. I am not sure I did either.

Mr. EBRIGHT. But the issue to me seems to be crystal clear through all of that example. And that is, we have a confusion here between making and using that is causing a lot of delay, if not, in fact, denial, of process patents that elsewhere in the world are available to inventors. And whether that is applied to a software program, to a biotechnology starting product, or to a saw, it seems to me that it is in everybody's best interest to clear up that confusion that now exists. This bill, the passage of this bill will, indeed, do that.

Mr. BOUCHER [presiding]. OK. Thank you very much. I don't have anything further to ask of these witnesses. Shall we go on to the next panel?

With the subcommittee's thanks, this panel is excused. We appreciate very much your attendance here this morning.

Mr. BOUCHER. Our next witnesses today include Donald S. Chisum, a professor of law at the University of Washington who is testifying today on behalf of the American Intellectual Property Law Association. Professor Chisum has testified numerous times before this subcommittee in the past, and we welcome him back today.

Second, Mr. William F. Marsh is the assistant general gounsel for patents at Air Products and Chemicals, Inc., in Allentown, PA.

He will be testifying on behalf of the Intellectual Property Owners, Inc.

Finally, Mr. Robert Weilacher will testify on behalf of the American Bar Association. Mr. Weilacher is an attorney at Beveridge, DeGrandi & Weilacher, and is an expert in the field of intellectual property protection.

We welcome this panel of witnesses. Without objection, your prepared statements will be made a part of the record. We would urge that you keep your oral summaries to 5 minutes.

And we will be happy to begin with you, Mr. Weilacher.

STATEMENT OF ROBERT G. WEILACHER, ATTORNEY, BEVERIDGE, DeGRANDI & WEILACHER, WASHINGTON, DC, ON BEHALF OF THE SECTION OF PATENT, TRADEMARK AND COPYRIGHT LAW, AMERICAN BAR ASSOCIATION

Mr. WEILACHER. Thank you very much. Members of the subcommittee, thank you for the invitation to participate in today's hearing in connection with H.R. 1417. My comments in opposition to H.R. 1417 represent the views of the Section of Patent, Trademark and Copyright Law of the American Bar Association, and not the ABA as a whole.

The proposed legislation, H.R. 1417, which is entitled "Biotechnology Patent Protection Act of 1991," is in fact a misnomer because it is not limited to the field of biotechnology. It actually relates to all areas of technology. Consequently, the legislation would alter the statutory standard and patent law precedent as it applies to all technologies. It is a major change, indeed.

Various individuals, groups and organizations have testified in connection with earlier versions of this legislation and we have testimony today in connection with this proposed legislation emphasizing the problems of the biotechnology industry. Our section of ABA recognizes these problems and are sympathetic to those problems. However, we believe that H.R. 1417 is not the way to address the problems.

As we see it, there are two particular objections. First and foremost is that H.R. 1417 would create a per se rule of patentability; in other words, it mandates that processes which make or use a novel or a nonobvious machine, manufacture composition of matter would become automatically patentable and would not be examined for obviousness in the Patent Office.

Now, under U.S. laws, U.S. patents have a presumption of validity. Therefore, patents granted under the proposed legislation with unexamined claims would enjoy a presumption of validity. And, even if the underlying claims to the machine, manufacture or composition of matter would be invalid in some future litigation, the process claims would continue, presumably, to enjoy that presumption. We feel that it is not in the public interest to have unexamined patents enjoy this status.

Second, we feel that H.R. 1417 would enable the patent applicant to have process claims in these unexamined process patents which would be, in fact, broader in scope than the underlying composition, machine or manufacture. There is nothing in the legislation that we can see which mandates that the process claims must be

commensurate in scope with the underlying composition, machine or manufacture claims.

We have the following recommendation to make. Instead of crafting new legislation, we would use the Patent and Trademark Office to revise their regulations and interpretations of existing statutes and instruct the examiners on how to examine process claims in a more enlightened approach, paying more particular attention to the decisions of the Court of Appeals for the Federal Circuit.

So, in summary, we do support the effort to prevent piracy of American ingenuity, know-how and technology, but we simply feel that H.R. 1417 is not the vest vehicle to do that.

Thank you very much. That completes my testimony.

Mr. BOUCHER. Thank you very much.

[The prepared statement of Mr. Weilacher follows:]

Prepared Statement of Robert G. Weilacher, Attorney, Beveridge, DeGrandi & Weilacher, on Behalf of the Section of Patent, Trademark, and Copyright Law, American Bar Association

I am Robert G. Weilacher of the Washington, D.C. law firm of Beveridge, DeGrandi, & Weilacher.

Thank you for the invitation to participate in today's hearing and for the opportunity to testify in connection with H.R. 1417.

My comments in opposition to H.R. 1417 represent the views of the Section of Patent, Trademark & Copyright Law of the American Bar Association. These comments have not been submitted to, nor have they been approved by, the House of Delegates, nor the Board of Governors, of the American Bar Association -- and, accordingly, should not be construed as representing any official position of the ABA.

The proposed legislation H.R. 1417 which is entitled "Biotechnology Patent Protection Act of 1991" is in fact a misnomer because it is not limited to the field of biotechnology. It actually relates to all areas of technology and applies to all kinds of inventions including such diverse areas as electronics, computer technology, chemicals, mechanical engineering and machinery. In other words, H.R. 1417 covers a large field of

technology of which biotechnology is only a part, although a significant part. Furthermore, this legislation would alter the flexible 40-year Section 103 standard and patent law precedent as it applies to all technologies -- a major change!

Various individuals, groups, and organizations have testified in connection with the earlier version of this legislation and will or have already testified in connection with the proposed H.R. 1417 and have emphasized the problems of the biotechnology industry. The United States is still the world leader in research, development and the manufacture of a wide variety of biotechnology products. Tremendous amounts of money are required for investment in that industry and without the protection offered by patents, there is no incentive for individuals or companies to make investments because their inventions and technology would be easily copied or appropriated by others.

A particular problem has been mentioned by supporters of H.R. 1417 and that is the lack of patent protection for processes that have been developed to produce important new and nonobvious biological materials. If the new process is similar to known processes which have been patented or described in the past, the Patent Office will not grant the patent on that process. Without such process protection in the United States, products are frequently made overseas utilizing United States developed ingenuity, know-how and information -- and even while using a

patented machine, manufacture or composition of matter. These products are then shipped to the United States without any compenaation whataoever to the U.S. originators of this intellectual property.

Our Section of the ABA recognizes theae problems. We are aympathetic especially to those people who have invested large amounts of money or are ready to invest large amounts of money in a project which has the potential of creating jobs in this country but without assurance that such investment will be protected.

H.R. 1417 is not the best way to achieve the intended results for reaaons which we will now discuss.

The problem with H.R. 1417 can be summarized as involving two particular objections. First and foremost is that H.R. 1417 would create a per se rule of patentability. In other words H.R. 1417 mandates that processes which make or use a novel and nonobvious machine, manufacture or composition of matter become automatically patentable and would not be examined for obviousness in the Patent Office. This would create patents directed to subject matter which realistically have never been subjected to the examination system of the United States Patent and Trademark Office. Under present law, U.S. patents have a presumption of validity. Therefore, these patents under H.R.

1417 with unexamined claims would enjoy a preaumption of validity. Thia meana that aomeone aeeking to challenge validity haa a heavy burden of presenting clear and convincing evidence, not merely a preponderance of evidence, to a court. It ia not in the public intereat to have unexamined patenta enjoy this atatus. Thia is queationable public policy.

Secondly, H.R. 1417 would enable a patent applicant to refile his pstent application numeroua timea and delay iasusnce of a patent in order to add additional proceaa clsima which may be much broader in acope than the underlying novel subject matter of the composition of matter, machine or manufacture. In other worda, there ia nothing in the legialation which requirea that the proceaa claima be commenaurate in acope with the aubject matter of the compoaition, machine or manufacture. The reault would be that it would be posaible to obtain a patent directed to a particular machine, for example, and then obtain a broad procesa claim of making or uaing this machine aa well as other machines.

In the biological area, for example, if one biological aubstance was the subject of a patent, the proceas claim could be written in auch a way aa to include making or uaing that one biological aubatance aa well aa aimilar onea and perhaps onea that are not similar. The potential exista for the grsnt of proceaa claima of very broad scope. Theae unexamined proceaa claima would then be

entitled to a presumption of validity which would be very difficult to overturn in a court of law.

We are concerned that in an effort to address the problems which are acknowledged to exist, this new legislation would create situations which would enable the imagination of man to go far beyond what is originally intended by this legislation.

Our Section of the ABA has the following recommendation to make in an effort to address this problem. Instead of crafting new legislation, the Patent and Trademark Office should revise their regulations and interpretation of existing statutes, and instruct examiners on how to examine process claims with a more enlightened approach to the patenting of process claims of a wide variety, as has been proscribed in decisions by the Court of Appeals for the Federal Circuit.

And so in summary we support the effort to correct problems that have been amply discussed and explained to the Congress and especially to prevent the piracy of U.S. ingenuity, know-how and technology. Under current law there is protection for products manufactured overseas by use of a patented process when these products are exported into the United States for which the U.S. innovators receive no compensation. We think that U.S. Patent and Trademark Office practice should properly track existing court

decisions. H.R. 1417 is not the best vehicle to accomplish that gosl.

That completes my testimony.

Thsnk you agsin for being able to participste in this hesring. I sm prepsred to sddress questions raised by you, Mr. Chsirman, snd other members of s subcommittee.

Mr. BOUCHER. We will be glad to hear from you, Mr. Marsh.

STATEMENT OF WILLIAM F. MARSH, ASSISTANT GENERAL COUNSEL, PATENTS, AIR PRODUCTS & CHEMICALS, INC., ALLENTOWN, PA, ON BEHALF OF THE INTELLECTUAL PROPERTY OWNERS, INC.

Mr. MARSH. Thank you. Mr. Chairman, and members of the subcommittee, thank you for this opportunity to present the views of Intellectual Property Owners, Inc., on H.R. 1417. My name is William Marsh and I am the assistant general counsel, Patents, Air Products & Chemicals, Inc.. But today, I am representing the views of IPO, with which my company agrees.

IPO is a nonprofit association representing owners of patents, trademarks, copyrights and trade secrets. IPO's members are responsible for a major portion of the private research and development conducted in the United States. I am a member of IPO's Board of Directors.

IPO has some biotechnology firms within its membership, but we do not presume to speak for the biotechnology industry. Our comments address the effects H.R. 1417, which is labeled the "Biotechnology Patent Protection Act of 1991," would have on the U.S. patent system as a whole. H.R. 1417 goes well beyond the narrow scope indicated by its title.

IPO's inability to support the enactment of H.R. 5664 in the previous Congress must be respectfully repeated today with respect to H.R. 1417. IPO and its members are also concerned by the amendments to S. 654, introduced in the Senate after the June hearings, and the impact such amendments could have on U.S. industry, research and competitiveness as a whole.

I would like to summarize my prepared testimony as follows:

All the arguments for H.R. 1417 seem to assume that the *In re Durden* case prevents process claims in the areas of concern by the biotech industry. *Durden* does not prevent such claims. And, in fact, the *Pleuddemann* and *Dillon* cases specifically repudiated such an incorrect interpretation and application of *Durden*.

H.R. 1417 adopts an unprecedented per se rule of patentability for certain process claims, thereby disrupting the 40-year legal history of section 103 of title 35.

Adoption of H.R. 1417 also flies in the face of the *Dillon* and *Pleuddemann* cases, cases that have great relevance to the exact issues being addressed by this legislation. The court in *Dillon* and *Pleuddemann* rejected the notion of either per se nonobviousness or per se obviousness, following instead the doctrine of case-by-case decisionmaking. *Pleuddemann* specifically addressed the types of claims the biotech industry are trying to obtain through this bill, and the case expressly held that such claims may be patentable, and the case, in fact, reversed the Patent and Trademark Office which had rejected such types of claims.

A per se rule of nonobviousness would lead to uncertainty in litigation if the underlying product claims were found invalid by prior art or otherwise. The Senate amendments exacerbate this problem. Likewise, the nonexamination of the process claims would cause uncertainty as to the application of the doctrine of equivalents and prosecution history estoppel to process claims.

United States industry will face higher costs and barriers to research and commercialization if H.R. 1417 is adopted in its present form. A profusion of patent claims of unexamined scope and patentability under traditional standards will inhibit healthy research and development and commercial activities within the United States. As patent owners, we can usually wait for a quality examination under current rules. As researchers and entrepreneurs, we cannot afford the issuance of poorly examined or doubtful patent claims because of the extreme cost and potential damages imposed on research and development which are unique to our U.S. system.

H.R. 1417 places no limits on the permissible scope of such process claims, and it does not present any limits to the imagination of patent attorneys. A per se rule of nonobviousness could result in allowed process claims encompassing large numbers of manipulative steps covering more subject matter than the inventive concept originated by the inventor. Thus, by requiring process claims to be granted automatically by the U.S. PTO without effective examination, H.R. 1417 could well encourage overclaiming in process claims.

Amendments such as those made to S. 654 which preserve the presumption of validity under 35 U.S.C. 282 for process claims after the underlying product or composition claims have been invalidated would be ill-advised.

The subcommittee should seek information from the Patent and Trademark Office on any pending cases that may clarify the application of *Durden* to biotechnology and other technology cases, and should ask the Patent and Trademark Office to issue an administrative directive to its examiners on the proper application of the *Durden* case.

We wish to compliment the sponsors of the bill and this subcommittee on their interest in effective patent protection. That is a strong interest of IPO. But we believe that that must be carefully considered and weighed and balanced so that the relief granted is appropriate and is not overly broad and will not cause more problems than it is designed to remedy.

Thank you very much.

Mr. BOUCHER. Thank you, Mr. Marsh.

[The prepared statement of Mr. Marsh follows:]

Prepared Statement of William F. Marsh, Assistant General Counsel, Patents, Air Products & Chemicals, Inc., Allentown, PA, on Behalf of the Intellectual Property Owners, Inc.

Mr. Chairman and Members of the Subcommittee:

Thank you for this opportunity to present the views of Intellectual Property Owners, Inc. (IPO) on H.R. 1417.

IPO is a nonprofit association representing owners of patents, trademarks, copyrights and trade secrets. IPO's members are responsible for a major portion of the private research and development conducted in the United States. I am a member of IPO's Board of Directors.

We have members in most technology-based industries, including biotechnology, chemical, pharmaceutical, computer, electronics and mechanical manufacturing, among others. Patents provide vitally important incentives for creating and commercializing inventions in all fields of technology.

IPO has some biotechnology firms within its membership, but we do not presume to speak for the biotechnology industry. Our comments address the effects H.R. 1417 would have on the U.S. patent system as a whole.

IPO recognizes the leadership role which America has taken in the world of biotechnology research. American companies and inventors have made landmark inventions relating to biotechnology that never would have been made without the prospect of exclusive patent rights. To this end, IPO compliments Representative Boucher and the cosponsors of H.R. 1417 for taking an interest in the patent rights available for the protection of inventions in this critically important science.

It should be noted for the record that IPO testified on September 25, 1990 at this subcommittee's hearings on House Bill H.R. 5664, a predecessor of H.R. 1417, and I testified

on June 12, 1991 before the Senate Subcommittee on Patents, Copyrights and Trademarks with respect to Senate bill S. 654, a bill similar to H.R. 1417.

IPO's inability to support the enactment of H.R. 5664 in the previous Congress must be respectfully repeated today with respect to H.R. 1417. IPO and its members are also concerned by the amendments to S. 654 introduced in the Senate after the June hearings and the impact such amendments could have on U.S. industry, research and competitiveness as a whole.

A Need Has Not Been Demonstrated

Although H.R. 1417 applies to patentable inventions in all technologies, the legislation appears to be a response to a perception that current patent law is not providing adequate protection for the important U.S. biotechnology industry. IPO submits that a compelling need for remedial legislation to correct a perceived infirmity in biotechnology protection has not been shown. Without such a showing, the Congress should not respond with such broad legislative changes.

Proponents of H.R. 1417 have pointed to two instances of problems they perceive from the present operation of our patent laws and system. First, they have drawn attention to the litigation between Amgen (a U.S. company) and Chugai (a Japanese company) over Chugai's U.S. importation of a recombinant protein known as "EPO". While the commercial impact of this single case history is worthy of note, the history of Amgen's patent application will reveal extenuating circumstances, i.e., an ongoing patent interference (priority contest) which has

delayed issuance of the process claims which, if issued to Amgen, would render moot the Amgen-Chugai example. The present legislation would not alter that situation.

Secondly, they point to the rote application of *In re Durden*, 763 F.2d 1406, 226USPQ359 (Fed. Cir. 1985) by the Patent and Trademark Office to biotech process claims covering the use of patentable materials, including host cells, and complain of the prosecution expense and delay, and even a loss of claims when applicants choose to abandon such claims in the face of continued examiner use of *Durden*-type rejections. The decision of the Court of Appeals for the Federal Circuit in the *In re Durden* case does not require such rote application. The Court of Appeals, sitting *en banc* on reconsideration in the case of *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (1990), expressly stated that the invention of a process for using a material must be considered as a whole, and may not be rejected merely because the process steps may be old or known. Judge Lourie, writing for the majority in *In re Dillon*, 919 F.2d at 695, 16 USPQ2d at 1903, stated:

> . . . Suffice it to say that we do not regard *Durden* as authority to reject as obvious every method claim reading on an old type of process, such as mixing, reacting, reducing, etc. The materials used in a claimed process as well as the result obtained therefrom, must be considered along with the specific nature of the process, and the fact that new or old, obvious or nonobvious, materials are used or result from the process are only factors to be considered, rather than conclusive indicators of the obviousness or nonobviousness of a claimed process. When any applicant properly presents and argues suitable method claims, they should be examined in light of all these relevant factors, free from any presumed controlling effect of *Durden*. *Durden* did not hold that all methods involving old process steps are obvious; the court in that case concluded that the particularly claimed process was obvious; it refused to adopt an unvarying rule that the fact that nonobvious starting materials and nonobvious products are involved ipso facto makes the process nonobvious. Such an invariant rule always leading to the opposite conclusion is also not the law. Thus, we reject the Commissioner's argument that we affirm the rejection of the method claims under the precedent of *Durden*.

The action needed is not an overruling of the *Durden* case, but a requirement that the Patent and Trademark Office follow existing law and fully examine process claims as a whole. This would be a result consistent with the basic principles of the patent laws and the extensive case law which provides guidance and a degree of predictability and certainty, both to patentees and to others of the public. It would be directly opposed, however, to the present proposal of *per se* patentability of process claims and the proposals to insure the presumption of validity even after the underpinning composition or product claims have been found invalid.

On the other hand, one can find many examples of process claims already allowed by the Patent and Trademark Office for making patentable recombinant proteins of substantial commercial importance. Tissue plasminogen activator, interleukin-3, alpha-interferon, and human growth hormone are examples. We believe a convincing case of jeopardy to the U.S. biotechnology industry has not been made.

H.R. 1417 reaches to all technologies -- all mechanical, electrical and chemical arts. This is a response by proponents of the bill to some criticisms levied against earlier versions which confined the statutory amendment to biotechnology alone. Critics urged that special legislation should not be afforded to a single technical discipline -- that special rules should not be created for biotechnology or any other technology category absent a clear showing of truly unique and special problems. IPO continues to support uniform applicability of the patent laws so far as is practical. But here, there has been insufficient consideration of the practical impact of H.R. 1417 outside of the biotechnology field.

Lack of PTO Obviousness Examination Will Cause Uncertainty

H.R. 1417 would declare patentable all claimed processes of making or using a machine, manufacture or composition of matter where such machine, manufacture or composition of matter is found patentable. Under existing law, the Patent and Trademark Office examines every claim in every patent application for compliance with 35 U.S.C. 103, for non-obviousness. Under H.R. 1417, the Patent and Trademark Office examiners would be required to find the process claims allowable once they have determined that such claims include a patentable machine, manufacture or composition of matter as an element.

Since 1836, when our patent laws were converted from a system of patent registration without examination to a system of examination of each claim for novelty, inventiveness (now non-obviousness) and utility, a hallmark of our system has been the careful and thorough examination of patent applications by the Patent Office to insure that inventors, while receiving the full measure of their invention, do not obtain claims that either take existing technology from the public or unduly cloud the rights of others to develop and practice technology in the field of the invention but outside the boundaries of the inventive contribution.

A primary purpose of patent examination in the PTO is to create a presumption of validity of patent claims and help avoid patent litigation. We are concerned that H.R. 1417, which would require the PTO to issue process claims without examination for novelty or nonobviousness when the related product claims are held patentable, would result in great uncertainty over the validity and scope of the process claims after the patent is issued.

Under H.R. 1417, if a product claim issued by the PTO were to be invalid because of prior art that was not known to the PTO during examination, an unexamined but issued process

claim might or might not be similarly held invalid. It would be invalid if it had been issued solely because it "depended upon" the product claim. We assume the PTO would not make a determination in each case whether the patentability of the process claims depended upon the patentability of the product claims, since such determination would require a claim-by-claim examination. In the case where the underlying product claim was invalid, a patent would exist containing process claims that would be entitled to no presumption of validity, contrary to 35 U.S.C. 282. How could such unexamined claims satisfy the requirement of Section 282 that "[e]ach claim of a patent...shall be presumed valid independently of the validity of other claims"?

IPO and its members are also concerned by the amendments made to S. 654 in the Senate which would allow separate product and process patents to be issued with an express preservation of the presumption of validity of the totally dependent process claims. If the process claims are not to be independently examined for patentability apart from their dependence on the product or composition claims, there is absolutely no basis for an independent presumption of validity of the process claims. It will encourage expensive and time-consuming litigation to pretend that there should be a continuing presumption of validity after the product or composition claims are found to be invalid. This will have an inhibiting effect on U.S. research and industry.

In testimony last year with respect to H.R. 5664, the Patent and Trademark Office cited reduction of cost of patent examination resulting from having to examine fewer claims as a reason for supporting the bill. Reduction of the cost of patent examination is a terrible excuse for eliminating effective examination of process claims. Improperly examined and issued claims cast a chilling shadow on U.S. research and industry. The huge expense and the judicial, technical and management time required to litigate questionable claims under the U.S. judicial

system would make such claims effective barriers to research and production by others in the field. If the process claims were never examined by the PTO for novelty and non-obviousness, expensive litigation would be necessary to determine the validity of the process claims. Moreover, even if the process claims were determined to be valid, uncertainty might still exist over the allowable scope and construction of the process claims coverage in the absence of prosecution history developed during examination. The doctrines of equivalents and prosecution history estoppel could not be applied to unexamined claims in the same way those doctrines are applied to examined claims.

Process claims that would be obvious or of doubtful validity apart from the product claims would proliferate with enactment of H.R. 1417. We believe attorneys advising clients should be concerned about the difficulty that would be encountered in answering questions about validity and infringement of a profusion of unexamined claims. Either as owners of patents or as companies affected by patents owned by others, we do not need a return to the "register and sue" climate that existed prior to the enactment of the highly regarded and emulated United States system of examination in the 19th century.

We agree with the letter to the Subcommittee dated November 6, 1991, from three former U.S. Commissioners of Patents and Trademarks. Their letter points out that the Patent Act of 1793, which permitted claims to issue without examination, was totally unacceptable to inventors and the public alike.

Another concern about H.R. 1417 is that its *per se* rule of nonobviousness could result in allowed process claims encompassing large numbers of manipulative steps covering more subject matter than the concept originated by the inventor. By requiring process claims to be

granted without novelty or nonobviousness examination by the PTO, which is likely to result in reduced examination or no examination under 35 U.S.C. 112 as well, H.R. 1417 could well encourage "overclaiming" in process claims. The result could be a proliferation of claims and confusion as to the scope and boundaries of infringement. This could lead to uncertainty and unnecessary litigation over the statutory requirement of 35 U.S.C. 112 to "particularly point out and distinctly claim" the invention. The existence of unexamined claims can only have a serious negative effect on research and commercialization within the United States and can only harm United States competitiveness in the world-wide community.

Amending Section 103 To Eliminate Nonobviousness Examination - A Premature Move

Proponents of H.R. 1417 advocate a statutory modification to Section 103 of Title 35 of the U.S. patent laws, the requirement that inventions be examined and found nonobvious in order to merit patent protection. Section 103 is the time-tested centerpiece of America's patent law. It defines a subjective, and yet the most pivotal, condition for patentability -- "nonobviousness".

Despite the subjective nature of Section 103, it has served America remarkably well for nearly 40 years. Because the legal standard for nonobviousness gives rise to interpretation and debate when applied to fact situations, the case law on this topic is rich and well developed. Patent practitioners and judicial bodies depend upon the rich case law precedent for deciding issues of nonobviousness -- issues which very often are dispositive of patent validity itself. Any action by Congress to alter the time-tested language of Section 103 to eliminate substantive examination of *any* claims would most certainly disturb the equilibrium which the courts have so diligently imparted to Section 103 through decades of interpretation.

Any legislative amendment to Section 103 must, therefore, be undertaken with profound caution. Other alternatives should be fully exhausted. IPO contends that a legislative attempt to clarify perceived problems caused by *In re Durden* should be considered only as a last resort. A much better solution is to allow the law in this area to mature through administrative and court decisions based on thoroughly presented factual situations.

Recent guidance on the application of *Durden* been provided by the Court of Appeals for the Federal Circuit in the case of *In re Dillon*, supra, and *In re Pleuddemann*, 910 F.2d 823, 15 USPQ2d 1732 (1990). While pending *ex parte* appeals within the U.S. Patent and Trademark Office are not public, perhaps the Subcommittee would be able to obtain information from the PTO as to whether pending cases exist that will clearly establish the patentability of process claims without the need for legislative action. Also, the Subcommittee should ask the Patent and Trademark Office to issue an administrative directive to its examiners on the application of *Durden*, to insure against rote application of *Durden*.

No Consensus Exists in the Patent Bar for Amendment of Section 103

The legal issues addressed by H.R. 1417 are obscure and difficult to appreciate. The bill focuses on nuances of chemical patent practice -- a highly specialized field of law embracing an enormous body of controlling case law. *Durden*, *Pleuddemann*, and *Dillon* were all chemical cases. Chemical patent law is a field beset with specialized terminology and unique but well-established rules of practice. What is needed at this juncture is study and debate by chemical patent practitioners as well as by representatives from biotechnology and the other technologies.

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IPO has seen no evidence that the chemical patent bar has spoken in favor of amending the nonobviousness requirement of 35 U.S.C. 103 in order to clarify a perceived problem with *In re Durden.* Respected coalitions of U.S. patent lawyers such as those in the American Intellectual Property Law Association (AIPLA) and the Patent, Trademark and Copyright Section of the American Bar Association (ABA) have opposed the changes, citing particular problems engendered by the bill and its amendments. Many lawyers who already have taken a public position are opposed to precipitously amending Section 103.

Any changes to the law will have profound and costly impacts. The patent bar should not be dismissed as "only the lawyers." They are experts in the field who represent not only a broad range of patentees but also a broad range of U.S. research and industry. They are aware of the particular problems that can occur and the costs those problems may impose on patent owners and the public. IPO, a long-standing proponent of strong patent and intellectual property protection, respectfully urges this Subcommittee to suspend further consideration of H.R. 1417 unless a compelling and widespread need for remedial legislation is demonstrated by the bill's proponents. We believe this showing is lacking.

Summary of Reasons Why H.R. 1417 is Undesirable

- H.R. 1417 adopts an unprecedented *per se* rule of patentability for certain process claims, thereby disrupting the 40-year legal history of Section 103 of Title 35.

- This *per se* rule is contrary to the emphasis by Judge Giles Rich in *Durden* on the desirability of case-by-case decision-making on questions of obviousness under Section 103.

- Adoption of H.R. 1417 also flies in the face of *Dillon* and *Pleuddemann*, cases that have great relevance to the issues being addressed by this legislation. The court in *Dillon* and *Pleuddemann* rejected the notion of either *per se* nonobviousness or *per se* obviousness, following instead the doctrine of case-by-case decision-making.

- A *per se* rule of nonobviousness would lead to uncertainty in litigation if the underlying product claims were found invalid, by prior art or otherwise. Likewise, the "non-examination" of the process claims would cause uncertainty as to the application of the doctrines of equivalents and prosecution history estoppel to process claims.

- Adoption of H.R. 1417 should not be determined by issues of economy or speed within the Patent and Trademark Office. Economy or speed within the Office, or considerations of opportunities for collecting additional fees, should not be the tail that wags the dog. A profusion of claims of unexamined scope and patentability under traditional standards will inhibit healthy research and development and commercial activity in the United States. As patent owners, we can usually wait for a quality examination under current rules. As researchers and entrepreneurs, we cannot afford the issuance of poorly

examined or doubtful patent claims, because of the extreme costs and potential damages imposed on research and development which are unique to our system.

- A *per se* rule of nonobviousness could result in allowed process claims encompassing large numbers of manipulative steps covering more subject matter than the inventive concept originated by the inventor. Thus, by requiring process claims to be granted automatically by the USPTO without examination, H.R. 1417 could well encourage overclaiming in process claims.

- Amendments such as those made to S. 654, which preserve the presumption of validity under 35 U.S.C. 282 for process claims after the underlying product or composition claims have been invalidated, would be ill-advised.

- The Subcommittee should seek information from the Patent and Trademark Office on any pending cases that may clarify the application of *Durden* to biotechnology and other technology cases, and should ask the Patent and Trademark Office to issue an administrative directive to its examiners on the application of *Durden*.

* * * * *

Again, we compliment Representative Boucher and the many cosponsors of this legislation for their interest in strengthening intellectual property protection. We look forward to working with

the Subcommittee to help ensure that U.S. patent law works as effectively as possible to protect American research and development efforts. However, we are unable to support enactment of H.R. 1417. We believe the objectives of H.R. 1417 are being realized through emerging court decisions, and we are opposed to a legislative solution of such magnitude as H.R. 1417 at this time. If the Patent and Trademark Office's examiners are continuing to have difficulty applying the clear mandate of the *Dillon* and *Pleuddemann* holdings to allow process claims, after examination, then an administrative directive within the PTO would appear to be the most appropriate solution.

Mr. BOUCHER. Mr. Chisum.

STATEMENT OF DONALD S. CHISUM, MEMBER OF THE BOARD OF DIRECTORS, AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, AND PROFESSOR OF LAW, UNIVERSITY OF WASHINGTON

Mr. CHISUM. Thank you. My name is Donald Chisum. I am a member of the board of directors of the American Intellectual Property Law Association, and I would like to thank the chairman and the members of the subcommittee for the opportunity to appear here today and present the views of the association.

The AIPLA believes in a strong, effective, efficient patent system, and it applauds the U.S. biotechnology industry's accomplishments as a great contribution to worldwide human health and welfare and a success story of the patent system. However, the bill under consideration would impact all fields of technology and would benefit many foreign research-based corporations at the expense of American enterprises and consumers. In fact, as we have pointed out in our statement, since foreign corporations are granted appropriately as many utility patents as American corporations, oftentimes the benefits bestowed by this legislation would go, in fact, to foreign corporations, not to U.S. enterprises.

We oppose the enactment of H.R. 1417 for five reasons. Fortunately, the chairman, I believe, has already referred to or, indeed, read all five reasons, so I will not repeat them. But I would like to comment on each of them, particularly in light of some of the testimony I have heard here today.

Our first point is that there is no demonstrated need for this legislation, it is truly a solution in search of a problem, and that there is no cited instance of commercial harm to a U.S. company. We have heard the example of Amgen. But, of course, Amgen is, again, one of the success stories of the American patent system. Their success in enforcing their patents has made front-page news over the last 2 years. It is pointed out that in one instance they did not obtain certain method-of-use claims in a patent they obtained. But, in fact, Amgen has filed further what are called continuation applications and has had method-of-use-type claims allowed. Those claims have not yet issued because they have been involved in further Patent and Trademark Office proceedings.

Our second point is that this bill really is directed to one single court of appeals decision, *In re Durden,* and purports to codify a previous decision in *In re Mancy.* And, if we have an instance here of Patent and Trademark Office examiners overzealously applying the *Durden* case, the remedy lies in the agency. They have the ability to direct their examiners to correctly apply the law.

Now, if, in fact, the *Durden* case is in some way inconsistent, for example, with prior decisions such as *In re Mancy,* the Patent and Trademark Office can well recognize that and indicate that it will follow the *Mancy* decision. The Court of Appeals for the Federal Circuit has indicated that should a conflict arise among their decisions the earlier, not the later, one is controlling.

The Patent and Trademark Office within the last 2 years has announced that, in another area, a particular court of appeals decision was inconsistent with prior decisions and created an adminis-

trative problem for them, and it declared that they will not follow it. So, we see no reason why they could not do that here also.

Our third reason for opposing this legislation is that the bill would set an unfortunate precedent. On the face of the statute, it indicates that a certain class of patent claims, certain method claims are subject to a different standard and are not examined, and we believe that that will in some at least intangible way undermine the public confidence in the patent system and in the presumption of validity of issued patents.

Fourth, we believe that indeed the bill does increase the number of persons in the United States who are potentially liable for patent infringements. It does not solely impact on enterprises. Now, I think the example in our statement of the sawmill has been somewhat maligned, but, in fact, we believe it would be quite a realistic scenario.

For example, assume you had a sawmill in my home State, the State of Washington, that sawed up a great deal of lumber and shipped it off to a building supply dealer in Florida, using a patented sawmill. Assume further that the enterprise in the State of Washington goes bankrupt. Any theoretical remedy the patent owner has against the sawmill in Washington is just that, a theoretical remedy.

If this bill were to pass, and if the patent owner were to obtain methods of using saws to, in a very conventional way, make lumber, they would have a remedy against the sellers and users of that lumber in other States, people who ordinarily would not become embroiled in these kinds of patent controversies.

Finally, we believe that this would add to our patent statutes a provision that does not exist as such in the European patent convention, Japanese patent statutes or, to our knowledge, in the patent laws of any other country. Now, we have heard that the patent offices in Japan and Europe do in fact issue patents relating to biotechnological processes, to methods of using and methods of making patentable subject matter, but so does the U.S. Patent and Trademark Office. It does not do so on a per se basis, or it should not do so on a per se basis, but those types of claims, indeed, are issued in this issue and we believe it will continue to be so even if this legislation is not enacted.

We thank you very much, and we would welcome any questions.

Mr. HUGHES. Thank you, Professor Chisum.

[The prepared statement of Mr. Chisum follows:]

PREPARED STATEMENT OF DONALD S. CHISUM, MEMBER OF THE BOARD OF DIRECTORS, AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, AND PROFESSOR OF LAW, UNIVERSITY OF WASHINGTON

The American Intellectual Property Law Association (AIPLA) is a national bar association of 7,000 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 association with universities, small business, and large business; and lawyers active in both the domestic and international transfer of technology.

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The inquiry of overriding importance presented by H.R. 1417 is determining its effect on the public interest and the public support of the U.S. patent system. Without question, the enactment of this bill would expand the ability to obtain patent rights beyond what the current law allows. The proponents of the bill have the burden of justifying the need for expanded rights. If the need is established, and we believe it is not, the Subcommittee must then go beyond that issue and judge whether the enactment of H.R. 1417 represents sound public policy.

The congressional sponsors of H.R. 1417 have expressed a desire to provide expanded patent rights to that segment of the American pharmaceutical industry engaged in biotechnology research and development. The AIPLA believes in a strong, effective, efficient patent system, and applauds the United States biotechnology industry's accomplishments as a great contribution to worldwide human health and welfare and a success story of the patent system. However, this bill would impact all fields of technology and would benefit many foreign research-based corporations at the expense of American enterprises and consumers. In fact, since foreign corporations are

granted more utility patents than American corporations, the benefit bestowed to foreign corporations is likely to outweigh the benefit to U.S. interests.

However, the imperative that the interests of the American public must be protected and maintained in the operation of our patent system transcends whether patents are owned by Americans or foreigners. The Supreme Court has pointed out that "the U.S. patent system embodies a carefully crafted bargain to encourage the creation and disclosure of new and nonobvious technology in return for the seventeen year period of exclusionary rights." Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150-51, 9 U.S.P.Q. 2d 1847, 1852 (1989). The Supreme Court emphasized that "the novelty and nonobviousness requirements of patentability reflect the understanding that free exploitation of ideas will be the rule , to which the protection of a federal patent is the exception." 489 U.S. at 151, 9 U.S.P.Q. 2d at 1852. As a matter of important public policy, the "exception" must remain absolutely justified.

The American patent system can only enjoy public support so long as it is understood that patents reward inventors for contributions which may enure to the public welfare. The ultimate test of patentability is found in Section 103 of Title 35, which H.R. 1417 would amend. That provision requires that to merit patent protection, an invention, in addition to being new and useful, must be unobvious to a person skilled in that art. Section 103 ensures that a patented invention not only contributes to the public, but also that the substance of the disclosure reaches a level of achievement that it enlightens other skilled persons and thereby promotes progress in the useful arts as the patent clause of the U.S. Constitution requires.

For two centuries, Congress and the Federal Judiciary have attempted to preserve the "carefully crafted bargain" or balance of competing interests referred to by the Supreme Court. We urge extreme caution and circumspection before any action is taken to tip this balance away from the public. The current state of patent system is not beyond improvement. However, we believe that the basic principles of our patent law, including the important principle in Section 103, are fair and well reasoned.

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The AIPLA opposes the enactment of H.R. 1417 for the following reasons.

1. The bill proposes an amendment to 35 U.S. Section 103 that is not needed. Its primary purpose is to "protect" the United States biotechnology industry from "unfair" competition, but its proponents cite no case of commercial harm to a U.S. company that this bill would have prevented, and we do not believe that a threat of such harm exists.

2. The bill would implicitly repudiate one possible interpretation of a single appeals court decision, *In re Durden*, by "codifying" an earlier decision, *In re Mancy*. If Patent and Trademark Office examiners are currently applying *Durden* overzealously, such erroneous applications can be promptly corrected by appropriate appellate procedures and should be immediately corrected by the PTO as a matter of administrative policy.

3. The bill would set an unfortunate precedent and damage the patent system's credibility by implying that certain classes of patent claims escape full PTO examination and are subject to a different, weaker, patentability standard.

4. The bill would possibly jeopardize existing patent rights and increase the number of persons potentially liable as patent infringers.

5. The bill would add a provision to our patent statutes that does not exist in the European Patent Convention, the Japanese patent statutes, nor to our knowledge, in the patent laws of any other country. This precedent might encourage other countries to adopt similar expansive aberrational patent law doctrines. American inventors' interest lies in harmonizing U.S. patent law with foreign patent laws. Enacting unique and unprecedented provisions in U.S. law, specially designed to "protect" a particular U.S. industry from foreign competition, works against that American interest.

A discussion of these points follows. However, it may be useful to first consider the commercial implications of patenting process inventions to better focus on the effects and context of H.R. 1417.

There are different legal and commercial considerations which attach to processes of making something and processes for using something to make something else. Generally speaking, patent claims to well understood or conventional processes of making a patentable product have no commercial significance. That is because the patent on the product includes the right to exclude others from making that product by any and every means. Likewise, a patent claim on the process of using a patentable product to make another patented product have no significance given the rights in the products themselves. Therefore, the significance of H.R. 1417 lies in its effect on the patentability of process

claims in cases either where a patented composition of matter is conventionally processed to make an unpatentable product or where a machine is used to make an unpatentable product.

Under current patent law conventional processes may or may not be patentable depending on a consideration of the invention as a whole. Section 103. Indeed, the patent statute expressly recognizes that new uses of old processes may be patentable. Sections 100, 101. However, what makes this a particularly sensitive area of patent protection is in the potential effect on commerce and trade in clearly unpatentable goods and materials, an arena where free competition is very often unaffected by patent rights. In biotechnology, a patentable "host cell" is used by conventional methods to make naturally occurring protein. The high degree of invention in the current state of this art and the special and regulated uses of the resulting purified proteins makes this an exceptional case in considering commerce in unpatentable products. But, H.R. 1417 must be evaluated in its potential commercial effect on such things as lumber cut from a patented saw, purified water made by a patented desalinization machine, or bottles made by a patented machine. During the course of trade in common articles such as lumber, water, or products in bottles, buyers, sellers and users rarely know how those products are manufactured.

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.

H.R. 1417 is a direct expansion of P.L. 100-418 which established potential liability for process patent infringement beyond the user of the patented process. H.R. 1417 would insure that method of use claims will be included in every patent for a machine, manufacture, or composition of matter if such is used to produce a product of any kind. The restraining effect on domestic and international commerce will, thereby, be expanded.

The Development of Section 103

The basic principles of patent law are straightforward: an invention which falls into one of the categories listed in Section 101, and which is new and useful as required by Sections 101 and 102, is patentable unless, as stated in Section 103,

> The differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

The establishment in 1952 of this nonobviousness test for patentability came after more than 100 years of struggle in the courts to determine on a patent by patent basis, whether the patentee had made an invention or not.

The patent statute of 1790 required that inventions must be new and useful to merit patent protection. But because the original statute did not provide for the examination or verification of these conditions, patents were issued on request. The determination of whether the patented subject matter met these tests, and was therefore valid, was left to the courts. Congress found this system unfair to the public (burdened with numerous invalid patents) and to inventors (forced to sort out patent rights in court) and abandoned it in the

Patent Act of 1836. The Patent Office was then created to examine applications for novelty and usefulness before patents were issued.

In 1850 the Supreme Court in Hotchkiss v. Greenwood, 52 U.S. (11 How.) 248 (1850) established that in addition to novelty and usefulness, that which was sought to be patented must constitute an "invention."

The Court said:

> "unless more ingenuity and skill... were required...than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention. In other words, the improvement is the work of the skilled mechanic, not that of the inventor."

In 1941, the Supreme Court in The Cuno Engineering Corp. v. The Automatic Devices Corp., 314 U.S. 84 (1941) in finding the patent in suit invalid said, "the new device, however useful it may be, must reveal the flash of creative genius." The enunciation of the unrealistic "flash of creative genius" standard led to the enactment of Section 103.

The Interpretation and Application of Section 103 by the Courts

"Thus, Section 103 exists to deny patent protection to claimed subject matter, which although novel, has contours that are so traced by the existing technology that the improvement is the work of a skillful mechanic and not that of the inventor." (See Bonito Boats 489 U.S. at 133-134). With respect to novel subject matter, "the goal of Section 103 is to effect the underlying policy of the patent system that , as Jefferson put it, 'the things which are worth to the public the embarrassment of an exclusive patent' outweigh the restrictive effect of the monopoly." Graham v. John Deere Co. 383 U.S. 1, 10-11, 15 L ed

2d 545, 552 (1966).

The germinal interpretation of S. 103 is Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966):

> Under Section 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

As stated in In re O'Farrell, 853 F. 2d 894, 902, 7 U.S.P.Q. 1673, 1680 (Fed. Cir. 1988), a case involving a biotechnology invention, "considering all of the evidence, this court must determine the correctness of the board's legal determination that the claimed invention as a whole would have been obvious to a person having ordinary skill in the art at the time the invention was made."

Thus *Graham* and its progeny have affirmed the intent of Congress to establish an objective standard for evaluating the issue of nonobviousness under Section 103. An objective standard, under which all evidence is considered, weighed and evaluated, does not afford absolute of certainty whether any particular invention will be nonobvious but does provide a high standard for patentable inventions so that only those who go beyond the contribution of the skilled mechanic will be rewarded with the 17 year exclusionary patent right.

The Effects of H.R. 1417 on Section 103

The proponents of the bill argue that the Federal Circuit decision in In re Durden, 763 F.2d 1406, 226 U.S.P.Q. 359 (1985) created a "loophole" in the law, and further, that "codifying" the decision of the Court of Customs and Patent Appeals in In re Mancy, 499 F.2d 1289, 182 U.S.P.Q. 303 (1974) by enacting H.R. 1417 will close the "loophole".

H.R. 1417 would not "codify" the *Mancy* decision, nor did the *Durden* decision create a "loophole" in the law. This bill would eliminate the application of Section 103 to process claims in certain circumstances, and thereby, change the basic premise of Section 103. The *Mancy* and *Durden* cases were decided by applying Section 103, as it now exists, to the facts presented. In *Mancy*, the process claim was found to be unobvious and patentable. In *Durden*, the process claim was found to be obvious and unpatentable. H.R. 1417 would amend Section 103 so that the result in *Mancy* would always occur, while the result in *Durden*, could never occur so long as the product made or used by the process is patentable.

Applying the patent law to both applications for patents and patents themselves involves a degree of uncertainty. The nonobvious standard allows for differing opinions depending on the nature and extent of the claimed invention and the teachings of the prior art. Each year, tens of thousands of patent applications are rejected by the PTO for various reasons to the dismay of applicants and their attorneys who believe these inventions should be patentable. Often these decisions are appealed to the Federal Circuit where sometimes the applicant prevails and sometimes does not. Often, issued patents are found by courts to be invalid. Therefore, there is superficial appeal in H.R. 1417 in that it would establish a per se rule of unobvious to process claims and remove uncertainty.

However, the desire of patent applicants and their attorneys for more certainty is not the issue. The central issue is whether, in determining unobviousness, a flexible standard based on applying the law after an analysis of all of the relevant facts, should be replaced by an inflexible standard where the relevant facts are by law ignored. The patent system would be badly served by establishing this legal fiction, especially because the existing statute in Section 103, and the cases interpreting it, provide a fair opportunity to obtain process patent rights.

There is no question that patent examiners currently rely on *Durden* as a basis of rejecting applied for process claims. We believe that reliance is often misplaced and is often in error, particularly in the field of biotechnology related inventions. However, that problem lies within the PTO, and, as we will discuss later, should be remedied by the PTO. The problem is not in Section 103 or the Federal Circuit.

The case of *In re Durden* involves a commonly occurring fact pattern but a highly unusual approach by the patentee in appealing the PTO rejection of the process claim. The appellant had obtained a patent on a carbamate compound and a second patent on a oxime compound made by processing the patented carbamate compound. In the case at bar, the appellant was seeking a third patent claiming the process of making the patented carbamate compound by using the patented oxime compound in a conventional manner.

Before the Federal Circuit, the appellant conceded that the claimed invention was obvious:

> To simplify the issues in this appeal, appellants concede that the claimed process, apart from the fact of employing a novel and unobvious starting material and apart from the fact of producing a new and unobvious product, is obvious.

> Appellants do not argue that differences in the chemical structure of either the starting oxime compound or the product produced would be expected to affect the reaction in any way which might render the claimed process unobvious.

The appellants' "Summary of Argument" states:

> A chemical process which (a) employs a novel and unobvious starting material or (b) is for the production of a novel and unobvious product compound or (c) which employs a novel and unobvious starting material and also is for the production of a novel and unobvious product compound, is patentable, regardless of the extent of other similarities to prior art processes. [Emphasis ours.]

In other words, the appellant was arguing to the court that Section 103 must be interpreted, at least as to chemistry, that "regardless" of the teachings prior art, processes in these circumstances are per se unobvious as H.R. 1417 would have it.

The court first stated the issue:

> "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 unobvious." [Emphasis ours.]

The court then stated the answer must be "not necessarily", and ultimately upheld the PTO rejection of the claim as obvious and unpatentable saying:

> We are sure that there are those who would like to have us state some clear general rule by which all cases of this nature could be decided. Some judges might be tempted to try it. But the question of obviousness under §103 arises in such an unpredictable variety of ways and in such different forms that it would be an indiscreet thing to do. Today's rule would likely be regretted in tomorrow's case. [Emphasis ours.]

This is hardly a case to stand for any certain approach to interpreting Section 103 regarding process inventions. In fact, the Federal Circuit has stated that *Durden* only stands for the

principle that each case must be decided on the basis of its own fact situation, Loctite Corporation v. Ultraseal Ltd., 781 F2d 861, 228 U.S.P.Q. 90 (Fed. Cir. 1985), and that *Durden* is not authority to reject as obvious every method claim reading on an old type of process. In re Dillon, 919 F2d 688, at 695, 16 U.S.P.Q. 2d 1897 at 1903 (Fed. Cir. 1990) (plurality opinion).

On the other hand, there is ample precedent in which courts have refused to apply a "necessarily nonobvious rule", as in *Durden*, but then found patent claims unobvious for convention processes of using a patentable starting material. In re Kuehl, 475 F2d 658, 177 U.S.P.Q. 250 (CCPA 1973). In re Pleuddemann, 910 F2d 823, 15 U.S.P.Q. 2d 1738 (Fed. Cir. 1990).

The rejected claims in *Kuehl* dealt with a method of using a patentable zeolite, "ZK-22", as a catalyst in hydrocarbon cracking. The PTO argued that the claimed method of use was the obvious method for using a zeolite catalyst. The appellant argued that the patentable nature of ZK-22 necessarily rendered the method of use claim patentable. The court rejected the appellant's argument and applied the statutory standard of Section 103 to the facts of the case. The court then specifically found that ZK-22 was not so similar to the zeolites of the prior art as to render its use to crack hydrocarbons obvious to one skilled in that art.

The invention in *Pleuddemann* related to a method for bonding a polymerizable material having aliphatic unsaturation and a mineral filler having hydroxyl functionality, and a method for priming a surface having hydroxyl functionality to improve its bonding to organic resins containing aliphatic unsaturation. Each method used the same specifically

defined organosilane compound. The organosilane compounds were themselves the subject of an issued patent. The products made using the organosilane had been conditionally allowed, subject only to being rewritten in independent form. It was, however, known in the art that organosilanes could be used as coupling agents.

The PTO rejected the method of use claims citing *Durden*. The court rejected the *Durden* argument, pointing out that *Durden* involved different facts and that the controlling law is found in Section 103. (It is illuminating to note that the author of the decisions in *In re Durden* and *In re Plueddemann* was Judge Giles S. Rich, one of the most distinguished patent law jurists in the world). The court, after dismissing *Durden* as non-controlling precedent, found the process claims unobvious stating:

> It is the properties of appellant's compounds as bonding/priming agents for certain polymers and fillers or support surfaces that give them their utility. As stated above, the compounds and their use are but different aspects of, or ways of looking at, the same invention and consequently that intention is capable of being claimed both as new compounds or as a new method or process 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 nonobvious. In this respect, therefore, 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 the cases dealing with the other. [Emphasis ours].

One year after the decision in *Kuehl*, the Court of Customs and Patent Appeals decided In re Mancy, 499 F2d 1289, 182 U.S.P.Q. 303 (CCPA 1974). *Mancy* isolated a naturally occurring microorganism found in the earth and applied for a patent on a conventional method of "brewing" that material to produce daunorubicin, a known antibiotic. The PTO rejected the patent application on the grounds that the method of using or

brewing a microorganism was conventional and obvious. The court reversed the PTO rejection, found the process unobvious and patentable and stated:

> [A]ppellants allege that the proper test for determining the obviousness of a process invention, where the difference between the claimed invention and the prior art resides in the material used in the process, was enunciated by the court in In re Kuehl, 475 F.2d 658[, 177 USPQ 255 (CCPA 1973),] wherein we held that a hydrocarbon cracking process was not even prima facie obvious where the particular zeolite catalyst used in the process was not known to the prior art, the obvious parallel being that the particular strain of microorganism used here was not known to the prior art.

The *Mancy* decision did nothing more than cite *Kuehl* as affirming the principle stated in Section 103 that in addressing claims to conventional processes, the invention as a whole must be considered in determining non-obviousness. The *Mancy* case did apply the principle to the field of biotechnology inventions.

In sum. the decisions in *Kuehl, Mancy, Dillon, Plueddemann* and other cases demonstrate that the current law provides a fair and equitable framework within process inventions are evaluated for nonobvious. There is no dispute that numerous patents. including numerous patents in the field of biotechnology, include claims for processes of using and processes of making patentable machines. manufactures and compositions of matter.

The Potential of H.R. 1417 to Prejudice Others

The negative effects of H.R. 1417, if enacted into law, are difficult to fully predict. Following are two examples of the potential for unjustifiable prejudice or harm to others when heretofore unpatentable claims for methods of use become patentable.

Example A. ACME Fertilizer Co. is granted a patent on compound A. Compound A is a truly superior fertilizer and successful sales begin immediately. Compound A also becomes the subject of research throughout the chemical industry.

Subsequently, the Jones Fertilizer Co. discovers that compound B, an adjacent homolog to compound A, is extremely useful in curing rubber. Compound B is structurally very closely related to compound A, and has the same superior properties as a fertilizer as does compound A. However, compound A is not useful to cure rubber. Discovering new uses of existing or closely related chemical compounds is commonplace.

Under current law, Jones would be able to patent compound B for use in curing rubber. A prima facie case of obviousness of compound B in view of compound A would be rebutted by showing the actual difference in properties. However, Jones would be unable to successfully claim compound B for use as a fertilizer because such a method of use would be obvious in view of compound A.

If H.R. 1417 were the law, the result would be quite different. Jones could successfully patent compound B as a method of curing rubber and for use as a fertilizer. The obviousness of compound B in view of compound A as a fertilizer could not be considered. Thereafter, a patent with that scope issued to Jones.

A third company, Smith Fertilizer, discovers that a previously known compound C, which is structurally similar to both A and B, unexpectedly is useful as a fertilizer but not as a rubber cure. In this circumstance, ACME may have a colorable claim for infringement of its fertilizer method-of-use claim against Smith under what is called "the doctrine of equivalents." The bill, by giving Jones an automatic right to a similar fertilizer method-of-use

claim, even though fertilizer use of compound B was otherwise obvious, would enable Jones to assert a similar infringement claim, thereby complicating and prejudicing ACME's right to license or enforce its patent and extending the period of time during which the public may not have free access to compounds similar to B for fertilizer purposes. Without the fertilizer method-of-use claim, Jones is much less likely to convince a court of infringement by equivalency because Jones' claims to compound B per se was based solely on its unexpected rubber cure property, which Smith's compound C does not possess. Also, granting Jones a fertilizer method-of-use claim may inappropriately make it more difficult for later inventors to obtain patent claims to other compounds discovered to be useful as fertilizers.

Example B. The Smith Company is in the business of harvesting trees, cutting the trees into lumber, and selling the lumber. As part of that business, Smith manufactures high speed saws. Over many years, Smith has improved its saws and has obtained patents on each of the improved machines. However, there is no difference from the first to the last patented saw in applying the cutting blade to the tree nor in the resulting lumber.

It may be that the patent on the first Smith saw could contain a claim for a method of using the saw to cut wood. But over the years, Smith's own saw patents and the patents of Smith's competitors are added to the prior art. Soon the claim for a method of using this type of saw to cut wood becomes obvious over the prior art, even though patents may issue on the improved saws themselves.

If H.R. 1417 were enacted, every patentable saw including Smiths will contain a method of using it to cut wood no matter how obvious it may be to use a saw to cut wood.

If one of Smith's competitors begins to manufacture and use a patented Smith saw, under current law, Smith could bring an action for patent infringement against that competitor. But now that Smith's patent on that saw includes a method of use claim, which would not have been granted but for H.R. 1417, those liable for patent infringement now will include every person who buys, sells, or uses lumber cut by the saws which infringe Smith's patented saw.

Also, an infringing Smith saw could be used outside of the U.S. by a foreign competitor of Smith to cut trees and import the resulting lumber into the United States. Again, Smith could take action against the direct infringer of the patent, in this case, by bringing an action in the International Trade Commission to prevent the importation of the lumber. But if damages and preventing domestic trade in that lumber is what Smith seeks, Smith will now have a cause of action for patent infringement against every person who buys, sells, or uses the lumber.

The General Counsel of the Department of Commerce in a letter of June 10, 1991 to Senator DeConcini regarding S.654, which is identical to H.R. 1417, said:

> ...S. 654 would not grant a patentee any greater rights vis-a-vis purely domestic infringers, because under section 154 of title 35 the holder of a patent to an invention, such as a host cell, may already exclude others from making or using that cell in the United States.

The General Counsel in a letter of July 5, 1990 to Chairman Kastenmeier on H.R. 3957, a predecessor bill to H.R. 1417, said:

> [H.R. 3957] would not grant a patentee any rights greater than those already assertable against someone who infringes the patent in the United States.

The clear import of these assertions is that the enactment of this bill will have no negative effect on persons in the United States i.e. the patentee would be granted no "greater rights" than are already provided by current law. The examples above demonstrate that is not correct.

In example A, the prejudice to the inventor/patentee ACME and to the consuming public from giving later inventor Jones an automatic right to method-of-use or method-of-making claims cannot be justified. To underline the injustice, imagine that Jones is a foreign corporation. Then the injury to ACME's business and employees and to United States consumers becomes an injury to a part of the U.S. economy and a windfall to foreign interests. While example B discusses saws, H.R. 1417 would effect every patentable machine, manufacture and composition of matter which is capable to producing a product where a method of use claim would be obvious in view of the prior art. Example B demonstrates that the enactment of the bill will allow patentees to enforce their rights against a multitude of persons who would have no legal exposure under current law. There is also no justification for this result.

The Need for H.R. 1417 Has Not Been Demonstrated

The primary stated purpose for the enactment of H.R. 1417 is that it is needed to protect the U.S. biotechnology industry from "unfair" foreign competition. The proponents further assert that H.R. 1417 is "consistent with the patent granting process now practiced in the European and Japanese Patent Offices," and therefore its enactment will provide for U.S. patent owners what is already provided to owners of foreign patents. We will discuss

these points in order.

The biotechnology industry in the U.S. has made extensive use of the U.S. patent system. The U.S. Patent and Trademark Office has issued hundreds of biotechnology patents, many affording broad protection for basic scientific discoveries. Virtually none of the major first-generation products to emerge from this industry has lacked effective patent protection, including human growth hormone, Factor VIII, erythropoietin, the interferons, human insulin, colony stimulating factors, interleukins, plasminogen activators, and a host of other entities. Many of these patents include process claims.

Although the industry is still in its infancy, its patent activities have spawned a plethora of lawsuits, many in foreign countries. Virtually none of the first-generation biotechnology products has escaped multi-million dollar litigation over enforcement of patent rights. In many cases dominating patents have been granted among various competitors. The interested parties have elected -- and sometimes been forced -- to pursue cross-licensing agreements in order to avoid the long, costly, and uncertain process of legal enforcement.

Against this backdrop of patent grants and patent litigation, the industry maintains it needs to expand its ability to obtain patent process rights to protect itself from unfair foreign competition. Yet the industry has not cited a single case of commercial harm to any company which has resulted from unfair foreign competition sanctioned so to speak, by the current state of the law.

The only case cited to demonstrate the need for H.R. 1417 does not do so. Amgen Corporation (Amgen), Genetics Institute (GI) and others in the biotechnology field engaged in extensive research relating to the protein erythropoietin (EPO). Amgen and GI were

both granted patents covering the purified protein as well as the gene cloning and expression of EPO. GI licensed its U.S. patent rights to Chugai Corporation (Chugai), a Japanese pharmaceutical company.

A multiforum legal contest between Amgen and GI/Chugai over the patent rights to EPO ensued. Amgen petitioned the International Trade Commission to prevent Chugai from importing purified EPO in the U.S.. The petition was dismissed on the grounds that the imported product did not infringe Amgen's patent, nor was the product made by a process protected by Amgen's patent. Later, in a patent infringement action brought by Amgen against GI/Chugai, the court found, inter alia, that Amgen had no legal right to market the very product Chugai was importing. Still later, the Federal Circuit reversed, inter alia, the district court holding that the GI patent was valid and enforceable. A patent interference, declared by the PTO, between the Amgen and GI patents has not been finally resolved to our knowledge, but does cover the very process claims which H.R. 1417 addresses. Under PTO procedures the winner of the interferences will be granted these process claims.

Several points are relevant to H.R. 1417. Amgen's failure at the International Trade Commission was not the result of any defect in Section 103, or in Section 337 of the Trade Act. Amgen's original patent application included claims for using the genetically engineered host cell it invented to produce EPO. During prosecution, Amgen voluntarily elected to drop its method of use claims from the application before the patent issued. The patent without those method of use claims was asserted at the ITC. Later, the PTO allowed Amgen's method of use claims, but instituted the interference proceedings referred to above.

Had these claims been in the patent asserted at the ITC, a decision on the merits of the case would have occurred.

Secondly, once the interferences are concluded Amgen is likely to be successful in ultimately securing the method of use claim it originally sought. While it is regrettable that this patent claim was not granted in the originally issued patent, the fact is that it will be granted under current law. This case may demonstrate an unfortunate choice by Amgen in cancelling its method of use claims. It does not demonstrate the need for enactment of H.R. 1417.

Finally, given the circumstances, it is inappropriate to characterize Chugai's importation of EPO as an "unfair" trading practice. Even if we assume that Chugai used the genetically engineered starting materials patented in the U.S. by Amgen to make EPO, that use violates neither U.S. nor Japanese law. In the course of this debate, it has been said that it is "unfair" for a foreign corporation to do something abroad, which, had it done the same in the U.S. would constitute patent infringement. While it might be viewed as unfair in some moral sense, the fact is that patent laws have no effect outside of a countries' borders. If Amgen wanted to prevent Chugai from using in Japan the product it invented, Amgen must secure a patent in Japan for the product. In a country to country trade law context, it may amount to an unfair trade practice for a country to deny to a U.S. inventor the legal ability to protect an invention within its territory. But even in that collateral sense, the notion of unfairness does not apply here because Japanese patent law is sufficient to afford protection to Amgen's invention.

The "level playing" field argument that H.R. 1417 would grant rights to patentees in the U.S which are currently granted in Europe and Japan prompts two comments. First, the playing field is inevitably already level in the sense that whatever patent rights exist in the U.S, those rights are available to U.S. and foreign inventors alike. The same is true in Europe and Japan for U.S. inventors. As mentioned earlier, foreign corporations are granted more U.S. patents than are U.S. corporations. Therefore, lowering the standard of patentability in the U.S. benefits U.S. and foreign patent applicants alike.

Currently, U.S. trade policy embraces the goal of ensuring that foreign countries have intellectual property laws which fairly and adequately allow for the protection and enforcement of U.S. inventions and other forms of intellectual property. For example, if a country did not allow patent protection for chemical inventions, in a trade context, we would consider that unfair. This trade related "level playing field" issue exists with lesser developed countries, but not with Europe and Japan for patent protection.

Second, neither the European Patent Convention, the Japanese patent statute, or, to our knowledge, the patent laws of any other country with an examination based patent system contain a provision which corresponds to H.R. 1417. In the European Patent Office (EPO) and the Japanese Patent Office (JPO) all claims for methods of using a patentable product are examined for nonobviousness. Because there is no per se unobvious patent provision, process claims may be rejected by patent examiners in both the EPO and JPO, and process patents may be found obvious and therefore invalid by European and Japanese courts. Therefore, the enactment of H.R. 1417 will not harmonize U.S. law with foreign law, and in fact the opposite is true. As this Subcommittee well knows, there is currently an

effort to harmonize the patent laws of all countries. In our opinion, this is an inopportune time for the U.S. to enact unique and unprecedented patent laws for the avowed purpose of "protecting" U.S. industry from foreign competition which has not been shown to be "unfair".

Administration of the Law by the PTO

We have explained earlier why the current law, both Section 103 and the cases interpreting it, provides a fair and workable legal framework within which process claims can be examined for unobviousness. We have also indicated that because patent applications present different facts, there will always be a measure of uncertainty as to the patentability of claimed inventions. That is an inevitable feature of the patent granting process. Each year many applications, which inventors and their attorneys believe present patentable inventions, are rejected by the PTO, and many more are amended before being allowed to issue as patents.

The fundamental responsibility of the PTO is to properly administer and interpret the law. The proponents of H.R. 1417 claim that the PTO is improperly relying on the *Durden* case to reject method of use claims in biotechnology applications. We have no evidence to believe this practice is widespread and believe that the PTO has not adopted this approach as a matter of policy. Without question, claims for broad recombinant processes for the production of proteins have been allowed i.e. Amgen for G-CSF, Genentech for TPA and Genetics Institute for Factor VII and M-CSF. And as explained earlier, such a process claim will almost certainly be issued to Amgen for EPO.

However, the assertion that patent examiners fail to understand and therefore sometimes misapply the law to process claims was given credence in testimony before this Subcommittee by the Solicitor of the PTO, Mr. McKelvy, on September 25, 1990 at a hearing on a predecessor bill to H.R. 1417 (The entire testimony of Mr. McKelvy is attached). In a response to a question by Mr. Boucher on the PTO opinion of the effect of *Plueddemann* on *Durden*, the Solicitor said,

> ... The *Durden* decision and the *Pleuddemann* decision are most difficult, in my judgment, to reconcile. And that being the case, maybe most patent examiners have more judgment than I do, but I think they are going to have a very difficult time in looking at any particular set of facts and determining whether *Pleuddemann* or *Durden* controls. In short, it is going to be on a case-by-case basis.
>
> ...I think it is because if you look at the two cases, which one are you to be persuaded by if you are a disinterested observer having two cases before you that are binding precedent?"

Later the following colloquy occurred:

> Mr. BOUCHER. And would it clarify the law if H.R. 5664 were to be enacted, effectively overruling *In re Durden* and returning to the prior law, which was the *In re Mancy* rule?
> Mr. McKELVEY. The bill which you mention is the latest introduced bill?
> Mr. BOUCHER. Yes.
> Mr. McKELVEY. Yes, it would, in my opinion.
> Mr. BOUCHER. All right, and that would help patent examiners and facilitate the process of resolving process claims?
> Mr. McKELVEY. It would, Mr. Chairman, I think in addition to that, it would also provide patent applicants and their attorneys with some measure of certainty in terms of giving advice on what you would patent and not patent.

Several comments are in order. *Durden* is not "binding" precedent for anything, save the clear statement by Judge Rich that given the facts of the case, the process claim, was not necessarily patentable. Judge Rich also said:

> We reiterate another principle followed in obviousness issue cases, which is to decide each case on the basis of its own particular fact situation. What we or our predecessors may have said in discussing different fact situations is not to be taken as having universal application.

Footnote 2, 763 F.2d at 1410, 226 USPQ at 361.

Second, *Durden* does not and cannot overrule *Mancy* (or *Kuehl*). It is well settled that decisions of the CCPA are the law of the Federal Circuit until overruled by the Federal Circuit in banc. South Corp. v. United States, 690 F.2d 1368, 215 USPQ 657 (Fed. Cir. 1982) (in banc). Therefore, the reasoning of the court in *Mancy* in applying Section 103 to a method of use claim is already "binding" precedent without the enactment of H.R. 1417. When the PTO cited *Durden* as justification for rejecting the method of use claims in *Plueddemann*, Judge Rich stated that *Durden* is not precedent for the rejection and ultimately found the claims patentable. If patent examiners were educated on this point, which was also stated in *Dillon*, then the examiners would not be faced with attempting to "reconcile" *Plueddemann* and *Durden*. They could then proceed to apply *Mancy* as illuminated by *Plueddemann*.

Finally, the Solicitor's testimony leaves one with the impression that the patent examiners operate as free agents to read and interpret the law for themselves. That is certainly not, or should not be, the case since the great majority of examiners are not lawyers. Clearly examiners need and frequently receive guidance from their supervisors on

the proper interpretation of the law. The Solicitor's testimony implies that in the law at issue here, they are not receiving that guidance.

As a matter of policy, the PTO clearly supports the principle that in chemical or biotechnology applications, when a patentable composition of matter is used to make another product, patentable or not, a method of use claim should be unobvious in a great majority of cases. We know this because the PTO supports H.R. 1417 which would go far beyond this principle. The *Kuehl*, *Mancy*, *Dillon*, and *Plueddemann* cases, and others, provide ample support for this principle.

Certainly it cannot be necessary for Congress to enact a bill for the purpose of forcing the PTO to apply the reasoning of the court in *Mancy* or *Plueddemann* for biotechnology inventions. We believe it would be more appropriate for the Commissioner to issue a directive to the examiners clarifying the law, particularly the non-precedential nature of *Durden*, to assist examiners properly apply Section 103. If there is an uncertainty in the examining corps regarding the difference between processes of making and methods of using patentable products, that should also be clearly explained.

* * *

This concludes our statement. Again, we appreciate the opportunity to participate in this proceeding.

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/Excerpts from Sept. 25, 1990, hearing/

Mr. BOUCHER. And then the ITC would have authority to bar the importation of the product coming from somewhere else utilizing that same patented host cell and the patented process?

Mr. MANBECK. Yes, sir, that is my opinion.

Mr. BOUCHER. So your view is that solves the problem entirely, and therefore we don't need to amend the ITC's statutory authority, is that correct?

Mr. MANBECK. Yes, sir, that is correct.

Mr. BOUCHER. I think that is very clear. Let me ask you this. Let us suppose that we are not successful in our effort to overrule *In re Durden* and the current law continues. How would the Patent and Trademark Office interpret process claims in light of the *Pleuddemann* decision? What effect would the *Pleuddemann* decision have on your current interpretation of *In re Durden?*

Mr. MANBECK. This is a very difficult question. Our solicitor, Mr. McKelvey, is here with us. I could ask him to comment if you would like.

Mr. BOUCHER. Sure. We would be happy to hear from him.

Sir, please state your name and your position for the record.

Mr. MCKELVEY. Mr. Chairman, I am Fred McKelvey, Solicitor of the Patent and Trademark Office.

Following up on Commissioner Manbeck's statement, the *Durden* decision and the *Pleuddemann* decision are most difficult, in my judgment, to reconcile.

Mr. BOUCHER. Could you pull the microphone a little bit closer?

Mr. MCKELVEY. And that being the case, maybe most patent examiners have more judgment than I do, but I think they are going to have a very difficult time in looking at any particular set of facts and determining whether *Pleuddemann* or *Durden* controls. In short, it is going to be on a case-by-case basis.

We have numerous patent examiners, all with the best of intentions, that are going to reach different results, as may our Board of Patent Appeals and Interferences, depending on who the panel is. If these two cases continue to exist side-by-side—and I might say it is not only *Durden* and *Pleuddemann*, but numerous other decisions as well—we are going to have, in my judgment, inconsistent application of the law, albeit with good intentions.

Mr. BOUCHER. Well, I hear you saying that the *Pleuddemann* decision doesn't do anything to clear up the confusion that exists in the law currently.

Mr. MCKELVEY. That is correct, Mr. Chairman.

Mr. BOUCHER. In fact, it may have even added to that confusion. Is that a fair statement?

Mr. MCKELVEY. In my judgment, that is a fair statement because both *Durden* and *Pleuddemann* start with a patentable material—apply a method to make a patentable final material. How you can say one is a method of using vis-a-vis the other a method of making is in the eye of the beholder. It depends on where you start.

Mr. BOUCHER. The latter being a method of manufacture?

Mr. MCKELVEY. Yes.

Mr. BOUCHER. The distinction was between using on the one hand and making on the other. You are saying that is a very difficult distinction for the PTO to apply?

Mr. McKelvey. Well, I think it is because if you look at the two cases, which one are you to be persuaded by if you are a disinterested observer having two cases before you that are binding precedent?

Mr. Boucher. And would it clarify the law if H.R. 5664 were to be enacted, effectively overruling *In re Durden* and returning to the prior law, which was the *In re Mancy* rule?

Mr. McKelvey. The bill which you mention is the latest introduced bill?

Mr. Boucher. Yes.

Mr. McKelvey. Yes, it would, in my opinion.

Mr. Boucher. All right, and that would help patent examiners and facilitate the process of resolving process claims?

Mr. McKelvey. It would, Mr. Chairman. I think in addition to that, it would also provide patent applicants and their attorneys with some measure of certainty in terms of giving advice on what you could patent and not patent.

Mr. Boucher. Well, thank you, sir. You are an excellent witness. [Laughter.]

Mr. Boucher. That concludes my questions. The gentleman from California.

Mr. Moorhead. Thank you. It is always good when you get a witness that testifies right.

The Intellectual Property Owners Association will testify later today in opposition to these bills. They believe that section 1 may legitimize the patenting of process claims that would be rejected today under the overclaiming doctrine. Would this be possible?

Mr. Manbeck. Is that question directed to me, Mr. Moorhead?

Mr. Moorhead. Yes.

Mr. Manbeck. It would be helpful to understand a little bit more of what is meant by the "overclaiming doctrine." At least I and my associates here have thought perhaps what is meant here by that term in this context, is the so-called exhausted combination, under which, for many years under the *Lincoln Engineering* case, the Patent and Trademark Office rejected claims as directed to "exhausted combinations."

There have been at least two cases treating the issue, and these cases—one a CCPA case and the other a Court of Appeals for the Federal Circuit case—hold that if claims are to be rejected in the Patent and Trademark Office or overturned in the courts on the basis of exhausted combination, one really must look at section 112 of the statute, and that this is what controls. Has the patentee disclosed and claimed with particularity and distinctness his invention? If he has done that, we understand he has met the intent of the patent laws and the patent would be granted.

Mr. Moorhead. In the testimony that will be offered, it says the Supreme Court of the United States in the *Lincoln Engineering* case struck down a patent based on what has been variously called the overclaiming, old combination or exhausted combination doctrine. That doctrine holds that an inventor is not permitted to hide the invention by inserting into patent claims large numbers of unnecessary elements or steps so that the claims fail to particularly point out the invention.

Mr. HUGHES. The gentleman from Virginia.

Mr. BOUCHER. Thank you very much, Mr. Chairman. Well, what I am hearing from this panel is very curious. I mean it sounds like, notwithstanding the testimony we have previously received from the Patent and Trademark Office, that there is a serious amount of confusion and a major problem with the law, and from universities that have need for certainty in this field and ability to get patent rights issued quickly and expeditiously, and from the biotechnology industry itself that there are major problems and uncertainties in the law, you seem to be saying that there is no problem. Is that a fair interpretation of your testimony? Mr. Marsh.

Mr. MARSH. Mr. Boucher, it is. I am amazed that we do not read the *Pleuddemann,* the *Dillon,* the *Durden* cases very carefully and actually look at the language and reasoning applied by the eminent jurists in those cases and then apply it as those cases have indicated they should be applied. The *Durden* case is very, very unique on its facts. It was requested to be taken up to the Court of Appeals for the Federal Circuit by the PTO. Concessions were made in order to frame an issue there. That case rejected the arguments of the patent applicant that, merely because they had a patentable starting material or a patentable product, they were automatically entitled to process claims. That is the holding of the court. It rejected that "merely because" argument.

Mr. BOUCHER. Mr. Marsh, without getting too much into the capillaries of that decision, the effect of it is very clear. And that is, that the Patent and Trademark Office is not issuing process patent claims under the state of facts presented by the biotechnology industry, the universities and others this morning.

Now, we have had at least one very clear example that we are all familiar with, it is notorious, where real harm was done, and that is in the case of EPO, the Amgen product, the importation into the United States of which was allowed, even though it was made with a process that itself was known utilizing a patented host cell. That was allowed.

Mr. MARSH. May I respond to that?

Mr. BOUCHER. Yes. I would like to ask you specifically why you believe that we don't have a problem in our law when that was specifically allowed.

Mr. MARSH. I believe in many circumstances the Patent Office is issuing process patent claims in the biotechnology industry as well as in other industries and other technologies. It is my information and belief, and I could stand corrected—I believe Mr. Allegretti could probably provide this information to this committee today, as to whether Amgen currently has pending process claims in the Patent and Trademark Office. My belief, or my information—I may be wrong on this, but I believe he could correct this very quickly—is that those process claims may be tied up in interference proceedings with the question of is someone else the proper inventor of those claims. I am not sure of that.

But I do know that in other areas the Patent Office, when looking at particular claims does, in fact, consider them nonobvious in many cases. I think if they read the *Pleuddemann* decision and the *Dillon* decision and apply that along with the *Mancy* decision we have a very workable system in the present state of the law that

says that if you have a new material and you use that material, or even make that material by a process, that the Patent Office should not be applying *In re Durden* in a rote manner, but should be looking at the process in light of the starting or ending material and deciding whether the process as a whole is inventive.

Mr. BOUCHER. Well, you heard this morning Commissioner Manbeck indicate that he feels that he has no alternative but to apply the law as announced in the *Durden* case. He also said that the *Pleuddemann* case, and this is on advice of his counsel, does nothing to clarify the situation; that, in fact, it perhaps makes it worse; and that there is such uncertainty at the present time that the biotechnology industry cannot have the confidence that its process patent claims in these circumstances are going to go forward. That much is very clear.

And I find it difficult in the face of all of that, practical obstacle though it may be, that you can sit here this morning and tell us that there is no problem to which we should respond. I would just respectfully differ with you. I think that perhaps you misperceive the role of the Congress. At a time when an administrative agency says that there is an enormous amount of legal uncertainty and Congress very readily can correct that uncertainty and create a smooth flowing process for people who need this patent protection, I, for one, think we have an obligation to do it.

You are certainly entitled to your opinion to the contrary. But I think if we adopt your course of action it could be years of expensive litigation with no guarantee that at the end of that we are going to arrive at the proper result. We know we can arrive at the proper result if we simply pass this bill.

Let me just mention one or two other items, and I will try not to prolong this, Mr. Chairman. You had indicated that, perhaps—I guess it was Mr. Chisum indicated that if there is some overzealous application of the *Durden* decision that the Patent and Trademark Office can take care of that on its own. But I would suggest to you that if the lawyers at the Patent and Trademark Office say that they have to follow that decision their application of it is not overzealous. That is simply what the law requires. And, obviously, they again this morning have told us that they have no choice. This is something they simply have to do. So, I wouldn't characterize it as overzealous. It is an application they feel is required by the law as announced by the court of appeals in the *Durden* decision.

Second, you had indicated that there might be some problem in creating a precedent if we passed this bill, and that in doing that we might undermine the confidence in existing patents. I fail to see how that could happen. Because there is nothing in this legislation that would take away a right that a current patentholder enjoys. We are adding rights through this measure. We are in no sense taking them away. So I fail to see how we could be undermining the confidence in existing patents by passing this measure.

By the way, if you want to respond to any of this you are welcome to do it.

Now, let me see if I can take a shot at responding to your example with the saw. As I understand your hypothetical, the use of that saw to cut down trees, if our bill were to pass, would then give someone—I guess the patentholder on the saw—the opportunity to

exercise an infringement action against a seller of the trees or maybe even somebody who bought the trees.

I would suggest to you, and I would like your response to this, that if you fear that under the passage of this bill, that same thing could probably happen today, and the reason is that under the *Pleuddemann* case anytime the subject of the patent is a use, as opposed to a manufacture, and in the case of the saw it clearly would be a use, then a patent infringement action could lie. And, so if you are afraid that that would happen under the terms of H.R. 1417, why are you not fearful that that would happen under the current law as announced in the *Pleuddemann* decision? Clearly a use of the product being contemplated in your example.

I will stop with those questions, and if you care to respond, I would be happy to hear your response.

Mr. HUGHES. Mr. Chisum.

Mr. CHISUM. Certainly. I think your first point had to do with the PTO, if they say their lawyers tell them that they are bound by the *Durden* decision and there is only one interpretation of the *Durden* decision. I have spent many years teaching law and I know that how to interpret cases is not always crystal clear and cases do not always dictate their own interpretation.

Second, in terms of the PTO I really would cite a specific instance. A few years ago a case came up called *In re Bond.* It dealt with a technical matter like the interpretation of so-called means plus function limitations. The Patent Office viewed that decision as creating a serious administrative problem for them and took the very convenient position, frankly, that that was inconsistent with prior cases and they were not going to follow it, or they were not going to follow a certain interpretation. So the Patent Office knows how to interpret cases properly and to reconcile conflicts among cases when they want to. And I cannot but speculate as to what reasons they don't want to in this instance.

The third has to do with your point about faith in the patent system. Patents are very fragile things. Under our system of justice, many times ultimately a patent is only worth something if a jury in a case is willing to say that is a valid patent and it is infringed—the right to trial by jury. And so the public very much directly participates in the patent system, and it indirectly participates by paying higher prices in some areas because patents are issued on products. And they do so because they believe, I think, that it is not only just, but that it furthers the development of the useful arts and technology.

But I think if it is perceived that any special interest group or industry is able to obtain exceptions or special provisions in the patent law that will start a process of undermining public confidence in our patent system.

I think your fourth hypothetical has some merit to it; that is, I believe in some circumstances indeed that could happen today. But the point is that under this new legislation there would, I think, clearly be a proliferation of use claims. Every patent attorney worth his salt will always add on a whole series of method of use and method of making claims even though the invention may be quite clearly just a new machine or a product, and that proliferation of claims will make patents more difficult to interpret and

easier to assert in a wider variety of circumstances. So I see that that would be a problem today. I just feel that it would be worse if we automatically and without examination validated into the patents method-of-use and making claims.

Mr. BOUCHER. Well, I would only offer this insight or thought, and that is, that I think we both agree that under the *Pleuddemann* decision your hypothetical probably would be actionable today. I think the reason it is not is that it is absurd. It is such an outlandish hypothetical that no one would attempt to assert a right in that sense because clearly that is not what the patent law is designed to address.

I would take the position that it would not be made worse under H.R. 1417 because clearly that remedy, if it could be enjoyed, could be enjoyed even at the present time.

I think what it really comes down to is this. You tend to point, the three of you, to absence of cases of demonstrable harm. I would argue that EPO is a case of demonstrable harm, and there are probably others. It is hard to find full evidence of all of the cases where people simply have not sought a patent because they realize it is going to be denied in light of *In re Durden*. It is virtually impossible to collect that kind of evidence.

But I think the real harm isn't measured by that test. The real harm is measured by the chilling effect that this uncertainty in the law has on the willingness of biotech companies to make major research and development investments. It is a research and development intensive industry. Enormous sums of money have to be spent at the outset in order to produce commercially acceptable products. And, given this uncertainty in the law, the real harm is the chilling effect that it has had on the willingness of companies to make that level of investment.

That is why, Mr. Chairman, I think this subcommittee should act to address the problem as it exists and view favorably the provisions of H.R. 1417.

My thanks, Mr. Chairman, to these witnesses for their testimony today.

Mr. HUGHES. Thank you. Let me take you back, if I might, to your statement, Professor Chisum, that the Patent and Trademark Office could resolve this easily internally, either administratively or otherwise, by their interpretations, and your suggestion that actually by way of precedent the PTO should be looking at the earlier decision in the event of a conflict, not the later decision. That would suggest that they should be looking to *Mancy*, not to *Durden*. Is that basically what you are saying?

Mr. CHISUM. That is correct.

Mr. HUGHES. OK.

Mr. CHISUM. If they perceive a conflict, the court of appeals has been very clear, they should follow the——

Mr. HUGHES. I know you indicated that you could only speculate as to why they haven't done that. Why don't you speculate for me?

Mr. CHISUM. I shouldn't have said that. I should have said I can't even speculate.

Mr. HUGHES. I would be interested in knowing, you know, why you think if they have this ability, and I have to believe that they have the best of legal advice available to them, if they have an out

by just a matter of interpretation and by using precedent, which they have used in the past, as you have indicated, when they find it convenient, why they haven't done so.

Mr. CHISUM. Well, first of all, Mr. Chairman, I can't speak officially on behalf of the AIPLA in that kind of speculation.

Mr. HUGHES. We agree with that.

Mr. CHISUM. But certainly if this were enacted, there is an easing of some administrative burdens upon the Patent and Trademark Office. Certain types of claims would simply now not even have to be thought about. They would simply be rubber stamped. And so for a certain category of claims they would be relieved of the administrative burden and the expense.

We are very sympathetic with the Patent and Trademark Office. We believe in a strong patent system. We believe in an effective examination system and high quality patents, and we think there are other solutions to the problem. But one possible speculation may be that this is administratively easy to deal with, to administer.

Mr. HUGHES. Mr. Marsh, what do you have to say about that?

Mr. MARSH. Again, I am speculating. I am speculating on my personal behalf at this point. But I agree with Professor Chisum on this point. That it appears to the Patent and Trademark Office to be a very efficient way of handling these process claims without further examination. They can look at the starting material, decide that is patentable, and then any claims that just assert that as an element, whether they are in the same patent or in a divisional case, can get passed on through, in essence, leaving it for the courts.

I think there is a great deal of momentum behind this bill, and its very broad ranging aspect is something that creates the momentum and encourages the administration, I think.

Mr. HUGHES. H.R. 1417 waives the nonobvious requirement for processes of making or using patentable products. The undesirable result flowing from the bill, as cited in your testimony, seems to arise from the "using" branch of the bill.

Suppose the bill were limited to making processes, would that address the concern? Anybody?

Mr. MARSH. I will respond to that. I don't believe that I see a major difference between the concepts of making or using. I think the issue relates to the patentability of the process in light of either the starting or the ending material, and I think they should be addressed somewhat similarly. My concern would be, if we perceive *Durden* in its very, very narrow holding to be a problem, that we need to somehow merely excise the reliance on *Durden* in that narrow holding and applying it in cases where it doesn't apply. I think that is what we need, rather than an extremely broad ranging bill such as H.R. 1417.

And I do not advocate doing this merely for the biotech or any other particular industry. But I believe what we need to do is use a scalpel in dealing with this problem, rather than using a sledgehammer where we don't know what the results will be.

Mr. HUGHES. How would we fix it? I mean, you have got to concede there is a problem. There is a problem. I mean, your remedy is a little different than is proposed in the bill. Your remedy is they

can fix it, you know, within the agency. All they have to do is administratively decide to fix it.

Work under the assumption that they are not prepared to do that. How would we fix it? How can we do that, then, surgically, as opposed to using a sledgehammer, as you suggest?

Mr. MARSH. We have explored in IPO and other groups methods of doing this. Unfortunately, as we come up with a process or a way of doing it, we raise other problems, downstream problems that we say we need to back away from at this particular point in time.

One suggestion has been the 271(g) route to address the particular problem that is coming up here. I have some problems with that myself, because what we are doing is extending protection beyond a gap of defined examined process claims if we follow that suggestion. I would prefer, personally, to see if there are going to be amendments, and if Congress feels the need to direct action by the agency now, that they direct it not to rely on *Durden*. That they remove that particular holding, rather than taking a very, very broad, new approach to the problem.

Mr. HUGHES. I am going to have to interrupt you because I have got about 4 minutes to catch that vote. I do have some other questions and I would rather, I think, come back.

We will stand in recess for about 10 minutes.

[Recess.]

Mr. HUGHES. The subcommittee will come to order.

Let me take you back, if I might, to your suggestion and testimony that PTO could internally resolve any problems. I think we left off by my asking what are the alternatives. Suppose PTO, which is their right, decides they don't want to do that for one reason or another, regardless of what you might speculate is the reason. We have a responsibility to ensure that we have a balanced system and that the creators of property of all kinds, whether biotechnology or whatever, are assured that their property rights are protected for a limited term. What is Congress to do? When does Congress step in?

Mr. MARSH. Mr. Hughes, right before the break you had asked me how I would surgically address this problem, and then we took the break. I feel that if the PTO is not going to properly address the situation I think it is the role of Congress then to specifically direct them to handle it in a balanced manner.

There were suggestions about amending 271(g) to take care of the importation problems.

Mr. HUGHES. Which you don't like.

Mr. MARSH. I don't like that. This is not an IPO position that I am going to suggest. This is a personal position, but I think it was picked up in someone else's statement, that it was suggested. And that is that section 103, in fact, be amended to overrule the *Durden* decision by incorporating essentially the language out of the *Dillon* decision that said *Durden* was not applicable. I would suggest that if this or similar—it has to be fine tuned. We have to be very careful about what we do. But I would prefer to amend 103 to say a process or method claim wherein an essential element is a composition of matter otherwise patentable to the applicant shall not be deemed to be unpatentable merely because the claim reads "on a

known process or combination of steps but shall be examined as a whole," giving consideration to the specific nature of the process or method and the fact that new or otherwise patentable materials are used or result from the process or method.

I think that clearly would overturn the *Durden* decision, and I think it codifies the basic premise of our patent laws which is that we reward patent claims that are carefully examined and determined to be patentable and to be clear and unambiguous and definable after we have determined that there is an invention that they relate to. I think that this type of an amendment, and again, it is imprecise, and I don't think it has seen the type of careful consideration by industry, by the bar, or by others, but I think it is one approach that could be taken that directly attacks the misapplication of *Durden* by the Patent and Trademark Office without changing drastically the law. And I would prefer to do it that way, myself.

Mr. HUGHES. Mr. Weilacher, I know that this is going to be unfair because you probably haven't examined this. But what is your initial reaction to this?

Mr. WEILACHER. Well, Mr. Chairman, I can't speak for ABA Patent Section because we only have limited blanket authority.

Mr. HUGHES. I understand. No, I want your personal reaction to it.

Mr. WEILACHER. I think that from what I have heard it does sound like an interesting approach to take because of the problems that we see with granting unexamined process claims just automatically. I think this focuses the examiner back on his role, which is to examine in accordance with the court decisions. And I think that this language or language which would give him some guidelines to examine his patent applications consistent with what the courts have said, it would be helpful for the examiner.

Mr. HUGHES. Professor Chisum.

Mr. CHISUM. Well, first, to start with, Mr. Chairman, I, with all due respect, do not believe there is a serious problem here in need of a solution. I am also a strong believer in not having legislation if it is not shown to be needed, particularly in the patent field.

Mr. HUGHES. Professor, we do that all the time.

[Laughter.]

Mr. CHISUM. I can just state my view, Mr. Chairman.

But, in the patent system there may be peculiar problems. There is a great deal at stake. The commercial interests are great. And every time there is a new patent statute or new legislation or even new administrative rules, there is a ripple effect through the private sector. Legal opinions are given. I wish I had 10 cents on the dollar for every legal expense that was occurred as a result of something like the Process Patent Act. So there is always an expense from legislation, even if it is viewed as a necessary cure to some slight problem.

For example, to use an analogy, if you have a slight fever that is bothering you a bit and will probably be over in 2 days, you don't take an antibiotic that will make your whole body ache for 3 weeks. The solution is way out of joint.

Mr. HUGHES. Let me rephrase the question. Let's work on the assumption that no fix is needed. Let me ask you if you will share

with me and the committee the impact that the language advanced by Mr. Marsh would have upon patent law?

Take your time. I realize it is kind of lengthy.

Mr. CHISUM. Well, I am not sure it would have a great impact. Because I am not sure it is that far off of what the current law is. But it would certainly have an immediate impact for people who would have to read it and figure out what it meant. I realize that may sound like a slight point.

Mr. HUGHES. It might be the lawyers' full employment bill of 1991?

Mr. CHISUM. That is correct. That is correct. So, if it is really not needed and really does restate the law, and we don't have a serious problem, as I believe we do not, the *Durden* case has been blown out of proportion by proponents of this legislation, then why do we need a simple statement which on first reading seems close to reflecting what we believe to be the law.

Mr. HUGHES. All right. Any member of the panel, are you aware of any other industry other than biotechnology where products are imported from abroad that are made by a process which uses a material patented in this country?

Mr. Marsh.

Mr. MARSH. Yes, I am. In the instance of cases where it may not be a composition or a biotech composition. It may be equipment. It may be a catalyst, and so forth. That is one of the—I mean, my company is affected directly by that, and that is one of the prices we pay for our patent system and our decisions over what to patent in foreign countries.

Mr. HUGHES. Professor Chisum.

Mr. CHISUM. It is my understanding the proposal is to bar importation into the United States of unpatented products that are made by—what?—machines or compositions of matter abroad? That would be one more step, extending the philosophy of the process patent legislation. I think when one gets into the area of the international impact of patent legislation at some point you have to draw a line. I think in our statement we point out that at some point we have to look to reciprocity and look to persuading other countries to provide adequate patent protection within their borders. I think there is only so far you can go in tracing back in time patent rights and extending them indirectly abroad.

So my personal view would be that we should very carefully consider the international trade implications and other aspects of extending our patent systems that far.

Mr. HUGHES. Do you know offhand when the patent application was filed for Amgen whether they applied for a process patent?

Mr. CHISUM. Do I, personally?

Mr. HUGHES. Yes.

Mr. CHISUM. I believe they did. I believe, and this is just by memory. I had one occasion, and I don't remember what the occasion was, I was aware, and maybe it is described in the *Amgen* v. *Chugai* litigation, that indeed Amgen did have claims, method-of-use-type claims using the host cells to produce EPO. They were I think initially rejected. I don't believe they were finally rejected and are subjected to even appeals. A patent was issued. But there are well-recognized procedures to continue to seek those claims,

and it is our understanding that indeed claims to methods of using host cells have been allowed to Amgen. They have not issued because of a pending interference over who was the first inventor. But the method of use claims were sought and they have been allowed by the Patent Office.

Mr. HUGHES. What, in your judgment, Mr. Weilacher—or Mr. Marsh—is the holding of *Pleuddemann?*

Mr. WEILACHER. I think it says that method of using a novel composition are patentable. I was glad to hear the Commissioner say that he wants to follow decisions of the court of appeals because I think that some of the examiners at least are not following that decision, and I think if they would follow that decision at least some of these problems could be overcome. And I think if they were looking at the *Durden* decision and reading the *Durden* decision carefully they would see that it was a very, very narrow holding. I think a part of the problem is that the Patent Office is using *Durden* broadly and ignoring *Pleuddemann.*

Mr. HUGHES. All right. Well, thank you very much.

I have some additional questions, but, unfortunately, I need to go to the floor. I would like to, if I might, direct some additional written questions to you, reserve that right, and the record will remain open for purposes of securing responses. Would 2 weeks be sufficient time?

[A chorus of yes.]

[The information appears in the appendixes.]

Mr. HUGHES. Thank you very much.

The panel has been very helpful. We thank you. And that concludes the hearing for today and the subcommittee stands adjourned.

[Whereupon, at 1:50 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

APPENDIXES

APPENDIX 1.—SERIES OF LETTERS (1–24) FROM NUMEROUS UNIVERSITIES ENDORSING H.R. 1417, SUBMITTED BY THE HON. RICK BOUCHER

Letter 1

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

President

New Brunswick • New Jersey 08903

908/932-7454

June 6, 1991

The Honorable Rick Boucher
The Honorable Carlos J. Moorhead
405 Cannon House Office Building
Washington, D.C. 20515

Dear Congressmen Boucher and Moorhead:

Rutgers, The State University of New Jersey welcomes this opportunity to comment on HR 1417 and S 654, which would amend Title 35 of the U.S. code with respect to patents on certain processes.

Rutgers is of the opinion that this legislation would correct current law which enables foreign manufacturers to export to the U.S. without license products of biotechnology that are fabricated using parts or processes patented in the U.S. If those same products were produced in the U.S. rather than elsewhere, the American manufacturer would have to be licensed or be charged with infringement. The proposed bill will grant jurisdiction to the International Trade Commission to exclude foreign products made using parts or processes patented in the U.S., closing the loophole through which foreign competitors are able to market in the U.S. products that infringe American biotechnology patents.

Moreover, by overruling In re Durden, which is cited frequently for denial of process patents, and by permitting product-by-process claims for items made using novel recombinant materials, HR 1417 and S 654 will encourage innovation in biotechnology by diminishing concern of inventors and investors about patent protection. HR 1417 and S 654 will stimulate conversion of discoveries to process patents by universities, and it will provide the U.S. biotechnology industry opportunity to compete as an equal with its Japanese and European competitors. Moreover, as presently constituted, the benefits of HR 1417 and S 654 would not be limited to innovation in biotechnology but would accrue to all process-related inventions.

The proposed legislation addresses questions of special interest to Rutgers, which has a record of support of legislation protective of intellectual property in general, and of university/industry interactions in particular. HR 1417 and S 654 will help perpetuate U.S. preeminence in biotechnology and related fields that offer promise for solution of many of the world's problems, including pollution, disease, energy, and hunger.

Sincerely,

Francis L. Lawrence

Letter 2

The President

June 14, 1991

Congressman Rick Boucher
405 Cannon House Office Building
Washington, DC 20515-4609

Dear Congressman Boucher:

Thank you for providing an opportunity to comment on your Bill, H.R. 1417, the "Biotechnology Patent Protection Act of 1991". We are pleased to support your efforts to bring the U.S. Patent laws into alignment with the patent laws of other nations and to provide an environment conducive to the most effective development of new technology. Not only will this benefit existing industry but it will also promote the development of new, start-up businesses in the United States.

Brown University believes strongly in its responsibility to bring the scientific discoveries of its faculty and researchers into the broadest possible use for the benefit of the general public. We recognize that an essential component of the commercialization process is a strong patent position which will allow companies licensed by Brown, and other universities, to make the substantial investments needed to bring a new product to market. In the emerging business of biotechnology and the medical applications of biotechnology these concerns are particularly important. We believe that your Bill will enhance the transfer of technology into the market place, contribute to the growth of U.S. industry, and, in general, improve the economy.

Your leadership on this issue is to be congratulated.

Sincerely,

Vartan Gregorian

Vartan Gregorian

Vice President for Research
Dean of the Graduate School
Telephone (313) 577 5600

Letter 3

Wayne State University
Detroit Michigan 48202

June 18, 1991

The Honorable Rick Boucher
U.S. House of Representatives
405 Cannon House Office Building
Washington, D.C. 20515

Dear Congressman Boucher:

Thank you for affording me the opportunity to share my views regarding H.R. 3957, the Biotechnology Patent Protection Act. Wayne State University is a supporter of this measure. From a national perspective, the bill is important as Biotechnology is one of only a handful of key, emerging industries in which the U.S. holds a clear, competitive advantage.

From a more parochial perspective, it is very important for institutions such as WSU to have strong patent protection. A significant percentage of the invention disclosures from University research are based on the new biological technologies. Stronger patent protection would increase the potential value of University assets.

Based on the above-mentioned reasons, I would like to again reiterate my support for your legislation. If ever I can be of assistance, please don't hesitate to call.

Sincerely,

Garrett T. Heberlein, Ph.D.
Vice President for Research
and Dean of the Graduate School

The University of Texas
Health Science Center at Houston

Letter 4

Thomas F. Burks, Ph.D.
Executive Vice President
Office of Research and Academic Affairs

P.O. Box 20036
Houston, Texas 77225
(713) 792-4875

May 21, 1991

The Honoreble Rick Boucher
Cheirman
Subcommittee on Science
Committee on Science, Space and
Technology
400 Cannon House Office Building
U.S. House of Repreeentativee
Waehington, D.C. 20515

RE: H.R. 3957, the Biotechnology
Petent Protection Act of 1990

Dear Cheirman Boucher:

The Univereity of Texae Heelth Science Center et Houeton ie engaged in reeearch ectivitiee thet encompaee the field of biotechnology ee well ee other diveree fielde in the medical eciencee. One of the goale of the Health Science Center ie to transfer the inventione genereted from our research to the public ee quickly and ee economically ee poeeible.

In furtherence of thie goal the Heelth Science Center eupporte etrong intellectual property lew protection for innovetions in all ereee of ecience including biotechnology. H.R. 3957 would cloee e loophole in the trede lew thet currently permite unfeir importation of biotechnology-derived producte. We eupport extending the International Trade Commieeion'e juriedicition to protect e patent owner'e rights egeinet importation of en identical drug thet ie produced in e foreign country. It ie e dieincentive to American companiee to allow foreign competitore legally to export to the U.S. biotechnology producte utilizing componente patented in the U.S., when thoee producte, if produced in the U.S., would conetitute patent infringement.

Univereity-baeed inventione ere licenee to U.S. corporetions, who in turn expend large eume of capital bringing the invention to the marketplace. If theee corporetione do not have adequate patent protection in the biotechnology field they will not be willing to inveet the capitel and time required to bring the biotechnology products to the marketplece. Thue the Americen public will not benefit from theee univereity-baeed inventione.

The Honorable Rick Boucher May 21, 1991

It is our belief that this legislation is in the best interest of university-based science, the biotechnology industry, and the public at large. The University of Texas Health Science Center at Houston supports the passage of H.R. 3975, the Biotechnology Patent Protection Act of 1990.

Sincerely,

Thomas F. Burks, Ph.D.
Executive Vice President
Research and Academic Affairs

JS/sf

xc: M. David Low, M.D., Ph.D.

Letter 5

A LAND-GRANT UNIVERSITY

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

OFFICE OF THE PRESIDENT

Blacksburg, Virginia 24061-0131
(703) 231-6231

May 22, 1991

MAY 3 1 1991

Congressman Rick Boucher
Congressman Carlos J. Moorhead
Members of Congress
Congress of the United States
House of Representatives
Washington, D.C. 20515

Dear Congressmen Boucher & Moorhead:

Thank you for informing me of your continuing efforts to strengthen our capabilities to develop and support new technologies. Your bill to modernize patent laws to support such development is welcomed by Virginia Tech. Currently we receive nearly 100 intellectual properties disclosures yearly and pursue patent protection on a large number of these properties.

A number of small companies have developed near the university and several of these involve biotechnology processes. We also license some of our inventions to larger U.S. firms.

It is obviously to the university's advantage to have a legal atmosphere that protects our industry partners from unfair or inappropriate competition on the international market - both at home and elsewhere. Your bill addresses several of the key elements in this area and we support your continued strong leadership.

Thank you both for your efforts and recognition of our needs.

Sincerely,

James D. McComas
President

JDM/gsw

UNIVERSITY OF MISSOURI-COLUMBIA

Office of the Chancellor

105 Jesse Hall
Columbia, Missouri 65211
Telephone (314) 882-3387

Letter C

May 15, 1991

The Honorable Rick Boucher
The Honorable Carlos J. Moorhead
The United States
House of Representatives
405 Cannon House Office Building
Washington, DC 20515

Dear Representatives Boucher and Moorhead:

I am happy to comment on H.R. 1417, the "Biotechnology Patent Protection Act of 1991," which you and your colleagues have recently introduced. Although brief, this proposed amendment focuses on an important issue of current patent policy and, if enacted, would promote further development of U.S. biotechnology. We are pleased to give it our strong support.

In our view, the proposed legislation would protect more effectively the entire inventive effort , from starting material to final product, and would create additional incentive for investigators and industry to exploit biotechnological breakthroughs for the benefit of society.

In supporting this legislation, we join our colleagues in the American Associate of Universities, the American Council on Education, and the National Association of State-Universities and Land-grant Colleges.

Sincerely,

Haskell Monroe
Chancellor

HM:ek

Letter 7

UNC CHARLOTTE
The University of North Carolina at Charlotte
Charlotte, N.C. 28223

Office of the Chancellor
704/547-2201

May 14, 1991

The Honorable Rick Boucher
House of Representatives
405 Cannon Office Building
Washington, D. C. 20515

Dear Congressman Boucher:

Thank you for your letter of April 29, inviting The University of North Carolina at Charlotte to comment on H.R. 3957, the "Biotechnology Patent Protection Act of 1990." I write in strong support of that bill.

The University endorses the specific points made by Sheldon E. Steinbach, Vice President and General Counsel of the American Council on Education, in his April 4, 1990, letter to Chairman Kastenmeier and enclosed in your letter of April 29. Our experience at The University of North Carolina at Charlotte is a clear demonstration of the soundness and accuracy of Mr. Steinbach's arguments.

The University of North Carolina at Charlotte is a public comprehensive University with approximately 14,000 students. The University has strong undergraduate and graduate programs in engineering and the sciences. For the last decade our annual research budget has been doubling, generally, every three to four years and our current research budget is well over $6 million. During the present fiscal year, thanks to a very active faculty in engineering and the sciences, the University secured its first three United States patents, and is actively pursuing interest in the private sector in finding commercial applications for those patents and a number of other inventions not yet patented. Thus in a relatively short time compared to other universities, we have gained a great deal of experience in marketing and licensing University inventions. That experience tells us that without strong patent protection for university inventions, it is extremely difficult, if not impossible, to interest private entities having appropriate manufacturing, production and marketing capabilities in commercializing our inventions.

The Honorable Rick Boucher
May 14, 1991
Page 2

Obviously, current law eliminates the incentive of such commercial entities to develop certain biotechnology products. We believe that strengthened patent protection for inventions in the biotechnology field will greatly assist this University and all other universities in obtaining commercial interest in university inventions, and will thus help the public to benefit from the results of University research. Based on our experience, we support H.R. 3957.

Sincerely,

J. H. Woodward
Chancellor

JHW/be

cc: Mr. Sheldon E. Steinbach
American Council on Education

Letter 8

AUBURN UNIVERSITY AT MONTGOMERY
Office of the Chancellor

May 13, 1991

The Honorable Rick Boucher
U. S. House of Representatives
405 Cannon House Office Building
Washington, DC 20515

The Honorable Carlos J. Moorhead
U. S. House of Representatives
2346 Rayburn House Office Building
Washington, DC 20515

Dear Congressmen Boucher and Moorhead:

Your letter of April 29, 1991, concerning H.R. 3957, the Biotechnology Patent Protection Act of 1990, was appreciated. After reviewing a synopsis of the bill, the letter from Sheldon E. Steinbach of the American Council on Education, and realizing that the bill is supported by three other important education associations, I am in favor of passage of this bill. It is apparently in the best long-range interest of higher education for such legislation to be enacted.

If I can provide further information regarding this matter, feel free to contact me.

Sincerely,

James O. Williams
Chancellor

JOW:sc

cc: Dr. James T. Kenny

7300 University Drive Montgomery, Alabama 36117-3596
(205) 244-3602 ATTNet 240-3602 FAX (205) 244-3762

Letter 9

UK UNIVERSITY OF KENTUCKY

Office of the Presiden

104 Administration Buildin
University of Kentuck
Lexington, Kentucky 40506-003
606-257-1701; FAX 606-257-17c

May 23, 1991

The Honoreble Rick Boucber, Cheirman
Subcommittee on Scieoce
Committee on Science, Spece end Technology
House of Representetives
405 Cennon House Office Building
Wesbington, D.C. 20515

Re: Biotechnology Petent Protection Act of 1990

Deer Cheirman Boucber:

I em writing in support of the Biotechnology Petent Protection Act. As president of e university witb biotechnoiogy releted reseercb programs, I feei thet the Biotechnology Petent Protectioo Act will benefit both the University of Kentucky, the broeder reseercb university community end society.

As wes pointed out in tbe Americen Council on Educetion's stetement, releting to H.R. 3957, the Biotechnology Petent Protection Act of 1990, universities ere not orgenized to menufecture, produce or market petentable ioventions. However, edequete petent protection essists universities in ettrectiog industriel sponsors willing to invest substentiel resources in bringing eerly stege biotechnology from the university setting to the market, where those biotechnology products cen benefit the public. Cooverseiy, without edequete peteot protectioo companies ere less likely to invest cepitel in brioging universitv ioveotioos to market and society is denied the benefits of those prodocts.

I eppreciete this opportunity to support the Biotechnology Petent Protection Act.

Very truly yours,

Chrles T. Wethington, Jr.
Presideot

CTW/bpi
00020528

Letter 10

Oklahoma State University

OFFICE OF THE PRESIDENT

STILLWATER, OKLAHOMA 74078-0001
107 WHITEHURST HALL
405-744-6384
405-744-6285 (FAX)

May 23, 1991

The Honorable Rick Boucher
U. S. House of Representatives
405 Cannon House Office Building
Washington, D. C. 20515

Re: H. R. 3957, the Biotechnology
Patent Protection Act of 1990

Dear Representative Boucher:

Please be assured that Oklahoma State University is committed to excellence in the classroom and in the laboratory. The quality of life we enjoy and seek to leave as a legacy is based on the creativity and ingenuity of this nation's scientists, and on the ability of business and industry to successfully market and commercialize new inventions. If our nation is to remain a business and economic leader, it is imperative that we maximize the use of all available resources — both human and industrial.

I strongly support the H.R. 3957 legislation introduced by you, Representative Moorhead, and Senators DeConcini and Hatch, which will change the patent law to minimize unfair foreign competition and to broaden protection for patented production processes. This legislation will serve as an incentive for scientists associated with the academe, as well as greatly benefit the short- and long-term interest of business and industry.

Thank you for sponsoring this important legislation.

Sincerely,

John R. Campbell
President

cc: Dr. Tom Collins
Dr. Norman Durham

Letter 11

TEXAS A&M UNIVERSITY
COLLEGE STATION, TEXAS 77843-1248
(409) 845-4016

Provost and Vice President
for Academic Affairs
E. Dean Gage

24 May 1991

The Honorable Rich Boucher
House of Representatives
Washington, D.C. 20515

Dear Mr. Boucher:

We appreciate your April 29, 1991 letter to William H. Mobley, President, Texas A&M University, soliciting our views on H.R. 3957, "A Bill to Amend Title 35, U.S. Code, with Respect to Patents on Certain Processes."

We note the endorsement of the Legislation provided by the American Council on Education and we concur with Sheldon Steinbach's comments in his letter to Committee Chairman Kastenmeier. In addition, however, our more immediate interests in the success of the Bill are stimulated by the fact that Texas A&M has a number of intellectual properties covered by both product and process biotechnology patents, which the bill would protect from unfair foreign competition by Japanese and European drug companies.

We strongly support H.R. 3957 and urge you to secure enactment of the bill.

Sincerely,

E. Dean Gage
Provost and Vice President
for Academic Affairs

TEXAS TECH UNIVERSITY
TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER
Office of the President

Lubbock, TX 79409-2013
(806) 742-2121
FAX (806) 742-2138

Letter 12

May 30, 1991

The Honorable Rick Boucher
Chairman
Subcommittee on Science
Committee on Science, Space and Technology
400 Cannon House Office Building
U. S. House of Representatives
Washington, D.C. 20515

RE: H.R. 3957, the Biotechnology
Patent Protection Act of 1990

Dear Chairman Boucher:

Texas Tech University is engaged in research that encompasses biotechnology as well as other diverse fields in the sciences and engineering. One of the goals of the University is to transfer the technology generated from our research to the public sector as quickly and as economically as possible.

In furtherance of this goal, Texas Tech University supports strong intellectual property law protection for inventions in all areas of science including biotechnology. H.R. 3957 would close a loophole in the trade law that currently permits unfair importation of certain biotechnology-derived products. We support extending the International Trade Commission's jurisdiction so it can protect a patent owner's rights against importation of an identical product that is produced in a foreign country. It is a disincentive to American companies to allow foreign competitors to legally export to this country biotechnology products which utilize components patented in the U.S., when those same products, if produced in the U.S., would constitute patent infringement.

The Honorable Rick Boucher
May 30, 1991
Page 2

University-based inventions are licensed to U.S. corporations, who in turn expend large sums of capital bringing the invention to the marketplace. If these corporations do not have adequate patent protection in the biotechnology field they will not be willing to invest the capital and time required to bring the biotechnology products to the marketplace. Thus, neither the University nor the American public will benefit from these university-based inventions.

It is our belief that this legislation is in the best interest of university-based science, the biotechnology industry, and the public at large. For this reason, Texas Tech University supports the passage of H.R. 3975, the Biotechnology Patent Protection Act of 1990.

Sincerely,

Robert W. Lawless
President

Letter 13

UNIVERSITY OF FLORIDA

JOHN V. LOMBARDI
PRESIDENT

May 31, 1991

The Honorable Carlos J. Moorhead
Member of Congress
The Honorable Rick Boucher
Member of Congress
United States House of Representatives
405 Cannon House Office Building
Washington, D.C. 20515

Dear Mr. Moorhead and Mr. Boucher:

As a major research university with a strong interest in technology transfer, the University of Florida is supportive of all measures to strengthen the United States patent system. The Biotechnology Patent Protection Act of 1991 will close a loophole in the trade law that currently permits unfair importation of biotechnology-derived products. Currently, if a company cannot produce a drug in the United States because someone else holds a patent on the technology, the company can move the production offshore and then legally import it. The legislation's benefits would primarily assist biotechnology patents, but the benefits would accrue to all process-related inventions. Therefore, the University of Florida supports the proposed legislation.

We are also concerned about the rising cost to file and prosecute documents within the United States Patent and Trademark Office. Recently, all fees increased over 50%. Although such increases may be affordable to large industry, increases dramatically affect single inventors, small businesses, and universities. We understand there is continued discussion to increase these fees again. As you know, encouraging universities to patent and license the inventions resulting from federally-sponsored research is a positive federal policy. Raising the patent fees of not-for-profit institutions, such as universities, would work against this policy.

We appreciate the opportunity to comment on proposed legislation affecting universities and technology transfer.

Sincerely yours,

cc: Dr. Donald R. Price

226 TIGERT HALL, GAINESVILLE, FLORIDA 32611 904-392-1311
EQUAL EMPLOYMENT OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Letter 14

THE UNIVERSITY OF WYOMING
LARAMIE, WYOMING 82071

OFFICE OF THE PRESIDENT
(307) 766-4121

May 31, 1991

The Honorabls Rick Boucher
U.S. House of Representatives
405 Cannon House Office Building
Washington, DC 20515

Dear Rspressntative Boucher:

Thank you very much for your letter of April 29 with Repressntativs Moorhead concerning you rscently introduced "Biotschnology Patent Protection Act of 1991", H.R. 1417. Thank you also for providing me with a copy of the Bill as introduced on March 13, 1991 by you and Representative Moorhead.

The University of Wyoming is strongly supportive of H.R. 1417. We believe that your Bill will serve to protect the vital interests of the biochemical, molscular biological, and biotechnology segments of American universities as wsll as the legitimate interests of American corporations and American consumers.

I will shortly draft a letter to Reprssentative Craig Thomas (R-Wy) urging his support for H.R. 1417.

Sincsrely,

Terry P. Roark
President

CASE WESTERN RESERVE UNIVERSITY · CLEVELAND, OHIO 44106

Letter 15

May 30, 1991

The Honorable Rick Boucher
The Honorable Carlos J. Moorhead
Members of Congress
House of Representatives
Washington, D.C. 20515

Dear Messrs. Boucher and Moorhead:

I appreciated very much your keeping us informed of your significant efforts in the patent field. It is helpful to us to be aware of congressional deliberations on this subject. Case Western Reserve University is a research intensive institution, actively engaged in seeking patents and commercializing research. In particular, we are active in biomedical research, being a member both of Ohio's Edison Biotechnology Center (with several hospitals) in Cleveland, and the Animal Biotechnology Center in Athens, Ohio.

Your general focus of strengthening patent law is helpful to our efforts of bringing the benefits of university technology to industry and the public. We support that focus. Clearly, you are addressing the priority issues in this field.

Please call on us if we can ever provide detailed testimony or background information.

Sincerely,

Agnar Pytte

Agnar Pytte
President

AP:gt

Office of the President
Adelbert Hall, Room 23
2040 Adelbert Road
(216) 368-4344

THE UNIVERSITY OF TEXAS SYSTEM
601 COLORADO STREET AUSTIN, TEXAS 78701

Letter 16

June 7, 1991

Office of the Chancellor
(512) 499-4200

The Honorable Rick Boucher
U.S. House of Representatives
405 Cannon House Office Building
Washington, D.C. 20515

Dear Congressman Boucher:

I am sorry for the delay in responding to your April 29, 1991, letter soliciting views on legislation you have introduced to improve the Nation's patent system. Your letter was not received in my office until May 14, 1991. I immediately asked the General Counsel of The University of Texas System to review your bill. His recommendation, which I endorse, is to support HR 1417 (and S 654).

We agree that the bill will modernize the patent laws in a manner that will facilitate the development of the biotechnology industry. However, we also believe that the bill will provide a fundamental and necessary change to insure that protection is available for both products and processes in appropriate circumstances.

The University of Texas System is composed of eight general academic institutions and six health related components. Research and protection of the fruits thereof obviously are of major importance to all of our component institutions, and HR 1417 is directly relevant to our protection efforts. Not only do we encourage passage of this bill, we also solicit your support in assuring that university research is provided an exemption from patent infringement in the event that legislation is enacted similar to the Patent Remedy Clarification Act (seeking to eliminate states' sovereign immunity from patent infringement) which was introduced in the last Congressional session but was not passed. We believe that such an exemption is crucial in precluding potentially harassing patent litigation that would stymie research in the university community.

With best wishes,

Sincerely,

Hans Mark

Hans Mark
Chancellor

HM:bb

University of Delaware

Letter 17

OFFICE OF THE PRESIDENT
NEWARK, DELAWARE 19716

(302) 451-2111

May 30, 1991

The Honorable Rick Boucher
The Honorable Carlos J. Moorhead
405 Cannon House Office Building
Washington, DC 20515

Dear Representatives Boucher and Moorhead:

Thank you for the information on HR 1417, the Biotechnology Patent Protection Act of 1991. We have examined this bill in light of the University of Delaware's patent activity and conclude that its enactment would substantially improve the United States patent system. Certain University cases would certainly directly benefit from this amendment to Section 103, Title 35. In view of the changing world market of the 1990s, we also see a great advantage to bringing our patent law into conformance with that of Europe and Japan.

This legislation is clearly a positive step in improving our capability to compete in technological innovation, and we are happy to offer our endorsement of this bill.

Rick, I hope that you are well. I am pleased that you remain interested in higher education, as I remember in the most positive terms your assistance and counsel during my tenure at Virginia Tech.

Sincerely,

David P. Roselle
President

AN EQUAL OPPORTUNITY UNIVERSITY

Letter 18

HARVARD UNIVERSITY
OFFICE FOR TECHNOLOGY AND TRADEMARK LICENSING

June 11, 1991

The Honorable Rick Boucher
The Honorable Carlos J. Moorhead
Members of Congress
House of Representatives
Washington, D.C. 20515

Dear Congressmen Boucher and Moorhead:

I am writing in reply to your request for comments on the Biotechnology Patent Protection Act of 1991 (HR 1417).

Harvard University has made a strong commitment to transferring technology created as part of its research activities to industry so that products can be developed which, hopefully, will have a positive impact on the public welfare. In order to accomplish this objective, Havard files a number of patent applications each year in the biotechnology field.

As you can imagine, the patent applications we file are generally on fairly basic innovations rather than fully developed products. In order for companies to make the investment necessary to develop these early-stage inventions into products, considerable risk of money and effort is involved. For that risk to be worthwhile, the company must be assured that the patents being licensed to them will provide adequate protection against unlicensed competition.

The Biotechnology Patent Protection Act of 1991 will strengthen the protection of inventions involving biotechnology processing from infringement by foreign manufacturers -- something much to be desired. The Bill would also bring U.S. patent law closer to the European and Japanese law in this area. By reducing the uncertainty of the enforceability of of biotechnology process patents in light of the In re Durden, 763 F.2d 1406, decision, the Act should increase the willingness of U.S. companies to invest in the development of products based on biotechnology processes.

University Place • Fourth Floor South • 124 Mt. Auburn Street • Cambridge, MA 02138-5701
Telephone (617) 495-3067 • Facsimile (617) 495-9568

Congressmen Boucher and Moorhead
June 11, 1991
Page two

With the understanding that the Council on Governmental Relations is working with the drafters to improve the clarity of the Act, Harvard is pleased to add its voice to support the objectives of the Biotechnology Protection Act of 1991.

Sincerely,

Joyce Brinton
Director

cc: Robert Scott
John Shattuck
Daniel Steiner, Esq.

Lecter 19

Julius R. Krevans, MD
Chancellor
San Francisco CA 94143-0402
415/476-2401

University of California San Francisco A Health Sciences Campus
School of Dentistry
School of Medicine
School of Nursing
School of Pharmacy
The Graduate Division
The Medical Center
The Research Institutes

June 10, 1991

The Honorable Rick Boucher
U.S. House of Representatives
405 Cannon House Office Building
Washington, D.C. 20515-0442

Dear Congressman Boucher:

I write on behalf uf the University of California, San Francisco, to express strong support for H.R. 1417, the Biotechnology Patent Protection Act of 1991. The United States, by virtue of the strengths of university- and government-based programs, leads the world in basic research underlying the rapidly developing biotechnology industry. Our nation's young biotechnology industry is also the world's leader in the development and manufacture of biotechnology products. However, while poised to become a new, major force in both the national and global economies, our biotechnology industry struggles with serious disadvantages that threaten its growth and its competitiveness. In particular, we believe that current U.S. patent and trade laws do not provide strong enough protection to inventors who develop novel applications of biotechnology for health care, agriculture, and environmental management.

As you know, piracy of intellectual property is an easy, virtually risk-free way for foreign competitors to achieve competitive positions in the biotechnology marketplace. Unfortunately, weaknesses in U.S. patent law permit this to occur, erecting a significant barrier to investment in the industry's intellectual, operational, and capital needs. Closing existing loopholes in U.S. patent law will be an important step toward strengthening our biotechnology industry. In particular, the law must protect U.S. patent holders from importation of products that circumvent their patents. In addition, broadening coverage to include protection for patented production *processes*, as H.R. 1417 would do, would add much-needed, new protection. Without the protection of H.R. 1417, U.S. industry will have to continue to struggle with serious disincentives to investment.

Congressman Rick Boucher
June 10, 1991
Page 2

Our nation's universities will continue to provide the basic scientific discoveries that enable the biotechnology industry to forge ahead with its development of new processes, techniques and products for health care, agriculture, and environmental management. However, this young industry can only fulfill its promise if it receives the support it needs from Congress to ensure that it can compete internationally on a level playing field. H.R. 1417, the Biotechnology Patent Protection Act of 1991, is a major step in that direction, and we enthusiastically endorse it.

Sincerely,

Julius Krevans

Julius R. Krevans, M.D.

cc: Senior Vice Chancellor David J. Ramsay
Dean Joseph Martin
Dean Jere Goyan
Senator Dennis DeConcini
Senator Orrin Hatch

Letter 20

UNIVERSITY OF VIRGINIA

CHARLOTTESVILLE

OFFICE OF THE PRESIDENT

May 29, 1991

The Honorable Frederick C. Boucher
United States House of Representatives
Cannon House Office Building
Washington, D.C. 20515

Dear Rick:

Thank you for soliciting our views on the proposed amendment to the patent system. After having researchers, faculty, University patent office administrators, and others consider H.R. 1417, the Biotechnology Patent Protection Act of 1991, I can assure you of our support for this proposal. The contemplated change may cut the cost of patent applications from the University, as well as prevent unfair competition from entities outside the United States.

We need strong intellectual property protection for innovations in the biotechnology area, and we support H.R. 1417 as important to establishing a positive, uniform, government-wide patent procedure.

Sincerely,

John T. Casteen, III
President

JTC:rg

MADISON HALL P.O. BOX 9011 22906-9011 TELEPHONE (804) 924-3337

University of Illinois
at Urbana-Champaign

Office of the Chancellor

Swanlund Administration Building
601 East John Street
Champaign, IL 61820

217 333-6290
217 244-4121 fax

Letter 21

July 2, 1991

The Honorable Rick Boucher
The Honorable Carlos J. Moorhead
Congress of the United States
House of Representatives
Washington, D.C. 20515

Dear Representatives Boucher and Moorhead:

On behalf of the University of Illinois at Urbana-Champaign, I am writing to endorse H.R. 1417, the Biotechnology Patent Protection Act of 1991. This bill will provide for consistent and fair availability of patent protection for certain specific types of process inventions which have heretofore been denied patent status under the law. It will also bring U.S. law covering the patentability of such processes more in line with the laws of other countries so that U.S. inventors of such processes and their corporate developers are not placed at a competitive disadvantage.

The process inventions involved are commonly found in biotechnology. Conventional biotechnology methods are often applied to newly discovered starting materials to produce existing drugs in greater quantities or in purer form than had heretofore been possible by classical isolation and purification techniques. Also, conventional starting materials and conventional methods may produce novel and patentable products. In our view, these specific types of "conventional" processes should automatically be protected by U.S. patent, so long as their novel counterpart products (either starting materials or end products) are also determined to be patentable.

Such processes are already patentable under Japanese and European law. Failure to be able to patent them in the U.S. undermines the value of these innovations to universities and to U.S. industry, upon which universities are so dependent for commercialization. If universities cannot obtain adequate patent protection for these processes, how can we license them to industry? How can U.S. companies make the substantial investments of resources needed to commercialize our academic inventions when the U.S. patent law places U.S. companies at such a competitive disadvantage? Foreign companies can legally avoid infringement of a U.S. patent on a novel starting material by taking it outside the U.S., making the desired end product and exporting the end product back into the U.S.

The situation seemingly poses a very serious threat to the U.S. biotechnology industry and will stifle research and development of new methods to make existing products more economical. However, we do not have first-hand experience as to how often the Patent Office is actually refusing to issue patents on such processes, or how difficult such a refusal is to overcome. To my knowledge, the

The Honorable Rich Boucher
The Honorable Carlos J. Moorhead
July 2, 1991
Page Two

University of Illinois at Urbana-Champaign has not yet attempted to patent these specific types of biotechnology processes and has therefore, not yet been refused a patent. Nevertheless, we believe that these specific types of processes should always be considered patentable. That is not currently happening. Passage of this legislation will once and for all remove the confusion and inconsistency which now surrounds this patentability issue.

It has been said that a legislative remedy is not necessary because the patentability of such processes ultimately will be upheld by the courts. However, in the meantime, waiting until the proper cases are brought forward will only continue the problem. We also do not believe universities or U.S. companies should have to foot the expensive legal bills needed to demonstrate that such processes are patentable. No one benefits from an uncertain patent law.

We have also heard concern that the requirement that the process and its counterpart novel product be in the same patent is too restrictive. Upon review of the situation, we believe this restriction is the simplest approach to prevent an applicant from unfairly extending the life of his patented product by filing and prosecuting a separate application on the process of making it. Nevertheless, there are other approaches to avoid such abuses, and we would support alternative language to "having a single patent issue on the application" should others deem that to be more appropriate. We have heard that the American Intellectual Property Law Association is considering making suggestions to this bill in this area.

In summary, on behalf of the University of Illinois at Urbana-Champaign, I endorse this legislation to clarify our patent law. In our view, it is in the best interest of U.S. industry, universities and the general public.

Sincerely,

Morton W. Weir
Chancellor

MWW:tlf

c: S. O. Ikenberry

Letter 22

THE UNIVERSITY OF NEW MEXICO
ALBUQUERQUE, NEW MEXICO 87131-0001
505-277-2626

OFFICE OF THE PRESIDENT

May 22, 1991

The Honorable Rick Boucher
The Honorable Carlos J. Moorhead
Members of Congress
House of Representatives
Washington, D. C. 20515

Dear Congressmen Boucher and Moorhead:

In response to your letter of April 29, 1991, I am pleased on behalf of the University of New Mexico to support passage of your bill, H.R. 1417 (S.634), primarily to prevent transportation of U. S. patented biological cells offshore where they can be used to formulate end products made by processes currently ineligible for protection by U. S. patent.

The opportunity to comment on this legislation is appreciated.

Sincerely,

Richard E. Peck

Richard E. Peck
President

REP:dj

Letter 23 *UNIVERSITY of PENNSYLVANIA*

Office of the President
100 College Hall
Philadelphia, PA 19104-6380
215-898-7221

June 27, 1991

The Honorable Rick Boucher
U.S. House of Representatives
428 Cannon House Office Building
Washington, D.C. 20515-4609

Dear Congressman Boucher:

Thank you very much for your letter concerning HR 1417, the Biotechnology Patent Protection Act.

The University of Pennsylvania has an active and rapidly growing technology transfer program that processes over 50 invention disclosures in the field of biotechnology each year. Our professional staff, working closely with our faculty and several patent firms with specialists in Biotechnology patent law, have been concerned over the past several years with the pace and nature of Patent Office responses to our patent applications.

The Patent Office, under current U.S. law, almost universally invokes the obviousness provision of Section 103 Title 35, United States Code, in the examination of our patents. This often results in costly, protracted prosecution of patents and ultimately forces us to narrow our patent claims to a point at which they are difficult to enforce. The guidelines provided in HR 1417 would stimulate biotechnology innovation and protect those who develop new products and processes.

America has invested heavily, though the NIH, the NSF, and with precious risk capital in creating an envious competitive advantage in biotechnology. Current patent law, however, appears to be compromising the ability of young companies and universities to contribute to the building of a national patent estate and patent blockade that will offer our nation the sustainable business advantage it has diligently earned and so desperately needs.

Please let us know how we at Penn might be able to support you further, and many thanks for your advocacy of this legislation.

Sincerely,

Sheldon Hackney

Sheldon Hackney
President

Letter 24

MASSACHUSETTS INSTITUTE OF TECHNOLOGY
[illegible]
Cambridge, Mass. [illegible]

TECHNOLOGY LICENSING OFFICE

TELEPHONE [illegible]
FACSIMILE [illegible]
TELEX [illegible]

May 30, 1991

The Honorable Rick Boucher
Member of Congress
House of Representatives
Washington, DC 20515

Dear Congressman Boucher:

M.I.T. supports your bill (HR 1417 -- the Biotechnology Patent Protection Act of 1991) currently before Congress. We believe that this bill will strengthen the position of U.S. biotechnology and will reduce the uncertainty of obtaining biotechnology patents.

M.I.T. files several dozen patents per year in the biotechnology field arising out of research in our Biology, Chemistry and Chemical Engineering Departments (including the Cancer Center and the Bioprocess Engineering Center). Our objective in acquiring such patents is to provide intellectual property protection for companies willing to commit to investing in the development of this technology to provide products for the public good.

Since university inventions arise primarily from basic research, they are typically very early in the product development cycle. Development of such inventions into products therefore usually involves substantial risk of time and money. It is therefore critical that we be able to offer patent protection through licensing to those companies willing to undertake such risky development, in order to induce them to make the required investments. Strong, clear patent laws are critical to our endeavors in this area.

The Biotechnology Patent Protection Act of 1991 will strengthen our ability to protect inventions in biotechnology processing from infringement by foreign manufacturers and will bring the U.S. to parity with European and Japanese patent law in this very important area. By reducing the uncertainty of the issuance of biotechnology process patents in light of the U.S. Patent and Trademark Office's interpretations of In re Durden, 763 F.2d 1406, the Act will reduce the cost of obtaining patent protection and will increase the incentives to invest in technology still in the patent pending stage.

We understand that the Council on Governmental Relations is working with drafters of the bill to clarify some potential ambiguities and we support this effort as we support the overall efforts of the Biotechnology Protection Act of 1991.

Sincerely,

John T. Preston
Associate Director

LLN/meh
Boucher.ltr530
cc: Dr. Charles Vest
Prof. David Litster

APPENDIX 2.—LETTER FROM CHAIRMAN WILLIAM J. HUGHES, ENCLOSING A LETTER FROM JOHN J. KELLY, VICE PRESIDENT, SECRETARY AND GENERAL COUNSEL, ELECTRONIC INDUSTRIES ASSOCIATION, DECEMBER 3, 1991, TO HARRY F. MANBECK, JR., ASSISTANT SECRETARY AND COMMISSIONER, PATENT AND TRADEMARK OFFICE, U.S. DEPARTMENT OF COMMERCE, DECEMBER 23, 1991

ONE HUNDRED SECOND CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON THE JUDICIARY
2138 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6216

December 23, 1991

The Honorable Harry F. Manbeck, Jr.
Commissioner
U.S. Patent & Trademark Office
U.S. Department of Commerce
2121 Crystal Drive, Suite 906
Washington, DC 20231

Dear Commissioner Manbeck:

Thank you for your testimony before the Subcommittee on Intellectual Property and Judicial Administration on H.R. 1417, the Biotechnology Patent Protection Act of 1991. The hearing served as a useful introduction to the difficult issue of how best to protect biotechnology inventions. There were a number of questions that I did not have the opportunity to ask you at the November 21st hearing, and I would be very grateful if you could respond to these questions in writing. These questions are as follows:

1. Has the Federal Circuit Court of Appeals decided any cases involving the specific question of the patentability of the process of using a host cell to make a recombinant product?

2. Is there an urgent need to stop the importation of recombinant products?

3. What impact would the proposed legislation have on inventions other than biotechnology? In particular, what effect would this change in law have on the patenting of computer software, and on otherwise unpatentable processes in the chemical, engineering, and mechanical arts?

4. What is the policy of the Patent and Trademark Office with regard to the patentability of recombinant proteins -- as distinct from the discovery and purification of naturally occurring proteins?

The Honorable Harry F. Manbeck, Jr.
December 23, 1991
Page Two

5. William F. Marsh, testifying at the November 21st Subcommittee hearing on behalf of Intellectual Property Owners, Inc., suggested that if a legislative remedy is necessary, instead of the approach taken in H.R. 1417, Congress should consider an alternative approach. He suggested that Congress amend section 103, to state that:

> A process or method claim wherein an essential element is a composition of matter otherwise patentable to the applicant shall not be deemed to be unpatentable merely because the claim reads "on a known process or combination of steps which shall be examined as a whole," giving consideration to the specific nature of the process or method and the fact that new or otherwise patentable materials are used or result from the process or method.

What are your views on this proposal?

6. Enclosed is a letter from the Electronic Industries Association (EIA) presenting its views in opposition to H.R. 1417. In particular, the letter discusses the effect H.R. 1417 could have on the cost of doing business, the value of existing patents, information in the public domain, and the bill's potential conflicts with existing patent law, Supreme Court decisions and the U.S. Constitution. What are your responses to the arguments EIA raises in opposition to H.R. 1417?

I would appreciate a reply at your earliest convenience. Again, thank you for your testimony and for your continued assistance to the Subcommittee.

Sincerely,

Bill Hughes

William J. Hughes
Chairman
Subcommittee on Intellectual Property
and Judicial Administration

Enclosure

RECEIVED

DEC 3 1991

Sub on Courts

ELECTRONIC INDUSTRIES ASSOCIATION

December 3, 1991

The Honorable William J. Hughes
Chairman
House Judiciary Committee
Subcommittee on Intellectual Property
and Judicial Administration
207 Cannon House Office Building
Washington, D.C. 20515

Dear Chairman Hughes:

The Electronic Industries Association ("EIA") appreciates the opportunity to present its views on the Boucher Bill, H.R. 1417, entitled "Biotechnology Patent Protection Act of 1991".

With more than 1,000 participating companies, EIA is the full-service national trade organization representing the spectrum of United States companies manufacturing electronic products. U.S. electronic sales during 1990 were estimated to be $266 billion.

At the outset, we should note that the title of the bill refers to biotechnology patent protection, but the bill is not limited to biotechnology. Rather, the substance of the legislation applies to all industries. We recommend that the text of the bill be amended to limit its application to the field of biotechnology. However, if the intent of the legislation is to change patent law applicable to all industries, then EIA recommends that H.R. 1417 be retitled to more accurately reflect its intended scope.

EIA opposes H.R. 1417 because it adds many uncertainties to present law that may take additional litigation to resolve. This, we believe, is not in the public interest and may significantly increase the cost of doing business. For example, members of the public will be required to consider an additional element in making business decisions which is unnecessary under present law. That additional element is determining the best course of action with respect to unsearched, unchallengeable process claims permitted under the bill.

We also believe the substance of the bill may conflict with present law. For example, it may conflict with the statute it proposes to amend, it may conflict with decisions of the Supreme

Court, and it may conflict with the underlying principles of the patent system as reflected in the U.S. Constitution. The following discussion explains in more detail the issues identified above.

COST OF DOING BUSINESS MAY INCREASE

The bill, if enacted into law, could severely impact member companies of EIA because the cost of doing business may be significantly increased. Specifically, the bill expands patent rights to unexamined processes which conceivably could encompass prior art. In this regard, the bill provides that if a patent applicant has a patentable claim to a new machine (host cell), the applicant will automatically be granted claims for all processes using that machine for making an unpatentable product. What this means is that such process claims would be automatically granted by the Patent and Trademark Office without any search of the prior art for nonobviousness -- which process claims may potentially be unpatentable as written because of uncited prior art. Any time spent by members of EIA in trying to address these unsearched claims results in added expense.

Now when an EIA member develops a new product, it normally performs what is called a clearance search of unexpired patents to determine if patented claims exist that might block the member's freedom of action to manufacture and market the product. The intent is to avoid litigation upon marketing the new product. If an adverse patent is uncovered during the clearance search, the member company performs a validity search of the patent. The search particularly focuses on prior art that was not cited by the Patent and Trademark Office which may render the adverse patent claims to be obvious. It is not uncommon to find prior art which renders the claims invalid for obviousness. If the bill is enacted into law, a member company would have to decide how to evaluate the unsearched process claims. The member company would have to decide whether to redesign the product around the unsearched process claims so as to become noninfringing or to seek a license from the patent owner under a patent which the member may believe to be invalid as obvious, or decide not to take a license and risk litigation of the unsearched process claims.

Whatever course of action is taken, it will result in greater cost to do business. If a license is sought to avoid litigation, the payment of royalties results in an increase in the cost to do business over that required under the present system. If an attempt is made to redesign the member company's process around the unsearched process claims, the redesign will result in added cost of doing business. Also, if the course of action is to do nothing and risk litigation, there will be an increased cost of doing business if litigation is the result. Even where the machine

patent claims are found obvious and ultimately deemed invalid, the unsearched process claims will have to be addressed, creating an added cost over the present system.

If this legislation is passed, every patent attorney "worth his salt" will insert process claims as broad as the new law will allow. Under the bill, attorneys would be entitled to claim "all processes for using the machine of claim 1 for making the product X". And such claims will be unexamined for obviousness. In the present litigious environment, such broad claims are likely to produce a significant increase in patent litigation.

In this connection, in 1793, Congress discontinued examination of patent applications. However, due to excessive and protracted litigation, in 1836 Congress reinstituted examination. Thus there is basis to conclude that the cost of such added litigation over the present system may slow down the progress of the useful arts and create an impediment to anyone seeking to enter the market.

THE PUBLIC MAY NO LONGER HAVE THE RIGHT TO USE ART IN THE PUBLIC DOMAIN

On a slightly different point, no one can deny that under the present system the public has the right to make an obvious implementation of art that is prior to the process claims in the patent. If process claims are automatically granted without search, there is bound to be prior art related to those claims which the public would ordinarily have the right to use. If the bill is enacted into law, the public may no longer have the right to rely on prior art in making its business decisions.

EXISTING PATENTS MAY BE ERODED

If H.R. 1417 is enacted into law, there are likely to be unexpired patents belonging to others that are related to the unsearched process claims. The automatic granting of unsearched process claims may erode the value of those earlier prior patents. Licensees may be required to pay double tribute to practice the The invention of the prior art patent as well as the unsearched process claims. The Supreme Court has addressed this problem.

In the case of McClurg v. Kingsland, 42 U.S. 202 (1843), the Court recognized the authority of Congress to legislate in the patent area so long as the rights they create by legislation do not take away the rights of property in existing patents. H.R. 1417 may erode the rights of prior art patent owners by diminishing the value of their existing patents.

THE BILL MAY CONFLICT WITH THE STATUTE IT PROPOSES TO AMEND

If H.R. 1417 is enacted into law, it may conflict with the statute it amends. For example, under the bill, if machina claims are found valid, it is not clear that procass claims are subject to challenge by the public. Yet 35 U.S.C. § 103 requiras that the differences between the subject matter sought to be patented and the prior art are such that tha subject matter as a whole must not be obvious. However, one may argue that the bill automatically makes all obvious procass claims patentable, and that such claims therefore are not subject to challenga by mambers of the public.

Similarly, if machine (host cell) claims ara not asserted in court but only the unsesrched process claims, tha bill would again suggest that the automatically allowed process claims may not be subjact to challenga. We urge that tha bill be amanded to provida for tha ability of the public to challenge the nonobviousness of those unsearched procass claims.

Then, under 35 U.S.C. § 282, a patent is prasumed valid, and the U.S. Court of Appeals for tha Federal Circuit has held that the one asserting invalidity must overcoma the presumption by clear and convincing evidence. The prasumption exists because of the search and examination conducted by an examiner of tha Patant and Trademark Office. Under the bill, if the machine claims ara found valid, the process claims may not be subject to challenga even though no search has been conducted. If the machina claims are found invalid, tha remaining process claims may, under tha prasent statute, be presumed valid. Therefore, a conflict may axist because claims unexamined for obviousness, under all logic, should not be accorded a presumption of validity. Tha presumption should apply only when an axaminstion for obviousness has been completed (not when no examination had been made). It is therefore suggested that § 282 be amended to provida that no presumption shall apply to unsearched patent claims. For axampla, tha statuta may be chsnged to read: "A patent is presumed valid only with respect to patent claims examined for obviousness."

THE BILL MAY CONFLICT WITH SUPREME COURT DECISIONS

If H.R. 1417 is anacted into law, it may be in conflict with Suprema Court dacisions because it, in effect, may enable control of the sale of unpatented products. In essence, what is sought to be protected undar the bill is control of the sale of tha unpatentabla end product (e.g., a product which alrasdy axists in natura) mada by an unpatanted process carried out by a patented machina. Tha bill appears to legitimize usa of a process which may otherwise be unpatentable under present law for controlling an

unpatented product. This may condone a practice which the Supreme Court has condemned as improper. For example, in Morton Salt Co. v. G.S. Suppiger Co., 314 US 488 (1942), the Supreme Court found it to be an improper extension of the patent grant for the patent owner to control (i.e., tying) the sale of unpatented salt tablets when used in the patented machine, because the practice extended beyond the scope of the claims. The bill may expand patent rights beyond the invention contained in the patented machine claims so as to cover control of the sale of staple "salt tablets" through use of a process that may be otherwise unpatentable under present law. Such a doctrine becomes more important when one considers there are many businesses that sell unpatented staple articles of commerce. Under the bill, the sale of those unpatented staple articles of commerce may become an infringement of the process claims even if the unsearched process claims are obvious. This is particularly troublesome if the seller of the products does not know how they were made.

THE BILL MAY CONFLICT WITH THE CONSTITUTION

If enacted into law, H.R. 1417 may conflict with the underlying principles of the patent system as reflected in Article I, Section 8, clause 8 of the U.S. Constitution. That clause provides for granting exclusive rights for limited times to inventors provided the discovery promotes "the progress of ... the useful arts".

The Supreme Court in Graham v. John Deere Co., 383 U.S. 1 (1966) and Bonito Boats v. Thunder Craft, Inc., 109 S.Ct. 971 (1989), has made several observations regarding limitations on Congressional authority in legislating patents rights.

1. Article I, Section 8, clause 8 of the Constitution is both a grant of power to legislate and a limitation.

2. Congress in the exercise of that power may not overreach the restraints imposed by the Constitution.

3. Congress may not authorize the grant of patents when the effect is to remove existent knowledge from the public domain or to restrict free access to material already available.

4. Congress does not have unlimited discretion to decide that patents should be easily or freely given.

The type of process claims granted under the bill may not meet these tests.

Further, in Deller's Walker on Patents (Second Edition), Volume 1, page 84, reference is made to a 1930 Report of the U.S. Senate relating to Plant Patents. That report emphasized the intent of the constitutional use of the term "inventor". The term was intended to identify someone who is the creator of something "new". Unsearched process claims may not be "new".

In view of the above, the bill may be in conflict with the U.S. Constitution because of the granting of patent rights to unexamined process claims which may be obvious (i.e., not "new").

CONCLUSION

In conclusion, if H.R. 1417 is enacted into law, it may cause such an expansion of the present patent right that it may significantly add to the cost of doing business. Additionally, the legislation would appear to conflict with the present law in several major respects. On the other hand, if the process claims are properly searched for unobviousness, the presumption of validity might apply to the process claims, and patent owners may be able to control use of their patented process claims against others even though the products produced are in the public domain. The present statute, 35 U.S.C. § 103 has provided a reasonable and workable solution to protect process inventions that as a whole advance the state of the art.

EIA sees no need for Congress to expand the patent right so as to potentially include obvious advances in the art. We believe all claims sought to be patented should be treated alike by undergoing the same examination for nonobviousness by the Patent and Trademark Office.

Respectfully yours,

John J. Kelly
Vice President, Secretary and
General Counsel

Maurice H. Klitzman
Of Counsel

APPENDIX 3.—LETTER FROM HARRY F. MANBECK, JR., TO CHAIRMAN WILLIAM J. HUGHES, FEBRUARY 13, 1992

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

FEB 13 1992

Honorable William J. Hughes
Chairman
Subcommittee on Intellectual Property
and Judicial Administration
Committee on the Judiciary
House of Representatives
Washington, D.C. 20515-6216

Dear Mr. Chairman:

Thank you for your letter containing supplemental questions regarding H.R. 1417, the Biotechnology Patent Protection Act of 1991. I am pleased to enclose our answers to those questions and hope that they may be of help in your assessment of this legislative proposal.

Sincerely,

Harry F. Manbeck, Jr.
Assistant Secretary and Commissioner
of Patents and Trademarks

Enclosures

Question. Has the Federal Circuit Court of Appeals decided any cases involving the specific question of the patentability of the process of using a host cell to make a recombinant product?

Answer. To date, the Federal Circuit Court of Appeals has not decided a case involving the specific question of the patentability of a process of using a host cell to make a recombinant product. In a recent case, however, the Federal Circuit held that claims in a patent directed to a host cell per se that was used to produce recombinant erythropoietin do not cover a process within the meaning of 19 U.S.C. 1337(a)(1)(B)(ii). Amgen Inc. v. International Trade Commission, 902 F.2d 1532, 14 USPQ2d 1734 (Fed. Cir. 1990). That section of the Tariff Act of 1930, as amended, like section 271(g) of the patent law, prohibits the importation of articles that are produced by using a process covered by a U.S. patent. Thus, the host cell patent could not be used under either the patent law or the Tariff Act of 1930 to prevent the importation of recombinant erythropoietin produced using the patented host cell.

Question. Is there an urgent need to stop the importation of recombinant products?

Answer. At this time, we are aware of only one situation in which someone has imported recombinant products that were produced abroad by using a host cell patented by another. However, as more and more biotechnologically engineered products are approved by the FDA, it may reasonably be expected that the number of unauthorized imports will increase if patent protection cannot be obtained in the United States for processes that use patentable host cells but that are otherwise conventional. Accordingly, it would be desirable to enact legislation along the lines of H.R. 1417 before there is a dramatic increase in the importation of products made abroad with the unauthorized use of technology patented in this country.

Question. What impact would the proposed legislation have on inventions other than biotechnology? In particular, what effect would this change in law have on the patenting of computer software, and on otherwise unpatentable processes in the chemical, engineering, and mechanical arts?

Answer. The provisions of the proposed legislation do not relate to any particular technology. Thus, the legislation would have the same effect on the resolution of the issue of obviousness of any invention in any field of technology that is claimed in the form of a process claim. However, the determination that a process is nonobvious would only be made if that process either uses or makes a product that itself is both novel and nonobvious.

Because the proposed legislation applies only to one criterion of patentability, i.e., nonobviousness under 35 U.S.C. 103, it does not necessarily ensure the patentability of a process claim even if such process uses or makes a patentable product. That process could well be unpatentable because it does not meet the requirement of utility under 35 U.S.C. 101, or because it is not sufficiently described to enable someone skilled in the art to use the process, thus failing the requirements of 35 U.S.C. 112. In sum, to be considered patentable, a process must meet all other statutory requirements in addition to the criterion of nonobviousness.

Accordingly, the proposed legislation is not likely to have any impact on the patentability of inventions related to computer software. One of the threshold and controversial issues of patentability that arises with respect to such an invention is whether it falls within the scope of statutory subject matter that is eligible for patent protection under 35 U.S.C. 101. We have published a legal analysis of this issue in the Official Gazette on September 5, 1989, as guidance for examiners and information to the public. A copy is enclosed for your convenience. Since the proposed legislation addresses only section 103, it does not appear to affect resolution of issues that arise under section 101 with respect to inventions related to computer software.

Question. What is the policy of the Patent and Trademark Office with regard to the patentability of recombinant proteins -- as distinct from the discovery and purification of naturally occurring proteins?

Answer. A naturally occurring product may be patentable if it has been changed or substantially altered as a result of purification. For example, patents have been granted for purified prostaglandin, for a biologically pure microorganism culture, or for the purified, naturally occurring chemical compound that lends strawberries their distinctive flavor. Accordingly, purified, naturally occurring proteins are eligible for patent protection.

The patentability of purified, naturally occurring products and recombinant proteins is subject to the same criteria of novelty, nonobviousness and utility as any other invention. Generally, the fact that a known product is made by a new process does not render the product itself patentable, even though the process may be patentable in its own right. Thus, if a recombinant product is the same as a naturally occurring product that has previously been purified, or if the recombinant product cannot be distinguished from the purified, naturally occurring product, it would not be patentable. However, if it can be demonstrated that the

recombinant protein possesses unexpected properties relative to the purified, naturally occurring protein, it may well be patentable.

Question. William F. Marsh, testifying at the November 21st Subcommittee hearing on behalf of Intellectual Property Owners, Inc., suggested that if a legislative remedy is necessary, instead of the approach taken in H.R. 1417, Congress should consider an alternative approach. He suggested that Congress amend section 103, to state that:

> A process or method claim wherein an essential element is a composition of matter otherwise patentable to the applicant shall not be deemed to be unpatentable merely because the claim reads "on a known process or combination of steps which shall be examined as a whole," giving consideration to the specific nature of the process or method and the fact that new or otherwise patentable materials are used or result from the process or method.

What are your views on this proposal?

Answer. In our view, this proposal would not add the degree of certainty that is needed to provide a mechanism for patent applicants to avoid a conclusion, along the lines of In re Durden, that a claim directed to a process of making or using a patentable product was obvious under section 103. First, the reference to a process claim "wherein an essential element is a composition of matter" raises several questions. This reference seems to address only processes in which a patentable product is used. A process for making a patentable element does not appear to be encompassed, leaving unclear the treatment such a process is to be accorded. Further, the limitation "essential" may cause uncertainty. A particular patentable material may not necessarily be indispensable to the operation of the process, although it represents a commercially significant improvement over the prior art. Also, the term "composition of matter" may open disputes as to whether a particular element used in the process is that or is an article of manufacture.

The phrase "known process or combination of steps which shall be examined as a whole" is also unclear because the terminology in the context of the proposal is confusing. Further, we do not understand how the phrase starting with the words "giving consideration" is intended to modify the initial mandatory requirement that a process "shall not be deemed to be unpatentable." This is especially so in light of the indication that consideration be given "to the specific nature of the process or method," which appears to raise additional questions of interpretation. Also, the phrase referring to "new or otherwise patentable materials" raises the possibility that new

materials would qualify for consideration even though they are not patentable. Another uncertainty arises from the use of the term "materials" that has no antecedent in the proposal.

Question. Enclosed is a letter from the Electronic Industries Association (EIA) presenting its views in opposition to H.R. 1417. In particular, the letter discusses the effect H.R. 1417 could have on the cost of doing business, the value of existing patents, information in the public domain, and the bill's potential conflicts with existing patent law, Supreme Court decisions and the U.S. Constitution. What are your responses to the arguments EIA raises in opposition to H.R. 1417?

Answer. Increasing cost of doing business. In his argument that enactment of H.R. 1417 would increase the cost of doing business, Mr. Kelly makes several statements that need to be clarified and corrected. First, the bill would not expand patent rights to "unexamined" processes. The criteria of utility under 35 U.S.C. 101 and enablement under 35 U.S.C. 112 would continue to be evaluated. The bill would only address the requirement of nonobviousness under 35 U.S.C. 103. As a consequence, an applicant would not "automatically be granted claims for all processes" using a patentable material. Those claims would only be granted if they met the other criteria of patentability. Further, these processes would not "encompass" prior art, because the patentable product made or used is not part of the prior art.

Mr. Kelly further notes that, after developing a new product, EIA member companies perform clearance searches of unexpired patents and validity searches of those patents that might block the manufacture and marketing of the product. Potential blocking patents issued in accordance with the concept expressed in H.R. 1417 could take two forms. One form would simply be a single patent containing claims to a process and claims to a product made by or used in such process. Alternatively, claims to a product might appear in one patent and claims for using or making that product would appear in another patent endorsed with a terminal disclaimer setting its expiration date to be the same as product patent. Neither situation should present an unusually different or financially excessive problem to the company. Given such a patent or patents as a potential block to the company's plans, the company would conduct the usual validity search to attempt invalidation of the patented product upon which the nonobviousness determination of the process claim in that patent or another patent was based. Should this search be successful, the company could then show, on the basis of a prior art search, that the process without the benefit of the patented product was conventional.

There may, however, be more processes patented along the lines of H.R. 1417 than would have been without enactment of the bill. Accordingly, there may be some added cost in sorting out the patentability of these process claims if the claim to the product made or used by the process proves to be invalid. To minimize this problem, we proposed that H.R. 1417 be amended to ensure that claims issued in accordance with the bill's provisions not be entitled to the benefit of a determination of nonobviousness if the product was determined to lack novelty or nonobviousness. However, if the product claims successfully withstand a validity search, the company would not be authorized to make or use that product by any process during the patent term, regardless of whether the process was patented or was conventional and known.

The right to use art in the public domain. Mr. Kelly further argues that the public may no longer have the right to use art in the public domain. We do not understand that argument in light of the fact that if the product made or used by a process is patented in its own right, the public may be prevented from making or using that product in the United States during the life of the patent. The question whether processes similar to the patented ones are conventional and disclosed in prior art is not material, because the public may not use or make the patented product without authorization regardless of the patentability or conventionality of the process in question. On the other hand, the public may use any process in the public domain as long as no patented material is used by or results from such process.

Erosion of existing patents. Another argument made by Mr. Kelly is that existing patents may be eroded. In our view, the granting of patent protection to a process making or using a particular patentable product does not impinge on the rights derived from unexpired patents relating to such processes generally. If a process patented by another is used in combination with a new and patentable product, the earlier process patent may in fact be the dominating one. In such case, the earlier process patentee may prevent the patent owner of the new product and process from using the earlier process together with the new product, or with any other product for that matter. The product patent owner, in turn, can prevent the earlier process patentee from using his specific product in connection with the process patented earlier. As a matter of fact, the product patent owner may exclude all others from using the patented product in the United States regardless of whether his patent also includes a process claim using such product. In other words, existing process patent rights are not affected by the later patenting of a process claim that uses a specific patentable product. Under our present system, as well as under the system proposed by H.R. 1417, a third party who wanted to practice the general process patented by one party, together with a product patented by another party, would have to obtain a license from both patentees.

The bill's conflict with 35 U.S.C. 103. The fourth argument against H.R. 1417 is that it may conflict with the statute it proposes to amend. In support of that allegation, Mr. Kelly notes that if the bill were enacted and if thereafter machine (product) claims of a particular patent were found to be valid, it would not be clear whether process claims (presumably present in that patent and directed to using or making that product) would be subject to public challenge. This argument is not clear to us because under our present system, as well as that proposed by H.R. 1417, a product patentee can prevent others from making or using the patented product (machine) in the United States regardless of whether there are additional process claims in the patent. The only further protection afforded by such process claims is the ability of the patentee to proceed against products imported into the United States that were made abroad with the unauthorized use of the patentee's machine. We do not believe it is Mr. Kelly's intention to support the continuation of unauthorized imports of products made abroad with the use of technology patented in this country. Such practice is not in the interest of American patentees in general and EIA member companies in particular.

It is further argued that under 35 U.S.C. 282, patent validity is presumed and that even if product claims are later found invalid, the process claims, whose nonobviousness depends upon the patentability of the product, would continue to be presumed valid. While this is true under the wording of H.R. 1417 as introduced, we made a specific proposal at the hearing on this bill before your Subcommittee on November 21, 1991, to remove the benefit of presumed nonobviousness of process claims in accordance with the provisions of this bill, if the product made or used by the process was found to lack patentability. Adoption of this proposal would alleviate Mr. Kelly's concern on this point.

The bill's conflict with Supreme Court decisions. Mr. Kelly's fifth argument is that enactment of H.R. 1417 may be in conflict with decisions of the Supreme Court because it could enable control of the sale of unpatented products. In essence, he states that enactment of the bill would permit "control of the sale of the unpatentable end product... made by an unpatented process..." First, it should be noted that the process in question would in fact be patented. Second, Mr. Kelly's difficulty with a process patentee's control over unpatented products made by the process is not caused by enactment of H.R. 1417. It is already embodied in our present law, specifically in 35 U.S.C. 271(g), which provides that "[w]hoever without authority imports into the United States or sells or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer." This provision is aimed at protecting products that were made by a patented process, regardless of their patentability.

The Supreme Court decision in Morton Salt, cited to support the argument of an improper tying practice, is inapplicable in this case. In Morton Salt, the forced purchase of an unpatented product to be used in a patented machine was found to be beyond the scope of patent protection for the machine. By contrast, enactment of H.R. 1417 would provide for a patented process that uses patented material to make an unpatented product. Another possibility would be a patented process that produces a patented product. Neither instance appears to open an opportunity to tie patented with unpatented subject matter. Considering further that third parties could not use the patented material or make the patented product in the United States without authorization, regardless of the existence of additional process claims, we are at a loss regarding the applicability of Mr. Kelly's argument and the Morton Salt decision to the concept proposed by H.R. 1417.

The bill's conflict with the Constitution. Mr. Kelly's last argument against enactment of H.R. 1417 is that the bill may conflict with the Constitution. We do not perceive any inconsistency between the bill's intent, the relevant clauses of the Constitution or the observations made by the Supreme Court regarding limitations on Congressional authority in legislating patent rights. Further, Mr. Kelly states that "[u]nsearched process claims may not be 'new'" and, therefore, contravene the intent of the constitutional use of the term "inventor." First, as we have already noted, the process claims in question are not unsearched. They are in fact examined to determine whether they meet the requirements of patentability. Only nonobviousness is presumed because of their direct reference to a patentable material or product. Second, a process that uses a new and nonobvious material is itself new by definition. In other words, the criterion of novelty regarding such a process is never in question and H.R. 1417 does not address this requirement of patentability. The bill only addresses the criterion of nonobviousness. Accordingly, Mr. Kelly's argument appears to be misdirected.

4,631,581. Re. S. N. 288,287. Filed Dec. 21, 1988. Cl. 358/93. METHOD AND APPARATUS MICROPHOTOMETERING MICROSCOPE SPECIMENS. K. S. Carlsson. Owner of Record: *Sarastro AB, Stockholm, Sweden.* Attorney or Agent: Rodney A. Daniel. Ex. Gp.: 262

4,637,810. Re. S. N. 300,320. Filed Jan. 23, 1989. Cl. 474/253. ADJUSTABLE ENDLESS BELT. Paul Beck. Owner of Record: *Inventor.* Attorney or Agent: Richard E. Lyon, Jr., Ex. Gp.: 356

4,638,805. Re. S. N. 303,384. Filed Jan. 27, 1989. Cl. 128/344. SELF-VENTING BALLOON DILATION CATHETER METHOD. Philip E. Powell. Owner of Record: *Cutson Kabushiki Kaisha, Tokyo, Japan.* Attorney or Agent: Edward J. Lynch. Ex. Gp.: 336

4,649,479. Re. S. N. 321,439. Filed Mar. 9, 1989. Cl. 364/300. DEVICE DRIVER AND ADAPTER BINDING TECHNIQUE. Hira Advani, et al., Owner of Record: *International Business Machine Corp., Armonk, N. Y.,* Attorney or Agent: Kenneth C. Hall. Ex. Gp.: 232

4,662,355. Re. S. N. 384,773. Filed July 25, 1989. Cl. 294/82.120. SELF EQUALIZING DEVICE. John P. C. Hogg. Owner of Record: *Honda Giken Kogyo, Tokyo, Japan.* Attorney or Agent: Fred C. Philpitt. Ex. Gp.: 312

4,680,840. Re. S. N. 383,316. Filed July 20, 1989. Cl. 29/25.35. METHOD FOR PREPOLARIZING AND CENTERING A PIEZOCERAMIC POWER SWITCHING DEVICE. John D. Harnden, et al., Owner of Record: *Inventor(s).* Attorney or Agent: Patrick G. Burns. Ex. Gp.: 326

4,681,064. Re. S. N. 382,739. Filed July 19, 1989. Cl. 119/021. MOBILE FAN FOR POULTRY FARMING. William E. Lallisson, Sr., et al., Owner of Record: *William E. Lallisson, Jr., Salisbury, Md.* Attorney or Agent: Edward B. Hunter. Ex. Gp.: 333

4,682,308. Re. S. N. 383,831. Filed July 21, 1989. Cl. 367/71. ROD-TYPE MULTIPOLE SOURCE FOR ACOUSTIC WELL LOGGING. Jing-Yau Chung. Owner of Record: *Exxon Production Research Co., Houston, Tex.,* Attorney or Agent: Herbert E. O'Neil. Ex. Gp.: 222

4,705,305. Re. S. N. 362,895. Filed June 6, 1989. Cl. 228/180.2. CHIP CARRIER MOUNTING DEVICE. Leslie J. Allen, et al., Owner of Record: *Rexchem Corp., Menlo Park, Calif.,* Attorney or Agent: Simon J. Belcher. Ex. Gp.: 325

4,728,065. Re. S. N. 346,928. Filed May 3, 1989. Cl. 248/129. FOLDABLE MACHINIST'S TOOL TRAY. David J. Coon. Owner of Record: *Inventor.* Attorney or Agent: R. H. Fox. Ex. Gp. 355

4,805,164. Re. S. N. 382,525. Filed July 19, 1989. Cl. 369/58. DISC INCLINATION DETECTING APPARATUS. Hiroshisa Yamaguchi, et al., Owner of Record: *Teac Corp., Tokyo, Japan.* Attorney or Agent: Michael N. Meller. Ex. Gp.: 235

REQUESTS FOR REEXAMINATION FILED

Notice under 37 CFR 1.11(c). The requests for reexamination listed below are open to inspection by the general public at the indicated Examining Groups. Copies of the requests and related papers may be obtained by paying the fee therefor established in the Rules (37 CFR 1.19(a)).

In the event correspondence to the patent owner is not received, this notice will be considered to be constructive notice to the patent owner and reexamination will proceed (37 CFR 1.248(a)(3) and 1.525(b)).

3,911,138. Reexam. No. 90/001,811. Requested July 21, 1989. Cl. 424/352. ARTIFICIAL BLOOD AND METHOD FOR SUPPORTING OXYGEN TRANSPORT IN ANIMALS. Leland C. Clark. Owner of Record: *Children's Hospital Medical Center, Cincinnati, Ohio.* Attorney or Agent: Wood, Herron & Evans. Ex. Gp.: 120. Requester: Sughrue, Mion, Zinn, Macpeak & Seas, 2100 Pa. Ave., Washington, D. C.

4,374,520. Reexam. No. 90/001,812. Requested July 24, 1989. Cl. 128/155. SYSTEM AND METHOD FOR BANDAGING A PATIENT. Frederic Grossman. Owner of Record: *Baxter International Inc., Deerfield, Ill.* Attorney or Agent: Unknown. Ex. Gp.: 330. Requester: Owner

4,575,826. Reexam. No. 90/001,810. Requested July 17, 1989. Cl. 365/222. REFRESH GENERATOR SYSTEM. Mark E. Dean. Owner of Record: *IBM Machines Corp., Armonk, N. Y.* Attorney or Agent: Unknown. Ex. Gp.: 233. Requester: Owner

4,789,277. Reexam. No. 90/001,813. Requested July 26, 1989. Cl. 501/105. METHOD OF CUTTING USING SILICON CARBIDE WHISKER REINFORCED CERAMIC CUTTING TOOLS. James F. Rhodes, et al., Owner of Record: *Advanced Composite Materials Corp., Greer, S. C.* Attorney or Agent: Banner, Birch, McKie, et al., Ex. Gp.: 110. Requester: Precision Materials Group, Danvers, Mass.

Patentable Subject Matter

Mathematical Algorithms and Computer Programs

The following represents a recent legal analysis done by Associate Solicitor Lee E. Barrett, an attorney in the Office of the Solicitor of the Patent and Trademark Office, on the subject of the patentability of mathematical algorithms and computer programs. The analysis is published for the benefit of the public.

August 9, 1989 FRED E. McKELVEY
Solicitor

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Discussion

I. *Statutory Subject Matter - 35 U.S.C. § 101*

Inventions may be patented only if they fall within one of the four statutory classes of subject matter of 35 U.S.C. § 101: "process, machine, manufacture, or composition of matter." *See Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 483, 181 USPQ 673, 679 (1974):

> [N]o patent is available for a discovery, however useful, novel, and nonobvious, unless it falls within one of the express categories of patentable subject matter of 35 U.S.C. § 101.

Subject matter that does not fall within one of the statutory classes of 35 U.S.C. § 101 is said to be "nonstatutory" or to be "unpatentable subject matter."

The broad language of § 101 is intended to dilineate a "general industrial boundary" of patentable invention. *In re Bergy*, 596 F.2d 952, 974 n.11, 201 USPQ 352, 372 n.11 (CCPA 1979), *vacated*, 444 U.S. 1028, *aff'd sub nom., Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The first statutory class, process, is defined in 35 U.S.C. § 100(b) and refers to *acts*, while the last three classes, machine, manufacture and composition of matter, refer to physical *things*; therefore, the general field of patentable invention consists of new acts and new things. *Id.* The classes relevant to this discussion are "process" and "machine." A "process" is equivalent to a "method." *Bergy*, 596 F.2d at 965, 201 USPQ at 364. The term "machine" is used interchangeably with "apparatus." *In re Prater*, 415 F.2d 1393, 1395 n.11, 162 USPQ 541, 543 n.11 (CCPA 1969).

The question of whether a claimed invention satisfies the other conditions for patentability is "wholly apart from whether the invention falls into a category of statutory subject matter" (emphasis deleted). *Diamond v. Diehr*, 450 U.S. 175, 190, 209 USPQ 1, 9 (1981) (citing *Bergy*, 596 F.2d at 961, 201 USPQ at 361). As stated in *Parker v. Flook*, 437 U.S. 584, 593, 198 USPQ 193, 198-99 (1978):

> The obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new [i.e., novel under § 102] or obvious [§ 103].

See also In re Sarkar, 588 F.2d 1330, 1333 n.10, 200 USPQ 132, 137 n.10 (CCPA 1978) ("If the subject matter as claimed is subject to patenting, i.e., if it falls within § 101, it must then be examined for compliance with §§ 102 and 103").

Legislative history indicates that Congress contemplated that the subject matter provisions be given a broad construction and were intended to "include anything under the sun that is made by man." *Diamond v. Chakrabarty*, 447 U.S. at 309, 206 USPQ at 197. Any process, machine, manufacture, or composition of matter constitutes statutory subject matter *unless* it falls within a judicially determined exception to § 101. *In re Pardo*, 684 F.2d 912, 916, 214 USPQ 673, 677 (CCPA 1982). Exceptions include laws of nature, physical phenomena and abstract ideas. *Diehr*, 450 U.S. at 185, 209 USPQ at 7, and cases cited therein. This analysis addresses whether mathematical algorithms and computer programs are statutory subject matter.

II. *Mathematical Algorithms*

A. *Mathematical algorithms per se are not a statutory "process" under § 101*

A mathematical algorithm is defined as a "procedure for solving a given type of mathematical problem." *Gottschalk v. Benson*, 409 U.S. 63, 65, 175 USPQ 673, 674 (1972); *Flook*, 437 U.S. at 585 n.1, 198 USPQ at 195 n.1; *Diehr*, 450 U.S. at 186, 209 USPQ at 8. Mathematical algorithms are nonstatutory because they have been determined not to fall within the § 101 statutory class of a "process." *Benson*. "[A]n algorithm, or mathematical formula, is like a law of nature, which cannot be the subject of a patent." *Diehr*, 450 U.S. at 186, 209 USPQ at 8. The exception applies only to *mathematical* algorithms since any process is an "algorithm" in the sense that it is a step-by-step procedure to arrive at a given result. *In re Walter*, 618 F.2d 758, 764 n.4, 205 USPQ 397, 405 n.4. (CCPA 1980); *Pardo*, 684 F.2d at 915, 214 USPQ at 676.

Although mathematical algorithms *per se* are nonstatutory, as stated in *Diehr*, 450 U.S. at 187-88, 209 USPQ at 8-9:

> [A] claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer. . . . [I]n *Parker v. Flook* we stated that "a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm." 437 U.S. at 590. It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection. As Justice Stone explained four decades ago:
>
> > "While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be." *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86, 94 (1939). [Citations omitted.]

The Supreme Court thus recognizes that mathematical algorithms are "the basic tools of scientific and technological work." *Benson*, 409 U.S. at 67, 175 USPQ at 675, and should not be the subject of exclusive rights, whereas technological application of scientific principles and mathematical algorithms furthers the constitutional purpose of promoting "the Progress of . . . Useful arts." U.S. Const. art. I, § 8. It is also recognized that mathematical algorithms may be the most precise way to describe the invention.

Where claims involve mathematical algorithms, as stated in *In re Abele*, 684 F.2d 902, 907, 214 USPQ 682, 687 (CCPA 1982):

> The goal is to answer the question "What did applicants invent?" If the claimed invention is a mathematical algorithm, it is improper subject matter for patent protection, whereas if the claimed invention is an application of the algorithm, § 101 will not bar the grant of a patent.

The tests for determining whether claims containing mathematical algorithms are statutory have gradually evolved in the courts since the Supreme Court's decision in *Benson* in 1972.

B. *Evolution of the two-part test for mathematical algorithm-statutory subject matter*

The proper legal analysis of mathematical algorithm-statutory subject matter cases is the two-part test of *In re Freeman*, 573 F.2d 1237, 197 USPQ 464 (CCPA 1978), as modified by *Walter* and *Abele*. *See In re Meyer*, 688 F.2d 789, 796, 215 USPQ 193, 198 (CCPA 1982) ("A more comprehensive test for cases involving mathematical algorithms is set forth in *In re Abele*"). A review of the evolution of the analysis provides some useful insights into the application of the test.

In *Benson*, the Supreme Court concluded that claims directed to a particular algorithm for converting binary coded decimal numbers to binary numbers was not statutory subject matter. The Supreme Court further concluded that any patent issued on those claims "would wholly pre-empt the mathematical formula and to practical effect would be a patent on the algorithm itself." 409 U.S. at 72, 175 USPQ at 676. These two conclusions formed the basis for the two-part analysis of the Court of Customs and Patent Appeals (CCPA) in *Freeman*, 573 F.2d at 1245, 197 USPQ at 471:

> First, it must be determined whether the claim directly or indirectly recites an "algorithm" in the *Benson* sense of that term, for a claim which fails even to recite an algorithm clearly cannot wholly preempt an algo-

rithm. Second, the claim must be further analyzed to ascertain whether it as entirety it wholly preempts that algorithm.

In 1978, the Supreme Court held in *Flook* that a claim need "not . . . cover every conceivable application of the formula" to be nonstatutory. 437 U.S. at 586, 198 USPQ at 196. This decision left undefined what constitutes statutory subject matter. In *Walter*, the CCPA modified the second step of *Freeman* to require a more positive approach to determining what is claimed. 618 F.2d at 767, 205 USPQ at 407:

> If it appears that the mathematical algorithm is implemented in a specific manner to define structural relationships between the physical elements of the claim (in apparatus claims) or to refine or limit claim steps (in process claims), the claim being otherwise statutory, the claim passes muster under § 101. If, however, the mathematical algorithm is merely presented and solved by the claimed invention, as was the case in *Benson* and *Flook*, and is not applied at any manner to physical elements or process steps, no amount of post-solution activity will render the claim statutory; nor is it saved by a preamble merely reciting the field of use of the mathematical algorithm.

The CCPA noted that while the second step of *Freeman* was "*stated* at terms of preemption" it had consistently been applied "in the spirit of the foregoing principles." 618 F.2d at 767, 205 USPQ at 407.

In *Abele*, the CCPA further modified the second part of the test to provide a more comprehensive test. 684 F.2d at 906-7, 214 USPQ at 686:

> Appellants summarize the *Walter* test as setting forth two ends of a spectrum: what is now clearly nonstatutory, i.e., claims in which an algorithm is merely presented and solved by the claimed invention (preemption), and what is clearly statutory, i.e., claims at which an algorithm is implemented at a specific manner to *define structural relationships* between the physical elements of the claim (at an apparatus claim) or to *refine or limit steps* (at a process). Appellants urge that the statement of the test at *Walter* fails to provide a useful tool for analyzing claims at the "gray area" which falls between the two ends of that spectrum. We agree that the board's understanding and application of the *Walter* analysis justifies appellant's position. However, the *Walter* analysis quoted above does not limit patentable subject matter only to claims at which structural relationships or process steps are defined, limited or refined by the application of the algorithm.
>
> Rather, *Walter* should be read as requiring no more than that the algorithm be "applied in any manner to physical elements or process steps," provided that its application is circumscribed by more than a field of use limitation or non-essential post-solution activity. Thus, if the claim would be "otherwise statutory," *id.*, albeit inoperative or less useful without the algorithm, the claim likewise presents statutory subject matter when the algorithm is included. This broad reading of *Walter*, we conclude, is at accord with the Supreme Court decisions [holding "that a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer," *Diamond v. Diehr*, 450 U.S. at 187, 209 USPQ at 8].

The reason for the modification of the test was because, as noted in *Abele*, 684 F.2d at 909, 214 USPQ at 688:

> The algorithm [in *Abele*] does not necessarily refine or limit the earlier steps of production and detection as would be required to achieve the status of patentable subject matter by the board's narrow reading of *Walter*.

The second test of *Abele* suggests that the determination of whether the algorithm is "applied at any manner to physical element or process steps" may be made by viewing the claims without the algorithm and determining whether what remains is "otherwise statutory." This analysis focuses on identifying the statutory process at the claim and is consistent with previous cases such as *Walter*, 618 F.2d at 769, 205 USPQ at 409 ("Examination of each claim demonstrates that each has no substance apart from the calculations involved"). The technique of viewing the claim without the mathematical algorithm is not inconsistent with the requirement that claims must be considered "as a whole" under § 101.

The requirement that claims be considered "as a whole" arose out of the now rejected "point of novelty" approach to statutory subject matter. Under the "point of novelty" approach, if a claim considered without the nonstatutory subject matter was unpatentable over the prior art (i.e., if the algorithm was at the "point of novelty" of the claim), the claims were found to not recite statutory subject matter. This approach was consistently rejected by the CCPA. *See In re Chatfield*, 545 F.2d 152, 191 USPQ 730 (CCPA 1976), *cert. denied*, 434 U.S. 875 (1977); *In re Deutsch*, 553 F.2d 689, 193 USPQ 645 (CCPA 1977); *In re de Castelet*, 562 F.2d 1236, 195 USPQ 439 (CCPA 1977); *Freeman*, *Sarkar*, *Walter*. The point of novelty approach was finally put to rest in *Diehr*, 450 U.S. at 188-89, 209 USPQ at 9:

> In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. . . . The "novelty" of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.

Under the second test of *Abele*, the claims are considered without the algorithm to determine whether what remains is "otherwise statutory," *not* to determine whether what remains is novel and nonobvious.

C. *Application of the two-part test*

1. *Step 1 - presence of a mathematical algorithm*

a. *Mathematical algorithm*

A mathematical algorithm is a "procedure for solving a given type of mathematical problem." In this sense, a mathematical algorithm refers "to methods of calculation, mathematical formulas, and mathematical procedures generally." *Walter*, 618 F.2d at 764-65 n.4, 205 USPQ at 405 n.4. "The type of mathematical computation involved does not determine whether a procedure is statutory or nonstatutory." *In re Gelnovatch*, 595 F.2d 32, 41, 201 USPQ 136, 145 (CCPA 1979). A "claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under § 101." *Flook*, 437 U.S. at 595 n.18, 198 USPQ at 199 n.18.

Mathematical algorithms may represent scientific principles, laws of nature, or ideas or mental processes for solving complex problems. *See Meyer*, 688 F.2d at 794-95, 215 USPQ at 197.

> Scientific principles, such as the relationship between mass and energy ($E = mc^2$), and laws of nature, such as the acceleration of gravity, namely $a = 32$ ft./sec.^{2}, can be represented in mathematical format. However, some mathematical algorithms and formulae do not represent scientific principles or laws of nature: they represent ideas or mental processes and are simply logical vehicles for communicating possible solutions to complex problems.

See also Safe Flight Instrument Corp. v. Sundstrand Data Control, Inc., 706 F. Supp. 1146, 10 USPQ2d 1733 (D Del. 1989) (mathematical algorithm representing a natural phenomenon, windshear). No distinction is made between mathematical algorithms invented by man, and mathematical algorithms representing discoveries of scientific principles and laws of nature which reveal a relationship that has always existed.

b. "Process" versus "apparatus" claims

Since mathematical algorithms have been determined not to fall within the § 101 statutory class of a "process," attempts have been made to circumvent the nonstatutory subject matter rejection by drafting mathematical algorithms as "machine" claims. The technique used is to draft the method steps in terms of "means for" language permitted by 35 U.S.C. § 112, sixth paragraph. While such a claim is technically a "machine" or "apparatus" claim, the courts have held that form of the claim does not control whether the subject matter is statutory. *See In re Meuwerps*, 609 F.2d 481, 485, 203 USPQ 812, 815-16 (CCPA 1979):

> Labels are not determinative in § 101 inquiries. "*Benson* applies equally whether an invention is claimed as an apparatus or process, because the form of the claim is often an exercise in drafting." *In re Johnson*, 589 F.2d 1070, 1077, 200 USPQ 199, 206 ([CCPA] 1978). "Though a claim expressed in 'means for' (functional) terms [under 35 U.S.C. § 112, sixth paragraph] is said to be an apparatus claim, the subject matter as a whole of that claim may be indistinguishable from that of a method claim drawn to the steps performed by the 'means.'" *In re Freeman*, 573 F.2d at 1247, 197 USPQ at 472. Moreover, that the claimed computing system may be a "machine" within "the ordinary sense of the word," as appellant argues, is irrelevant. The holding in *Benson* "forecloses a purely literal reading of § 101."

The test for determining whether "means for" apparatus claims should be treated as method claims is stated in *Walter*, 618 F.2d at 768, 205 USPQ at 408:

> If the functionally-defined disclosed means and their equivalents are so broad that they encompass any and every means for performing the recited functions, the apparatus claim is an attempt to exalt form over substance since the claim is really to the method or series of functions itself . . . . In such cases the burden must be placed on the applicant to demonstrate that the claims are truly drawn to specific apparatus distinct from other apparatus capable of performing the identical functions.
>
> If this burden has not been discharged, the apparatus claim will be treated as if it were drawn to the method or process which encompasses all of the claimed "means." *See In re Meuwerps*, 609 F.2d at 485, 203 USPQ at 815-816; *In re Johnson*, 589 F.2d at 1077, 200 USPQ at 206; *In re Freeman*, 573 F.2d at 1247, 197 USPQ at 472. The statutory nature of the claim under § 101 will then depend on whether the corresponding method is statutory.

See also Meyer, 688 F.2d at 795 n.3, 215 USPQ at 198 n.3; *Abele*, 684 F.2d at 909, 214 USPQ at 688; *Pardo*, 684 F.2d at 916 n.6, 214 USPQ at 677 n.6; *Arshal v. United States*, 621 F.2d 421, 427-28, 208 USPQ 397, 404 (Ct. Cl. 1980), *cert. denied*, 449 U.S. 1077 (1981), *reh'g denied*, 450 U.S. 1050 (1981). In *Meuwerps*, the limitation of various "means" in claim 1 to include certain "electric circuits" did not prevent the claim from being treated as a method. A claim is not presumed to be statutory simply because it is in apparatus form.

c. Form of the mathematical algorithm

The first step of the analysis is to determine whether the claim directly or indirectly recites a mathematical algorithm. A mathematical algorithm can appear in many forms. As stated in *Freeman*, 573 F.2d at 1246, 197 USPQ at 471:

> The manner in which a claim recites a mathematical algorithm may vary considerably. In some claims, a formula or equation may be expressed in traditional mathematical symbols so as to be immediately recognizable as a mathematical algorithm. *See, e.g., In re Richman*, 563 F.2d 1026, 195 USPQ 340 ([CCPA] 1977); *In re Flook*, 559 F.2d 21, 195 USPQ 9 ([CCPA] 1977), *cert. granted sub nom., Parker v. Flook*, [437 U.S. 584] (1978). Other claims may use prose to express a mathematical computation or to indirectly recite a mathematical equation or formula by means of a prose equivalent therefor. *See, e.g., In re de Castelet*, *supra* (claims 6 and 7); *In re Waldbaum*, 559 F.2d 611, 194 USPQ 465 ([CCPA] 1977). A claim which substitutes, for a mathematical formula in algebraic form, "words which mean the same thing," nonetheless recites an algorithm in the *Benson* sense. *In re Richman*, *supra* 563 F.2d at 1030, 195 USPQ at 344. Indeed, the claims at issue in *Benson* did not contain a formula or equation expressed in mathematical symbols.

Claims which include mathematical formulas or calculations expressed in mathematical symbols clearly include a mathematical algorithm. Mathematical algorithms in prose form may be expressed as literal translations of the mathematical algorithm (e.g., substituting the expression "division" or "taking the ratio" for a division sign) or may be expressed in words which indicate the mathematical algorithm. *See Safe Flight Instrument*, 706 F. Supp. at 1148, 10 USPQ2d at 1734 (subtracting); *Abele*, 684 F.2d at 908 n.8, 214 USPQ at 687 n.8 ("The algorithm, calculating the difference, is defined in the specification as a Gaussian weighting function"); *In re Taner*, 681 F.2d 787, 790, 214 USPQ 678, 681 (CCPA 1982) (summing); *In re Johnson*, 589 F.2d 1070, 1079, 200 USPQ 199, 208 (CCPA 1978) ("'computing' connotes the execution of one or a sequence of mathematical operations"); *In re Waldbaum*, 559 F.2d 611, 194 USPQ 465 (CCPA 1977) (method of claim 1 "to count" the number of busy lines "solves a mathematical problem, to wit, *counting* a number of busy lines in a telephone system," *In re Bradley*, 600 F.2d 807, 810 n.4, 202 USPQ 480, 484 n.4 (CCPA 1979), *aff'd by an equally divided court sub nom., Diamond v. Bradley*, 450 U.S. 381, 209 USPQ 97 (1981)).

It is not always possible to determine by inspection of the claim whether it indirectly recites a mathematical algorithm. In such instances the analysis "requires careful interpretation of each claim in the light of its supporting disclosure." *Johnson*, 589 F.2d at 1079, 200 USPQ at 208. *See also id.* at 1078-79, 200 USPQ at 208 ("the flow diagrams which form part of the specification disclose explicit mathematical equations which are to be used in conjunction with each of these [claimed] steps [of 'determining' or 'correlating']"); *Waldbaum*, 559 F.2d 611, 194 USPQ 465 ("series of steps for manipulating binary numbers within a procedure for calculating the number of binary 1's and 0's present" was considered a mathematical algorithm. *Gelnovatch*, 595 F.2d at 39, 201 USPQ at 143); *In re Sherwood*, 613 F.2d 809, 818, 204 USPQ 537, 545 (CCPA 1980), *cert. denied*, 450 U.S. 994 (1981) ("claims must be said to include the indirect recitation of a mathematical equation"); *Meyer*, 688 F.2d at 795, 215 USPQ at 198 (claims indirectly "recite a mathematical algorithm, which represents a mental process that a neurologist should follow").

2. Step 2- is the mathematical algorithm "applied in any manner to physical elements or process steps?"

The second test is to determine whether the mathematical algorithm is "applied in any manner to physical elements or process steps." The guideline for the analysis should be the CCPA's suggestion in *Abele* to view the claim without the mathematical algorithm to determine whether what remains is "otherwise statutory"; if it is, it does not become nonstatutory simply because it uses a mathematical algorithm. It is recognized that "[t]he line between a patentable 'process' and an unpatentable 'principle' is not always clear." *Flook*, 437 U.S. at 589, 198 USPQ at 197. There are no definitive "tests for determining whether a claim positively recites statutory subject matter." *Meyer*, 688 F.2d at 796 n.4, 215 USPQ at 198 n.4. Nevertheless, some useful guidelines may be synthesized out of the court decisions.

a. Post-solution activity

If the only limitation aside from the mathematical algorithm is insignificant or non-essential "post-solution activity," the claimed subject matter is nonstatutory. *Flook*, 437 U.S. at 590, 198 USPQ at 197:

> The notion that post-solution activity . . . can transform an unpatentable principle into a patentable process assaults form over substance. A competent draftsman could attach some form of post-solution activity to almost any mathematical formula; the Pythagorean theorem would not have been patentable, or partially patentable, because a patent application contained a final step indicating that the formula, when solved, could be usefully applied to assisting surveying techniques.

Insignificant post-solution activity by itself is insufficient to constitute a statutory process. In *Flook*, the final step of adjusting an alarm limit was not sufficient. *See also Safe Flight* (final step of "means for processing said windshear signal to provide an indication representing the magnitude thereof" not sufficient); *Abele*, 684 F.2d at 909, 214 USPQ at 688 (final step of display: "that the result is displayed as a shade of gray rather than as simply a number provides no greater or better information, considering the broad range of applications encompassed by the claims"); *Walter*, 618 F.2d at 770, 205 USPQ at 409 (final step to dependent claim of magnetic recording: "If § 101 could be satisfied by the mere recordation of the results of a nonstatutory process on some record medium, even the most unskilled patent draftsman could provide for such a step"); *Gelnovatch*, 595 F.2d at 41 n.7, 201 USPQ at 145 n.7 (final step of storing outputs: "each of the steps of the claimed process, except perhaps the final step of equating the process outputs to the values of the last set of process inputs, directly or indirectly recites a mathematical computation"); *Sarkar*, 588 F.2d at 1332 n.6, 200 USPQ at 136 n.6 (final step of constructing an obstruction at a location determined by a mathematical model: "Sarkar no longer relies upon bridge of data construction as post-solution activity steps effective to bring his process within § 101"); *de Castelet*, 562 F.2d at 1244, 195 USPQ at 446 (final step of transmitting: "That the computer is instructed to transmit electrical signals, representing the result of its calculations . . . does not transform the claim into one for a process merely using an algorithm").

The absence of post-solution activity or the fact that any post-solution activity may be trivial is only one factor to be considered. On one hand, as stated in *Walter*, 618 F.2d at 767-68, 205 USPQ at 407:

> if the end-product of a claimed invention is a *pure number*, as in *Benson* and *Flook*, the invention is nonstatutory regardless of any post-solution activity which makes it available for use by a person or machine for other purposes.

On the other hand, as stated in *Abele*, 684 F.2d at 908 n.9, 214 USPQ at 687 n.9:

> "the fact that [the] equation is the final step is not determinative of the section 101 issue." *In re Richman*, 563 F.2d at 1030, 195 USPQ at 343. *Accord, In re Tanner*, 681 F.2d 787 ([CCPA] 1982), *overruling In re Christensen*, 478 F.2d 1392, 178 USPQ 35 ([CCPA] 1973).

The particular order of the steps should not be determinative of the statutory subject matter inquiry.

b. Field of use limitations

A mathematical algorithm is not made statutory by "attempting to limit the use of the formula to a particular technological environment." *Diehr*, 450 U.S. at 191, 209 USPQ at 10. Thus, "field of use" or "end use" limitations in the claim preamble are insufficient to constitute a statutory process. This is consistent with the usual treatment of preambles as merely setting forth the environment. *See Flook* (the preamble, while limiting the application of the claimed method to "a process comprising the catalytic chemical conversion of hydrocarbons" did not serve to render the method statutory); *Walter*, 618 F.2d at 769, 205 USPQ at 409 ("Although the claim preambles relate the claimed invention to the art of seismic prospecting, the claims themselves are not drawn to methods of or apparatus for seismic prospecting"); *de Castelet*, 562 F.2d at 1244 n.6, 195 USPQ at 446 n.6 ("The potential for misconstruction of preamble language requires that compelling reason exist before that language may be given weight"; *Compare Waldbaum*, 559 F.2d at 616 n.6, 194 USPQ 469 n.6 (portion of preambles referred to in method portion of claims "are necessary for completeness of the claims and are proper limitations thereto").

c. Data-gathering steps

If the only limitations in the claims in addition to the mathematical algorithm are data-gathering steps which "merely determine values for the variables used in the mathematical formulae used in making the calculations," such antecedent steps are insufficient to change a nonstatutory method of calculation into a statutory process. *See In re Richman*, 563 F.2d at 1030, 195 USPQ at 343; *Sarkar*, 588 F.2d at 1335, 200 USPQ at 139 ("If the steps of gathering and substituting values were alone sufficient, every mathematical equation, formula, or algorithm having any practical use would be per se subject to patenting as a 'process' under § 101"); *Gelnovatch*, 595 F.2d at 41 n.7, 201 USPQ at 145 n.7 ("claimed step of perturbing the values of a set of process inputs (step 3), in addition to being a mathematical operation, appears to be a data-gathering step"). Where the claim "presents data gathering steps not dictated by the algorithm but by other limitations which require certain antecedent steps" the claim may present statutory subject matter. *Abele*, 684 F.2d at 908, 214 USPQ at 687.

d. Transformation of something physical

In determining whether the claim recites a statutory process or a nonstatutory mathematical algorithm, it is useful to analyze whether there is transformation of something physical into a different form. One distinction is made between transformation of physical "signals" from one physical state to a different physical state, a statutory process in the electrical arts, and mere mathematical manipulation of "data" which, by itself, is not a statutory process. *Compare Tanner* (conversion of "substantially spherical seismic signals" into "a form representing the earth's response to cylindrical or plane waves" was statutory process); *Sherwood*, 613 F.2d at 819, 204 USPQ at 546 (conversion of amplitude-versus-time seismic traces into amplitude-versus-depth seismic traces was statutory process because it "converts one physical thing into another physical thing just as any other electrical circuitry would do"); and *Johnson* (technique for removing unwanted noise from a seismic trace was statutory process); *with Walter*, 618 F.2d at 768, 770, 205 USPQ at 407, 409 (if "the claimed invention produces a physical thing . . . the fact that it is represented in numerical form does not render the claim nonstatutory" but finding that the "signals" claimed "may represent either physical quantities or abstract quantities" and thus were to the algorithm itself and not a particular application); *Richman* (method of calculating airborne radar boresight correction angle from "a plurality of signal sets" not statutory); *Gelnovatch*, 595 F.2d at 42, 201 USPQ at 145 (where "the claims solely recite a method whereby a set of numbers is computed from a different set of numbers by merely performing a series of mathematical computations, the claims do not set forth a statutory process"); and *Benson* (conversion of binary coded decimal numbers into pure binary numbers not statutory). It is manifest that the statutory nature of the subject matter does not depend on the labels "signals" or "data."

e. Structural limitations in process claims

Another issue is the effect of structural limitations in method claims. While structural limitations in method claims are not improper, they are usually not entitled to patentable weight unless they somehow affect or form an essential part of the

process. *See Benson*, 409 U.S. at 73, 175 USPQ at 677 (claim 5 recited use of a "reentrant shift register"); *Waldbaum*, 559 F.2d at 616, 194 USPQ at 469 (machine limitations in data processor method claims); *de Castelet*, 562 F.2d at 1244, 195 USPQ at 447 ("Claims to nonstatutory processes do not automatically and inevitably become patentable upon incorporation of reference to apparatus"). The related problem of specific structural language in apparatus claims has been treated, *supra*, in section II.C.1.b.

D. *Examples*

1. *Diamond v. Diehr*

The following claim was held to recite statutory subject matter.

> 1. A method of operating a rubber-molding press for precision molded compounds with the aid of a digital computer, comprising:
>
> providing said computer with a data base for said press including at least,
>
> natural logarithm conversion data (ln),
>
> the activation energy constant (C) unique to each batch of said compound being molded, and
>
> a constant (x) dependent upon the geometry of the particular mold of the press,
>
> initiating an interval timer in said computer upon the closure of the press for monitoring the elapsed time of said closure,
>
> constantly determining the temperature (Z) of the mold at a location closely adjacent to the mold cavity in the press during molding,
>
> constantly providing the computer with the temperature (Z),
>
> repetitively calculating in the computer, at frequent intervals during each cure, the Arrhenius equation for reaction time during the cure, which is
>
> $\ln v = CZ + x$
>
> where v is the total required cure time,
>
> repetitively comparing in the computer at said frequent intervals during the cure each said calculation of the total required cure time calculated with the Arrhenius equation and said elapsed time, and
>
> opening the press automatically when a said comparison indicates equivalence.

Step 1 The claim contains an equation for controlling the in-mold time: $\ln v = CZ + x$.

Step 2 The claimed subject matter is statutory because it recites an "otherwise statutory" process in addition to the mathematical algorithm. As stated in *Abele*, 684 F.2d at 907, 214 USPQ at 686:

> In *Diehr*, were the claims to be read without the algorithm, the process would still be a process for curing rubber, although it might not work as well since the in-mold time would not be as accurately controlled.

The steps in the process, 450 U.S. at 187, 209 USPQ at 8:

> include installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time.

The statutory nature of the claim is not based on the post-solution activity of opening the press, but on the application of the mathematical algorithm to the whole process.

2. *Parker v. Flook*

The following claim in *Flook* was held to recite nonstatutory subject matter.

> 1. A method for updating the value of at least one alarm limit on at least one process variable involved in a process comprising the catalytic chemical conversion of hydrocarbons wherein said alarm limit has a current value of
>
> $Bo + K$
>
> wherein Bo is the current alarm base and K is a predetermined alarm offset which comprises:
>
> (1) determining the present value of said process variable, said present value being defined as PVL;
>
> (2) determining a new alarm base B1 using the following equation:
>
> $B1 = Bo(1.0 - F) + PVL(F)$
>
> where F is a predetermined number greater than zero and less than 1.0;
>
> (3) determining an updated alarm limit which is defined as $B1 + K$; and thereafter
>
> (4) adjusting said alarm limit to said updated alarm limit value.

Step 1 The claim contains a mathematical algorithm comprising determining a new alarm base in step (2) and computing an "alarm limit" in step (3).

Step 2 When viewed without the steps of the mathematical algorithm, steps (2) and (3), the only limitations remaining are the preamble limitation restricting the field of use to "a process comprising the catalytic chemical conversion of hydrocarbons", the data-gathering step of step (1); and the post-solution step of step (4). None of these limitations comprises an "otherwise statutory" process. The claim seeks to protect a method for computing an "alarm limit" rather than the application of the computation within an otherwise statutory process.

3. *In re Abele*

In *Abele*, claim 5 was held to recite nonstatutory subject matter under § 101 whereas dependent claim 6 was statutory.

> 5. A method of displaying data in a field comprising the steps of
>
> calculating the difference between the local value of the data at a data point in the field and the average value of the data in a region of the field which surrounds said point for each point in said field, and
>
> displaying the value of said difference as a signed gray scale at a point in a picture which corresponds to said data point.
>
> 6. The method of claim 5 wherein said data is X-ray attenuation data produced in a two dimensional field by a computed tomography scanner.

Step 1 Claim 5 contains a mathematical algorithm, "calculating the difference," which is defined in the specification to a Gaussian weighting function.

Step 2 When claim 5 is viewed without the mathematical algorithm, the only remaining limitation is the post-solution activity of displaying the result. The display by itself did not constitute an "otherwise statutory" process. The court held that "the algorithm is neither explicitly nor implicitly applied to any certain process." 684 F.2d at 909, 214 USPQ at 688. However, when dependent claim 6 is added to the limitations of claim 5, 684 F.2d at 908, 214 USPQ at 687-88:

> Were we to view the claim absent the algorithm, the production, detection and display steps would still be present and would result in a conventional CAT-scan process. . . . [W]e view the production, detection, and display steps as manifestly statutory subject matter and are not swayed from this conclusion by the presence of an algorithm in the claimed method.

III. *Computer Programs*

A. *"Computer programs" versus "computer processes"*

A "process" or "algorithm" is a step-by-step procedure to arrive at a given result. In the patent area, a "computer

process" or "computer algorithm" is a process, i.e., a series of steps, which is performed by a computer. A "[computer] program is a sequence of coded instructions for a digital computer." *Benson*, 409 U.S. at 65, 175 USPQ at 674. Computer programs are equivalently known as "software."

Unfortunately for discussion in this area, "[b]oth the series of steps performed by a computer, and the software directing those steps, have acquired the name 'computer programs.'" *Gelnovatch*, 595 F.2d at 45 n.5, 201 USPQ at 148 n.5 (Markey, C.J., dissenting). What is sought to be protected by patent is the underlying process. As stated in *Gelnovatch*, 595 F.2d at 44, 201 USPQ at 147:

> Confusion may be avoided if it be realized that what is at issue is not the "program," i.e., the software, but the process steps which the software directs the computer to perform.

See, e.g., Mascorp, 609 F.2d at 483, 203 USPQ at 814 ("The [claimed] invention is implemented via a computer program written in FORTRAN IV, either built into the calculating machine, or loaded into a general purpose computer").

B. *Statutory nature of computer processes*

1. *The Supreme Court has not ruled on the patentability of computer programs*

The Supreme Court has not ruled on whether computer processes are *per se* statutory or nonstatutory. The decisions in *Benson*, *Flook* and *Diehr* all dealt with claims viewed as mathematical algorithms. In *Benson* and *Diehr*, the claims contained mathematical algorithms implemented by a computer. In *Benson*, the Court held that the claims preempted the use of the mathematical algorithm, but did not hold that "any program servicing a computer" would be nonstatutory. In *Diehr*, the Court held that the claims otherwise defined a statutory process for curing rubber, and that the inclusion of a mathematical algorithm or computer program did not make claim nonstatutory. The claim in *Flook* did not involve a computer process.

In *Dann v. Johnston*, 425 U.S. 219, 189 USPQ 257 (1976), *rev'g on other grounds*, *In re Johnston*, 502 F.2d 765, 183 USPQ 172 (CCPA 1974), which involved a "machine system for automatic record-keeping of bank checks and deposits," the Court declined to discuss the § 101 issue of the general patentability of computer programs. 425 U.S. at 220, 189 USPQ at 258:

> . . . We find no need to treat that question in this case, however, because we conclude that in any event respondent's system is unpatentable on grounds of obviousness, 35 U.S.C. § 103.

In *Diamond v. Bradley*, an equally divided Supreme Court affirmed the CCPA's decision in *Bradley*. The claims were directed to computer "firmware," which refers to microinstructions permanently embodied in hardware elements, and not to a computer application or process. The CCPA found that the claims literally recited a machine and that, in applying the two-part test of *Freeman*, the claims did not recite a mathematical algorithm.

2. *The CCPA has held that computer processes are statutory unless they fall within a judicially determined exception*

In *Pardo*, the most recent CCPA case on computer processes, the CCPA stated that, 684 F.2d at 916, 214 USPQ at 677:

> . . . any process, machine, manufacture, or composition of matter constitutes statutory subject matter unless it falls within a judicially determined exception to section 101.

The major (and perhaps only) exception in the area of computer processes is the mathematical algorithm. Although not binding precedent on the Federal Circuit, the district court in *Paine, Webber, Jackson & Curtis, Inc. v. Merrill Lynch, Pierce, Fenner & Smith*, 564 F. Supp. 1358, 1367, 218 USPQ 212, 218 (D. Del. 1983) stated:

> The CCPA [has] . . . held that a computer algorithm, as opposed to a mathematical algorithm, is patentable subject matter.

If a computer process claim does not contain a mathematical algorithm in the *Benson* sense, the second step of the *Freeman-Walter-Abele* test is not reached, and the claimed subject matter will usually be statutory.

The traditional approach by the CCPA to the PTO's rejection of computer processes as nonstatutory subject matter has been to apply the two-part test for mathematical algorithms and to find statutory subject matter if the claims do not recite a mathematical algorithm. *See Pardo*, 684 F.2d at 916, 214 USPQ at 676 (process for converting source program into object program: "we are unable to find any mathematical formula, calculation, or algorithm either directly or indirectly recited in the claimed steps of examining, compiling, storing, and executing"); *In re Toma*, 575 F.2d 872, 877, 197 USPQ 852, 856 (CCPA 1978) (process for translating a source natural language, e.g., Russian, to a target natural language, e.g., English: "[we] are unable to find any direct or indirect recitation of a procedure for solving a *mathematical* problem"); *In re Phillips*, 608 F.2d 879, 883, 203 USPQ 971, 975 (CCPA 1979) (process for preparing architectural specifications: "Our analysis of the claims on appeal reveals no recitation, directly or indirectly, of an algorithm in the *Benson* and *Flook* sense"); *Freeman*, 573 F.2d at 1246, 197 USPQ at 471 ("The method claims here at issue do not recite process steps which are themselves mathematical calculations, formulae, or equations"); *Deutsch*, 553 F.2d 689, 692, 193 USPQ 645, 648 (CCPA 1977) (method of operating a system of manufacturing plants: "Nothing in the methods claimed by Deutsch preempts a mathematical formula, an algorithm, or any specific computer program"); *Chatfield*, 545 F.2d at 158, 191 USPQ at 736 (method of reassigning priorities within a computer: "[the] independent claims contain neither a mathematical formula nor a mathematical algorithm").

If the computer process is found to contain a mathematical algorithm, it must then pass the second part of the *Freeman-Walter-Abele* test for statutory subject matter. *See, e.g., Sherwood*; *Mascorp*; *Gelnovatch*.

Arguably, other exceptions such as "methods of doing business" and "mental steps" may be raised if a claim is not a true computer process, but merely recites that an otherwise nonstatutory process is performed on a computer. *de Castelet*, 562 F.2d at 1244, 195 USPQ at 447 ("Claims to nonstatutory processes do not automatically and invariable become patentable upon incorporation of reference to apparatus"). These would appear to be exceptions with very narrow application to claims which are not limited to implementation by a machine. For example, while a "method of doing business" *per se* is not statutory subject matter, "a method of operation on a computer to effectuate a business activity" has been held to be statutory subject matter. *Paine, Webber v. Merrill Lynch*, 564 F. Supp. at 1369, 218 USPQ at 220. *See also Deutsch*, 553 F.2d at 692 n.5, 193 USPQ at 648 n.5 (claims were not a method of doing business because "[t]hey do not merely facilitate business dealings"); *Johnston*, *rev'd on other grounds*, *Dann v. Johnston* (apparatus claims directed to system for automatic record-keeping of bank checks and deposits did not cover a method of doing business). Similarly, machine or computer implementation of "mental steps" is statutory subject matter. *Prater*; *In re Bernhart*, 417 F.2d 1395, 163 USPQ 611 (CCPA 1969); *In re Musgrave*, 431 F.2d 882, 167 USPQ 280 (CCPA 1970); *Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673 (1972); *In re Christensen*, 478 F.2d 1392, 178 USPQ 35 (CCPA 1973).

Chronological Order Case List

In re Prater, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969)
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In re Chatfield, 545 F.2d 152, 191 USPQ 730 (CCPA 1976), *cert. denied*, 434 U.S. 875, 195 USPQ 465 (1977)
In re Deutsch, 553 F.2d 689, 193 USPQ 645 (CCPA 1977)
In re Waldbaum, 559 F.2d 611, 194 USPQ 465 (CCPA 1977)
In re Richman, 563 F.2d 1026, 195 USPQ 340 (CCPA 1977)
In re de Castelet, 562 F.2d 1236, 195 USPQ 439 (CCPA 1977)
In re Freeman, 573 F.2d 1237, 197 USPQ 464 (CCPA 1978)
In re Toma, 575 F.2d 872, 197 USPQ 852 (CCPA 1978)
Parker v. Flook, 437 U.S. 584, 198 USPQ 193 (1978)
In re Sarkar, 588 F.2d 1330, 200 USPQ 132 (CCPA 1978)
Hirschfeld v. Banner, 462 F. Supp. 135, 200 USPQ 276 (D.D.C. 1978), *aff'd without opinion*, 615 F.2d 1368 (D.C. Cir. 1980), *cert. denied*, 450 U.S. 994, 210 USPQ 776 (1981)
In re Grimwatch, 595 F.2d 32, 201 USPQ 136 (CCPA 1979)
In re Mancorps, 609 F.2d 481, 203 USPQ 812 (CCPA 1979)
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In re Sherwood, 613 F.2d 809, 204 USPQ 537 (CCPA 1980), *cert. denied*, 450 U.S. 994, 210 USPQ 776 (1981)
In re Walter, 618 F.2d 758, 205 USPQ 397 (CCPA 1980)
Arshal v. United States, 621 F.2d 421, 208 USPQ 397 (Ct. Cl. 1980), *cert. denied*, 449 U.S. 1077 (1981), *reh'g denied*, 450 U.S. 1050 (1981)
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Diamond v. Bradley, 450 U.S. 381, 209 USPQ 97 (1981), *aff'g by an equally divided Court*, *In re Bradley*, 600 F.2d 807, 202 USPQ 480 (CCPA 1979)
In re Pardo, 684 F.2d 912, 214 USPQ 673 (CCPA 1982)
In re Taner, 681 F.2d 787, 214 USPQ 678 (CCPA 1982)
In re Abele, 684 F.2d 902, 214 USPQ 682 (CCPA 1982)
In re Meyer, 688 F.2d 789, 215 USPQ 193 (CCPA 1982)
Paine, Webber, Jackson & Curtis, Inc. v. Merrill Lynch, Pierce, Fenner & Smith, 564 F. Supp. 1358, 218 USPQ 212 (D. Del. 1983)
Safe Flight Instrument Corp. v. Sundstrand Data Control, Inc., 706 F. Supp. 1146, 10 USPQ2d 1733 (D. Del. 1989)

EXTENSION OF TIME FOR FILING NOTICES OF OPPOSITION TO MARKS PUBLISHED IN THE OFFICIAL GAZETTE DATED JULY 4, 1989

Copies of the Trademark Official Gazette date July 4, 1989 were not mailed until July 11, 1989. Therefore, for marks published in the Trademark Official Gazette dated July 4, 1989, Notices of Opposition filed by August 10, 1989 will be considered timely.

August 16, 1989.

JEFFREY M. SAMUELS,
Assistant Commissioner for Trademarks.

APPENDIX 4.—LETTER FROM CHAIRMAN WILLIAM J. HUGHES, TO D. DENNIS ALLEGRETTI, PARTNER IN THE LAW FIRM OF ALLEGRETTI & WITCOFF, LTD., DECEMBER 23, 1991

ONE HUNDRED SECOND CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON THE JUDICIARY
2138 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6216

December 23, 1991

D. Dennis Allegretti, Esq.
Allegretti & Witcoff, Ltd.
75 State Street
Boston, MA 02109

Dear Mr. Allegretti:

Thank you for testifying before the Subcommittee on Intellectual Property and Judicial Administration on H.R. 1417, the Biotechnology Patent Protection Act of 1991. Your testimony was extremely useful to the Subcommittee as we determine how best to protect biotechnology inventions, and, at the same time, safeguard the balance and flexibility of our patent system. There were a number of questions that I did not have the opportunity to ask you at the November 21st hearing, and I would be very grateful if you could respond to these questions in writing. These questions are as follows:

1. How will H.R. 1417 affect the patenting of chemical, computer, and other processes in areas outside of biotechnology?

2. What are your views on the Administration's proposed amendments to H.R. 1417?

3. Are there any examples, other than recombinant Erythropoietin, of biotechnology products that have been made abroad through use of a host cell patented in the United States and then imported into this country?

4. Could the Patent and Trademark Office (PTO), or patent applicants themselves, eliminate the need for legislation by designating processes for producing recombinant products through use of a host cell as "processes of using" as defined in Pleuddemann?

5. Have there been any improvements over time in PTO's review and determination of biotechnology process patent applications?

6. Aside from the problem of unfair imports, what if any consequences could result if a biotechnology process does not have patent protection?

D. Dennis Allegretti, Esq.
December 23, 1991
Page Two

7. Do you see any danger that enactment of H.R. 1417 could create uncertainty in the area of process patent law?

I appreciate your interest and the expertise that you shared with the Subcommittee on this important matter.

Sincerely,

Bill Hughes

William J. Hughes
Chairman
Subcommittee on Intellectual Property
and Judicial Administration

WJH:efv

APPENDIX 5.—LETTER FROM D. DENNIS ALLEGRETTI, TO CHAIRMAN WILLIAM J. HUGHES, JANUARY 20, 1992

JAN 27 1992

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Sub on Courts

January 20, 1992

The Honorable William J. Hughes
Chairman
Committee on Intellectual Property
and Judicial Administration
House of Representatives
2138 Rayburn House Office Building
Washington, D.C. 20515-6216

Dear Mr. Chairman:

Thank you very much for your kind letter of December 23, 1991. I offer the following responses for your further consideration of the issues raised by the seven questions which you posed to me.

1. I believe that there will be increased efforts by patent applicants to obtain process claims in other areas of technology, directed toward meeting some of the same needs as those which have been made manifest for biotechnology. For example, in the economically important field of petroleum refining, U.S. patented processes applicable to the importation of refined products made by such processes represent subject matter of great potential benefit to that U.S. industry.

2. I have not had an opportunity to apply any personal study to such amendment as the Administration may have proposed, and I am therefore unable to offer any useful comments to you.

3. Yes, tissue plasminogen activator (t-PA), the important drug for treating heart attacks, was imported. Only the successful enforcement of its process patent assured domestic protection for the U.S. developer, Genentech, Inc. Also, monoclonal antibodies for treating sepsis have been made abroad and imported into the U.S.

4. I do not believe that this would be a satisfactory solution, because the lack of a clear legislative direction would, in my view, only give rise to both procedural and policy disputes as between the PTO and applicants, which would cast a pall of judicially unresolved uncertainties for many years to come.

5. Although there have been some improvements in the examination of biotechnology process patents, the quality of such practice remains highly uneven from one Patent Office examiner to another.

6. I believe that the absence of such patent protection adversely affects present and future business commitments for the domestic development of innovative and cost effective processes. There is a consequent business incentive to maintain important new processes as trade secrets, thereby restraining disclosure to the public and inhibiting the advancement of the arts and sciences which the Patent Law is intended to promote.

7. I see no risk of uncertainty at all in process patent law by HR1417, neither for U.S. biotechnology or any other U.S. industry. As I noted in my testimony, a failure to enact HR1417 is likely in my view to impel the Patent Office toward an operating practice of allowing only very narrow and

specific process claims. Such patents as would result are of little or no practical use against foreign competition because they can be readily avoided by trivial variations in the making of the same products. This bad likelihood can only be avoided by the availability of protection against the importation of recombinant biotechnology products which are produced by patented host cells or DNA sequences.

I am grateful to you for the opportunity to offer my views, as a trial practitioner in recent and current biotechnology patent litigation, to the Subcommittee. Thank you for your kind comments and the many courtesies of your outstanding staff.

Sincerely,

Dennis Allegretti

DDA/ms

APPENDIX 6.—LETTER FROM CHAIRMAN WILLIAM J. HUGHES, TO GEORGE W. EBRIGHT, PRESIDENT AND CHIEF EXECUTIVE OFFICER, CYTOGEN CORP., DECEMBER 23, 1991

ONE HUNDRED SECOND CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON THE JUDICIARY
2138 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6216

December 23, 1991

Mr. George W. Ebright
President and Chief Executive Officer
Cytogen Corporation
c/o Ms. Lisa Raines
Industrial Biotechnology Association
1625 K Street, N.W.
Suite 1100
Washington, D.C. 20006

Dear Mr. Ebright:

Thank you for testifying before the Subcommittee on Intellectual Property and Judicial Administration on H.R. 1417, the Biotechnology Patent Protection Act of 1991. Your testimony was extremely useful to the Subcommittee as we determine how best to protect biotechnology inventions, and, at the same time, safeguard the balance and flexibility of our patent system. There were a number of questions that I did not have the opportunity to ask you at the November 21st hearing, and I would be very grateful if you could respond to these questions in writing. These questions are as follows:

1. How will H.R. 1417 effect the patenting of chemical, computer, and other processes in areas outside of biotechnology?

2. What support exists for H.R. 1417 outside of the biotechnology industry?

3. What are your views on the Administration's proposed amendments to H.R. 1417?

4. Aside from the problem of unfair imports, what if any consequences could result if a biotechnology process does not have patent protection?

5. Are there any examples, other than recombinant Erythropoietin, of biotechnology products that have been made abroad through use of a host cell patented in the United States and then imported into this country?

Mr. George W. Ebright
December 23, 1991
Page Two

6. Could the Patent and Trademark Office (PTO), or patent applicants themselves, eliminate the need for legislation by designating processes for producing recombinant products through use of a host cell as "processes of using" as defined in Pleuddemann?

7. Have IBA-member companies received process patents for biotechnology processes?

8. What impact, if any, would the proposed legislation have on the cost of biotechnology products?

9. Are there any biotechnology products that you can identify that may not be available to the American public because of the Durden decision?

10. Have there been any improvements over time in PTO's review and determination of biotechnology process patent applications?

I appreciate your interest and the expertise that you shared with the Subcommittee on this important matter.

Sincerely,

Bill Hughes

William J. Hughes
Chairman
Subcommittee on Intellectual Property
and Judicial Administration

WJH:efv

APPENDIX 7.—LETTER FROM RICHARD D. GODOWN, PRESIDENT, INDUSTRIAL BIOTECHNOLOGY ASSOCIATION (RESPONDING TO LETTER TO GEORGE W. EBRIGHT), to HON. WILLIAM J. HUGHES, JANUARY 31, 1991

IBA

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DNA Corporation

Michael J.P. Schmeltzer
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James R. Shadowen
TSI Corporation

Mark B. Skaggs
Genetics, Inc.

Mark A. Tarmoy
Genetics Institute

January 31, 1992

The Honorable William J. Hughes
Chairman
House Intellectual Property Subcommittee
207 Cannon House Office Buildign
Washington, DC 20515

Subject: Biotechnology Patent Protection Act (H.R. 1417)

Dear Chairman Hughes:

The Industrial Biotechnology Association (IBA) and its 115 member companies are grateful for having had the opportunity to appear before your Subcommittee to testify in support of the Biotechnology Patent Protection Act (H.R. 1417). We deeply appreciate your interest in ensuring that our patent system provide adequate protection for biotechnology inventions.

George Ebright has asked me to respond to your letter of December 23, 1991 raising several questions about the legislation. I am happy to respond.

1. How will H.R. 1417 affect the patenting of chemical, computer, and other processes in areas outside of biotechnology?

H.R. 1417 is not industry specific. It overrules Durden in a manner that will make it easier to obtain process patent protection for all process-oriented technologies.

IBA expects that H.R. 1417 will have its greatest impact in the biotechnology field because so many biotechnology products are not themselves eligible for patent protection. The insulin example contained in our testimony is illustrative of this point. While nonbiotechnology processes would enjoy the same benefits, the need for H.R. 1417 for other technologies is not nearly as important because the end product in such areas is usually patentable.

IBA joins with PTO in believing that Durden should be overruled for all industries because (1) the application of Durden is not limited to biotechnology and (2) there is substantial precedent that is inconsistent with Durden. These are not cases that were narrowly decided on specific facts, but rather pronouncements made by the Court regarding important broad principles of patent law contained in 35 U.S.C. 103.

Nor did these cases involve the playing of word games in which the decision is based on fictional differences between a method of making and a method of using. Decisions like In re Pleuddemann (910 F.2d 823, 15 USPQ 2d 1738 (C.A.F.C. 1990)), even though they reached the right result, got there on spurious grounds, namely differentiating between methods of making and methods of using.

Until Durden, the Court had never deviated from its position that applicant's own teaching cannot be used against him or her -- in other words, the application in which the claim is made is not prior art. In In re Mancy (499 F.2d 1289, 182 USPQ 303 (C.C.P.A. 1974)), the Court reiterated its position that "under Section 103 neither a novel product made by, nor a novel starting material used in, the process can be treated as prior art." Yet Durden held, in essence, that it was obvious how to make a product that never existed before.

Perhaps the explanation for the Court's aberrant decisions lies in the fact that it has consistently overlooked another of its important pronouncements as to what constitutes prior art. Specifically, there are
a long line of cases decided by the Court that clearly state that to qualify as patent-defeating prior art, the art relied on must be enabling. As stated concisely in Beckman Instruments v. LKB Producter AB (892 F. 2d 1547, 13 USPQD 2d 1301 (C.A.F.C. 1989)), "In order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or method," citing In re Payne et al. (606 F. 2d, 203 USPQ 245 (C.C.P.A. 1979)). Payne put it slightly differently, "References relied upon to support a rejection under 35 U.S.C. 103 must provide an enabling disclosure, i.e. they must place the claimed invention in the possession of the public."

A determination that a final product, or a substance used in making it, is patentable necessarily means that that product or that substance was not in the possession of the public. Therefore, a decision that a process is obvious because the process resembles an old process -- even though the end product or a substance essential for its production was not in possession of the public -- is a wrong decision, clearly contrary to a solidly established principle of the Court.

In its recent Amgen decision (Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F. 2d 1200, 18 USPQ 1016 (C.A.F.C. 1991)), the Federal Circuit restated its requirement that "Both the suggestion and the expectation of success must be found in the prior art, not in applicant's disclosure." Where either or both the product and an intermediate are demonstrably novel and

unobvious, there can be no such suggestion or expectation.

IBA believes that, when considering the subject matter as a whole, the patentability of a product dictates that the corresponding process should also be patentable. As the Court said in In re Hoeksema (399 F. 2d 269, 158 USPQ 596 (C.C.P.A. 1968)), "We are certain, however, that the invention as a whole is the claimed compound and a way to produce it." The emphasis on and is the Court's, not ours.

2. **What support exists for H.R. 1417 outside of the biotechnology industry?**

As noted in our answer to the first question, there is much less practical necessity for the passage of H.R. 1417 outside the biotechnology area. Nevertheless, several other organizations have endorsed the legislation or its predecessor in the 101st Congress, H.R. 3957. IBA would be pleased to provide you with written documentation of the endorsements of any or all of the organizations mentioned below.

Industry organizations urging enactment of H.R. 1417 include the National Association of Manufacturers (which represents approximately 13,000 U.S. manufacturers, including most of the Fortune 500); the Pharmaceutical Manufacturers Association (representing the U.S. pharmaceutical industry); and the National Venture Capital Association (representing American venture capitalists and investors in entrepreneurial companies).

The bill has also been endorsed by several organizations representing American universities, including the American Council on Education (representing over 1,600 colleges, universities, and other higher education institutions); the National Association of State Universities and Land Grant Colleges (representing our country's public colleges and universities); and the Council on Governmental Relations (representing America's most research-intensive universities).

In addition, a number of major universities have directly endorsed the legislation, including Rutgers, the State University of New Jersey; Massachusetts Institute of Technology; University of Texas; Case Western Reserve University; University of Virginia; University of Wyoming; University of Florida; University of Texas Health Science Center at Houston; Texas Tech University; Texas A&M University; Oklahoma State University; University of Kentucky; Virginia Polytechnic University and State University; University of Delaware; Harvard University; University of California at San Francisco; Wayne State University; Brown University; University of

Illinois at Urbana-Champaign; and University of Pennsylvania.

The bill is also supported by the Bush Administration and was unanimously approved by the Senate Judiciary Committee.

Having demonstrated the broad support for this legislation, we would like to take this opportunity to comment on the arguments by some opponents of the legislation.

Some opponents suggest that to establish a per se rule of patentability will unfairly take something from the public. But if a patent is granted on a process that the public could not have practiced -- because it did not have in its possession one or more necessary elements of the process, such as the end product or intermediate
-- what has been taken away? The legislation does not enable the generic patenting of any process to make any protein by using any recombinant host cell. It enables patenting of the specific process for making a specific protein using a specific gene and host cell.

IBA believes that closer analysis of the hypothetical examples suggested by opponents reveals that virtually every imagined possible evil either could not arise as postulated or already is potentially present in existing law.

For instance, AIPLA cites as an example the possibility that, if the the bill is enacted, a process patent could be issued on the method of using a patented saw to cut timber, thereby rendering importation of the timber an act of infringement. However, this example concerns a method of using, which is governed by Plueddemann, not a method of making governed by Durden. As Professor Chisum ultimately conceded under questioning by Representative Boucher, the possibility that such a process patent would be issued already exists under current law and would not be affected in any material way by this legislation. The fact that such absurd process patents have not been issued, even though theoretically possible under Pleuddemann, demonstrates that PTO recognizes the inappropriateness of applying Pleudemann to such cases.

There are also those who argue that no legislation is necessary, that decisions such as In re Pleuddemann suggest that PTO and the Court will eventually come to the right decision. In 1988, when IBA first identified the Durden problem, several of our member companies also took this view, hoping that the Court would overrule Durden if presented with the right test case. Instead, in cases like Pleuddemann and Dillon, the Court distinguished Durden

on the basis that methods of making and methods of using should be treated differently.

Thus, three years after IBA identified the Durden problem, the case still has not been overruled. In some industries -- biotechnology being one -- a new company denied protection to which it is entitled may not survive until the time when PTO and the Courts get it right.

Finally, we would like to note that although the Chemical Manufacturers Association and Intellectual Property Owners, Inc. have declined to support the bill, several of their most prominent member companies have endorsed it, including such New Jersey-based companies as Ciba-Geigy and American Cyanamid.

3. What are your views on the Administration's proposed amendments to H.R. 1417?

IBA supports, in fact prefers, the Administration's proposed revisions to H.R. 1417. We believe their amendment more effectively addresses the Durden problem than does the bill's original language. However, as discussed later in this answer, we believe that the Administration's proposal can be improved upon.

The problem that the Administration's proposal successfully addresses is that H.R. 1417 as written would not apply to the majority of biotechnology processes. This is because H.R. 1417 states that the legislation applies -- i.e., Durden is overruled -- only in cases where:

(1) the product and process claims are contained in the same patent application; and

(2) a single patent is issued covering both sets of claims.

Unfortunately, while the former requirement is no problem, the latter requirement is not necessarily within the control of the applicant.

In most cases where an applicant meets the former requirement, PTO "restricts" the application -- that is divides it into two or more "divisional" patent applications -- on the grounds that the original application contained two or more separate inventions.

Typically, product claims and process claims are divided into separate applications, and further divisions may occur in each category. For instance, end product claims may be placed in a

separate application from intermediate product claims, and methods of making an end product may be separated from methods of using an end product. One IBA member company reports having a single patent application divided into 37 divisional applications. The fact that PTO collects separate fees for each divisional application perhaps induces the Office to issue frequent and multiple restriction requirements.

If PTO restricts an application (i.e., orders it to be divided), then each separate application will issue as a separate patent, thereby contravening the requirement that a single patent issue on both product and process claims. When IBA protested that the "single patent" requirement effectively gutted the legislation, PTO agreed that the requirement should be deleted.

However, PTO felt that if it grants process patent protection in cases where the patentability of the process depends on the patentability of a product, then a "terminal disclaimer" should be required. A terminal disclaimer is a provision in a later-issuing patent stating that the patent expires on the date of a specified earlier issued patent.

For example, if PTO divides a patent application into product and process claims, and the product patent issues in year 1 and the process patent issues in year 3, a terminal disclaimed placed on the process patent would state that it has a 15 year term-- so as to co-terminate with the product patent -- rather than a full 17 year term.

In support of this view, PTO argued that if the process is not independently patentable, then the product and process are essentially a single invention and it would be inappropriate to give them a combined patent term in excess of 17 years.

But PTO's views on terminal disclaimers are inconsistent. On the one hand, PTO argues that product and process are <u>different</u> inventions for the purpose of issuing a restriction requirement, dividing the application into numerous divisional applications, and collecting multiple fees. On the other hand, PTO argues that product and process constitute the <u>same</u> invention, for the purpose of determining whether a terminal disclaimer is appropriate.

It would be acceptable to IBA if PTO was consistent on the same v. different invention issue. If PTO believes that product and process are essentially the same invention, then it should not divide the application into two or more parts. Keeping both sets of claims in a single application would result in a single patent issuing, with all claims expiring simultaneously. It would also

save applicants the additional expense -- both attorneys' fees and PTO fees -- of pursuing several related applications.

But if PTO believes that product and process are different inventions for restriction purposes, then they should also be different inventions for termination purposes, and no terminal disclaimer should apply.

And, in fact, this consistency is required under current law. Current law provides that a terminal disclaimer applies only if an application is restricted at the election of the applicant. PTO may not require a terminal disclaimer if the restriction occurs at the insistence of PTO. This is because the only legal grounds for PTO to restrict an application is that it contains more than one different invention, and terminal disclaimers are only permitted when more than one patent issues for a single invention.

Consequently, our members see terminal disclaimers on PTO-restricted applications as a diminution of their existing patent rights. PTO did not agree, and so we negotiated a compromise, which is contained in the Administration's amendment. The intent of that language is to provide that process claims that are granted the benefits of the per se nonobviousness rule must co-terminate with the product claims on which they depend for patentability, but that independently patentable inventions are entitled to the same 17 year terms to which they are entitled under current law.

If its amendment is enacted, the Administration intends by rulemaking to provide an applicant with the option of either demonstrating the independent patentability of a process notwithstanding Durden (as must be done under current law) or proceeding under the per se nonobviousness rule established by this legislation. If he elects to demonstrate the independent patentability of a process, he is entitled to the full 17 year term available under current law for both product and process inventions, without co-termination. If he elects to rely on the per se nonobviousness rule, he may be required to accept a terminal disclaimer on the later issuing patent.

Since an applicant may rely on the per se rule as a matter of convenience to expedite issuance of his process claims, the Administration's amendment provides that there is no presumption that process claims are invalid if the product claims which form the basis for invoking the per se rule are invalidated. Any litigation should provide the patentee with the opportunity to prove that the process claims are independently patentable.

Although IPA supports the compromise language, we would prefer

language that did not change existing terminal disclaimer rules by permitting a patent application to be treated as containing a single invention for terminal disclaimer purposes and multiple inventions for restriction practice and fee collection purposes. We also feel that the requirements of a single patentee for both product and process is unnecessary.

On the issue of Amgen's proposed amendment, we would like to note that the company's most recent version was carefully crafted to respond to the Administration's objections to earlier versions of the bill and amendment.

4. Aside from the problem of unfair imports, what if any consequences could result if a biotechnology process does not have patent protection?

Absent patent protection that is effective against offshore manufacturers, there will be an increased tendency to rely on trade secrets for protection, thereby impeding the disclosure of technology, which is an important objective of the patent system.

In addition, inadequate patent protection could inhibit investment in biotechnology and thus would retard the development of this innovative industry in the United States, whereas enforceable patent protection stimulates investment in new industries. Enactment of legislation to remedy this problem would encourage investors to support our industry and provide further stability to an emerging industry.

5. Are there any examples, other than recombinant Erythropoietin, of biotechnology products that have been made abroad through use of a host cell patented in the United States and then imported into this country?

The biotechnology industry is still in its infancy with few important products yet approved for marketing. However, we are aware of two other examples.

(a) In litigation between Genentech and Burroughs Wellcome concerning tissue plasminogen activator (TPA), it was revealed that Burroughs Wellcome had imported its version of TPA into the United States before Genentech's process patent issued. In fact, Burroughs Wellcome was asserting this as one of its non-infringement defenses.

(b) A St. Louis, MO patent attorney has informed IBA staff of

a situation concerning a client she represents. The client company has a host cell patent but not a corresponding process patent. It has licensed the U.S. manufacturing rights to a second company for a specified royalty on sales. The second company, however, later began manufacturing in Canada and importing the unpatented end product into the U.S., claiming that no royalty is owed on U.S. sales if the product is made abroad. In the absence of a process patent, the client company has no right to prevent such importation. The client company did not permit the attorney to reveal its identity to IBA because the client company is hoping to negotiate a royalty for these sales.

6. Could the Patent and Trademark Office (PTO), or patent applicants themselves, eliminate the need for legislation by designating process for producing recombinant products through use of a host cell as "processes of using" as defined in Pleuddemann?

Some companies have reported to IBA that they have unsuccessfully attempted to characterize their recombinant processes as methods of using a host cell, rather than methods of making an end product. In these cases, the companies report that the patent examiners refused to accept this characterization.

Furthermore, even if the PTO instructs examiners not to apply Durden to such cases, there will always be an uncertainty as to the enforceability of the patent as long as Durden remains as viable precedent in the courts.

7. Have IBA-member companies received process patents for biotechnology processes?

Yes, but not uniformly and often not without considerable difficulty, expense and delay. As our testimony noted, many small companies and universities have forfeited the process patent protection to which they appear to be entitled because they could not afford to incur the necessary patent prosecution expenses.

Amgen estimates that the cost of overcoming Durden, and seeking to defend its product patent until it gained process claims, included millions of dollars in legal fees and a delay in obtaining process patent protection of approximately three years. No company should be forced to assume this burden, and many small companies cannot.

8. What impact, if any, would the proposed legislation have on the cost of biotechnology products?

H.R. 1417 should not affect the cost of biotechnology products in any significant way. On balance, the legislation would lower the cost of health care in the U.S. by preserving the incentive to develop new biotechnology products which, though in themselves not inexpensive, dramatically reduce the cost of treating disease conditions by shortening hospital stays, reducing need for surgical intervention, returning disabled patients to work, etc.

9. Are there any biotechnology products that you can identify that may not be available to the American public because of the Durden decision?

No, but it can be expected that biopharmaceutical products that are not themselves patentable will not be developed unless they are for rare diseases, in which case the quasi-patent protection provided by the Orphan Drug Act might be available as a form of surrogate patent protection.

10. Have there been any improvements over time in PTO's review and determination of biotechnology process patent applications?

PTO's review and determination of biotechnology process patent applications was and is dependent upon which examiner is responsible for a particular application. There might be a slight trend toward more favorable consideration of such applications. However, as long as Durden remains as viable precedent, there will remain uncertainty as to how any process patent will be treated by the courts. Obtaining a patent is only an intermediate milestone on the road to the ultimate goal: the ability to enforce the patent against unauthorized users.

***

Thank you for the opportunity to respond to your questions on this important legislation. IBA would welcome the opportunity to work closely with you and your staff as you continue your deliberations on this bill. Your staff is invited to call Lisa Raines, vice president for government relations, if IBA can provide further assistance.

Very truly yours,

APPENDIX 8.—LETTER FROM CHAIRMAN WILLIAM J. HUGHES, TO LITA L. NELSEN, ASSOCIATE DIRECTOR, TECHNOLOGY LICENSING OFFICE, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, DECEMBER 23, 1991 (NO RESPONSE RECEIVED)

ONE HUNDRED SECOND CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON THE JUDICIARY
2138 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6216

December 23, 1991

Ms. Lita L. Nelsen
Associate Director
Technology Licensing Office
Massachusetts Institute of Technology
28 Carlton Street
Room F32-300
Cambridge, Massachusetts 02139

Dear Ms. Nelson:

Thank you for testifying before the Subcommittee on Intellectual Property and Judicial Administration on H.R. 1417, the Biotechnology Patent Protection Act of 1991. Your testimony was extremely useful to the Subcommittee as we determine how best to protect biotechnology inventions, and, at the same time, safeguard the balance and flexibility of our patent system. There were a number of questions that I did not have the opportunity to ask you at the November 21st hearing, and I would be very grateful if you could respond to these questions in writing. These questions are as follows:

1. How will H.R. 1417 affect the patenting of chemical, computer and other processes in areas outside of biotechnology?

2. Could the Patent and Trademark Office (PTO), or patent applicants themselves, eliminate the need for legislation by designating processes for producing recombinant products through use of a host cell as "processes of using" as defined in Plaudemann?

3. Have there been any improvements over time in PTO's review and determination of biotechnology process patent applications?

4. Aside from the problem of unfair imports, what if any consequences could result if a biotechnology process does not have patent protection?

5. What other issues, if any, relating to patent law and biotechnology are of concern to the university research community?

Ms. Lite Nelson
December 23, 1991
Page Two

I appreciate your interest and the expertise that you shared with the Subcommittee on this important matter.

Sincerely,

Bill Hughes

WILLIAM J. HUGHES
Chairman
Subcommittee on Intellectual Property
and Judiciel Administration

WJH:efv

APPENDIX 9.—STATEMENT OF RICHARD G. WATERMAN, PH.D., ON BEHALF OF THE DOW CHEMICAL CO., NOVEMBER 21, 1991

My name is Richard Waterman. I have been in the patent profession for almost 34 years, and for the past 14 years have been General Patent Counsel for The Dow Chemical Company.

My background includes being: past president and currently on the Executive Committee of the Association of Corporate Patent Counsel, an organization of heads of patent departments of about 180 of the largest U.S. Corporations; past Chairman of the Intellectual Property Committee of the Chemical Manufacturers Association and currently on that committee; on the Board and Executive Committee of Intellectual Property Owners Inc.; a participating alternate on the current Advisory Commission on Patent Law Reform; and on the Advisory Committee to the USPTO on patent harmonization.

Dow's corporate headquarters are located in Midland, Michigan. Dow manufactures and supplies more than 2,000 products and services, including chemicals and performance products, plastics, hydrocarbons and energy, and consumer specialties - which include agricultural products, pharmaceuticals and consumer products. The company operates 181 manufacturing sites in 32 countries, and employs 62,000 people around the world.

In 1990, Dow spent $1.1 billion for research and development, and it relies on the U.S. patent system to protect much of this investment. Consequently, Dow is a large user of the patent system. In 1990 the U.S. Patent and Trademark Office (PTO) granted Dow 400 patents. Dow ranks 17th in all corporations receiving U. S. patents, and ranks 7th among U.S. companies receiving U.S. patents. Approximately 50% of these patents include process claims.

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

H.R. 1417 would change the way the PTO would examine patents for patentability by creating a new standard . . . a zero standard approach for patentability because it mandates something to be patentable. Nothing under current law is ordained patentable! Everything has to pass the Title 35 patentability tests of novelty (Section 102) and nonobviousness (Section 103). This bill would change Section 103 by, in effect, inserting an asterisk denoting that one of the two cornerstones will no longer apply where process claims are included with product claims. To use a broad brush approach as embodied in H.R. 1417 is an overreaction because Section 103 applies to every instance where an application includes process claims along with the ancillary machine, manufacture or composition claims.

We understand the uncertainty faced by those in the biotechnology field. Dow, too, is exploring biotechnology opportunities. However, this kind of remedy seems advantageous only on its face, because the remedy goes way beyond what is needed to fix the problem.

First, let us look at what H.R. 1417 is intended to accomplish, and that is to allow the granting of process claims which would be enforced almost exclusively against imports. This is because if one obtains a claim to a machine, manufacture, or composition of matter, the patentee can enforce those claims against anyone making, using or selling them in the U.S.A. It would be claims to the process of using the machine, manufacture or composition of matter that would be enforced against imports. They would be enforced under 35 USC 271(g) against the products made by the process. The question is, should unexamined claims be given the benefit of such force.

The problem with H.R. 1417 is that it would permit almost an infinite number of process claims because it makes no distinction between a process of making and a process of using. For example, if one had a claim to a composition of matter, probably there would be only a limited number of ways (and claims) of making that composition. On the other hand, conceivably there would be numerous and expansive ways to draft claims to cover schemes on how it could be used.

By way of further example, let us presume we have an invention which involves an improvement on a drilling bit for drilling oil (the improved bit lasts longer). If someone uses that bit in the U.S., the patentee can sue for infringement on the claim covering the bit. Presume the patentee received a claim under H. R. 1417 for "a process of drilling oil using the improved drilling bit", and the bit is used outside the U.S. Then the patentee, under Section 271(g), could sue for infringement against anyone importing, using, or selling the oil produced using the drill bit, i.e., the product of the process. There is no change whatever in the oil produced and there is no other use for the improved patented drill bit. Does the use of the improved drilling bit to drill for oil really rise to the level of invention, and should a patentee have the right to exclude the importation of the oil produced? I believe most would think it does not.

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

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

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

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

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

To follow the indiscriminate granting of process claims under H.R. 1417 would surely lead to considerable uncertainty and a proliferation of harassing litigation. Such attempts to enforce unexamined process claims would generate contempt and distrust for the U.S. patent system. This would indeed be lamentable, coming at a time when the patent system is most respected by the innovation and investment communities.

It would also come at a time when there is already heightened concern about the increase in the cost and complexity of litigation. This is one of the principal concerns of the Advisory Commission on Patent Law Reform. Much of this concern is directed at the unavailability of District Courts to handle civil trials. But proliferation of litigation caused by uncertainty of rights will only compound the frustration already present. In the fight to bring some balance to our litigious society, Congress needs to assure itself in drafting legislation that it is not creating unnecessary litigation.

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

The only innovation this legislation would stimulate is that of patent attorneys. These people would extend themselves to create process claims on any patentable machine, manufacture or composition of matter. They would be compelled to do so. They have a duty to their client to seek as broad patent coverage as the law will allow. Not only that, they would be compelled to do it in order to avoid claims for malpractice, for if they failed to include process claims covering as many uses of the machine, manufacture, or composition of matter as can be dreamed up, then surely they would expose themselves to suit. Claims of this nature would expand the right to exclude under the patent system far beyond the inventive contribution behind the patent.

To be dealt with in the final analysis, is the increase in law suits filed to determine the rights for each and every patent which includes process claims along with their attendant product claims granted pursuant to H.R. 1417. In effect, we will have exchanged examination by the PTO for examination by the courts. This will confound and delay the ability to enforce other meritorious patents, and thus impede competitiveness, including the competitiveness of the biotechnology field.

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

Perhaps this problem could be remedied by a paragraph added to Sec. 103 such as the following:

> A process or method claim wherein an essential element is a machine, manufacture or composition of matter otherwise patentable to the applicant shall not be deemed to be unpatentable merely because the claim reads on a known process or combination of steps but shall be examined as a whole, giving consideration to the specific nature of the process or method and the fact that new and otherwise patentable materials are used in or result from the process or method.

This paragraph reflects the commonly accepted standard of patentability that the patent profession now recognizes.

Another possible remedy would be to address the issue of infringement instead of changing the standard for patentability. This might be done by a parallel provision to Section 271(g), e.g. a product-of-a-product (likened to the 271(g) product-of-a-process).

I respectfully urge this Subcommittee to not recommend passage of H.R. 1417 and to encourage other alternatives or resources to solve the apparent concern of the biotechnology industry.

APPENDIX 10.—LETTER FROM WILLIAM G. MORIN, DIRECTOR, COUNCIL ON HIGH TECHNOLOGY, NATIONAL ASSOCIATION OF MANUFACTURERS, TO CHAIRMAN WILLIAM J. HUGHES, NOVEMBER 21, 1991

National Association
of Manufacturers

International Economic Affairs

November 21, 1991

The Honorable William J. Hughes
Chairman, Subcommittee on Intellectual Property
and Judicial Administration
Committee on the Judiciary
U.S. House of Representatives
207 Cannon House Office Building
Washington, DC 20515

Dear Mr. Chairman:

The National Association of Manufacturers (NAM) would like to go on record in favor of H.R. 1417, legislation that would remedy a major problem facing U.S. biotechnology companies: the lack of effective process patent protection.

Technological innovation has been one of America's strengths, and its importance continues to grow. Key to the innovation process, NAM believes, is the efficacious protection of inventive knowledge so as to enable its creators to reap the benefits of their efforts. Toward this end, the association has long supported clear and adequate protection of U.S. intellectual property rights, both at home and abroad.

For these reasons, NAM supports passage of H.R. 1417, the Biotechnology Patent Protection Act of 1991. It is our belief that H.R. 1417 would help alleviate the uncertainties in patent protection caused by the decision of the Court of Appeals for the Federal Circuit in *In Re Durden*. By creating a situation that permits inequitable appropriation of U.S. intellectual property rights, the *Durden* ruling puts U.S. biotechnology companies at a disadvantage compared to their foreign competitors. The intent of H.R. 1417 is simply to raise the level of protection for American inventors to a stage comparable to that enjoyed by inventors in other countries.

NAM does, however, believe that two changes should be made to H.R. 1417 before the measure is enacted. These changes are technical and do not affect the substance of the bill. Accordingly, NAM recommends that the new paragraph to be added to Section 103 of title 35 of the United States Code read as follows (with the suggested changes appearing in boldface):

> When a process of making or using a machine, manufacture, or composition of matter is sought to be patented in the same application as such machine, manufacture, or composition of matter, such process shall not be considered as obvious under this section if, **as of the effective filing date on which such process is first**

> disclosed, such machine, manufacture, or composition of matter is novel under section 102 and nonobvious under this section. If the patentability of such process depends upon such machine, manufacture, or composition of matter, then the Office may require that a single patent shall issue on the application.

NAM believes these changes to be non-controversial.

There is considerable agreement on the need for the changes proposed in H.R. 1417 and significant bipartisan support of it. NAM urges you and the Subcommittee to proceed expeditiously with this legislation. Also, we respectfully request that this letter be included in the record for the Subcommittee's November 21, 1991, hearing on H.R. 1417.

Thank you for your consideration.

Sincerely yours,

William G. Morin

William G. Morin
Director, Council on
High Technology

APPENDIX 11.—LETTER FROM JAMES S. RUBIN, LEGISLATIVE COUNSEL, NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS, TO CHAIRMAN WILLIAM J. HUGHES, NOVEMBER 6, 1991

JAMES S. RUBIN
Attorney at Law
7004 Boulevard East-22D
Guttenberg, N.J. 07093

Admitted in DC & NY
Not admitted in NJ

Telephone & Fax
(201)869-6151

November 16, 1991

Hon. William J. Hughes
Chairman, Subcommittee on Intellectual Property
and Judicial Administration
Committee on the Judiciary
United States House of Representatives
207 Cannon House Office Building
Washington, D.C. 20515

Re: H.R. 1417

Dear Mr. Chairman:

The undersigned represents the National Association of Pharmaceutical Manufacturers (NAPM). The NAPM is the largest trade association representing generic drug manufacturers and their bulk active ingredient suppliers (both domestic and foreign). On behalf of NAPM, I wish to express our appreciation for this opportunity to submit our views for the record on H.R. 1417 -- the so-called "Biotechnology Patent Protection Act of 1991". You may be interested to know that the position expressed hereunder passed three separate NAPM committees (Bulk, Legislative, and Board of Directors) unanimously.

The reason I used the phrase "so-called" in describing the Short Title of the Bill is because this legislation is not at all limited to the biotechnology industry. As a matter of fact, if it were so limited the NAPM would not be opposed. However, this bill goes way beyond the biotechnology field and can have dire consequences for the generic drug industry. At a time when this nation's health costs are soaring, and Congress and the American public are seeking ways to curtail these high costs, we submit that legislation that can cause higher prices for generic products--or

even make it impossible for some expensive brand-name products to ever be subjected to generic competition--should be considered only if there is an otherwise overwhelming need and no other way to address that need.

Unfortunately, we believe that H.R. 1417 meets neither of those tests and does have potential to so interfere with the ability of the generic drug industry to obtain necessary active ingredients that we urge defeat of this legislation in its present form. As a parsonal aside, I make that statement despite my high respact for the sponsors of this legislation--particularly Congressman Moorhead and his counsel, Mr. Mooney, with whom I worked so closely several years ago in their successful attempt to enact the Process Patent Amendments of 1988. Based upon conversations with staff and with the Patent Office, I do not believe there was any intent to harm the generic drug industry. It just appaars to be an unintended result; but, a result nevertheless.

The reason for the potential damage to the generic drug industry is that, as I previously pointed out, this legislation impacts not only biotechnology, but chemical intermediates used in the production of pharmaceutical active ingredients. It is these ingredients that are needed by generic drug manufacturers in order to provide safe and effective low cost alternatives to brand-name products (as envisioned by the Waxman-Hatch Act of 1984, of which this Committee played such a vital role).

Prior to the Process Patent Amendments Act of 1988, a generic manufacturer purchasing bulk chemicals merely had to be concerned (from a patent perspective) with whether or not the very ingredient it was purchasing was under patent protection. If the patent on the ingredient itself had expired, the generic manufacturer was safe in purchasing and/or importing that chemical. In response to foreign pirating of significant U.S. patented processes and the

sale of the resulting product in the U.S., the Process Patent Amendments were enacted. That new law changed the situation so that, if the bulk chemical were manufactured by a U.S. patented process, then the use of that chemical could nevertheless be considered an act of infringement. But that new law was intentionally crafted to afford as much protection to the U.S. generic drug industry as possible. Thus, a number of safeguards otherwise previously foreign to U.S. patent law were enacted. Those safeguards included the requirement of patent holders to respond to generic manufacturers' requests by listing all their unexpired process patents for a particular product and the concept of a "good-faith infringer". Processes for making intermediates were only included within that new law if they were not materially changed; and the intermediates themselves were not included in that finely-honed compromise.

The proposed legislation would undo some of those safeguards. That is because it would allow a patentee to obtain patent protection for an old, well-known process as long as the intermediate itself were patentable. Presently, when a generic manufacturer makes a Request for Disclosure pursuant to the Process Patent Amendments, neither the patent holder nor the manufacturer making the request need be concerned with intermediate patents unless there also exists a process patent for making those intermediates. Thus, if a foreign manufacturer is able to respond that it used an old process (for making the product and intermediates) that appeared in an already-expired patent or has been known in the art for years, the generic manufacturer can safely import that chemical without fear of liability under the Process Patent Amendments.

Unfortunately, many patent holders presently do (wrongly) include intermediate product patents when they respond to a Request for Disclosure for process patents. This has the effect of unnecessarily intimidating foreign manufacturers who are unfamiliar

with the nuences of the Process Petent Amendments end ceuses some of those manufacturers to hesitate or even refuse to supply chemicels to U.S. generic companies for fear of extensive patent litigetion. However, patent ettorneys ere presently able to edvise their clients to ignore those unsolicited intermediate patents since they were not rightfully listed. As I stated eerlier, H.R. 1417 would change thet by bringing old, known processes under the protection of the Process Petent Amendments. **This added potential for patent evergreening and intimidation of suppliers of chemicals to the generic drug industry is the reason thet NAPM opposes and urges defeat of H.R. 1417 in its present form.**

If you or your staff have any questions or would like our help in trying to amend the legisletion to remove its negetive consequences on the U.S. generic drug industry, we would be more-then-pleased to respond.

Sincerely,

James S. Rubin
Legisletive Counsel,
Netionel Associetion of
Phermaceuticel Manufacturers

APPENDIX 12.—LETTER FROM NORMAN L. BALMER, CHIEF PATENT COUNSEL, UNION CARBIDE CORP., TO CHAIRMAN WILLIAM J. HUGHES, NOVEMBER 15, 1991

UNION CARBIDE CORPORATION 39 OLD RIDGEBURY ROAD, DANBURY, CT 06817-0001
LAW DEPARTMENT

November 15, 1991

The Honorable William J. Hughes
Chairman
Subcommittee on Intellectual Property
and Judicial Administration
U.S. House of Representatives
207 Cannon House Office Building
Washington, DC 20515-6216

Dear Mr. Chairman:

Union Carbide Corporation is pleased to provide these comments on H.R. 1417, the Biotechnology Patent Protection Act of 1991. Union Carbide invests nearly $200 million per year in support of research and development and views a strong patent system as essential to protect its investment in research and development. Union Carbide, however, does not view H.R. 1417 as enhancing the incentives of the patent system in fostering domestic innovation. One of the major difficulties of the proposed legislation is its potential effect upon innocent, remote users of technology. The per se rule for patentability of certain process claims proposed in H.R. 1417 would result in cost to domestic industry and society as a whole which is greater than any benefits gained by the biotechnology industry.

As explained in greater detail below:

- In re Durden is not of adverse precedential value to the biotechnology industry.
- No nexus is required by H.R. 1417 between the patentable composition of matter, article or machine and the scope of the process claims that would be per se patentable.
- Expansive process claims would therefore be granted for processes in which the patentable composition of matter, article or machine is materially changed or becomes a trivial and non-essential component of another product.
- The direct infringer of such expansive process claims could be innocent, remote users having no knowledge of, or control over, the direct use of the patentable composition of matter, article or machine, and defense of patent infringement litigation is an unwarranted burden on the innocent, remote users.

- Congress can avoid such untoward and unintended effects upon innocent, remote users by either appropriate amendments to H.R. 1417 to establish a nexus, or preferably, extend 35 USC 271(g) to address squarely the problem raised by the biotechnology industry.

Union Carbide's In re Durden Appeal

Much has been said about the In re Durden decision of the Court of Appeals for the Federal Circuit, but little is mentioned about the facts. Union Carbide is in a unique position to comment on In re Durden as Union Carbide was the owner of the Durden patent application. Union Carbide appealed the rejection of Durden's process claimed to the Court at the request of the Patent and Trademark Office. Union Carbide unambiguously conceded to the Court that the claimed process was obvious over a prior disclosure by another teaching the same process using a similar starting material to produce a similar product. In affirming the Patent and Trademark Office decision rejecting Durden's process claims, the Court explicitly limited its decision to the particular facts of that case and cautioned that its decision not be generalized or used as a rule for future cases. The Court said that in process cases the judgment must be exercised in determining patentability, and hence, the Patent and Trademark Office must examine the patentability of the process claims.

The Current Law Requires a Nexus

The Court of Appeals in a later decision, In re Pleuddemann, reaffirms that the Durden decision does not necessitate that processes using novel materials are unpatentable. Rather, the Court indicates that in determining the patentability of a process, the properties which render the novel materials patentable, must be taken into account. Indeed, the general rule expressed by Pleuddemann is that the use of a novel material is patentable. One can readily appreciate the nexus between a material having unique properties and its use which flows from those properties. Because of this nexus, it is reasonable to expect in biotechnology that the use of a patentable host cell should be patentable.

The Impact of H.R. 1417 on the Innocent, Remote Users

While the proposed legislation would secure by statute the principles expressed by the Court in Pleuddemann, the scope of legislation extends far beyond these principles. Of primary concern to Union Carbide is that the proposed legislation requires no nexus between the patentable material and the scope of the process using the material for the process to be per se patentable. The legislation is unparalleled with the laws of any foreign country. For instance, in Europe, a patent applicant is entitled to claim any process for making a patentable composition. Hence, a nexus exists between the process for making of the composition and the composition itself.

This nexus is not required by the proposed legislation. By way of example, an inventor invents a catalyst useful in making a previously known solvent. Under the existing law as expressed, in part, by Pleuddemann, the inventor would be entitled to a patent on the catalyst and its use to make the solvent. However, the inventor could fashion a process claim which recites

> "In a process for transporting humans using a vehicle which has a coating on the exterior, the improvement wherein the coating is applied using a coating composition comprising a solvent which has been made by a reaction in the presence of the novel catalyst."

The ironic result of such a process claim, which would be per se patentable under the proposed legislation, is that the vehicle would neither contain the solvent (which evaporates to leave the coating) nor the novel catalyst (which is separated from the solvent when the solvent is made), yet the driver of the vehicle is a direct infringer of the claimed process. Because the proposed legislation extends to machines and manufactures as well as compositions of matter, similarly expansive process claims would be per se patentable if the use of the machine or manufacture were recited in the process claim. An inventor could claim a process for converting petroleum to useful chemicals wherein the novelty resided in a new pump for transporting the petroleum. Process patents would be granted far beyond the contribution of the inventor. Moreover, innocent users would be alleged process patent infringers, yet they could have no reasonable basis for knowledge of, let alone control over, the use of the novel machine, manufacture or composition of matter.

Legislative Alternatives

Congress was faced with similar concerns in developing the 1988 Process Patent Reform Act. Note that 35 USC §271(g) (Public Law 100-418, sec. 9003, 102 Stat. 1563-4) states in part that "A product which is made by a patented process will, for purposes of this title, not be considered to be so made after – (1) it is materially changed by a subsequent process; or (2) it becomes a trivial and nonessential component of another product."

Union Carbide urges that if the subcommittee ascertains that legislation is required, consideration be given to enacting legislation which does not adversely affect the innocent, remote user. Alternative approaches include (1) limiting the per se patentability of Section 103 to processes for making the patentable machine, manufacture or compositions of matter or the direct use of the machine, manufacture or composition of matter or (2) extending 35 USC 271(g) to prevent the importation of a direct product made using a patented composition of matter. The second approach provides the advantages of directly addressing the concerns

expressed by the biotechnology industry (importation of product made by using patented host cells) without perturbing the existing law for determining patentability and presumption of validity. We recognize that under either alternative approach, the Patent and Trademark Office would have to conduct an examination of process patent applications, an effort that could be eliminated by the operation of H.R. 1417 as introduced. However, the cost incurred through the performance of examinations by the Patent and Trademark Office will be offset in costs incurred by innocent, remote users in defending themselves.

Thank you for allowing Union Carbide to contribute its position to the record on this important issue.

Very truly yours,

Norman L. Balmer
Chief Patent Counsel

NLB:fv

cc: Hon. Carlos Moorhead
Ranking Minority Member

APPENDIX 13.—LETTER FROM WILLIAM M. STOVER, VICE PRESIDENT, FEDERAL GOVERNMENT RELATIONS, CHEMICAL MANUFACTURERS ASSOCIATION, TO CHAIRMAN WILLIAM J. HUGHES, NOVEMBER 14, 1991

CMA
CHEMICAL MANUFACTURERS ASSOCIATION

RECEIVED

William M. Stover
Vice President-Government Relations

November 14, 1991

RECEIVED
NOV 1 3 1991

The Honorable William J. Hughes
Chairman
Intellectual Property and Judicial
Administration Subcommittee
Judiciary Committee
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The Chemical Manufacturers Association (CMA) is pleased to provide these comments on H.R. 1417, the Biotechnology Patent Protection Act of 1991. CMA is sympathetic to the concerns that prompted this legislation, although we are opposed to the particular approach adopted in H.R. 1417. We believe a more narrowly drawn approach can both satisfy the needs of the biotechnology industry and prevent potential damage to the U.S. patent system.

CMA is a non-profit trade association whose member companies represent 90 percent of the productive capacity for basic industrial chemicals in the United States. CMA's member companies are among the most frequent users of the U.S. patent system. Consequently, the industry has an interest in legislation, like H.R. 1417, which affects fundamental patent provisions.

H.R. 1417 would amend 35 U.S.C. §103 to adopt a per se rule of patentability for certain process patent claims. The amendment adopted by the Subcommittee, while helpful, still raises a number of concerns for chemical manufacturers. The legislation has been promoted as a means of addressing cases involving the use of a host cell, effectively overruling the In re Durden decision of the Court of Appeals for the Federal Circuit. Durden pertains to a very narrow and unique fact pattern, as pointed out by the Court in its later In re Plueddemann decision and its en banc decision, In re Dillon.

In Durden, the applicant conceded that apart from the fact that the starting material and product were novel, the claimed process was obvious over disclosures using the same process for similar starting materials and products. The court in Plueddemann clearly and correctly points out that Durden does not require that processes for using novel agents be found unpatentable. Rather, the Court in essence stated that in processes using novel agents, the properties which

render the novel agents patentable also render the processes patentable. Thus, Pleuddemann indicates that the Court would find claims for processes using patentable host cells to be patentable. It is possible that, as drafted, H.R. 1417 would inadvertently and adversely effect domestic industry at large if enacted.

H.R. 1417 would reward the creativity and ingenuity of patent attorneys in drafting process claims. For example, an invention pertaining to a pipeline pump design (a manufacture) can be couched in terms of a process claim for transporting a petroleum stream using the pump. One can argue that the transported petroleum is a product of the process claim, and upon entry into the United States, a potential infringement action would exist. Combined with the potential conflicts that could arise with 35 U.S.C. § 272, the net result could be a material disruption in international commerce. Moreover, inventors of say, catalysts, will be encouraged to write broad and expansive process claims, to include even the article made using a composition of matter employing the catalyst.

As noted earlier, CMA is sympathetic to the biotechnology industry's concerns that new material might not be patentable under the existing statutory standard. Rather than support an amendment which has far reaching consequences for all patent users, however, CMA would prefer to see the measure more narrowly drawn. Several alternatives are available, one of which we have detailed in the attachment. CMA looks forward to a continuing dialogue with the Committee on how best to address this issue.

CMA would welcome the opportunity to discuss with you, and other appropriate representatives of the biotechnological industry and patent bar, how H.R. 1417 might be structured to serve the needs of all patent users. Indeed, we would be happy to make appropriate arrangements if such a meeting would be desired. If in the interim we may provide any additional information, please have your staff contact Rose Marie Sander, Legislative Representative, Patents (202) 887-1123, or Michael P. Walls, Assistant General Counsel (202) 887-1170.

Sincerely,

William M. Stover
Vice President
Federal Government Relations

Enclosure

One possible alternative includes a relatively narrow approach to 35 U.S.C. §271(g) (new material underlined):

(g) Whoever without authority imports into the United States or sells or uses within the United States a product which is <u>either</u> made by a process or <u>made as a direct product (including products further purified, refined or separated or combined in solution or mixture with other components) by using a composition of matter</u> patented in the United States shall be liable as an infringer if the importation, sale, or use of the product occurs during the terms of such process <u>or composition of matter</u> patent. In an action for infringement of a process <u>or composition of matter</u> patent, no remedy may be granted for infringement on account of the non-commercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use of sale of the product. A product which is made by a patented process <u>or made by using a patented composition of matter</u> will, for purposes of this title, not be considered to be so made after:

1) it is materially changed by subsequent processes; or

2) it becomes a trivial and nonessential component of another product.

Conforming amendments to other Code sections, including Section 103, may still be required, even under this alternative.

APPENDIX 14.—LETTER FROM JOHN L. PICKITT, PRESIDENT, COMPUTER AND BUSINESS EQUIPMENT MANUFACTURERS ASSOCIATION, TO CHAIRMAN WILLIAM J. HUGHES, MARCH 20, 1991

Computer and Business Equipment Manufacturers Association 311 First Street, NW Suite 500 Washington, DC 20001 (202) 737-8888 Fax (202) 638-4922

March 20, 1992

The Honorable William J. Hughes
Chairman
House Subcommittee on Intellectual Property
& Judicial Administration
341 Cannon House Office Building
Washington, DC 20515

Dear Mr. Chairman:

CBEMA, the Computer and Business Equipment Manufacturers Association, wishes to take this opportunity to share with you our views on H.R.1417/S.654, "The Biotechnology Patent Protection Act of 1991". In short, our membership opposes the legislation in principle because it is presently drafted so broadly as to apply to all technologies, including electrical and computer arts, and not just to the biotechnology industry.

CBEMA represents the leading edge of high technology companies in the U.S. computer, business equipment and telecommunications industries. Our members had combined estimated sales of more than $262 billion in 1990, making up about 5% of the U.S. gross national product, and employed about 1.2 million workers in the United States last year. CBEMA members file for and receive a large number of patents every year, and therefore have a direct and immediate interest in legislation that would change current patent law and practice.

CBEMA provides leadership for the industry on key public policy issues. CBEMA has historically strived to improve intellectual property protection available to its members, and to that end, has supported strong U.S. and foreign patent laws as a major means both to protect the intellectual property of inventors and to promote increased trade of information technology industry products.

CBEMA supports strong U.S. and foreign patent laws not only for the interests of its members, but also for the strong public policy reasons that underlie the patent system. Patents serve public policy when they disseminate new technology quickly and fully, and create new and innovative products. On the other hand, public policy is defeated when patents are improperly granted. In CBEMA's opinion, patents are granted improperly when a full examination procedure is not carried out on instruments that have such broad applicability. CBEMA has encouraged the Patent and Trademark Office to take steps to improve the searching of all technologies.

With particular regard to S.654/H.R.1417, CBEMA considers the concept of automatic allowance of patent claims without examination, which the legislation would permit, to be imprudent regardless of what other claims have been examined and found to be novel and non-obvious. Such unexamined

claims in a patent grant will be applied with a presumption of validity against the public at large and against industry to no positive benefit, and possibly to much harm.

Referring specifically to electrical and computer arts, CBEMA holds that an automatic allowance of process claims would create significant mischief in the information technology industry. As an example of the difficulties that would arise in computer industry art, assume that a claim for a new computer system that is composed of multiple elements and circuits in a given relationship is examined and found to be novel and non-obvious. Under S.654/H.R.1417, a claim in the same application covering a "process of making or using" that computer system "shall not be considered as obvious".

The problem with the above example for the electrical and computer arts is in determining precisely how co-extensive the computer process must be to the claimed computer system before the law applies to allow the computer process claim without examination. Must every word in the process claim be identical to the product claim except for the insertion of process action words? If some of the elements claimed in the computer systems invention do not relate to a specific process step, can they be eliminated? Can there be descriptors added to modify the process action words? Can equivalent words be substituted? Can adjectives be added or deleted?

The foregoing problems arise because, in most cases in the electrical and computer arts, an invention is claimed as a combination of individual elements and circuits. There is no end-result biological substance, as in the biotechnology arts, for which claims for its making or use can be clearly drafted and appropriately limited to application to that substance. Because of the multiplicity of elements and circuits in a claimed computer invention and the myriad ways of defining that combination invention, including the addition or deletion of different elements and the use of different adjectives for describing those elements, this concept of automatic allowance, which the two bills would permit, simply would not work in the electrical and computer arts, and would provide the opportunity for much mischief and misuse of the patent process in the information technology industry.

An automatic, "per se" patentability would result in a multiplication of claims of unexamined scope and of dubious enforceability. Further, the legislation as currently drafted could weaken present patent protection by actually establishing different classes of patent claims, some of which would be immune from full examination and therefore would be subject to a lesser standard.

The Constitutional directive to secure for limited times to inventors the exclusive right to their inventions has served this country and our industry well. But it is essential for a proper working of the system that each

claim of invention be examined on its own merits to determine that it is a true invention before exclusive rights are granted over the industry and the public at large.

There are additional significant technical problems with this legislation relating to the validity of the unexamined process claims, the mechanics of applying the doctrine of equivalents and prosecution history estoppel to unexamined claims, which we would be happy to discuss with your or your staff.

While we oppose the two bills in their current forms, we would appreciate the opportunity to work with you to help craft legislation which resolves the problems understood to be faced by the biotechnology industry without impairing the intellectual property rights currently permitted to others. If you have questions or comments, or if we can be of further assistance, please contact Ingrid Voorhees of our staff at 202/626-5754.

Thank you for your consideration.

Sincerely,

John L. Pickitt

John L. Pickitt
President

cc: The Honorable Carlos J. Moorhead
Members of the House Intellectual Property and Judicial Administration Subcommittee
The Honorable Harry F. Manbeck, Jr.

APPENDIX 15.—MEMORANDUM FROM GORDON M. BINDER, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, AMGEN, INC. (WITH ATTACHMENTS), TO CHAIRMAN WILLIAM J. HUGHES, NOVEMBER 18, 1991

AMGEN

GORDON M. BINDER
Chairman and
Chief Executive Officer

TO: The Honorsble Willism J. Hughea

FROM: Gordon M. Binder

DATE: November 18, 1991

RE: The Need for Protection Againat Unfair Foreign Exploitation of Biotechnology Patents

---

Patenta are the life-blood of atsrtup biotechnology compsniea. Pstents sre used to sttract the venture capital which ia necesaary to finance the companies' resesrch on new health csre products. Pstenta slao allow biotechnology compsnies to enter into licensing sgreements that reault in a revenue stresm until producta csn be spproved and effective. Strong pstent protection laws sre easential to the success of the biotechnology industry. Aa the Preaident's Council on competitivenesa ststed, "[t]he uncertsinties in intellectual property righta for innovstion in the biotechnology ares continue to hamper the induatry."

Current patent law does not adequately protect the biotechnology industry for two reasona. Firat, the decision of the Court of Appeals for the Federal Circuit, In re Durden, has made it difficult for biotechnology companies to secure procesa patent protection. Second, foreign competitors hsve diacovered a loophole in the patent laws which allows s foreign company to

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infringe host cell product patents held by U.S. companies. The infringing company is also allowed to import and market the product manufacutured by the host cell in the U.S.

An example of this problem arose in 1983 when Amgen applied to the United States Patent and Trademark Office ("USPTO") for patent protection of its developments regarding recombinant erythropoietin ("rEPO"). In late 1987, the USPTO granted Amgen a patent which included claims to the gene encoding erythropoietin and recombinant host cells containing this gene. However, because of the Court of Appeals for the Federal Circuit's decision, In re Durden, which held that in the case of a starting material that is not novel and a resulting product that is not novel, a process patent cannot issue, the USPTO would not allow claims to the process for making rEPO using the patented host cells.

More than a year after the grant of Amgen's patent claiming the host cell required to produce rEPO, Amgen finally obtained allowance of process claims. At this time, issuance of the process patent awaits resolution of an interference proceeding at the USPTO. Amgen estimates that it experienced at least a three year delay in obtaining enforceable process patent protection as a result of In re Durden.

Biotechnology companies in the United States are also challenged by foreign competitors who exploit a loophole in the United States patent laws. A Japanese competitor is utilizing a recombinant host cell, for which Amgen holds a United States patent, to manufacture rEPO in Japan. The competitor seeks to import and market rEPO in the United States. This competitor is attempting to do what no company can legally do in the United States- manufacture rEPO and compete with Amgen in the U.S. market.

Amgen is not the only entity facing this problem. A brief patent search indicates that there are other small biotechnology companies and universities that have obtained only host cell protection. If the loophole in the patent laws is not closed these companies and universities could also experience foreign infringement of their host cell patents.

During the last Congress, Congressman Boucher and others introduced legislation to resolve both the process patent and host cell patent problems. The original Boucher legislation would have overruled In Re Durden, as it applies to biotechnology, and would have excluded products from the United States, or from interstate commerce within the United States, if they were produced overseas in violation of a United States product patent describing a biotechnology process. The provision which would have excluded products made in violation

of a United States product patent was dropped by Representative Boucher because Amgen was in litigation with a competitor over the gene and recombinant host cell patent and because of problems with the General Agreement on Tariffs and Trade ("GATT").

Neither of these problems exist any longer. The Court of Appeals for the Federal Circuit recently resolved the litigation between Amegen and its competitor by holding that Amgen's patent on the gene and recombinant host cells, which produce rEPO is valid and enforceable; the competitors patent was also invalidated. Potential problems with the GATT can be resolved simply by deleting the amendments to the Tariff Act. By retaining the amendments to Title 35 of the U.S. Code, shipment into the United of products made overseas in violation of a U.S. product patent can be avoided.

The foreign infringement of product patents loophole results in the unfair exploitation of U.S. technology and the export of U.S. jobs. To retain the United States leadership in biotechnology, this loophole must be closed. This may be accomplished through the attached amendment, which has been carefully crafted to respond to comments by the Administration.

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AMGEN

PROPOSED AMENDMENT TO
BIOTECHNOLOGY PATENT PROTECTION ACT

Background

Current legislstion pending before the House snd Senste Judicisry Committeea (H.R 1417 snd S.654 -- The Biotechnology Pstent Protection Act) would hsve the effect of grestly facilitating the sward of pstents on biotechnology proceasea, principally through overturning the case of In re Durden. 1/

In a July 1990, letter from the Department of Commerce General Counsel, Wendell L. Willkie II, to former Representstive Robert Ksstenmeier (the "Willkie letter") on aimilar legialstion, the Department expreased agreement with the need to overturn In re Durden as it spplies to biotechnology processes. The Willkie letter expressed disagreement, however, with s provision in the proposed legislstion intended to close s loophole thst enables foreign infringers to engage in off-shore activity that would violste U.S. pstent lswa if conducted within the United States.

1/ In re Durden, 763 F.2d 1406 (Fed Cir. 1985), the Court of Appesls for the Federal Circuit held thst s process of making or uaing s patentsble compound is not itself necesssrily patentsble simply because it mskes or usea thst compound.

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In October, 1991 the Department of Commerce, in a letter to Senator Charlea Graaaley from Aaaiatant Secretary and Patent Commiaaioner Harry F. Manbeck, Jr. (the "Manbeck letter") addreaaed an amendment to S. 654 propoaed by Amgen that had attempted to meet moat of the objections raiaed in the Willkie letter.

Amgen believea that providing protection to product patent holdera who lack proceaa patenta againat off-shore infringera ia an esaential element of biotechnology patent protection legialation. We have reviaed the amendment, taking into account commenta in the Willkie and Manbeck lettera; the reaulting propoaal reaponda to their legitimate objectiona.

Section 337 Amendments

The Willkie letter expreaaed oppoaition to protecting biotechnology patents through amendmenta to aection 337 of the Tariff Act of 1930. For thia reason, the new propoaal doea not include amendmenta to Section 337 included in the original legialation.

Necessity of Amendment

Both the Willkie and the Manbeck lettera expreaa the view that it is unneceaaary to extend enforcement of the rights of a patent claiming biotechnological material to producta made

using such material if the current impediments to obtaining patents on biotechnology processes are removed by legislation.

Any suggestion that merely overturning In re Durden is by itself sufficient to protect the biotechnology industry is premature. There are several instances of biotechnology companies and universities having patents which claim host cells that do not includes claims to a process for making a product using that host cell. When faced with the rejection of a process claim because of In re Durden, many applicants may be forced, because of cost or other reasons, to accept claims limited to host cells and abandon any process claims. For these companies and universities in such instances the overturning of In re Durden is insufficient.

In effect, the letters appear to guarantee that in all cases the patentee of a biological material would be assured that process protection is available. Obviously, no one can provide such assurances.

For these reasons, the assertion that the proposed amendment is unnecessary is simply incorrect.

Limiting Relief to a Particular Industry

Both letters express opposition to limiting relief to a particular industry.

First, and most importantly, it is the peculiar nature of the biotechnology industry that makes this amendment

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necessary. Due to differencea in technology, other induatriea simply do not hsve the problem the propoaed amendment sddresses. Prior to the dawn of biotechnology, there waa, to our knowledge, no instance of gaining product pstent protection on the technological process used to produce a product. Other induatries are protected from the uae of patented technology oversess through psrsllel smendments spplicable to procesa pstents enscted in 1988. (The 1988 lsw ia discuased below.)

In addition, of courae, many lawa applicable to certain aegmenta of induatry have been enacted over the yeara. Perhsps the most relevsnt example is pstent term extenaion legislstion, which includea apecial proviaions sssuring patent term extension for products manufactured primsrily through the uae of recombinsnt DNA technology, even if an identical product manufactured in a different way is alresdy on the msrket. See 35 U.S.C. § 156(s)(5)(B).

Definition of the term "biotechnological material"

Following csreful review of the Willkie and Manbeck letters' concerna over the definition of biotechnological materisl, the propoaed definition aatiafiea the concerna expressed in the lettera. Under the new amendment, the term "biotechnologicsl material" meana any hoat cell, DNA sequence, vector or host cell, which ia utilized in the production of the product."

Amendment to Section 154 of Title 35, United States Code

Both letters express concern that the protections sought by Amgen would expand patent protection beyond the products made using the patented material. The Willkie letter (page 6) suggests clarifying language and our amendment incorporates the suggested language.

The Effective Date Issue

In both letters, the Department of Commerce expresses concern that the effective date of such legislation not be construed as "retroactive." Given these concerns, the appropriate effective date for the proposed Biotechnology Patent Protection Act should be based upon the effective date generally established by the 1988 Process Patent Amendments Act for the following reasons:

Legislation Impacting Commercial Relationships

The effective date of legislation often has an impact on contemplated or existing commercial relationships. Indeed, legislation potentially affecting such relationships many times has an immediate effective date, or is made effective shortly after enactment. For example, in several situations involving the importation of products, Congress has enacted legislation that has immediate effect.

- Antidumping Measures. In 1988, Congress enacted a number of measures designed to prevent the circumvention of

existing dumping and countervailing duty orders by importation of parts of the products subject to the orders rather than the products themselves. Trade and Competitiveness Act of 1988, P.L. 100-418, 100th Cong., 2d Sess. (1988) §§ 1311-1337 (Amendments to Title VII of the Tariff Act of 1930 (19 U.S.C. § 1671 et seq.)). In order to remedy this problem, the 1988 Act amended the Tariff Act to allow the application of dumping and countervailing duty orders to "merchandise sold in the United States [...] completed or assembled in the United States from parts or components produced in the foreign country with respect to which such order or finding applies." Trade and Competitiveness Act, supra, § 1321(a), codified at 19 U.S.C. § 1677j. The Amendments to the antidumping and countervailing duty provisions were explicitly made applicable to "articles entered, or withdrawn from warehouse for consumption" as of the date of the legislation's enactment. Trade and Competitiveness Act, supra, § 1337(d), codified at 19 U.S.C. § 1671 Note.

- ITC Jurisdiction to Prohibit Unfair Imports. The 1988 Trade and Competitiveness Act, discussed above, also contained provisions designed to enhance the protection of products claimed by U.S. patents from competition by importation of infringing products from other countries. The Process Patent Amendments Act of 1988, supra, made several amendments to the existing protections provided under Section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337. The effect of

theae amendmenta waa to relax that proviaion'a requirement of a showing of potential harm to an American induatry, and to expand the authority of the ITC to bar importation of gooda infringing U.S. patenta. Again, the amendments were made effective upon enactment, without apecial proviaion for exemption of any commercial tranaactiona already ongoing. Trade and Competitivenesa Act, supra, § 1342(d), codified at 19 U.S.C. § 1337 Note.

- Ban On Imports From Terrorist Countries. Congresa haa alao exerciaed ita plenary power over interatate and foreign commerce to ban, or delegate to the Preaident the authority to ban, the importation of goods where either the product itself or the country of export ia antithetical to U.S. security or valuea. An example of auch legialation is the proviaion in the International Security and Development Cooperation Act of 1985, P.L. 99-83, 99th Cong., lat Sess. (1985) § 505, codified at 22 U.S.C. § 2349aa-9. While the Act waa enacted on August 8, 1985, and did not go into effect until October 1, 1985, P.L. 99-83, § 1301, the import bans authorized by the Act will be effective upon implementation by the Preaident. No proviaion ia made for exemption of existing or ongoing tranaactiona.

It ia clear, in light of theae and many other examples of legislative acts with immediate effect, that when Congress determines that exiating lawa governing importa are unfair, or

contrary to the national interest, it has willingly corrected such laws with an immediate effective date.

Process Patent Legislation

While, as noted above, it is not unusual for the effective date of legislation to be immediate (or shortly after enactment), in some cases involving imports, Congress has provided for "grandfather" exemptions for goods already in the flow of commerce. The most relevant example is the 1988 Process Patent Protection Act, 2/ which amended the law to protect against commercial distribution of products made overseas in violation of a U.S. process patent.

The Process Patent Protection Act was made effective six months after enactment:

> (a) IN GENERAL. The amendment made by this subtitle takes effect 6 months after the date of enactment of this Act and subject to subsections (b) and (c), shall apply only with respect to products made or imported after the effective date of the amendments made by this subtitle. 3/

In addition, Congress provided two exceptions to the general prohibition stated above. The first is as follows:

> (b) EXCEPTIONS. The amendments made by this subtitle shall not abridge or effect the right of any person or

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2/ P.L. 100-418, 100th Cong., 2nd Sess. (1988) §§ 9001-9007, codified at 35 U.S.C. §§ 1 Note, 154, 271, 271 Note, 287, 295.

3/ Sec. 9006(a). Subsection (c) is not relevant to this discussion.

> sny successor in business of such person to continue to use, sell or import sny specific product slresdy in substsntisl snd continuous ssle or use by such person in the United Ststes on Jsnusry 1, 1988. . . .

35 U.S.C. § 271 Note.

This exception wss accompanied by s second exception designed to spply to s specific industry:

> ". . . or for which substsntisl prepsrstion by such person for such ssle or use wss made before such dste, to the extent equitsble for the protection of commercisl investments msde or business commenced in the United Ststes before such dste . . ."

Id.

As the sccompsnying Senste Report indicstes, the second exception wss solely crsfted on behslf of the generic phsrmsceuticsl industry. The Congress was concerned about the unique situstion of thst industry, which hsd seversl Abbrevisted New Drug Applicstions ("ANDA's") which hsd not yet spproved st the time of the legislstion's effective dste. Becsuse msny of the generic compsnies could not meet the "substsntisl snd continuous use or ssle" exception, Congress went one step further snd included sn "equitsble exception" for products hsving submitted abbrevisted spplicstions for premsrket spprovsl, but not yet in commercisl use.

The Committee confirmed thst this exception was unique when it ststed:

> Apsrt from this psrticulsrly sensitive sres [generic drug ANDA's], the Committee envisions thst the courts will interpret the scope of the grsndfsther clause (i.e., exemptions from the substsntisl and continuous

> sale or use standard) in the individual cases brought before them with a view to the qualifying language 'to the extent equitable' in the provision. Ordinarily a party whose business before the grandfather date involved infringing activity should be able to continue import, use or sell the product as necessary to maintain the same level of business but not to expand such business by increasing the volume of products that he is using or selling, unless of course he has prospectively committed himself to such increases in a contract made prior to the grandfather date. . . . 4/

As the Senate report language indicates, this so-called "equitable exception" was not the norm, but purely an aberration provided for at the behest of a politically popular and potent interest group -- the generic pharmaceutical industry. No such "equitable exception" need be extended to any group in the biotechnology patent protection legislation. Nevertheless, as explained below, the proposed amendment includes an effective date provision identical to that in the 1988 law.

Amgen's Proposed Amendment

Enclosed is a proposed amendment to S.654 and H.R. 1417. The proposal amends Title 35, U.S. Code, to protect against commercial distribution of products in the United States made overseas in violation of a U.S. product patent on biotechnological material. It has been carefully crafted to

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4/ S. Rep. No. 83, 100th Cong., 1st Sess. at 59 (1987).

reflect, wherever possible, the positions taken in the Willkie and Manbeck letters.

It should be noted that the Willkie letter includes the following suggestion relating to the effective date of the provision contained in previous legislation designed to provide the same protections sought by the proposed amendment:

> "Should [the provision] be retained, we would favor that its amendments apply prospectively, although parties now in litigation should be left to settle any disputes in accordance with the law in force at the time at which the acts in question occurred. We defer to the Congress with respect to any other exceptions which might have to be made to take into account equitable considerations for the protection of commercial investments made or business commenced in the United States, before the effective date of the amendments."

Willkie letter at 6.

As previous testimony to the Congress (attached) indicates, all patent litigation between Amgen and its competitors has been resolved. Thus, no settlement of such disputes is called for.

There is merit to Mr. Willkie's suggestion that Congress resolve the effective date issue based on equitable considerations. For this reason, the proposed amendment includes effective date language taken in total from the 1988 process patent law. Thus, the amendment's grandfather clause includes a six month delay in effective date; in addition, it includes <u>both</u> the "substantial and continuous sale or use" and "equitable exception" language from the 1988 law designed to

protect against unfair foreign exploitation of proceaa patenta. Thua, the propoaed effective date proviaiona are clearly prospective in nature.

In sum, the encloaed amendment reaponda to the overwhelming majority of concerna expreaaed in the Willkie and Manbeck lettera. In particular:

- The amendmenta to Section 337 are deleted.
- It includes clarifying language to the definition of "biotechnological material" and to Section 154, aa auggeated in the letters.
- The amendment includes the effective date proviaions Congresa provided in 1988 with reapect to producta made overseas in violation of U.S. process patents.

1090U/1703o

AMENDMENT TO S. 654

Offered by _____

Insert the following at the end of the bill:

SEC. 4. 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 --

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

(B) by inserting "(1)" after "in this title";

(C) by striking "and if the invention" and inserting

"(2) if the invention";

(D) by inserting after "producta 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

(E) by adding at the end the following:

"(b) For purpoaea of this aection, the term 'biotechnological material' meana any host cell, DNA sequence, or vector."

(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 subsection (c)(2), ahall apply only with respect to producta made or imported after the effective date of the amendments made by this section.

(2) Exceptions. The amendments made by thia aection shall not abridge or affect the right of any person, or any succesaor to the buainesa of such person, (i) to continue to use, aell, or import any specific product already in aubstantial and continuoua sale or use by such peraon in the United Statea on January 1, 1991, or (ii) for which substantial preparation by such person for auch sale or uae 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.

1458L

STATEMENT OF GORDON BINDER
CHAIRMAN AND CHIEF EXECUTIVE OFFICER

AMGEN, INC.

Mr. Chairman and Members of the Committee, I am Gordon Binder, Chief Executive Officer and Chairman of the Board 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 with unfair foreign competition.

Amgen is the acknowledged leader in the development and production of recombinant erythropoietin (or rEPO). Epogen® is Amgen's only approved product. However, Amgen's marketing of this product in the United States is being challenged by a foreign competitor who is exploiting a loophole in United States patent and trade laws. Our Japanese competitor produced a rEPO product in Japan by using a recombinant host cell on which Amgen holds a U.S. patent and they plan to import and market the product in this country. It was this loophole in the patent and trade laws -- allowing foreign companies to make a product overseas using technology patented by a U.S. company -- technology that they could not use in the United States -- which was tested by Amgen before the International Trade Commission (ITC) and subsequently the U.S. Court of Appeals for the Federal Circuit (CAFC). The

resulting denial by the ITC and CAFC of any protection for Amgen from unfair foreign competition convinced Representative Boucher and others that changes must be made in the United States patent and trade laws to protect our biotechnology industry from unfair competition and delays in obtaining enforceable patent protection. In fact, the Court of Appeals opinion characterized the changes as "a task for the Congress, which can explore its impact and side effects". 1/ We congratulate Mr. Boucher, Mr. Moorhead, Mr. Sensenbrenner, Mr. Hyde, Mr. Berman and others for recognizing this type of unfair competition and working to pass legislation to stop it.

BACKGROUND

Amgen, Inc.

Since its founding in 1980, Amgen has been dedicated to the development of human pharmaceuticals using advances in recombinant DNA technology and molecular biology. Amgen started with a $19 million private-equity funding, involving venture capital firms and two major corporations. The company increased its net worth through public stock offerings in 1983, 1986 and 1987. Now one of America's leading biotechnology firms, Amgen spent eight years and over $100 million to develop

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1/ Amgen, Inc. v. U.S. International Trade Commission, No. 89-1523 (Fed. Cir., April 27, 1990) at 17.

biotechnology firms, Amgen spent eight years and over $100 million to develop its rEPO product, pioneering a genetically-engineered pharmaceutical of enormous medical value to many thousands of patients suffering from anemia.

The development of rEPO began with the cloning of the gene encoding erythropoietin which was first accomplished by Amgen scientists. rEPO represents a breakthrough therapy for more than 100,000 Americans on dialyais who auffer from anemia associated with kidney failure. For these patients, rEPO replaces the natural erythropoietin the diseased kidneys are no longer able to produce. Amgen's Epogen® alleviates often severe and debilitating anemia, and allows patients to resume a more normal life. Leaders in the medical community have called Epogen® the most significant development for patients with renal disease since the advent of dialysis.

The primary treatment for severe anemia previously was repeated blood transfusions which present hazards (i.e., exposure to AIDS and hepatitis), and provide 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 difficult to obtain. Previously a form of the protein was found only in minute quantities in urine, and to this day this product cannot be effectively used for human testing or treatment. Through 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.

Amgen applied for patent protection for its developments regarding recombinant erythropoietin in late 1983. In October 1987, the U.S. Patent and Trademark Office ("PTO") granted Amgen a patent which includes claims to the gene encoding erythropoietin and recombinant host cells containing this gene. This patented technology is the only practical means of producing rEPO. However, because of *In re Durden* the USPTO would not at that time 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 patent awarded to Amgen did not have appropriate process claims, on November 1, 1987, the President

of Genetica Inatitute publicly atated that Chugai (Genetics Institute's licenaee) would aimply avoid Amgen's patent by manufacturing recombinant EPO overaeaa and then import the product into the United Statea. Genetica Inatitute's recombinant host cell had been ahipped to Japan, thua allowing Chugai to conduct manufacturing activitiea in Japan that would constitute patent infringement if conducted in the United Statea. Chugai ia hoping to do what no company can do in the United States -- manufacture rEPO and compete with Amgen in the United States market.

In 1988, Chugai formed Chugai-Upjohn, a partnership with the Upjohn Company to market Chugai'a rEPO and imported rEPO for clinical triala in the United Statea. Becauae Amgen'a rEPO enjoys orphan drug excluaivity for the chronic renal failure indication, 3/ Chugai'a rEPO cannot be approved by FDA for chronic renal failure. Chugai can file an application with the FDA for other uaea of rEPO. Upon approval of that application, Chugai could commence importing rEPO from Japan and aell it in the United Statea.

3/ The Orphan Drug Act authorizea the award by the Food and Drug Administration of aeven years of marketing excluaivity for a drug deaignated for a rare diaeaae or condition. The law'a definition of 'rare diaeaae of condition' includea one which affecta less than 200,000 people in the United States. See Section 526(a)(2) of the Federal Food, Drug and Coametic Act. Epogen®, approved for the treatment of anemia aaaociated with chronic renal failure, is a drug that meeta auch definition.

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 three year delay in issuance of enforceable process patent protection was engendered by In re Durden.

More than a year following the filing of Amgen's first patent application, Genetics Institute filed an application which resulted in a patent on a process which purportedly further purified an EPO product from human urine as well as on a "purified" version of this EPO product. The CAFC has recently held this patent to be invalid. 4/

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 and obtained allowance of process claims. However, issuance of the process patent awaits resolution of an interference proceeding at the USPTO.

4/ Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd. and Genetics Institute, Inc., No. 90-1273, ___ F.2d ___ (Fed. Cir., 1991).

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 ("ITC") 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 a 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 recombinant erythropoietin, 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

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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.

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 that 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 337a) 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. This Trade Act protection prohibits the foreign enterprise from taking jobs 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 rEPO and held that Chugai's activities in use of the patented host cell to manufacture rEPO, if practiced in the United States, would constitute infringement. 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, however, 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 affirmed the ITC's decision one year later. The opinion included a clear statement that the remedy "is a task for the Congress" and not the courts. 7/

Litigation in the District Courts

In October 1987, Amgen sued Chugai and Genetics Institute for patent infringement and brought a declaratory judgement 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. 8/ However, the court categorically

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7/ See page 2.

8/ Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 13 U.S.P.Q.2d 1737 (D. Mass., 1990).

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. 9/

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 recent CAFC's 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.
- Genetics Institute cannot legally manufacture rEPO in the United States without infringing Amgen's host cell patent. However, Chugai can continue to escape the applicability of U.S. patent laws by manufacturing rEPO in Japan and importing it into the United States.

9/ See page 6.

- Since 1983, Amgen haa had pending a proceas 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 proceaa claims haa not iaaued.

- Becauae the ITC and the CAFC have held that Section 337(a) appliea only to traditional process claima, and not claima on the biological materiala eaaential for the production of rEPO, Chugai remaina free to produce rEPO abroad by uaing Amgen'a patented technology, and import the rEPO product into the United Statea. Only becauae Chugai'a rEPO haa not been approved by FDA ia Chugai unable to enjoy the fruita of ita scheme to use Amgen's technology in Japan to manufacture recombinant EPO for aale in the United Statea.

COMMENTS ON S. 654, AND THE NEED FOR ADDITIONAL PROTECTIONS

Mr. Chairman, Amgen'a experience reveala a aignificant weaknesa in U.S. patent and trade laws that were drafted prior to the dawn of biotechnology. In our opinion, the legislation before thia Committee forms the baaia for a long overdue updating of the law to overcome unintentional barriera to the award of biotechnology procesa patents and protection against the unfair competition resulting from the uae of U.S. patented technology by foreign competitora overaeaa.

S. 654 ia deaigned to counter the effect of the In re Durden decision for biotechnology patenta to the extent that In

re Durden may prohibit pioneers from obtaining process patent protection on a process using recombinant host cells. As noted earlier, although Amgen has overcome a rejection under In re Durden and obtained allowed process claims with respect to rEPO, 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.

S. 654 does not, however, completely insure that results such as the one that faced Amgen are corrected and not permitted to occur in the future. In Amgen's view, additional protections are necessary to prevent one from doing offshore what one cannot do in the United States and still compete in the United States market.

Last year, Senator DeConcini introduced legislation (S. 2326, 101st Cong., 2d Sess.) designed to overcome such unfair competition in two ways. First, it proposed to provide that the protections of Section 337(a) are not limited to traditional process patents. Second, it proposed amendments to Title 35, U.S. Code, to extend the enforcement rights of a patentee of biotechnological material to products made using such material. The necessity of this provision was best set forth by Senator DeConcini himself last year in the statement announcing introduction of S. 2326 last year:

> Contrary to the intention of the 1988 amendments to section 337 . . . the International Trade Commission has recently ruled that foreign manufacturers are still permitted to take patented biotechnology materials offshore to produce a product to ship back into the United States without legal recourse to the patentee. This practice has had a deleterious effect on the American biotechnology industry. 10/

The author of the House companion bill (H.R. 3957, 101st Cong., 2d Sess.), Representative Boucher, was equally adamant about the need to expand the judicial interpretation of Section 337:

> Congress recognized in the 1988 trade bill the principle of preventing the importation of foreign products when the manufacture of the product in the United States would be an act of patent infringement. Granting the International Trade Commission jurisdiction over such foreign products will not extend any new patent rights but will expand the available legal remedies for existing rights.
>
> * * * * * *
>
> In 1987 the biotechnology field yielded nearly 36,000 jobs, of which half were for scientists and engineers. Approximately 33 States are engaged in some type of research and biotechnology effort. <u>In light of this investment, the United States can ill afford to let another leading technically oriented</u>

10/ 136 Cong. Rec. S3107-3108 (daily ed., March 22, 1990) (remarks of Sen. DeConcini).

industry fall victim to unfair competition. 11/

Nothing has changed since these bills were introduced that alleviates the need for remedies provided in the legislation introduced last year.

We are thus disappointed that this year's legislative proposal, S. 654, abandons the straightforward provisions of the earlier legislation. Congress should directly update the law to protect against foreign competitors using technology claimed by U.S. biotechnology patents and competing in the U.S. market. For the reasons set forth below, the more indirect method chosen by the sponsors of S. 654 does not completely close the 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.

Commerce Department Bill Report on
Biotechnology Patent Protection Legislation

Mr. Chairman, Amgen is aware that S. 654 is designed to accommodate the views of the Department of Commerce

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11/ 136 Cong. Rec. E214 (daily ed. Feb. 7, 1990) (remarks of Rep. Boucher).

expressed in a July 1990 letter to Congress. The letter expressed agreement with the need to overturn In re Durden as it applies to biotechnology processes, but voices several objections to the provisions amending Section 337 of the Tariff Act of 1930, as well as Title 35 of the United States Code, to extend enforcement of the rights of a patent claiming biotechnological material used in the manufacture of a recombinant product. The principal reasons advanced in the letter against these provisions are its impact on the GATT negotiations, as well as the view that they would be unnecessary if the provisions which would overturn In re Durden were enacted. We believe that the first objection can be overcome through redrafting; the second objection is, in our view, too speculative to insure protection of United States technology.

The GATT problems can be overcome simply by deleting the amendments to the Tariff Act, but retaining the Title 35 amendments. While denying the biotechnology industry the ability to rely upon the protections of the ITC, this compromise would effectively prevent a company from profiting in the U.S. market based upon activities predicated upon foreign infringements of valid U.S. patents.

In Amgen's view, any thesis that merely overturning In re Durden is by itself sufficient to protect the biotechnology industry is premature. 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.

Amgen recommends legislation to this Committee that amends Title 35, U.S. Code, to render persons who import, sell or use in the United States products made overseas by infringing product claims on biotechnological material 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.

CONCLUSION

Amgen, America's leading independent biotechnology company, spent three 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 transferring technology overseas to avoid U.S. patent laws, has attempted to enter the United States market based on a relationship whose

success was predicated upon acts which would be an infringement of a valid U.S. patent if conducted in the United States. When unintended loopholes in laws designed to protect against unfair acts are discovered, should the loopholes remain and one who perpetuates an unfair act be rewarded with permisison to benefit from the loopholes indefinitely? 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.

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APPENDIX 16.—NEWS ARTICLE BY BOB DAVIS AND ROSE GUTFELD, "BUSH TO PROPOSE RULES TO SPUR BIOTECHNOLOGY," THE WALL STREET JOURNAL, FEBRUARY 19, 1992, AT B6

Bush to Propose Rules to Spur Biotechnology

Aim Is to Aid Development Of New Products Made By Genetic Engineering

By BOB DAVIS
And ROSE GUTFELD
Staff Reporters of THE WALL STREET JOURNAL

WASHINGTON—The Bush administration plans to propose a new regulatory framework for the emerging biotechnology industry that would slash rules across several agencies and spur commercialization of new genetically engineered products.

The new rules would provide a roadmap for research, testing and commercialization of products, including new strains of crops and microbes used to clean coal or produce fuel. As reported, the initial rule would eliminate many field tests now required for genetically engineered pesticides. But the structure now envisioned would go far beyond pesticides to guide regulatory treatment of all biotech products—including those not even conceived yet—that will spread into the atmosphere. The goal is to spur development of this non-drug segment of biotechnology.

The $4 billion industry today consists nearly entirely of pharmaceuticals. But the administration anticipates that the industry will grow to $50 billion in the next 10 years, with much of the growth to non-drug areas such as agriculture, manufacturing and environmental restoration. Products in these areas have been slow in coming, partly because of regulatory hurdles that the administration wants to dismantle. So far, about 300 products have been experimentally field-tested, in anticipation of commercial development.

At the heart of the proposed framework is the principle that products made by genetic engineering are generally no different than products made by conventional means and don't require special treatment. A draft report by an interagency working group on biotechnology applies that principle to products that would be released into the environment. The report says such products should be regulated only if they pose an "unreasonable risk"—when the benefit of protecting public health clearly outweighs the cost of regulation.

The new structure is expected to be adopted by the working group, headed by White House Counselor Boyden Gray, as early as today. The group had been split for five years over the policy, with the Environmental Protection Agency, which has argued for stricter controls, pitted against White House officials. But the effort to resolve the controversy got a big boost from President Bush's drive to deregulate.

Richard Godown, president of the Industrial Biotechnology Association, said that the adoption of the regulatory framework would especially help speed the commercialization of food and agricultural products.

But environmentalists immediately attacked the proposal and said that easing regulation would endanger the public. Margaret Mellon, a biotech specialist at the National Wildlife Federation, said the White House could use the framework to force agencies to scrap rules requiring companies to field-test new biotech products and requiring researchers to guard against releasing new organisms into the atmosphere during laboratory work.

The first set of regulations under the new approach will be those designed to govern the experimental release of genetically engineered pesticides. The rules, would exempt many companies from having to seek EPA approval before conducting small-scale field tests to see if the products damage the environment.

But the White House's plans for biotechnology range far beyond pesticides. The Agriculture Department, for instance, last year proposed rules to oversee the $180 million in grants it doles out annually. Under the rules, researchers would have been expected to determine how best to isolate their experiments by analyzing the danger posed by the organisms and the ability of the organisms to spread. But White House and Agriculture Department officials now say they will have to rewrite those proposals, so that researchers would consider the cost of confining an experiment.

Combination of Acne Drug, Interferon Shows Promise in Fighting Some Cancers

By JERRY E. BISHOP
Staff Reporter of THE WALL STREET JOURNAL

A new therapy combining an anti-acne drug with interferon produced highly promising results in skin and cervical cancers that were resistant to conventional treatment with surgery or radiation.

In the first human tests of the new chemotherapy, cancer researchers in Texas and Mexico used a combination of two Hoffmann-La Roche Inc. drugs. The first was 13-cis-retinoic acid, sold by Roche under the brand name Accutane for the treatment of acne; the second was alpha interferon, sold by Roche under the brand name, Roferon-A, for the treatment of two uncommon cancers.

Hoffmann-La Roche, the U.S. unit of Roche Holding Ltd. of Basle, Switzerland, supported the experiments, as did the American Cancer Society.

Among 26 patients with advanced skin cancers that had resisted all other treatments, 19 patients experienced a shrinkage of at least 50% to the size of their tumors, including seven who had a complete disappearance of their cancers.

Among 26 women with advanced cervical cancers, 13 had a regression in tumor size of at least 50%, including one woman whose cancer disappeared completely.

It's not yet known how long the benefits of the new chemotherapy will last. Some of the patients have relapsed after brief regressions of the cancers while in others the effects have lasted a year or longer, said Irwin H. Krakoff, one of the researchers at the University of Texas M.D. Anderson Cancer Center in Houston who carried out the experiments.

"We wouldn't even think of saying this is curative," Dr. Krakoff said. He called the results "encouraging" because it is the first time this combination of drugs has shown an anti-cancer effect when given systemically, that is by pill for the Accutane and by injection for the interferon.

Moreover, the drug combination had an effect to cancers of a type and stage that heretofore had been beyond effective treatment. All the patients had a type of cancer known as squamous cell carcinoma. Squamous cells, which resemble paving stones when viewed under the microscope, comprise the exposed or outermost lining of various tissues and organs, to this instance, the skin and the cervix of the uterus.

Squamous cell carcinoma of the skin is the second most common human cancer, the first being cancer of the skin's next lower layer of cells, the basal cells. About 90% of patients with squamous cell skin cancer are cured by surgery and radiation. "The remaining nearly 10% of patients who are not cured, however, represent tens of thousands of cases requiring a new therapeutic approach," the researchers reported in the current issue of the Journal of the National Cancer Institute. They said that about 3,000 persons die annually in the U.S. from squamous cell skin cancer.

The M.D. Anderson team reported it had treated 26 patients with the Accutane-Roferon combination, all of whom suffered squamous cell skin cancer that had withstood treatment by surgery and radiation. The cancers had begun to spread in all the patients and in half the patients skin cancer cells had metastasized or migrated to other organs.

Among the 14 patients whose cancers were still confined to the skin, six had a complete remission of their tumors and seven had a 50% or greater regression, according to the researchers, led by cancer specialist Scott M. Lippman. Among the remaining 14 in whom the cancer had metastasized, one had a complete remission and five had partial responses.

A second research team from M.D. Anderson reported it had gone to Guadalajara, Mexico, to work with Mexican cancer researchers in treating women with advanced squamous cell cancers of the cervix. Among the 26 Mexican women, who've been under treatment for two to four months, one patient has had a complete remission and 12 have had partial regressions, the researchers reported. One of these patients has already had a relapse.

Among the 13 women classed as "nonresponders," the cancers in nine seemed to have stopped growing, the researchers reported. But in the other four women, the cancer has progressed.

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