AN ACT TO AMEND TITLE 35, UNITED STATES CODE, WITH RESPECT TO PATENTS ON BIOTECHNOLOGICAL PROCESSES

P.L. 104-41 109 STAT. 351

November 1, 1995

PUBLIC LAW

1) **Public Law No. 104-41 as enacted November 1, 1995.**

REPORTS

104th Congress

2) **House Report No. 104-178 to accompany H.R. 587, "Biotechnological Process Patents," 104th Congress, July 11, 1995.**

103rd Congress

3) **Senate Report No. 103-82 to accompany S. 298, the "Biotechnology Patent Protection Act of 1993," 103rd Congress, July 1, 1993.**

4) **House Report No. 103-728 to accompany H.R. 4307, "Applications for Process Patents," 103rd Congress, September 20, 1994.**

102nd Congress

5) **Senate Report No. 102-260 to accompany S. 654, the "Biotechnology Patent Protection Act of 1991," 102nd Congress, March 11, 1992.**

HEARINGS

104th Congress

6) **"Patents on Biotechnological Processes; and to Authorize use by Regulation the Representation of Woodsy Owl," Hearing before the Subcommittee on Courts and Intellectual Property of the Committee on the Judiciary, 104th Congress, March 29, 1995.**

103rd Congress

7) **"Amending Title 35, United States Code, With Respect to Patents on Certain Processes," Hearing before the Subcommittee on Intellectual property and Judicial Administration of the Committee on the Judiciary, 103rd Congress, June 9, 1993.**

8) **"Applications for Process Patents," Hearing before the Subcommittee on Intellectual Property and Judicial Administration of the Committee on the Judiciary, 103rd Congress, May 5, 1994.**

102nd Congress

9) **"Biotechnology Patent Protection Act," Hearing before the Senate Subcommittee on Patents, Copyrights, and Trademarks of the Committee on the Judiciary, 102nd Congress, June 12, 1991.**

10) **"Biotechnology Patent Protection Act of 1991," Hearing before the House Subcommittee on Intellectual Property and Judicial Administration of the Committee on the Judiciary, 102nd Congress, November 21, 1991.**

101st Congress

11) **"Biotechnology Patent Protection" Hearing before the House Subcommittee on Courts, Intellectual Property, and the Administration of Justice of the Committee on Judiciary, 101st Congress, September 25, 1990.**

Public Law 104–41
104th Congress

An Act

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

Nov. 1, 1995
[S. 1111]

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

SECTION 1. BIOTECHNOLOGICAL PROCESS PATENTS; CONDITIONS FOR PATENTABILITY; NONOBVIOUS SUBJECT MATTER.

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

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

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

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

"(b)(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if—

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

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

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

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

"(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.

"(3) For purposes of paragraph (1), the term 'biotechnological process' means—

"(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to—

"(i) express an exogenous nucleotide sequence,

"(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

"(iii) express a specific physiological characteristic not naturally associated with said organism;

"(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and

"(C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).".

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SEC. 2. PRESUMPTION OF VALIDITY; DEFENSES.

Section 282 of title 35, United States Code, is amended by inserting after the second sentence of the first paragraph the following: "Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1).".

35 USC 103 note.

SEC. 3. EFFECTIVE DATE.

The amendments made by section 1 shall apply to any application for patent filed on or after the date of enactment of this Act and to any application for patent pending on such date of enactment, including (in either case) an application for the reissuance of a patent.

Approved November 1, 1995.

LEGISLATIVE HISTORY—S. 1111 (H.R. 587):

HOUSE REPORTS: No. 104–178 accompanying H.R. 587 (Comm. on the Judiciary).
CONGRESSIONAL RECORD, Vol. 141 (1995):
Sept. 28, considered and passed Senate.
Oct. 17, H.R. 587 and S. 1111 considered and passed House.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 31 (1995):
Nov. 1, Presidential statement.

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104TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPORT
104–178

BIOTECHNOLOGICAL PROCESS PATENTS

JULY 11, 1995.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. MOORHEAD, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 587]

The Committee on the Judiciary, to whom was referred the bill (H.R. 587) to amend title 35, United States Code, with respect to patents on biotechnological processes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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PURPOSE AND SUMMARY

The purpose of H.R. 587 is to provide for a modified examination of biotechnological process patents. Under the provisions of H.R. 587 a biotechnological process will not have to undergo a separate review of nonobviousness under certain conditions. If the process uses or produces a patentable composition of matter, the process will be determined nonobvious for the purpose of examination of biotechnological process claims. The expedited review will resolve

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the delays and inconsistent determinations faced by biotechnological process patent applicants under present PTO practices without harm to the basic principles of patentability.

BACKGROUND AND NEED FOR THE LEGISLATION

Patents can be granted on any invention that is included within the statutory subject matter provisions, including processes under 35 U.S.C. § 101.[1] A patent on an invention gives the patent owner the right to exclude others from making, using or selling that invention. A process patent may be obtained for a new method of use or new method of making a product. A process patent can be infringed if the process is used in making any product or used in any manner covered by the process patent. If a patent is obtained on a product, the owner of the patent can prevent the manufacture, the sale or the importation of that particular product in the United States. The owner of a United States patent cannot prevent the manufacture or sale of that patented product in another country, unless a patent is obtained in that country.

It is not uncommon to seek a product patent with process claims relating to the same invention. A process can be described in simple terms such as a new method of draining swamps to more complex processes detailing the exact steps that take place when a starting material is pasteurized, pressurized, radiated or subjected to other procedures. Product and process patents claims are each subject to examination under the same principles of patent law, including examining criteria such as novelty, nonobviousness, and usefulness.

If a patent containing process claims is granted on the manufacturing process or development process of a particular product, then the owner of the patent also can prevent the manufacture or sale of a product made using that process. Under the provisions of the Process Patent Amendments Act of 1988, the process owner also can prevent importation of the product if the product is made overseas using the patented process.[2] A patent may be obtained on the starting materials or materials used in a process but unless a patent on the process is obtained (or a patent on the final product), the final product could be produced overseas and imported back into the United States for sale without infringing the patent on the materials used in the process.

A problem arises in those situations in which the final product produced by a process may not be patentable. Without a patent on the final product or a patent on the process, the original developer of the product cannot take advantage either of basic product patent

[1] 35 U.S.C. § 101 states: "Whoever invents of discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

[2] The Process Patent Amendments Act of 1988 was contained in The Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100–418 (1988) and is found at 35 U.S.C. § 271(g): "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 liable as an infringer, if the importation, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent 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 that product. 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."

protection or the process patent protection permitted under the Process Patent Amendments Act of 1988.[3]

Under present patent law, an owner of a product patent can prevent others in the United States from using or making a patented product even in the absence of a process patent. The value of the process patent is the ability to prevent others from importing a non-patentable product that was made by use of a protected process. The value of the process patent is the ability to prevent others from importing a non-patentable product that was made by use of a protected process.

H.R. 587 and related predecessor bills were developed as a result of two conflicting and irreconcilable decisions issued by the Court of Appeals for the Federal Circuit, *In re Durden,* 763 F. 2d 1406 (Fed. Cir. 1985) and *In re Pleuddemann,* 910 F. 2d 823 (Fed. Cir. 1990).

In re Durden concerned a process patent claim which had been rejected by the PTO. The case involved a chemical process. The applicants for the patent argued on appeal that while individual process steps were obvious, the use of a novel and nonobvious starting material and the production of a new and nonobvious product meant that the process should be patentable. The Court concluded that the use of a new starting material and/or the development of a patented product did not automatically ensure the nonobviousness of a process or the grant of a process patent. The Court noted that if every process using a new or novel material was granted a patent, then simple processes such as dissolving or heating would be patentable when using a new compound.[4]

Following this case, there were complaints from various industry groups that the PTO was automatically rejecting process claims under circumstances similar to *In re Durden.* In the subsequent case of *In re Pleuddemann,* the Court emphasized that *In re Durden* was not to be read as a "per se" rule against patenting old processes using new starting materials or producing new products. The Court stated that each invention had to be viewed as a whole and considered on its individual facts.[5]

In holding of *In re Pleuddemann,* the Court distinguished *In re Durden* on the grounds that the fact situation there involved a process of "making", and *In re Pleuddemann* involved a process of "using."[6] The Court did not specifically overrule *In re Durden* but relied on the distinction of "using" versus "making." The distinction between the two types of processes was lost on many and caused others to manipulate phrasing in developing patent applications to ensure that processes were "using" instead of "making." At two different hearings during the 103d Congress of the then Subcommittee on Intellectual Property and Judicial Administration, testimony was provided which indicated that in several cases the patent applicant had originally written a claim as a "making" process. After the examiner rejected the claims on the basis of *In re Durden,* the

[3] The amendments were intended to provide protection to domestic U.S. process patent holders against foreign companies using the U.S. patented process overseas and importing the resulting product into the U.S. without any recourse by the process patent owner for infringement.

[4] *In re Durden,* 763 F. 2d 1406, 1410 (Fed. Cir. 1985)

[5] *In re Pleuddeman,* 910 F. 2d 823, 828 (Fed. Cir. 1990).

[6] *Id.,* at 827.

claims were rewritten as a "using" claim and were approved by the examiner.[7]

The holdings in *In re Durden* and *In re Pleuddemann* have led to inconsistent practices by the PTO in the examination of applications for process patents. The result has been that some process patents have been granted without any delay or controversy while other applications, similar in nature, have been rejected or required to be defended at length with the patent examiner.[8]

Legislation was developed as a response to a perceived failure on the part of PTO to grant process patents based on the *In re Durden* decision and the resulting importation problem due to the inability of inventors to obtain process patents.[9] While the holdings of *In re Durden* and *In re Pleuddemann* have been applied generally, the resulting problems were considered to affect particularly biotechnology applications because of the nature of the products produced. In the case of biotechnology products, the final product is a naturally occurring substance despite the fact that it has never been able to be produced before in commercially viable quantities.[10]

The final unpatentable product is often developed or synthesized through the use of a "host cell" that has been genetically altered in a way to produce the final product in large quantities. The host cell is usually patentable. The issue is whether the process, by which the final product is produced, also can be patented.

Since the host cell is patented, the host cell cannot be used in the United States without the patent owner's permission and no products can be produced in the United States from that host cell. Without a United States process patent, however, the host cell can be taken offshore and used to make the final product. The final product produced from the host cell can be imported back into the United States for commercial sale. The owner of the patented host cell has no recourse because there is no "use" of the patented host cell in the United States and thus no infringement. Since there is no patent on the process by which the final product was produced, the importation of the product cannot be challenged.

Clearly, obtaining a process patent could solve the importation problem for the biotechnology industry. H.R. 587 is necessitated by the difficulty of obtaining timely and adequate process patent protection under present court rulings and PTO interpretation.

The approach taken in H.R. 587 is industry specific, as were some prior bills designed to take care of the problem. Although industry specific legislation, particularly in the context of patent law,

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[7] Legislative Hearing during 103d Congress on H.R. 4307, before the Subcommittee on Intellectual Property and Judicial Administration of the House Committee on the Judiciary, 103d Cong., 2d Sess. (May 5, 1994) (Testimony of Lisa J. Raines); Amending Title 35, United States Code, With Respect to Patents on Certain Processes, Hearing on H.R. 760, before the Subcommittee on Intellectual Property and Judicial Administration of the House Committee On The Judiciary, 103d Cong., 1st Sess., Serial No. 32 (June 9, 1993) (Testimony of George W. Enbright, p. 42; Testimony of Steven M. Odre, p. 51).

[8] Legislative Hearing during 103d Congress on H.R. 4307, supra (Testimony of Lisa J. Raines); Amending Title 35, United States Code, With Respect To Patents On Certain Processes, Hearing on H.R. 760, supra (Testimony of George W. Enbright, p. 42).

[9] Legislative Hearing during 103d Congress on H.R. 4307, supra (Testimony of Lisa J. Raines); Amending Title 35, United States Code, With Respect To Patents on Certain Processes, Hearing on H.R. 760, supra (Testimony of George W. Enbright, p. 42).

[10] Legislative Hearing during 103d Congress on H.R. 4307, supra (Testimony of Lisa J. Raines); Amending Title 35, United States Code, With Respect To Patents On Certain Processes, Hearing on H.R. 760, supra (Testimony of Michael Kirk, p. 22; Testimony of George W. Enbright, p. 41).

is generally not favored, considerable opposition to a more comprehensive solution proposed by other predecessor bills, such as H.R. 4307, made their enactment unlikely. As a result of concerns raised by certain industries as to the impact of a broad change in patent law, the applicability of H.R. 587 has been limited to biotechnological processes only. The computer industry, the electronics industry and others previously raised questions as to the ability of certain patent owners to secure patents that would have such extensive coverage that public domain processes would be combined with new products to obtain patent coverage to the detriment of the industry.[11] The chemical industry also raised questions as to the scope and potential infringement of patents issued under the revised examination process proposed in H.R. 4307, as introduced, and as amended.

The legislation impacts only one element of patentability of biotechnological processes—the element of nonobviousness. There is no guarantee of patentability if the process claim satisfies the special nonobviousness provisions of the revised § 103. The process must still satisfy all other requirements of patentability, including the utility requirement under 35 U.S.C. § 101 and the enabling provisions of 35 U.S.C. § 112 which require sufficient description provisions of the invention and claims, described in "full, clear and concise, and exact terms," so that other skilled in the art can use the process. Process claims patented pursuant to the proposed revisions of § 103 would not enjoy greater protection than process claims granted under present law.

Resolution of this problem will provide both certainty for patent applicants in the field of biotechnology and protection against foreign competition. Once process patents are awarded, foreign companies will not be able to take advantage of the inability of the United States manufacturer to obtain a product patent. There is no question, as some opponents have argued, that, in many cases, a product patent provides better protection than a process patent against foreign manufacture and importation of the product into the United States. However, if a product patent is unobtainable because of the nature of the final product, it is essential that some other protection be afforded. In the opinion of the Committee, the appropriate protection is a process patent and the infringement protection pursuant to 35 U.S.C. § 271(g) against importation of products resulting from foreign use of the patented process.

The unpredictability of the patent examination process has become a critical problem for development of new technologies, such as biotechnology. With a mitigation of uncertainty, that industry can now better assess the chances and risks associated with the patent application process. The granting of a process patent will no longer depend on the chance of the wording of a claim or the preference of an examiner in applying the holding of *In re Durden* versus the holding of *In re Pleuddemann.*

H.R. 587 is in no way intended to reduce or eliminate any requirements of the patent laws of the United States other than pro-

[11] Legislative Hearing during 103rd Congress on H.R. 4307, supra (Testimony of Roger S. Smith; testimony of Richard G. Waterman); Amending Title 35, United States Code, With Respect To Patents On Certain Processes, Hearing on H.R. 760, supra (Testimony of Robert A. Armitage, p. 70).

viding, upon election of an applicant, that a biotechnological process using or resulting in a composition of matter found upon examination to be novel and nonobvious, shall likewise be found nonobvious.

It is intended that biotechnological processes using or resulting in a composition of matter, otherwise patentable to the applicant, be entitled to full patent protection including the benefits of enforcement, specifically of 35 U.S.C. §271(g). It is not intended by this bill that applicants be given the right to extend patent claims to all upstream or downstream processes leading to or resulting from use of the patented composition of matter in a way that would create infringement liability on parties not making or using the patented composition of matter, except as is already provided under existing law for infringement.

There are presently two cases being considered by the U.S. Court of Appeals for the Federal Circuit which may have a bearing on the matter considered in H.R. 587.[12] The Court still has not issued opinions in these cases which might resolve the perceived inconsistencies of the two previous opinions of the Court, *In re Durden* and *In re Pleuddemann.* The two cases were argued in November 1992. There has been no indication when the Court might issue the decisions. In any event, it is by no means certain that the two cases will resolve the underlying issues. On the other hand, because H.R. 587 is restricted to biotechnological processes, its enactment would not moot these cases, as they involve chemical processes.

The PTO testified before the Subcommittee that it does not believe it can resolve the problem administratively because of the two seemingly conflicting Court opinions.[13]

CONCLUSION

The extended history of H.R. 587 and related legislation speaks to the need to have the inconsistency existing in case law and in PTO examination procedures resolved. Testimony over several Congresses has amply illustrated the difficulties faced by patent applicants in satisfying the dictates of two seemingly inconsistent Court opinions, *In re Durden* and *In re Pleuddemann.* The inability of the PTO to make changes administratively and the lack of direction from the Court makes Congress the appropriate forum to address this matter.

The award of patent protection ensures a greater degree of protection for businesses in the United States. Biotechnology companies are faced with competition form overseas companies who derive the benefits from the innovations and investments of American companies without any of the risks. A resolution of the examination practices for biotechnological processes that are linked to patentable compositions of matter would ensure that United States manufacturers can better protect the extensive investment made in research and development.

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[12] *In re Ochiai,* No. 92–1446 (Fed. Cir. filed July 22, 1992); *In re Brouwer,* No. 92–1225 (Fed. Cir. filed March 11, 1992).

[13] Legislative Hearing on H.R. 587, before the Subcommittee on Courts and Intellectual Property of the House Committee on the Judiciary, 104th Cong., 1st Session (March 29, 1995).

HEARINGS

The Committees' Subcommittees on Courts and Intellectual Property held one day of hearings related to the issues contained in H.R. 587. The hearing was held on March 29, 1995. Testimony was received from the following four witnesses: Mr. H. Dieter Hoinkes, Senior Counsel, Office of Legislative and International Affairs, Patent and Trademark Office, United States Department of Commerce; Mr. Henry Linsert, Chairman and Chief Executive Officer, Martek Biosciences Corporation, Columbia, Maryland; Michele Cimbala, Ph.D. and J.D., Partner, Sterne, Kessler, Goldstein and Fox; and Mr. Steven Odre, Senior Vice President, Amgen Incorporated, Thousand Oaks, California with additional material submitted by Biotechnology Industry Organization (Bio).

The Subcommittee on Intellectual Property and Judicial Administration held a hearing on a related bill, H.R. 4307 on May 5, 1994. The witnesses at the hearing were Mr. Michael Kirk, Administrator for Legislation and International Affairs, Patent and Trademark Office, United States Department of Commerce; Mr. Gerald Mossinghoff, President, Pharmaceutical Research and Manufacturers of America (formerly known as Pharmaceutical Manufacturers Association); Ms. Lisa Raines, Vice President, Government Relations, Genzyme Corporation; testifying on behalf of the Biotechnology Industry Organization; Mr. Roger Smith, Assistant General Counsel, IBM Corporation; and Mr. Richard Waterman, General Patent Counsel, Dow Chemical Company.

A hearing on related legislation, H.R. 760 was held by the Subcommittee on Intellectual Property and Judicial Administration on June 9, 1993. The witnesses at the hearing were The Honorable Rick Boucher, Congressman, 9th District, Virginia; The Honorable Dennis DeConcini, Senator, Arizona; Mr. Michael Kirk, Acting Commissioner, United States Patent and Trademark Office, United States Department of Commerce; Mr. G. Kirk Raab, Chief Executive Officer, Genentech, Inc., testifying on behalf of the Biotechnology Industry Organization (formerly known as the Industrial Biotechnology Association and the Association of Biotechnology Companies); Mr. Steven M. Odre, Vice-President for Intellectual Property, Amgen, Inc.; Mr. William L. LaFuze, President, American Intellectual Property Law Association; and Mr. Robert Armitage, testifying on behalf of the Intellectual Property Owners, Inc. and on behalf of the National Association of Manufacturers.

COMMITTEE CONSIDERATION

On May 16, 1995 the Subcommittee on Courts and Intellectual Property met in open session and ordered reported the bill H.R. 587, by a voice vote, a quorum being present. On June 7, 1995 the Committee met in open session and ordered reported the bill H.R. 587 without amendment by a voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

In compliance with clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, the Committee reports that the finding and recommendations of the Committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Rep-

resentatives, are incorporated in the descriptive portions of this report.

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT HEARINGS

No findings or recommendations of the Committee on Government Reform and Oversight were received as referred to in clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives.

NEW BUDGET AUTHORITY AND TAX EXPENDITURES

Clause 2(l)(3)(B) of House Rule XI is inapplicable because this legislation does not provide new budgetary authority or increased tax expenditures.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

In compliance with clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, the Committee sets forth, with respect to the bill, H.R. 587, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 403 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 15, 1995.

Hon. HENRY J. HYDE,
Chairman, Committee on the Judiciary,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has reviewed H.R. 587, a bill to amend title 35, United States Code, with respect to applications for process patents, as ordered reported by the House Committee on the Judiciary on June 7, 1995. CBO estimates that enactment of H.R. 587 would result in no significant costs to the federal government and in no costs to state and local governments. Enacting H.R. 587 would not affect direct spending or receipts. Therefore, pay-as-you-go procedures would not apply to the bill.

H.R. 587 would expand the definition of a non-obvious process for purposes of considering the patentability of biotechnological processes. The bill also would remove the presumption of validity for a biotechnological process patent if its approval was based on a product patent that was later said to be invalid.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is John Webb.

Sincerely,

JAMES L. BLUM
(For June E. O'Neill, *Director*).

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee estimates that H.R. 587 will have no significant impact on prices and costs in the national economy.

SECTION-BY-SECTION ANALYSIS

SEC. 101. CONDITIONS FOR PATENTABILITY; NONOBVIOUS SUBJECT MATTER

Section 101 adds a clarifying standard to 35 U.S.C. § 103. Section 103 requires that for a patent to be obtained, the subject matter must be nonobvious. Under § 103, if the "subject matter as a whole would have been obvious at the time the invention was made * * *." a patent cannot be granted.

The section provides that an application with a biotechnological process claim which is linked to a patentable composition of matter will be considered nonobvious under § 103. If a patentable composition of matter is either produced by a biotechnological process or used as part of that process, the process claims will be considered nonobvious.

The examination of the process claims will proceed under the revised provisions of § 103 if the applicant for a patent elects in a timely fashion to proceed under the new subsection.

For a biotechnological patent application to be considered nonobvious under the proposed revision of § 103, there are several conditions which must be met. First, the claims to the process and the patentable composition of matter, to which the process is linked, must be contained in the same application or have the same effective filing date. Second, the patentable composition of matter and the process must be owned by the same person or be subject to an obligation of assignment to the same person. Third, the composition of matter used or resulting from the process sought to be patented must be novel under § 102, must be nonobvious on its own merits and must, in all other ways, be patentable.

If process claims are granted under this standard, they must appear in the same patent containing the claims to the patentable composition of matter used or made by the process. If there are two different patents issued for the composition of matter and for the biotechnological process claims relating to the composition of matter, the process patent must expire on the same date as the patent on the composition of matter, notwithstanding the statutory patent term set pursuant to 35 U.S.C. § 154.

To ensure that the term "biotechnological process" is not misinterpreted, a definition is provided that specifies these processes as being methods of using a product produced either by organisms that were genetically altered or otherwise induced to express characteristics not naturally associated with them, by cell fusion procedures, or by a composition of both.

SEC. 102. PRESUMPTION OF VALIDITY; DEFENSES

This section amends 35 U.S.C. § 282 which elaborates on the validity of each patent and patent claim. Since a biotechnological process claim examined under the terms of § 103(b)(1) is linked to a patentable composition of matter for a determination of nonobviousness, if a claim for such composition of matter is held invalid, the process to which it is linked, shall no longer be entitled to rely on the claim for a presumption of nonobviousness.

SEC. 103. EFFECTIVE DATE

The Act and the amendments made by the Act shall take effect on the date of enactment and will apply to any patent application filed on or after the date of enactment and any patent applications pending on the date of enactment.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

TITLE 35, UNITED STATES CODE

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PART II—PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS

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CHAPTER 10—PATENTABILITY OF INVENTIONS

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§ 103. Conditions for patentability; non-obvious subject matter

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if 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. Patentability shall not be negatived by the manner in which the invention was made.

(b)(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a "biotechnological process" using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if—

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

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

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

(A) shall also contain the claims to the composition of matter used in or made by that process, or

(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.

(3) For purposes of paragraph (1), the term "biotechnological process" means—

(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to—

(i) express an exogenous nucleotide sequence,

(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

(iii) express a specific physiological characteristic not naturally associated with said organism;

(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and

(C) a method of using a product produced by a process defined by (A) or (B), or a combination of (A) and (B).

(c) Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

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PART III—PATENTS AND PROTECTION OF PATENT RIGHTS

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CHAPTER 29—REMEDIES FOR INFRINGEMENT OF PATENT, AND OTHER ACTIONS

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§ 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity. *Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1).*

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Calendar No. 128

103D CONGRESS *1st Session* | SENATE | REPORT 103–82

BIOTECHNOLOGY PATENT PROTECTION ACT OF 1993

JULY 1 (legislative day, JUNE 30), 1993.—Ordered to be printed

Mr. BIDEN, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany S. 298]

The Committee on the Judiciary, to which was referred the bill (S. 298) relating to an amendment to title 35, United States Code, to provide conditions for the patentability of biotechnological process patents, and for other purposes, having considered the same reports favorably thereon and recommends that the bill do pass.

CONTENTS

I. PURPOSE

The purpose of S. 298 is to amend the Patent Code to provide additional protection for biotechnological inventions. Senate bill 298 will eliminate barriers to biotech process patenting, and thereby increase innovation and stimulate the development of new products and processes.

69–010

II. LEGISLATIVE HISTORY

Senate bill 298, the Biotechnology Patent Protection Act of 1993, was introduced by Senator DeConcini and Senators Hatch, Heflin, Kennedy, Kohl, Lautenberg, Specter, Grassley, Brown, and Domenici on February 3, 1993. It was polled out of the Judiciary Subcommittee on Patents, Copyrights and Trademarks on March 16, 1993. Senate bill 298 was ordered reported by the full Judiciary Committee on May 16, 1993, by unanimous consent.

The Biotechnology Patent Protection Act has its origins in the 101st Congress, when Senator DeConcini and Representative Boucher each introduced the Biotechnology Patent Protection Act of 1990. The respective bills differed only in their effective date.

After introducing these bills, Representative Boucher and Senator DeConcini as well as Representative Kastenmeier, then Chairman of the House Judiciary Subcommittee on Courts, Intellectual Property and the Administration of Justice, solicited the views of the Department of Commerce. In a July 1990 response letter, the Department expressed agreement with the need for the legislation but voiced objections to the provisions amending section 337 of the 1930 Tariff Act, as well as to title 35 of the United States Code, which would extend enforcement of the rights of a patent claiming biotechnological material used in the manufacture of a recombinant product.

In consideration of the views of the Department of Commerce, Representative Boucher introduced a second bill, H.R. 5664, in the 101st Congress. A hearing in the House was held, but there was no further action on these bills in the 101st Congress.

In the 102d Congress, Senator DeConcini introduced S. 654, the Biotechnology Patent Protection Act of 1991, on March 13, 1991, with Senators Hatch, Kohl, Lautenberg, Specter, and Grassley. Representative Boucher introduced companion legislation, H.R. 1417, in the House of Representatives on the same day. As introduced in the 102d Congress, S. 654 and H.R. 1417 had identical language to H.R. 5664 from the 101st Congress.

After the introduction of S. 654, Senator DeConcini wrote to the Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, Harry F. Manbeck, Jr., to express concern that the bill's positive effects would be unnecessarily circumscribed by overruling *In re Durden*[1] in cases where only a single patent issues. Wendell L. Willkie II, the General Counsel of the Department of Commerce, responded to the DeConcini letter on June 10, 1991, stating the Commerce Department's support for S. 654 and suggesting an amendment to alleviate Senator DeConcini's concerns.

On June 12, 1991, the Subcommittee on Patents, Copyrights and Trademarks held a public hearing on S. 654. On July 25, 1991, the Subcommittee reported S. 654 to the full Committee with an amendment in the nature of a substitute that incorporated the suggested language in the Willkie letter. Senate bill 654 as amended favorably passed the Judiciary Committee unanimously on November 21, 1991. The Senate took up S. 654, with an amendment in the nature of a substitute, and passed the bill unanimously on September 18, 1992. The amendment, offered by Senator Heflin, cre-

[1] 763 F.2d 1406 (Fed. Cir. 1985).

ated remedies for patented "host cells" and other essential intermediates and is now title II of S. 298.

Title I of S. 298 is identical to S. 654 except that it applies exclusively, rather than primarily, to biotechnological processes.

III. DISCUSSION

A. Background

"Biotechnology" is a broad term coined to encompass manmade process which manipulate biological components. The Office of Technology Assessment defines biotechnology as "any technique that uses living organisms (or substances from those organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses."[2]

Biotechnology is a multidisciplinary science, combining biology, chemistry, material science, physics, computer science, and medicine. It is used in diverse industries from pharmaceuticals, agriculture, and veterinary medicine to environmental cleanup and new energy resources. Widely known products made with the use of biotechnology include home pregnancy tests, diagnostic tests for human immunodeficiency virus (HIV), insulin, sweeteners such as aspartame (the sweetener marketed as Nutrasweet), and the enzyme used to turn glucose into highly sweet fructose.

Man has used processes involving biological organisms for hundreds of centuries, and continues to use them in a vast array of areas today. Yeast, a fungus used for fermentation to produce alcoholic beverages and to leaven dough, is one example of an organism that has been processed since the dawn of history. The best beef and pork in the world are the result of selective crossbreeding, and more recently, of artificial insemination. Penicillin and other naturally occurring antibiotics are commercially produced with microorganisms, and the 1992 Winter Olympic Games produced snow by using organisms that promote ice crystallization.

Today's biotechnology is far more complex than that of yesteryear. In the 1950's, Watson and Crick discovered the deoxyribonucleic acid (DNA) double helix, a complex molecule made of billions of single atoms which functions as a genetic template. The basis of much of the biotechnology industry today is the elucidation of relatively minute sections of DNA. Until the advent of the computer chip and advanced electronics, efforts to determine the makeup and function of these minute sections were essentially trial and error. Biotechnology has made it possible to create and test molecules with relative precision. The capability of creating these organic molecules has led to dramatic breakthroughs in the ability to improve human life.

All living things are composed of cells, from one-celled bacteria to giant multicellular whales. Each cell contains a complete genetic "blueprint" of the organism encoded in a long molecule, DNA. DNA guides the construction and functions of the organism by directing cellular synthesis of proteins.

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[2] U.S. Congress, Office of Technology Assessment, New Developments in Biotechnology: Ownership of Human Tissues and Cells-Special Report," OTA–BA–337 (Washington, DC: U.S. Government Printing Office, March 1987).

Sections of DNA, called genes, contain chemical instructions that guide the cell's machinery in constructing proteins. Proteins give living things their unique characteristics. Some proteins give structure to living organisms. Others mediate the chemical reactions that are necessary for organisms to function. Proteins are sequences of amino acids whose major role is to act as catalysts for chemical reactions in the body. When acting as a biocatalyst, proteins are known as enzymes.

Some people are born with problems with their DNA in certain genes. These genetic defects scramble the coded instructions in the gene, causing the cell to produce a defective protein or no protein at all. This has serious consequences for the health of the individual. If the function of the defective or missing protein is important, the person may die without it. In other cases, normally functioning genes may develop problems due to infection, age or other factors. These genes may develop abnormal characteristics, leading in some cases to cancer or arthritis.

Because proteins can regulate chemical reactions, determining which specific protein performs which function is vitally important in fighting disease. For example, by preventing a given chemical reaction from occurring by removing or tying up the reaction-specific catalyst, it may be possible to stop the growth of diseased cells. Similarly, by enabling the occurrence of a given reaction by supplying a missing gene, an organism's own system can be forced to produce beneficial chemicals, such as insulin. Biotechnology is responsible for these marvels of science.

Several technologies are available for performing these feats, including recombinant DNA. Recombinant DNA technology uses naturally occurring enzymes to clip out fragments of DNA and then insert the fragment containing a specific gene into a different cell, altering that cell so that it carries a new genetic message. This technology has enabled scientists to successfully generate human insulin with *E. coli,* bacteria inhabiting the human digestive tract.

These microorganisms then grow at a tremendous rate; some have a generation time of 30 minutes or less. The multiple copies of the microbe produce large amounts of the desired protein. Consequently, proteins that occur in minute quantities in nature can be produced in large quantities through recombinant technology. The proteins produced by the microorganisms are also free of viral contamination that might contaminate the protein if extracted from human tissue or fluids.

This complex research is expensive and can take many years to yield practical results. It is estimated that it takes an average of 12 years to bring a drug from discovery through final FDA approval.[3] The biotechnological industry contends that the average cost of discovery and bringing a single drug to market today exceeds $230 million.[4] In combination, private- and government-sponsored research exceeded $4 billion in 1988, and the industry still

[3] Thompson, "High Cost of Rare Diseases, When Patients Can't Afford to Buy Lifesaving Drugs," Washington Post Health, June 25, 1991.

[4] "Anticompetitive Abuses of the Orphan Drug Act; Invitation to High Prices," hearing before the Senate Judiciary Subcommittee on Antitrust, Monopolies and Business Rights, 102d Cong., 2d sess. (1992), (statement of John P. McLaughlin, vice president and general counsel of Genentech, Inc.), (citations omitted).

continues to grow because of the enormous need for biotechnology products.[5]

Commerical successes in 1990 garnered the U.S. biotechnological industry sales of $2.9 billion, doubling the sales of 1989 and quadrupling the amount for 1988.[6] However, the biotechnology industry faces formidable challenges in continuing this groundbreaking research. Japan has targeted pharmaceutical development as an industry of vital economic importance.[7] Europe invests heavily in biotech research and actually leads in the production of monoclonal antibodies.[8] Therefore, it is vitally important that the United States maintain its edge in this competitive and fast paced industry by continuing its investment in biotechnical breakthroughs.

B. Biotechnology patenting

Biotechnology, an intensely competitive industry, requires effective, enforceable intellectual property laws to deter piracy of its inventions. Currently, however, patent protection for biotech products is difficult to obtain under current U.S. law and is unavailable in many foreign countries. Without such protection, venture capitalists fearful of an inability to recover their investment may refuse to provide R&D costs which, in turn, jeopardizes future biotechnological advancements.[9]

Biotech products are often the recombinant versions of a naturally occurring substance usually found in an animal or plant. When the scientific literature or other available information reveals that the naturally occurring version of the protein has been purified to some extent, even if it has not been definitively characterized, a patent for the recombinant version may be denied for lack of novelty. In patent law terms, the product has already been discovered.[10] 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. Inventors of some recombinant versions of naturally occurring products have found it difficult to obtain adequate patent protection because of the mere existence of literature disclosing incomplete information about the natural protein.[11]

A second hurdle inventors must overcome is that a patent application for a recombinant product may be denied because it is deemed obvious, and thus unpatentable, despite its novelty. In many cases, although the protein has never before been isolated in

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[5] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: U.S. Investment in Biotechnology—Special Report," OTA–BA–401. (Washington, DC: U.S. Government Printing Office, July 1988.)

[6] "Biotechnology Patent Protection Act of 1991," hearing on S. 654 before the Judiciary Subcommittee on Patents, Copyrights and Trademarks, 102d Cong., 1st sess. (1991), [hereinafter hearings], (statement of Henri Termeer, president and CEO of Genzyme Corporation, on behalf of Industrial Biotechnology Association).

[7] The President's Council on Competitiveness, "Report on National Biotechnology Policy," at 5, Washington, DC (February 1991).

[8] Id.

[9] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: Patenting Life—Special Report," OTA–BA–370 at 101 (Washington, DC: U.S. Government Printing Office, April 1989), [hereinafter OTA report].

[10] See generally, Murashige, "Section 102/103 Issues in Biotechnology Patent Prosecution," 16 A.I.P.L.A., Q.J. 294, 303–04 (1988–89); Andrews, "Unaddressed Question in the Amgen Case," N.Y. Times, Mar. 9, 1991, at A30.

[11] A natural protein is a protein encoded by DNA that occurs in nature. A recombinant protein is a protein encoded by DNA that has been produced by combining genetic material from at least two different sources.

a substantially pure form or the product is not well characterized prior to the recombinant synthesis, if its basic properties and some aspects of its structure are known, the Patent and Trademark Office (PTO) may assert that the use of recombinant technology to make a pure form of such a product is obvious. The ability to obtain a patent for a purified version of a protein merely to block the use of a process to make commercially viable quantities of a recombinant version of the protein has been criticized.[12]

The mere existence of a previously discovered protein should not, by itself, always preclude the issuance of a patent for a recombinantly created version of the same protein. The rationale under which a patent may be granted for a product existing in nature is that in its natural form, such a product is not available and useful to the public without further isolation and purification. The law as currently expressed provides that to be considered obvious:

> the differences between the subject matter sought to be patented *and the prior art* [must be] 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.[13]

The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) and its predecessor, the U.S. Court of Customs and Patent Appeals (C.C.P.A.), have reiterated many times that an applicant's disclosure in a patent application cannot be treated as prior art in determining the obviousness of the claimed invention.[14] The court has also emphasized that the invention as a whole must be considered in assessing obviousness.[15] Finally, the court has cautioned that a patentability determination must be made as of the time the invention was made, and not as part of a hindsight reconstruction of the invention given the applicant's disclosure.[16]

Because questions of novelty and obviousness often preclude product patents, the biotechnology industry has become heavily dependent upon process patents. Yet, product patents are generally considered to provide better protection for drugs than process or use patents because the latter two types usually can be circumvented more easily. Additionally, it may be more difficult to detect the infringement of a process patent than the product patent because products are available to the public, but the processes used to make them are kept secret within the walls of a manufacturer.

The biggest problem facing the U.S. biotech industry is the lack of clarity in the rules for patentability of biotech processes. Sound investment decisions require a degree of economic certainty. The lack of legal certainty for biotechnology process patents affects the

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[12] See Merges & Nelson, "On the Complex Economics of Patent Scope," 90 Colum. L. Rev. 839, 903–04 (1990). See also *Scripps Clinic & Research Found.* v. *Genentech, Inc.*, 666 F.Supp. 1379 (N.D. Cal. 1987), modified on reconsideration, 678 F.Supp. 1429 (N.D. Cal. 1988), summ. judgment granted, 707 F.Supp. 1547 (N.D. Cal. 1989), aff'd in part, rev'd in part, vacated in part, 927 F.2d 1565 (Fed. Cir. 1991), (reserving for further analysis by the district court the issue whether a patent on a purified protein should serve to block a patent on a recombinant version of the same protein).

[13] 35 U.S.C. 103 (1988), (emphasis added).

[14] See, e.g., *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1567–88 (Fed. Cir. 1987), cert. denied, 481 U.S. 1052 (1987); *In re Katz*, 687 F.2d 450 (C.C.P.A. 1982).

[15] See *John Deere Co.* v. *Graham*, 333 F.2d 529 (8th Cir. 1964), aff'd 383 U.S. 1 (1966).

[16] *In re Kuehl*, 475 F.2d 658, 663–65 (C.C.P.A. 1973).

probability of return on investment and inhibits some venture capital investments.[17]

C. In re Durden

A major defect in U.S. patent case law has led the PTO to an inconsistent application of *In re Durden,*[18] a nonbiotech patent case, to important biotechnology-derived processes. A PTO supervisor noted that the use of this case as a basis for rejecting process patent claims in biotechnology is on the rise, as many examiners routinely apply it to biotechnology issues.[19]

Durden involved a challenge to the denial of a patent for a process to make a novel chemical. The process was similar to that of a previously issued patent; however, the *Durden* process utilized a novel and nonobvious, but related, starting material and produced a novel and nonobvious, but related, end product. It appeared predictable that once the new starting material and new product were disclosed, the old process would work with the new starting material to produce the new product. The court in *Durden* concluded, in the narrow factual context of that case, that the chemical process was obvious and not patentable, even though both the specific starting material employed and the product obtained were novel and nonobvious.

The Federal Circuit thus held, on the facts before it, that a process 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 case-by-case basis. In following *Durden,* the PTO believes that it cannot interpret section 103 to require that a process be held patentable merely because a patentable material was either used or made by that process.

Consequently, the PTO has cited *Durden* in denying patents to processes for producing proteins which use as starting materials, DNA, vectors or biological microorganisms made by recombinant DNA technology. This denial of process claim protection is routine even if the starting materials are found by the PTO examiner to be novel and nonobvious and, therefore, patentable in their own right.

Durden precludes needed patent protection for biotechnology processes and has been roundly criticized by commentators and legal practitioners.[20] Since the *Durden* decision it has become increasingly difficult to obtain process patent protection in the United States for genetic engineering inventions. Although some inventors overcome *Durden* rejections, the uncertainty in this area of the law has lead to inconsistent results by examiners.

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[17] OTA report, supra note 10.

[18] 763 F.2d 1406 (Fed. Cir. 1985).

[19] Wiseman, "Biotechnology Patent Practice—A Primer," 16 A.I.P.L.A., Q.J. 394, 411 (1988–89). See generally Litman, "Obvious Process Rejection Under 35 U.S.C. 103," 71 J. Pat. and Trademark Off. Soc'y 775 (1989); Wegner, "Much Ado About Durden," 71 J. Pat. and Trademark Off. Soc'y 785 (1989).

[20] See Murashige, supra note 11; Wegner, supra note 20; Comment, "The Elimination of Process: Will the Biotechnology Patent Protection Act Revive Process Patents?" 24 J. Marshall L. Rev. 263 (1990); McAndrews, "Removing the Burden of Durden Through Legislation: H.R. 3957 and H.R. 5664," 72 J. Pat. and Trademark Off. Soc'y 1188, (1990); Beier and Benson, "Biotechnology Patent Protection Act," 68 Denv. U.L. Rev. 173 (1991).

The inconsistent application of *Durden* by the PTO has also led to severe delay or denial of issuance of process patent protection to deserving inventors. The Federal Circuit acknowledges that there have been conflicting views on this issue both in the PTO Board of Appeals and in the C.C.P.A.[21]

Moreover, case law exists in this area which conflicts with the *Durden* reasoning and which would be more appropriately applicable to biotechnology process patents.[22] The application of *Durden* by the PTO to biotechnology cases, which involve microorganisms, conflicts with *In re Mancy*.[23]

In *Mancy,* the court held that a standard method of culturing microorganisms to produce antibiotics could not be treated as prior art in determining the patentability of a similar method using a patentable microbe to produce an antibiotic therefrom. In other words, novelty and nonobviousness of the microbe imparted patentability to a method using it.

To the detriment of biotechnology process patent applicants, the PTO has felt constrained to follow *Durden* rather than *Mancy.* More troubling is the fact that the reasoning in *Mancy* is the law for inventions in Europe and Japan, where the patenting of process inventions that use patentable starting materials has long been recognized.[24]

The Federal Circuit revisited the issue of the patentability of processes in *In re Pleuddemann.*[25] In that case the patentee had a patent to a starting material that he used in a process to make a patentable final product. Apart from the use of the patented starting material, the method (process) of making the final product was admittedly already known. The Federal Circuit held that the method of using the patented starting material to produce the patentable final product was patentable in this particular case.

Although the Federal Circuit attempts to distinguish *Pleuddemann* from *Durden,* it is difficult, if not impossible, to reconcile these two cases. It is not clear why a method of using a starting material should be treated differently, for purposes of determining nonobviousness, from a method of making the end product. Yet, under *Pleuddemann,* the former is per se nonobvious, while the latter is not.

The PTO and the courts continue to apply *Durden* to reject claims involving methods of using novel DNA sequences and other recombinant intermediates to make protein products. The classic *Durden* rejection maintains that a process of making a protein using a novel DNA sequence is obvious, because others have previously used the same process with other DNA sequences to make other proteins. As a result of *Pleuddemann,* it might be asserted that recombinant DNA patent applications no longer need fear such a *Durden* rejection of process-of-using claims which are based upon a novel DNA sequence encoding a desired protein X. Unfortunately, biotechnology companies have reported that the PTO has generally rejected this reasoning.

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[21] *Durden,* 763 F.2d at 1409.

[22] See, e.g., *In re Mancy,* 499 F.2d 1289 (C.C.P.A. 1974). See also *In re Kuehl,* 475 F.2d 658 (C.C.P.A. 1973).

[23] 499 F.2d 1289 (C.C.P.A. 1973).

[24] *Termeer,* supra note 7.

[25] 910 F.2d 823 (Fed. Cir. 1990).

A prudent attorney certainly would seek to use *Pleuddemann* to the client's advantage by rephrasing "a recombinant DNA process of making protein X" into a *Pleuddemann*-style process-of-using claim, such as, "contacting DNA with cellular enzymes or with a transcription/translation apparatus." However, as noted above, examiners are asserting that such claims are really a process-of-making claim in disguise.

Alternatively, some have argued that given the right case on appeal, the Federal Circuit might, at some future date, reverse *Durden* by applying a *Pleuddemann*-type analysis, finding that making is also not obvious because the *Durden*-type rejection presumes the new starting material or novel product to be prior art. While this possibility is consistent with the analysis in *Pleuddemann,* there clearly is no certainty that such a future decision will ever occur, particularly as the court has rejected this approach over the past 20 years.[26]

Some had hoped the November 9, 1990, rehearing of *In re Dillon*[27] would provide guidance regarding *Durden* and perhaps overrule it. In very clear dicta, the Federal Circuit summarized its attitude regarding *Durden* as follows:

> 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*.[28]

Therefore, *Durden* is very much alive, but weakened and unpredictable in its application by the individual patent examiner, the Board of Appeals and Interferences, and the courts.

Durden-type rejections remain an even greater problem following *Pleuddemann* because the Federal Circuit explicitly avoided questioning *Durden* as good law, and distinguished *making* and *using* as two different types of process claims.[29] A patent applicant may ask what new route to protect a recombinant DNA process claim is available after *Pleuddemann*. The answer is not clear because *Pleuddemann* does not address that question. One could rephrase *making* claims as *using* claims, but PTO has rejected this approach and it could take years before it is known whether the Federal Circuit agrees. The committee believes that congressional passage of

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[26] Once again, there is an appeal now before the Federal Circuit, which raises the conflict between *Durden, Albertson,* and now *Pleuddemann.* See *In re Ochiai* (Appeal No. 92–1446). Although *Ochiai* has been orally argued, a final decision by the Federal Circuit is not imminent. Similar to *Pleuddemann,* the *Ochiai* appeal creates further confusion by appearing to be a future solution to a problem the Federal Circuit refuses to resolve.

[27] 919 F.2d 688 (Fed. Cir. 1990), (en banc).

[28] *Id.* at 695 (emphasis in original).

[29] *Pleuddemann,* 910 F.2d at 827.

clear statutory language that explicitly removes the *Durden*-style rejection is a more direct and unambiguous route to protect recombinant DNA method-of-making protein claims.

The PTO, along with the Industrial Biotechnology Association and other witnesses, has opined that *Pleuddemann* has not clarified the law and leaves patent applicants unable to predict with reasonable certainty whether they can obtain process patents of this nature. Testifying before the House Judiciary Subcommittee on Courts, Intellectual Property and the Administration of Justice, then Patent Commissioner Manbeck stated that, "the distinction between *Pleuddemann,* on the one hand, and *Durden* and *Albertson*[30] on the other hand is esoteric, at best."[31] Appearing with Manbeck, the Solicitor of the PTO, Fred McKelvey, responded affirmatively to Representative Boucher's inquiry that the "*Pleuddemann* decision doesn't do anything to clear up the confusion that exists in the law currently."[32]

Manbeck further testified that the PTO will continue to have difficulty during the 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 product.

Title I of S. 298 amends section 103 of title 35, the Patent Code, to effectively avoid the Federal Circuit decision in *In re Durden.* Title I resolves the *Durden* dilemma by providing that a biotechnological process of making or using a product may be considered nonobvious if the starting material or resulting product is novel and nonobvious. Additionally, title I provides certainty and needed incentives for the biotechnology industry, incentives to grow and not be deterred by our patent laws. It will allow the United States to continue to lead biotechnology research worldwide and will provide essential protection to an industry that generates billions of dollars for the U.S. economy.

D. Importation

Title II of S. 298 provides a solution to another deficiency in our law that has created an obstacle for the U.S. biotechnology industry. Under present U.S. patent law, the holder of a patent to an organism, such as a host cell or part thereof, such as a DNA sequence or vector, can preclude another from using the organism in the United States. However, without patent protection for the process of using that organism, the inventor has no effective remedy against someone who takes the patented organism to another country, uses it to produce a protein-based product, and imports that product back into the United States.

The lack of an effective remedy to prohibit this blatant exploitation of patented U.S. technology is illustrated by Amgen, Inc.'s inability to prevent importation of erythropoietin (EPO) into the United States from Japan by Chugai Pharmaceutical Co. This controversial and public patent dispute in biotechnology[33] involved the

[30] 332 F.2d 379 (C.C.P.A. 1964).

[31] "Biotechnology Patent Protection: Hearing on H.R. 3957 and H.R. 5664," before the Subcommittee on Courts, Intellectual Property and the Administration of Justice of the House Committee on the Judiciary, 101st Cong., 2d sess. 18 (1990) (statement of Harry F. Manbeck, Jr., Asst. Sec. and Commissioner of Patents and Trademarks, U.S. Dept. of Commerce).

[32] Id. at 27.

[33] *See, e.g.,* Andrews, *Mad Scientists,* BUS. MONTHLY, May 1, 1990, at 54.

innovative product, recombinant erythropoietin (rEPO), as litigated in *Amgen, Inc.* v. *Chugai Pharmaceutical Co.*[34] Amgen's patent, at the time of that litigation, did not contain a claim to a process of making EPO using patented host cells. The International Trade Commission (ITC) refused to interpret the claims to the host cells alone as constituting a process claim under existing law. Consequently, Amgen was denied relief based upon its patented host cells since the ITC held that such claims to "host cells" *per se* were not process of making claims.

In this case, Amgen had conducted ground-breaking scientific research enabling it to produce commercially viable commodities of rEPO.[35] This major scientific and medical advance did not, however, give Amgen sufficient patent rights to prevent importation of competing products from Japan even though Amgen's competitors could not produce rEPO within the United States without infringing Amgen's patents.

Amgen is not the only entity facing this problem today. There are other small biotechnological companies and universities that have obtained only host cell protection. Indeed, some of these entities many have given up rights to process claims in order to receive protection of the host cell.

Title II specifically addresses the dilemma faced by biotechnology companies and universities trying to protect their patented biotechnological materials by providing a remedy against infringing foreign competitors. After the passage of this legislation, U.S. innovators will no longer be forced to watch helplessly as foreign companies reap the harvest to which the innovator is entitled.

S. 298 will create a level playing field by allowing a patent owner to enforce a patent claiming a host cell against a foreign manufacturer who imports a product into the United States made using the host cell. It makes no sense that U.S. patents of this nature are only enforced against U.S.-based manufacturers.

E. Additional benefits

Although not the primary purpose of the legislation, S. 298 also offers the ancillary benefit of reducing the increasingly high transaction costs associated with patent prosecutions and litigation by providing certainty in the law for both the PTO and the process patent applicants.[36] The high costs of such litigation may seriously drain the research budgets of biotech companies.[37] Unfortunately, the chilling effect of a process rejection has fallen most heavily upon those who lack the resources to pursue process patents, small companies and universities. The most disturbing potential ramification of inadequate intellectual property protection is that some promising therapies will not be pursued.

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[34] 705 F. Supp. 94 (D. Mass. 1989), *aff'd in part and rev'd in part,* 927 F.2d 1200 (Fed. Cir. 1991), *cert. denied,* 112 S.Ct. 169 (1991).

[35] As of early 1993, Amgen is currently alone on the market with its version of EPO, EPOGEN, because of provisions of the Federal Food, Drug, and Cosmetic Act, §527, 21 U.S.C. 360(cc) (1988). Under this Act, the sponsor of a new drug or biologic can, if certain market criteria are met, obtain market exclusivity for a period of seven years. In this case, Amgen obtained market exclusivity because it established that rEPO was a safe and effective therapy for treatment of chronic renal failure, the relevant patient population of which is less than 200,000.

[36] OTA Report, *supra* n. 10, at 56–58.

[37] U.S. Congress, Office of Technology Assessment, "Commercial Biotechnology: An International Analysis," 403 (1984).

In many respects this legislation is considered a continuation of the congressional policy behind the Process Patent Amendments Act of 1988. Without appropriate process claims in their patents, biotechnology inventors cannot take advantage of the benefits of the act. As a consequence, the advantages of the act are essentially nullified for the biotechnology industry. Finally, S. 298 helps harmonize our laws with those of our trading partners, at least with regard to biotechnology intellectual property.

IV. VOTE OF THE COMMITTEE

On March 16, 1993, the Subcommittee on Patents, Copyrights and Trademarks reported S. 298 to the Committee on the Judiciary. On May 6, 1993, the Committee on the Judiciary, a quorum being present, favorably reported by unanimous consent S. 298.

V. TEXT OF S. 298 AS REPORTED

[103d Cong., 1st sess.]

A BILL To amend title 35, United States Code, with respect to patents on biotechnological processes

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

TITLE I—BIOTECHNOLOGICAL PROCESS PATENTS

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

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

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

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

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

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

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

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

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

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

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

"(ii) appear in the same patent application, different patent applications, or patent which is owned by the same

person and which expires or is set to expire on the same date.

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

SEC. 102. NO PRESUMPTION OF INVALIDITY.

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

SEC. 103. EFFECTIVE DATE.

The amendments made by this title shall apply to all United States patents granted on or after the date of the enactment of this Act and to all applications for United States patents pending on or filed after such date of enactment, including any application for the reissuance of a patent.

TITLE II—BIOTECHNOLOGICAL MATERIAL PATENTS

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

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

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

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

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

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

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

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

(5) by adding at the end thereof the following:

"(b) For purposes of this section, the term 'biotechnological material' is defined as any material (including a host cell, DNA se-

quence, or vector) that is used in a biotechnological process as defined under section 103(d).".

(c) EFFECTIVE DATE.—

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

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

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

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

VI. SECTION-BY-SECTION ANALYSIS

TITLE I. BIOTECHNOLOGICAL PROCESS PATENTS

Section 101. Conditions for patentability; Nonobvious subject matter

Section 101 would amend section 103 of title 35, United States Code, to ensure that under certain circumstances, a biotechnological 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 product and process claims must be sought to be patented in the same application. Continuing applications would also be eligible where the specified conditions are met.

The amendment to section 103 would thus provide a mechanism for applicants to avoid a conclusion that a biotechnological process of making or using a patentable product is obvious under this section, overruling the decision in *In re Durden,* 763 F.2d 1406 (Fed Cir. 1985). Process patents granted under 103(c) would not affect an existing process patent right.

With regard to patent terms, section 101 provides that process claims that are granted the benefits of the nonobviousness rule under subsection 103(c) must coterminate with the product claims on which they depend for patentability. The purpose of this provision is to prevent a patent applicant from obtaining an effective patent term in excess of seventeen years (and any applicable patent term extension) on what would be essentially a single invention.

The committee does not intend to deprive independently patentable inventions of the patent terms to which they are entitled under current law. Therefore, if an applicant elects to demonstrate the independent patentability of a process, notwithstanding a possible *Durden* rejection, rather than rely on the nonobviousness rule established in the legislation, the invention is entitled to the full 17-year term (and any applicable patent term extension) available

under current law for both product and process inventions, without cotermination.

Thus, applicants have the option of either demonstrating the independent patentability of a process (as must be done under current law) or proceeding under the nonobviousness rule established by this legislation. Independent patentability may be demonstrated, for example, by showing the nonobviousness of the process (for example, through proof that the process demonstrates unpredictable results).

Applicants who unsuccessfully attempt to demonstrate independent patentability do not forfeit their right to amend their application to one that relies upon the rule established by this legislation. However, an applicant who so amends his application is required to have his process claims coterminate with his product claims. In such cases, patent term extension will continue to be available to extend the term beyond the termination date otherwise established.

Section 101 would simplify and provide certainty in the determination of patentability of biotechnological processes using or making novel and nonobvious products, for applicants who comply with its requirements.

This legislation would also make our patent law consistent with the patent granting process now practiced in the European and Japanese Patent Offices. Under the law of these trading partners, process claims are granted automatically.

Section 102. Presumption of validity

Since an application may rely on the nonobviousness rule established in this legislation to expedite issuance of his or her process claims rather than risk the costs and delays involved in overcoming a *Durden* rejection, section 102 provides that there is no presumption that process claims are invalid if the product claims, which form the basis for invoking the nonobviousness rule, are invalidated. This does not mean that such process claims will be treated as not obvious; rather the inventor must show that such a process is not obvious without relying on this legislation. Any litigation should provide the patentee with the opportunity to prove that the process claims are independently patentable.

Section 103. Effective date

The amendments made by this act are effective on the date of enactment. The amendments apply to all patents granted on or after the date of enactment, all patent applications pending on the date of enactment, and all patent applications filed after the date of enactment. Patent applications include applications for reissuance of a patent.

TITLE II. BIOTECHNOLOGICAL MATERIAL PATENTS

Section 201. Infringement by importation, sale or use

Section 201 would close the loophole that currently allows foreign exploitation of patented biotechnological material (through the unfair use of such materials offshore tomake a commercial product) by amending section 271 of title 35, United States Code, to provide

that it is an act of infringement for any person who wrongfully imports into the United States or sells or uses within the United States a product made by using a patented biotechnological material. Under the bill's definition, a biotechnological material is any material that is used in a biotechnological process. This includes, but is not limited to, host cells, DNA sequences, and vectors.

Under this section, a person may continue to use, sell, or import products so made if the products are being used or sold in a substantial and continuous manner on the date of enactment. A person may also continue to use, sell, or import products if substantial preparation to do so was made before the date of enactment, keeping in mind the value of the invention and the need to protect innovation from free riding.

Section 201 would take effect 6 months after the date of enactment and shall only apply to products made or imported after the effective date of the amendments made by this section.

VII. COST ESTIMATE

In accordance with paragraph 11(a), rule XXVI, of the Standing Rules of the Senate, the committee offers the report of the Congressional Budget Office:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 10, 1993.

Hon. JOSEPH R. BIDEN, Jr.,
Chairman, Committee on the Judiciary,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has reviewed S. 298, a bill to amend title 35, United States Code, with respect to patents on certain processes, as ordered reported by the Senate Committee on the Judiciary on April 8, 1993. CBO estimates that enactment of S. 298 would result in no significant costs to the federal government and in no costs to state and local governments. Enactment of S. 298 would not affect direct spending or receipts. Therefore, pay-as-you-go procedures would not apply to the bill.

Title I of S. 298 would expand the definition of non-obvious subject matter for purposes of patentability. The title also would prohibit the Patent and Trademark Office from holding invalid a patent claim for a process solely because the end product or the items used in the process lack novelty or are obvious.

Title II would make liable for patent infringement those who import, sell, or use patented biotechnological material without the patent holder's authorization.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is John Webb.

Sincerely,

ROBERT D. REISCHAUER,
Director.

VIII. Regulatory Impact Statement

In compliance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the committee has concluded that no significant additional regulatory impact would be incurred in carrying out the provisions of this legislation. After due consideration, the committee concluded that the changes in existing law contained in the bill will not increase or diminish any present regulatory responsibilities of the U.S. Department of Commerce or any other department or agency affected by the legislation.

IX. Changes in Existing Law

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 298, as reported, are shown as follows (existing law proposed to be omitted is enclosed in brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

UNITED STATES CODE

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TITLE 35—PATENTS

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CHAPTER 10—PATENTABILITY OF INVENTIONS

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§ 103. Conditions for patentability; non-obvious subject matter

(a) A patent may not be obtained through though the invention is not identically disclosed or described as set forth in section 102 of this title, if 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. Patentability shall not be negatived by the manner in which the invention was made.

(b) Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. (Added November 8, 1984, Public Law 98–622, sec. 103, 98 Stat. 3384.)

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

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

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

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

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

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

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

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

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CHAPTER 14—ISSUE OF PATENT

* * * * * * *

§ 154. Contents and term of patent

(a) Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, *for the term of seventeen years,* subject to the payment of fees as provided for [in this title] *in this title, (1)* of the right to exclude others from making, using, or selling the invention throughout the United States [and, if the invention], *(2) if the invention* is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process, *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,* referring to the specification for the particulars thereof. A copy of the specification and drawings shall be annexed to the patent and be a part thereof. (Amended July 24, 1965, Public Law 89–83, sec. 5, 79 Stat. 261; December 12, 1980, Public Law 96–517, sec. 4, 94 Stat. 3018; August 23, 1988, Public Law 100–418, sec. 9002, 102 Stat. 1563.)

(b) For purposes of this section, the term "biotechnological material" is defined as any material (including a host cell, DNA sequence, or vector) that is used in a biotechnological process as defined under section 103(d).

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CHAPTER 28—INFRINGEMENT OF PATENTS

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§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.

* * * * * * *

(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.

CHAPTER 29—REMEDIES FOR INFRINGEMENT OF PATENT, AND OTHER ACTIONS

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§ 282. Presumption of validity; defenses

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

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103D CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
103–728

APPLICATIONS FOR PROCESS PATENTS

SEPTEMBER 20, 1994.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BROOKS, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 4307]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred the bill (H.R. 4307) to amend title 35, United States Code, with respect to applications for process patents, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. EXAMINATION OF PROCESS PATENT APPLICATIONS FOR OBVIOUSNESS.

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

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

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

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

"(b)(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if—

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

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

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

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

"(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.".

79–006

SEC. 2. PRESUMPTION OF VALIDITY; DEFENSES.

Section 282 of title 35, United States Code, is amended by inserting after the second sentence of the first paragraph the following: "Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1).".

SEC. 3. EFFECTIVE DATE.

The amendments made by section 1 shall apply to any application for patent filed on or after the date of the enactment of this Act and to any application for patent pending on such date of enactment, including (in either case) an application for the reissue of a patent.

EXPLANATION OF AMENDMENT

Inasmuch as H.R. 4307 was reported with a single amendment in the nature of a substitute, the contents of this report constitute an explanation of that amendment.

SUMMARY AND PURPOSE

The purpose of H.R. 4307 is to provide for a modified examination by the Patent and Trademark Office (PTO) of certain process claims. Under the provisions of H.R. 4307, a process will not have to undergo a separate review of nonobviousness under certain conditions. If the process uses or produces a patentable composition of matter, the process will be determined nonobvious for the purpose of examination of process claims. The expedited review will resolve the delays and inconsistent determinations faced by process patent applicants under present PTO practices without harm to the basic principles of patentability.

COMMITTEE ACTION AND VOTE

A reporting quorum being present, the Judiciary Committee ordered reported an amendment in the nature of a substitute for the bill on June 29, 1994 by voice vote.

The Judiciary Committee's Subcommittee on Intellectual Property and Judicial Administration, a reporting quorum being present, ordered reported an amendment in the nature of a substitute to the Committee on June 16, 1994 by voice vote.

HEARINGS

The Subcommittee on Intellectual Property and Judicial Administration held a hearing on H.R. 4307 on May 5, 1994. The witnesses at the hearing were Mr. Michael Kirk, Administrator for Legislation and International Affairs, Patent and Trademark Office, United States Department of Commerce; Mr. Gerald Mossinghoff, President, Pharmaceutical Research and Manufacturers of America (formerly known as Pharmaceutical Manufacturers Association); Ms. Lisa Raines, Vice President, Government Relations, Genzyme Corporation, testifying on behalf of the Biotechnology Industry Organization; Mr. Roger Smith, Assistant General Counsel, IMB Corporation; and, Mr. Richard Waterman, General Patent Counsel, Dow Chemical Company.

A hearing on related legislation, H.R. 760, was held by the Subcommittee on Intellectual Property and Judicial Administration on June 9, 1993. The witnesses at the hearing were The Honorable

Rick Boucher, Congressman, 9th District, Virginia; The Honorable Dennis DeConcini, Senator, Arizona; Mr. Michael Kirk, Acting Commissioner, United States Patent and Trademark Office, United States Department of Commerce; Mr. G. Kirk Raab, Raab, Chief Executive Officer, Genentech, Inc., testifying on behalf of the Biotechnology Industry Organization (formerly known as the Industrial Biotechnology Association and the Association of Biotechnology Companies); Mr. Steven M. Odre, Vice-President for Intellectual Property, Amgen, Inc.; Mr. William L. LaFuze, President, American Intellectual Property Law Association; and, Mr. Robert Armitage, testifying on behalf of the Intellectual Property Owners, Inc., and on behalf of the National Association of Manufacturers.

DISCUSSION

BACKGROUND

Patents can be granted on any invention that is included within the statutory subject matter provisions, including processes under 35 U.S.C. § 101.[1] A patent on an invention gives the patent owner the right to exclude others from making, using or selling that invention. A process patent may be obtained for a new method of use or new method of making a product. A process patent can be infringed if the process is used in making any product or used in any manner covered by the process patent. If a patent is obtained on a product, the owner of the patent can prevent the manufacture, the sale or the importation of that particular product in the United States. The owner of a United States patent cannot prevent the manufacture or sale of that patented product in another country, unless a patent is obtained in that country.

It is not uncommon to seek a product patent with process claims relating to the same invention. A process can be described in simple terms such as a new method of draining swamps to more complex processes detailing the exact steps that take place when a starting material is pasteurized, pressurized, radiated or subjected to other procedures. Product and process patents claims are each subject to examination under the same principles of patent law, including examining criteria such as novelty, nonobviousness, and usefulness.

If a patent containing process claims is granted on the manufacturing process or development process of a particular product, then the owner of the patent also can prevent the manufacture or sale of a product made using that process. Under the provisions of the Process Patent Amendments Act of 1988, the process owner also can prevent importation of the product if the product is made overseas using the patented process.[2] A patent may be obtained on the

[1] 35 U.S.C. § 101 states: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

[2] The Process Patent Amendments Act of 1988 was contained in The Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100–418 (1988) and is found at 35 U.S.C. § 271(g): "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 liable as an infringer, if the importation, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no

Continued

starting materials or materials used in a process but unless a patent on the process is obtained (or a patent on the final product), the final product could be produced overseas and imported back into the Untied States for sale without infringing the patent on the materials used in the process.

A problem arises in those situations in which the final product produced by a process may not be patentable. Without a patent on the final product or a patent on the process, the original developer of the product cannot take advantage either of basic product patent protection or the process patent protection permitted under the Process Patent Amendments Act of 1988.[3]

Under present patent law, an owner of a product patent can prevent others in the United States from using or making a patented product even in the absence of a process patent. The value of the process patent is the ability to prevent others from importing a non-patentable product that was made by use of a protected process.

H.R. 4307 and related predecessor bills were developed as a result of two conflicting and irreconcilable decisions issued by the Court of Appeals for the Federal Circuit, *In re Durden,* 763 F.2d 1406 (Fed. Cir. 1985) and *In re Pleuddemann,* 910, F.2d 823 (Fed. Cir. 1990).

In re Durden concerned a process patent claim which had been rejected by the PTO. The case involved a chemical process. The applicants for the patent argued on appeal that while individual process steps were obvious, the use of a novel and nonobvious starting material and the production of a new and nonobvious product meant that the process should be patentable. The Court concluded that the use of a new starting material and/or the development of a patented product did not automatically ensure the nonobviousness of a process or the grant of a process patent. The Court noted that if every process using a new or novel material was granted a patent, then simple processes such as dissolving or heating would be patentable when using a new compound.[4]

Following this case, there were complaints from various industry groups that the PTO was automatically rejecting process claims under circumstances similar to *In re Durden.* In the subsequent case of *In re Pleuddemann,* the Court emphasized that *In re Durden* was not to be read as a "per se" rule against patenting old processes using new starting materials or producing new products. The Court stated that each invention had to be viewed as a whole and considered on its individual facts.[5]

In the holding of *In re Pleuddemann,* the Court distinguished *In re Durden* on the grounds that fact situation involved a process of "making" and *In re Pleuddemann* involved a process of "using."[6] The Court did not specifically overrule *In re Durden* but relied on

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adequate remedy under this title for infringement on account of the importation or other use or sale of that product. 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."

[3] The amendments were intended to provide protection to domestic U.S. process patent holders against foreign companies using the U.S. patented process overseas and importing the resulting product into the U.S. without any recourse by the process patent owner for infringement.

[4] *In re Durden,* 763 F.2d 1406, 1410 (Fed. Cir. 1985).

[5] *In re Pleuddemann,* 910 F.2d 823,/828 (Fed. Cir. 1990).

[6] *Id.,* at 827.

the distinction of "using" versus "making." The distinction between the two types of processes was lost on many and caused others to manipulate phrasing in developing patent applications to ensure that processes were "using" instead of "making." At two different hearings of the Subcommittee on Intellectual Property and Judicial Administration testimony was provided which indicated that in several cases the patent applicant had originally written a claim as a "making" process. After the examiner rejected the claims on the basis of *In re Durden,* the claims were rewritten as a "using" claim and were approved by the examiner.[7]

The holdings in *In re Durden* and *In re Pleuddemann* have led to inconsistent practices by the PTO in the examination of applications for process patents. The result has been that some process patents have been granted without any delay or controversy while other applications, similar in nature, have been rejected or required to be defended at length with the patent examiner.[8]

Legislation was developed as a response to a perceived failure on the part of the PTO to grant process patents based on the *In re Durden* decision and the resulting importation problem due to the inability of inventors to obtain process patents.[9] While the holdings of *In re Durden* and *In re Pleuddemann* have been applied generally, the resulting problems were considered to affect particularly biotechnology applications because of the nature of the products produced. In the case of biotechnology products, the final product for commercial sale often is not patentable because the final product is a naturally occurring substance despite the fact that it has never been able to be produced before in commercially viable quantities.[10]

The final unpatentable product is often developed or synthesized through the use of a "host cell" that has been genetically altered in a way to produce the final product in large quantities. The host cell is usually patentable. The issue is whether the process, by which the final product is produced, also can be patented.

Since the host cell is patented, the host cell cannot be used in the United States without the patent owner's permission and no products can be produced in the United States from that host cell. Without a United States process patent, however, the host cell can be taken offshore and used to make the final product. The final product produced from the host cell can be imported back into the United States for commercial sale. The owner of the patented host cell has no recourse because there is no "use" of the patented host cell in the United States and thus no infringement. Since there is

[7] Legislative Hearing on H.R. 4307, before the Subcommittee on Intellectual Property and Judicial Administration of the House Committee on the Judiciary, 103d Cong., 2d Sess. (May 5, 1994) (Testimony of Lisa J. Raines); Amending Title 35, United States Code, With Respect To Patents On Certain Processes, Hearing on H.R. 760, before the Subcommittee on Intellectual Property and Judicial Administration of the House Committee On The Judiciary, 103d Cong., 1st Sess., Serial No. 32 (June 9, 1993) (Testimony of George W. Enbright, p. 42; testimony of Steven M. Odre, p. 51).

[8] Legislative Hearing on H.R. 4307, supra (Testimony of Lisa J. Raines); Amending Title 35, United States Code, With Respect To Patents On Certain Processes, Hearing on H.R. 760, supra (Testimony of G. Kirk Raab, pp. 37, 53, Appendix 1; testimony of Steven M. Odre, p. 49).

[9] Legislative Hearing on H.R. 4307, supra (Testimony of Lisa J. Raines); Amending Title 35, United States Code, With Respect To Patents On Certain Processes, Hearing on H.R. 760, supra (Testimony of George W. Enbright, p. 42).

[10] Legislative Hearing on H.R. 4307, supra (Testimony of Lisa J. Raines); Amending Title 35, United States Code, With Respect To Patents On Certain Processes, Hearing on H.R. 760, supra (Testimony of Michael Kirk, p. 22; testimony of George W. Enbright, p. 41).

no patent on the process by which the final product was produced, the importation of the product cannot be challenged.

Clearly, obtaining a process patent could solve the importation problem for the biotechnology industry as well as other industries facing similar difficulties. H.R. 4307 is necessitated by the difficulty of obtaining timely and adequate process patent protection under present court rulings and PTO interpretation.

The approach taken in H.R. 4307 is not industry specific as were some prior bills designed to take care of the problem. Industry specific legislation, particularly in the context of patent law, generally is not favored. The issue addressed by the legislation, and by the judicial interpretations which preceded it, is a general principle of patent law. It is not restricted nor intended to apply to only one industry, but rather to all of those industries for which appropriate process patent protection has been unduly difficult to obtain. The reach of the problem is demonstrated by *In re Durden,* which involved a chemical patent.

As a result of concerns raised by certain industries as to the impact of a broad change in patent law, the amendment in the nature of a substitute takes a middle ground approach. The computer industry, the electronics industry and others raised questions as to the ability of certain patent owners to secure patents that would have such extensive coverage that public domain processes would be combined with new products to obtain patent coverage to the detriment of the industry.[11] The chemical industry also raised questions as to the scope and potential infringement of patents issued under the revised examination process proposed in H.R. 4307, as introduced.

H.R. 4307, as introduced, used the term "product" instead of "composition of matter" throughout the bill. In an effort to address the concerns of the various industry groups, the legislation was narrowed by replacing "product" with "composition of matter."

The term "composition of matter" is one of the several statutory classes of patentable subject matter allowed under 35 U.S.C. § 101. The term, for purposes of determining patentable subject matter, has been used in United States patent law since 1793.[12] While there have been few cases that interpret the term, those cases have narrowly interpreted "composition of matter" as it is applied to classes of inventions.[13] The statutory class of "composition of mat-

[11] Legislative Hearing on H.R. 4307, supra (Testimony of Roger S. Smith; testimony of Richard G. Waterman); Amending Title 35, United States Code, With Respect To Patents On Certain Processes, Hearing on H.R. 760, supra (Testimony of Robert A. Armitage, p. 70.

[12] Patent Act of 1793, ch. 11, 1 Stat. 318 (1783).

[13] See, generally, *Diamond* v. *Chakrabarty,* 447 U.S. 303 (1980) (micro-organism is patentable subject matter as a nonnaturally occurring manufacture or composition of matter); *Cochrane* v. *Badische Anilin,* 111 U.S. 293 (1884) (an improvement in certain non-natural dyes could be considered a composition of matter); *Powder Co.* v. *Powder Works.* 98 U.S. 126 (1878) (composition of matter includes compounds and mixtures such as nitroglycerin and gunpowder); *Jacobs* v. *Baker,* 74 U.S. 295 (1868) (secret guard chamber within a jail although considered "compounded of matter" was determined not to be a composition of matter); *P.E. Sharpless Co.* v. *Crawford Farms, Inc.,* 287 F. 655 (S.D.N.Y. 1923) (composition of matter could be the intermixture of two or more ingredients, which develop a different or additional properties that the several ingredients individually do not possess in common); *Shell Development Company* v. *Watson,* 149 F. Supp. 279 (D.D.C. 1957) (composition of matter covers composition of two or more substances and includes composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids).

ter" has not been interpreted to be interchangeable with the other statutory classes of invention.

In cases involving the patentability of computer software and a determination of what falls within 35 U.S.C. § 101 statutory subject matter, software programs have not been characterized as compositions of matter.[14] The term is perceived not to encompass more traditional articles of manufacture or machines and to be less broad than the term "product."

The legislation impacts only one element of patentability—the element of nonobviousness. There is no guarantee of patentability if the process claim satisfies the special nonobviousness provisions of the revised § 103. The process must still satisfy all other requirements of patentability, including the utility requirement under 35 U.S.C. § 101 and the enabling provisions of 35 U.S.C. § 112 which require sufficient description provisions of the invention and claims, described in "full, clear and concise, and exact terms," so that others skilled in the art can use the process. Process claims patented pursuant to the proposed revisions of § 103 would not enjoy greater protection than process claims granted under present law.

Resolution of this problem will provide both certainty for patent applicants and protection against unfair foreign competition. Once process patents are awarded, foreign companies will not be able to take advantage of the inability of the United States manufacturer to obtain a product patent. There is no question, as some opponents have argued, that, in many cases, a product patent provides better protection than a process patent against foreign manufacture and importation of the product into the United States. However, if a product patent is unobtainable because of the nature of the final product, it is essential that some other protection be afforded. In the opinion of the Committee, the appropriate protection is a process patent and the infringement protection pursuant to 35 U.S.C. § 271(g) against importation of products resulting from foreign use of the patented process.

The unpredictability of the patent examination process has become a critical problem for development of new technologies, such as biotechnology. With a mitigation of uncertainty, industry can better assess the chances and risks associated with the patent application process. The granting of a process patent will no longer depend on the chance of the wording of a claim or the preference of an examiner in applying the holding of *In re Durden* versus the holding of *In re Pleuddemann.*

A concern raised by some industry groups other than the biotechnology industry, such as the chemical industry, and certain members of the patent bar has been the possibility of overreaching process claims which would seek to extend the scope of patent protection far downstream or upstream of the actual inventive contribution. Such action, it has been argued, would unnecessarily restrict commercial and research activities. The concern is that the bill's elimination of an obviousness examination of the process claims, once the invention of the composition of matter that is used

[14] See, generally, *Diamond* v. *Diehr,* 450 U.S. 175 (1981); *Arrhythmia Research Tech.* v. *Corazonix Corp.,* 958 F.2d 1053 (Fed. Cir. 1992); *In re Abele,* 684 F. 2d 902 (C.C.P.A. 1982).

or made by the process was found novel and nonobvious, would result in the submission of process claims seeking to patent, and thereby control, extended processes encompassing steps already in the public domain.

H.R. 4307 is in no way intended to reduce or eliminate any requirements of the patent laws of the United States other than providing, upon election of an applicant, that a process using or resulting in a composition of matter found upon examination to be novel and nonobvious, shall likewise be found nonobvious. The chemical industry believes that, because of the numerous entities in its chain of technology development, product development, production and commerce, it could be vulnerable to overbroad patent claims which could disrupt chemical businesses and create a disincentive to innovate. The Committee believes that H.R. 4307 will not result in overreaching process claims that could have the effect of unreasonably restricting research and commercial activities.

It is intended that processes using or resulting in a composition of matter, otherwise patentable to the applicant, be entitled to full patent protection including the benefits of enforcement, specifically of 35 U.S.C. §271(g). It is not intended by this bill that applicants be given the right to extend patent claims to all upstream or downstream processes leading to or resulting from use of the patented composition of matter in a way that would create infringement liability on parties not making or using the patented composition of matter, except as is already provided under existing law for infringement.

The European Patent Office uses an examination process similar to that proposed in H.R. 4307. The applicable guidelines which control examination state:

> If an independent claim is new and nonobvious, there is no need to investigate the obviousness of any claims dependent thereon. Similarly, if a claim to a product is new and nonobvious, there is no need to investigate the obviousness of any claims for a process which inevitably results in the manufacture of that product or any claims for use of that product * * *.[15]

The European examination provisions were discussed at the May 5, 1994 Subcommittee on Intellectual Property and Judicial Administration hearing which produced no evidence to suggest that this particular examination provision had created any difficulties for any patent owners, including the American owners of European issued patents.[16] There was no suggestion that the patents issued by the European Patent Office were less valid because of this "failure to examine" the process claims independently for nonobviousness.

There are presently two cases being considered by the U.S. Court of Appeals for the Federal Circuit which may have a bearing on the matter considered in H.R. 4307.[17] The Court still has not issued opinions in these cases which might resolve the perceived inconsistencies of the two previous opinions of the Court, *In re Durden* and

[15] See, Guidelines For Examination in the European Patent Office, Part C, Guidelines for A Substantive Examination, September 1989, Chapter IV, § 9. Inventive Step, Subsection 9.5a.

[16] Legislative Hearing on H.R. 4307, supra.

[17] *In re Ochiai*, No. 92–1446 (Fed. Cir. filed July 22, 1992); *In re Brouwer*, No. 92–1225 (Fed. Cir. filed March 11, 1992).

In re Pleuddemann. The two cases were argued in November 1992. There has been no indication when the Court might issue the decisions. In any event, it is by no means certain that the two cases will resolve the underlying issues.

The PTO testified before the Subcommittee that it does not believe it can resolve the problem administratively because of the two seemingly conflicting Court opinions. The PTO expressed concerns that an administrative solution might be open to future legal challenge.[18]

LEGISLATIVE HISTORY

H.R. 4307 was introduced on April 28, 1994. A related predecessor bill, H.R. 760, was introduced on February 3, 1993. H.R. 760 would amend Title 35 to change the standard for granting process patents only for biotechnological processes and to amend the standards for patent infringement relating only to the importation of products using patented biotechnological materials. On June 9, 1993 the Subcommittee held a legislative hearing on H.R. 760.[19]

H.R. 760 is a successor to H.R. 1417 which was considered in the 102d Congress, and to H.R. 3957 and H.R. 5564, which were considered in the 101st Congress. During the 102d Congress, legislative hearings were held on H.R. 1417 on November 21, 1991.[20] Another day of oversight hearings were held on November 20, 1991 concerning general issues related to biotechnology.[21] There were hearings held on September 25, 1990 on H.R. 3957 and H.R. 5564 during the 101st Congress.[22]

During the 102d Congress, the Senate considered S. 654, legislation similar to H.R. 1417. The Senate Judiciary Committee approved the bill on November 25, 1991 and it was reported favorably to the full Senate on March 11, 1992.[23] The Senate approved a compromise version of S. 654 on September 18, 1992 which was not taken up by the House. The compromise was specific only to biotechnology.

The Senate companion bill to H.R. 760, S. 298, was approved by the Senate Judiciary Committee on May 6, 1993. the bill was reported favorably to the full Senate on July 1, 1993 and was passed by the full Senate on July 15, 1993.[24] H.R. 760 and S. 298 are identical to S. 654 as passed by the Senate in the 102d Congress.

The premise of all the legislative efforts has been similar, although the proposals have ranged from generic changes in patent law to biotechnology specific solutions to the problems believed to be faced primarily by that industry.

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[18] Legislative Hearing on H.R. 4307, supra, (Testimony of Michael Kirk).

[19] Amending Title 35, United States Code, With Respect To Patents On Certain Processes, Hearing on H.R. 760, supra.

[20] Biotechnology Patent Protection Act of 1991, Hearing on H.R. 1417, Before the Subcommittee on Intellectual Property and Judicial Administration of the House Committee on the Judiciary, 102d Cong., 1st Sess., Serial No. 101 (November 21, 1991).

[21] Biotechnology Development and Patent Law, Hearing Before the Subcommittee on Intellectual Property and Judicial Administration of the House Committee on the Judiciary, 102d Cong., 1st Sess., Serial No. 98 (November 20, 1991).

[22] Biotechnology Patent Protection, Hearing on H.R. 3957 and H.R. 5564, Process Patent Amendments of 1990, Before the Subcommittee on Courts, Intellectual Property and the Administration of Justice of the House Committee on the Judiciary, 101st Cong., 2d Sess., Serial No. 122 (September 25, 1990).

[23] S. Rep. 102–260, 102d Cong., 2nd Sess. (1992).

[24] S. Rep. 103–82, 103d Cong., 1st Sess. (1993).

CONCLUSION

The extended history of H.R. 4307 and related legislation speaks to the need to have the inconsistency existing in case law and in PTO examination procedures resolved. Testimony over several Congresses has amply illustrated the difficulties faced by patent applicants in satisfying the dictates of two seemingly inconsistent Court opinions, *In re Durden* and *In re Pleuddemann.* The inability of the PTO to make changes administratively and the lack of direction from the Court makes Congress the appropriate forum to address this matter.

The award of patent protection ensures a greater degree of protection for businesses in the United States. Companies are faced with competition from overseas competitors who derive the benefits from the innovations and investments of American companies without any of the risks. A resolution of the examination practices for processes that are linked to a patentable compositions of matter would ensure that United States manufacturers can better protect the extensive investment made in research and development.

SECTION-BY-SECTION ANALYSIS

SECTION 1. EXAMINATION OF PROCESS PATENT APPLICATIONS FOR OBVIOUSNESS

Section 1 adds a clarifying standard to 35 U.S.C. § 103. Section 103 requires that for a patent to be obtained, the subject matter must be nonobvious. Under § 103, if the "subject matter as a whole would have been obvious at the time the invention was made * * *." a patent cannot be granted.

The section provides that an application with a process claim which is linked to a patentable composition of matter will be considered nonobvious under § 103. If a patentable composition of matter is either produced by a process or used as part of a process, the process claims will be considered nonobvious.

The examination of the process claims will proceed under the revised provisions of § 103 if the applicant for patent elects in a timely fashion to proceed under the new subsection.

For a process patent application to be considered nonobvious under the proposed revision of § 103, there are several conditions which must be met. First, the claims to the process and the patentable composition of matter, to which the process is linked, must be contained in the same application or have the same effective filing date. Second, the patentable composition of matter and the process must be owned by the same person or be subject to an obligation of assignment to the same person. Third, the composition of matter used or resulting from the process sought to be patented must be novel under § 102, must be nonobvious on its own merits and must, in all other ways, be patentable.

If process claims are granted under this standard, they must appear in the same patent containing the claims to the patentable composition of matter used or made by the process. If there are two different patents issued for the composition of matter and for the process claims relating to the composition of matter, the process patent must expire on the same date as the patent on the composi-

tion of matter, notwithstanding the statutory patent term set pursuant to 35 U.S.C. § 154.

SECTION 2. PRESUMPTION OF VALIDITY; DEFENSES

This section amends 35 U.S.C. § 282 which elaborates on the validity of each patent and patent claims. Since a process claim examined under the terms of § 103(b)(1) is linked to a patentable composition of matter for a determination of nonobviousness, if a claim for such composition of matter is held invalid, the process to which it is linked, shall no longer be entitled to rely on that claim for a presumption of nonobviousness.

SECTION 3. EFFECTIVE DATE

The amendments will apply to any patent application filed on or after date of enactment and any patent applications pending on the date of enactment.

EFFECTIVE DATE

The Act and the amendments made by the Act shall take effect on the date of enactment.

COMMITTEE OVERSIGHT HEARINGS

In compliance with clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, the Committee reports that the findings and recommendations of the Committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Representatives, are incorporated in the descriptive portions of this report.

COMMITTEE ON GOVERNMENT OPERATIONS OVERSIGHT FINDINGS

No findings or recommendations of the Committee on Government Operations were received as referred to in clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives.

NEW BUDGET AUTHORITY AND TAX EXPENDITURES

Clause 2(l)(3)(B) of House rule XI is inapplicable because this legislation does not provide new budgetary authority or increased tax expenditures.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

In compliance with clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, the Committee sets forth, with respect to the bill H.R. 4307, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 403 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 1, 1994.

Hon. JACK BROOKS,
Chairman, Committee on the Judiciary,
U.S. House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has reviewed H.R. 4307, a bill to amend title 35, United States Code, with respect to applications for process patents, as ordered reported by the House Committee on the Judiciary on June 29, 1994. CBO estimates that enactment of H.R. 4307 would result in no significant costs to the federal government and in no costs to state and local governments. Enactment of H.R. 4307 would not affect direct spending or receipts. Therefore, pay-as-you-go procedures would not apply to the bill.

H.R. 4307 would expand the definition of a non-obvious process for purposes of considering its patentability. The bill also would remove the presumption of validity for a process patent if its approval was based on a product patent that was later held to be invalid.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is John Webb.

Sincerely,

ROBERT D. REISCHAUER,
Director.

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee estimates that H.R. 4307 will have no significant inflationary impact on prices and costs in the national economy.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

TITLE 35, UNITED STATES CODE

* * * * * * *

PART II—PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS

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CHAPTER 10—PATENTABILITY OF INVENTIONS

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§ 103. Conditions for patentability; non-obvious subject matter

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if 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. Patentability shall not be negatived by the manner in which the invention was made.

(b)(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if—

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

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

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

(A) shall also contain the claims to the composition of matter used in or made by that process, or

(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.

(c) Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

PART III—PATENTS AND PROTECTION OF PATENT RIGHTS

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CHAPTER 29—REMEDIES FOR INFRINGEMENT OF PATENT, AND OTHER ACTIONS

* * * * * * *

§ 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity. *Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under sec-*

tion 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1).

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Calendar No. 421

102D CONGRESS *2d Session*	SENATE	REPORT 102-260

BIOTECHNOLOGY PATENT PROTECTION ACT OF 1991

MARCH 11 (legislative day, JANUARY 30), 1992.—Ordered to be printed

Mr. BIDEN, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany S. 654]

The Committee on the Judiciary, to which was referred the bill (S. 654) relating to an amendment to title 35, United States Code, to provide conditions for the patentability of certain patents for processes, and for other purposes, having considered the same, reports favorably thereon with an amendment to S. 654 in the nature of a substitute and recommends that the bill as amended do pass.

CONTENTS

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. CONDITIONS FOR PATENTABILITY; NON-OBVIOUS SUBJECT MATTER.

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

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

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

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

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

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

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

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

SEC. 2. PRESUMPTION OF VALIDITY.

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

SEC. 3. EFFECTIVE DATE.

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

I. PURPOSE

The purpose of S. 654 is to amend our Patent Code to afford needed additional protection for process inventions, primarily in the field of biotechnology. S. 654 will eliminate barriers to process patenting thereby increasing innovation and thus stimulating the development of new products and processes.

II. LEGISLATIVE HISTORY

In the 101st Congress, Senator DeConcini and Representative Boucher each introduced the Biotechnology Patent Protection Act of 1990. Representative Boucher introduced H.R. 3957, on February 6, 1990. S. 2326 was then introduced by Senator DeConcini on March 22, 1990. The bills differed only in their effective date.

After introducing these bills, Representative Boucher and Senator DeConcini as well as Representative Kastenmeier, then Chairman of the House Judiciary Subcommittee on Courts, Intellectual Property and the Administration of Justice, solicited the views of the Department of Commerce. In a July 1990 response letter, the Department expressed agreement with the need for the legislation but voiced objections to the provisions amending section 337 of the 1930 Tariff Act, as well as to title 35 of the United States Code, which would extend enforcement of the rights of a patent claiming biotechnological material used in the manufacture of a recombinant product.

In consideration of the views of the Department of Commerce, Representative Boucher introduced a second bill, H.R. 5664, in the 101st Congress. There was no further action on these bills in the 101st Congress.

In the 102d Congress, Senator DeConcini introduced S. 654, the Biotechnology Patent Protection Act of 1991 on March 13, 1991,

with Senators Hatch, Kohl, Lautenberg, Specter, and Grassley. Companion legislation, H.R. 1417, was introduced in the House of Representatives by Representative Boucher on the same day. As introduced in the 102d Congress, S. 654 and H.R. 1417 had identical language to H.R. 5664 from the 101st Congress.

In conjunction with the introduction of S. 654, Senator DeConcini also wrote to the Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, Harry F. Manbeck, Jr., requesting the administration's position on the legislation as well as its views on alternative language proposed by DeConcini. Senator DeConcini expressed concern in the letter that the positive effects of S. 654 would be unnecessarily circumscribed by limiting the legislation to overrule *In re Durden*[1] in cases only where a single patent issues. The result, he contended, may be that examiners in the Patent and Trademark Office could frustrate the intent of the new law by making a restriction requirement.

Senator DeConcini suggested in the correspondence that a possible solution to this problem would be to amend the legislation so that its benefits would also be provided in cases where the product and process become separated by virtue of such a restriction requirement. Thus, recognizing the need to address the potential ramifications of the language of S. 654 as introduced, DeConcini enclosed in his letter to Manbeck the text of a suggested amendment to S. 654.[2]

On June 10, 1991 Wendell L. Willkie II, the General Counsel of the Department of Commerce, responded to the DeConcini letter, outlining the Administration's position on S. 654 and their comments on the suggestive alternative language in the DeConcini correspondence. Willkie stated that the Administration had concluded that common inventorship was not essential as long as there was common ownership of the product and process inventions. However, Willkie asserted that the Administration continued to believe that "different patents issued on the product and on the process of making or using that product must be set to expire on the same date unless a process of making or using a product is an invention separately patentable from the product." In response the Administration stated its support for S. 654 and suggested its own alternative language.

On June 12, 1991 the Subcommittee on Patents, Copyrights and Trademarks held a public hearing on S. 654. On July 25, 1991, the subcommittee reported S. 654 to the full Committee with an amendment in the nature of a substitute that incorporated the suggested language in the Willkie letter. S. 654 as amended favorably passed the Judiciary Committee unanimously on November 21, 1991.

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[1] 763 F.2d 1406 (Fed. Cir. 1985).

[2] The DeConcini proposed amendment contained the following language and would amend sec. 103 of title 35.

> A process of making or using a machine, manufacture, or composition of matter is not unpatentable 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, claims to the process and claims to the machine, manufacture, or composition of matter are entitled to the same effective filing date and appear either (a) in the same patent, or (b) in different patents which (1) are owned by the same person, (2) name the same inventor, and (3) are set to expire on the same date.

III. Discussion

A. BACKGROUND

"Biotechnology" is a broad term coined to encompass man-made processes which manipulate biological components. The Office of Technology Assessment defines biotechnology as "any technique that uses living organisms (or substances from those organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses." [3]

Biotechnology is a multidisciplinary science, combining biology and chemistry, material science and physics, computer science and medicine. It is used in diverse industries from pharmaceuticals, agriculture, and veterinary medicine to environmental cleanup and new energy resources. Widely known products made with the use of biotechnology include home pregnancy tests, diagnostic tests for human immunodeficiency virus (HIV), insulin, and sweeteners such as aspartame (the sweetener marketed as Nutrasweet) and the enzyme used to turn glucose into highly sweet fructose.

While the term "biotechnology" is relatively new, man has used processes involving biological organisms for centuries. Yeast is a fungus, familiarly used for fermentation to produce alcoholic beverages and leaven dough. The best beef and pork in the world are the result of selective cross-breeding, more recently with artificial insemination. Penicillin and other naturally occurring antibiotics are commercially produced with micro-organisms and the 1992 Winter Olympic Games produced snow by using organisms that promote ice crystallization.

Today's biotechnology is far more complex than that of yesteryear. In the 1950's Watson and Crick discovered the DNA double helix, a complex molecule made of billions of single atoms, which functions as a genetic template. The basis of much of the biotechnology industry today is the elucidation of relatively minute sections of DNA.

Until the advent of the computer chip and advanced electronics, efforts to determine the makeup and function of these minute sections was essentially trial and error. However, biotechnology has made it possible to create and test molecules of choice with relative precision. And the capability to create these organic molecules has created dramatic breakthroughs in the ability to make human life better.

All living things are composed of cells, from tiny, one-celled bacteria to giant multicellular whales. Each cell contains a complete genetic "blueprint" of the organism encoded in an enormously long molecule called deoxyribonucleic acid (DNA). DNA guides the construction and functions of the organism by directing cellular synthesis of proteins.

Sections of DNA called genes contain chemical instructions that guide the cell's machinery in constructing proteins. Proteins give living things their unique characteristics. Some proteins give structure to living organisms. Others mediate the chemical reactions

[3] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: Ownership of Human Tissues and Cells-Special Report." OTA-BA-337 (Washington, DC: U.S. Government Printing Office, March 1987).

that are necessary for organisms to function. Proteins are sequences of amino acids whose major role is to act as catalysts for chemical reactions in the body. When acting as a biocatalyst, proteins are known as enzymes.

Some people are born with problems with their DNA in certain genes. These genetic defects scramble the coded instructions in the gene, causing the cell to produce a defective protein or no protein at all. This has serious consequences to the health of the individual; if the function of the defective or missing protein is important, the person may die without it. In other cases, normally functioning genes may develop problems due to infection, age, or other factors. These genes may develop abnormal characteristics, leading in some cases to cancer or arthritis.

Because proteins can regulate chemical reactions, determining which specific protein performs which function is vitally important in fighting disease. For example, by preventing a given chemical reaction from occurring by removing or tying up the reaction-specific catalyst, it may be possible to stop the growth of diseased cells. Or, by enabling a given reaction to occur by supplying a missing gene which codes for an enzyme in an organism's own system, an organism's own system can be forced to produce beneficial chemicals, such as insulin. It is this marvel of science that biotechnology has opened up.

Several technologies are available for performing these feats. Today's hot technologies include recombinant DNA and monoclonal antibodies. Recombinant DNA technology uses naturally occurring enzymes to clip out fragments of DNA and then insert the fragment containing a specific gene into a different cell, altering that cell so that it carries a new genetic message. This technology has enabled scientists to successfully generate human insulin with E. coli, which are bacteria inhabiting the human digestive tract.

These micro-organisms then grow at a tremendous rate; some have a generation time of 30 minutes or less. The multiple copies of the microbe produce large amounts of the desired protein. Consequently, proteins that occur in minute quantities in nature can be produced in large quantities through recombinant technology. The proteins produced by the micro-organisms are also free of viral contamination that might contaminate the protein if extracted from human tissue or fluids.

This complex research is expensive and can take many years to yield practical results. It is estimated that it takes an average of 12 years to bring a drug from discovery through final FDA approval.[4] In 1988 the average cost of discovery and bringing a single drug to market exceeded $100 million,[5] and today exceeds $230 million.[6] In combination, private- and government-sponsored research exceeded

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[4] Thompson, "High Cost of Rare Diseases, When Patients Can't Afford to Buy Lifesaving Drugs", Washington Post Health, June 25, 1991.

[5] Lippard, "Molecular Basis of Drug Design," in Biotechnology and Materials Science-Chemistry for the Future 31 (1988).

[6] "Anticompetitive Abuses of the Orphan Drug Act: Invitation to High Prices: Hearing Before the Senate Judiciary Subcommittee on Antitrust, Monopolies and Business Rights," 102d Cong., 2d sess. (January 21, 1992). (statement of John P. McLaughlin, vice president and General Counsel of Genentech, Inc.) (citations omitted).

$4 billion in 1988, and the industry is growing because of the enormous need for biotech products.[7]

Commercial successes in 1990 garnered the U.S. biotechnical industry sales of $2.9 billion, doubling the sales of 1989 and quadrupling the amount for 1988.[8] However the biotechnology industry faces formidable challenges in continuing this groundbreaking research. Japan has targeted pharmaceutical development as an industry of vital economic importance.[9] Europe invests heavily in biotech research and actually leads in the production of monoclonal antibodies.[10]

B. BIOTECHNOLOGY PATENTING

Because of intense competition, the biotechnology industry relies heavily on intellectual property law to fend off piracy of its inventions. However, patent protection for biotech products is sometimes difficult to obtain under current U.S. law and unavailable in many foreign countries. Without such protection it becomes difficult to recoup R&D costs which, in turn, stifles invention.[11]

Biotech products are often the recombinant versions of a naturally occurring substance usually found in an animal or plant. When the scientific literature or other available information reveals that the naturally occurring version of the protein has been purified to some extent, even if it has not been definitively characterized, a patent for the recombinant version may be denied for lack of novelty. In patent law terms, the product has already been discovered.[12] 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. Inventors of some recombinant versions of naturally occurring products have found it difficult to obtain adequate patent protection because of the mere existence of literature disclosing incomplete information about the natural protein.[13]

A second hurdle inventors must overcome is that a patent application for a recombinant product may be denied because it is deemed obvious, and thus unpatentable, despite its novelty. In many cases, although the protein has never before been isolated in a substantially pure form or the product is not well characterized prior to the recombinant synthesis, if its basic properties and some aspects of its structure are known, the Patent and Trademark

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[7] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: U.S. Investment in Biotechnology—Special Report." OTA-BA-401 (Washington, DC: U.S. Government Printing Office, July 1988).

[8] "Biotechnology Patent Protection Act of 1991: Hearing on S. 654 Before the Judiciary Subcommittee on Patents, Copyrights and Trademarks," 102d Cong., 1st sess. (1991) (statement of Henri Termeer, president and CEO of Genzyme Corporation on behalf of Industrial Biotechnology Association).

[9] The President's Council on Competitiveness. "Report on National Biotechnology Policy" at 5, Washington, DC (February 1991).

[10] Id.

[11] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: Patenting Life—Special Report." OTA-BA-370 at 101 (Washington, DC: U.S. Government Printing Office, April 1989).

[12] See generally, Murashige, "Section 102/103 Issues in Biotechnology Patent Prosecution," 16 A.I.P.L.A. Q.J. 294, 303-04 (1988-89); Andrews, "Unaddressed Question in the Amgen Case," New York Times, Mar. 9, 1991, sec. 1, at 30, col. 5.

[13] A natural protein is a protein encoded by DNA that occurs in nature. A recombinant protein is a protein encoded by DNA that has been produced by combining genetic material from at least two different sources.

Office may assert that the use of recombinant technology to make a pure form of such a product is obvious. The ability to obtain a patent for a purified version of a protein to block the use of a process to make commercially viable quantities of a recombinant version of the protein has been criticized.[14]

The mere existence of a previously discovered protein should not, by itself, always preclude the issuance of a patent for a recombinantly created version of the same protein. The rationale under which a patent may be granted for a product existing in nature is that in its natural form, such a product is not available and useful to the public without further isolation and purification. The law as currently expressed provides that to be considered obvious:

> the differences between the subject matter sought to be patented *and the prior art* [must be] 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.[15]

The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) and its predecessor, the U.S. Court of Customs and Patent Appeals (C.C.P.A.), have reiterated many times that an applicant's disclosure in a patent application cannot be treated as prior art in determining the obviousness of the claimed invention.[16] The court has also emphasized that the invention as a whole must be considered in assessing obviousness.[17] Finally, the court has cautioned that a patentability determination must be made as of the time the invention was made, and not as part of a hindsight reconstruction of the invention given the applicant's disclosure.[18]

Because questions of novelty and obviousness often preclude product patents, the biotechnology industry has become heavily dependent upon process patents. Yet, product patents are generally considered to provide better protection for drugs than process or use patents because the latter two types usually can be circumvented more easily. Additionally, it may be more difficult to detect the infringement of a process patent than the product patent because products are available to the public, but the processes used to make them are kept secret within the walls of a manufacturer.

The biggest problem facing the United States biotech industry is the lack of clarity in the rules for patentability of biotech processes. Sound investment decisions require a degree of economic certainty. The lack of legal certainty for biotechnology process patents, generated from case law, affects the probability of return on

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[14] See Merges & Nelson, "On the Complex Economics of Patent Scope," 90 Colum. L. Rev. 839, 903-04 (1990). See also *Scripps Clinic & Research Found.* v. *Genentech, Inc.*, 666 F.Supp. 1379 (N.D. Cal. 1987), modified on reconsideration, 678 F.Supp. 1429 (N.D. Cal. 1988); *Scripps Clinic & Research Found.* v. *Genentech, Inc.*, 707 F.Supp. 1547 (N.D. Cal. 1989); *Scripps Clinic & Research Found.* v. *Genentech, Inc.*, 724 F.Supp. 690 (N.D. Cal. 1989), aff'd in part rev'd in part, vacated in part, *Scripps Clinic & Research Found.* v. *Genentech, Inc.*, Nos. 89-1541, -1542, -1543, -1646, 1647 (Fed. Cir., Mar. 11, 1991) (LEXIS, Genfed library, U.S. App. file 3925) (reserving for further analysis by the district court the issue whether a patent on a purified protein should serve to block a patent on a recombinant version of the same protein).

[15] 35 U.S.C. 103 (1988) (emphasis added).

[16] See *Panduit Corp.* v. *Dennison Mfg. Co.*, 810 F.2d 1561, 1567-88 (Fed. Cir. 1987), cert. denied, 481 U.S. 1052 (1987); *In re Katz*, 687 F.2d 450 (C.C.P.A. 1982).

[17] See *John Deere Co.* v. *Graham*, 333 F.2d 529 (8th Cir. 1964), aff'd, 383 U.S. 1 (1966).

[18] *In re Kuehl*, 475 F.2d 658, 663-65 (C.C.P.A. 1973).

investment and has had a stifling effect on some venture capital investments.[19]

C. CASE LAW

In re Durden

A major defect in U.S. patent case law has led the Patent and Trademark Office to an inconsistent application of *In re Durden*,[20] a nonbiotech patent case, to important biotechnology-derived processes. As recognized by a Patent Office supervisor, the use of this case as a basis for rejecting process patent claims in biotechnology is on the rise.[21] This is so because many examiners have been routinely applying the *Durden* case to biotechnology.

Durden involved a challenge to the denial of a patent for a process to make a novel chemical. The process was similar to that of a previously issued patent; however, the *Durden* process utilized a novel and nonobvious, but related, starting material and produced a novel and nonobvious, but related, end product. It appeared predictable once the new starting material and new product were disclosed, that the old process would work with the new starting material to produce the new product. The court in *Durden* concluded, in the narrow factual context of that case, that the chemical process, otherwise obvious, was not patentable even though both the specific starting material employed and the product obtained, were novel and nonobvious.

The Federal Circuit thus held, on the facts before it, that a process 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 believes that it cannot interpret section 103 to require that a process be held patentable merely because a patentable material was either used or made by that process.

Consequently, the Patent Office has cited *Durden* in denying patents to processes for producing proteins which use as starting materials, DNA, vectors or biological micro-organisms made by recombinant DNA technology. This denial of process claim protection is routine even if the starting materials are found by the Patent Office examiner to be novel and non-obvious and, therefore, patentable in their own right.

Durden precludes needed patent protection for biotechnology processes and has been roundly criticized by commentators and legal practitioners.[22] Since the *Durden* decision it has become in-

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[19] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: Patenting Life—Special Report." OTA-BA-370 at 101 (Washington, DC: U.S. Government Printing Office, April 1989).

[20] 763 F. 2d 1406 (Fed. Cir. 1985).

[21] Wiseman, "Biotechnology Patent Practice—A Primer," 16 A.I.P.L.A. Q.J. 394, 411 (1988–89), see generally Litman, "Obvious Process Rejection Under 35 U.S.C. 103," 71 J. Pat. & Trademark Off. Soc'y (1989); Wegner, "Much Ado About Durden," 71 J. Pat. & Trademark Off. Soc'y 785 (1989).

[22] See Murashige, "Section 102/103 Issues in Biotechnology Patent Prosecution," 16 A.I.P.L.A. Q.J. 294 (1988–89); Wegner, "Much Ado About Duren," 71 J. Pat. & Trademark Off. Soc'y, 785 (1989); Comment, "The Elimination of Process: Will the Biotechnology Patent Protection Act

Continued

creasingly difficult to obtain process patent protection in the United States for genetic engineering inventions. Although some inventors overcome *Durden* rejections, the uncertainty in this area of the law has lead to inconsistent results by examiners.

The inconsistent application of *Durden* by the Patent and Trademark Office has led to severe delay or denial of issuance of process patent protection to deserving inventors. The Federal Circuit acknowledges that there have been conflicting views on this issue both in the Patent Office Board of Appeals and in the C.C.P.A.[23]

Moreover, case law exists in this area which conflicts with the *Durden* reasoning and which would be more appropriately applicable to biotechnology process patents.[24] The application of *Durden* by the Patent Office to biotechnology cases, which involve microorganisms, conflicts with *In re Mancy.*[25]

In *Mancy*, the court held that a standard method of culturing microorganisms to produce antibiotics could not be treated as prior art in determining the patentability of a similar method using a patentable microbe to produce an antibiotic therefrom. In other words, novelty and nonobviousness of the microbe imparted patentability to a method using it.

To the detriment of biotechnology process patent applicants, the Patent and Trademark Office has felt constrained to follow *Durden* rather than *Mancy*. Troubling is the fact that the reasoning in *Mancy* is the law for inventions in Europe and Japan, where the patenting of process inventions that use patentable starting materials has long been recognized.[26]

In re Pleuddemann

The Federal Circuit revisited the issue of the patentability of processes in *In re Pleuddemann.*[27] In that case the patentee had a patent to a starting material that he used in a process to make a patentable final product. Apart from the use of the patented starting material, the method (process) of making the final product was admittedly already known. The Federal Circuit held that the method of using the patented starting material to produce the patentable final product was patentable in this particular case.

Although the Federal Circuit attempts to distinguish *Pleuddemann* from *Durden,* it is difficult, if not impossible, to reconcile these two cases. It is not clear why a *method of using a starting material* should be treated differently, for purposes of determining non-obviousness, from a *method of making the end product.* Yet, under *Pleuddemann,* the former is per se non-obvious, while the latter is not.

Revive Process Patents?," 24 John Marshall L. Rev. 263 (1990); McAndrews, "Removing the Burden of Durden Through Legislation: H.R. 3957 and H.R. 5664," 72 J. Pat. & Trademark Off. Soc'y 1188, (1990); Beier and Benson, "Biotechnology Patent Protection Act," 68 U. of Denver L. Rev. 173 (1991).

[23] *Durden,* 763 F. 2d at 1409.

[24] See, e.g., *In re Mancy,* 499 F.2d 1989 (C.C.P.A. 1974). See also *In re Kuehl,* 475 F.2d 658 (C.C.P.A. 1973).

[25] 499 F.2d 1289 (C.C.P.A. 1973).

[26] "Biotechnology Patent Protection Act of 1991: Hearing on S. 654 Before the Judiciary Subcommittee on Patents, Copyrights and Trademarks," 102d Cong., 1st sess. (1991) (statement of Henri Termeer, president and CEO of Genzyme Corp. on behalf of Industrial Biotechnology Association).

[27] 910 F.2d 823, 15 U.S.P.Q. 2d 1738 (Fed. Cir. 1990).

The Patent Office and the courts continue to apply *Durden* and reject claims involving methods of using novel DNA sequences and other recombinant intermediates to make protein products. The classic *Durden* rejection maintains that a process of making a protein using a novel DNA sequence is obvious, because others have previously used the same process with other DNA sequences to make other proteins. As a result of *Pleuddemann,* it might be asserted that recombinant DNA patent applications no longer need fear such a *Durden* rejection of process-of-using claims which are based upon a novel DNA sequence encoding a desired protein *X*. Unfortunately, the situation is not clear.

A prudent attorney certainly would seek to use *Pleuddemann* to the client's advantage by rephrasing "a recombinant DNA process of making protein *X*" into a *Pleuddemann*-style process-of-using claim, such as, "contacting DNA with cellular enzymes or with a transcription/translation apparatus." However, it is not clear that such a semantic change would always be successful. For example, an examiner could assert that such a claim was really a process-of-making claim in disguise.

Alternatively, some have argued that given the right case on appeal, the Federal Circuit might, at some future date, reverse *Durden* by applying a *Pleuddemann*-type analysis finding that *making* is also not obvious because the *Durden*-type rejection presumes the new starting material or novel product to be prior art. While this possibility is consistent with the analysis in *Pleuddemann,* there clearly is no certainty that such a future decision will ever occur, particularly as the court has rejected this approach over the past 20 years.

Some had hoped the November 9, 1990, rehearing of *In re Dillon*[28] would provide guidance regarding *Durden* and perhaps overrule it. In very clear dicta, the Federal Circuit summarized its attitude regarding *Durden* as follows:

> 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.*[29]

Therefore, *Durden* is very much alive, but weakened and unpredictable in its application by the individual patent examiner, the Board of Appeals and Interferences, and the courts.

Durden-type rejections remain an even greater problem following *Pleuddemann* because the Federal Circuit explicitly avoided ques-

[28] 919 F.2d 688 (Fed Cir. 1990) (en banc).
[29] Id. at 695 (emphasis in original).

tioning *Durden* as good law, and distinguished *making* and *using* as two different types of process claims.[30] A patent applicant may ask what new route to protect a recombinant DNA process claim is available after *Pleuddemann?* The answer is not clear because *Pleuddemann* does not address that question. One could rephrase *making* claims as *using* claims and then wait years to see whether the Patent Office and the courts will accept this semantic manipulation as a means of avoiding a *Durden*-style obviousness rejection. The committee believes that congressional passage of clear statutory language that explicitly removes the *Durden*-style rejection is a more direct and unambiguous route to protect recombinant DNA method-of-making protein claims.

The Patent and Trademark Office, along with the Industrial Biotechnology Association and other witnesses, has opined that *Pleuddemann* has not clarified the law and leaves patent applicants unable to predict with reasonable certainty whether they can obtain process patents of this nature. Testifying before the House Judiciary Subcommittee on Courts, Intellectual Property and the Administration of Justice, Commissioner Manbeck stated that, "the distinction between *Pleuddemann,* on the one hand, and *Durden* and *Albertson* [31] on the other hand is esoteric, at best.[32] Appearing with Commissioner Manbeck, the Solicitor of the Patent and Trademark Office, Fred McKelvey, responded affirmatively to Representative Boucher's inquiry that the *"Pleuddemann* decision doesn't do anything to clear up the confusion that exists in the law currently." [33]

Manbeck further testified that the Patent Office will continue to have difficulty during the 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 product.

D. SENATE BILL 654

S. 654 amends section 103 of title 35, the Patent Code, to effectively avoid the Federal Circuit decision in *In Re Durden.* S. 654 resolves the *Durden* dilemma by providing that a process of making or using a product will not be considered obvious if the starting material or resulting product is novel and non-obvious. Additionally, S. 654 provides certainty and needed incentives for the biotechnology industry, incentives to grow and not to be deterred by our patent laws. It will allow the United States to continue to lead biotechnology research world-wide and will provide essential protection to an industry that generates billions of dollars for the U.S. economy.

By providing a mechanism to avoid *Durden,* S. 654 provides a solution to another deficiency in our law that has created an obstacle for the U.S. biotechnology industry. Under present U.S. patent law,

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[30] *Pleuddemann,* 910 F.2d at 827.

[31] 332 F.2d 379, 141 U.S.P.Q. 730 (C.C.P.A. 1964).

[32] "Biotechnology Patent Protection: Hearing on H.R. 3957 and H.R. 5664 Before the Subcomm. on Courts, Intellectual Property and the Administration of Justice of the House Comm. on the Judiciary," 101st Cong., 2d sess. 18 (1990) (statement of Harry F. Manbeck, Jr., Asst. Sec. and Commissioner of Patents and Trademarks, U.S. Dept. of Commerce).

[33] Id. at 27.

the holder of a patent to a host cell would be able to preclude another from using the cell in the United States. However, without patent protection for the process of using that cell, the inventor has no effective remedy against someone who takes the patented host cell to another country, uses it to produce a protein, and imports that protein back into the United States.

The importance of process claim protection is illustrated by Amgen, Inc.'s inability to prevent importation of erythropoietin (EPO) into the United States from Japan by Chugai Pharmaceutical Co. This most controversial and public patent dispute in biotechnology [34] involved the innovative product, recombinant erythropoietin (rEPO), as litigated in *Amgen, Inc.* v. *Chuqai Pharmaceutical Co.*[35] Amgen's patent did not contain a claim to a process of making EPO using patented host cells. The International Trade Commission (ITC) refused to interpret the claims to the host cells alone as constituting a process claim under existing law. Consequently, Amgen was denied relief based upon its patented host cells since the ITC held that such claims to "host cells" per se were not process of making claims.

In this case, Amgen had conducted groundbreaking scientific research enabling it to produce commercially viable commodities of rEPO.[36] This major scientific and medical advance did not, however, give Amgen sufficient patent rights to prevent importation of competing products from Japan even though Amgen's competitors could not produce rEPO within the United States without infringing Amgen's patents.

If at the end of a long and uncertain period of discovery of innovated drug products and development of patented technology, a U.S. innovator must watch helplessly as infringing foreign imitators reap the harvest to which the innovator is entitled, there will be a substantial diminution or elimination of the economic incentives intended to encourage those efforts. Ultimately, the reforms of this legislation are likely to provide sufficient protection to overcome the lack of host cell protection experienced by American companies such as Amgen. However, by providing a mechanism to avoid *Durden*, this legislation provides only a partial solution to the deficiency in our law that created obstacles to U.S. biotechnology companies such as Amgen.

Amgen is not the only entity facing this problem today. There are other small biotechnology companies and universities that have obtained only host cell protection. Indeed, some of these entities may have given up rights to process claims in order to receive protection of the host cell. If the loophole in the patent laws is not closed, these companies and universities could also experience the problem faced by Amgen—competition from a foreign competitor who can do what no U.S. manufacturer may lawfully do. Thus, the

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[34] See, e.g., Andrews, "Mad Scientists", Bus. Month, May 1, 1990, at 54.

[35] 9 U.S.P.Q. 2d 1833 (D. Mass. 1989); 13 U.S.P.Q. 2d 1737 (D. Mass. 1989): 927 F.2d 1200 (Fed. Cir. 1991); 14 U.S.P.Q. 2d 1734 (Fed. Cir. 1990).

[36] Amgen is currently alone on the market with its version of EPO, EOPGEN, because of provisions of the Federal Food, Drug, and Cosmetic Act, § 527, 21 U.S.C. 360 (cc) (1988). Under this act, the sponsor of a new drug or biologic can, if certain market criteria are met, obtain market exclusivity for a period of 7 years. In this case, Amgen obtained market exclusivity because it established that rEPO was a safe and effective therapy for treatment of chronic renal failure, the relevant patient population of which is less than 200,000.

committee is hopeful that this issue ultimately may be resolved by Congress in the near future.

Although not the primary purpose of the legislation, S. 654 also offers the ancillary benefit of reducing the increasingly high transaction costs associated with patent prosecutions and litigation by providing certainly in the law for both the Patent and Trademark Office and the process patent applicants.[37] The high costs of such litigation may seriously drain the research budgets of biotech companies.[38] Unfortunately, the chilling effect of a process rejection has fallen most heavily upon those who lack the resources to pursue process patents, small companies and universities. The most disturbing potential ramification of inadequate intellectual property protection is that some promising therapies will be pursued.

S. 654 is consistent with the structure of existing law and avoids the unnecessary creation of sui generis forms of intellectual property protection. Unlike the situation faced by Congress in the context of mask work protection, S. 654 does not fundamentally alter the requirements of patentability. Rather, S. 654 clearly modifies the test for obtaining a process patent for all forms of invention. Most importantly, S. 654 is the least drastic alternative to solve a limited problem.

In many respects this legislation is considered a continuation of the Congressional policy behind the Process Patent Amendments Act of 1988. Without appropriate process claims in their patents, biotechnology inventors cannot take advantage of the benefits of the Process Patent Amendments Act of 1988. As a consequence, the advantages of the Process Patent Amendments Act of 1988 are essentially nullified for the biotechnology industry. Finally, S. 654 will make our laws in greater harmony with those of our trading partners.

S. 654 has the support of the administration, the Industrial Biotechnology Association, the Pharmaceutical Manufacturers Association, the National Association of Manufacturers, the National Venture Capital Association, the Association of University Technology Managers, and the America Council on Education as well as numerous universities in their own capacity.

IV. Vote of the Committee

On July 25, 1991, the Subcommittee on Patents, Copyrights and Trademarks, a quorum being present, reported S. 654, with an amendment in the nature of a substitute, to the Committee on the Judiciary by voice vote.

On November 21, 1991, the Committee on the Judiciary, a quorum being present, favorably reported by unanimous consent S. 654 as reported by the subcommittee.

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[37] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: Patenting Life—Special Report." OTA-BA-370 at 56-58 (Washington, D.C. : U.S. Government Printing Office, April 1989). U.S. Congress, Office of Technology Assessments.

[38] U.S Congress, Office of Technology Assessment, "Commercial Biotechnology: An International Analysis" 403 (1984).

V. Section-by-Section Analysis

Section 1. Conditions for patentability; non-obvious subject matter

Section 1 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 non-obvious. To obtain this determination, the product and process claims must be sought to be patented in the same application. Continuing applications would also be eligible where the specified conditions are met.

The amendment to section 103 would thus provide a mechanism for applicants 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 line of the decision in *In re Durden,* 763 F.2d 1406 (Fed. Cir. 1985). Process patents granted under 103(c) would not affect an existing process patent right.

With regard to patent terms, section 1 provides that process claims that are granted the benefits of the non-obviousness rule under subsection 103(c) must coterminate with the product claims on which they depend for patentability. The purpose of this provision is to prevent a patent applicant from obtaining an effective patent term in excess of 17 years (and any applicable patent term extension) on essentially a single invention.

The committee does not intend to deprive independently patentable inventions of the patent terms to which they are entitled under current law. Therefore, if an applicant elects to demonstrate the independent patentability of a process, notwithstanding a possible *Durden* rejection, rather than rely on the non-obviousness rule established in the legislation, he or she is entitled to the full 17-year term (and any applicable patent term extension) available under current law for both product and process inventions, without coterminations.

Thus, applicants have the option of either demonstrating the independent patentability of a process (as must be done under current law) or proceeding under the non-obviousness rule established by this legislation. Independent patentability may be demonstrated, for example, by showing the non-obviousness of the process.

Applicants who unsuccessfully attempt to demonstrate independent patentability do not forfeit their right to amend their application to one that relies upon the rule established by this legislation. However, an applicant who so amends his application is required to have his process claims coterminate with his product claims. In such cases, patent term extension will continue to be available to extend the term beyond the termination date otherwise established.

Section 1 would simplify and provide certainty in the determination of patentability of processes using or making novel and non-obvious products, for applicants who comply with its requirements. It would also make our patent law consistent with the patent granting process now practiced in the European and Japanese Patent Offices.

Section 2. Presumption of validity

Since an applicant may rely on the non-obviousness rule established in this legislation to expedite issuance of his or her process claims rather than risk the costs and delays involved in overcoming a *Durden* rejection, section 2 provides that there is no presumption that process claims are invalid if the product claims, which form the basis for invoking the non-obviousness rule, are invalidated. Any litigation should provide the patentee with the opportunity to prove that the process claims are independently patentable.

Section 3. Effective date

The amendments made by this act are effective on the date of enactment. The amendments affect all patents granted on or after the date of enactment, all patent applications pending on the date of enactment, and all patent applications filed after the date of enactment. Patent applications include applications for reissuance of a patent.

VI. Cost Estimate

In accordance with paragraph 11(a), rule XXVI, of the Standing Rules of the Senate, the committee offers the Report of the Congressional Budget Office:

U.S. Congress,
Congressional Budget Office,
Washington, DC, November 25, 1991.

Hon. Joseph R. Biden, Jr.,
Chairman, Committee on the Judiciary,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has reviewed S. 654, a bill to amend title 35, United States Code, with respect to patents on certain processes, as ordered reported by the Senate Committee on the Judiciary on November 21, 1991. CBO estimates that enactment of S. 654 would result in no significant costs to the federal government and in no costs to state and local governments. Enactment of S. 654 would not affect direct spending or receipts. Therefore, pay-as-you-go procedures would not apply to the bill.

S. 654 would expand the definition of non-obvious for purposes of patentability. The bill also would prohibit the Patent and Trademark Office from holding patent claims invalid solely because the product or inputs themselves lack novelty or are obvious.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is John Webb, who can be reached at 226–2860.

Sincerely,

Robert D. Reischauer,
Director.

VII. Regulatory Impact Statement

In compliance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the committee has concluded that no significant additional regulatory impact would be incurred in carrying

out the provisions of this legislation. After due consideration, the committee concluded that the changes in existing law contained in the bill will not increase or diminish any present regulatory responsibilities of the U.S. Department of Commerce or any other department or agency affected by the legislation.

VIII. Changes in Existing Law

In compliance with paragraph 12 of Rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 654 as reported are shown as follows (existing law proposed to be omitted is enclosed in brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

UNITED STATES CODE

* * * * * * *

TITLE 35—PATENTS

* * * * * * *

CHAPTER 10—PATENTABILITY OF INVENTIONS

* * * * * * *

§ 103. Conditions for patentability; non-obvious subject matter

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if 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. Patentability shall not be negatived by the manner in which the invention was made.

(b) Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. (Added November 8, 1984, Public Law 98-622, sec. 103, 98 Stat. 3384.)

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

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

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

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

* * * * * * *

CHAPTER 29—REMEDIES FOR INFRINGEMENT OF PATENT, AND OTHER ACTIONS

* * * * * * *

§ 282. Presumption of validity; defenses

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

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PATENTS ON BIOTECHNOLOGICAL PROCESSES; AND TO AUTHORIZE USE BY REGULATION THE REPRESENTATION OF "WOODSY OWL"

HEARING

BEFORE THE

SUBCOMMITTEE ON COURTS AND INTELLECTUAL PROPERTY

OF THE

COMMITTEE ON THE JUDICIARY HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTH CONGRESS

FIRST SESSION

ON

H.R. 587

TO AMEND TITLE 35, UNITED STATES CODE, WITH RESPECT TO PATENTS ON BIOTECHNOLOGICAL PROCESSES

AND

H.R. 1269

TO AMEND THE ACT OF JUNE 22, 1974, TO AUTHORIZE THE SECRETARY OF AGRICULTURE TO PRESCRIBE BY REGULATION THE REPRESENTATION OF "WOODSY OWL"

MARCH 29, 1995

Serial No. 16

Printed for the use of the Committee on the Judiciary

U.S. GOVERNMENT PRINTING OFFICE

92-223 CC WASHINGTON : 1995

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-052061-4

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PATENTS ON BIOTECHNOLOGICAL PROCESSES; AND TO AUTHORIZE USE BY REGULATION THE REPRESENTATION OF "WOODSY OWL"

WEDNESDAY, MARCH 29, 1995

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

The subcommittee met, pursuant to notice, at 10:02 a.m., in room 2237, Rayburn House Office Building, Hon. Carlos J. Moorhead (chairman of the subcommittee) presiding.

Present: Representatives Carlos J. Moorhead, Howard Coble, Bob Goodlatte, George W. Gekas, Elton Gallegly, Charles T. Canady, Patricia Schroeder, John Conyers, Jr., Xavier Becerra, and Rick Boucher.

Also present: Representatives Barney Frank and Sheila Jackson Lee.

Staff present: Thomas E. Mooney, counsel; Mitch Glazier, assistant counsel; Sheila Wood, secretary; and Betty Wheeler, minority counsel.

OPENING STATEMENT OF CHAIRMAN MOORHEAD

Mr. MOORHEAD. The Subcommittee on Courts and Intellectual Property will come to order.

Today the subcommittee is conducting a hearing on two bills introduced by myself and a number of members of the subcommittee. H.R. 587 deals with patents on biotechnological processes, and H.R. 1269, introduced at the request of the Department of Agriculture, to authorize the Secretary to prescribe by regulation the representation of the U.S. environmental symbol "Woodsy Owl" of the Department of Agriculture. We would have heard testimony on the redesigning of one of the best known U.S. symbols for environmental improvement. However, the Department was unable to get the necessary clearance for testimony.

Mrs. SCHROEDER. Mr. Chairman, you're making this up.

[Laughter.]

Mr. MOORHEAD. You know, it sounds silly, but they want it. So if it's important to the Department of Agriculture and it certainly doesn't cost anything to do, we might just as well give them what they want. "Woodsy Owl" and his solution, "Give a hoot. Don't pollute" is recognized by over 70 percent of all the American house-

holds and over 90 percent of the households which have children under the age of 10. The costume is 26 years old, and they want some assistance in redesigning it. They want the protection that comes from that.

So we'll get their testimony in later this week, and if we need more testimony, we'll set it for another day.

The first bill that we have before us, H.R. 587, the biotech process patent bill, has been considered by this subcommittee in the past two Congresses. Although the scope of the legislation has been modified, the primary issue under consideration is the extent to which the patent system provides adequate protection for biotechnological developments. To date, this bill will be the subcommittee's sixth hearing on the issue. Similar legislation has passed the Senate three times and the House once. Proponents of the legislation maintain that unfriendly court decisions block them from getting necessary and appropriate patent protection. As a result, predatory foreign competitors are attempting to explain the deficiencies in U.S. law by making our firms' products overseas and importing them back into the United States with impunity.

There is no question that the biotechnology industry plays a significant role in the U.S. economy. Witnesses today will testify to that fact and also will emphasize the heavy investment of capital required to bring new biotechnology products to the market. Many of the biotechnological products being developed result in drugs needed to treat a wide arrange of illnesses and conditions, ranging from the common medical problems to life-threatening diseases.

The legislation mandates a change in patent law exclusively for biotechnological products. Industry-specific legislation is an approach we tried to avoid in the past. However, the various generic proposals we've seen in the past few years attracted criticism and opposition. Opponents turned to—or perhaps I should say we have returned to—solutions which are limited to changes in the law affecting only biotechnology. While that may be unusual in the history of U.S. patent law, it may prove to be the best solution. This is the type of bill that passed the Senate twice in the last Congress.

[The bills, H.R. 587 and 1269, follow:]

I

104TH CONGRESS
1ST SESSION

H. R. 587

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

IN THE HOUSE OF REPRESENTATIVES

JANUARY 19, 1995

Mr. MOORHEAD (for himself, Mr. BOUCHER, Mr. SENSENBRENNER, Mr. COBLE, Mr. FRANK of Massachusetts, Mr. GALLEGLY, Mr. GOODLATTE, Mr. GEKAS, Mr. BONO, Mr. CANADY of Florida, and Mr. HOKE) 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 biotechnological processes.

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

BIOTECHNOLOGICAL PROCESS PATENTS

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

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

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

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

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

"(b)(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a 'biotechnological process' using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if—

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

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

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

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

"(B) shall, if such composition of matter is claimed in another patent, be set to expire on the

same date as such other patent, notwithstanding section 154.

"(3) For purposes of paragraph (1), the term 'biotechnological process' means—

"(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to—

"(i) express an exogenous nucleotide sequence,

"(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

"(iii) express a specific physiological characteristic not naturally associated with said organism;

"(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and

"(C) a method of using a product produced by a process defined by (A) or (B), or a combination of (A) and (B).".

SEC. 102. PRESUMPTION OF VALIDITY; DEFENSES.

Section 282 of title 35, United States Code, is amended by inserting after the second sentence of the first paragraph the following: "Notwithstanding the preceding sentence, if a claim to a composition of matter is held in-

valid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1).".

SEC. 103. EFFECTIVE DATE.

The amendments made by section 101 shall apply to any application for patent filed on or after the date of enactment of this Act and to any application for patent pending on such date of enactment, including (in either case) an application for the reissuance of a patent.

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104TH CONGRESS
1ST SESSION

H. R. 1269

To amend the Act of June 22, 1974, to authorize the Secretary of Agriculture to prescribe by regulation the representation of "Woodsy Owl".

IN THE HOUSE OF REPRESENTATIVES

MARCH 21, 1995

Mr. MOORHEAD (for himself, Mr. SENSENBRENNER, Mr. COBLE, Mr. BONO, and Mr. BOUCHER) introduced the following bill; which was referred to the Committee on the Judiciary

---

A BILL

To amend the Act of June 22, 1974, to authorize the Secretary of Agriculture to prescribe by regulation the representation of "Woodsy Owl".

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 1 of the Act entitled "An Act to prevent the unauthorized manufacture and use of the character 'Woodsy Owl', and for other purposes", approved June 22, 1974 (16 U.S.C. 580p), is amended—

(1) by amending paragraph (1) to read as follows:

"(1) the term 'Woodsy Owl' means the name and representation of a fanciful owl who furthers the slogan, 'Give a Hoot, Don't Pollute', originated by the Forest Service of the United States Department of Agriculture;"; and

(2) in paragraph (2) by striking the period at the end and inserting "; and".

O

Mr. MOORHEAD. I would like to yield at this time to my good friend, Pat Schroeder, the ranking Democratic member of the subcommittee.

Mrs. SCHROEDER. Well, Mr. Chairman, I thank you very much for yielding, and I join you in welcoming our witnesses today. I really came to see what the fashion police had recommended for "Woodsy Owl," but I guess he won't be here this time.

But I really do think it's very critical, too, that our patent law keep pace with the technology changes that we see, so that the areas in biotechnology can have a level playing field vis-a-vis our competitors. I agree with you this bill has strong bipartisan support. It's supported from the administration, and we hope that the roadblocks that we saw when we passed this before have been removed by making it more industry-specific. So let's hope that this time this can be the last hearing we have to have, and maybe this will end up being a real bill with a real signing. And I thank you for moving forward on it.

Mr. MOORHEAD. I recognize the gentleman from Florida.

Mr. CANADY. I have no statement.

Mr. MOORHEAD. I will recognize the gentleman from Virginia, Mr. Boucher.

Mr. BOUCHER. Thank you very much, Mr. Chairman, for holding this hearing today and also for the very strong partnership that you and I have enjoyed over the past several years as we have worked to assure a proper level of patent protection for the biotechnology industry. H.R. 587 will assure that protection, and I'm very pleased to be joining with you in sponsoring the measure.

The problem that we face today in its simplest terms is that with reference to the biotechnology industry our patent law has a glaring deficiency which operates to the advantage of foreign firms that seek to exploit the American market by expropriating American innovation.

Through this Nation's history, the basic patent that was awarded to inventors was on the final product. It was new and original, and a product patent provided all the protection that was needed to secure the fruits of innovation, but product patents are typically not available in the world of biotechnology because the goal of the biotechnologist is to take beneficial substances that occur naturally in nature but in minute quantities and then manufacture those substances in large enough amounts to attain commercial viability. Since the final product is a substance that occurs in nature, the product itself is not subject to the award of patent.

Therefore, the biotechnology industry must rely on patents on the host cell, the DNA sequence, the vector, or other unique starting material and on the process that is applied to that starting material in order to achieve the creation of the final product. A patent on a novel starting material is effective if another manufacturer in this country uses it in violation of the patent, but our International Trade Commission lacks jurisdiction to exclude items manufactured overseas through the use of a starting material patented in the United States. The only meaningful protection U.S. investors can, therefore, receive that will be truly effective protection against foreign pirating of their work is on the process itself, and it is in

the award of process patents for biotechnology that the deficiency in our law exists.

In the 1985 decision *In re Durden,* the Court of Appeals for the Federal Circuit held that a known process applied to a novel starting material to create a known product does not meet the test of nonobviousness, and therefore, the process patent application was denied. Since that time, numerous process patents have been denied in similar circumstances. It should be noted that both in Europe and in Japan process patents are routinely available when a known process is tied to a novel starting material, and so the biotechnology industry in those regions obtains greater protection for its innovation than is typically available here in the United States. And that is the typical circumstance of the biotechnology patent application in which a known process is used upon a novel starting material.

Our International Trade Commission can exclude products made overseas using processes that are patented in the United States, but it cannot exclude the products if the only patent is on the starting material itself. In the absence of effective process patent protection, foreign firms have taken starting materials patented in the United States, applied a process for which patent protection was denied here, and then imported the product back into this country. It is that practice that we are attempting to prohibit. And our approach for doing so is by facilitating the award of process patents for biotechnology innovations by directing that these patents be awarded when the starting material is novel, even if the process has been used in other circumstances. The patent would be linked to those instances in which the process is used in conjunction with the novel starting material.

This reform is very much needed to protect and stimulate research investment in an enormously important industry. It was originated in the United States. It is producing new medicines that promote health and save lives, and it makes a major contribution to the United States, balance of trade. H.R. 587 offers a simple and effective solution to a major problem confronting the industry, and I very much hope, Mr. Chairman, that with your leadership and support from members of this subcommittee on both the Democratic and Republican side that we can report the measure favorably to the full committee and obtain House passage in the near future.

Thank you very much.

Mr. MOORHEAD. Thank you.

Our ranking member on the Committee on the Judiciary is here. John Conyers is recognized.

Mr. CONYERS. Thank you, Mr. Chairman.

I don't have as much detail as your cosponsor, Mr. Boucher, but I do want to signal support for the measure before us and the importance of the hearings here today. Obviously, we're taking a look at *Durden,* and I observe several things here.

First, this is a matter that could have been resolved by the courts but wasn't, and so it appears that congressional review is warranted, but there are two questions that hang over the effort that we have here today and I'd like to invite our witnesses to

make any comments about them, if they choose in the course of their presentations.

The first consideration is, how many cases has the *Durden* standard been used to reject claims for process patents generally and for biotech cases in particular? In other words, how serious is the problem of delays and is this particularly a problem for the biotechnology industry or does it extend really into a larger area, the chemical area, as well?

The second matter that I would like to hear comments from is that although I am sympathetic to industry-specific approaches, rather than to apply these new rules for all industries, as last year's bill did, what are the implications in the future for the Patent Office? Will there still be delays and inconsistencies for nonbiotechnology patent applications? In other words, is there still a problem with *Durden* that will remain until, if ever, the courts address this issue?

And, again, I think this hearing is right on time, and I thank the chairman for allowing me to make that statement.

Mr. MOORHEAD. The gentleman from Massachusetts, Mr. Frank.

Mr. FRANK. Thank you, Mr. Chairman. I notice that we have two bills on today, and I want to first say that I think it is essential that we move on the piece of legislation which is very important for our economy, but I would also like to speak about the process patent bill as well.

[Laughter.]

Mr. FRANK. And the Chair is to be commended for scheduling this hearing so quickly. This is a matter this subcommittee and committee acted on previously. It is a very important and very logical step forward. Keeping the law abreast of technology is impossible, but we can at least hold down the legs, and this is an effort to catch up legally with technology.

I know we have had varying opinions expressed on the question about whether or not it was industry-specific or broader, as the ranking minority member has mentioned. And my own view on this has been, frankly, that this is so important for the biotechnology industry that I could teach it round or I could teach it flat, in the words of the old standard of flexibility. Obviously, there were advantages to going forward with an industry-specific one because you don't engage some of the broader opposition, and I fully concur with the chairman's decision to go forward with this.

This is a very important piece of legislation. I, having sat through the hearing last year and listening to the arguments against it, was very unimpressed with them. No one has shown me that this does any damage. This is as close as you can usually come to a bill that does some good and no harm, and I hope that we will move it quickly and that it will not get entangled, as it previously has in the Senate, in their relevant issues and will go forward.

So I thank you for giving us a chance to vote on this bill and to take advantage of the great momentum created by the "Woodsy Owl" clothing issue to sneak this one through.

[Laughter.]

Mr. MOORHEAD. We have a guest member of the full committee here this morning, Ms. Jackson Lee from Texas. Do you have a comment you'd like to make?

Ms. JACKSON LEE. Mr. Chairman, not one that will take any more than a couple of seconds. First, to thank you and the ranking member for allowing me to join in on an issue that is extremely important to my district, the 18th District in Texas. For a long time in Houston the biotechnology community has talked about an opening statement that I see in one of the speaker's remarks, to be encouraged and to be enhanced. So I'm delighted to be able to participate in the hearing and to listen and certainly support the thrust of where we're going and applaud the sponsors of this legislation because I think this is taking us, clearly, into the 21st century.

Mr. MOORHEAD. Thank you.

Mr. FRANK. Mr. Chairman, I forgot, if I might, just one more word. The subcommittee where I'm ranking member has a bill on the floor today, and this may apply to some of my colleagues as well. The term limits constitutional amendment will have its brief last flicker of hope on the floor today, and I will, therefore, have to be there. And I just want to say that by way of explanation because I'll be leaving shortly, but my absence from this hearing is not a sign of lack of interest, but rather that we have to be down there on the floor.

Mr. MOORHEAD. Our first witness is from the Patent and Trademark Office, Mr. Dieter Hoinkes, the Senior Counsel at the Patent and Trademark Office, specializing in legislative matters and international affairs. He holds a degree in mechanical engineering from the University of Rochester and has earned his law degree from the George Washington University of School of Law. In recognition of his contributions, Mr. Hoinkes is the only Government official ever to have been elected a member of the International Association for the Protection of Intellectual Property. That's AIPPI, a worldwide association of over 6,500 intellectual property professionals. Mr. Hoinkes is no stranger to this subcommittee. He has provided us with advice and good counsel on pending legislation for many years. We're grateful for your input. We value your views very highly.

Our second witness will be Mr. Henry Linsert, chairman of the board of directors from Martek Biosciences Corp. Mr. Linsert has been chairman of the board since 1987 and their chief executive officer since 1988. He received a master of arts degree from George Washington University and a bachelor of arts from Duke University, both in economics.

Our last witness is Mr. Steven Odre, who serves as Amgen's vice president, associate general counsel for intellectual property. Mr. Odre received his bachelor's degree in chemistry from Union College and his masters degree in analytical biochemistry from Purdue University. Mr. Odre also earned a doctorate in law from Chicago Kent School of Law. You didn't miss very many schools. Mr. Odre lives with his family in Westlake Village, CA.

Welcome, gentleman. We have your written statements, which I ask unanimous consent be made a part of the hearing record, and I ask that you summarize your statements in 10 minutes or less. I will ask that the subcommittee hold their questions until all three panelists have completed their oral presentations.

Mr. Hoinkes, you may begin.

STATEMENT OF H. DIETER HOINKES, SENIOR COUNSEL, OFFICE OF LEGISLATIVE AND INTERNATIONAL AFFAIRS, PATENT AND TRADEMARK OFFICE, U.S. DEPARTMENT OF COMMERCE

Mr. HOINKES. Thank you, Mr. Chairman, for this generous introduction.

Mr. Chairman and members of the subcommittee, I am pleased to testify on H.R. 587, a bill that would amend our patent law to afford needed additional protection for inventions in the field of biotechnology. Our biotech industry needs encouragement to expand its research and development efforts, to continue its growth and competitiveness without falling victim to unfair foreign competition. And, as a consequence, the administration supports this bill.

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

We have previously discussed the example of an inventor who genetically engineers a host cell that is used to produce a product, such as a new protein pharmaceutical. The engineered host cell is likely to receive patent protection. The same cannot be said, however, for processes making or using that host cell, or even for the protein pharmaceutical itself.

As has been already stated, this may be because the processes are conventional combinations of well-known procedures or because the protein was known, even if only in trace quantities, before the inventor developed a way of producing it on a commercial scale. The result in both instances is that the inventor can take action only against someone using the host cell within the United States. A third party can, therefore, use the patented host cell outside of this country, import the resulting product, and effectively circumvent liability for patent infringement.

Judicial interpretations of the patentability of processes based on patentable starting materials or yielding patentable end products are in conflict and have been so over the past 30 years. And, therefore, the Patent and Trademark Office cannot interpret title 35, section 103, to find a process based on patentable starting materials or yielding a patentable end product not obvious as a matter of course. Rather, the Patent and Trademark Office has been forced to determine on a case-by-case basis whether a process is obvious in view of the prior art despite the fact that it is specifically based on a patentable starting material or results in a specific patentable end product.

As a consequence, without legislative guidance, patent applicants will continue to be unable to predict with reasonable certainty whether they can obtain process patent protection in situations where logically it should be provided. In this respect, the amendment proposed by H.R. 587 would simplify and provide certainty for applicants who comply with its requirements in the determination of patentability of certain biotechnological processes. This would make our patent law consistent, at least in the field of biotechnology, with the patent examination standards now practiced in the European and Japanese Patent Offices.

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Because the proposed legislation applies only to one criterion of patentability—that this, nonobviousness under 35 U.S.C. 103—it does not necessarily ensure the patentability of a process claim, even if such processes uses or makes a patentable composition of matter. 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., section 112.

When we testified before this subcommittee on predecessor bills of H.R. 587, we expressed the administration's preference for a nonindustry-specific amendment to 35 U.S.C. 103 to address the legal uncertainties that continue to exist regarding the patentability of processes making or using patentable materials. However, we also stated that the administration could accept legislation providing relief for only the biotech industry because considerable opposition to a more comprehensive solution proposed by other predecessor bills makes its enactment not feasible.

Enactment of H.R. 587 would represent, therefore, a step in the right direction by preventing unfair competitors from circumventing the rights of patent owners in the biotechnology industry simply by shifting the location of the infringing activities. The administration supports this bill, and I would be pleased to try to answer any questions you may have on it.

Thank you.

[The prepared statement of Mr. Hoinkes follows:]

PREPARED STATEMENT OF H. DIETER HOINKES, SENIOR COUNSEL, OFFICE OF LEGISLATIVE AND INTERNATIONAL AFFAIRS, PATENT AND TRADEMARK OFFICE, U.S. DEPARTMENT OF COMMERCE

Mr. Chairman and Members of the Subcommittee, I am pleased to testify on H.R. 587, a bill that would amend our patent law to afford needed additional protection for inventions in the field of biotechnology. Our biotechnology industry needs encouragement to expand its research and development efforts to continue its growth and competitiveness, without falling victim to unfair foreign competition. The Administration supports this bill.

Section 101 of H.R. 587 would amend section 103 of title 35, United States Code, to ensure that under certain circumstances a biotechnological process would not be considered obvious if it either makes or uses a composition of matter that itself is novel and nonobvious. To obtain this determination, claims directed to the process and the composition of matter must be sought to be patented in the same application, or in separate applications having the same effective filing date. In addition, the composition of matter and the process must be owned by the same person and the claims to the composition of matter and the process must be issued either in the same patent, or in different patents expiring on the same date.

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

Foreign piracy of U.S. technology through exploitation of a legal loophole such as this should not be tolerated.

The problem has been aggravated by two factors: (1) the present state of court precedent interpreting the statutory law governing the patentability of processes using patentable "starting" materials, and (2) the rapidly evolving state of the art in genetic engineering of proteins. Current law interpreting the patentability of processes based on patentable starting materials, or resulting in patentable end products, stems from two holdings by the U.S. Court of Appeals for the Federal Circuit. In *In re Durden,* 763 F.2d 1406, 226 USPQ 359 (Fed. Cir. 1985), the Federal Circuit held, on the facts before it, that a process of using a patentable "starting compound" to make a patentable "end product" was not patentable. The court reasoned that because the process itself was well known for compounds similar to the patentable starting compound, applying the process to this compound would be obvious. The Federal Circuit was careful to indicate in its opinion that the patentability of each process must be evaluated on a case-by-case basis. Thus, in following the interpretation of the law by the Court in *Durden,* the Patent and Trademark Office cannot interpret 35 U.S.C. 103 to find a process, based on patentable starting materials and yielding a patentable end product, nonobvious as a matter of course. Rather, the Patent and Trademark Office has been forced to determine, on a case-by-case basis whether a process is obvious in view of the prior art, despite the fact that it is specifically based on a patentable starting material or results in a specific patentable end product.

The Federal Circuit had an opportunity to reconsider the *Durden* holding in *In re Pleuddemann,* 910 F.2d 823, 15 USPQ 2d 1738 (Fed.Cir. 1990). Pleuddemann invented a patentable starting material which he used in a process to make a patentable final product. Apart from the use of the patented starting material, the method of making the final product was conventional. The Federal Circuit held, on the facts of that case, that it was not obvious to use the patented starting material to make the patentable final product. The Patent and Trademark Office believes that the result reached in *Pleuddemann* is correct from the standpoint of policy. Notwithstanding attempts by the Federal Circuit in *Pleuddemann* to distinguish *Durden,* however, it is difficult, if not impossible, to reconcile these two cases, as well as an earlier decision by the Court of Customs and Patent Appeals in *In re Albertson,* 332 F.2d 279, 141 USPQ 730 (CCPA 1964). The legal standard governing the obviousness of processes that make or use patentable materials is again before the Federal Circuit, (*In re Ochiai* (Appeal No. 92–1446)). This appeal, raising as an issue the conflict between *Durden, Albertson* and *Pleuddemann,* has been under advisement since November 2, 1992.

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

In this respect, the amendment proposed by H.R. 587 would simplify and provide certainty for applicants who comply with its requirements in the determination of patentability of biotechnological processes using or making novel and nonobvious compositions of matter. These processes would, of course, be deemed nonobvious only to the extent that they specifically recited using or making a particular patentable composition of matter. This would make our patent law consistent, at least in the field of biotechnology, with the patent examination standards now practiced in the European and Japanese Patent Offices. 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 composition of matter. That process could well be unpatentable because it does not meet the requirement of utility under 35 U.S.C. 101, or because it is not sufficiently described to enable someone skilled in the art to use the process, thus failing the requirements of 35 U.S.C. 112. In sum, to be considered patentable, a process must meet a number of statutory requirements besides non obviousness.

H.R. 587 would provide an effective means of protecting biotechnology patented in the United States from unfair foreign competitors. At the same time, it would endeavor not to burden the retail industry and the consuming public because under section 271 (g) of title 35, no infringement remedies against unauthorized retail sellers and noncommercial users of the product made by the patented process can be obtained, unless there was no adequate remedy available "upstream" against importers or wholesalers of that product. Further, no remedy is available if that product was materially changed by subsequent processes or if it became a trivial and nonessential component of another product. And, generally, remedies for infringe-

ment are not available before the person subject to liability had notice of infringement with respect to that product.

When we testified before this Subcommittee on predecessor bills of H.R. 587, we expressed the Administration's preference for a non-industry-specific amendment to 35 U.S.C. 103 to address the legal uncertainties that continue to exist regarding the patentability of processes making or using patentable materials. However, we also stated that the Administration could accept legislation providing relief for only the biotechnology industry because considerable opposition to a more comprehensive solution proposed by other predecessor bills made their enactment not feasible.

Enactment of H.R. 587 would represent a step in the right direction by preventing unfair competitors from circumventing the rights of patent owners in the biotechnology industry simply by shifting the location of their infringing activities.

Section 102 of H.R. 587 provides that a process claim issued under the provisions of new paragraph (b) of section 103 will no longer be considered nonobvious solely on the basis of the composition of matter it uses or produces, if a claim to such composition of matter is held invalid. This provision ensures the independence of judicial review of the validity of a process claim issued under the provision of new paragraph (b) of section 103 and lays to rest criticism that such a process claim enjoys an unfettered presumption of validity.

Section 103 of H.R. 587 provides for the effective date of the amendment proposed by this bill. We favor the generally prospective application of the bill's provision, although it should be pointed out that it does permit a certain amount of retroactivity, because all patent applications pending on the date of enactment of this bill, including applications for reissue of patents, would be subject to its provisions. In accordance with section 251 of title 35, any patent granted no more than two years prior to the filing of a reissue application may be reissued, enlarging the scope of its claims. Thus, if the original patent disclosed a process of using a host cell claimed in that patent, a reissue application could be filed and would benefit from the new law. Of course, the enlarged scope of any reissued patent would be subject to the intervening rights provisions of 35 U.S.C. 252, and, therefore, the rights of persons who relied on present law regarding their business decisions would not be adversely affected.

We do have one drafting suggestion of a technical nature. Given the narrow scope of the process claims eligible for consideration under new paragraph (b) of section 103, it would be appropriate to substitute the term "product" for the phrase "composition of matter." This substitution would permit consideration also of biotechnological processes that use or result in articles of manufacture and would not limit them to only one statutory class of inventions, namely compositions of matter.

H.R. 587 would provide the means that could be used by applicants who desire greater certainty in obtaining protection for biotechnological processes that make or use patentable products. As part of our patent laws this would go a long way in closing another loophole that so far has provided an unfair advantage to unauthorized users abroad of technology patented in the United States. I would be pleased to try to answer any questions you may have on H.R. 587.

Mr. MOORHEAD. We'll propose questions after all participants on the panel have all completed their statement.

Our next witness is Mr. Henry Linsert, chairman and chief executive officer of Martek.

Would you also introduce your chief counsel who's with you?

STATEMENT OF HENRY ("PETE") LINSERT, CHAIRMAN AND CEO, MARTEK BIOSCIENCE CORP., ON BEHALF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION, ACCOMPANIED BY MICHELE CIMBALA, PH.D., J.D., PATENT ATTORNEY, STERNE, KESSLER, GOLDSTEIN & FOX

Mr. LINSERT. Yes. On my right is Michele Cimbala, who is a patent attorney that can answer any detailed questions in the patent area. This is a fairly——

Mr. MOORHEAD. You're recognized for 10 minutes.

Mr. LINSERT. Yes.

Chairman Moorhead and members of the subcommittee, my name is Henry Linsert, and I go by "Pete," and I'm chairman and

CEO of Martek Biosciences Corp. in nearby Columbia, MD. Today I'm testifying on behalf of the Biotechnology Industry Organization, which I'll refer to as BIO.

My testimony will outline BIO's position on the Biotechnology Process Patent Protect Act, H.R. 587, introduced by Chairman Moorhead on January 19, 1995, and cosponsored by Congressman Boucher and nine other Members of the House of Representatives.

BIO represents more than 570 biotechnology companies, academic institutions, State biotechnology centers, and related organizations in 47 States and more than 20 nations. BIO members are involved in the research and development of health care, agriculture, and environmental biotechnology products.

And this morning, as I mentioned, I'm accompanied by Michele Cimbala, Ph.D. and J.D., partner of the law firm of Sterne, Kessler, Goldstein & Fox of Washington, DC. Michele has an extensive biotechnology patent practice, and she and her firm are active members of BIO's intellectual property committee. I know the value of patents and the importance of this legislation, but I need Michele's assistance to answer any of the technical questions you might have about the law or the bill.

I'd like to summarize BIO's recommendation. BIO supports the chairman's proposal and urges the subcommittee to report it to the full House Judiciary Committee without amendment. BIO, and its predecessor, the Industrial Biotechnology Association, have been seeking a remedy for the problems posed by the *Durden* case since 1989. We had hoped that the legislation to reverse the *Durden* case would be enacted in the 102d or the 103d Congress. Last year, because different versions of the legislation were passed by the House and the Senate, the bill was not sent to the President and did not become law.

We are delighted with the leadership of Chairman Moorhead in introducing this bill so early in the session and setting such a high priority on its enactment into law. We look forward to working with him and the members of the subcommittee and the full committee to complete this unfinished business. We wish to acknowledge the leadership of Congressman Boucher on this issue for the past 6 years.

Well, let me begin with a background of Martek and the biotechnology industry and the importance of intellectual property protection and then proceed to an analysis of the basis and the terms of this bill. First, let me talk about Martek. Martek is a biosciences corporation that's primarily conducting research and development since its beginning in 1985. To support this effort, Martek has raised over $25 million of equity capital and obtained approximately $6 million from 40 small business innovation research grants, primarily from the National Institutes of Health. Starting with five scientists in 1995—or 1985, excuse me—Martek now employs 70 people directly, primarily life sciences scientists, and next Monday that will expand to 90 people, as we've purchased a fermentation facility in Kentucky to bring our research into practice with new products that I'll be mentioning in a minute. Indirectly, also, we employ numerous others through subcontracts for clinical research as well as suppliers of equipment and services.

Martek develops products for improved health and nutrition from microalgae, and microalgae are a separate kingdom of organisms in nature and really are the rain forests of the world's oceans, lakes, and rivers. They do many things differently than other organisms, and, thus, are a great source of unusual compounds of potential value to humans. Martek's roots go back 10 to 15 years to technology developed by NASA and Martin Marietta. We are 10 years old this year and have been conducting research and development on these unusual creatures since inception. Our lengthy R&D is finally beginning to pay off with the introduction of four product families.

The first one is based on an unusual fatty acid that microalgae make, strangely enough, are found concentrated in the gray matter of human brains, the retina, the heart, and nervous tissue, basically, wherever there's electrical activity in the body. Humans have a great deal of brain development after birth, unlike other mammals, and this requires a dietary supplementation for fatty acids, essentially, for such development.

I brought a bottle of this oil. This is the material that makes up a significant portion of your brain.

Mr. GEKAS. Would you pass it around?

[Laughter.]

Mr. LINSERT. And these fatty acids normally are provided to infants in human breast milk, but are not found in infant formula. Over the past 5 years, there's been a growing and increasingly body of evidence that indicates the lack of these fatty acids in infant formula can lead to long-term IQ deficiencies and behavioral problems. This not only applies to infants born normally on time, but is especially true for low birth weight or preterm infants, which make up about 250,000 infants born annually in the United States each year.

As a result of its lengthy R&D, Martek has developed patentable manufacturing technology that will provide these fatty acids in mass economic quantities to support infants and their mothers throughout the world. And last fall our product was introduced in a preterm infant formula in Belgium, and we expect to see widespread application by the end of the year this year in Europe and probably in the United States in 1996 and 1997.

Also, there's a story developing on these unusual oils for certain types of dementia, Alzheimer's being one, and low levels of the brain of these oils in dementia patients is beginning be to determined not only in animal models, but human models, and we're working on products that will address that area with some capsules, where these oils are encapsulated in a clear gel cap, and we hope to make these available not only to adults, but women who choose to breast feed their children who can raise the amount in their milk. So these oils are an exciting part of the future of our company, and we believe that we can make a great contribution to infant nutrition and perhaps a contribution to help the nutrition of the elderly.

We also—these products have an agricultural component, and, basically, the algae that we use are a fermentable type and we're converting really U.S. corn and soybeans into high value-added oils that we believe that we'll be shipping around the world in large

quantities over the next 5 to 10 years. So this is our major product that we have coming out from Martek right now.

Our other contributions we expect to make are new enabling technology that could lead to much more efficient ways of developing pharmaceuticals. Another area is a new low-cost way of diagnosing gastrointestinal problems using the breath rather than the invasive procedures, and possibly a new generation of antibiotics from algae.

Our products are really a tiny portion of what biotechnology is bringing to humans in the near-term future, and it's really an exciting time for Martek, and we're just part of a very exciting industry. It's a pleasure to work in it every day.

Well, the major issue that we face in the biotechnology industry—and we're made up of about 1,300 companies, about 265 of which are publicly traded—is getting money and capital formation. It takes personally about half of my time. And intellectual property is just an indispensable portion of persuading investors to provide this capital to the industry. I know every one of the investors and analysts that come to see us and talk to us, every one of the questions goes deeply into the patent area. So it's very important to us.

And bringing a biotechnology drug to the market today is both a lengthy and expensive process. Initial testing of the drug for final approval from the FDA can take 10 to 12 years, and this process can go from $150 to $350 million. So both the time and the length and the cost of the process is a tremendous impediment for a small biotechnology company to get a success product to the market.

We're today, as an industry, we're in one of the worst financial crisis of our history, and a major contributing factor to this crisis was the recent drug price assault and also the whole sense of the cloud over the industry from some of these assaults. I know the American exchange biotechnology indexes declined by 50 percent since January 1993.

Ernst & Young reports there are currently 27 biotechnology therapies and vaccines on the market with 270 in human development and over 2,000 in early research stages. As these products move into clinical trials, expenses increase. So the need for capital for our companies to fund research is increasing right at the time when the industry is coping with a major financial crisis.

We think there's a critical synergy between intellectual property protection and capital formation for the industry. This fact has been demonstrated in a sophisticated economic analysis of the values of patents to the biotechnology and their importance in capital formation for the biotechnology industry. The estimates go from anywhere $200,000 to $800,000 of the value per patent. I believe, based on our experience in the company, that's probably a low figure. Our whole value is dependent upon the strength of our intellectual property that we have.

The Biotechnology Process Patent Protection Act focuses on process patents. It is often difficult to obtain process patents for the genetic engineering method of making human proteins, where in the *Durden* case a new process is not patentable if its steps are obvious, even if it uses novel starting material. The chairman's bill would provide protection for the process if the starting material is novel and nonobvious.

The Patent and Trademark Office has interpreted the *Durden* case to apply to biotechnology as follows: everyone knows how to make a drug using recombinant DNA. You simply identify the gene that codes for the desired protein and then insert it into a cell in such a way that the cellular machinery receives the instruction from the gene. Therefore, the fact that an inventor has adopted this basic technology to new genes so as to produce a new protein will not entitle him to a process patent unless he can demonstrate unexpected results. Put in another way, the PTO is interpreting this case to say that biotechnology is an obvious technology and, therefore, biotechnology processes for making drugs fail to meet the criteria for patentability contained in 35 U.S.C. 103.

Since genetic engineering is the only commercial feasible method of manufacturing human proteins, a patent on the recombinant manufacturing process can be tantamount to a product patent, but without the process patents the biotechnology industry simply does not have the means whereby to prevent piracy of U.S. inventions by foreign companies who want to sell to the United States.

The chairman's bill would overrule the application of *Durden* to biotechnology processes, thus, restoring the law as it existed prior to 1985. It ensures that innovative biotechnology processes are eligible for process patent protection. It will lead to greater certainty and predictability for biotechnology intellectual property, and it will decrease unnecessary litigation. Europe and Japan have already provided their inventors with process patent protection in the situations covered by this legislation. The bill brings the U.S. process patent law into conformity with European and Japanese law.

The bill would also 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 it itself is novel and nonobvious. To obtain this determination, the process and product claims must be sought to be patented in the same application. Divisional applications would also be eligible.

The bill provides——

Mr. MOORHEAD. Could you summarize in a minute?

Mr. LINSERT. Thank you. Yes.

Well, we—BIO is a major success story and we support this legislation as a great help to the industry, and I thank you very much for the time. I apologize for running over my time, sir.

Mr. MOORHEAD. That's quite all right. Thank you.

[The prepared statement of Mr. Linsert follows:]

PREPARED STATEMENT OF HENRY ("PETE") LINSERT, CHAIRMAN AND CEO, MARTEK BIOSCIENCES CORP., ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION

Chairman Moorhead and members of the Subcommittee. My name is Henry ("Pete") Linsert and I am Chairman and CEO of Martek Biosciences Corporation of Columbia, Maryland.

I am testifying today on behalf of the Biotechnology Industry Organization (BIO). My testimony will outline BIO's position on the Biotechnology Process Patent Protection Act, H.R. 587, introduced by Chairman Moorhead on January 19, 1995 and cosponsored by Congressman Boucher and nine other members of the House of Representatives. BIO represents more than 570 biotechnology companies, academic institutions, state biotechnology centers and related organizations in 47 states and more than 20 nations. BIO members are involved in the research and development of health care, agricultural and environmental biotechnology products.

I am accompanied this morning by Michele Cimbala, Ph.D. and J.D., Partner in the law firm of Sterne, Kessler, Goldstein and Fox of Washington, D.C. Michele has an extensive biotechnology patent practice and she and her firm are active members of BIO's Intellectual Property Committee. I know the value of patents and the importance of this legislation, but I need Michele's assistance to answer any technical questions you may have about the law or the bill.

SUMMARY OF BIO RECOMMENDATION

BIO supports the Chairman's proposal and urges the Subcommittee to report it to the full House Judiciary Committee without amendment. BIO and its predecessor, the Industrial Biotechnology Association (IBA), have been seeking a remedy for the problems posed by the *In re Durden* case since 1989. We had hoped that legislation to reverse the *Durden* case would be enacted in the 102nd or 103rd Congress. Last year because different versions of the legislation were passed by the House and Senate, the bill was not sent to the President and did not become law. We are delighted with the leadership of Chairman Moorhead in introducing this bill so early in this session and setting such a high priority on its enactment into law. We look forward to working with him and the members of the Subcommittee and the full Committee to complete this unfinished business. We wish to acknowledge the leadership of Congressman Boucher on this issue for the past six years.

Let me begin with some background on Martek, the biotechnology industry and the importance of intellectual property protection and then proceed to an analysis of the basis and terms of this bill.

BACKGROUND ON MARTEK

Martek Biosciences Corporation has primarily conducted R&D since its beginning in 1985. To support this effort, Martek has raised over $25 million in equity capital and obtained approximately $6 million from 40 small business innovation grants, primarily from National Institutes of Health (NIH). Starting with 5 scientists in 1985, Martek now employs 70 people directly, primarily life sciences scientists. Indirectly, we employ numerous others through subcontracts for clinical research, as well as suppliers of equipment and services.

Martek develops products for improved health and nutrition from microalgae. Microalgae are a separate kingdom of organisms in nature and are the "rain forests" of the world's oceans, lakes and rivers. They do many biochemical things differently than other organisms, and thus are a great source of unusual compounds of potential value to humans. Martek's roots go back 10–15 years to technology developed by NASA and Martin Marietta. We are 10 years old this year and have been conducting research and development on these unusual creatures since inception. Our lengthy R&D is finally beginning to pay off with the introduction of 4 product families.

The first one is based on unusual fatty acids that microalgae make that, strangely enough, are found concentrated in the gray matter of human brains, the retina, the heart and nervous tissue, and basically wherever there is electrical activity in the body. Humans have a great deal of brain development after birth, and this requires dietary supplementation for fatty acids essential for such development. These fatty acids are provided in human breast milk, but are not found in infant formula. Over the last 5 years there has been a growing and increasingly convincing body of evidence that indicates that the lack of these fatty acids in infant formula can lead to long-term IQ deficiencies and behavioral problems. This not only applies to infants born normally on time, but is true especially for low birth weight and preterm infants, which make up approximately 250,000 infants born annually in the United States alone. As a result of its lengthy R&D, Martek has developed patentable manufacturing technology that will provide these fatty acids in mass, economic quantities to support infants and their mothers throughout the world. Martek's technology will use fermentable micro algae that will turn low cost U.S. corn and soybeans into high value-added vegetable oils rich in these fatty acids for blending into infant formula, foods and dietary supplements for export around the world.

Other contributions that Martek expects to make over the coming years are: (1) new enabling technology that could lead to a much more efficient way of developing new pharmaceuticals; (2) a new, low cost way of diagnosing gastrointestinal problems using human breath rather than the current expensive and invasive procedures using tubes inserted through the throat into the stomach or slivers of liver taken out with large needles; and, (3) a new generation of antibiotics, effective against some of the most antibiotic resistant pathogens.

Martek's products are a tiny portion of what biotechnology is bringing to humans in the near-term future. Its an exciting time at Martek and an exciting time for the biotechnology industry.

BACKGROUND ON THE BIOTECHNOLOGY INDUSTRY

The biotechnology industry consists of over 1,300 companies, of which approximately 265 are publicly traded. Our industry has a powerful presence in the State of California The first biotechnology company, Cetus Corporation, was founded in San Francisco in 1971. Today, San Francisco is home to over 200 biotechnology companies, which employ approximately 13,000 employees. The Los Angeles area has over 70 biotechnology companies, and the San Diego area is home to over 100 companies. In 1992, forty-seven biopharmaceutical companies in California reported revenues of $3.37 billion. Due to the application of biotechnologies pioneered by California companies, employment in the state has grown 130% since 1972.

The overriding issue for entrepreneurs in the biotechnology industry is capital formation. Intellectual property protection is indispensable in persuading investors to provide this capital to the industry.

Bringing a biotech drug product to the market today is both a lengthy and expensive process. Initial testing of the drug to final approval from the Food and Drug Administration can take 10–12 years, and this process can cost anywhere from $150 to $359 million. Both the length and cost of the process are a tremendous impediment for small biotechnology companies to be successful bringing a product to the market.

After raising enormous amounts of capital, and conducting cutting-edge research, a company can find that its lead product is not approved by the Food and Drug Administration. We work in an industry which cannot sell and market its products without government approval and the requirements for approval are onerous.

The scientific research by the biotechnology industry is exceedingly expensive. The Office of Technology Assessment finds that the *average* cost per new chemical entity (NCE) developed is $359 million.[1] This survey did not cover the cost of developing a biotechnology drug, but analyses done by our industry find that the cost of developing a biotechnology drug may be similar. We know that Genzyme and Amgen, two member companies of BIO, raised $328 and $406 million, respectively, in equity before they brought their first products to market. Genentech has spent $1.6 billion on research and development and has four basic products on the market.

In a 1994 survey by *Business Week*, six of the top ten firms in the U.S. in terms of research expenditures per employee were biotechnology companies—Biogen ($208,724), Genentech ($117,594), Genetics Institute ($107,657), Immunex ($92,693), Amgen ($83,302), and Chiron ($64,263).[2] On average, biotech firms spend $59,000 per employee on research. The U.S. corporate average was $7,476 for 1993. Ernst & Young reports that biotechnology companies spent $7 billion on research in 1994, a 23 percent increase over 1992.[3] The research is expensive for one simple reason; we are advancing basic and applied science at the same time.

Total sales for the biotech industry were $7.7 billion in 1994. However, since biotechnology companies spend such a large percentage of their capital on research and development, the industry experienced a net loss of $4.1 billion in 1994, and has lost approximately $14 billion over the last 5 years. The biotechnology industry, in fact, has never had a profitable year and only one percent of companies are profitable.

Public financing was especially difficult for biotechnology companies in 1993. The American Stock Exchange Biotechnology Index lost 32.6 percent in 1993 alone. Several public biotech companies were forced to do private investment in public equity (PIPE) financing, deals where public companies sell stock to private investors at a discount to their current stock price. 1993 was a difficult year because in large part investors were scared by the *de facto* price controls in the Administration's health care plan. They feared that some widely discussed points of health care reform would mean that they would not recoup their investment in a company that was close to bringing a product to market. According to many press accounts and three BIO surveys of our companies developing therapies for AIDS, cancer, and other deadly and costly diseases, our companies are cutting back on research.

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[1] U.S. Congress, Office of Technology Assessment, Pharmaceutical R&D: Costs, Risks and Rewards, OTA–H–522 (Washington, DC: U.S. Government Printing Office, February 1993).

[2] Peter Coy et al, "What's the Word in the Lab? Collaborate," *Business Week*, (June 27, 1994), 78–103.

[3] Ernst & Young, *Biotech 95 Reform, Restructure, Renewal*, The Ernst & Young Ninth Annual Report on the Biotechnology Industry IX (1994).

The industry is now in-the-middle of one of the worst financial crises in its history. A major contributing factor to this crisis was the Administration's assault on drug prices. The AMEX biotechnology stock index has now declined by 50% since January, 1993.

Ernst & Young reports that there are currently 27 biotechnology therapeutics and vaccines on the market, with 270 in human development, and over 2,000 in early research stages. As products move into clinical trails, expenses increase. So, the need for capital for our companies to fund research is increasing right at the time when the industry is coping with a financial crisis.

Ernst & Young reports that biotech companies, on average, have 25 months of capital left at their current burn rates (the rate at which capital is being expended.) According to a recent report by Dr. Robert Goldberg of the Gordon Public Policy Center at Brandeis University, 75 percent of biotechnology companies have 2 or fewer years of capital left. That means that a staggering 983 companies will need to go to the market in the next two years or face severely restricting their activities, going out of business, merging or selling rights to a larger firm.

Synergy Between Patent Protection and Capital Formation

There is a critical synergy between intellectual property protection and capital formation for the biotechnology industry. This fact has been demonstrated in a sophisticated economic analysis of the value of patents to the biotechnology and their importance in capital formation for the biotechnology industry.

The analysis was undertaken by Dr. David Austin, a fellow at Resources for the Future (RFF) in Washington, D.C. and documented in a paper entitled "Estimating Patent Value and Rivalry Effects: An Event Study of Biotechnology Patents." The paper analyzes the value of patents, and their effect on competing companies and on the biotechnology industry in particular. Dr. Austin confined the study to biotechnology firms because, "their research intensity is known to be very high; they rely heavily on patent protection; and their patent races tend to be extremely competitive."[4] Dr. Austin further states that since there are relatively few biotechnology products yet brought to the market, "companies need an effective way to signal their future prospects and attract investment capital. patents serve this function."[5]

Dr. Austin references earlier economic estimates in this field in the introduction to the paper. He cites a 1984 paper by Griliches, which found that a successful patent is worth about $200.000. He also cites a study by Pakes, 1985, which found that when a firm receives a patent it "indicates that events have occurred that increase the firm's market value by $810,000."[6]

The results of Dr. Austin's study indicate that there is a significant reaction in the stock market when certain broad types of patents are announced as allowed or issued. When a patent is listed in the *Wall Street Journal,* it positively affects the value of the stock for the company receiving the patent, and negatively affects the stock price of competitors to that company. Dr. Austin defines a "significant" increase in valuation as $1.7 million on a company capitalized at an average of $400 million. The report also indicates that there is a positive correlation between stock price, when a patent is filed and issued, and research and development expenditures. In addition, the report indicates that the granting of an important patent appears to raise the net value of the entire industry.

Dr. Austin concludes the report with a discussion of the policy implications of the findings. The report states "current patent policy is very crude, from the standpoint of economic theory, and certainly is not strongly linked to the value of the patent."[7] If patent examiners were provided with better information, Dr. Austin believes patent examiners and judges that help determine the scope of a patent would be able to bring greater economic rationality into their decision-making. Finally, Dr. Austin concludes the report by suggesting that a study of the long-term effects of rival patents is a necessary next step in this line research.

We have recently seen a specific example of the relationships between patents and stock price. A biotech company received a patent on a certain type of gene therapy and the New York Times reported that the stock price "surged today after the

[4] Austin study page 3.
[5] Austin study page 4.
[6] Austin study page 2.
[7] Austin study page 32.

company was assigned a broad patent covering a fundamental type of gene therapy. . . ." The companies shares jumped 17.6% the first day.[8]

It is easy to see the relationship between the capital formation pressures faced by the biotechnology industry and Dr. Austin's study. Stock prices and market value are a critical variable in the ability of a company to raise capital. Patents give investors confidence and influence their willingness to put their capital at risk. The shortage of capital in the biotechnology industry means that the protection of intellectual property has never been more critical for the ability of the industry to survive and prosper. Enactment of the Chairman's bill will strengthen intellectual property protection for biotechnology inventions and help to ensure that the industry has the capital it needs to fund life-saving and life-enhancing research.

BIOTECHNOLOGY PROCESS PATENT PROTECTION ACT

This legislation focuses on process patents. It is often difficult to obtain process patents for the genetic engineering method of making human proteins because under *In re Durden,* 763 F.2d 1406 (CAFC 1985), a new process is not patentable if its steps are obvious, even if it uses a novel starting material. The Chairman's bill would provide protection for the process if the starting material is novel and nonobvious.

The Patent and Trademark Office (PTO) has interpreted the *Durden* case to apply to biotechnology as follows: Everyone knows how to make a drug using recombinant DNA. You simply identify the gene that codes for the desired protein and then insert it into a cell in such a way that the cellular machinery receives the instruction from the gene. Therefore, the fact that an inventor has adapted this basic technology to a new gene so as to produce a new protein will not entitle him to a process patent unless he can demonstrate "unexpected results."

Put another way, the PTO is interpreting this case to say that biotechnology is an "obvious" technology and therefore biotech processes for making drugs fail to meet the criteria for patentability contained in 35 U.S.C. 103.

Since genetic engineering is the only commercially feasible method for manufacturing human proteins, a patent on the recombinant manufacturing process can be tantamount to a product patent. But without process patents, the biotechnology industry simply does not have the means whereby to prevent piracy of U.S. inventions by foreign companies that want to sell to the U.S.

Under *Durden,* biotechnology companies cannot prevent importation of a product made abroad 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 on the host cell. However, the steps of the biotechnology process may be, and typically are, conventionally 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 in the United States 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., *Amgen, Inc.* v. *United States International Trade Commission,* 902 F.2d 1532, 14 USPQ 1734 (Fed. Cir. 1990). Thus, our law currently provides an unfair advantage to unauthorized users abroad of technology patented in the United States.

Durden, a chemical case, is in direct conflict with *Mancy* and other cases involving microorganisms. It 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.

The Federal Circuit was split in *Durden* and the reasoning in the case has been heavily criticized by the patent bar. 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* either legislatively or judicially.

[8] "A Biotech Company Is Granted Broad Patent and Stock Jumps," New York Times, March 23, 1995 at D1.

A patent applicant is generally required to incur substantial expenses in overcoming initial *Durden* rejections. This problem have been particularly severe for universities and small companies, which often lack the resources necessary to fight a *Durden* rejection. All four universities considered in one study—Wisconsin, Johns Hopkins, California, and Columbia—forfeited the process patent protection to which they appear to be entitled.

Failure to obtain adequate patent protection will discourage private sector investment in biotechnology research and frustrate university attempts to successfully transfer the technologies they develop. It will also enable foreign companies, employing foreign workers, to use U.S.-invented technologies to sell products to American consumers.

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.

Notwithstanding an attempt by the Federal Circuit to distinguish *Pleuddemann* from *Durden*, it is difficult, if not impossible, to reconcile these two cases. It is not clear why a method of using a starting material should be treated differently, for purposes of determining non obviousness, from a method of making the end product. Yet, under current law, the former is per se non obvious, while the latter is not.

The PTO and others have expressed the opinion that *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 PTO 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 product.

In this respect, the Chairman's bill 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 or making or using a patentable product.

The Chairman's bill would overrule the application of *Durden* to biotechnology processes, thereby restoring the law as it existed prior to 1985. It ensures that innovative biotechnology processes are eligible for process patent protection. It will lead to greater certainty and predictability for biotechnology intellectual property, and it will decrease unnecessary litigation.

Europe and Japan already provide their inventors with process patent protection in the situations covered by this legislation. The bill brings U.S. process patent law into conformity with European and Japanese law.

The Chairman's bill 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 making or using a product, if that product itself is patentable. Thus, a patent on the method of making a protein by using a host cell would produce a basis for an infringement action under section 271(g) of title 35, United States Code. The patentee could also petition the U.S. International Trade Commission to issue an exclusion order under section 337 of the Tariff Act of 1930. At the same time, the bill 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.

The bill would also 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 product and process claims must be sought to be patented in the same application. Divisional applications would also be eligible.

The bill provides a mechanism for applicants 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 line of the decision of the *Durden* case.

This legislation has broad bipartisan support in the House and Senate, and has been endorsed by the Bush and Clinton Administrations.

BIO appreciates the support of the PTO for this legislation. This support is one of several demonstration's of the PTO's support for intellectual property protection for the biotechnology industry. BIO and the PTO have worked closely on a series of initiatives, including the PTO's proposed Guidelines on Biotechnology Utility issues, which BIO strongly supports. The utility guidelines will expedite consideration

of patent applications for biotechnology inventions and ensure that biotechnology companies are not required to complete human clinical trials before a patent can be secured. It is very difficult for biotechnology companies to raise the capital they need to fund clinical trials until they can demonstrate that their inventions are protected with patents. The utility issue is another example of the synergy between patents and capital formation.

CONCLUSION

The biotechnology industry is a major success story in the making in America. It is the more entrepreneurial industry in terms of research intensity and capital formation. It thrives on innovation and long term risk-taking. We should ensure that our patent code recognizes its unique characteristics and needs.

Thank you for the opportunity to testify here today. Michele and I are happy to answer your questions.

Mr. MOORHEAD. Our next witness is from my part of the country, from southern California, Mr. Steven Odre, senior vice president of Amgen, Inc., Thousand Oaks, CA, and, actually, I understand a constituent of mine.

Welcome.

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

Mr. ODRE. Thank you very much.

Good morning. Mr. Chairman and members of the subcommittee, I greatly appreciate the opportunity to appear before you this morning to share with you some of the experiences of Amgen and impress upon you the need for patent reform to ensure that America's innovative biotechnology industry can maintain its leading position in the world economy. I have direct personal experience with this very problem that is being addressed by H.R. 587, and I have seen firsthand just how the biotech industry in the United States has been disadvantaged by an interpretation of the CAFC's decision in the *In re Durden* which has made it difficult for biotechnology companies to secure on a consistent basis process patent protection.

The high level of investment in research and development required to bring to market the remarkable new products made available for the first time by biotechnology requires that effective, enforceable patent protection be provided as an incentive for such developments. Although present patent and trade laws provide some degree of protection, a significant problem currently exists providing a loophole which gives our foreign competitors a decided advantage over domestic companies. This loophole should be closed.

Mr. Chairman, my written statement describes the details of Amgen's experience following 6 years of litigation and the expenditure of millions of dollars trying to protect its interest in what at the time was our only product, from which all but the most bias would agree was an unfair act. We at Amgen believe that this experience will convince this committee that the patent laws must be updated to keep pace with and to protect biotechnology inventions.

Amgen has a patent to a host cell, the only known way to produce recombinant erythropoietin, that has been litigated, relitigated, and upheld at the CAFC. Yet, today, it is unenforceable—it is enforceable—excuse me—only against domestic manufacturers. Although protected from U.S. competitors, under its patent rights Amgen was unable to deal with the Japanese competitor

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

Today, if one obtains a patent claiming only a recombinant host cell, it does not automatically follow that one would also receive patent protection for a process of producing a product by means of that patented host cell. Therefore, it is not possible to prevent the importation of the product made abroad using the patented host cell. Consequently, a foreign manufacturer is allowed to do what no domestic manufacturer is permitted to do, market in the United States a product made from the patented host cell. U.S. patent law must allow domestic and foreign manufacturers to compete on a level playing field, one on which U.S. companies are not placed at a competitive disadvantage by U.S. law. Unless Congress closes this loophole, the consequences will be a continued shift to offshore manufacture of recombinant products and a loss of jobs and investment in the U.S. biotech industry. It is Amgen's belief that changes must be made in the U.S. patent laws to protect our biotech industry and provide effective remedies from unfair competition. The courts have made it clear that this is a "task for the Congress, which can explore its impact and side effects."

Mr. Chairman, Amgen's experience reveals a weakness in the U.S. patent and trade laws that were drafted prior to the dawn of biotechnology. The legislation before this committee proposes a significant step toward removing unintentional barriers to the award of biotechnology process patents and providing long overdue protection against the unfair competition resulting from the use of U.S. patented technology by foreign competitors overseas. We support this legislation, but believe that it can be strengthened.

H.R. 587 does not completely close the loophole that exists today. Congress should update the law to prevent foreign competitors from doing what domestic companies cannot do. In its present form, H.R. 587 does not create a complete level playing field that we recommend. It makes no sense that we apply our patents only against ourselves. No one here today would suggest that a host cell patent should not be enforced against a domestic manufacturer. Why, then, should the same patent not be enforced against a foreign manufacturer who is doing exactly what the domestic manufacturer cannot do; namely, sell the product produced by the host cell in the United States? Unless this loophole is closed, the law today gives every manufacturer, domestic and foreign, the incentive to manufacture overseas and thereby avoid the scope of U.S. patent laws protecting host cell claims.

Amgen, thus, recommends legislation to this committee that would amend title 35, U.S. Code, to render persons who import, sell, or use in the U.S. products made overseas by infringing product claims on biotechnological material liable as infringers, and, thus, subject to actions in the U.S. District Court. This would per-

mit domestic and foreign manufacturers to compete on equal footing for the U.S. market.

Despite the protection proposed by H.R. 587, the situation confronted by Amgen may arise again in the future. Although previously my colleagues in the profession have argued that bills similar to H.R. 587 would solve 90 percent, even 95 percent, of the problem, why shouldn't the entire problem be resolved, especially in view of the fact that this further amendment to title 35 would not grant a patentee any greater rights against any domestic infringer, because under U.S. law 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.

To reiterate, Amgen seeks a level playing field, nothing more, nothing less, thereby allowing all U.S. and foreign manufacturers to compete equally in the United States. If one other U.S.-based company must face the same problems, delays, and expense encountered by Amgen, it is one too many.

I would like to take one minute to address the questions that were raised by Congressman Conyers. Regarding the first question, how many cases have been involved in the U.S. Patent Office that the Patent Office has refused to grant patent process claims in view of *Durden,* I can't give you an exact number. I think the Patent Office probably can help you out, but I think it has been very large. My experience, and the experience of others in the biotech industry, talking with them, it is a consistent problem we've had.

The second question I think is very important regarding, will this provide consistency? The answer: yes, it will help remove the inconsistencies we have now, further remove. The host cell protection, when you look at host cell protection, again, as the Patent Office has said, we've had those claims—have been allowed for many years. The host cell protection has been the scope of that protection determined by the courts. I have about 7 years' experience with that. I can tell you that the courts know what a host cell is, what type of scope; everybody knows. I think there is no doubt that the Patent Office has been consistent regarding these host cell protections, hopefully, with the passage of the bill regarding title 1, will provide consistent protection also with respect to process claims.

Thank you very much for this opportunity to appear today, and Mr. Chairman, we'd like to work with you and this committee and the administration in crafting appropriate legislation that meets the needs of the entire biotech industry. Thank you.

[The prepared statement of Mr. Odre follows:]

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

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

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

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

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

BACKGROUND

AMGEN, INC.

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

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

PATENT AND REGULATORY STATUS

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

In late 1983, Amgen applied for patent protection for the gene encoding rEPO and host cell necessary to manufacture rEPO, as well as for the process for making rEPO and the recombinant erythropoietin product itself. In October 1987, the U.S. Patent and Trademark Office ("USPTO") granted Amgen a patent which includes claims to the gene encoding erythropoietin and recombinant host cells containing

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

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this gene. However, because of *In re Durden*[2] the USPTO refused at that time to allow claims to the process for making rEPO using the patented host cells.

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

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

DELAYS RESULTING FROM IN RE DURDEN

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

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

THE INTERNATIONAL TRADE COMMISSION 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 U.S. patent.

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

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

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

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

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

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

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

In 1988, as part of its revisions to the trade law,[6] Congress changed the authority of the ITC to make it easier for American innovators to obtain protection from unfair acts.

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

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

LITIGATION IN THE DISTRICT COURTS

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

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

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

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

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

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

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

COMMENTS ON H.R. 587 AND THE NEED FOR ADDITIONAL PROTECTIONS

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

H.R. 587 is designed to counter the effect of the *In re Durden* decision for biotechnology patents to the extent that *In re Durden* may prohibit pioneers from ob-

[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.

[7] *Amgen, Inc.* v. *Chugai Pharmaceutical Co., Ltd.*, 13 U.S.C.Q2d 1737 (D. Mass., 1980).

taining process patent protection on a process using recombinant host cells. As noted earlier, although Amgen has overcome a rejection under *In re Durden,* obtained allowed process claims with respect to rEPO, and expects to receive a U.S. patent having such claims, Amgen has no desire to see other members of the biotechnology industry experience similar delays in obtaining enforceable protection. Strengthening the patent laws to protect pioneering innovators is critical to the United States biotechnology industry—and clearly is in the national interest. Nothing has changed since similar bills were first introduced in 1989 that alleviates the need for remedies provided in the legislation introduced this year.[8]

H.R. 587 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, the thesis that merely overturning *In re Durden* is by itself sufficient to protect the biotechnology industry is incorrect. 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. 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. For these small companies and universities the overturning of *In re Durden* is insufficient. We are thus disappointed that this year's legislative proposal abandons the straightforward provisions of the earlier legislation.

For the reasons set forth above, the more indirect method chosen by the sponsors of H.R. 587 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. In our view, 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.

Amgen recommends legislation to this Committee—similar to legislation passed by the United States Senate during the previous Congress—that not only overturns the negative effects of *In re Durden,* but also amends Title 35, U.S. Code, to render persons who import, sell or use in the United States products made overseas by "infringing" claims to biotechnological material from which such products are made, i.e., host cells liable as infringers, and thus subject to actions in U.S. District Court. This would provide a "level playing field" which would permit domestic and foreign manufacturers to compete on equal footing in the U.S. market.

A copy of the Senate-passed bill is attached for your convenience. Title II includes the protection sought by Amgen (as did previous provisions of House bills on the subject sponsored by several Members of this Subcommittee).

CONCLUSION

Amgen—America's leading independent biotechnology company—spent six years and millions of dollars trying to protect its interest in what was at the time its only product from what all but the most biased would agree is an unfair act. In contrast, a foreign competitor, by using Amgen's patented technology and enter the United States market notwithstanding the fact that the same conduct would infringe Amgen's U.S. patent if conducted in the United States. Congress should update the law to protect against foreign competitors using technology claimed by U.S. biotechnology patents and competing in the U.S. market and close unintended loopholes that allow competitors to unfairly reap the benefit of inventiveness, initiative, and entrepreneurship which the United States has invested—loopholes which, if not properly remedied, will have a negative impact on the United States economy by discouraging revolutionary breakthroughs in the development of important new medical therapies.

We congratulate Members of the Subcommittee for recognizing the necessity to increase the certainty regarding the intellectual property rights for the biotechnology industry and provide a "level playing field" between domestic and foreign biotechnology competitors. Congress should send a clear message that foreign competitors must compete fairly with the United States biotechnology industry.

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[8] It has been asserted by some that the courts will eventually resolve the issue addressed by H.R. 587. It has been over six years since this argument first surfaced and we are still awaiting judicial resolution. Opponents of the bill continue to disregard the uncertainty regarding the scope of any court decision and the resulting confusion it may produce.

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103D CONGRESS
1ST SESSION

S. 298

IN THE HOUSE OF REPRESENTATIVES

JULY 19, 1993

Referred to the Committee on the Judiciary

AN ACT

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

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

TITLE I—BIOTECHNOLOGICAL PROCESS PATENTS

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

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

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

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

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

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

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

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

"(3)(A) the machine, manufacture, or composition of matter, and the claimed process invention at the time it was made, were owned by the same per-

son or subject to an obligation of assignment to the same person; and

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

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

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

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

SEC. 102. NO PRESUMPTION OF INVALIDITY.

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

of matter is determined to lack novelty under section 102 of this title or to be obvious under section 103 of this title.".

SEC. 103. EFFECTIVE DATE.

The amendments made by this title shall apply to all United States patents granted on or after the date of the enactment of this Act and to all applications for United States patents pending on or filed after such date of enactment, including any application for the reissuance of a patent.

TITLE II—BIOTECHNOLOGICAL MATERIAL PATENTS

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

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

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

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

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

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

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

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

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

(c) EFFECTIVE DATE.—

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

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

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

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

Passed the Senate July 15 (legislative day, June 30), 1993.

Attest: WALTER J. STEWART,

Secretary.

Mr. MOORHEAD. Thank you, Mr. Odre.

We'll now have a round of questions. Each Member will be limited to 5 minutes, including myself. My timer here will let me know. And if there's a need for a second round, then we'll have a second round.

Mr. Hoinkes, from past discussion of the PTO and from past testimony, it's been suggested that the matter can be resolved simply by applying the totality of the case law and not focusing primarily on the whole *In re Durden,* what is the problem with this type of administrative solution?

Mr. HOINKES. Well, Mr. Chairman, I fully realize that these suggestions have been made in the past. Regrettably, we cannot come to an administrative solution given the contradictory cases on this subject matter that have been handed down for the past 30 years, both by the Court of Appeals for the Federal Circuit and its predecessor court, the Court of Customs and Patent Appeals. They have taken quite similar fact situations and have in some cases come out one way, in other cases have come out another way, and have left us basically no guidance on how administratively to be consistent with legal precedent.

As a matter of fact, there is before the court, even at this time, a case that is on all fours with this fact situation, and that is *In re Ochiai.* That case has been under advisement at the CAFC now since November 1992, and it appears that the court does not seem to be too much in a rush to resolve that which it, frankly, should resolve. And in order to help us to administer the patent laws correctly, we would welcome legislative relief since judicial relief does not seem to be forthcoming any time soon.

Mr. MOORHEAD. Your testimony indicates that the Patent Office could support a change in section 103 along the lines of H.R. 587. Would that change result in an examination system for biotech process patents similar to that under the European or Japanese office?

Mr. HOINKES. Indeed, it would, Mr. Chairman. If H.R. 587 were enacted, it would give a patent applicant an avenue of basically circumventing *In re Durden,* as it were, and putting himself into a position that is just about identical to the examination practices that are presently conducted by the European Patent Office and by the Japanese Patent Office. Of course, both in Japan and in Europe their approach is generic. In other words, it is not biotechnology-specific. So at least for biotechnology patent applicants here it would be very similar to the Japanese and to European procedure.

Mr. MOORHEAD. Are you aware of any problems encountered by either the European or Japanese Patent Offices in granting process patents without examining for obvious——

Mr. HOINKES. Mr. Chairman, we have not heard of one.

Mr. MOORHEAD. In fact, we're on the right track then.

Mr. Odre, would the amendment you're requesting broaden the product patents that's not available under present law and make it unnecessary to use the new process patent protection provided under our bill, H.R. 587?

Mr. ODRE. Well, first of all, I don't think it would make the process protection—it would not make unnecessary the process protection under the title 1. Secondly, would it provide a broader scope

of protection? It would provide a broader scope of protection to the extent that host cell that are valid issued patents today, and the Patent Office gives us, what it allows today, would be enforceable against a foreign manufacturer who would be using that host cell offshore and importing it into the United States.

Mr. MOORHEAD. Would you comment on that, Mr. Hoinkes?

Mr. HOINKES. You're referring to title 2, as has been previously suggested?

Mr. MOORHEAD. Yes, the amendment that's being requested.

Mr. HOINKES. Well, Mr. Chairman, I must say that we have commented on this proposal before in the context that it could be acceptable if properly drafted, if narrowed as it were, and if the approach that was suggested along the lines of H.R. 587 would not be enacted. In other words, we have suggested that the administration could accept this as an alternative if the amendment to section 103 was not feasible. And taking a look at title 2 as presently drafted, we basically consider both of them to be sort of the belts-and-suspenders approach.

The proposal is certainly one that broadens, as presently drafted, a claim to a biotech material. It basically makes a megaclaim out of it because whenever, however, wherever, and regardless how remote, a product was made using a biotech material, it cannot be imported, for instance, because it would be infringing. Now in that respect, this proposal has none of the safeguards that would be present in H.R. 587 regarding the remedies for infringement to protect noncommercial or retail users, or if the use was trivial, nonessential, or that an infringer must be notified before being liable for infringement. In other words, as presently worded, this particular proposal is basically almost like a license to ambush.

Now, proponents have said that this is needed to protect those patentees that cannot make use of process claims because their patents to biotechnology products were granted without them, and they now cannot obtain protection through process claims because their patents are more than 2 years old. As you know, under H.R. 587 there is a certain amount of retroactivity, in that patents that are less than 2 years old from the date of issue or from the date of enactment of H.R. 587 could be reissued with appropriate process claims, if they have support for that in their specification.

But there are cases out there which were issued before those 2 years and that may have not had process claims because of difficulties during prosecution and probably because of *Durden*. Now we don't know how many cases are out there that are in that category, but if title 2 is to be used to help only these patentees—in other words, that 5 percent that has been referred to—then it appears that it might not be needed after enactment of H.R. 587. And, so the question arises whether title 2, even if properly drafted, should have a prospective effect. But these are just some comments on the proposal without basically taking a position on it. We have to look very carefully at it.

Mr. MOORHEAD. Well, thank you very much. My time has expired.

I recognize the gentlelady from Colorado, Mrs. Schroeder.

Mrs. SCHROEDER. Thank you very much, Mr. Chairman, and thanks to the panel. It was very helpful.

As the gentleman from Massachusetts said, this committee also has a bill on the floor. So a lot of us are going to be running in and out, and we apologize for that kind of craziness, but it's been that kind of year.

Let me talk—Mr. Hoinkes, you said in your testimony the administration's preference was for an approach that was not industry-specific; right——

Mr. HOINKES. Correct.

Mrs. SCHROEDER [continuing]. That you still backed this even though——

Mr. HOINKES. Well, yes, Mrs. Schroeder. The problem is that for years we had supported a basically generic approach to this problem because the problem is not limited to the biotechnology industry. It does affect applicants in the chemical arts. There's no question about it.

Mrs. SCHROEDER. And Europe and——

Mr. HOINKES. And Europe has——

Mrs. SCHROEDER [continuing]. And Japan?

Mr. HOINKES [continuing]. An absolute generic approach; that is absolutely correct. But every time a bill that tried to solve this problem generically was brought to the floor it created such opposition and such howls of protest that one had to realistically reassess the situation and say, all right, if we can't have it generically, let's take a look where apparently the shoe hurts most, and that seems to be in the biotechnology industry. And if we can take one step forward and help the biotechnology industry, then so be it. Better to have a small solution than no solution at all.

Mrs. SCHROEDER. And maybe that moves us eventually to a more generic approach——

Mr. HOINKES. Well, the possibility is there. As experience is gained through the years, possibly with this approach in the biotech industry, other people would realize that it wasn't as bad as they had feared, and maybe a generic approach is still in the wings.

Mrs. SCHROEDER. I was interested in the question the chairman was asking about Mr. Odre's proposal and I was interested in watching your body language. You seemed to want to say something. So maybe we should continue the debate, if that's OK, Mr. Chairman.

Mr. ODRE. With respect to title 2?

Mrs. SCHROEDER. Yes.

Mr. ODRE. OK. The language in title 2 is very similar to the language that has been in title 2 since probably about 1990, if I'd have to compare all the statutes. This at times—nobody has objected to title 2 based on the language of title 2. I think the importance of title 2—and now I'm going to switch hats from testifying to my hat as a litigator; I've been involved in litigation at Amgen for 7 years—it's extremely important to have certainty and consistency. We have host cell claims that have been allowed. We know what they are, as I said earlier. And, in terms of being able to enforce those against what I consider foreign manufacturers who are basically stealing the technology, using it, and importing these products, I think it is important in terms of everybody knows what host

cells protection is, and I feel that that is one of the best ways to do it.

Title 1 will give effective process protection, I do believe, but title 1, people are going to get questioned: What is the scope of these types of claims? It's going to be an issue as long as there are lawyers in the future, we will have issues and we're going to have court tests regarding the scope of this language.

I think title 2 provides a very effective means for the biotech industry right now to give us enforceable protection on patents that we have. There's no doubt about these patents are valid and they're enforceable against U.S. companies. All the way up to the Supreme Court, that has been held true. So my view on title 2 is, I think, we're prepared to work with the language, if it's a language issue, but I don't think anybody has argued that title 2 provides—is unnecessary in view of title 1. I think title 2—nobody has objected to title 2 per se. I can go back to past testimonies. I believe people were in favor of title 2.

Thank you very much.

Mrs. SCHROEDER. Did you have anything you wanted to add to this or is this enough?

Mr. HOINKES. Oh, no, Mrs. Schroeder, I certainly don't want to exacerbate the dialog here, but I do recall in previous administrations letters from the General Counsel of the Department of Commerce to this subcommittee saying that title 2 was unnecessary in light of title 1. I can supply these letters for the committee.

So, in fact, there hasn't been unfettered support for title 2. In fact, when you really come down to it, yes, there may be litigation as to the meaning of protection of a process claim, but that's the facts of life. And if we can get this particular bill through Congress, I think we will have really achieved a giant step at least for the field of biotechnology.

Mrs. SCHROEDER. Mr. Linsert, or anyone else, do you have any specific examples of foreign companies taking advantage of American companies being unable to get process patents?

Mr. LINSERT. I don't.

Ms. CIMBALA. BIO has not researched that issue formally. I'm certain that we can and perhaps submit a written statement later, if you'd like.

Mrs. SCHROEDER. That might be helpful when we go to the floor to show we didn't make this up, don't you think, Mr. Chairman? If there's something there, I think it would be helpful to show why we do need this, and why, to make the playing field level, this is a very important thing.

[See appendix.]

Mrs. SCHROEDER. I think my time, too, has expired, Mr. Chairman, and I know I have to go to the floor to work on this bill. So thank you, and thanks again to the panel.

Mr. MOORHEAD. I recognize the gentleman from North Carolina, Mr. Coble, for 5 minutes.

Mr. COBLE. I thank the chairman.

Mr. Linsert, the gentleman from Pennsylvania asked if you planned to dispense your brain oil. If you do, I need a graciously generous serving. So if you'll keep that in mind—with unanimous consent perhaps, I ask for that.

[Laughter.]

Mr. COBLE. Mr. Hoinkes, I'm about to put a question to you which is rhetorical in nature, not unlike your asking me if I think I'm doing a good job as a Congressman. My question to you, sir, is: Do you think you all, you and your able staff over at PTO, have been misapplying the law relating to the examination of process patents in denying or delaying the issuance of process patents? Now I'm not suggesting that you are. What gives rise to my question is the article that appeared in the University of Denver School of Law law review some 3 or 4 years ago where the writers pretty well do suggest that there has been erroneous and inconsistent application in *In re Durden,* and I would be happy to hear from you.

Mr. HOINKES. Well, Mr. Coble, the first part of my answer would be, no, we're not misapplying the law. And if one looks at the application of *Durden,* basically, what the case held was that if the steps were otherwise conventional just because a process claim uses a patentable starting material to arrive at a patentable end product does not make that claim unobvious. That's the pure and simple holding of the case. It then continued that everything had to be really examined on a case-by-case basis, and, frankly, that's what we're doing. We're examining on a case-by-case basis, and we're saying just because you have a patent on starting material does not necessarily mean that your case is nonobvious. Well, this is what the court is telling us to do.

And, it's truly difficult because the court has also almost made a game of the situation because we're dealing in semantics. We're deliberating whether we have a claim that uses a starting material, or whether we have before us a claim that makes an end product. Apparently, even though you have got the same starting material and the same process, if you are saying you are making an end product using the starting material, then apparently you have a problem, because the court holds this to be unpatentable. Under a later decision, however, if you turn the thing around and say you are using a patentable starting material—and, by the way, I'm coming out with this patentable end product—the court is saying, well, on the facts of that case, this seems to be patentable. We don't know whether we're coming or going as far as these court decisions are concerned. And, as I've said before, you've got another decision, another case, sitting before the CAFC right now and it's getting mighty cold up there.

So the short answer to your question, sir, was, basically, we think we are applying the law as the court has told us to.

Mr. COBLE. Mr. Linsert and Mr. Odre, I was going to ask you a question that I believe the lady from Colorado pretty well—I was going to ask you for specific instances and numbers, if you have them, of foreign companies that are taking advantage of U.S. firms' inability to obtain process patent protection, and I think that's the same question she put to you all in your response. If you all can get that information to us, I would be appreciative.

[See p. 46 for information requested.]

Mr. COBLE. I'll ask this to either member or all the members of the panel. It has been said—and I don't recall where I read this—that two-thirds of biotechnology process patents are issued only after a *Durden* rejection is made and subsequently overcome with

evidence of "unexpected results." Can you all comment or illuminate further on this conclusion? Any or all—ladies first.

Ms. CIMBALA. I would say that sounds quite accurate to me in my practice for biotechnology for our process patents. We can almost predict which claims will get a *Durden* rejection, and if we are not able to overcome it by the manner in which you suggested, we must simply keep filing and take it to appeal to keep the case pending and have every, then, process claim heard by the appellate level.

Mr. COBLE. Doctor, do you think—it is your opinion, then, that this is an unusually or an unreasonably excessive number?

Ms. CIMBALA. Yes, I do.

Mr. COBLE. Anybody else want to weigh in on this?

Mr. ODRE. I can agree that there is a large number. I don't know if it's two-third. I think—but one of the problems is the uncertainty. You don't know whether *Durden* will apply. It is on a case-by-case basis. *Durden* says that in the opinion: it should be interpreted case-by-case. But, unfortunately, perhaps not all the examiners go on a case-by-case basis. It's very difficult in defense of the Patent Office, it's a very difficult situation they're faced with. And with a large number of examiners, sure, there will be some inconsistencies whether *Durden* will be applied, may not be applied in a very similar case.

Mr. COBLE. Mr. Chairman, a final comment. I guess what bothers me about this is perhaps more ideological than anything else. A rejection is forthcoming, and then, subsequently, overcome. What bothers me is the little guy or the little woman or maybe the small university or college who may well be impoverished compared to the optimum applicant who can sustain the wherewithal of this. I guess that's the nature of the beast, you know, not unlike the impoverished plaintiff going against the deep-pocketed defendant. But do you all have any suggestion as to whom that pain can be assuaged? I don't have, but I wondered if—to make it easier on the little guy. Do each of you want to weigh in on that or do you have an idea?

Mr. LINSERT. Well, any elimination of uncertainty in the application process, which is, of course, what we're here to talk about today, and we believe the chairman's bill is a step toward reducing that uncertainty and eliminating——

Mr. COBLE. At least clarify it to some extent.

Mr. LINSERT. Clarifying and eliminating some of these appeals, and the individual patent examiners are fighting each day to do their job, and to have clarity in their job speeds up the whole process.

I know in our little company the last 2 years we've—last year we paid $340,000 to our patent attorneys to do our extensive year, and the year before it was about $310,000. So we're a little company, and you get a sense of the magnitude. This is a big expense for us.

Mr. COBLE. I'm sure it is.

Mr. LINSERT. And this type of clarification is going to be helpful for us small guys.

Mr. COBLE. Well, my time has come and gone. Thank you all for being with us. Thank you, Mr. Chairman.

Mr. MOORHEAD. Thank you.

One of the real tenacious battlers over the long struggle to get this legislation enacted into law has been the gentleman from Virginia, Mr. Boucher.

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

Mr. Odre, let me inquire for a few minutes of you about the potential need for having two solutions to this problem instead of one. Title 1 of the old legislation, which is reflected in this bill, would extend effective process patent protection by overruling *In re Durden* and, therefore, assuring that the International Trade Commission would have ample jurisdiction to exclude products that are manufactured overseas using a host cell or other starting material that is patented here in the United States through the use of a process that also is patented here in the United States. And that would seem to me to be an effective solution to the overall problem in and of itself.

You have recommended that we also provide a second solution, and that is to confer upon the appropriate U.S. district court jurisdiction to determine that a patent infringement has occurred whenever the product is manufactured overseas merely using the starting material that has been patented here in the United States, without regard to the process or a process patent.

It would seem to me that either of these solutions in and of themselves would be sufficient to solve the problem. Do you contend that both solutions are necessary to provide effective relief?

Mr. ODRE. OK, I will agree with you that both solutions—both title 1 and title 2 will provide effective protection.

Mr. BOUCHER. Either one taken alone?

Mr. ODRE. Either one. At worst, it will provide protection. Title 2 in some instances may grant additional protection where the process claims have not been allowed or in a situation where process claims have been limited by requiring to put in certain parameters and the like during early prosecution.

Mr. BOUCHER. So, to restate that, where there is some problem in obtaining the process patent, you would like to have underlying protection by being able to exclude the product if it was manufactured overseas using a patented starting material?

Mr. ODRE. Right. What we're asking for is to have domestic manufacturers treated the same as foreign manufacturers. With the host cell claim, we can stop every domestic manufacturer from making the product. All we want to do is not have a foreign company or a U.S. company ship a host cell offshore, which has been done, and will attempt to try to now import that product. That's simply all we're asking for.

Mr. BOUCHER. Thank you. Well, with that having been said, I think what we can conclude from that is that either solution is effective in and of itself as long as you get adequate process patent protection. That's the key. If you can get that adequate protection, that solution in and of itself gives you the protection you need with respect to the import situation, which is the entire problem we face.

Mr. ODRE. I will agree that, yes, title 1 will give you effective protection.

Mr. BOUCHER. All right. Let me ask Mr.—and I'm sorry I don't know how to pronounce your name, the gentleman at the end of the table from the Patent Office.

Mr. HOINKES. Hoinkes.

Mr. BOUCHER. Yes. Let me ask you if you have any response to the suggestion that Mr. Odre has made while title 1 offers significant protection and sufficient protection in the event that the process patent is effectively awarded, that it would also be helpful to have an underlying protection by being able to exclude the product that is manufactured with a patented host cell without regard to the process that is used. Do you have any reaction to the recommendation that both of those protections be adopted?

Mr. HOINKES. Well, Mr. Boucher, I cannot give you a formal administration position on the subject.

Mr. BOUCHER. Just a practical suggestion as to whether or not the second approach that's recommended would be helpful or if you see any practical problems with it.

Mr. HOINKES. Well—obviously, the more one can get, the better one is off. The real question is, does one need as much as one wants?

Mr. BOUCHER. And, that's the question I'm asking you.

Mr. HOINKES. Well, Mr. Boucher, in my humble opinion, if you get title 1, you've got plenty.

Mr. BOUCHER. All right, thank you very much.

Mr. Linsert, let me ask you, if I may, to talk a little bit about the economic condition of the biotechnology industry. Talk a little bit, if you would, about the level of investment that has been made by the biotechnology industry overall, about the number of employees that exist within that industry, and about the contribution that it makes on an annual basis to the American balance of trade, if you have those numbers.

Mr. LINSERT. I don't have those numbers in front of me. I—the biotechnology industry has become a major industry over the last 10 to 15 years, and it's really the industry of the future for the country. We are a net generator of jobs and we expect to be a generator of jobs over really as far out on the horizon that I can see. Many, many products are coming into being, and the contribution that this industry is going to make to the country is just a fantastic one. We can submit those numbers and we have those numbers, and I apologize for not being—having those——

Mr. BOUCHER. That's fine. If you could submit that to us, it would be extremely helpful.

Mr. LINSERT. Thank you.

[See appendix, p. 57.]

Mr. BOUCHER. With those questions, that's all that I have. Thank you, Mr. Chairman.

Mr. MOORHEAD. Thank you.

I will recognize the gentleman from Pennsylvania.

Mr. GEKAS. I thank the chairman.

I take it from the testimony that has been offered, and in looking over the written portions thereof, that no one is concerned about what conflict, if any, there exists or any juxtaposition with the tenets of GATT. I would ask Dr. Cimbala, if I could, if the recent ac-

commodations reached in GATT in any way affect any of what we're attempting to do here.

Ms. CIMBALA. I don't believe so. I see no conflict at all.

Mr. GEKAS. What was the major portion of GATT that had to do with patents and intellectual property protection generally, if——

Ms. CIMBALA. Well, we changed our patent term.

Mr. GEKAS. Yes. Oh, just the term?

Ms. CIMBALA. Yes, to run 20 years from filing of the earliest U.S. priority document.

Mr. GEKAS. So that elongation of the term has nothing to do with what we're attempting to do here?

Ms. CIMBALA. Not the subject matter that's protectable, no.

Mr. GEKAS. All right. OK. The other question that I have is with respect to testimony of Mr. Linsert. I'm interested in a tangential portion of what you testified, that $6 million of the capital that you were able to attract came from 40 small business innovation grants, primarily from NIH. I'm a supporter of NIH and all its ventures; I'm a little dismayed at some of the proposed cuts that are built into our platform forthcoming.

And I would like to know, are you talking about 40 grants from 40 different small businesses?

Mr. LINSERT. No. This is—we had submitted 40 different projects that we had been funded for.

Mr. GEKAS. I see.

Mr. LINSERT. In fact, all—I would say Martek probably wouldn't be in existence without this program. It's been a fantastic program for the company.

These oils that you're looking at here in this infant formula wouldn't be here without those grants because that was—the initial exploratory research was funded under those small business innovation research grants. We've been one of the—we've been very fortunate and been one of the more successful companies in the biotechnology industry in obtaining these grants.

Mr. GEKAS. So we're talking about basic grants, basic research——

Mr. LINSERT. Yes.

Mr. GEKAS [continuing]. From NIH?

Mr. LINSERT. Yes.

Mr. GEKAS. And then your company goes into applied research, is that it, or——

Mr. LINSERT. Well, there's a program that's set aside for small businesses where the NIH, as well as other government agencies, request proposals in certain subject areas, and we then submit a normal proposal for research that has a commercial possibility behind it. This is not just research for research's sake, but definitely has a commercial end behind it. And this is then the subject of our research grants that we've submitted.

Mr. GEKAS. So these applications that you file, these 40 that we're talking about here, resulting in a grant directed to your company?

Mr. LINSERT. Yes. Yes, sir.

Mr. GEKAS. And you have onboard the scientists bank that——

Mr. LINSERT. Yes, that's correct.

Mr. GEKAS [continuing]. Proceeds to process; is that correct?

Mr. LINSERT. That's correct. And when we don't, we usually link up with a university to combine talents to work on this.

Mr. GEKAS. And do you take that grant money and use it to hire the university bank of scientists, or how do you——

Mr. LINSERT. Most of it goes for the company and funds our science and normal activities and expenses incurred that you do in research. And in the case where we're missing some expertise that we need to help, we'll go out to the university and contract for the services of a particular scientist or a particular scientist with some instruments that we might not have at Martek. So it's a combination, and in some cases you'll go out to certain clinics where we, again, lack certain expertise. So you'll—that's how it generally works.

Mr. GEKAS. Do you have any applications—are there recurrent applications you have with NIH, annual applications, or is it a one-shot type of application?

Mr. LINSERT. No, usually, there are solicitations that come out twice a year, and we comply with that schedule.

Mr. GEKAS. I would like very much, and I would use it on the floor when the debate comes about on NIH—I would be very interested if you could supply me with like an impact statement as to your company, should the discretionary cuts that are being applied to NIH—should they go into effect, if you can do that for me. Perhaps a discussion that you could hold with NIH, the people that you deal with there, on that score could help you help me.

Mr. LINSERT. OK. I don't know if the cuts affect this program, and I'll find out and see what the story is.

Mr. GEKAS. I don't, either, but——

Mr. LINSERT. OK.

Mr. GEKAS [continuing]. I would like to know.

Mr. LINSERT. Yes. It's been a great program for our company, and it's been really the fountain of all our product ideas that we're bringing to the market.

[The information requested follows:]

MARTEK
BIOSCIENCES
CORPORATION

6480 DOBBIN ROAD • COLUMBIA, MARYLAND 21045 • (410) 740-0081 • FAX (410) 740-2985

March 31, 1995

The Honorable George W. Gekas
2410 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Gekas:

At the hearing on the Biotechnology Process Patent Protection Act, H.R. 587 on March 30,1995, you requested that I provide you more information on Martek's NIH support. In total, NIH has funded 29 Martek projects for a total of approximately $5.4 million. I have attached a printout of the different Martek projects that the NIH has supported. The most important point behind the numbers, however, is that Martek wouldn't have made it if wasn't for NIH support in the early stages of the company. Furthermore, NIH's support with its Small Business Innovation Research Grant program has provided Martek with the basic technology for all of its four product areas. This support also played a significant role in Martek's ability to raise four rounds of private venture capital and was critical to the company in its successful initial public offering in late 1993.

Martek is now on the verge of bringing its first major product to market consisting of two fatty acids that are found in the brain, retina and nervous tissue throughout the body. (NIH helped fund early R&D for this project.) These fatty acids are found in human milk, but not in infant formula. There is a growing body of evidence that a deficiency of these fatty acids leads to a lower IQ and increased probability of behavioral problems. Martek now has approximately 40% of the world's manufacturers of infant formula under license and the product is now on the market in Belgium. Widespread use of the product is expected to begin in Europe later in 1995 and in the US in 1996 to improve infant formula by more closely matching human milk. Dietary supplementation of these fatty acids may also have use for the elderly and lactating women.

In a business sense, Martek lives today because of past NIH support. In the future, past NIH's support for Martek's research should lead to major contributions to nutrition, possibly a new generation of antibiotics, new diagnostics and lower drug development costs. Enclosed is an annual report that list in more detail, Martek's full product line and their potential contribution to human health and well being.

I understand that you are instrumental in the Congressional Biomedical Caucus. I would like to know more about the caucus and it Martek could be helpful to it.

If I can be of any assistance to you or the NIH programs in the future, please let me know.

Sincerely,

Henry (Pete) Linsert Jr.
Chairman & CEO

FOR YOUR INFORMATION: PP&L Resources, Inc.'s Response to PECO Energy's Unsolicited Proposal

Public Affairs Contacts: Linda Curry Bartholomew, Vice President-Public Affairs (610) 774-5201
Frank K. Gates, Director-State Public Affairs (717) 257-5954
Robert J. O'Hara, Director-State Public Affairs (610) 774-4470
John S. Sparkman, Director-Federal Public Affairs (202) 662-8755
Public Affairs Fax (Allentown Office) (610) 774-5884

* * * * * * * * * * * *

Contact: Robert J. Grey, Vice President, General Counsel and Secretary (610) 774-5587
PP&L Resources, Inc.
Two North Ninth St.
Allentown, Pa. 18101

PP&L Resources to Evaluate PECO Proposal
Hecht says PP&L Resources Board Will Analyze
Several Areas of Significant Concern in Unsolicited Proposal

ALLENTOWN, Pa.---PP&L Resources, Inc. (NYSE:PPL), parent company of PP&L, said Monday (8/14) that it would evaluate the unsolicited proposal it has received from PECO Energy Company (NYSE:PE) and respond to the proposal as and when appropriate.

William F. Hecht, chairman, president and chief executive officer of PP&L Resources, replied in a letter to Joseph Paquette Jr., the chairman of PECO, that PECO's proposal would be given careful consideration by the PP&L Resources Board.

Hecht noted, however, that the PECO proposal contained "several areas of substantial concern," including the real effect on PP&L's shareowners, employees and other constituencies; whether the PECO proposal would result in any rate increases for PP&L customers; how the "savings" suggested by PECO would be realized; and whether the value of the combined enterprise would be negatively impacted by PECO's past investment costs, which PECO may not be able to recover from its customers in a deregulated environment. These costs have been estimated by industry analysts to be in a range from $4.86 billion to $7 billion.

Hecht said that the PP&L Resources Board, working with outside legal and financial advisers, will study the proposal.

Here's the text of Hecht's letter to Paquette:

Dear Joe:

I am in receipt of your letter of August 14, 1995. I am disappointed that you took this precipitous step despite my earlier correspondence in which I requested that you not take any further action before the Board of PP&L Resources assesses the wisdom of combining our two companies and determines whether any such combination would be beneficial to the shareowners and other investors, customers, employees and other constituencies of PP&L Resources. Nevertheless, the Board will fully evaluate your proposal, give it careful consideration, and respond to you as and when appropriate.

Based upon your prior correspondence, I would point out that there are several areas of substantial concern to the Board. As I specifically indicated to you in our previous discussions, PP&L Resources is particularly troubled by PECO's high-cost structure and seriously concerned about its ability, in a deregulated environment, to recover its considerable past investment costs. Your proposal still fails to address these and other critical issues.

As you are probably well aware, PP&L Resources takes significant pride in what it has accomplished. In spite of a difficult economic environment, PP&L has succeeded in providing reliable power to our residential, commercial and industrial customers at rates that are substantially lower than those of PECO. Because we have kept our retail rates stable over the past decade, we have helped our communities grow and rebound from a long and arduous recession. We have been able to achieve our long-term objectives of charging rates that are fair and attractive to customers, while generating sufficient earnings to provide our shareowners with an attractive total return on their investment.

Among the specific issues raised by your proposal that the PP&L Resources Board will be studying include:

-- Whether PECO will be able to recover its past investment costs in a competitive environment and whether these costs, if unrecoverable, will diminish the value of the combined enterprise at the expense of PP&L Resources shareowners. Some industry analysts have calculated that PECO's unrecoverable costs could be in a range from $4.86 billion to $7 billion. For example, in a July 1995 report, Moody's Investors Service estimated that PECO's unrecoverable costs are more than $4.86 billion and represent 114 percent of PECO's book equity.

-- Whether PECO ultimately will pass on any of its costs to PP&L customers through rate increases. We note that PECO's rates are among the highest in Pennsylvania; in fact, they are as much as 55 percent higher than PP&L's.

-- Whether PECO can realistically achieve its projected "savings" of about $2 billion over 10 years and whether these "savings" will come at the expense of PP&L's employees in the form of terminations; at the expense of PP&L customers in terms of service levels; and, ultimately, at the expense of the communities PP&L serves.

-- The impact of the implied 16 percent reduction in dividends on PP&L shareowners.

These are just a few of the matters we will be addressing in our evaluation. As you can appreciate, these are not insignificant questions for our Board to consider, and they have major implications and potential ramifications for our shareowners and other investors, customers, employees and other constituencies. I can assure you that, working with our outside legal and financial advisors, we will diligently analyze and evaluate your proposal and respond in due course.

PP&L supplies electricity to a 10,000-square-mile area of 29 counties in Central Eastern Pennsylvania. Among the communities it serves are Allentown, Bethlehem, Harrisburg, Hazleton, Lancaster, Scranton, Wilkes-Barre and Williamsport.

Mr. GEKAS. All right, thank you. I have no further questions. I yield back the balance of my nontime.

Mr. MOORHEAD. Thank you.

I recognize the gentleman from Virginia, Mr. Goodlatte.

Mr. GOODLATTE. Thank you, Mr. Chairman. I don't have any questions.

Mr. MOORHEAD. Mr. Boucher, do you have any further questions?

Mr. BOUCHER. Nothing further, Mr. Chairman.

Mr. MOORHEAD. We've had a good panel this morning, and I want to thank all of you for coming.

I have one question that I want to ask Mr. Hoinkes relating to our good friend, "Woodsy Owl," it's not a part of the record of this bill; it's a part of the record of H.R. 1269. The Department of Agriculture will be redesigning "Woodsy Owl." If the new design should be similar to a design in existence, shouldn't the similar design already in existence be permitted to continue? Should we add some prior user rights language to the bill?

Mr. HOINKES. Well, thank you, Mr. Chairman. As you well know, as you have stated yourself, the administration has not formulated a position on this legislation.

Mr. MOORHEAD. I understand.

Mr. HOINKES. And——

Mr. MOORHEAD. Well, the Department of Agriculture evidently has or they wouldn't have asked for it.

Mr. HOINKES. Well, such is life. I can give you a few personal comments on this, especially in reply to your query. I suppose that what is being proposed by H.R. 1269 is that this proposal would sort of legislatively undress "Woodsy Owl" and just leave him with the characterization that he is fanciful. Well, sort of given the much wider scope of coverage proposed for "Woodsy" now, it is not unlikely that there may be somebody out there who is using a fanciful owl that is the same or very similar to the one being developed by the Forest Service.

For your information, there are, for instance, 195 trademarks registered and about 36 applications that use fanciful owls within the ambit of their trademark. Now it would seem prudent, therefore, to include in any amendment that is proposed in H.R. 1269 some type of a grandfather clause that protects any prior use of a fanciful owl design.

Now just by reference, this was done in legislation creating the U.S. Olympic Committee, for instance, and language could be crafted that is quite similar to that which is used in—I think it's title 36, section 371, or some such, a language that could say something along the lines that any person who actually uses a fanciful owl in any form or for any lawful purpose prior to the date of enactment of this particular bill shall not be prohibited by this section from continuing such lawful use for the same purposes, et cetera, et cetera. That would be very, very useful to protect those people who are presently using fanciful owls for lawful purposes.

Mr. MOORHEAD. Thank you.

Mr. Becerra from California has returned, and he has questions he wanted to ask on H.R. 587.

Mr. BECERRA. Thank you, Mr. Chairman. I appreciate that.

I only have a couple of questions, and, quite honestly, in going in and out of the hearing, I don't know if they have been answered. So forgive me if they have.

First, let me thank the panelists for being here, and I think at least this time around it looks like we probably have some legislation that can get through without too much of a problem.

One of my questions will relate to the fact that we have narrowed the scope of the bill to deal only with the biomedical industry, but my first question—and let me ask Mr. Hoinkes?

Mr. HOINKES. Hoinkes.

Mr. BECERRA. Mr. Hoinkes, does section 103 of the bill dispose of any pending cases that are before the Court of Appeal, making it thereby possible for those firms that filed the case to get their patents, or are they outside the biomedical industry?

Mr. HOINKES. I do believe that they are outside the biomedical.

Mr. BECERRA. So in terms of their cases pending in the court—and it's been quite some time since we've been waiting for them to decide——

Mr. HOINKES. 1992.

Mr. BECERRA. Yes, since 1992. Those cases will not be affected by this legislation?

Mr. HOINKES. I think that is correct, sir.

Mr. BECERRA. Given that—and I ask this of any of the panelists—what do we expect to be the ramifications of passage of this legislation for the other industries? I would imagine that the folks that are right now waiting close to 3 years now for the court to make a decision that are not biomedical firms are probably interested in trying to do the same type of thing, where they will be able to get themselves a niche in the law that protects them. What do we see as the ramifications of providing specific relief for a particular industry in an area that obviously goes beyond just one particular use or product? Open for anyone to answer.

Mr. ODRE. Well, this isn't the first time that we've had industry-specific legislation, especially in the patent laws. Under the patent laws, there is a patent term extension that applies only to the pharmaceutical industry, and there may be other examples my colleagues may have, but for sure there are other examples of industry-specific-type legislation.

Ms. CIMBALA. I also believe the ramifications will only be positive ones. I believe, if anything, this will provide the guidance that the other industries need to amend the law accordingly.

Mr. BECERRA. A followup to that question, guidance, any guidance you may offer on any future legislation we may have to draft to deal with other industries, since this is specific to the biomedical industry—do you expect that what we come up with ultimately to spread this to other industries will look very similar to the legislation we have today, or will there have to be other accommodations made to make sure that we're able to get consensus on a bill that could expand the scope of protection to other industries beyond what we're doing today?

Ms. CIMBALA. I would not be surprised if it was very similar. Biotechnology has its own unique problems; there's no denying that, but in terms of broadening the language of the bill to encompass other industries, if and when those other industries decide that

they, in fact, need this to protect their U.S. patent rights and their technologies in the United States, I believe it would be very simple.

Mr. BECERRA. Anyone else?

[No response.]

Mr. BECCERA. Thank you, Mr. Chairman. That's all I had to ask.

Mr. MOORHEAD. Thank you.

I'd like to thank the witnesses for coming today. You've really helped us out a lot on your testimony.

This concludes our hearings on these two bills. The record will remain open.

Mr. MOORHEAD. Thank you for your cooperation.

The subcommittee stands adjourned.

[Whereupon, at 11:35 a.m., the subcommittee adjourned.]

APPENDIX

LETTER DATED APRIL 5, 1995, FROM BIOTECHNOLOGY INDUSTRY ORGANIZATION WITH ENCLOSURE ENTITLED, "THE U.S. BIOTECHNOLOGY INDUSTRY: FACTS AND FIGURES," 1994/1995 EDITION

Bio

BIOTECHNOLOGY INDUSTRY ORGANIZATION

April 5, 1995

The Honorable Carlos J. Moorhead
Chairman, Subcommittee on
Courts and Intellectual Property
2346 Rayburn HOB
Washington, D.C. 20515

Dear Chairman Moorhead:

We again thank you for scheduling and chairing last Wednesday's hearing on your biotechnology process patent bill. It was a very good forum for all of us to discuss the need for the bill and the benefits it will provide biomedical research.

I am writing to respond to two questions raised at the hearing: (1) information on the size and scope of the U.S. biotechnology industry; and (2) the nature and extent of the Durden problem.

Enclosed for your review are the most recent economic data regarding the biotechnology industry and a compendium of information provided at earlier hearings on the Durden problem which document its nature and extent.

In addition, we refer you to the printed hearing record of the June 9, 1993 hearing entitled "Amending Title 35, United States Code, With Respect to Patents on Certain Processes." The testimony of Kirk Raab, Chairman and CEO of Genentech appears at pages 36-38 and his letter and survey at page 79-83 provide points and data regarding the Durden problem.

Finally, our witness at the hearing, Pete Linsert, has provided information directly to Congressman Gekas in response to his request regarding the role of SBIR grants at the National Institutes of Health.

Thank you for your leadership on this important issue. Please let us know how we can be helpful.

Sincerely,

Chuck Ludlam,
Vice President,
Government Affairs

Biotechnology Industry Organization

THE U.S. BIOTECHNOLOGY INDUSTRY:

FACTS

AND

FIGURES

1994/1995 Edition

TABLE OF CONTENTS

Bio

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

Executive Summary

The biotechnology industry is one of the cornerstone industries of America's future economic growth. As some of our current industries become obsolete, the biotechnology industry is poised to provide high-skilled, high-wage jobs of the future. In fact, the United States is the world leader in biotechnology. Right now, 1,311 biotechnology companies employ 103,000 people in the U.S. The biotechnology industry is also a substantial exporter of products, and as the industry grows, this will continue. In 1994, the biotechnology industry had sales of $7.7 billion, a 10% increase over the previous year.

The industry spent $7 billion in 1994 on research and development and $18 billion has been spent over the last 3 years. A recent Business Week article points out that the top 7 U.S. companies in R&D spending per employee are biotechnology companies, and 6 of the top 10 companies in R&D as a percentage of sales are biotechnology companies. In addition, the biotechnology industry compares very favorably with the pharmaceutical industry in terms of R&D intensity. R&D expenditures per employee in the biotechnology industry were $68,000 in 1994, compared to $39,000 per employee for the established pharmaceutical industry.

It will not be possible for the industry to sustain its current level of research intensity if the capital markets do not become more receptive. Presently, 26% of public biotechnology companies can expect to last less than one year at their current cash burn rates. A full 50% of public biotech companies have only enough capital to last two years or less. In addition, the American Stock Exchange Biotechnology Index, a leading indicator for the industry, lost 21% during the first three quarters of 1994.

The figures in this report signify the promise of the biotechnology industry, while also exhibiting its fragility. The hurdles for companies to be successful are substantial, but the potential continues to drive the biotechnology industry forward. In order to succeed, the industry needs FDA streamlining, additional product successes, and an increased receptiveness from the capital markets.

SUMMARY PROFILE OF THE U. S. BIOTECHNOLOGY INDUSTRY[1]

Sales

The American biotechnology industry continues to move forward with commercial development. Total industry sales reached $7.7 billion in 1994, a 10% increase over 1993 and a 28% increase over 1992. Public biotechnology companies sales accounted for $5.2 billion of that total, a 20% increase over 1993. The following table sets out a sales breakdown for particular market segments[2] of public biotech companies:

Market Segment	Avg. 1994 Sales/Co. (Avg./ $ millions)	Percentage Increase over 1993
Diagnostic	$10.4	1%
Therapeutic	$20	24%
Agricultural	$12.3	158%
Supplier	$20.9	(47%)
Industrial, Environmental and Services	$69.9	81%

Markets

As the biotechnology industry continues to grow, there is more information available on markets for biotechnology products. Below are some valuations of market segments for existing biotechnology products and predictions of markets for future biotechnology products and the industry as a whole:

* The European market for biotechnology related goods and services is about $45 billion (ECU 38 billion).[3]

* The world market for industrial enzymes was valued at over $900 million for 1993.[4]

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[1]Except as otherwise noted, all data is derived from Ernst & Young, Biotech 95 Reform, Restructure, Renewal, Ninth Annual Report on the Biotechnology Industry (G. Steven Burrill and Kenneth B. Lee, Jr., 1994). The report tracks the industry from July 1, 1993 through June 30, 1994.

[2]Market definitions: The diagnostic and therapeutic categories include human health care products; the agricultural category includes microbial crop protectants, plant genetics, food processing and animal health; the supplier category includes instrumentation, lab supplies, reagents and other similar products; and the chemical, environmental and services category includes fine chemicals and bioremidiation.

[3]Kenward, Michael, "Survey Shows European Market for Biotech-Related Industry," BioWorld Today, October 3, 1994, p.1.

[4]Stroh, William H., "Trends in Use of Industrial Bioprecessing Enzymes for the 21st Century," Genetic Engineering News, September 15, 1994, Pgs. 10-11.

- Frost & Sullivan, a market intelligence company, reports that the total market revenues for the U.S. agricultural biotechnology industry in 1993 were $107.5 million and predicts that by the year 2000 "they should amount to nearly $2 billion."[5]

- Frost & Sullivan also predicts that the gene therapy market will "generate $2.6 billion in worldwide revenues by the turn of the century."[6]

- In 1992, the President's Council on Competitiveness predicted that biotechnology would be a $50 billion industry by the year 2000.[7]

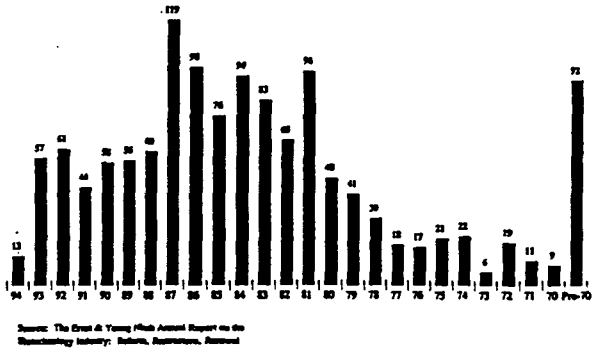
Number of Companies, Company Size and Age

The American biotechnology industry is an industry of small businesses. There are currently 1,311 companies in the biotechnology industry, with 265 of those being public companies. Of the public companies, 37% have fewer than 50 employees, 18% have between 51 and 135 employees, and 12% have between 135 and 299 employees.

The American biotechnology industry is young. Although there were 93 biotech companies in the U.S. before 1970, the real growth period for the industry began in the early 1980s and peaked in 1987, when 121 new companies were founded. During 1994, the industry grew by 39 companies, a 3% increase.

The Biotechnology Industry

Year of Company Founding



[5]"U.S. Agricultural Biotechnology Markets," Frost & Sullivan, July 1994.

[6]"Frost & Sullivan Predicts Gene Therapy Market to Top $2 Billion By the Year 2000," Genetic Engineering News, September 15, 1994, Pg. 42.

[7]The President's Council on Competitiveness, Report on National Biotechnology Policy (February 1991). By way of comparison, the pharmaceutical industry produced nearly $85 billion in sales for 1994.

Research and Development

The American biotechnology industry's research and development (R&D) expenditures are among the highest of all U.S. industry segments. R&D accounted for 43% of total costs and expenses incurred by public biotechnology companies in 1994. R&D expenditures (as defined by generally accepted accounting principles) for the entire biotechnology industry in 1994 reached $7.0 billion, a 23% increase from 1993.

* A recent Business Week survey of the R&D intensity of all industries points out that the biotechnology industry is one of the most R&D-intensive industries in the United States: the top 7 U.S. companies in R&D spending per employee are biotechnology companies, and 6 of the top 10 U.S. companies as a percentage of sales are biotechnology companies.[8]

* R&D expenditures as a percentage of sales in the biotechnology industry were 91% in 1994, compared to 16% for the pharmaceutical industry.

* R&D expenditures per employee in the biotechnology industry were $68,000 in 1994, compared to $39,000 per employee for the pharmaceutical industry.

Financing

The American biotechnology industry currently lacks needed capital. Cash use for public biotechnology companies increased by 16% in 1994. At the same time, cash sources increased by only 9 percent. This has led to a 27% decline in the survival index[9] for the median public biotech company, from 34 months to 25 months.

* Twenty-six percent of public biotech companies can expect to last less than one year at their current cash burn rates. A full 50% of public biotech companies have only enough capital to last two years or less.

* The market capitalization for the biotechnology industry dropped 15% from July 1, 1992 through June 30, 1994, going from $48 billion to $41 billion.

[8] Coy, Peter, "What's the Word in the Lab? Collaborate," Business Week, June 27, 1994, pgs. 78-80.

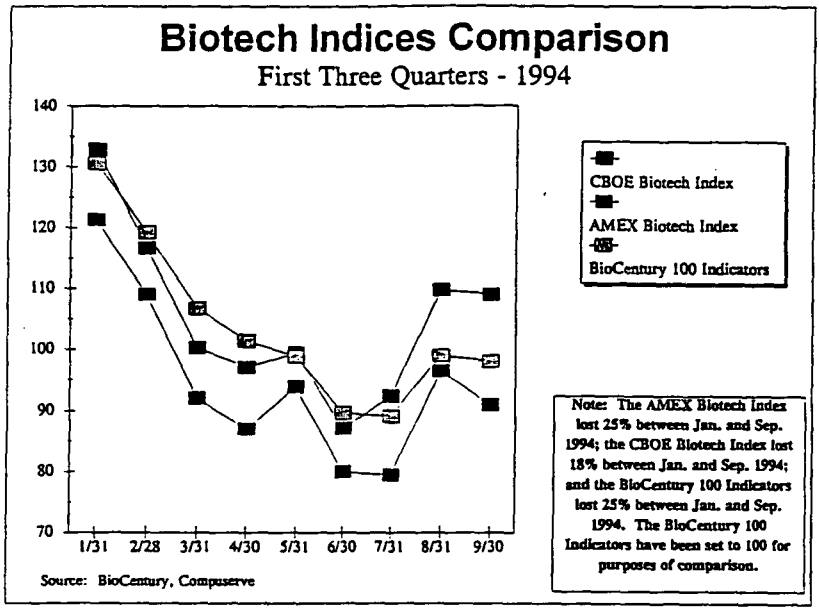
[9] The Survival Index, prepared by Ernst & Young, is a measurement of the amount of time a company can expect to survive with their existing supply of capital, at their current rate of spending.

* Three indices which track the biotechnology industry have posted significant losses for the first three quarters of 1994:

- The BioCentury 100™ Indicators[10] has dropped 35% for the first three quarters of 1994.

- The CBOE Biotechnology Index[11] has dropped 10% for the first three quarters of 1994.

- The Amex Biotech Index[12] has dropped 21% for the first three quarters of 1994.



[10]The BioCentury stock tables track 208 issues that report prices and volume on a daily basis. The BioCentury 100™ is a subset of the total list used to monitor overall price and volume trends.

[11]The Chicago Board of Exchange (CBOE) Biotechnology index consists of 15 companies meant to represent a cross-section of the biotechnology industry.

[12]The American Stock Exchange Biotech Index consists of 15 biotechnology companies, and is weighted towards companies with a large market capitalization, or Tier 1 companies.

A. 1994 STATISTICAL SUMMARY: U.S. BIOTECHNOLOGY INDUSTRY

Number of Companies and Employees

Total number of biotechnology companies: 1,311 (3% increase over 1993)

Total number of public biotechnology companies: 265 (13% increase over 1993)

* Average number of biotech companies founded per year in the 1980s: 80

Total number of biotech employees: 103,000 (6% increase over 1993)

Revenues, Sales, Income, Market Capitalization, Assets and Net Loss

Total revenues:	$11.2 billion (12% increase over 1993)
Total product sales:	$7.7 billion (10% increase over 1993)
Total market capitalization:	$41 billion (9% decrease from 1993) (as of June 30, 1994)
Total assets (public companies):	$16.2 billion (14% increase over 1993)
Net loss:	$4.1 billion (14 % increase over 1993)[13]

Over the last four years, the biotechnology industry has a net loss of approximately $14 billion.

[13] Reason for loss: The industry is not yet fully commercialized and companies lack product revenue streams against which to offset growing R&D, manufacturing, sales, and distribution expenditures.

Research and Development

Total industry R&D: $7 billion (23% increase over 1993)

* R&D expenditures as a percentage of sales: 91%
  (Compare with 16% for the pharmaceutical industry)

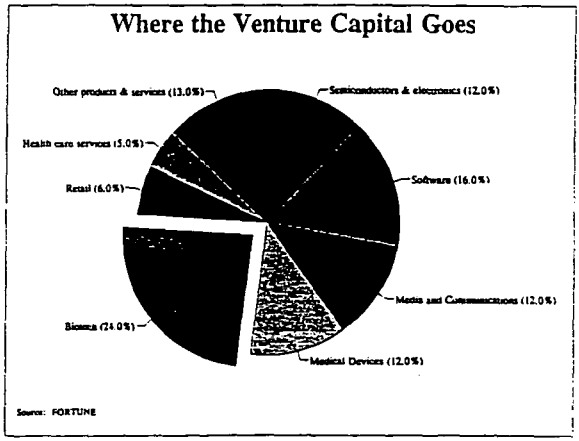
* Average R&D expenditures per employee: $68,000
  (Compare with $39,000 for the pharmaceutical industry)

Total federal investment in biotechnology research: $4.3 billion[14]

Venture Capital[15]

Venture capital biotech disbursements in 1993: $283 million
(8% increase over 1992)

Venture capital disbursements for all industries in 1993: $3.1 billion
(17.2% increase over 1992)



[14]Federal Coordinating Council for Science, Engineering and Technology, Biotechnology for the 21st Century: Realizing the Promise (June 30, 1993). This figure represents the relative distribution of Federal biotechnology research dollars for FY 1994.

[15]Statistics in this section are from: "National Venture Capital Association 1993 Annual Report," Venture Economics, 1993.

Profile by Market Segment (all companies/public companies)

Therapeutic	42% / 69%
Diagnostic	26% / 15%
Supplier	15% / 5%
Ag-bio	8% / 8%
Chemical, Environmental and Services	9% / 3%

Profile by Size (public companies)

Small (1-50 employees)	37%
Mid size (51-135 employees)	33%
Large (136-299 employees)	18%
Top tier (300+ employees)	12%

B. PRODUCTS AND PATENTS

Product Information

Therapeutics and Diagnostics:

There are now 26 biotechnology therapeutics and vaccines on the market.[16] U.S. public biotech companies have over 270 therapeutics in human clinical development, and an estimated 2,000 drugs in early development stages according to Ernst & Young.

Two new therapeutic biotech products were approved in 1994: Oncaspar® for treatment of acute lymphoblastic leukemia (ALL), produced by Enzon, Inc., marketed by Rhone-Poulenc Rorer, and ReoPro™ for treatment of cardiac complications for high-risk angioplasty patients, produced by Centocor, Inc.. Two products were approved for new indicatiens in 1994: Neupogen® (produced by Amgen, Inc.), which was originally approved for the treatment of neutropenia in chemotherapy patients, was approved for bone marrow transplant patients who experience neutropenia; and Nutropin® (produced by Genentech, Inc.), originally approved for the treatment of growth failure due to chronic renal failure, was approved for the treatment of growth hormone inadequacy. And Cerezyme®, a new version of Ceredase® (both products produced by Genzyme Corp.) which is completely derived from biotechnology, was approved, also for the treatment of Gaucher's disease.

A listing and description of the 26 therapeutic and vaccine biotechnology products can be found in the BIO publication, Biotechnology Drug Products.

Food and Agriculture:

Fifteen new pesticides containing biologically active ingredients were registered by EPA during the past year. This represented one half of the new registrations issued by the Agency. Among the products receiving approval were a new microbial product for control of termites, several biological fungicides, and a viral insecticide for use on vegetable crops. Progress continues on improving biological methods of control. Several new insecticidal products have entered field testing.

Calgenes' Flavr-SAVR® tomato with controlled ripening properties was approved for marketing by FDA, as were tomatoes by Zeneca Plant Sciences and DNA Plant Technology. Also, Calgenes' lauric acid derived from canola oil, which is a component of soaps and detergents, was approved for marketing by the USDA. Several hundred field trials of genetically engineered plants, such as corn, cotton, squash, potatoes, etc., were conducted in 1994. Potatoes, genetically altered to have higher starch content, are under evaluation by the food processing industry. These potatoes take up less oil when made into french fries or potato chips. Regulatory approval is being sought for insect resistant corn, cotton, and potatoes. Herbicide tolerant cotton should be generally available in 1995, decreasing the net amount of herbicides needed to control weeds on this crop.

[16]This number is according to BIO estimates.

Industrial and Environmental

The industrial and environmental sectors of the biotech industry are researching products to improve chemical and fuel production and clean up environmental pollutants. Certain aspects of this sector are in the early development stage: Bioremediation, the use of microorganisms to degrade toxic materials to harmless substances, is proving to be a cost effective alternative to land fills and incineration for both pollution prevention and remediation.

Industrial enzymes such as proteases and amylases are widely used in laundry detergents. These biotechnology products breakdown a variety of stains, improving detergent performance in the warm water wash cycle that most consumers now use. Enzymatic detergent enhancers are biodegradable and the lower wash temperature saves energy. Enzymes are being studied as alternatives to chemical processes for manufacturing dyes and pharmaceuticals. A microorganism genetically engineered to produce indigo, an important textile dye, was approved for use by EPA.

The industry is continuing to explore new research areas, including biosensors, which combine biotechnology with materials and electronics technology to produce monitoring devices with potential applications in health care, pollution control and control of industrial processes. These devices could be used, for example, to monitor glucose or cholesterol levels or to detect water and air pollutants.

Patents[12]

Patents are crucial in the valuation of biotech companies and in a company's access to capital. Biotechnology patent filings in the U.S. grew by approximately 3.5% during fiscal year 1994. For 1988, the U.S. Patent and Trademark Office (PTO) had 67 biotechnology examiners. At the end of fiscal year 1994, they had 165 biotechnology examiners, and the experience level of the examiners had increased, allowing for quicker reviews.

Biotech applications submitted to PTO (FY 1994):	13,500
Estimated number of submissions by 1995:	14,400
Approximate average review time for a biotech patent:	20.8 months
Approximate average review time for all other patents:	19.8 months
Number of biotech patents issued:	Approx. 4,000
(67% to U.S. inventors, 15% to EC inventors, 13% to Japanese inventors, 5% other nationalities)	

[12]The information contained in this section is derived from a conversation on Thursday, November 3, 1994 with Barry S. Richman, Director, Biotechnology section, Patent and Trademark Office.

C. THE USE OF STOCK OPTIONS AS A FORM OF COMPENSATION BY U.S. BIOTECHNOLOGY COMPANIES

Radford Associates/Alexander & Alexander Consulting Group has recently released the 10th annual edition of the Biotechnology Compensation and Benefits Survey. The report was conducted in association with the Biotechnology Industry Organization.

A total of 263 biotechnology companies participated in the survey, with compensation data being reported for over 33,000 incumbents in executive, management and benchmark positions. Sixty-two percent of companies participating are public, and 38% are private. The company size breakdown is as follows:

47%	under 100 employees
33%	100-299 employees
13%	300-999 employees
7%	1000+ employees

The survey found that 87% of biotechnology companies have a stock or long-term incentive plan. Of those companies, 78% offer their stock option plan on a company-wide basis. Plan types include: incentive stock options (ISO), non-qualified stock options (NQSQ), restricted stock, long term bonus, stock appreciation rights (SAR), phantom stock and performance share/unit.

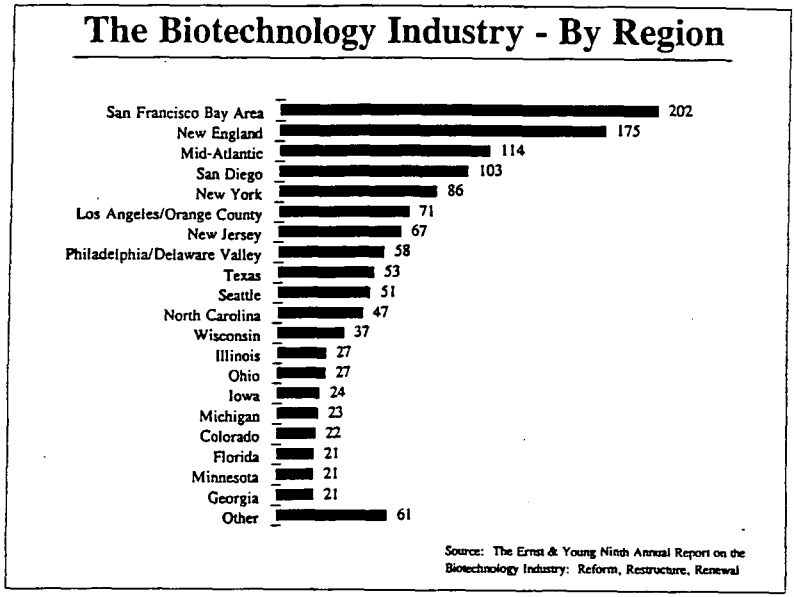
Participation in the stock option plans is as follows:

Chief Executive Officer	100%
Executives (VPs)	97%
Directors	95%
Managers	92%
Senior Technical Exempts	90%
Senior Non-Technical Exempts	86%
Supervisors	86%
Intermediate Technical Exempts	85%
Intermediate Non-Technical Exempts	85%
Entry Technical Exempts	82%
Entry Non-Technical Exempts	82%
Nonexempt	80%

As with senior management positions, budgeted merit increases have gradually declined over the last five years for both exempt and nonexempt positions. For the current salary planning year (1994), budgeted merit increases average 5.3% for exempts and 5.2% for nonexempts; targeted merit increases for the next salary planning year average 5.1% for both exempts and nonexempts.

D. THE U.S. BIOTECHNOLOGY INDUSTRY: GEOGRAPHIC AREA DEMOGRAPHICS AND FINANCIAL HIGHLIGHTS

There are four areas of the country with a major biotech presence – the San Francisco Bay Area, New England (comprised of Massachusetts, Connecticut, Rhode Island, New Hampshire, Vermont, and Maine), the Mid-Atlantic Region (comprised of Washington, D.C., Maryland, and Virginia), and San Diego – but, as shown in the graph below and in the following tables, several other regions also have a significant biotechnology presence.



Further information about selected areas follows (in alphabetical order).

Biotechnology Companies in Florida

Florida contains 3% of all U.S. biotechnology companies. As a region, it ranks 18th in terms of geographic concentration of biotechnology companies.

1994 financial highlights (publicly traded companies only):

Product sales	$160 million (21% increase from 1993)
Total revenue	$165 million (19% increase from 1993)
R&D spending	$ 11 million (0% increase over 1993)
Total assets	$141 million (14% increase over 1993)

Biotechnology Companies in the Los Angeles/Orange County Region

The Los Angeles/Orange County area contains 5% of all U.S. biotechnology companies. As a region, it ranks 6th nationwide in terms of geographic concentration of biotechnology companies.

1994 financial highlights (publicly traded companies only):

Product sales	$1.72 billion (20% increase over 1993)
Total revenue	$1.86 billion (20% increase over 1993)
R&D spending	$310 million (44% increase from 1993)
Total assets	$2.22 billion (27% increase over 1993)

Biotechnology Companies in the Mid-Atlantic Region

The Mid-Atlantic Region, which comprises Washington, D.C., Maryland and Virginia, contains 7% of all U.S. biotechnology companies. As a region, it ranks third nationwide in terms of geographic concentration of biotechnology companies.

1994 financial highlights (publicly traded companies only):

Product sales	$392 million (16% increase over 1993)
Total revenue	$489 million (11% increase over 1993)
R&D spending	$257 million (47% increase over 1993)
Total assets	$785 million (35% increase over 1993)

Biotechnology Companies in Minnesota

Minnesota contains 2% of all U.S. biotechnology companies. As a region, it ranks 18th in terms of geographic concentration of biotechnology companies.

1994 financial highlights (publicly traded companies only):

Product sales	$ 57 million (2% increase over 1993)
Total revenue	$ 64 million (7% increase over 1993)
R&D spending	$ 17 million (42% increase over 1993)
Total assets	$108 million (10% decline from 1993)

Biotechnology Companies in the New England Area

The New England area, which comprises Massachusetts, Connecticut, Rhode Island, New Hampshire, Vermont, and Maine, contains 15% of all U.S. biotechnology companies. As a region, it ranks 2nd nationwide in terms of geographic concentration of biotechnology companies.

1994 financial highlights (publicly traded companies only):

Product sales	$651 million (6% increase over 1993)
Total revenue	$1.02 billion (24% increase over 1993)
R&D spending	$653 million (27% increase over 1993)
Total assets	$2.66 billion (10% increase over 1993)

Biotechnology Companies in New York State

New York State contains 6% of all U.S. biotechnology companies. As a region, it ranks 5th in terms of geographic concentration of biotechnology companies.

1994 financial highlights (publicly traded companies only):

Product sales	$64 million (56% increase over 1993)
Total revenue	$121 million (22% increase over 1993)
R&D spending	$132 million (17% increase over 1993)
Total assets	$395 million (7% increase over 1993)

Biotechnology Companies in the Philadelphia/Delaware Valley Region

The Philadelphia/Delaware Valley region contains 3% of all U.S. biotechnology companies. As a region, it ranks 8th nationwide in terms of geographic concentration of biotechnology companies.

1994 financial highlights (publicly traded companies only):

Product sales	$51 million (23% decrease from 1993)
Total revenue	$113 million (35% decrease from 1993)
R&D spending	$159 million (15% decrease from 1993)
Total assets	$489 million (20% decrease from 1993)

Biotechnology Companies in the San Diego

The San Diego area contains 10% of all U.S. biotechnology companies. As a region, it ranks 4th nationwide in terms of geographic concentration of biotechnology companies.

1994 financial highlights (publicly traded companies only):

Product sales	$ 195 million (107% increase over 1993)
Total revenue	$350 million (51% increase over 1993)
R&D spending	$358 million (2% increase over 1993)
Total assets	$1.23 billion (0% increase over 1993)

Biotechnology Companies in the San Francisco Bay Area

The San Francisco Bay area contains 19% of all U.S. biotechnology companies. As a region, it ranks 1st nationwide in terms of geographic concentration of biotechnology companies.

1994 financial highlights (publicly traded companies only):

Product sales	$1.24 billion (12% increase over 1993)
Total revenue	$1.98 billion (13% increase over 1993)
R&D spending	$1.03 billion (5% increase over 1993)
Total assets	$5.72 billion (22% increase over 1993)

Biotechnology Companies in the Seattle

The Seattle area contains 3% of all U.S. biotechnology companies. It ranks 10th in terms of geographic concentrations of biotechnology companies nationwide.

1994 financial highlights (publicly traded companies only):

Product sales	$126 million (125% increase over 1993)
Total revenue	$ 144 million (52% increase over 1993)
R&D spending	$ 476 million (261% increase over 1993)
Total assets	$427 million (7% increase over 1993)

Biotechnology Companies in Texas

Texas contains 4% of all U.S. biotechnology companies. It ranks 9th in terms of geographic concentrations of biotechnology companies nationwide.

1994 financial highlights (publicly traded companies only):

Product sales	$39 million (5% increase over 1993)
Total revenue	$42 million (2% increase over 1993)
R&D spending	$ 32 million (33% increase over 1993)
Total assets	$126 million (56% increase over 1993)

7)

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

HEARING

BEFORE THE

SUBCOMMITTEE ON INTELLECTUAL PROPERTY AND JUDICIAL ADMINISTRATION

OF THE

COMMITTEE ON THE JUDICIARY HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

ON

H.R. 760

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

JUNE 9, 1993

Serial No. 32

Printed for the use of the Committee on the Judiciary

U.S. GOVERNMENT PRINTING OFFICE

77-796 CC WASHINGTON : 1994

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

ISBN 0-16-044440-3

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

WEDNESDAY, JUNE 9, 1993

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

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

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

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

OPENING STATEMENT OF CHAIRMAN HUGHES

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

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

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

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

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

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

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

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

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

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

I

103D CONGRESS
1ST SESSION

H. R. 760

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

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 3, 1993

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

---

A BILL

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

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

TITLE I—BIOTECHNOLOGICAL PROCESS PATENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

SEC. 102. NO PRESUMPTION OF INVALIDITY.

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

SEC. 103. EFFECTIVE DATE.

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

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

TITLE II—BIOTECHNOLOGICAL MATERIAL PATENTS

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

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

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

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

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

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

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

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

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

(c) EFFECTIVE DATE.—

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

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

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

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

O

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

Mr. MOORHEAD. Thank you, Mr. Chairman.

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

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

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

In addition to the ability to obtain and enforce a patent, small companies, in particular, must be concerned about obtaining a patent in a timely fashion. Last year the pendency of a biotech patent application was 27 months, with the backlog of applications increasing from 17,000 in 1990, to almost 20,000 in 1992. I am concerned that with the cut in the PTO budget that they will not be able to reduce this backlog.

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

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

This bill modifies the test for obtaining a process patent. It overrules *In re Durden,* 1985, a case frequently criticized that has been cited by the Patent Office as grounds for denial of biotech patents, as well as chemical and other process patent cases.

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

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

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

Welcome again to our guests this morning.

Mr. HUGHES. The gentleman from Florida.

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

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

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

Mr. HUGHES. Without objection.

Mr. MCCOLLUM. Thank you.

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

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

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

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

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

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

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

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

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

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

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

Mr. HUGHES. I thank the gentleman.

[The prepared statement of Mr. McCollum follows:]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Who would like to go first?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Mr. HUGHES. Thank you very much, Senator.

[The prepared statement of Mr. DeConcini follows:]

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

Chairman Hughes, Ranking Member Moorhead, and members of the subcommittee, thank you for permitting me to speak today on H.R. 760, the Biotechnology Patent Protection Act of 1993.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Is floor action scheduled on S. 298?

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

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

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

Mr. HUGHES. Thank you.

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

Do the members have any questions of the Senator?

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

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

Mr. DECONCINI. Thank you, Mr. Chairman.

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

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

Mr. BOUCHER. Thank you, Mr. Chairman.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Thank you, Mr. Chairman.

Mr. HUGHES. Well, thank you.

[The prepared statement of Mr. Boucher follows:]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The gentleman from California.

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

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

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

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

Mr. HUGHES. Thank you.

Any members have any questions?

The gentleman from Florida.

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

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

Do you have any responses to those?

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

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

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

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

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

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

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

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

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

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

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

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

Mr. MCCOLLUM. Thank you.

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

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

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

Mr. HUGHES. The gentleman from North Carolina.

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

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

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

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

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

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

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

Mr. COBLE. Thank you.

Thank you, Mr. Chairman.

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

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

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

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

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

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

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

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

Thank you very much.

Mr. BOUCHER. Thank you very much.

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

He has had a long and illustrious career at the Patent and Trademark Office. He has been a principal U.S. negotiator for trade related intellectual property rights issues in the Uruguay Round of GATT talks.

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

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

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

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

You may proceed as you see fit.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Thank you.

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

[The prepared statement of Mr. Kirk follows:]

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

Mr. Chairman and Members of the Subcommittee:

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