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

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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

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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 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

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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 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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