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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

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[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

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[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-

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[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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