20 House Report No. 96-1307, 96th Cong., 2d Sess. (1980) *

[Part 1]

AMENDING THE PATENT AND TRADEMARK LAWS

September 9, 1980--Ordered to be printed

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

REPORT

[To accompany H.R. 6933]

[Including cost estimate and comparison of the Congressional Budget Office]

The Committee on the Judiciary to whom was referred the bill (H.R. 6933) entitled: "To amend the patent and trademark laws", having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendment to the text of the bill is a complete substitute therefor and appears in italic type in the reported bill.

The title of the bill is amended to reflect the amendment to the text of the bill.

STATEMENT

The Need for the Legislation

Many analysts of the U.S. economy have warned that the roots of the current recession lie in a longer term economic malaise which arises out of a failure of American industry to keep pace with the increased productivity of foreign competitors.n1

According to the Committee for Economic Development, "the slowing of productivity improvement during the past few years parallels the discouraging decline in the rate of investment in plant and equipment."n2 The rate of investment as a proportion of GNP has averaged about one half the rate for France and Germany and about one third the rate for Japan. Further, the situation does not appear to be improving. There has been an especially significant decline in total U.S. expenditures for research and development, as measured in constant dollars since 1970.n3 Since the primary means of improving productivity lies in the creation of new technologies, the decline in expenditures for research and development is especially significant to the health of the overall economy.

Testimony presented to the Subcommittee on Courts, Civil Liberties and the Administration of Justice also indicates that the Federal Government is bearing an ever increasing share of the burden of financing basic research and development.n4 This means that the effective commercialization of government financed research is becoming an ever more important issue for those who are concerned with industrial innovation. The patent policies governing the utilization of government funded research will become even more important when the research expected to flow out of recent Congressional enactments such as the Energy Security Act of 1980n5 begins to produce usable new technologies. It is highly likely that the fuel which powers our automobiles and the boilers which heat our homes will owe part of their chemical composition or mechanical operation to patented research developed in part by government funds. At the present time U.S. companies desiring to use government funded research to develop new products and processes must confront a bewildering array of 26 different sets of agency regulations governing their rights to use such research. This bureaucratic confusion discourages efficient use of taxpayer financed research and development.

HISTORY OF THE BILL

The crisis in U.S. productivity and the governmental role in it has not gone unnoticed, however. In May of 1978 the President called for a major policy review of industrial innovation as the key to increased productivity in the United States. This White House call to action resulted in the creation of an advisory Committee of more than 150 senior

representatives from the industrial, public interest, labor, scientific, and academic communities. The work of the Advisory Committee was overseen by a cabinet level coordinating committee chaired by the Secretary of Commerce. The Committee studied all the areas in which federal government policy impacts on productivity and innovation in the private sector. These fields of inquiry included: economic and trade policy; environmental, health and safety regulations; anti-trust enforcement; federal procurement policies, and federal patent and information policies.

When the advisory committee issued its 300 page report last year, a key segment contained recommendations on government patent policy. These recommendations, in turn, were received by the President, and formed the basis of a major legislative proposal which was conveyed to the Congress. Special emphasis was placed on the role of the patent system and the patent policy regarding government funded research in promoting industrial innovation. These patent related recommendations were forwarded to the Committee on the Judiciary and are embodied in H.R. 6933 and H.R. 3806.

H.R. 6933 has three major thrusts. First, it strengthens investor confidence in the certainty of patent rights by creating a system of administrative reexamination of doubtful patents. Secondly, it strengthens the financial resources of the Patent Office to provide fast and accurate processing of patent applications by revising the fee structure of the Office. Finally, the existing melange of 26 different agency policies on vesting of patent rights in government funded research is replaced by a single, uniform national policy designed to cut down on bureaucracy and encourage private industry to utilize government funded inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application.

H.R. 3806 embodies another recommendation of the Advisory Committee and the President. It grants jurisdiction over appeals in patent cases to a single court of appeals--ending the current legal confusion created by 11 different appellate forums, all generating different interpretations of the patent law. The new court will do a great deal to improve investors' confidence in patented technology.

In addition to the three broad areas already outlined, H.R. 6933 addresses the special needs of Universities and small businesses when they attempt to deal with Patent issues arising out of government contracts. Both of these groups lack the resources to cope with the bewildering regulatory and bureaucratic problems associated with transfer of patent rights pursuant to government contracts; and the university sector in particular is an important link to the private sector.

The Subcommittee on Courts, Civil Liberties and the Administration of Justice held seven days of hearings on H.R. 6933 and related patent law proposals. In all, over thirty witnesses from Government, the private Bar, industry, education, small business, and the judiciary offered testimony on the various legislative proposals before the subcommittee. Hearings were followed by four days of markup, during which H.R. 3806, creating a new Court of Appeals for the Federal Circuit, H.R. 6933, containing reforms in patent policy and procedures, and H.R. 6934, clarifying the law of copyright of computer programs, were reported favorably. Each bill was reported unanimously. The unanimous votes, particularly on H.R. 6933, were cast only after careful examination of the legislation in light of the criticisms made during the hearings and after consultation with members of the Committee on Science and Technology, which shares jurisdictional interest. During the course of markup H.R. 6933 was amended substantially to respond to criticisms raised during the hearing.

SUMMARY OF THE BILL

H.R. 6933, as amended, addresses four major issues. Section 1 provides for a system of administrative reexamination of patents within the patent office. This new procedure will permit any party to petition the patent office to review the efficacy of a patent, subsequent to its issuance, on the basis of new information about preexisting technology which may have escaped review at the time of the initial examination of the patent application. Reexamination will permit efficient resolution of questions about the validity of issued patents without recourse to expensive and lengthy infringement litigation. This, in turn, will promote industrial innovation by assuring the kind of certainty about patent validity which is a necessary ingredient of sound investment decisions.

The cost incurred in defensive patent litigation sometimes reaches $ 250,000 for each party, an impossible burden for many smaller firms. The result is a chilling effect on those businesses and independent inventors who have repeatedly demonstrated their ability to successfully innovate and develop new products. A new patent reexamination procedure is needed to permit the owner of a patent to have the validity of his patent tested in the Patent office where the most expert opinions exist and at a much reduced cost. Patent office reexamination will greatly reduce, if not end, the threat of legal costs being used to "blackmail" such holders into allowing patent infringements or being forced to license their patents for nominal fees.

The reexamination of issued patents could be conducted with a fraction of the time and cost of formal legal proceedings and would help restore confidence in the effectiveness of our patent system.

The bill does not provide for a stay of court proceedings. It is believed by the committee that stay provisions are unnecessary in that such power already resides with the Court to prevent costly pretrial maneuvering which attempts to circumvent the reexamination procedure. It is anticipated that these measures provide a useful and necessary alternative for challengers and for patent owners to test the validity of United States patents in an efficient and relatively inexpensive manner.

Sections 2 through 5 of H.R. 6933 provide for a new fee structure for the patent office. At the present time patent examination fees are established by statute, last revised in 1967. When enacted, the present fee structure provided revenues which met 67 percent of the costs of operating the Patent Office. Inflation has now reduced the impact of those fees to the point where they generate only 27 percent of the funding necessary to the operation of the office.

At the present time patent fees average about $ 239 per application.n6

H.R. 6933 would entirely revise the fee structure. It grants the Commissioner the power to establish fees. As introduced, the bill provided that the fee level would be revised yearly to generate 60 percent of the revenue needed to operate the office. However, the subcommittee amended the bill to reduce that level to 50 percent. This was in response particularly to criticism from small business and individual inventors that the fees would place too great a burden on those groups.

In order to further soften the impact on small business and individual inventors, the fees are to be paid in four installments over the life of the patent. This system, known as maintenance fees, is in use in most advanced industrial nations and has the advantage of deferring payment until the invention begins to return revenue to the inventor.

Should the invention prove to have no commercial value, the inventor has the option of permitting the patent to lapse, thus avoiding all further fees.

Section 6 of H.R. 6933 provides for a uniform policy governing the disposition of patent rights in government funded research.

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SECTION-BY-SECTION ANALYSIS

Reexamination

Section 1 of the bill would add seven new sections to the patent laws to establish a patent reexamination system. These seven new sections would constitute chapter 30 of title 35 of the United States Code.

Section 301. Citation of prior art

Section 301 provides statutory authority for the citation to the Patent and Trademark Office (PTO) of prior art consisting of patents or printed publications which a person believes to have a bearing on the patentability of any claim of a particular patent. Section 301 would make clear that a citation of prior art is not to be included in the official file on a patent unless the citer submits a written statement as to the pertinency and applicability to the patent. Section 301 also would require the PTO to keep the identity of the citer of prior art confidential if the citer so requests in writing. Without the confidentiality provision, competitors of a patent owner might be reluctant to cite prior art to the PTO.

Section 302. Request for reexamination

Section 302 provides authority for any person to seek reexamination by the PTO on the basis of the patents and printed publications cited under section 301. Such a person need not be the one who cited prior art under section 301. The person could even be the patentee.

Section 302 requires that the person seeking reexamination pay a fee established by the Secretary. Under section 2 of this bill, the Secretary would be required to establish a fee to recover the estimated average cost of a reexamination proceeding. Thus, those who request reexamination would pay for it.

Section 302 requires the Commissioner to send a copy of the request promptly to the patent owner, as shown by the records of the Office. The patent owner would have to see that his ownership and current address are recorded properly so that the request is not sent to a previous owner.

Section 303. Determination of issue by Commissioner

Subsection 303(a) requires the Commissioner to determine if a "substantial new question of patentability" is raised in connection with any claims of the patent against which a patent or printed publication is cited and to order reexamination upon a positive determination. Further, it would permit the Commissioner to initiate reexamination without a request upon a determination that a substantial new question of patentability is raised by patents or publications discovered by him or cited under the provisions of section 301. This authority to initiate reexamination without a request is not intended to abrogate in any way the right of the United States to sue to cancel a patent obtained by fraudulent means.

This "substantial new question" requirement would protect patentees from having to respond to, or participate in unjustified reexaminations. Further, it would act to bar reconsideration of any argument already decided by the Office, whether during the original examination or an earlier reexamination.

Subsection 303(b) requires that the Commissioner's determination be recorded in the file of the patent and a copy promptly sent to the patent owner and the person requesting the reexamination.

Subsection 303(c) makes final and nonappealable a decision by the Commissioner not to conduct reexamination. In such a case, however, a portion of the reexamination fee could be returned.

No one would be deprived of any legal right by a denial by the Commissioner of a request for reexamination. A party to a reexamination proceeding could still argue in any subsequent litigation that the PTO erred and that the patent is invalid on the basis of the cited prior art.

Section 304. Reexamination order by Commissioner

Section 304 specifies the initial steps to be taken where the Commissioner determines that reexamination should be ordered. Upon issuance of a determination ordering reexamination, the patent owner would be given the opportunity to file a statement with the Office and, if he wishes, to propose an amendment to the specification or claims of his patent as well as a new claim or claims in response to the Commissioner's determination. The patent owner would be required to serve a copy of any such statement and any proposed amendment on the person requesting reexamination, who would be permitted to file a reply with the Office, with service required on the patent owner.

Section 305. Conduct of reexamination proceedings

Section 305 governs the conduct of the actual reexamination proceeding. Section 305 specifies that after the initial exchange permitted under section 304, the PTO will utilize the same procedures it uses for the initial examination of patent applications under patent law sections 132 and 133 . The patent owner could propose an amendment to his patent specification or claims, as well as propose a new claim or claims, to distinguish his invention from the prior art cited under section 301. However, the bill would prohibit the Commissioner from granting during reexamination any amended or new claim that enlarges the scope of a claim of the original patent. Also, the bill would require reexamination to be promptly handled, so as to make it as helpful as possible.

Section 306. Appeal

Section 306 grants a patent owner the right to pursue the same appeal routes available to patent applicants. An adverse decision on reexamination by the primary examiner could be appealed to the Board of Appeals. Adverse final decisions on reexamination by the Board of Appeals or by the Commissioner could be appealed to the U.S. Court of Customs and Patent Appeals or de novo review of the reexamination decision could be sought in the United States District Court for the District of Columbia.

Section 307. Certificate of patentability, unpatentability, and claim cancellation

Section 307(a) requires the Commissioner at the conclusion of reexamination to cancel any patent claim found to be unpatentable, confirm any patent claim found to be patentable, and add any amended or new claims found to be patentable.

Subsection 307(b) provides intervening rights similar to those provided by patent law section 252 with respect to reissued patents. Thus, a person practicing a patented invention would not be considered an infringer for the period between issuance of an invalid patent and its conversion through reexamination to a valid patent.

It ordinarily is in the interests of both parties to expedite the disposition of patent litigation. A party discovering new prior art on which reexamination might be conducted ordinarily will reveal it promptly to the patent owner. If he does not, the court may exercise its equity power by allowing the patent owner to request reexamination later in the trial, or precluding the party from relying on such prior art or by other appropriate measures.

Administrative Fee Setting

Section 2 of the bill would restructure and modernize completely section 41 of title 35, United States Code--the basic fee provision of the patent laws.

The committee recognizes that the PTO, in issuing patents and registering trademarks, performs a significant public service in implementing the Federal patent and trademark laws and also confers benefit on private persons who seek to protect their intellectual property. The Committee, therefore, supports the premise that patent applicants and those seeking to register trademarks should bear a significant share of the cost of operating the PTO by the payment of fees. However, the Committee has made certain amendments to the formula which empowers the Commissioner to set these fees. Certain costs of operating the PTO confer no direct benefit on applicants but rather go to meet the responsibility of the Federal Government to have a PTO in order to execute the law. For example, the cost of executive direction and administration of the office, including the Office of the Commissioner and certain agency offices involved with public information, legislation, international affairs and technology assessment. Maintaining the public search room confers a general public benefit, as does the maintenance of the patent files in depository libraries. The contribution to the World Intellectual Property Organization relative to the Patent Cooperation Treaty is a treaty obligation. These costs should be paid for entirely from appropriated funds.

The committee inserted the word "actual" in this legislation to describe those costs which should be assumed 50 percent by applicants. Patent applicants should bear through the payment of fees, 25 percent in processing of fees, and 25 percent in maintenance fees, the costs of the patent examiners and their clerical support, as well as quality review, appeals, interferences, and patent printing including internal PTO printing costs. Also, "actual" is intended to exclude from such costs the acquisition or replacement of equipment where such acquisition or replacement involves substantial capital outlays. Such expenditures would be paid from the Patent and Trademark Office's appropriation. The cost of data and document retrieval systems, however, to the extent that these expenditures goes toward the reclassification of the patent search file, should be borne 50 percent by the public. These are the actual costs of processing patent applications, and activity which confers certain direct benefits on private persons.

The committee notes that the PTO furnishes to the public copies of issued patents for a fee. The costs to the PTO of such copies should be charged to applicants.

The trademark examiners and their clerical support, the trial and appeal process, and trademark printing should be paid for to the extent of 50 percent by applicants for the registration of trademarks.

Some of the cost of operating the PTO confers no direct benefit to the general public, but rather goes to providing services to private parties. The cost of customer services such as providing copies should be recovered 100 percent in fees. Also, in the patent process, drafting and assignment should be self-supporting.

Illustrative Example of PTO Recovery Policy--Based on Fiscal
Year 1981 Budget

I. Government 100 percent: Commissioner (includes Office of Information Services); Office of Legislation and International Affairs; Management planning; Administrative services; Automatic data processing; and Search room.

II. Government 50 percent/users 50 percent: Examination--professional staff; Quality review; Clerical force; Appeals; Interferences; Patent printing; Solicitor; Data and document retrieval; publication services; Examination of trademarks; Trademark trial and appeals; and Trademark printing.

III. Users 100 percent: Customer services; drafting; and assignment.

Section 41. Patent fees

Subsection 41(a) authorizes the Secretary of Commerce to set fees administratively for processing a patent application, for maintaining a patent in force, and for providing all other patent services and materials.

Subsection 41(b) requires the Secretary of Commerce to establish fees for processing patent applications, from filing to disposition by issuance or abandonment, equal in aggregate to 25 percent of the estimated average cost of

actually processing an application. As fee revenues and costs change, the Secretary would adjust fees to achieve the specified recovery rate once every three years. These fees are those of the type now specified in paragraphs 1, 2, 3, and 6 of existing subsection 41(a) of the patent laws. The Secretary would have authority to eliminate or change the amounts of any of the present fees and establish others, so long as a fee charged directly relates to the actual processing of patent applications and the aggregate fees for an application effect the specified 25 percent recovery rate.

Subsection 41(b) would treat design patent processing fees differently than fees for other types of patents. Since the costs to the Office of processing design patent applications are significantly lower and maintenance fees will not be imposed, design patent applicants would be charged fees equal in aggregate to 50 percent of the estimated cost of processing such an application.

Subsection 41(c) requires the payment of maintenance fees three times in a patent's life--six months prior to the fourth, eighth and twelfth anniversaries of the patent's seventeen-year term. As required by the Paris Convention for the Protection of Industrial Property, subsection 41(c) permits late payment during a six-month grace period. Failure to pay an applicable maintenance fee by the end of the grace period would result in expiration of the patent on the date the grace period ends.

Subsection 41(c) also requires the Secretary to establish maintenance fees at levels that recover 30 percent of the costs to the Office for the year in which such maintenance fees are received of processing all applications for patents other than design patents, from filing through disposition by issuance or abandonment, by the fifteenth year following enactment of the Act.

Subsection 41(d) requires the Secretary to establish fees for all other patent-related services and materials at levels which will recover the full costs to the Office of performing those services or providing those materials. Fees would be adjusted as costs vary. Subsection 41(d), however, would maintain the existing subsection 41(a)(9) fee of $ 50 for providing a despository library with uncertified printed copies of the specifications and drawings for all patents issued in a year.

Subsection 41(e) allows the Commissioner to waive any fee for a service or product provided to a government agency. This authority now is provided in existing subsection 41(c).

Subsection 41(f) limits the adjustment of patent application processing fees and maintenance fees to once every three years.

Subsection 41(g) imposes a notice requirement on effective date of new or adjusted fees.

Crediting of Fee Revenue to the PTO Appropriation Account

Section 3 of this bill would amend section 41 of title 35, United States Code, by completely rewriting it.

Section 42. Patent and Trademark Office funding

Subsection 42(a) makes all fees for Patent and Trademark Office services and materials payable to the Commissioner of Patents and Trademarks. This provision is carried over from existing section 42.

Subsection 42(b) requires all fee revenues and all Patent and Trademark Office appropriations to be credited to the Patent and Trademark Office Appropriation Account in the Treasury of the United States. At present, Patent and Trademark Office fee revenues are deposited in the general fund of the Treasury and are unavailable for directly funding PTO activities.

Subsection 42(c) makes fee revenues credited to the PTO Appropriation Account available to the Secretary of Commerce to carry out the activities of the Patent and Trademark Office. Budgetary control is maintained since the PTO would continue to receive appropriations and the use of fee revenues would be limited "to the extent provided for in an appropriations Acts."

Subsection 42(d) authorizes the Secretary to refund any fee paid by mistake or any account paid in excess of that required. This authority is found in existing section 42.

Technical Amendment

Section 4 of the bill is a technical amendment to section 154 of the patent laws necessitated by creation of the maintenance fee system.

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Transitional Provisions

Section 8. Effective date

Section 8 provides for the taking effect of the bill's various provisions.

Section 8(a) specified and that the fee setting authority provisions of the bill and the conforming technical amendment take effect upon enactment. Nevertheless, these fees need not be set to recover the levels specified in the bill (25 percent recovery for patent processing and full recovery for providing materials and services in patent and trademark cases) until the first day of the first fiscal year beginning one calendar year after enactment. This will provide at least a year to determine the amounts and natures of fees needed.

Subsection 8(b) provides that the reexamination provisions of this bill take effect six months after enactment and apply to patents then in force or issued thereafter.

Subsection 8(c) provides that the authority to credit fee revenues to the Office's Appropriation Account take effect as of the first day of the first fiscal year beginning one calendar year after enactment. Thus, at least one year would be available to obtain needed administrative approval and implement an appropriate accounting system. However, until section 3 takes effect, the Secretary, in order to pay reexamination costs, may credit the Patent and Trademark Office Appropriation Account with the revenues from collected reexamination fees.

Subsection 8(d) continues existing fees until new fees are established.

Subsection 8(e) provides that maintenance fees shall not be applicable to patents applied for prior to the day of enactment of this Act.

Subsection 8(f) provides that sections 6 and 7 of this bill which establish a uniform patent policy and make necessary conforming amendments to existing laws take effect six months after enactment.

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Estimated Cost of the Legislation

It is estimated that there will be no additional costs to the United States due to the provisions of H.R. 6933. As the statement of the Congressional Budget Office indicates, there will be a substantial savings to the United States as a result of the legislation.

Statement of the Congressional Budget Office

Click here to view image.

Dear Mr. Chairman: Pursuant to Section 403 of the Congressional Budget Act of 1974 , the Congressional Budget Office has prepared the attached cost estimate for H.R. 6933, a bill to amend the patent and trademark laws.

Should the Committee so desire, we would be pleased to provide further details on this estimate.

Sincerely, James Blum
(For Alice M. Rivlin, Director).

CONGRESSIONAL BUDGET OFFICE--COST ESTIMATE, AUGUST 28, 1980

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Reexamination of patents

H.R. 6933 would allow any party to petition the PTO to reexamine a patent for validity. The cost of reexamination would be paid by the party based on a fee structure established by the Commissioner of Patents. It is anticipated that the number of patent applications for reexaminations will be limited by the cost involved and the potential for commercial development. Based on rates currently available in foreign countries for similar procedures, as well as estimates provided by the PTO, it is estimated that the number of appeals will be approximately 500 in fiscal year 1981, increasing to 2,000 by 1982, and remain relatively stable thereafter.

Although the bill does not specifically authorize funding for this purpose, it is assumed that additional staff will be required to handle the reexamination procedures. Based on PTO data, it is estimated that the average cost per employee, including overhead and benefits, would be approximately $ 40,000 in fiscal year 1981. Assuming approximately 30 hours per reexamination, plus clerical support, it is estimated that approximately 55 appeals could be reviewed annually by a professional staff member. It is estimated that the cost of this procedure would be approximately $ 0.4 million in fiscal year 1981, which reflects six month's activity. Costs are estimated to be $ 1.4 million in fiscal year 1982, increasing to $ 2.5 million by fiscal year 1985. It is assumed, however, that the full amount required by the PTO for salaries and expenses would be recovered by fees set at the beginning of the fiscal year and adjusted annually for inflation and anticipated workload. It is assumed that fees would be included with the request for reexamination and reflected as a reimbursable to the agency, resulting in a net outlay of around zero in each fiscal year.

Revision of fee structure

H.R. 6933 would restructure the current fee structure for patents and trademarks. Currently, the PTO recovers approximately 20 percent of the cost of processing patents and approximately 30 percent of the cost of issuing trademarks. These fees are deposited in the general fund of the Treasury.

The bill would allow the PTO to recover up to 25 percent of the average processing costs and 25 percent of the maintenance costs for patents, the latter fee collected in four installments over the life of the patent. In addition, the PTO would be allowed to recover a maximum of 50 percent of the cost of issuing trademarks. All fees for patents and trademarks could be adjusted no more than once every three years and would be credited to the PTO as a reimbursable to the agency, rather than as a revenue to the Treasury.

It is assumed that the revised fee structure for trademarks would be implemented early in the second quarter of fiscal year 1981, and for patents beginning in fiscal year 1982. It is assumed that the agency costs for processing patents and trademarks from which recovery could be made would be approximately $ 84 million in fiscal year 1982, increasing to approximately $ 109 million by fiscal year 1985. It is assumed that an average recovery rate of 25 and 50 percent, adjusted every third year, would be established for processing fees for patents and for trademarks, respectively. Patent maintenance fees would be collected three times in a patent's life--around the forth, eighth, and twelfth year. Since the first payment would not be made until fiscal year 1986, it is not reflected in the table below.

[By fiscal years, in millions of dollars]

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Committee Vote

H.R. 6933 was approved by the Committee on the Judiciary on August 20, 1980, by a voice vote.

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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 I--PATENT AND TRADEMARK OFFICE

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CHAPTER 4--PATENT FEES

Sec.

41. Patent fees.

42. Payment of patent fees; return of excess amounts.

[§ 41. Patent fees

[(a) The Commissioner shall charge the following fees:

[1. On filing each application for an original patent, except in design cases, $ 65; in addition on filing or on presentation at any other time, $ 10 for each claim in independent form which is in excess of one, and $ 2, for each claim (whether independent or dependent) which is in excess of ten. For the purpose of computing fees, a multiple dependent claim as referred to in section 112 of this title or any claim depending therefrom shall be considered as separate dependent claims in accordance with the number of claims to which reference is made. Errors in payment of the additional fees may be rectified in accordance with regulations of the Commissioner.

[2. For issuing each original or reissue patent, except in design cases, $ 100; in addition, $ 10 for each page (or portion thereof) of specification as printed, and $ 2 for each sheet of drawing.

[3. In design cases:

[a. On filing each design application, $ 20.

[b. On issuing each design patent: For three years and six months, $ 10; for seven years, $ 20; and for fourteen years, $ 30.

[4. On filing each application for the reissue of a patent, $ 65; in addition, on filing or on presentation at any other time, $ 10 for each claim in independent form which is in excess of the number of independent claims of the original patent, and $ 2 for each claim (whether independent or dependent) which is in excess of ten and also in excess of the number of claims of the original patent. Errors in payment of the additional fees may be rectified in accordance with regulations of the Commissioner.

[5. On filing each disclaimer, $ 15.

[6. On appeal for the first time from the examiner to the Board of Appeals, $ 50; in addition, on filing a brief in support of the appeal, $ 50.

[7. On filing each petition for the revival of an abandoned application for a patent or for the delayed payment of the fee for issuing each patent, $ 15.

[8. For certificate under section 255 or under section 256 of this title, $ 15.

[9. As available and if in print: For uncertified printed copies of specifications and drawings of patents (except design patents), 50 cents per copy; for design patents, 20 cents per copy; the Commissioner may establish a charge not to exceed $ 1 per copy for patents in excess of twenty-five pages of drawings and specifications and for plant patents printed in color; special rates for libraries specified in section 13 of this title, $ 50 for patents issued in one year. The Commissioner may, without charge, provide applicants with copies of specifications and drawings of patents when referred to in a notice under section 132.

[10. For recording every assignment, agreement, or other paper relating to the property in a patent or application, $ 20; where the document relates to more than one patent or application, $ 3 for each additional item.

[11. For each certificate, $ 1.

[(b) The Commissioner may establish charges for copies of records, publications, or services furnished by the Patent and Trademark Office, not specified above.

[(c) The fees prescribed by or under this section shall apply to any other Government department or agency, or officer thereof, except that the Commissioner may waive the payment of any fee for services or materials in cases of occasional or incidental requests by a Government department or agency, or officer thereof.]

§ 41. Patent fees

(*a*) *The Commissioner of Patents will establish fees for the processing of an application for a patent, from filing through disposition by issuance or abandonment, for maintaining a patent in force, and for providing all other services and materials related to patents. No fee will be established for maintaining a design patent in force.*

(*b*) *By the first day of the first fiscal year beginning on or after one calendar year after enactment of this Act, fees for the actual processing of an application for a patent, other than for a design patent, from filing through disposition by issuance or abandonment, will recover in aggregate 25 per centum of the estimated average cost to the Office of such processing. By the first day of the first fiscal year beginning on or after one calendar year after enactment, fees for the processing of an application for a design patent, from filing through disposition by issuance or abandonment, will recover in aggregate 50 per centum of the estimated average cost to the Office of such processing.*

(*c*) *By the fifteenth fiscal year following the date of enactment of this Act, fees for maintaining patents in force will recover 25 per centum of the estimated cost to the Office, for the year in which such maintenance fees are received, of the actual processing all applications for patents, other than for design patents, from filing through disposition by issuance or abandonment. Fees for maintaining a patent in force will be due three years and six months, seven years and six months, and eleven years and six months after the grant of the patent. Unless payment of the applicable maintenance fee is received in the Patent and Trademark Office on or before the date the fee is due or within a grace period of six months thereafter, the patent will expire as of the end of such grace period. The Commissioner may require the payment of a surcharge as a condition of accepting within such six-month grace period the late payment of an applicable maintenance fee.*

(*d*) *By the first day of the first fiscal year beginning on or after one calendar year after enactment, fees for all other services or materials related to patents will recover the estimated average cost to the Office of performing the service or furnishing the material. The yearly fee for providing a library specified in section 13 of this title with uncertified printed copies of the specifications and drawings for all patents issued in that year will be $ 50.*

(*e*) *The Commissioner may waive the payment of any fee for any service or material related to patents in connection with an occasional or incidental request made by a department or agency of the Government, or any officer thereof. The Commissioner may provide any applicant issued a notice under section 132 of this title with a copy of the specifications and drawings for all patents referred to in that notice without charge.*

(*f*) *Fees will be adjusted by the Commissioner to achieve the levels of recovery specified in this section; however, no patent application processing fee or fee for maintaining a patent in force will be adjusted more than once every three years.*

(*g*) *No fee established by the Commissioner under this section will take effect prior to sixty days following notice in the Federal Register.*

[§ 42. Payment of patent fees; return of excess amounts

[All patent fees shall be paid to the Commissioner who, except as provided in sections 361(b) and 376(b) of this title, shall deposit the same in the Treasury of the United States in such manner as the Secretary of the Treasury directs, and the Commissioner may refund any sum paid by mistake or in excess of the fee required by law.]§ 42. Patent and Trademark Office funding

(*a*) *All fees for services performed by or materials furnished by the Patent and Trademark Office will be payable to the Commissioner.*

(*b*) *All fees paid to the Commissioner and all appropriations for defraying the costs of the activities of the Patent and Trademark Office will be credited to the Patent and Trademark Office Appropriation Account in the Treasury of the United States, the provisions of section 725e of title 31, United States Code, notwithstanding.*

(*c*) *Revenues from fees will be available to the Commissioner of Patents to carry out, to the extent provided for in appropriation Acts, the activities of the Patent and Trademark Office.*

(*d*) *The Commissioner may refund any fee paid by mistake or any amount paid in excess of that required.*

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PART II--PATENTABILITY OF INVENTIONS AND
GRANT OF PATENTS

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CHAPTER 14--ISSUE OF PATENT

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§ 154. Contents and term of patent

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 [issue] fees as provided for in this title, of the right to exclude others from making, using, or selling the invention throughout the United States, 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.

* * * * *

CHAPTER 30--PRIOR ART CITATIONS TO OFFICE AND REEXAMINATION OF PATENTS

Sec. 301. 301. Citation of prior art.

Sec. 302. Request for reexamination.

Sec. 303. Determination of issue by Commissioner.

Sec. 304. Reexamination order by Commissioner.

Sec. 305. Conduct of reexamination proceedings.

Sec. 306. Appeal.

Sec. 307. Certificate of patentability, unpatentability, and claim cancellation.

§ 301. Citation of prior art.

Any person at any time may cite to the Office in writing prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent. If the person explains in writing the pertinency and manner of applying such prior art to at least one claim of the patent, the citation of such prior art and the explanation thereof will become a part of the official file of the patent. At the written request of the person citing the prior art, his or her identity will be excluded from the patent file and kept confidential.

§ 302. Request for reexamination

Any person at any time may file a request for reexamination by the Office of any claim of a patent on the basis of any prior art cited under the provisions of section 301 of this title. The request must be in writing and must be accompanied by payment of a reexamination fee established by the Commissioner of Patents pursuant to the provisions of section 41 of this title. The request must set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested. Unless the requesting person is the owner of the patent, the Commissioner promptly will send a copy of the request to the owner of record of the patent.

§ 303. Determination of issue by Commissioner

(*a*) *Within three months following the filing of a request for reexamination under the provisions of section 302 of this title, the Commissioner will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. On his own initiative, and at any time, the Commissioner may determine whether a substantial new question of patentability is raised by patents and publications discovered by him or cited under the provisions of section 301 of this title.*

(*b*) *A record of the Commissioner's determination under subsection (a) of this section will be placed in the official file of the patent, and a copy promptly will be given or mailed to the owner of record of the patent and to the person requesting reexamination, if any.*

(*c*) *A determination by the Commissioner pursuant to subsection (a) of this section that no substantial new question of patentability has been raised will be final and nonappealable. Upon such a determination, the Commissioner may refund a portion of the reexamination fee required under section 302 of this title.*

§ 304. Reexamination order by Commissioner

If, in a determination made under the provisions of subsection 303(a) of this title, the Commissioner finds that a substantial new question of patentability affecting any claim of a patent is raised, the determination will include an order for reexamination of the patent for resolution of the question. The patent owner will be given a reasonable period, not less than two months from the date a copy of the determination is given or mailed to him, within which he may file a statement on such question, including any amendment to his patent and new claim or claims he may wish to propose, for consideration in the reexamination. If the patent owner files such a statement, he promptly will serve a copy of it on the person who has requested reexamination under the provisions of section 302 of this title. Within a period of two months from the date of service, that person may file and have considered in the reexamination a reply to any statement filed by the patent owner. That person promptly will serve on the patent owner a copy of any reply filed.

§ 305. Conduct of reexamination proceedings

After the times for filing the statement and reply provided for by section 304 of this title have expired, reexamination will be conducted according to the procedures established for initial examination under the provisions of sections 132 and 133 of this title. In any reexamination proceeding under this chapter, the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301 of this title, or in response to a decision adverse to the patentability of a claim of a patent. No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding under this chapter. All reexamination proceedings under this section, including any appeal to the Board of Appeals, will be conducted with special dispatch within the Office.

§ 306. Appeal

The patent owner involved in a reexamination proceeding under this chapter may appeal under the provisions of section 134 of this title, and may seek court review under the provisions of sections 141 to 145 of this title, with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the patent.

§ 307. Certificate of patentability, unpatentability, and claim cancellation

(*a*) *In a reexamination proceeding under this chapter, when the time for appeal has expired or any appeal proceeding has terminated, the Commissioner will issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent any proposed amended or new claim determined to be patentable.*

(*b*) *Any proposed amended or new claim determined to be patentable and incorporated into a patent following a reexamination proceeding will have the same effect as that specified in section 252 of this title for reissued patents on the right of any person who made, purchased, or used anything patented by such proposed amended or new claim, or who made substantial preparation for the same, prior to issuance of a certificate under the provisions of subsection* (*a*) *of this section.*

* * * * *

[Part 2]

SEPTEMBER 23, 1980.--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 Government Operations, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany H. R. 6933]

[Including cost estimate of the Congressional Budget Office]

The Committee on Government Operations, to whom was referred the bill (H.R. 6933) entitled "To amend the patent and trademark laws," having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

* * * * *

It was determined that Sections 1 through 5, dealing with certain procedures and fees, were not within the jurisdiction of the committee. The committee's jurisdiction does cover those sections dealing with Government policies for retaining or disposing of contract inventions developed during the course of or under Government contracts and related matters, and those sections dealing with the reorganization or transfer of individual units of Government.

* * * * *

FOOTNOTES:

[n1] Footnote 1. Report of the President's Advisory Committee on Industrial Innovation, Sept., 1979.

[n2] Footnote 2. *Stimulating Technological Progress.* A statement by the Research and Policy Committee of the Committee for Economic Development, Jan. 1980, pp. 2-7.

[n3] Footnote 3. *Science Indicators,* National Science Board, 1976, pp. 108-115.

[n4] Footnote 4. Testimony of Pindaros Roy Vagelos, M.D., before the subcommittee on Courts, Civil Liberties and the Administration of Justice, April 15, 1980, transcript p. 14.

[n5] Footnote 5. P.L. 96-294 .

[n6] Footnote 6. Testimony of Honorable Sidney Diamond, Commissioner of Patents, April 24, 1980--p. 50.

*. The following is the text of those portions of the House Report by the Committee on the Judiciary (Part 1) and Committee on Government Operations (Part 2) relating to patent fees and patent reexamination. Those portions dealing with section 6 of H.R. 6933 and with other matters are omitted in view of the substantial amendments made to section 6 by the Senate.

PROCESS PATENT AMENDMENTS ACT OF 1987

April 22, 1987.--Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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

REPORT

[To accompany H.R. 1931]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred the bill (H.R. 1931) to amend title 35, United States Code, with respect to patented processes, 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. SHORT TITLE.

This Act may be cited as the "Process Patent Amendments Act of 1987 ".

SEC. 2. RIGHTS OF OWNERS OF PATENTED PROCESSES.

Section 154 of title 35, United States Code, is amended by inserting after "United States", the following: "and, 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".

SEC. 3. INFRINGEMENT FOR IMPORTATION OR SALE.

Section 271 of title 35, United States Code, is amended by adding at the end the following new subsection:

"(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 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 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 beocmes [*sic*] a minor or nonessential component of another product.".

SEC. 4. DAMAGES FOR INFRINGEMENT.

(a) Limitations and Other Remedies.--Section 287 of title 35, United States Code, is amended--

(1) in the section heading by striking "Limitation on damages" and inserting "Limitation on damages and otherr [*sic*] remedies";

(2) by inserting "(a)" before "Patentees"; and

(3) by adding at the end the following:

"(b)(1) An infringer under section 271(g) shall be subject to all the provisions of this title relating to damages and injunctions except to the extent those remedies are modified by this subsection or section 6 of the Process Patent Amendments Act of 1987 . The modifications of remedies provided in this subsection shall not be available to any person who--

"(A) practiced the patented process;

"(B) owns or controls, or is owned or controlled by, the person who practices the patented process; or

"(C) had knowledge before the infringement that a patented process was used to make the product the importation, use, or sale of which constitutes the infringement.

"(2) No remedies for infringement under section 271(g) of this title shall be available with respect to any product in the possession of, or in transit to, the infringer before the infringer had notice that the product was made by a process patented in the United States.

"(3) In an action brought for infringement under section 271(g), the court shall take into consideration the good faith and reasonable business practices demonstrated by the infringer and the need to restore the exclusive rights of the patentee.

"(4) For the purposes of this subsection, notice of infringement means actual knowledge, or receipt of notification, that a product was made by a patented process without authorization of the patentee. A notification shall constitute notice of infringement only if it is in writing and sets forth facts which are sufficient to establish that there is a substantial likelihood that the product was made by the infringing process. Filing an action for infringement shall constitute notice of infringement only if the pleadings or other papers filed in the action meet the requirements of a notification set forth in the preceding sentence. For the purposes of this subsection, a person who obtains a product made by a process patented in the United States in a quantity which is abnormally large in relation to the volume of business of such person or an efficient inventory level shall be rebuttably presumed to have actual knowledge that the product was made by such patented process.".

(b) Technical Amendment.--The item relating to section 287 of title 35, United States Code, in the table of sections for chapter 29 of such title is amended to read as follows:

"§ 287. Limitations on damages and other remedies; marking and notice.".

SEC. 5. PRESUMPTION IN CERTAIN INFRINGEMENT ACTIONS.

(a) Presumption That Product Made by Patented Process.--Chapter 29 of title 35, United States Code, is amended by adding at the end the following:

"**§ 295. Presumption: Product made by patented process**

"In actions alleging infringement of a process patent based on the importation, sale, or use of a product which is made from a process patented in the United States, if the court finds--

"(1) that a substantial likelihood exists that the product was made by the patented process, and

"(2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine,

The product shall be presumed to have been so made, and the burden of establishing that the product was not madeby the process shall be on the party asserting that it was not so made.".

(b) Conforming Amendment.--The table of sections for chapter 29 of title 35, United States Code, is amended by adding after the item relating to section 294 the following:

"295. Presumption: Product made by patented process.".

SEC. 6. EFFECTIVE DATE.

(a) In General.--The amendments made by this Act shall apply only to products made or imported after the date of the enactment of this Act, but shall not abridge or affect the right of any person or any successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on January 1, 1987, or 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 commerical investments made or business commenced in the United States before such date.

(b) Retention of Other Remedies.--The amendments made by this Act shall not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930, or under any other provision of law.

SEC. 7. REPORTS TO CONGRESS.

(a) Contents.--The Secretary of Commerce shall, not later than the end of each 1-year period described in subsection (b), report to the Congress on the effect of the amendments made by this Act on the importation of ingredients to be used for manufacturing products in the United States in those domestic industries that submit complaints to the Department of Commerce, during that 1-year period, alleging that their legitimate sources of supply have been adversely affected by the amendments made by this Act.

(b) When Submitted.--A report described in subsection (a) shall be submitted with respect to each of the five 1-year periods which occur successively beginning on the date of the enactment of this Act and ending five years after that date.

Purpose of the Legislation

The purpose of this bill is to provide meaningful protection to owners of patented processes. Under current patent law, owners of such patents have remedies for unauthorized use of the process only if the process was used in the United States. As a consequence, while a domestic manufacturer using the patented process would infringe the process patent, a foreign manufacturer who imports the product would not. There is also no remedy against parties who use or sell the product, regardless where it is made.

The value of new manufacturing techniques is reflected in the resulting products. A new process may enhance the quality of the product produced, or the new process may permit the product to be made much more economically. In some cases, for example biotechnology, the new process may be the only method of producing a new product. In all of these instances, the advantage to the process patent owner is realized by suing or selling the product, or licensing others to do so. As a consequence, the unfettered ability of others to import, sell or use a product made by the patented process, severely diminishes the value of a U.S. process patent. It also results in the loss of American jobs, particularly in new technology areas.

The only remedy available to the owner of a process patent is under sections 337 and 337a of the Tariff Act of 1930, as amended. Under section 337, the patent owner may petition the International Trade Commission (ITC) to determine that the importation of the product of a patented process constitutes an unfair trade practice, and to exclude the product from entry. This remedy requires the patent owner to establish that the product was made by the patented process and that the importation will damage an efficiently and effectively operated domestic industry, prevent the establishment of such an industry, or will restrain or monopolize trade in the United States. Even if the ITC finds a violation, the President can disapprove such determination. If the petitioner is successful, the ITC will exclude the goods from entry. Regarding goods that have already entered the United States, the ITC can issue a cease and desist order against an individual firm. However, these orders are not effective if importers of offending products can easily find alternative channels. Also, if the importation is discovered after the goods have entered commerce, the patent owner may be left with no remedy since the ITC does not have the authority to award damages to a patentee who, therefore, is not compensated for past injuries.

The laws of many other industrialized countries protect process patent owners there against unauthorized sale or use of products made by the patented process, or the importation of such products into these countries. This bill would expand the scope of our patent laws to tailor them more closely to the national laws of these countries and, thereby, provide owners of process patents in the United States the protection now available abroad to owners of foreign process patents.

Background

The issue of expanded process patent protection is one in which Congress must face serious and legitimate questions about the United States balance of trade. Enactment of this legislation would be an impressive first step in furthering the protection of United States intellectual property rights, in reducing the trade deficit, and in improving American competitiveness in the world marketplace.

This background statement is divided into three sections: (1) an analysis of current patent law; (2) a discussion of the advantages of current remedies; and (3) disadvantages of current remedies.

Protection of United States
Process Patents Under Current Law

American patent law has long recognized the validity of securing for inventors the right to exclude others from practicing an invention that consists of a method of making a product. Process patent protection has been a part of United States law since at least the 19th century.n1 Process patents extend intellectual property protection for new and useful processes, art or methods of creating an object. Since 1952 there has been an explicit statutory acknowledgment of the availability of process patent protection.n2 Process patents, however, have been granted only partial protection against acts of infringement.n3 This is so because, unlike product patents, the use of a patented process outside the United States and a subsequent importation of the product is not an act of patent infringement. The failure fully to protect American process patents harms American businesses and products results contrary to the public interest. Virtually all of our major trading partners adequately protect process patents, thus leaving American patent holders in a position to become the victims of unfair competition.

Process patent protection today is of central importance in the pharmaceutical industry, to the development of solid state electronics, for the manufacture of certain amorphous metalsn4 and, perhaps most significantly, for the biotechnology industry. For most biotech companies the best--and sometimes only--available protection for their intellectual property is a process patent.n5 Such patents are effective in securing for the inventor the right to prevent others from practicing that invention in the United States. Because such protections are limited to the territory of the United States, it is possible--if not likely--for a process patent holder to face domestic competition from persons who have used the patented process to create a product overseas and then shipped it into the United States. In these situations the patent owner cannot sue for patent infringement; rather, the owner is relegated to the United States International Trade Commission (ITC) to seek *limited non-monetary relief.*n6

The failure of American patent law to make unlawful the importation of goods made using an American process patent has deep historical roots. American patent law--like the law of other nations--does not have an extraterritorial effect.n7 To provide that American law should govern conduct that occurs in other countries would conflict with basic notions of national sovereignty. For that reason, American patent law has always required that the infringing act occur within the United States territory.n8 With respect to process patents, courts have reasoned that the only act of infringement is the act of making through the use of a patented process; therefore, there can be no infringement if that act occurs outside the United States.n9

From a public policy perspective, this rationale is not adequate because it ignores the reality that the offending act is the importation of a product made through the use of a protected process patent or its subsequent sale within the United States. There is no logical reason to exclude from the ambit of patent infringement acts associated with the abuse of a United States process as long as they occur within the reach of United States domestic law.n10 Moreover, as the President's Commission on Industrial Competitiveness has found, the failure to extend such protection diminishes the economic value of United States process patents.n11 Without domestic legal protection, competitors using the protected process may accent the limited risks of foreign production and importation in exchange for lower foreign production costs. There is no policy justification for encouraging such overseas production and concurrent violation of United States intellectual property rights.

The courts cannot solve this defect. The Congress can. The compelling nature of this policy deficiency has been evident to lenders in both the legislative and executive branches.n12

As for any policy decision, an assessment of the advantages and disadvantages of the remedies available under current law can be a fruitful endeavor.

ADVANTAGES OF CURRENT REMEDIES

Owners of intellectual property may currently seek relief before the United States International Trade Commission (ITC) under section 337 of the Tariff Act of 1930 , 19 U.S.C. 1337 and 1337a .n13 The ITC may grant relief if it is shown that the responding parties have engaged in an unfair method of competition and unfair acts in the importation of articles into the United States, or their sale by the owner, importer, consignee, or agent of either, the effect or tendency of which is to substantially injure or destroy an industry efficiently and economically operated in the United States.n14 The most commonly asserted unfair trade practice is alleged patent infringement. Proceedings before the ITC present patent owners with a number of opportunities for enforcement that would not ordinarily come into play in the context of a patent infringement lawsuit.n15 Among the possible advantages of bringing a case before the ITC are the fact that the agency is under a statutory deadline to conclude the case within 12 months after filing.n16 The ITC may extend this

period up to 18 months for complex cases.n17 In some cases this truncated time frame may preclude discovery opportunities and can be seen as a disadvantage. Moreover, the ITC, acting with the advice of an expert staff, must determine within 30 days after the complaint is filed whether to commence the investigation.n18

The second advantage to the ITC proceeding is the relative ease of enforcement. The ITC can issue exclusion orders which direct the Customs Service to prevent goods from coming into the United States.n19 The exclusion orders can extend to non-respondents if a pattern or practice of abuse has been shown.n20 In cases where personal jurisdiction exists, the ITC may also issue cease and desist orders.n21 Thus, with respect to some domestic purchasers of foreign-made goods, a type of injunctive relief is possible.

The third arguable advantage is that respondents in an ITC proceeding may not assert a counterclaim.n22 Other factors to consider include possible differences between the ITC and Federal district courts on questions such as patent misuse or patent validity. This difference should be slight because the reviewing court for both fora is the Court of Appeals for the Federal Circuit.

The assistance of the ITC can be viewed as an advantage or a disadvantage. The early active intervention of the ITC staff can help frame the issues and provide inexpensive expert assistance. On the other hand, such intervention is designed to reveal to each side the strengths or weaknesses of the other side's case.

There are some discovery problems in ITC proceedings in foreign countries. For example, Japan does not honor ITC requests for assistance. While the unavailability of discovery can be remedied by orders precluding the admissibility of evidence when discovery efforts have been thwarted, some foreign countries may be more likely to honor requests from Federal District Courts.

A final--and as yet unresolved problem--is that an ITC decision on patent validity may not result in the application of *res judicata* or collateral estoppel in a subsequent judicial proceeding. This limitation comes into play in the context of non-process patents when a patent holder seeks relief in addition to that provided before the ITC.

DISADVANTAGES OF CURRENT REMEDIES

The advantages of using the ITC to enforce a process patent are however, outweighed by at least four disadvantages.n23

First, and foremost, no damages may be obtained pursuant to an ITC order. For the domestic producer who has already suffered a monetary loss as a result of process patent piracy, future oriented relief is an incomplete remedy. The absence of a sufficient deterrent means that many overseas manufacturers and their domestic merchandisers are willing to absorb the risk of an ITC proceeding as a cost of doing business. Enactment of the proposed process patent legislation is the best way patent holders can expect to see a diminution in the abuse of their patents by overseas manufacturers.n24

The second major drawback is that any relief granted by the ITC can be nullified by the President for foreign policy or other reasons. Before 1985, this possibility was more likely in cases where the jurisdiction of the ITC was in question or where the remedies were harsh or overly broad.n25 For the first time in memory, President Reagan on January 4, 1985, overturned the ITC decision to exclude "grey market goods" on policy grounds.n26 Disagreeing with a written opinion by the ITC,n27 the President refused to uphold the exclusion order. Thus, there is less reason to believe that an ITC decision will be tried and decided in a neutral, judicial type of forum free from political, foreign policy or commercial considerations.

The third difficulty in an ITC proceeding for the owner of a process patent is that the statutory criteria are somewhat vague and susceptible to uncertain interpretations. In addition to showing that the respondents have imported goods using an unfair method of competition or in violation of a process patent, it is necessary to show injury to a domestic industry. The ITC has issued somewhat confusing opinions about the prerequisites to showing that a domestic industry exists.n28 It also appears difficult to show the separate requirement of "injury" if one's business is still showing a profit.n29 Assuming that the domestic industry has been injured, the complainant must also show that the industry is efficiently and economically operated. While this criterion has not yet produced anomalous results,n30 this is a trade policy issue which should be irrelevant in terms of process patent infringement and protection of intellectual property. In an ITC proceeding, complainant must show that the imports involved have either the effect to destroy or substantially injure the domestic industry or have a tendency to destroy or substantially injure the domestic industry.n31 Thus, the complainant must introduce proof concerning: (1) loss of customers; (2) decline in production, sales or profits; (3) suppressed prices; (4) decline in employment; and or (5) significant market penetration by the imports.n32 The

burden of showing such injury is on the complainant as is showing the casual link between the imports and the injury. As the ITC staff has aptly observed:

In establishing injury, complainants sometimes have difficulty in showing the necessary nexus--or casual link--between respondents' alleged unfair acts and the demise or slowing of a complainant's domestic industry. Thus, respondents may argue that a decline in sales or profits for complainant's product, rather than being the result of sales of respondents imported goods, is instead the result of a shift in demand to another type of product or of the sales of non-infringing goods by non-respondents.n33

This requirement places a complainant on entirely different footing than one alleging a violation arising under a patent or copyright statute.

Finally, even if the party meets all of these criteria, the ITC must evaluate whether the public interest will be served by the issuance of cease and desist or exclusion order.n34 This consideration which would also be irrelevant in patent litigation, is a potential pitfall in process patent enforcement actions. In many cases, the use of a patented process overseas will result in the production of goods that are substantially less expensive than those made domestically. Consumer advocates could easily argue that such cost consideration alone would preclude the issuance of an ITC order. While the ITC will usually balance cost considerations with the impact of its decision on the vitality of our intellectual property laws, a decision to decline an order solely on the grounds of cost would not be automatically rejected on appeal. In determining whether to issue an exclusion, the Commission must give consideration to the effect of that remedy on the: (1) public health and welfare; (2) competitive conditions in the U.S. economy; (3) the production of like or directly competitive articles in the U.S.; and (4) the U.S. consumer.n35 Moreover, the ITC, by law and regulation, must consult on this question with other federal agencies and outside groups.n36

The looseness of this "public interest" test can be seen in the two cases the ITC relied on to deny an exclusion order. In one, the ITC denied complainant relief because the imported goods were to be used by Ford Motor Company to improve congressionally-mandated fuel efficiency, and domestic industry could not meet the demand.n37 The other involved the use of basic research equipment in nuclear structure physics.n38

It is possible to argue that the current ITC procedures and remedies are sufficient. However, in the view of the Committee, such an argument appears to ignore the reality of the United States international trade deficit. Moreover, such a view tends to obscure the importance of comparing the level of protection American laws afforded patent holders to that given by our major trading partners. Virtually all of the industrialized market-economy countries, in particular the European Economic Communityn39 and Japan,n40 provide greater protection for their process patents than does the United States. Holders of American process patents are disadvantaged in the United States market because of this defect in domestic law at the same time, American inventors must comply with foreign patent laws that preclude the importation of a product made through the use of a patented process protected by a foreign patent. The net-result is that current law actually encourages the loss of American jobs.

CONCLUSION

Notions of fairness and logic dictate expanded protection for United States process patents. Without such protection, owners of an important type of intellectual property will be relegated to the use of an inadequate administrative remedy and will suffer competitive disadvantages. It is to be hoped that the legitimate concern over international trade will give this issue the visibility it deserves.

STATEMENT

The United States Congress has previously turned its attention to process patent reform. During the last three Congresses, many bills have been introduced to solve issues relating to process patent protection in American law. Each of the bills had as its core the belief that process patents deserve greater protection.

During the 98th Congress, one of the bills passed the House of Representatives. See H.R. 6286, Title I (by Rep. Kastenmeier).n41 This bill provided that importation of a product made outside the United States in violation of a process patent constitutes an act of patent infringement. The Senate took no action on the bill.n42

In the 99th Congress, new bills were introduced in the House of Representatives by Rep. Kastenmeier, H.R. 4539, and Moorhead, H.R. 1069 and H.R. 3776. These bills did not distinguish between products made using patented process within the United States and those made outside the United States. H.R. 1069 and H.R. 3776 also provided that once

discovery concerning the patented process has been exhausted, a rebuttable presumption arises that the goods have been made in violation of a process patent.

On September 9, 1986, the Committee on the Judiciary reported H.R. 4899 (House Report 99-807). That bill was passed by the House on September 16, 1986 on the suspension calendar. The Senate took up H.R. 4899 on October 3, 1986, amended the bill, passed it, returned the bill to the House, and asked for a conference. After an unsuccessful attempt to pass the Senate amendment by unanimous consent on October 26, 1986, the House amended the Senate amendment to the House bill and returned the measure to the Senate. No further action was taken on the bill, and for the second Congress in a row, the legislation was stalled.

During the 100th Congress, new legislation was introduced in the House: H.R. 369 (Rep. Moorhead), title III of H.R. 1155 (Rep. Michel), and H.R. 1718 (Rep. Kastenmeier). Legislation has also been introduced in the Senate: title III of S. 539 (Sen. Dole), S. 568 (Sen. Hatch), S. 573 (Sen. Lautenberg); and S. 635 (Sen. Thurmond).

The Committee--acting again through the Subcommittee on Courts, Civil Liberties and the Administration of Justice--held two days of oversight hearings on the general issue of Intellectual Property and Trade. On March 18, 1987, testimony was received from the Honorable Ralph Oman (Register of Copyrights) and Alice Zalik (former Assistant General Counsel, United States Trade Representative). On March 26, 1987, testimony was received from Honorable Donald W. Peterson (on behalf of the Administration) and Profesor David Lange (School of Law, Duke University).

On April 1, 1987, the subcommittee marked-up H.R. 1718, which is identical to the bill first passed by the 99th Congress. Representative Moorhead offered a substitute amendment, the text of which was identical to the second bill passed by the House during the 99th Congress. The amendment was agreed to and, a quorum of Members being present, the subcommittee reported favorably the legislation to the full Committee in the form of a clean bill. H.R. 1931 was introduced by Representative Moorhead, with cosponsorship from Mr. Kastenmeier, Mrs. Schroeder, Mr. Hyde, Mr. Lungren, Mr. Crockett, Mr. DeWine, Mr. Morrison of Connecticut, Mr. Boucher, Mr. Coble, Mr. Slaughter of Virginia, Mr. Cardin, Mr. Hughes, and Mr. Fish.

On April 8, 1987, the full committee marked-up H.R. 1931 and a quorum of Members being present, favorably reported the bill by voice vote, no objection being heard.

Section-by-Section Analysis

SECTION 1: SHORT TITLE

Section 1 provides that this legislation may be referred to as the "Process Patent Amendments Act of 1987 ".

SECTION 2: RIGHTS OF OWNERS OF PATENTED PROCESSES

Section 2 provides that section 154 of title 35, United States Code, is amended by adding to the present rights held by the patent owner, the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by a patented process.

SECTION 3: INFRINGEMENT FOR IMPORTATION OR SALE

Section 3 amends section 271 of title 35, United States Code, by adding a new subsection (g). This subsection provides that 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. Liability exists, however, only if the importation, sale or use of the product occurs in the United States during the term of such process patent. Liability is further limited by the second sentence of proposed subsection (g). This limitation provides that no remedy may be granted for the infringement caused by the importation or other sale of that product. In essence, this means that the patent holder must look in the first instance to the more involved parties (that is, the importer or wholesaler, before seeking relief from the user or retailer). This provision does not preclude action against a user or retailer, but rather affects the liability phase of an infringement proceeding. The bill is intended to supplement the rights and remedies presently available under existing patent law.

Proposed subsection (g) further provides that a product which is made by a patented process will for purposes of title 35 not be considered to be so made after it was materially changed by subsequent processes, or after it became a minor or nonessential component of another product. This intended scope of protection is an important consideration when the patentee is enforcing his or her rights for infringing acts involving the product of the process. The easy case is where the product which results from the process is imported, sold, or used in its form immediately after manufacture. If

the patented process produced chemical X, anyone importing, using, or selling chemical X made by that process is liable for infringement.

However, the scope of this law reaches beyond the easy case or fact situation. The Committee intends to provide protection to process patent owners which is meaningful and not easily evaded. The process may produce chemical X, which is subsequentially subjected to further processing or manufacturing steps. If the subsequent modifications change the basic structure of chemical X so that a clearly different chemical Y results, the connection between the patented process and the product chemical Y is broken. As a consequence, the fact that chemical X was materially changed precludes a claim of infringement for the importation, use, or sale of chemical Y. Also, commerce in chemical Y does not prejudice the rights of the process patent owner whose commercial stake is in chemical X.

However, the subsequent processing modifications of chemical X may only be trivial or of a conventional nature even though a material change occurred in chemical X. For example, modifications which result in the formation of simple derivatives, including salts or esters, or the removal of impurities, are not material changes of chemical X. The same holds true if chemical X is an important intermediate product, such as a polymer, which can materially be changed into an end product, albeit by trivial or conventional processes. In this respect, a product will be considered made by the patented process, regardless of any subsequent changes, if it would not be possible or commercially viable to make that product but for the use of the patented process. In judging the commercial viability, the courts shall use a flexible standard which is appropriate to the competitive circumstances.

Processing steps which only change shape, size or form are also not material. For example, if chemical X were a polyester resin, the use, sale, or importation of the resin could constitute an act of infringement regardless of whether the resin was formed into yarn or fabricated into some other physical object. Similarly, if chemical X was the active ingredient of a pharmaceutical product, or one of its active ingredients, liability for infringement is not avoided by putting chemical X in a tablet or some other dosage form.

The patented process may produce a product which is used as a component of a second product. The form of the immediate product of the process may or may not be altered. The issue then arises whether the importation, sale, or use of the second product constitutes infringement of the process patent.

The Committee intends that liability for infringement exists if the immediate product of the process becomes an integral, important or essential feature of the second product. An important fact question is whether the manufacturer of the second product chose to use the product of the process to gain quality and advantages provided by it. For example, if the manufacturer of the second product informs potential purchasers of such qualities and advantages, it would indicate that the first product was intentionally used for this purpose, and infringement would lie.

However, if the product of the process is a minor or nonessential component of a second product, no liability for infringement should exist. An indication of this circumstance would be that the product of the process was chosen for no identifiable reason from among other, equally useful, products. For example, the patented process may produce a stain repellent used to treat the upholstery of automobile seats. In such case, the importer, user, or seller of the automobile would not be liable for infringement.

SECTION 4: DAMAGES FOR INFRINGEMENT

Section 4 amends section 287 of title 35, United States Code, by the addition of a new subsection (b) which enumerates certain limitations on the damages and other remedies to which the patentee may be entitled. In a related regard, section 6 of H.R. 1931 also provides for certain limitations relating to damages and injunctions by specifying the effective date of this legislation.

New subsection (b) of section 287 is divided into four paragraphs.

Paragraph (1) modifies the remedies available to a patentee, except for three categories of infringers to whom all the provisions of title 35 relating to damages and injunctions apply. They are infringers who: (A) practiced the patented process, (B) are related to the person who practiced the patented process by way of ownership or control, or (C) had knowledge before the infringement that a patented process was used to make the product in question.

With respect to other infringers, paragraph (2) specifies that the patentee has no remedy for infringement available with respect to any product which was in the possession of, or in transit to, the infringer before the infringer had notice that the product was made by a process patent in the United States.

Paragraph (3) provides that in an action brought for infringement under section 271(g) of title 35, United States Code, the court shall take into consideration the good faith and reasonable business practices demonstrated by the infringer and the need to restore the exclusive rights of the patentee through an adequate remedy.

The field of biotechnology is particularly susceptible to commercial "uses" without sales. For example, a patent may cover a process for producing a microorganism using recombinant DNA technology. The microorganism is then used to produce a particular commercial end-product of great value. The bill's provisions limiting remedies against users are not intended to apply to such commercial uses. The Committee believes that without expeditious remedies against use-based infringement, merely stopping importation and non-retail sale of the microorganism after its entry into the country fails to prevent commercial use of the microorganism. Furthermore, the microorganisms already brought in the subsequently reproduced or used to make the commercial end-product. Processing steps that reproduce microorganisms or are used to make the end-product, are by definition an integral, important, or essential feature of the second product.

Further, a reviewing court may, where it deem it equitable, mitigate the adverse economic consequences to the innocent infringer if such action is indicated from the facts in the particular case. Here, the Committee does not intend that in appropriate circumstances a court be precluded from imposing remedies provided for in other sections of title 35, United States Code, such as those relating to injunctions (section 283), willful infringement (section 284), or attorneys fees (section 285).

Paragraph (4) defines the term "notice" to mean actual knowledge or receipt of a notification, that a product was made by a patented process without authorization of the patentee. Accordingly, unless the infringer had actual knowledge of the infringement, notification must be given to the infringer to start the damage clock running. The notification, however, constitutes adequate notice of infringement only if it is in writing and sets forth sufficient facts to establish that there is a "substantial likelihood" that the product was made by the infringing process.

The purpose of paragraph (4) is to assure that process patents are not used to harass innocent purchasers of products who have no knowledge of the processes used to manufacture the product which they purchase from other. In order to establish a substantial likelihood, the notice may include the following: (1) a copy of each asserted patent; and (2) an explanation of the facts that form the basis for the relief that infringment has occurred.

The filing of an action for infringement is notice to the person against whom such action is directed. Other persons not directly connected with such action would not have received adequate or actual notice under this section. Also, filing an action for infringement constitutes adequate notice to the infringer only if the pleadings or other papers filed in the action show that substantial likelihood of infringement exists.

Paragraph (4) further provides that a rebuttable presumption of actual knowledge by the infringer exists if products made by a process patent in the United States were obtained in quantities which are abnormally large in relatin to the volume of business conducted by the infringer or if the quantity exceeds an efficient inventory level.

Section 5: Presumption in Certain Infringement Actions

Section 5 would add a new section 295 of title 35, United States Code, which establishes a rebuttable presumption that a product that could have been made using the patented process was in fact so made. This presumption addresses a great difficulty a patentee may have in proving that the patented process was actually used in the manufacture of the product in question in those cases, where the manufacturer is not subject to discovery under the Federal Rules of Civil Procedure. For example, patent owners will frequently be unable to obtain information concerning the nature of processes being practiced by foreign manufacturers. Shifting the presumption should create no substantial burden, as an accused infringer should be in a much better position to establish that the product was made by another method.

This rebuttable presumption, however, cannot be casually established. To minimize the risk of harassing litigation intended, for instance, to discourage firms from carrying competing products, the presumption would only be available if the patentee demonstrates, on the basis of available evidence, first that the "substantial likelihood" exists that the product was made by the patented process. Secondly, the patentee would also be required to show that despite a reasonable effort, it was impossible to determine what process was used in the manufacture of the product in question. Thus, patentees would have to make initial good faith efforts to prove these two elements in their infringement cases. Placing this burden on patentees should help eliminate frivolous suits. Concerning reasonable efforts by the patentee, such efforts can be made by attempting to obtain discovery, or showing that efforts to obtain discovery of information located in a foreign country would be futile. If the patentee satisfies this two-prong test, the burden of establishing that the products was not made by the process shall be on the party asserting that it was not so made.

A mere denial by the defendant would not be adequate to satisfy this burden. At a minimum, the Committee would expect that the defendant would have to introduce evidence, for example affidavits from the manufacturer with supporting documentation adequate to demonstrate that a non-infringing process was used. Of course, the Committee recognizes that such information may be confidential and would expect the court to take appropriate action to safeguard such confidential material.

The Committee further recognizes that at the time of giving notice, the plaintiff will not have had the benefits of the discovery process and thus the notice requirement is not intended to impose harsh evidentiary burden on the plaintiff. Rather, the plaintiff is expected to set forth facts which the plaintiff could reasonably be expected to have on hand and which form the basis for a reasonable belief that the product was made using the patented process.

It is the Committee's intention, however, that when a defendant meets the burden of producing evidence to rebut the plaintiff's showing of substantial likehood of infringement, the burden of persuading the court will be on the patent owner. As in all civil litigation, the plaintiff bears the burden of establishing the truth of the complaint by a preponderance of the evidence, in order to prevail. Thus, the patent owner always has the ultimate burden of producing evidence adequate to persuade the court that infringement exists. A reviewing court can draw inferences from a defendant's unwillingness to disclose the process used, or why efforts to learn of the process were unsuccessful. Of course, courts will apply the ordinary rules of evidence.

Substantial likelihood of infringement may be shown by direct or circumstantial evidence. Adequate circumstantial evidence for example, could include telltale signs of the use of the patented process which could be found in the product itself. When chemical processes are used, unique trace impurities or a characteristic pattern of impurities may be present which fingerprint the process of manufacture. Circumstantial evidence also could include a showing that the patented and process represent a substantial improvement in effeiciency over prior processes and that no alternative, economically feasible process exists. This could be demonstrated by showing that the sales price of the product would have to be considerably higher if the product was made by any known process other than the patented one.

Section 6: Effective Date

Section 6 provides for the effective date of this legislation and a grandfather clause exempting certain commercial arrangements. In general, the amendments made by this Act will apply only to products made or imported after its date of enactment, but shall not abridge or affect the right of any person or any successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on January 1, 1987. These rights shall also not be abridged or affected in those instances where substantial preparation was made by such person before January 1, 1987 for the sale or use of the product in question. However, all of these rights may only remain in force to the extent that their being continued is equitable for the protection of commercial investments made, or business commenced, in the United States before January 1, 1987. The grandfather clause does not apply to any product protected by a process patent or process patent that is involved in litigation commenced on or before the date of enactment, including actions before the International Trade Commission.

Subsection (b) of section 6 clarifies that the amendments made by this Act do not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under section 337 of the tariff Act of 1930, or under any other provision of law.

Specifically the Committee does not intend that it shall be an act of infringement to import a product which is made by a process patented in the United States "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale or drug." See § 271 (e)(1) of title 35, United States Code. Congress previously decided that certain actions do not constitute patent infringements and this Act does not change that prior policy decision.

Section 7: Reports to Congress

Section 7 provides that the Secretary of Commerce shall annually reort [*sic*] to the Congress the effect of the amendments on the importation of ingredients to be used for manufacturing products in the United States on those industries that submit complaints to the Department of Commerce. Complaints submitted to the Department of Commerce during the one-year period must allege that the particular domestic industry's legitimate sources of supply have been adversely affected by the amendments made by this Act. Subsection (b) of this section specifies when the reports are to be submitted. Such reports, if any, are to be submitted annually for five years following enactment of this Act.

Oversight Findings

The Committee makes no oversight findings with respect to this legislation.

In regard to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives , no oversight findings have been submitted to the Committee by the Committee on Government Operations.

Statement of the Committee on Government Operations

No statement has been received on the legislation from the House Committee on Government Operations.

New Budget Authority

In regard to clause 2(l)(3)(B) of rule XI of the Rules of the House of Representatives , H.R. 1931 creates no new budget authority or increased tax expenditures for the Federal Government.

Inflationary Impact Statement

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives , the Committee finds that the bill will have no foreseeable inflationary impact on prices or costs in the operation of the national economy.

Federal Advisory Committee Act of 1972

The Committee finds that this legislation does not create any new advisory committees within the meaning of the Federal Advisory Committee Act of 1972 .

Committee Vote

On April 8, 1987, H.R. 1931 was ordered reported favorably by the Committee on the Judiciary, by voice vote, a quorum of members being present.

Cost Estimate

In regard to clause 7 of rule XXIII of the Rules of the House of Representatives , the Committee agrees with the cost estimate of the Congressional Budget Office.

U.S. Congress,
Congressional Budget Office,
Washington, DC, April 21, 1987.

Hon. Peter W. Rodino, Jr.,
Chairman, Committee on the Judiciary,
House of Representatives, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has reviewed H.R. 1931, the Process Patent Amendments Act of 1987 , as ordered reported by the House Committee on the Judiciary, April 8, 1987.

H.R. 1931 would extend to patent owners the right to exclude others from using or selling in the United States, or importing into the United States, a product made by a patented process. As a result of the provisions of this bill, the holder of a process patent would be allowed, with certain restrictions, to seek damages for patent infringements. After certain court findings, the product would be presumed to have been made by a patented process, and the burden of proving otherwise would fall on the alleged infringer. H.R. 1931 would also require the Secretary of Commerce to submit to the Congress annual reports for five years on the effectiveness of the amendments.

Based on information from the Patent and Trademark Office, CBO estimates that enactment of this bill would not result in significant additional costs to the federal government and will not affect the budgets of state or local governments.

If you wish further details on this estimate, we will be pleased to provide them.

With best wishes,

Sincerely,

Edward M. Gramlich,
Acting Director.

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

* * * * *

CHAPTER 14--ISSUE OF PATENT

* * * * *

§ 154.Contents and term of patent

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, of the right to exclude others from making, using, or selling the invention throughout the United States *and, 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*, 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.

* * * * *

PART III--PATENTS AND PROTECTION OF PATENT RIGHTS

* * * * *

CHAPTER 28--INFRINGEMENT OF PATENTS

* * * * *

§ 271.Infringement of patent

(a) * * *

* * * * *

(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 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 sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be made after--

(1) it is materially changed by subsequent processes; or

(2) it becomes a minor or nonessential component of another product.

* * * * *

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

281. Remedy for infringement of patent.

* * * * *

287. Limitation on damages; marking and notice.

287. Limitations on damages and other remedies; marking and notice.

* * * * *

295. Presumption: Product made by patented process.

* * * * *

287. Limitation on damages and other remedies; marking and notice

(a) Patentees, and persons making or selling any patented article for or under them, may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent, or when, from the character of the article, this can not be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

(b)(1) An infringer under section 271(g) shall be subject to all the provisions of this title relating to damages and injunctions except to the extent those remedies are modified by this subsection or section 6 of the Process Patent Amendments Act of 1987 . The modifications of remedies provided in this subsection shall not be available to any person who--

(A) practiced the patented process;

(B) owns or controls, or is owned or controlled by, the person who practiced the patented process; or

(C) had knowledge before the infringement that a patented process was used to make the product the importation, use, or sale of which constitutes the infringement.

(2) No remedies for infringement under section 271(g) of this title shall be available with respect to any product in the possession of, or in transit to, the infringer before the infringer had notice that the product was made by a process patented in the United States.

(3) In an action brought for infringement under section 271(g), the court shall take into consideration the good faith and reasonable business practices demonstrated by the infringer and the need to restore the exclusive rights of the patentee.

(4) For the purposes of this subsection, notice of infringement means actual knowledge, or receipt of notification, that a product was made by a patented process without authorization of the patentee. A notification shall constitute notice of infringement only if it is in writing and sets forth facts which are sufficient to establish that there is a substantial likelihood that the product was made by the infringing process. Filing an action for infringement shall constitute notice of infringement only if the pleadings or other papers filed in the action meet the requirements of a notification set forth in the preceding sentence. For the purposes of this subsection, a person who obtains a product made by a process patented in the United States in a quantity which is abnormally large in relation to the volume of business of such person or an efficient inventory level shall be rebuttably presumed to have actual knowledge that the product was made by such patented process.

* * * * *

Sec. 295. Presumption: Product made by patented process

In actions alleging infringement of a process patent based on the importation, sale, or use of a product which is made from a process patented in the United States, if the court finds--

(1) that a substantial likelihood exists that the product was made by the patented process, and

(2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine,

the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.

* * * * *

Senate Report No. 100-83, 100th Cong., 1st Sess. (1987)

PROCESS PATENTS AMENDMENTS ACT OF 1987

June 23, 1987.--Ordered to be printed

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

R E P O R T
[To accompany S. 1200]

The Committee on Judiciary, to which was referred the bill (S. 1200) to amend Title 35, United States Code, with respect to patented processes, patent misuse and licensee challenges to patent validity, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

CONTENTS

Click here to view image.

[Editor's Note: Legislative history and material dealing with patent misuse and licensee challenge has been omitted.]

II. TEXT OF BILL

TITLE I--PROCESS PATENT AMENDMENTS ACT OF 1987

SEC. 101. RIGHTS OF OWNERS OF PATENTED PROCESSES.

Section 154 of title 35, United States Code, is amended by inserting after "United States," the following: "and, 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,".

SEC. 102. INFRINGEMENT FOR IMPORTATION, SALE, OR USE.

Section 271 of title 35, United States Code, is amended by adding at the end the following new subsection:

"(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".

SEC. 103. DAMAGES FOR INFRINGEMENT

(a) LIMITATIONS AND OTHER REMEDIES.--Section 287 of title 35, United States Code, is amended--

(1) in the section heading, by striking "LIMITATION ON DAMAGES" and inserting "LIMITATION ON DAMAGES AND OTHER REMEDIES";

(2) by inserting "(a)" before "Patentees"; and

(3) by adding at the end the following:

"(b)(1) An infringer under section 271(g) shall be subject to all the provisions of this title relating to damages and injunctions except to the extent those remedies are modified by this section or section 105 of the Process Patent Amendments Act of 1987 . The modifications of remedies provided in this subsection shall not be available to any person who--

"(A) practiced the patented process;

"(B) owns or controls, or is owned or controlled by, the person who practiced the patented process; or

"(C) had knowledge before the infringement that a patented process was used to make the product the importation, use, or sale of which constitutes the infringement.

"(2) No remedies for infringement under section 271(g) shall be available with respect to any product in possession of, or in transit to the party, or which the party has made a binding commitment to purchase and which has partially or wholly manufactured, before the party had notice of infringement as defined in paragraph (5). The party shall bear the burden of proving any such possession, transit, binding commitment, or manufacture. If the court finds that (A) the party maintained or ordered an abnormally large amount of infringing product, or (B) the product was acquired or ordered by the party to take advantage of the limitation on remedies provided by this paragraph, the court shall limit theapplication of this paragraph to that portion of the product supply which is not subject to such a finding.

"(3)(A) In making a determination with respect to the remedy in an action brought for infringement under section 271(g), the court shall consider--

"(i) the good faith and reasonable business practices demonstrated by the defendant,

"(ii) the good faith demonstrated by the plaintiff with respect to the request for disclosure as provided in paragraph (4), and

"(iii) the need to restore the exclusive rights secured by the patent.

"(B) For purposes of subparagraph (A), the following are evidence of good faith: a request for disclosure by a party, a response by the party receiving the request for disclosure within 60 days, and submission of the response by the party who received the disclosed information to the manufacturer, or if not known, the supplier with a request for a written statement that the process claimed in the disclosed patent is not used. The failure to perform any such acts is evidence of absence of good faith unless there are mitigating circumstances. Mitigating circumstances shall include the case in which, due to the nature of the product, the number of sources for products, or like commercial circumstances, a request for disclosure is not necessary or practicable to avoid infringement.

"(4) For purposes of paragraph (3), 'a request for disclosure' means a written request made to a party then engaged in the manufacture of a product to identify all process patents owned by or licensed to the party as of the time of the request that the party then reasonably believes could be asserted to be infringed under section 271(g) if that product were imported into, or sold or used in, the United States by an unauthorized party. A request for disclosure is further limited to a request--

"(A) made by a party regularly engaged in the United States in the sale of the same type of products as the party to whom the request is directed, or a request which includes facts showing that the requester plans to engage in the sale of such products in the United States;

"(B) made prior to such party's first importation, use, or sale of units of the product produed by an infringing process and prior to notice of infringement; and

"(C) which includes a representation by the requesting party that it will promptly submit the patents identified to the manufacturer, or if not known, the supplier of the product to be purchased by the requestor, and will request from that manufacturer or supplier a written statement that none of the processes claimed in those patents is used in the manufacture of the product.

"(5)(A) For the purpose of this subsection, notice of infringement means actual knowledge, or receipt by a party of a written notification, or a combination thereof, of information sufficient to persuade a reasonable person that it is likely that a product was made by a patented process.

"(B) A written notification from the patent holder charging a party with infringement shall specify the patent alleged to have been used and reasons for a good faith belief that such process was used. If the patent holder has actual knowledge of any commercially feasible process other than the patented process which is capable of producing the allegedly infringing product, the notification shall set forth such information with respect to the other processes only as is reasonably necessary to fairly explain the patent holder's belief and is not required to disclose any trade secret information.

"(C) A party who receives a written notification as described in the first sentence of such subparagraph (B) and fails to thereafter seek information from the manufacturer, or if not known, the supplier, as to whether the allegations in the notification are true shall, absent mitigating circumstances, be deemed to have notice of infringement. This provision shall apply even though the notification does not establish notice of infringement under subparagraph (A).

"(D) A party who fails to make the submission referred to in subsection (b)(4)(C) shall be deemed to have notice of infringement.

"(E) Filing of an action for infringement shall constitute notice of infringement only if the pleadings or other papers filed in the action meet the requirements of subparagraph (A).".

(b) TECHNICAL AMENDMENT.--The item relating to section 287 of title 35, United States Code, in the table of sections for chapter 29 of such title is amended to read as follows:

"287. Limitations on damages and other remedies; marking and notice".

SEC. 104. PRESUMPTION IN INFRINGEMENT ACTIONS.

(a) IN GENERAL.--Chapter 29 of title 35, United States Code, is amended by adding at the end the following:

"§ 295. Presumption: Product made by patented process

"In actions alleging infringement of a process patent based on the importation, sale, or use of a product which is made from a process patented in the United States, if the court finds--

"(1) that there is evidence establishing a substantial likelihood that the product was made by the patented process, and

"(2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine, the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made."

(b) CONFORMING AMENDMENT.--The table of sections for chapter 29 of title 35, United States Code, is amended by adding after the item relating to section 294 the following:

"295. Presumption: Product made by patented process".

SEC. 105. EFFECTIVE DATE.

(a)(1) IN GENERAL.--The amendents made by this title shall apply only to products made or imported after the date of the enactment of this Act.

(2) EXCEPTIONS.--This title shall not abridge or affect the right of any person or any successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on May 15, 1987, or 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 investments made or business commenced in the United States before such date. This paragraph shall not apply to any person or any successor in business of such person using, selling, or importing a product produced by a patented process that is the subject of a

patent process enforcement action commenced before January 1, 1987, before the International Trade Commission, that is pending or in which an order has been entered.

(b) RETENTION OF OTHER REMEDIES.--The amendments made by this title shall not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930, or under any other provision of law.

SEC. 106. REPORTS TO CONGRESS.

(a) CONTENTS.--The Secretary of Commerce shall, not later than the end of each 1-year period described in subsection (b), report to the Congress on the effect of the amendments made by this title on the importation of ingredients to by used for manufacturing products in the United States in those domestic industries that submit complaints to the Department of Commerce, during that 1-year period, alleging that their legitimate sources of supply have been adversely affected by the amendments made by this title.

(b) WHEN SUBMITTED.--A report described in subsection (a) shall be submitted with respect to each of the five 1-year periods which occur successively beginning on the date of the enactment of this Act and ending five years after that date.

III. TITLE I--PROCESS PATENT AMENDMENTS ACT OF 1987

A. Purpose of Amendment

As amended, title I of S. 1200 provides patent owners the new right to sue for damages and seek an injunction in Federal district court when someone, without authorization, uses or sells in the United States, or imports into the United States a product made by their patented process.

B. History of Legislation

The importance of strengthening process patent protection was first recognized in 1966 by President Johnson's Commission on the Patent System; then in 1979 by President Carter's Domestic Policy Review on Industrial Innovation, and again in 1985 by President Reagan's Commission on Industrial Competitiveness. More recently, it was included in President Reagan's competitiveness initiative of 1987 and strongly endorsed by the President's Commission on Industrial Competitiveness in 1984.

The Process Patent Amendments Act of 1987 , title I of S. 1200, is the result of a carefully crafted compromise reached between Senators DeConcini, Hatch, Lautenberg and a wide variety of parties interested in process patent legislation. On April 22, 1987, the Patents, Copyrights and Trademarks Subcommittee held a hearing on predecessors to this bill, S. 568, which was introduced in the 100th Congress by Senators Hatch and DeConcini and S. 573, which was introduced by Senator Lautenberg. Hearings on Process Patent legislation was also held in both the 98th and 99th Congresses. S. 568 contained the same language as S. 1543, which passed the Judiciary Committee and the Senate unanimously during the 99th Congress. On May 13, 1987 the Patents Subcommittee reported S. 568 with an amendment in the nature of a substitute which was then introduced as title I of S. 1200 on May 14, 1987 by Senators DeConcini, Hatch, and Lautenberg. S. 1200 as amended passed the Judiciary Committee unanimously on June 4, 1987. The Judiciary Committee will include S. 1200 in the Senate Omnibus Trade Act of 1987 .

C. Discussion

America's leading position in technology innovation throughout the world is credited in large part to the stimulus of its patent system, which stems ultimately from Article I, Section 8, clause 8 of the Constitution which states, "The Congress shall have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries ..." In the past two decades, however, it has become necessary to modernize our patent laws. As compared with those of our major trading partners, the inadequate protection contained in U.S. process patent law has emerged as a major factor in the dynamics of global innovation and economic competition. In contrast to Japan and nearly all of the Western European nations, the United States does not provide patent protection against the importation, and subsequent use or sale, of products made abroad without authorization using a process patented in the United States except for a limited form of protection is afforded under the trade laws (19 U.S.C. 1337a) enforced by the International Trade Commission (ITC).

The U.S. patent laws recognize three basic types of inventions for which patents may be obtained: products, methods of use, and methods of manufacture. Patents on the last are also known as process patents, that is, patents on process inventions. A process patent covers a process for making a product, which may or may not be patented itself. Process patents promise to be increasingly important to a number of industries in the coming years, especially in the areas of industrial and pharmaceutical chemicals, optical fibres, and above all in the fields of biotechnology and bioengineering research. Biotechnology companies are often built around a new process for artificial manufacture of a substance that occurs in nature and is therefore itself unpatentable. A well known example is the Genentech Corporation of California, whose principal assets since its founding in 1976 have been process patents on revolutionary new ways of making human insulin and growth hormone.

Under our current patent laws, a patent on a process gives the patentholder the right to exclude others from using that process in the United States without authorization from the patentholder. The other two standard aspects of the patent right--the exclusive right to make or sell the invention--are not directly applicable to a patented process. S. 1200 proposes to also cover the importation, use or sale in the United States of products resulting from the process. The bill does not attempt to prevent the use of the process in another country. If the U.S. process patentholder has not obtained a similar patent in the other country, he has no right by virtue of his U.S. patent to prevent anyone from using the process in that country. However, if the U.S. patentholder does have a patent in the other country as well, he may seek remedy in the courts of that country. S. 1200 would protect against the entry into the U.S. marketplace of goods made abroad without authorization from the inventor who has a process patent in this country. The patent is on the process alone, but the entry of the goods made elsewhere by that process clearly encroaches on the rights of the patent owner.

The principle of process patent protection is also incorporated in the European Patent Convention, the Community Patent Convention, and the World Intellectual Property Organization (W.I.P.O.) Treaty on Harmonization. The following excerpt from a recent memorandum on process patent law prepared by the International Bureau of W.I.P.O. elaborates on the rationale for including products obtained from a patented process in the scope of the protection afforded by the process patent:

The extension (to the product of the process) seems to be an exception to the principle that the protection conferred by a patent or another title of protection for an invention is defined by the object of the invention. In the case of a process invention, a strict application of the said principle would mean that the owner of a process patent could only exclude others from using the patented process. The legal provisions which extend process protection to products obtained by the patented process are based on practical economic considerations. A process which leads to a specific product presents an economic value only through the product. However, it is not always possible to obtain a patent for the product; for example, the product may not be new or may--although new--lack inventive step. The invention of a new and inventive process for the production of such a product which is not patentable constitutes an important technological advance but the reward granted through a process patent is not important because--without an extension to the product--the process patent would be difficult to enforce (since infringement of the process is difficult to prove) and could even be circumvented by use of the process in another country where the process is protected. In order to make patent protection of a process meaningful, it is therefore necessary to consider the patented process and the resulting product as a whole, with the consequence that process protection is automatically extended to the resulting product even if the said product has not been claimed.n1

Foreign Process Patent Legislation

Importation, use and sale in the United States of products produced by processes patented in this country severely diminishes the value of such patents. This practice must be effectively countered by changes in the patent laws to protect the legitimate interests of U.S. inventors. Expanding the scope of our laws to bring them into conformity with the European Patent Convention and the national laws of many industrialized countries is necessary to protect the continued growth of American business. The following chart summarizes the protection offered to process patent holders in the group B or development market economy countries. In addition, some typical examples of foreign laws in this area are helpful for comparison. As the chart and summaries indicate, most countries' patent laws are structured so that the direct product of a patented process is also included within the scope of the patent. Nearly one-half of those countries make importation an act of infringement.

[Charts and summaries follow:]

PROCESS PATENT PROTECTION IN GROUP B COUNTRIES

Click here to view image.

1 EPC member.
2 Applies to new substances only.
3 No clear statutory provision.
4 Apparently applies in at least some situations.
5 Registration in Cyprus of a United Kingdom patent confers the same right in Cyprus.
6 No patent law.
7 Claims are permitted, but legal issues are apparently unsettled.
8 Liechtenstein and Switzerland constitute a single territory for patent purposes.
9 No copy of the national law was available.
10 Industrial property rights acquired in Italy are valid in San Marino and vice versa.

Denmark

Section 3

(1) The exclusive right conferred by a patent shall imply that no one except the proprietor of the patent may without permission exploit the invention:

(i) by making, offering, putting on the market or using a product which is the subject-matter of the patent, or by importing or stocking the product for these purposes;

(ii) by using a process which is the subject-matter of the patent or by offering the process for use in this country if the person offering the process knows, or it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent;

(iii) by offering, putting on the market or using a product obtained by a process which is the subject-matter of the patent or by importing or stocking the product for these purposes.

France

Chapter Three.--Rights and Obligations Attached to the Patent

Article 28.--1. The scope of protection conferred by a patent shall be determined by the terms of the claims. The description of the invention and the drawings, however, shall serve to construe the claims.

2. Where a patent relates to a process, the protection conferred by the patent shall extend to the products directly obtained by that process.

Article 29.--A patent confers the right to prohibit any other person, without the consent of the proprietor of the patent:

(a) from making, offering, putting on the market, using, or importing or storing for such purposes the product to which the patent relates;

(b) from using a process to which the patent relates, or, where such other person knows, or where it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, from offering the process for use within French territory;

(c) from offering, putting on the market, using, or importing or storing for such purposes the product obtained directly by the process to which the patent relates.

Great Britain

Statutes, Regulations, and Treaties

Patents Act 1977

Infringement

60.--(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say--

(a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;

(b) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;

(c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

§ 5.--No-one may make an occupation of the following without the consent of the patentee:--1. Manufacturing, importing or offering for sale an article which is patented or prepared by a patented method; or 2. Using the patented method.--The following is however, permissible having no regard for a Patent:--a) The use of articles accompanying or connected with means of transport from other countries when these come to this country for limited periods, and b) The continued use of articles arrived by and belonging to means of transport which have been purchased abroad for Icelandic currency or for an Icelandic vessel which has broken down at sea and been repaired abroad.

Italy

§ 2.--The patent concerning a new industrial method or process confers upon the patentee the exclusive use thereof.

The exclusive use includes also commercializing the product directly obtained by the new industrial method or process. If the product is a new one, every identical product is presumed to have been obtained, unless there is evidence to the contrary, but the method or process which is the subject of the patent.

Japan

3. "Working" in respect of an invention in this Law shall mean the following acts:

(1) In an invention of a thing, acts of manufacturing, using, transferring, leasing, exhibiting for the purpose of transfer or lease, or importing the thing;

(2) In an invention of a process, acts of using the process.

(3) In an invention of a process of manufacturing a thing, acts of using, transferring, leasing, exhibiting for the purpose of transfer or leave, or importing the thing produced by the process in addition to those as mentioned in the preceding items.

Portugal

Article 214. A penalty of 500 to 10,000 escudos, to which may be added imprisonment for a period of from one to six months, will be imposed on those who, during the period of legal protection, should prejudice the owner of a patent in the exercise of his right in any of the following ways:

1. Manufacturing, without license from the title holder, the articles or products covered by the patent;

2. Employing, without the said license, the means and processes or using new applications of means and processes forming the subject of the patent;

3. Importing, selling, offering for sale, putting in circulation or concealing, in bad faith, products obtained in any of the ways referred to.

Sweden

Section 3

The exclusive right conferred by a patent implies, with the exceptions stated below, that no one except the proprietor of the patent may, without the proprietor's consent, use the invention by

(1) making, offering, putting on the market or using a product protected by the patent or importing or possessing such product for these purposes;

(2) using a process which is protected by the patent or, while knowing, or it being obvious from the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, offering the process for use in this country;

Statutes, Regulations and Treaties

(3) offering, putting on the market, or using products made by a process protected by the patent or importing or possessing the product for these purposes.

Switzerland

If the invention concerns a process, the effects of the patent shall extend to the immediate products of the process.

Section 67

If the invention concerns a process for the manufacture of a new product, every product of the same composition shall be presumed to have been made by the patented process until proof to the contrary has been adduced.

Subsection 1 shall apply by analogy in the case of a process for the manufacture of a known product if the patentee shows prima facie evidence of infringement of the patent.

West Germany

Part Nine.--Infringement of Patent

Article 74

(1) A person who uses an invention contrary to the provisions of Articles 6, 7 and 8 may be sued by the injured party to enjoin such use.

(2) A person making such use intentionally or negligently shall be liable for compensation to the injured party for the damage suffered therefrom. If the infringer has acted with only slight negligence, the court may fix, in lieu of compensation, an indemnity being between the damage to the injured party and the profit which has accrued to the infringer.

(3) In the case of an invention whose subject matter is a process for the production of a new substance, any substance of the same nature shall, in the absence of proof to the contrary, be deemed to have been produced by the patented process.

Need for Modernization of U.S. Process Patent Law

The United States has historically given different treatment to product and process patents, while so many other industrialized countries give uniform, full protection to both. The Commissioner of Patents and Trademarks, Donald Quigg, has suggested that the U.S. patent system is older than many of the European systems and that the ultimate historical origin of the omission of process patent protection may have been simply that in earlier commercial eras processes had not become so significant as they are in the present high-technology milieu. At the same time, adjacent European countries would become more aware more quickly of importations of products made outside by processes patented in the receiving country.

Many industrial countries, Japan and Germany for example, have only recently adopted product patent protection in the pharmaceutical area, having previously confined patent protection on drugs to the processes used to make them, in the interest of promoting wider and easier availability of medicines for their populations. Thus when a new medicine comes on the market, competitors would only have to find a new way to produce it and could go on the market immediately, without waiting for any patent on the medicine itself to expire. Because it was the only form of protection allowed for pharmaceutical products, broader process patent protection was developed in those countries, covering not only domestic use of the process, but also importation, use or sale of the products obtained from the process. On the other hand, when Germany and Japan (in 1967 and 1975 respectively) broadened their laws to cover pharmaceutical product patents, they did not eliminate patent protection of processes and their resulting products.

Most countries that provide process patent protection extending to the products have also established a rebuttable presumption shifting the burden of proof to the defendant if the plantiff presents evidence meeting some threshold of

reasonable likelihood that the product was made by the patented process (France and Sweden are the only exceptions). However, many of these countries add a limitation that this presumption is only available in the case of processes for making "new" products. By contrast, as discussed further below and in the sectional analysis, S. 1200 allows the rebuttable presumption in any process patent infringement action under the bill, on the theory that every genuinely novel and useful (hence patentable) process invention deserves the full protection of the law, regardless of whether the resulting product is new or not. The example of the biotechnology industry is relevant here, in its efforts to develop recombinant DNA processes to produce already existing natural substances such as growth hormones. Another point of difference, again discussed at length below, is the limitation in the process patent laws of most industrialized nations to products made "directly" from the process; Japan and Sweden are the only exceptions to this rule. S. 1200 introduces a new phrase, "materially changed by subsequent processes; or ... becomes a trivial and nonessential component of another product," to serve the same general purpose of restricting the scope of the bill to exclude ultimate products that, because of intervening manufacturing steps, cease to have a reasonable nexus with the patented process.

An integral part of the debate on strengthening U.S. process patent protection has been the alternative remedy under the trade laws against importation of products made abroad using a process patented in the United States (Section 337a of the Tariff Act of 1930 , 19 U.S.C. 1337a). Section 337 originated in 1922 as an antidote to a range of unfair methods of competition in import trade. It was not widely used until the 1974 strengthening amendments providing for more timely and effective remedies, the principal change being that the ITC was given full authority to order remedies, subject only to veto by the President for policy reasons. In process patent cases brought before the ITC, the available remedies under section 337a are exclusion of the goods from entry, and, if the goods have already entered, cease and desist orders against particular firms that have received them.

In order to obtain these remedies from the ITC, the complainants must show that their patented processes were used in manufacturing the imported products, that an efficiently and economically operated industry utilizing the patent exists in the United States, and that the imported product had the effect or tendency of destroying or substantially injuring the domestic industry. After making these findings, the ITC must in addition decide that enjoining the importation of the infringing goods is in the public interest. Only then can the ITC provide relief to the process patentholder; and even then, its decision is subject to a binding Presidential veto.

The ITC, unlike a Federal court in a patent infringement suit, can award no damages. Payment of damages to the patentholder has the effect of compensating inventors and penalizing infringers for the economic injury due to the infringement, and also acts as a deterrent against future infringements. Furthermore, the tests that must be met to win an ITC order excluding the infringing products are more elaborate than in a Federal court action where all that is necessary is to show infringement. The requirement in the ITC proceeding to show that the importation of infringing goods is causing substantial injury to an efficiently run domestic industry requires the patentowner to show more than infringement. The patentee must show that there is an industry in the United States which generally means that the patentholder must practice a patented process commercially in the United States before he may enforce it. Morever, the industry must be efficiently and economically operated. The patentee also must show sufficent harm to justify relief. These requirements utilize an approach that has never been a part of our patent system. Instead, our system is based on the conviction that the public is well served by the disclosure of the invention in return for a limited period of the exclusivity for the inventor, even if the latter chooses not to commercialize the invention during this period.

A hypothetical example illustrates this difference. Suppose an American company has obtained a process patent. The issued patent discloses the details of its new process for all the world to see. But for one reason or another, the American company has not yet been able to begin marketing the product. In that situation, the company may be unable to prove the existence of establishment of a domestic industry, and therefore unable to stop foreign pirates who use the published process and import the resulting products for sale in this country. A similar predicament might beset a university that obtains a process patent but is still involved in negotiations with potential licensees. To be sure, there may be some scope in a Section 337 investigation for treating impairment for prevention of a domestic patentholder's efforts to establish an industry here as substantial injury. But this whole issue simply does not arise in an ordinary infringement suit under the patent laws, where the only question is whether a valid patent has been infringed.

Even where the process patent has engendered an efficiently run domestic industry, the patentholder has the additional burden of showing that the industry has been injured by the entry of infringing articles. This circumstance was illustrated in the recent *Corning* case against Sumitomo before the ITC (In the Matter of Certain Optical Waveguide Fibers; Investigation No. 337-TA-189). Corning succeeded in establishing that its patents were valid and were being infringed by Sumitomo's imported products. Further, it proved that two legitimate domestic industries, efficiently and economically operated, had grown under the Corning patents. However, because the ITC found that

Sumitomo's infringing imports did not substantially injure either of those domestic industries, it found no violation of Section 337, and Corning was unable to obtain any relief.

Finally, in the best of circumstances, where the full ITC remedy is obtained, the patentholder is saddled with an expensive and burdensome proceeding, with no prospect of having his injury compensated, only brought to a hold prospectively. By the same token, the ITC remedy has little deterrent value. Foreign manufacturers are not punished for simply infringing U.S. process patents by importing their products into the country until they are enjoined, with no further penalty. Still, the ITC forum will remain a useful supplement in process patent infringement situations after S. 1200 is enacted. The ITC can provide speedy and comprehensive injunctive relief (covering many ports of entry in a single proceeding) while the patentholder awaits the outcome of the trial in the federal court to obtain damages.

In fact, measures under consideration within the Senate Trade Bill incorporate S. 486, introduced by Senator Lautenberg and others, which would lower some of the standards that must be met in an ITC process patent infringement investigation, such as eliminating the injury requirement. None of these proposals, however, are conceived by their advocates as being a substitute for achieving the needed modernization of the patent laws themselves that allows infringement by importation of goods made abroad using a patented process. Commissioner Quigg concurs with this view in his statements on the issue: "Although ITC proceedings are an important adjunct to enforcement of patent rights, they should not be the sole remedy available to process patentholders against competition from offshore manufacturers.n2 Commissioner Quigg has also stated:

... I think it is important to keep 337, because that is a short-term compact operation which the patent owner can use to prevent the market from slipping away to foreign manufacturers. Patent litigation in the Federal courts is a more prolonged thing. It is not likely that you would be able to get a preliminary injunction during the litigation, and therefore the 337 approach does have a benefit for U.S. patentholders.n3

It is worth noting that the ITC itself has in the past recommended that a distinction be maintained between the patent-type protection for process inventions that is sought in S. 1200 and the trade-type protection currently afforded by ITC adjudications in process patent proceedings. The Commission has asserted that its principal expertise is in micro-economic analysis of industrial competitiveness and the trade situation, factors that would not necessarily have a bearing on the pure issues of patent validity and enforcement considered in straight infringement cases before the federal courts. Some experts analyzing process patent legislation, on the other hand, maintain that the ITC remedy in its current form is adequate and the appropriate way of addressing the problem of infringing importations. They point out that ITC exercises *in rem* rather than *in personam* jurisdiction: its orders go only to the goods themselves that are being imported and used or sold here. These experts contend that this focus on the goods is fair because once the goods have passed beyond the hands of the original manufacturer, the persons handling them can no longer be assumed to be knowledgeable of the process used to make the goods. This situation differs from the analogous one involving product patents, because in a case involving product patents, the person holding the goods actually has in hand everything necessary to ascertain whether there is infringement of a patent. A comparison of the tangible item with the description and diagrams in the patent itself may well reveal an infringement. In the process patent situation, the persons holding the goods after they have left the manufacturer do not have in their hands the specific infringing element, the process by which the product was made at some point in the past, and it is not always possible to deduce the exact process that was used by an analysis of the product at hand.

IMPLEMENTATION OF PROCESS PATENT LEGISLATION

In approving S. 1200, the Committee rejects the view that the U.S. purchaser from an overseas manufacturer who makes goods using a process patented in the United States has no responsibility for the patent infringement involved. On the whole, it should be the burden of business entrepreneurs who purchase goods to check beforehand for possible infringement, whether of product or process patents. They do so, now in the case of product patents, and S. 1200 will encourage them to do so with respect to process patents. It is reasonable to expect that the more conscientious and legitimate importers would indeed concern themselves to a greater degree with the question of whether the goods they are importing infringe a U.S. patent, if S. 1200 is enacted, because such importers may find themselves otherwise emmeshed in litigation that may be more expensive than the importation is worth to them.

The primary target of the U.S. process patentholder will naturally be the manufacturer, who is practicing the process and importing the resulting goods into the United States. If that manufacturer is subject to the jurisdiction of the U.S. courts then it would be the preferred defendant because of its direct knowledge of the process. Since the manufacturer may not be subject to jurisdiction, S. 1200 also allows the patentholder to sue the persons receiving the

goods in this country in the belief that they may be in the best position, apart from the manufacturer, to determine how the goods were made. The U.S. purchaser may protect itself in a number of ways: by specifying in the contract how the goods are to be made, or by eliciting a contractual commitment from the foreign manufacturer either to come into the U.S. courts itself to defend an infringement suit or to indemnify the purchaser against such a suit. See also Section 2-312(3), Uniform Commercial Code (implied warranty against patent infringement).

At the same time, the Committee is sensitive to the special difficulties that may attend a charge of process patent infringement for persons who import, use or sell the products but do not themselves practice the process. The Committee is also sensitive to the concern that the bill might be abused for aggressive business purposes to harass U.S. competitors whose operations depend on importing goods from overseas. S. 1200 is intended to be a strong disincentive to the importation, use or sale of products that are made by an infringing process, but it should not simply be a weapon for patentholders to use indiscriminately to try to stop all entry of products that compete with products made by their patented process. Only goods made by an unauthorized use of the patented process should be threatened by the bill. With a view to addressing those concerns about potential abuse by patentholders, and undue burdens on defendants in actions brought under S. 1200, the Committee devised a system of damage limitations for different classes of defendants, incorporated a new procedure encouraging advance communications between process patent owners and purchasers or importers of goods in order to encourage infringement avoidance, and established a notice requirement structured to insure that the alleged infringer receives enough information to allow a reasonable assessment of whether the goods are being manufactured by a process patented in the United States.

The Committee-approved bill envisions three types of infringers:

(1) The manufacturer who uses the process without authorization who is fully liable under the bill if he engaged in importing, using or selling the resulting product in the United States.

(2) An infringing importer, user or seller who had knowledge before the infringement that a patented process was used by the manufacturer to make the product which the importer or retailer uses or sells is fully liable under the bill and is not able to utilize the modifications of damages and other remedies available under the bill for innocent infringers.

(3) An innocent (i.e. unknowing) infringing retailer or importer, user or seller who does not himself use the process, is entitled to take advantage of the limitations on damages and other remedies available under S. 1200.

As was mentioned earlier, S. 568 is the same as S. 1543 of the 99th Congress, which unanimously passed this Committee and the Senate but which failed to become enacted during the hectic closing hours of Congress last year. S. 1200 follows the same general philosophy as S. 568. In S. 568 and in S. 573, damages only lay for infringements that occurred after notice. Moreover, such damages were limited by an 18-month grace period for retailers and a 6-month grace period for non-retailers with respect to the disposal of inventory. During those time periods, damages would have been limited to reasonable royalties in order to give the notice recipient sufficient time to dispose of inventory and make rational business decisions without unnecessarily exposing himself to potentially damaging risks.

Those 6-and 18-month periods were criticized by some as "compulsory licenses." The Committee did not interpret reasonable royalties for inventory for a limited period of time to constitute even an extremely loose conception of a compulsory license. In fact, the phrase "compulsory license" implies an ongoing right of the licenses to do business in perpetuity without permission from the patent owner. Such a right has no place in U.S. patent law, and no such right was contemplated in S. 1543 or S. 568. Nevertheless, the Committee changed the legislation in order to accommodate the concerns of the parties who raise this issue. Thus, S. 1200 does not contain any such mention of time periods nor does it require any payment to the patentholder with respect to inventory disposal. Instead, S. 103(a)(2) provides that there are no remedies for infringement under this bill for product in possession, in transit to, or for which there is a binding commitment to purchase and which has been wholly or partially manufactured prior to notice of infringement.

However, if the notice recipient maintained or ordered an abnormally large amount of infringing product, the amount of product constituting the excessive inventory is subject to an infringement action. This Committee continues to believe that the aforementioned 6-and 18-month inventory provisions of S. 1543 and S. 568 are reasonable. Thus, we would encourage the courts to presume that a party who maintains or orders an amount of infringing product that cannot be used or sold after notice within 18 months by retailers or 6 months by non-retailers, is either maintaining an abnormally large inventory or is attempting to take advantage of the limitations of this bill. Such a finding would still permit the use or sale of 6 and 18 months of product without liability, but would put an infringer at risk for the amount of product in excess. Similarly, we encourage the courts to presume that the 6-and 18-month inventories are reasonable

and that a party should not be subject to liability for such an inventory unless he was otherwise attempting to take advantage of this section or lost this limitation for other reasons, such as lack of good faith or actual knowledge.

Under S. 1200, a party planning to import a product which is the same as a currently produced product may make a request for disclosure to the current manufacturer. This request asks the manufacturer to list all process patents owned by or licensed to the manufacturer as of the time of the request that the manufacturer then reasonably believes could be asserted to be infringed. In the normal case, the manufacturer will respond to the request with a list of process patent numbers, and the potential infringer will use this information to advise his supplier of what processes to avoid using. Failure to present the information received from a request for disclosure to the supplier will result in a finding that the potential infringer had notice of infringement, such that remedies for infringement will be available with respect to any goods imported beyond that time.

Defending against patent infringement charges is a normal burden of doing business in America and around the world in the technologically sophisticated commercial conditions of the 1980's. The limitations on damages in S. 1200, combined with the advance disclosure procedure, should eliminate the possibility of aggressive use of process patent infringement charges to harass innocent purchasers (whether in fact infringing or not). The remedy limitation here is not to be construed as a compulsory license, nor as a precedent for other areas of patent law or types of patent infringement. The Committee finds the "grace period" policy to be justified only in the context of a bill intended to strengthen process patent protection. It is justified because of the elusive character of process inventions, from the standpoint of infringers who are involved only with the resulting products and not with the use of the process itself. From the beginning of congressional consideration of process patent reform in 1983 all proponents of the legislation have accepted the restriction of the scope of the bill to exclude innocent (i.e. unknown) infringing activity that occurs before the infringer is on notice. The remedy limitations are simply a mechanism for realizing this principle in practice by allowing the unknowing infringers, once notice is established, to sell a reasonable amount of inventory accumulated prior to notice with limitations on their exposure to damages. The temporary grace periods have as their sole purpose to allow the infringer to rid himself of products he had purchased and fulfill business commitments made prior to the time he had notice of the infringement of a U.S. process patent, and to either close down his business in this time or to find an alternative source of supply that does not infringe the patent. The remedy limitation is only available once for a given product: if the importer, wholesaler or distributor chooses to shift to a different supplier, he will be fully liable from the time of notice should the process patentholder bring another action against him with respect to the same product. Of course, the importer or retailer must be an innocent infringer, i.e. not have knowledge that the products were made by the patented process, to be eligible for the remedy limitation.

Similarly, the treatment of retailers should not be construed as an unlimited compulsory license, but as a temporary reprieve to allow them to move to non-infringing suppliers and liquidate their inventory without disrupting their businesses. Infringers fall into this category only if they obtain the illicit goods from a party in the United States who does not use the patented process. If a retailer has resources to send agents to other countries to seek suppliers, then he should be able and willing to exercise more vigilance. By using the request for disclosure procedure, he may seek out legitimate manufacturers who do not avail themselves of processes patented in this country to make products intended for export to this country. However, the Committee recognizes that in some cases, it may not be useful for retailers to avail themselves of the request for disclosure opportunity. Therefore, S. 1200 clarifies that while it is generally evidence of good faith when a party requests disclosure, the failure to request disclosure is not absence of good faith if there are mitigating circumstances. For example, for many retailers, due to the nature of the product, the number of sources for products, or like commercial circumstances, a request for disclosure may not be necessary or practicable as a means to avoid infringement. The rationale in S. 1200 is to shelter only purchasers who are remote from the manufacturer and not in the position to protect themselves in contracts with the party who is actually using the process.

While this new request for disclosure procedure will assist in avoiding intimidation of potential innocent infringers, it should be noted that the problem of using patents for illegitimate purposes of harassment is neither new nor limited to process patents. The Committee notes that the courts are not powerless to deal with the problem. For example, the federal judiciary, under Rule 11 of the revised Federal Rules of Civil Procedures , has lately taken a more stringent attitude toward an attorney's responsibility to investigate the soundness of a complaint before filing it. And the patent law itself allows the court, in an appropriate case, to order a patent owner to pay his adversary's attorney's fees and other expenses.

An additional safeguard against abuse of S. 1200 is the requirement that the notification from the patent holder charging the party with infringement must provide a specificity of information that will permit the accused party to make a reasonable business decision as to whether to continue his activities or seek a new source for the product. Notice

of infringement occurs when the alleged infringer has a combination of information sufficient to persuade a reasonable person that it is likely that a product was made by a patented process. This combination of information will include actual knowledge which may be acquired from the request for disclosure procedure, the information contained in the notification from the patent holder and any other information known to the accused relevant to the issue of infringement. In issuing a notification, the patentholder must specify the patent alleged to have been used and the reasons for a goodfaith belief that such process was used. If the patent holder has actual knowledge of any commercially feasible process other than the patented process which is capable of producing the allegedly infringing product, the notification shall set forth such information with respect to the other processes only as in reasonably necessary to fairly explain the patent holder's belief and is not required to disclose any trade secret information. Thus, even if the patentholder decides to bring suit, unless his filing includes this information, he will be deemed to have served notice. Neither a vague unspecified claim of infringement, nor even a lawsuit embodying such a claim would suffice for notice of infringement; only a specific claim articulating the reasons for believing the patented process has been used, would expose the defendant to damage liability. The Committee anticipates that the difficulty of making this kind of showing will tend to discourage use of the new cause of action for the purpose of "business aggression."

Once the recipient of notice knows the exact patent or patents in question, and the reasons indicating that the process they cover was used in manufacturing the goods, he will be able to evaluate the claim, confer with the foreign manufacturer (or other supplier) and decide whether to discontinue importing goods or defend an infringement claim. The proposed notice requirements goes far beyond the norm for product patent cases (or for that matter process patent infringement cases under existing law) but the higher threshold is justified here, in the Committee's judgement, because of the special difficulties that may arise from the fact that the process was used by a party other than the defendant. The notice provision of S. 1200 is not intended as a procedent for other areas of patent protection. Despite its greater stringency, the Committee expects that the serving of notice will still fulfill its traditional role of avoiding the need for litigation in many situations.

Beside the extended notice requirement and damages limitations, S. 1200 includes two further protections for potential defendants: a grandfather clause stating that the bill shall not abridge or affect the right of any person to continue to use, sell or import products already in substantial and continuous sale or use in the United States on May 15, 1987, and a provision calling on the Department of Commerce to report annually to Congress during the first 5 years after enactment on the effect of S. 1200 on any domestic industries that submit formal complaints about interruption of legitimate sources of supply.

In reference specifically to the concerns voiced by the generic drug industry about the effects of S. 1200 on their overseas supplies, one potentially valuable resource is the Food and Drug Administration. It is the Committee's understanding that whenever a generic drug company applies for FDA approval of a new generic medicine, the FDA begins a Drug Master File (DMF) collecting among other things information from the supplier about the processes involved in generating the materials sold to and subsequently used by the generic company. The DMF is a confidential file, not available to the public or even to the generic company for inspection. The DMF is complied from information supplied directly to the FDA from the manufacturer and from inspections by FDA personnel in the factories of the manufacturer. However, if the file can be obtained by the U.S. courts under a protective order without violating any other provisions of law, it could be used to assist the court in resolving whether the patented process was used in making the goods in question. It might alleviate the need to rely on indirect forms of evidence, such as chemical analysis, to trace the process used.

The debate on the presumption clause in Section (4) of the bill goes back to the 98th Congress. At that time the Judiciary Committee reported a process patent measure without including the presumption in the text of the bill but indicating instead in the report that the Committee expected the courts to apply a presumption where warranted.n4 In the present Congress, the Committee decided to accede to the strong recommendations of the Administration and the industry advocates of the bill to include presumption in the statute itself.

The presumption would place the burden of proof on the defendant to come forward with evidence that the goods in question were not made by using the plaintiff's patented process after the plaintiff has made a reasonable but unsuccessful effort to ascertain the process actually used, and further has established a substantial likelihood that the goods were made by that process. The presumption mechanism stems from the basic principle behind the bill, that the U.S. purchaser of the goods is in the best position to make the arrangements necessary with foreign manufacturers and suppliers to assure that U.S. process patents are not violated. The Committee envisions that the plaintiff would make informal inquiries to the foreign manufacturer of the product (if identifiable) or make reasonable attempts to use the discovery procedures available in the foreign countries. Certainly, the presumption clause attempts to strike a balance.

Presumptions should not be casually established. To ensure that an unfair burden is not imposed on importers and distributors of noninfringing products, any provision dealing with this subject should, at a minimum, require the patentee to demonstrate, on the basis of available evidence, that a substantial likelihood exists that the product was produced by the patented process and, further, that a reasonable but unsuccessful effort was made to determine that the process was actually used in the production of the product. To establish a substantial likelihood, for example, a patentee might show that the patented process was the only known method, or the only commercially practical method, for producing the product, or that physical evidence, such as the exact chemical composition of the product, indicates the use of the patented process. A reasonable effort requirement could easily be satisfied in the United States through our discovery procedures. For a foreign manufacturer the patentee would have to take some reasonable step, such as writing to the manufacturer, to determine how the product was made and to have been unsuccessful in this regard. The reasonableness of the effort would depend on the facts of the case but should generally avoid the need for such measures as letters rogatory or suits in a foreign country. Exactly how much evidence will be needed in particular situations to satisfy the "substantial likelihood" condition will depend on the circumstances. However, the patentee's burden would be less than that of proving successfully at trial by a fair preponderance of the evidence that a product in question was in fact made by the patented process but would be more than a slight possibility that the product was so made.

Most of our trading partners that extend process patent protection to the products made by the processes do also provide for a rebuttable presumption for shift in the process burden of proof. But many of them also limit the application of the new presumption to processes for making "new" products. The drawbacks of this approach may be illustrated by the recombinant DNA processes for producing naturally occurring substances, which cannot themselves be patented and which are in no sense "new." Thus, this approach would deprive some of the most important process innovators of the value of the presumption. The Committee rejects this approach because there is no clear justification for discriminating against certain types of process inventions. In order to secure a patent, a new process must be deemed useful, novel and unobvious--the same criteria that are applied to product inventions. If a process invention satisfies these criteria, then it is in the interests of society to have it publicly disclosed in return for a limited period of exclusivity for the inventor, regardless of whether the process leads to a "new" or "old" product. A good example of the latter was presented to the House Judiciary Committee during a hearing on this issue by Genentech Corporation; a new, more economical process they have developed in conjunction with Lubrizol Corporation for producing Vitamin C.n5 Enactment of S. 1200 would help Genentech protect itself against an influx of Vitamin C produced abroad by means of their economical new process, and produced all the more cheaply because the foreign manufacturer had no R&D expenses in procuring the process. But under the "new product" approach, Genentech would not benefit from the presumption clause in bringing suits for such infringement of its process.

Most of the foreign patent statutes that extend process protection to the product resulting from the process also include the limitation that the product must be made "directly" from the process. The significance of this qualification is discussed at length in the section-by-section analysis. The basic point is that if a final product has undergone a material change after being initially produced by the patented process, then it should no longer be covered within the scope of protection offered by S. 1200.

Some parties urged the Committee to include the word "directly" in the statutory language of the bill, making the U.S. law conform to the norm of industrialized nations and insuring that process patent protection does not become too broad. A number of industry advocates of the bill on the other hand were concerned that including the word "directly" might unduly restrict the scope of the bill if it were interpreted narrowly to exclude products that had been altered in trivial ways after the stage of manufacture where the patented process was used. The Committee concluded that both parties were seeking the same balance, and reached the decision to exclude products that had been "materially changed by subsequent processes; or ... become a trivial and nonessential component of another product." Inevitably the courts will have to assess the permutations of this issue of proximity to or distance from the process on a case-by-case basis. The section-by-section analysis offers guidance and examples for the interpretation of this provision.

Because of our obligations under the GATT treaty to refrain from trade discrimination, the process patent bill was crafted to apply equally to the use or sale of a product made by a process patented in this country whether the product was made (and the process used) in this country or in a foreign country. As explained earlier, the bill is prompted by the use of patented processes in other countries followed by the importation of the resulting products into this country. The use of the process in this country is already an act of infringement under existing patent law, and such an infringing party would be subject to the jurisdiction of the U.S. courts. Thus the inclusion of domestic process patent infringement in the scope of a bill to extend protection to the products is regarded by the Committee as a formality to conform to the

GATT, with little or no practical consequences in patent enforcement. The American Bar Association suggested in a letter to the Committeen6 that an alteration should be made in the presumption clause to make clear that if a suit is brought under the bill against a purchaser of goods made domestically by infringing a process patent, then the presumption is not applicable since there is no obstacle to obtaining discovery to determine the process used to make the goods. The Committee accepts the ABA's reasoning that the presumption should not be operative in this situation, but concludes that no change in the language of the bill is necessary. The presumption would never apply in the situation of domestic process patent infringement because a reasonable effort on the part of the plaintiff would require obtaining discovery against the manufacturer who is actually practicing the process in this country and who is therefore subject to the U.S. courts' jurisdiction, as might not be the case with foreign manufacturers. In any case, the Committee does not expect or intend the bill to be used to sue purchasers of the product, when the infringing manufacturer can be sued instead.

Concerns were raised, at a Senate hearing and elsewhere, that process patent legislation would undermine the Drug Price Competition and Patent Term Restoration Act, which became law in the 98th Congress (P.L. 98-417). Generally, this law combined an expedited procedure for FDA approval of generic imitation on brand-name drugs. The generic companies contended that if their supply of raw materials from overseas sources is reduced by process patent infringement suits, then the goals of P.L. 98-417 would be undermined. With the protections built into the substitute approved by the Committee, the generic pharmaceutical industry now supports S. 1200. It should be recognized, in particular, that the grandfather clause gives an exception for the many new generic medicines that have been approved or whose applications have been submitted to the FDA during the period between enactment of P.L. 98-417 (signed into law on September 24, 1984) and May 15, 1987.

Once the patent on a brand-name drug has expired, anyone is free to make, use or sell the product (assuming FDA clearance), but if there is an unexpired patented process for making the drug, then other parties must find a different way to make it. Again, in order to obtain a patent, the process must be novel, useful and unobvious, an invention whose disclosure would benefit the public as envisioned in the Constitution. To obtain a process patent on a useful, new way to make a medicine is not to prolong or "evergreen" the product patent on the medicine itself, even if the patentholder for the process and original product is the same inventor. No responsible critic of S. 1200 has ever maintained that goods made abroad by a process patented in the United States should be allowed to come into the United States to benefit competitors of the process patent-owner. To the extent that this is happening at present, S. 1200 is indeed intended to cut off such lines of supply, and to expose the beneficiaries, after adequate notice, to damage liability for their actions. The only issue has been whether the bill could also be used to cut off other, legitimate supplies from overseas, and in response to this concern the Committee has fashioned an elaborate system of pre-disclosure safeguards and limitations.

D. Section-by-Section Analysis

Section 101

Section 101 amends Section 154 of title 35, United States Code, by adding to the present rights held by the patent owner, the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by a patented process.

Section 102

Section 102 amends Section 271 of title 35, United States Code, by adding a new subsection (g). This subsection provides that whoever without authority imports in the United States or sells or uses within the United States a product which is made by a process patented in United States is liable as an infringer.

Since a process patentee can already prevent the use of the patented process by domestic manufacturers, the primary effect will be on foreign-made goods. These amendments will not give extraterritorial effect to U.S. law. U.S. patents will not prevent foreign manufacturers from using abroad the process covered by the U.S. patent, so long as the products they make thereby are sold and used abroad. But the amendments will prevent circumvention of a U.S. process patentee's rights through manufacture abroad and subsequent importation into the United States of products made by the patented process.

Specifically, the Committee does not intend that it shall be an act of infringement to import a product which is made by a process patented in the United States "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs." See 271(e)(1) of title 35, United States Code. Congress previously decided that certain actions do not constitute patent infringements and this Act does not change that prior policy decision.

The bill provides that no remedy may be granted for infringement resulting from the noncommercial use or retail sale of a product unless there is no adequate remedy on account of the importation or other use or sale of that product. The purpose of this provision is to protect retail sellers and the consumers who purchase products at retail for personal use and consumption from damages for infringement if adequate relief is obtainable from more involved parties.

The Committee intends the limitations on remedies against "noncommercial users" to be for the protection of those purchasers who enjoy personal use and consumption of the product produced by the allegedly infringing process, such as the patient who consumes a drug product or a home gardener who sprays a pesticide. The Committee does not intend this protection to be enjoyed by a party who uses a product produced by an allegedly infringing process in the production of another product, or who otherwise engages in further manufacturing, processing, or other industrial or business use of the product, other than that which may fall under the provision of Sec. 287(b)(2).

It should be noted that many of the "products" produced by patented biotechnology processes are themselves "used" in the manufacture of another product which is introduced into commerce. Consider a process patent held on a method for preparing a plasmid or other vector. The use of the plasmid or vector to insert a new gene into a living cell, instructing the cell to produce an important human protein (such as insulin or interferon) which will then be separated from the fermentation mash, purified, and packaged into single dosage forms, is a commercial use and is ineligible for the limited protection granted to non-commercial uses. The field of biotechnology is particularly susceptible to commercial "uses" without sales. For example, a patent may cover a process for producing a microorganism using recombinant DNA technology. The microorganism is then used to produce a particular commercial end-product of great value. The bill's provisions limiting remedies against users are not intended to apply to such commercial uses. The Committee believes that without expeditious remedies against use-based infringement, merely stopping importation and non-retail sale of the microorganism after its entry into the country fails to prevent commercial use of the microorganism.

An understanding of the statement that "A product which is made by a patented process will, for purposes of this title, not be considered to be so made after--(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product" is critical to understanding the scope of this legislation. The Committee intends a specific two-phase test to be implemented.

Many foreign patent statutes extending process protection to the product resulting from the process include the limitation that the patented product be made "directly" from the process. They use the word "directly" to exclude as an infringement the importation, use or sale of a product which is materially changed from the product resulting from the patented process by subsequent steps or processes. An example of the problem the Committee is addressing in this section is the extraction of minerals from the earth. These minerals may later be used to manufacture materials, which are still later embodied in components, which are in turn used in the assembly of the product in question. In this instance, the minerals have been "materially changed" within the meaning of this section.

The Committee agrees that once a product has been materially changed, then subsequent purchasers, users and sellers should no longer be liable for process patent infringement. However, the Committee decided against including the word "directly" in the statute out of concern that the word "directly" might have been construed too broadly and possibly exempt too many products that have been altered in insignificant ways after manufacture by the patented process. These products ought to be treated as infringing under the bill. The Committee expects the courts to exercise careful judgement in distinguishing those products that are too far removed from the patented process, and those that have been changed only in insignificant ways. The Committee believes that the courts will be in a better position to settle such issues without the standard of "directly" constraining their judgment.

The inclusion in the standard of the words "trivial and nonessential component" will further assist the court in distinguishing products that are too far removed from the patented process.

In order to give the courts Congressional guidance in what may be a difficult determination, the Committee notes that the bill would establish the following two-phased test:

1. A product will be considered made by the patented process regardless of any subsequent changes if it would not be possible or commercially viable to make that product but for the use of the patented process. In judging commercial viability, the courts shall use a flexible standard which is appropriate to the competitive circumstances.

2. A product will be considered to have been made by a patented process if the additional processing steps which are not covered by the patent do not change the physical or chemical properties of the product in a manner which changes the basic utility of the product by the patented process. However, a change in the physical or chemical

properties of a product, even though minor, may be "material" if the change relates to a physical or chemical property which is an important feature of the product produced by the patented process. Usually, a change in the physical form of a product (e.g. the granules to powder, solid to liquid) or minor chemical conversion, (e.g., conversion to a salt, base, acid, hydrate, ester, or addition or removal of a protection group) would not be a "material" change.

It is only those who import, use or sell a product after it has been materially changed or has become a trivial or nonessential component of another product who may avoid liability for process patent infringement. Even with that general guidance, the courts may frequently find themselves in a quandary on this most important phrase. There will be cases where the product has clearly been materially changed or become trivial and nonessential, under the two-phase test, and others where it clearly has not; however, many instances will be less clear. Some examples may help provide additional resources to the courts:

A metal strip with certain unique properties is produced by a U.S. patented process. A foreign competitor makes the strip using the process, then turns the strip into a core, puts the core in a transformer and imports the transformer into the United States. Even if there were other commercially or economically viable non-infringing processes for making the strip, this is still a clearcut case of infringement of the process patent that this Act is intended to prevent because the subsequent changes would not be considered material. Similarly, taking that metal strip and hear treating or annealing it in a magnetic field would not change the product as to avoid infringement.

If the patented process produces chemical X, any person importing, using or selling chemical X is liable for infringement.

If new entity, chemical Y, is produced from chemical X as the result of a material change, the court must also consider the other phase of the test before deciding if Y is infringing or non-infringing:

If the only way to have arrived at Y is to have used the patented process at some step, e.g., producing X as an intermediate, Y is infringing.

If there is more than one way to have arrived a Y, but the patented process is the only commercially viable way to have done so, Y is infringing.

If there are commercially viable non-infringing processes to have arrived at X, the connection between the patented process for producing chemical X and the ultimate product, chemical Y, is broken, and Y would be a non-infringing product having satisfied both phases of the test.

In the biotechnology field it is well known that naturally occurring organisms contain within them particular genetic sequences composed of unique structural characteristics. The patented process may be for the process of preparing a DNA molecule comprising a specific genetic sequence. A foreign manufacturer uses the patented process to prepare the DNA molecule which is the product of the patented process. The foreign manufacturer inserts the DNA molecule into a plasmid or other vector and the plasmid or other vecot containing the DNA molecule is, inturn, inserted into a host organism; for example, a bacterium. The plasmid-containing host organism still containing the specific genetic sequence undergoes expression to produce the desired polypeptide. Even if a different organism was created by this biotech procedure, if it would not have been possible or commercially viable to make the different organism and product expressed therefrom but for the patented process, the product will be considered to have been made by the patented process.

In the semiconductor industry, a manufacturer may have a process patent for forming a semiconductor structure in a semiconductor substrate. Subsequent processing to complete and finish the component does not materially change the semiconductor substrate in which the semiconductor structure formed. In addition, a court could determine that the cost of a semiconductor component was trivial in relation to the cost of the whole product, but if that same component is essential to the intended function of the whole product then it would be covered by this title.

The Committees recognizes the concern raised concerning possible overreach. One example is a process patent for extracting minerals from the earth. There is no intent that the minerals, eventually refined, with the product ending up as a component of an automobile which is imported into this country, should subject the importer to an infringement action. However, this must be distinguished from the importation of the mined minerals themselves. Similarly, this must be distinguished from the case wherein the patent covers a process for making shock absorber. Even if that shock absorber is put into a much larger and more expensive product, e.g., an automobile, the patent owner could still sue the importer of that automobile. Although injunctive relief might not be appropriate under those circumstances, some damage relief would be appropriate, based, for example, on an apportionment of the contribution of the infringing part

to the value of the whole product in which it is incorporated. Of course, the importer and wholesaler have other rights under this bill to limit liability, and the retailer may avail himself of other provision of this bill and have no liability for retail sales. Finally, there is no intent whatsoever for the innocent consumer to even be subject to suit.

Section 103

Section 103 amends Section 287 of title 35 by adding a new subsection (b) with five subparagraphs, which introduces limitations on the remedies available to a process patentholder when infringement is based on importation, sale or use of a patented process and conditions associated with the eligibility of the modification of remedies.

Paragraph (b)(1) provides that the modification of remedies outlined in subsection (b) are not available to three categories of infringers. For these three categories of infringers, all of the provision of title 35 relating to damages and injunctions apply. Paragraphs (b)(1) (A) through (C) define those infringers who are not entitled to any diminution of the monetary and injunctive remedies normally available to a patentholder. They include the party who actually carries out the process, or who controls or is controlled by that party. Thus, those who are closely connected with carrying out the process in the manner outlined, are fully liable for any direct acts of infringement they commit in the United States, as well as for any acts of inducement of infringement or contributory infringement committed through control inside or outside the territorial limits of this country. The bill is not intended to reward infringers who close their eyes to facts that a reasonable person would see. Similarly, it is not intended that a party should be permitted to qualify for reduction of or immunity from liability by intentionally avoiding the acquisition of knowledge.

Existing section 287 of title 35 states that damages for patent infringement may be recovered by the patentholder either from the time he marks his patented article with the patent number, or if he fails to mark, from the time he serves notice to the infringer. However, the courts have held that these prerequisites for damages apply only to product patents, and that persons who infringe a process patent by using the process in this country are fully liable from the beginning of the activity without notice from or marking by the patent owner. The Committee intends that this harsher standard apply also with respect to process patent infringers who use the process and engage in importing, using or selling the products in the United States. This would apply in a situation, for example, where a foreign manufacturer who uses a process patented in the United States but not in the country of manufacture, itself imports the products for use or sale here. In that situation, the foreign manufacturer would be liable for damages from the outset of the infringing activity even without receiving notice of infringement from the patent owner. Similarly, any party who knowingly imports, uses or sells products made without authority by a process patented in this country is fully liable for damages running from the time he begins knowingly engaging in such activity. On the other hand, a foreign manufacturer is not liable under the bill if he merely uses the process abroad (again assuming the U.S. inventor has not also patented the process in the foreign country) and sells the product there with no knowledge that the buyer will subsequently import the product here.

Paragraph (2) specifies that with regard to infringers not excluded under paragraph (1), the patentholder has no remedy for infringement with respect to any product which was in the possession of, or in transit to the party, of for which the party has made a binding commitment to purchase and which has been partially or wholly manufactured before the party had notice of infringement. The Committee intends that with respect to an infringer not excluded under paragraph (1), the patentholder has no remedy for infringement with respect to pre-notice inventory. However, if the court finds that the party maintained or ordered an abnormally large amount of infringing product, or the product was acquired or ordered by the party to take advantage of the limitation on remedies provisions, the court shall limit the application of the modification of remedies provisions to the reasonable portion of the inventory. For the purpose of this paragraph, an abnormally large inventory on hand or on order shall be presumed to exist if it cannot be sold in the normal course of the infringer's business in 18 months if the infringer is a retailer or in 6 months in any other case. Thus, courts should presume that maintaining or ordering an amount of infringing product that cannot be used and sold after notice of infringement within 18 months by retailers and 6 months by non-retailers is either maintaining an abnormally large inventory or an attempt to take advantage of the limitations of this bill. Such a finding would still permit the use or sale of 6 and 18 months of product without liability, but would put an infringer at risk for the amount of product in excess. Similarly, the Committee encourages the courts to presume that the 6 and 18 month inventories are reasonable and that a party should not be subject to liability for such an inventory unless he was otherwise attempting to take advantage of this section or lost this limitation for other reasons, such as lack of good faith or actual knowledge.

Paragraph (3) provides that in an action brought for infringement under section 271(g) of title 35, United States Code, the court shall take into consideration the good faith and reasonable business demonstrated by the defendant, the good faith demonstrated by the plaintiff with respect to the request for disclosure discussed below, and the need to restore the exclusive rights of the patentholder through an adequate remedy.

During the discussions and testimony leading to the adoption of this bill, the non-manufacturing groups likely to use or sell imported products stressed their need and desire to obtain information to assist them in avoiding infringement. A procedure to assist these groups in attaining this information is necessary because an importer of a product from a foreign manufacturer is ordinarily unable to obtain specific information from his supplier regarding the process used in manufacturing the imported product. The groups representing patentholders agreed to a procedure under which manufacturers would provide a listing of the patent numbers of process patents owned by or licensed to the manufacturer as of the time of the request that the manufacturer then reasonably believes could be asserted to be infringed in connection with the production of its product.

The request for disclosure procedure is explained in paragraph (4). The first step--the actual request for information is a formal request made by a party who is engaged in, or intends to become engaged in, the sale of a particular product. The request is directed to one or more other parties who are then engaged in the manufacture of the product, no the expectation they are most likely to hold pertinent process patents. Such a request should be made before the requester actually commences any activity which could result in infringement, and it should be made in all cases except those in which, because of the nature of the product, the number of parties to whom a request would need to be directed, or like circumstances, a request for disclosure would be impracticable or unnecessary. For example, due to the nature of the product or the number of sources for products, it may not be practicable for retailers to use this procedure to avoid infringement.

An illustration of the situation in which a request would be impracticable would be one in which a party intends to import a table that is simple and undistinguished, and the party knows that similar tables are made by many other companies. Since requests would have to be directed to a large number of companies and there is nothing unusual about the table to be imported, a request for disclosure is very unlikely to produce meaningful information. It is impracticable. However, if the subject table had a distinctive construction, and a similar one was being manufactured by only a few companies, the importer would be expected to request disclosure.

A request for disclosure is unnecessary when the party who would otherwise make it already has the information sought, for example, when a prior request was previously made to the same source and it is clear no additional patents have arisen since the earlier request. Of course, a court should be reluctant to conclude that a request was "unnecessary" when, in fact, the product is found to be made by an infringing process, and a request for disclosure might have avoided the infringement.

The second step in the procedure is the patentees's response to the request. The patentee is expected to provide a complete good faith response, identifying all process patents owned by or licensed to him that he reasonably believes could be used to make his own product. It is understood that the patentee's response will depend largely on the information available to him at the time the request is made. For example, it is also possible that the manufacturer may acquire additional relevant patents subsequent to the request for disclosure. The manufacturer is not precluded from making, indeed is encouraged to make, supplemental responses if the acquisition of additional information warrants it.

The request for disclosure must include a representation by the requesting party that it will submit the response to its manufacturer, or if not known, to its supplier, with the request for assurance that none of the processes of the disclosed patents is used in the manufacture of the product.

The requirement of "notice of infringement" embodied in various paragraphs of subsection (b), is intended to balance the interests of process patentees and parties who are infringing by using or selling the product, in good faith, without knowledge of the process used to produce it. The Committee does not intend that "notice" be a device through which infringers can escape liability by deliberately avoiding knowledge or failing to appreciate the significance of information available to them. What should be kept in mind is that no liability attaches in any event unless infringement of the patentee's rights has occurred: "notice" simply defines the point in time when someone who is, in fact, an infringer has sufficient information to make it reasonable to initiate the period of his accountability.

As stated in subparagraph (5)(A), the accumulation through actual knowledge, or receipt by a party of a written notification, or a combination thereof, of information will put the infringer on notice when, in the aggregate, it is sufficient to persuade a reasonable person that it is likely a patented process was or is being used. It is important to note that the issue to be resolved with respect to "notice of infringement" is not whether there are sufficient facts recited in the notification or known to the party notified to support the conclusion that there is infringement but rather only whether infringement is "likely." This is significantly less demanding than the "preponderance of evidence" standard a patentholder would face in proving infringement at trial. What is required is simply enough to bring home to the

infringer the presence of an appreciable likelihood of infringement, sufficient to make it reasonable to hold him accountable when he chooses to continue his activities.

Subparagraph (5)(B) relates to written notification addressed to the accused infringer by the patentholder. The written notification shall specify the patented process that is alleged to have been used and the reasons supporting a good faith belief that such process was used. If the patentholder has actual knowledge of other commercial processes for producing the particular product, the notification should set forth such information with respect to such processes only as is reasonably necessary to fairly explain the patent holder's belief and is not required to disclose any trade secret information.

Subparagraph (C) provides that a party who receives a written notification of infringement shall be deemed to have notice of infringement if he fails to seek responsive information from the manufacturer (or, if not known, the supplier) of the product he is using or selling, unless there are mitigating circumstances. The notification need only meet the first sentence of subparagraph (B) to trigger that requirement and that result; obviously it is unnecessary to provide the manufacturer with information tending to negate the use of other processes, since the manufacturer knows directly what process he is using. Similarly, this provision applies even though the notification does not contain enough information to constitute "notice of infringement."

A non-manufacturing party receiving a notification alleging infringement has an obligation to take reasonable steps to determine if there is any basis for the allegation and cannot evade liability by remaining ignorant of facts which might establish a likelihood of infringement. Any knowledge which a purchaser may acquire as a result of such inquiries will contribute to satisfying "notice of infringement," which can be satisfied by a combination of the information contained in a notification from the patent holder and any other information known to the party charged with infringement.

Since making an effective inquiry is not costly, and it has the potential of stopping, curtailing or avoiding infringement of the patent holder's rights, only the most compelling reasons should be accepted as excusing a failure by the recipient of a notification to submit it to his manufacturer/supplier for verification. An example of such "mitigating circumstances" would be death or incapacity of the person who was intended to make the submission or an inability to locate the manufacturer/supplier due to his no longer being in business or in circumstances where the product has passed through many hands.

For similar reasons, subparagraph (D) provides that a party who receives a response to a request for disclosure and who fails promptly to submit it to the manufacturer/supplier with a request for a written statement that none of the patented processes is used, is deemed to have notice of infringement. Submission of the response to a request for disclosure to the requester's manufacturer/supplier is mandated because that manufacturer knows the process being used and therefore is in the best position to avoid infringement or provide evidence that the patented process is not being used, if that is the case.

The mere act of submitting the patentee's response or notification to the manufacturer does not, however, automatically absolve a party from having notice of infringement. The Committee has not attempted to, and could not, spell out in detail all circumstances in which the infringer should be found to have notice. Nevertheless, the Committee expects the court to consider, in determining the presence or absence of notice, the information received (or lack thereof) by the importer from his manufacturer/supplier. For example, a party who sends to his manufacturer/supplier a notification of infringement or a response to a request for disclosure, and who does not receive from that manufacturer/supplier an adequate assurance that the patented process is not being used, and sufficient supporting information to make an assurance credible should almost certainly be found to have notice of infringment should he choose to continue to deal in the goods of that supplier/manufacturer.

Subparagraph (E) provides that filing of an action for infringement shall constitute notice of infringement only if the pleadings or other papers filed in the action meet the requirements of subparagraph (A), i.e. contain sufficient information to persuade a reasonable person that it is likely the product was made by a patented process. The Committee recognizes, however, that it may not always be clearcut when sufficient information exists to constitute "notice of infringement", and that patentholders may properly and lawfully bring suit irrespective of whether that technical requirement is met. Neither "notice of infringement" nor "notification" is a prerequisite for a legally sufficient complaint for patent infringement.

Even if "notice of infringement" is not satisfied by the initial papers filed in the action, this subparagraph recognizes that it may be satisfied at a later time by other papers filed in the action, including discovery obtained from the accused

infringer or third parties, additional information provided by the patentholder, expert witness statements or the like. As discussed earlier, remedies for infringement will not begin to accrue until the standard for notice of infringement is met, even if a legal action has already begun.

Section 104

Section 104 adds a new Section 295 to title 35, to establish in carefully defined circumstances, a rebuttable presumption that a product that could have been made by use of a patented process was in fact so made. This presumption addresses the great difficulties a patentee may have in proving that the patented process was used in the manufacture of the product in question where the manufacturer is not subject to the service of process in the United States. The burden of overcoming this presumption will be on the alleged infringer, regardless of whether the infringement charge is based on use, importation, or subsequent sale of the infringing article. While the defendant may not necessarily have in its possession the means necessary to rebut the presumption, it is likely to be in a far better position than the patentee to obtain them. Importers, for example, because of their relationships with foreign manufacturers, may be able to exert pressure on such manufacturers to produce the necessary information. Users and sellers who purchase possibly infringing articles from importers may be able to exert similar pressure on those importers, who would in turn influence foreign manufacturers. Of course, purchasers would retain whatever rights to indemnification they may have under contract or applicable State law.

Presumptions of manufacture by a patented process, however, should not be casually established. Importers and subsequent purchasers may be unable to obtain the information needed to overcome such presumptions when the products in question were not made by patented processes. At a minimum, the existence of the presumption will require a party who uses, sell, or imports a product that might have been made by a patented process to exercise greater care in business dealings to avoid increased liability. To minimize the risk of aggressive litigation intended to discourage firms from carrying competing products, the presumption will be available under Section 295 only when two conditions are satisfied.

First, the patentee must demonostrate on the basis of the evidence that is available that a 'substantial likelihood' exists that the product was made by the patented process. Such evidence could include chemical analysis of the product or indications or "marks" on the product itself, as well as expert testimony regarding known methods of production at costs that would justify sale of the product at the prices being charged. Exactly how much evidence will be needed in particular situations to satisfy the "substantial likelihood" condition will depend on the circumstances, However, the patentee's burden would be less than that of proving successfully at trial by a fair preponderance of the evidence that a product in question was in fact made by the patented process but would be more than a slight possibility that the product was so made. Second, the patentee must show that he or she has made a reasonable effort to determine what process was used in the manufacture of the product in question and was unable to do so. The reasonableness of the effort would include the use of discovery procedures under the Federal Rules of Civil Procedure or other good-faith methods, such as requesting the information from the manufacturer, if not subject to U.S. jurisdiction. These limitations on the availability of the presumption should make it available to patent owners who might otherwise be left with no remedy against an infringer, and should also adequately safeguard the rights of competitors.

The Committee notes that the rebuttable presumption would be inapplicable if the defendant has used the process in the United States, or has derived the products directly or indirectly from a manufacturer who used the process in the United States. In these circumstances, the discovery provisions of the Federal Rules of Civil Procedure and the equitable powers of Federal courts should be sufficient to allow the plaintiff to ascertain what process was employed. In this regard, the Committee trusts the courts to issue protective orders, in appropriate circumstances to prevent disclosure of the trade secrets and confidential business data of the parties. For example, the Committee expects protective orders to be used in encouraging foreign manufacturers to supply information pertinent to a process patent infringement suit revolving around goods made by such manufacturers. If information is obtained under a protective order that definitely determines the process used to make the goods in question, the presumption, would not be applicable.

Once the plaintiff has been found to be entitled to the presumption, the burden of producing evidence to establish that the product was not made by the process shifts to the defendant. Courts will continue to determine which party has the ultimate burden of persuasion and what amount of proof is necessary.

Section 105

Section 105(a) contains a grandfather clause exempting commercial arrangements that have been or were about to be entered into prior to May 15, 1987. The special importance of this provision for the generic pharmaceutical industry

was mentioned in the Statement. Since the Drug Price Competition and Patent Term Restoration Act of 1984 , over 100 abbreviated new drug applications (ANDA's) for generic medicines have been approved by the FDA. The Committee firmly believes it would be inequitable if process patent legislation were to interfere with the marketing of these newly approved generic drugs, or with other ANDA's that were pending but not yet approved on May 15, 1987, if substantial commercial investments had been made in them prior to that date.

That is, if a generic pharmaceutical company has made substantial commercial investment in preparing and filing an ANDA and is awaiting FDA approval as of May 15, 1987, or if the company had been granted an approval before that date and starts to market a generic medicine in the United States, the pharmaceutical products that the company imports, uses and sells in connection with the ANDA are protected under the grandfather clause. The generic company may expand or contract its business with these products, shift to different suppliers as necessary and continue to come under the protection of the grandfather clause.

Apart from this particularly sensitive area, the Committee envisions that the courts will interpret the scope of the grandfather clause in the individual cases brought before them with a view to the qualifying language "to the extent equitable" in the provision. Ordinarily, a party whose business before the grandfather date involved infringing activity should be able to continue to import, use or sell the product as necessary to maintain the same level of business, but not to expand such business by increasing the volume of products that he is using or selling, unless of course he has prospectively committed himself to such increases in a contract made prior to the grandfather date.

An important variation of this restriction could be illustrated as follows. If an importer contracts prior to May 15, 1987 to receive a certain volume of goods every month for the next 5 years, and a certain retailer contracts to purchase the goods from him during that period, both of these arrangements fall within the grandfather clause exempting them from the scope of the bill. If the retailer only contracts to purchase the goods for 3 years and the importer turns to another retailer afterwards, again the bill should not apply to the second retailer during the remaining 2 years of the importers contract, even though no contract with the second retailer existed prior to May 15, 1987, because the goods in question were contracted for by the importer before that date. However, if in this situation, the importer expands the volume of the goods he is importing, then the grandfather clause does not exempt him with respect to units beyond what he contracted for before the grandfather date.

In addition, the Committee does not intend that it shall be an act of infringement to import a product which is made by a process patented in the United States "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of a drug. See Sec. 271(e)(1) of title 35, United States Code. Congress previously decided that certain actions do not constitute patent infringements and this Act does not change that prior policy decision.

The Committee intends to provide the courts with flexibility to achieve an equitable solution in situations where the infringer has made a substantial investment necessary to sell or use the infringing product before this date. In that case, the investment was made during a time when use or sale of the product was not unlawful. The grandfather clause is modeled after 35 U.S.C. 252, and Section 107(d) of P.L. 98-662 (98 Stat. 3384) which Congress has provided for fundamentally the same purpose.

The Committee intends three other restrictions on the scope of the grandfather clause. The phrase "successors in business" does not include parties to whom the grandfathered infringer may license the goods; the phrase is meant only to allow the infringer who sells his business to pass on also its grandfathered status to the buyer of the business.

Secondly, the grandfather clause does not apply to any business whose product had already been the subject of International Trade Commission litigation before January 1, 1987. The Committee has included the grandfather exception for those parties who reasonably relied upon the law as it was when they made their investments so that they should not be penalized for such good faith reliances and should be allowed, to the extent equitable, to recoup those investments made in the United States. However, when the product has already been the subject of ITC litigation, there are no good faith reliances since the patent owner has already indicated his clear intention to enforce his process patent in any and all appropriate forums, and investments therefore occur at the alleged infringer's own risk. It is not the Committee's intention to deny patentholders the right to pursue process patent infringment actions in U.S. courts against alleged infringers who made commercial investments during the prosecution of the ITC suit.

Thirdly, the grandfather clause applies to products being purchased, imported, used or sold as part of an ongoing business operation before the grandfather date only with respect to the process of manufacture used at that time to make such products. If the manufacturer of the products later shifts to a different process, such as a process developed and

patented in the United States well after the grandfather date which the manufacturer in question has not been authorized to use, then units of the product made by this latter process are not protected by the grandfather clause, even if the U.S. wholesaler, importer or distributor had contracted with the manufacturer before the grandfather date for continued supply of the product. In order to keep products under the umbrella of the grandfather clause while fulfilling such a contract, the manufacturer would have to make them by the process contemplated at the time of contracting (or May 15, 1987). This example, incidentally makes plain that importers, wholesalers and distributors who come under the grandfather clause with respect to some product still would have a strong incentive to make a request for disclosure to all manufacturers in the United States who are marketing that same product in order to insure their eligibility for the remedy limitations in the event that their supplying manufacturer shifts to a different process at some point in the future and so disengages the protection of the grandfather clause.

Section 105(b) makes clear that the bill does not affect any remedies patent owners have under existing law. The new remedies for process patent owners provided by the bill are subject to general limitations which do not apply in suits under existing law by process patent owners against parties manufacturing in the United States. For example, the bill requires notice of infringement to persuade a reasonable person that it is likely that the product was made by a patented process. The bill limits remedies available with respect to products already in the possession of or in transit to the infringer, or which the infringer already has made a binding commitment to purchase. The bill encourages parties to request disclosure of the identity of certain process patents. The bill provides that a product which is made by a patented process will not be considered so made after it is materially changed by subsequent processes; or it becomes a trivial and nonessential component of another product. there is no intention to impose any of these limitations on owners of product patents or on owners of process patents in suits they are able to bring under existing law. Neither is there any intention for these provision to limit in any way the ability of process patent owners to obtain relief from the U.S. International Trade Commission.

Section 106

Section 106 instructs the Department of Commerce to report annually to Congress on the effect of the bill on any U.S. industries that submit formal complaints that they have lost legitimate sources of supply. Such reports will assist Congress in the unexpected event that the bill has a drastic adverse effect on some domestic industry, requiring emergency remedial measures.

[Editor's note: Part IV. TITLE II--PATENT MISUSE DOCTRINE REFORM has been omitted.]

Conference Report H.R. No. 100-576, 'Omnibus Trade and Competitiveness Act of 1988," 1085-90, April 20, 1988

TITLE IX--PATENTS

SUBTITLE A--PROCESS PATENTS

1. RIGHTS OF PATENT OWNERS (SEC. 1402 OF HOUSE BILL; SEC. 3301 OF SENATE AMENDMENT)

Present law

Title 35 grants process patent owners the right to exclude others from practicing the process in the United States.

House bill

Amends Title 35 to provide that issuance of a process patent includes the right to exclude others from using or selling in the U.S., or importing into the U.S. produces made by that process.

Senate amendment

Identical provision.

Conference agreement

The conferees agreed to the House and Senate provisions.

2. INFRINGEMENT LIABILITY (SEC. 1403 OF HOUSE BILL; SEC. 3302 OF SENATE AMENDMENT)

Present Law

No provision.

House bill

Provides that using, selling or importing a product made in violation of a U.S. process patent is an act of patent infringement. Limits remedies against mere users or retailers by requiring exhaustion of remedies against importers and non-retailer sellers. Liability is further limited by excluding products which have been materially changed by subsequent processes or if the product is a *minor or* nonessential component of another product.

Senate bill

Similar to House bill in that it provides that using, selling or importing a product made in violation of a U.S. process patent is an act of patent infringement. Limits remedies against mere users (for non-commercial use) or retailers by requiring exhaustion of remedies against importers and non-retailer sellers. Liability is further limited by excluding products which have been materially changed by subsequent processes or if the product is a *trivial and* nonessential component of another product.

Conference agreement

House recedes to the Senate on both "non-commercial use" and "trivial and" amendments.

As to the former, the House recession implies that exhaustion of other remedies must occur before recourse is made against a noncommercial user.

It should be noted that many of the "products" produced by patented processes are themselves "used" in the manufacture of another product which is introduced into commerce. Consider a process patent held on a method for preparing a plasmid or other vector. The use of the plasmid or vector to insert a new gene into a living cell, instructing the cell to produce an important human protein (such as insulin or interferon) which will then be separated from the fermentation mash, purified, and packaged into single dosage forms, is a commercial use and is ineligible for the limited protection granted to non-commercial uses. The field of biotechnology is particularly susceptible to commercial "users" without sales. For example, a patent may cover a process for producing a microorganism using recombinant DNA technology. The microorganism is then used to produce a particular commercial end-product of great value. The bill's provisions limiting remedies against users are not intended to apply to such commercial uses. The Committee believes that without expeditious remedies against use-based infringement, merely stopping non-retail sale of the microorganism after its entry into the country fails to prevent commercial use of the microorganism.

In the biotechnology field it is well known that all living organisms contain within them particular genetic sequences composed of unique structural characteristics. The patented process may be for the process of preparing a DNA molecule comprising a specific genetic sequence. A foreign manufacturer uses the patented process to prepare the DNA molecule which is the product of the patented process. The foreign manufacturer inserts the DNA molecule into a plasmid or other vector and the plasmid or other vector containing the DNA molecule is, in turn, inserted into a host organism; for example, a bacterium. The plasmid-containing host organism still containing the specific genetic sequence expresses that sequence to produce the desired polypeptide. Even if a different organism was created by this biotech procedure, if it would not have been possible or commercially viable to make the different organism and product expressed therefrom but for the patented process, the product will be considered to have been made by the patented process.

As to the latter, since neither the House nor the Senate bills proposed changes to the concept of apportionment of damages, House recession to the Senate does not signify a modification of this important patent law concept.

3. LIMITATION ON DAMAGES (SEC. 1404 ON HOUSE BILL; SEC. 3303 OF SENATE AMENDMENT)

Present law

No provisions.

House bill

Limitations do not apply to those who practice the process or who knew about the infringement before the fact. No remedies against products in possession or in transit at the time of notice. Court shall consider the good faith of the infringer and the rights of the patent owner. The notice that triggers infringement liability consists of: (1) actual

knowledge; or (2) notice of a *substantial likelihood* that the product was made by an infringing process. If a party has an excessive inventory actual notice or knowledge is rebuttably presumed.

Senate amendment

Same limitations as House bill in that limitations do not apply to those who practice the process or who knew about the infringement before the fact. No remedies against products in possession or in transit at the time of notice, except exemption also applies to goods for which a binding commitment to purchase has been made and such goods have been at least partially manufactured at the time of notice. Burden of proof is on the party seeking exemption. Same as House bill in that court shall consider the good faith of the infringer and the rights of the patent owner, except court shall also consider the patent owner's compliance with the request for disclosure procedure. As relates to request for disclosure, patent owners may be asked by importer to identify all process patents owned or licensed by that person which could be reasonably asserted as grounds for infringement. Patent owners must respond within 60 days. The requester for such information must agree to pass it along to the manufacturer or supplier with a request for a written statement that such protected processes are not used. Failure by either party to meet these obligations to be considered as a point in the determination of *good* faith. Notice of infringement is actual knowledge or written notification or combination thereof of information *sufficient to persuade a reasonable person it is likely* that a product was made by an infringing process. Receipt of the written notification absent mitigating circumstances, is deemed notice of infringement if the manufacturer/supplier is not contacted.

Conference agreement

The House and Senate compromised between the two bills.

First, the conferees adopted language that has the effect of deleting from the Senate amendment an exemption for goods for which a "party has made a binding commitment to purchase and which has been partially or wholly manufactured." This agreement resolves the primary objection raised by the Administration, thereby removing any arguments about the existence of a compulsory license. Also deleted is the last sentence of the Senate amendment in section 287(b)(2) relating to allocation of damages. The conferees adopted the formulation in the Senate amendment in section 287(b)(3)(A) and (B) with an amendment. The conferees deleted the 60 day deadline for replying to a request for disclosure and adopted a "reasonable time" limit. It is expected that a reasonable time for response to a request for disclosure shall ordinarily be no more than 60 days. In the event of mitigating circumstances, the burden to show why 60 days is not sufficient lies with the party failing to comply.

Second, the conferees also adopted the Senate amendment with respect to section 287(b)(4) with two amendments. In the event of a request for disclosure that is made to a person with a patent license (exclusive or non-exclusive) the recipient of such a request has the choice of either a direct response or passing the request for disclosure on to the licensor. Further, the conferees provided an exemption from the request for disclosure provisions. A person has marked the number of the patent covering the process used to made the product that the person sells in the United States is not required to respond to a request for disclosure. The Conferees recognize that products may already be in the stream of commerce or about to be manufactured at the time of enactment. Thus, a transition period is provided to allow for an exhaustion of packaging inventory. The marking requirement is derived from existing section 287 of title 35, United States Code. When referring to the option of marking products to avoid a response to a request for disclosure, the conferees contemplate that the marking appear on the immediate packaging of the product or if marking the package is not feasible on the product itself produced by the process patent.

Third, the conferees adopted language which requires that a person who has received a response to a request for disclosure shall pay to the party to whom the request is made a reasonable fee to cover the actual costs of complying with the request. The reimbursement of reasonable costs shall occur after the response, thereby not delaying in any way the request for disclosure. The reasonable costs shall be subject to three caps: first, the actual cost of any activity undertaken to comply with the request is the first limit and reasonable costs may not in any event exceed this actual cost; second, the reimbursement may not exceed the cost of a commercially available automated patent search of the matter involved; and third, in no event may reasonable costs exceed $ 500, a formal patent search not being required. Finally, a request for disclosure for purposes of this provision applies separately to each product. For example, a request for disclosure on two products triggers two separate reimbursements.

Fourth, the House recedes to the Senate on the question of notice with an amendment. Deleted from the Senate amendment is the explicit requirement that, as a part of the notification process, the patent owner set forth such persons actual knowledge of any commercially feasible process other than the patented process which is capable of producing

the allegedly infringing product. However, the conferees expect that some patent owners will find it necessary to discuss other processes to meet the requirements of providing "such information ... as is reasonably necessary to fairly explain [their] belief," that an infringing process was used. The factual basis for the belief that an infringing process has been used can also be shown by an infringing process has been used can also be shown by an indication that the protected process contains certain impurities that do not exist with respect to other alternative processes. Similarly, gross price disparities between the cost associated with use of the protected process and all others may be sufficient to meet this test.

Last, the House recedes to the Senate with respect to section 287(b)(5)(C) with an amendment and explanatory language. The term "mitigating circumstances" is meant to encompass the death or incapacity of the person who was intended to made the submission or an inability to locate the manufacturer/supplier due to his no longer being in business, or inability of the manufacturer to respond to the submission because such manufacturer has gone out of business. A person who receives a written notification described in subparagraph (B) or a written response to a request for disclosure described in paragraph (4) shall be deemed to have notice of infringement with respect to any patent referred to in such written notification or response unless that person, absent mitigating circumstances: first, promptly transmits the written notification or response to the manufacturer or, if the manufacturer is not known, to the supplier, of the product purchased or to be purchased by that person; and second, receives a written statement from the manufacturer or supplier which on its face sets forth a well grounded factual basis for a belief that the identified patents are not infringed. The term "on its face" refers to the four corners of the written statement received by the person making the request for disclosure.

4. PRESUMPTION OF INFRINGEMENT (SEC. 1405 OF HOUSE BILL; SEC. 3304 OF SENATE AMENDMENT)

Present law

No provisions.

House bill

If the court finds there is a substantial likelihood that the product was made in violation of the process patent *and* the claimant has made a reasonable effort to determine the process used, then there is a rebuttable presumption that the product has been made in violation of the process patent.

Senate amendment

Same, except for minor drafting problems.

Conference agreement

Senate recedes to the House.

5. EFFECTIVE DATE (SEC. 1406 OF HOUSE BILL; SEC. 3305 OF SENATE AMENDMENT)

Present law

No provisions.

House bill

Generally applies only to products made or imported after the date of enactment. *Exception* for persons in business using, selling or importing goods already in production on January 1, 1987. Other remedies not affected.

Senate amendment

Similar to House bill in that it generally applies only to products made or imported after the date of enactment, except for persons in businesses using, selling or importing goods already in production on May 15, 1987, and *exception* does not apply to parties with certain cases brought previously before the International Trade Commission.

Conference agreement

The House basically recedes to the Senate. However, the conferees agreed to insert "January 1, 1988" in lieu of "May 15, 1987". The conferees also agreed that the Act will become effective six months after the date of enactment.

6. REPORTS TO CONGRESS (SEC. 1407 OF HOUSE BILL; SEC. 3306 OF SENATE AMENDMENT)

Present law

No provisions.

House bill

Reports on effect of legislation to be submitted by Secretary of Commerce.

Senate amendment

Identical provisions.

Conference agreement

The conferees agreed to the House and Senate provisions, with one minor amendment to clarify the scope of the Secretary's report.

7. INFRINGEMENT OF PATENTS (SEC. 3401 OF SENATE AMENDMENT)

Present law

Patent misuse is a common law doctrine that has its roots in the equitable doctrine of unclean hands. Section 271 of Title 35, U.S. Code, provides that certain narrowly described activities of a patent owner shall not be considered patent misuse. Although some misuses of patents may constitute antitrust violations, others do not.

House bill

No provisions.

Senate amendment

Amends Title 35 to provide that a patent owner's licensing practices will not constitute patent misuse unless they violate the antitrust laws.

Conference agreement

The Senate recedes to the House.

8. LICENSE CHALLENGES (SEC. 3501 OF SENATE AMENDMENT)

Present law

Title 35 does not cover the rights of licensees and licensors in a patent license agreement where the validity of the patent is challenged in litigation. However, in 1969, the U.S. Supreme Court ruled in *Lear v. Adkins* that a licensee can challenge the validity of a patent, without giving up the benefits of the license during the challenge.

House bill

No provision.

Senate amendment

Amends Title 35 to provide that a licensee may challenge the validity of the licensed patent irrespective of an agreement between the parties barring such challenge. Also provides that the parties to a licensing contract may define their respective rights regarding the termination of a license and payment of royalties if the validity of the licensed patent is challenged.

Conference agreement

The Senate recedes to the House. The conferees came close to solving the issues and resolve to work positively towards enactment of legislation in the near future.

FOOTNOTES:

[n1] Footnote 1. *See generally,* Application of *Tarczy-Hornoch,* 397 F.2d 856 (C.C.P.A. 1968) (Judge Rich discusses the case law history of process patents).

[n2] Footnote 2. 66 Stat. 92, 773; 35 U.S.C. 100(b) (reprinted in *Industrial Property Laws and Treaties,* United States of America--Text 2-001).

[n3] Footnote 3. *Enka, B.V. of Arnhem, Holland v. E.I. du Pont, Etc.,* 519 F.Supp. 356, 362: D. Del. 1981)(19 U.S.C. 1337, 1337a does not give Federal District Courts jurisdiction over acts outside the U.S.). See generally, Note. "Importation of Articles Produced by Patented Processes: Unfair Trade Practices or Infringement." 18 *Geo. Wash. J. Int'l L. & Econ.* 129 (1984) (hereinafter cited as *"Note"*): Kaye & Plaia. "Unfair Trade Practices in International Trade Competition: A Review of Developments Under Section 337." 64 *J. Pat. Off. Soc'y.* 360 (1982); Ablondi & Vent. "Section 337 Import Investigations--Unfair Import Practices." 4 *Loy. Int'l. & Comp. L.J.* 27 (1981); *see also,* Stark. "Efforts by Treaty, Case and Statute to Provide Holders of Process Patents Protection Against Imported Goods Made by the Patented Process." 42 *J. Pat. Off. Soc'y.* 21 (1960); Comment, "Patent Protection Under the Tariff Act." 13 *Case W. L. Rev.* 377, 381-82 (1962); *see also,* DeLio & Worth. "A Review of Protection of Patent Interests from Unfair Methods of Competition in Importation." 25 *Geo. Wash. L. Rev.* 341 (1957), *reprinted in* 39 *J. Pat. Off. Soc'y.* 282 (1957) (hereinafter cited as *"DeLio & Worth"*); Rich, "Infringement Under Section 271 of the Patent Act of 1952 ", 35 *J. Pat. Off. Soc'y.* 476 (1953).)

[n4] Footnote 4. *Certain Amorphous Metal Alloys and Amorphous Metal Products.* 377-TA-143 (1984): *Innovation and Patent Law Reform: Hearings Before the Subcommittee on Courts. Civil Liberties and the Administration of Justice of the House Committee on the Judiciary,* 98th Cong., 2d Sess. 2581 (1984) (statement of Allied Corporation) (hereinafter *Innovation and Patent Law Reform*).

[n5] Footnote 5. The Office of Technology Assessment describes the nature of the process patent problem for biotechnology companies in its recent report. *Commercial Biotechnology: An International Analysis* 390, 391, 401, 405 (1984).

"Because many countries do not provide patent protection for the chemical products of biological processes, and because ... micro-organisms and subcellular entities will not be protectable *per se* under the patent laws of many countries, process protection may be the only protection available in many cases." R. Schwab, D. Jeffery, D. Conlin. *U.S. and Foreign Intellectual Property Law Relating to Biological Inventions* (1983), at 12 (unpublished contract report submitted to the Congress of the United States Office of Technology Assessment).

[n6] Footnote 6. Brunsvold, "Analysis of the United States International Trade Commission as a Forum for Intellectual Property Disputes", 60 *J. Pat. Off. Soc'y.* 505 (1978) (hereinafter cited as "Brunsvold").

[n7] Footnote 7. *In re Amtorg Trading Corporation,* 75 F.2d 826, 931-832 (1935) (citations omitted), *cert. denial* 276 U.S. 576 (1935).

[n8] Footnote 8. DeLio & Worth, *supra note* 3, at 286-344.

[n9] Footnote 9. *Id; Note* at 133: *United States v. Studiengesellschaft Kohle m.b.H.,* 607 F.2d 1122, 1127-28 (D.C. Cir. 1981) ("[a] sale of a product made by a patented process does not itself infringe the patent; it is the unauthorized use of the process that infringes the patent.") (citations omitted).

[n10] Footnote 10. This view was first enunciated by a governmental entity in 1966 when President Johnson's Commission on the Patent System recommended a change in the patent laws to protect process patents from overseas infringement. *Report of the President's Commission on the Patent System* (1966).

[n11] Footnote 11. President's Commission on Industrial Competitiveness. *Preserving America's Industrial Competitiveness,* at 328-9, 343 (1985).

[n12] Footnote 12. *See* remarks of Robert W. Kastenmeier, 132 Cong. Rec. H 1783 (daily ed. April 10, 1986). *See also* "Administration Trade Package: White House Maps Bill to Item Tide of Protectionism," *New York Times*, September 12, 1985. A1, D6.

The Administration trade bill included process patent reform, H.R. 1155 (Michel) (100th Cong., 1st Sess.), Office of the United States Trade Representative, Executive Office of the President, *Administration Statement on the Protection of U.S. Intellectual Property Rights Abroad*, April 7, 1986 (reprinted in 3 Int. Trade Rep. 481 (April 9, 1986).

[n13] Footnote 13. *See* Hearings on Intellectual Property and Trade before the Subcommittee on Courts Civil Liberties and the Administration of Justice House Committee on the Judiciary, 99th Cong. 2d Sess. (1986) (statement of Dr. Paula Stern) (hereinafter referred to as House Hearings). *See generally,* Staff of the International Trade Commission. Unfair Import Investigation Division, *Litigating Intellectual Property Cases of the International Trade Commission* (unpublished) (undated) (available from the ITC) (hereinafter cited as *"ITC Staff Paper"*).

[n14] Footnote 14. It should be noted that amendments to section 337 have also been proposed during the 100th Congress.

H.R. 1509 has been reported favorably by the Subcommittee on Courts, Civil Liberties and the Administration of Justice to the Committee on the Judiciary. This bill has also been incorporated *in hace verba* in H.R. 3, an omnibus trade bill which passed the House of Representatives.

These bills, in general, seek to facilitate enforcement of intellectual property rights in the ITC. Most of the bills eliminate the requirements that the complainants in the ITC show that an "injury" occurred if they can show intellectual property ownership and infringement. These bills also eliminate the requirement that the complainant establish that the affected industry is "efficiently and economically operated." While these changes, if adopted, may make the ITC a slightly more attractive forum for the adjudication of process patent disputes, such changes would not eliminate the need for legislation to permit infringement actions in the Federal district courts.

[n15] Footnote 15. *Id.* As of September 1983, the Commission had instituted 165 Section 337 actions.

[n16] Footnote 16. 19 U.S.C. 1337(b)(1) .

[n17] Footnote 17. 19 U.S.C. 1337(f)(1) .

[n18] Footnote 18. 19 C.F.R. 210.12 (1984) .

[n19] Footnote 19. 19 U.S.C. 1337(d) . Because ITC proceedings are *in rem* in nature, such orders are proper. *Sealed Air Corporation v. ITC,* 645 F.2d 967 (C.C.P.A. 1981).

In at least two cases involving process patents, the Commission has entered general exclusion orders which bar any goods made during the protected process. *Certain Multi-Cellular Plastic Film,* No. 337-TA-54 (In'tl Trade Comm. 1979) at 22-24; *aff'd sub nom., Sealed Air Corp. v. ITC.* 645 F.2d 976 (C.C.P.A. 1981); and *Certain Methods for Extracting Plastic Tubing,* No. 337-TA-110 (1982) at 19-21. This means that with a general exclusion order the burden of proof is on the importer to show that the goods were made by other than the protected process.

It is also possible to obtain a temporary exclusion order which excludes articles from entry into the United States during a course of an ITC investigation, unless the respondent posts an adequate bond. 19 U.S.C. 1337(e) .

[n20] Footnote 20. U.S.C. 1337 (d) .

[n21] Footnote 21. *Certain Airtight Cast-Iron Stoves,* No. 337-TA-69 (1981), 215 U.S.P.Q. (Int'l Trade Comm. 1980): *Note* at 140. n. 103.

[n22] Footnote 22. *ITC Staff Paper* at 8-9.

[n23] Footnote 23. In fairness it should be noted that commencement of an action in Federal court presents its own set of problems. Service of process can be a difficult procedural hurdle to overcome. Moreover, even if a patent holder obtains a judgment against a foreign manufacturer, enforcement can be difficult. *ITC Staff Paper* at 4-6.

[n24] Footnote 24. *See Resolution 101-3,* 1983 *A.B.A. Sec. on Pat., Trademark & Copyright L. Committee Rep.* 23-25. *Resolution 101-3,* 1984 *Summary of Proceedings, A.B.A. Sec. on Pat., Trademark & Copyright L. Committee Rep.* Damages available in a patent infringement lawsuit must be adequate to compensate but not less than a reasonable royalty. 35 U.S.C. 284 . In case of willful and wanton infringement, treble damages are available. *Id., Baumstimler v. Rankin,* 677 F.2d 1061 (5th Cir. 1982).

[n25] Footnote 25. *See, e.g., Certain Headboxes and Papermaking Machine Forming Sections for the Continuous Production of Paper and Components Thereof,* No. 337-TA-82 (1980) (remedy too broad), *see 46 Fed. Reg.* 32.361 (June 22, 1981) (President's disapproval), *investigation reopened.* No. 337-TA-82A, 217 U.S.P.Q. 179 (Int'l Trade Comm. 1981), *rev'd on other grounds sub. nom. Aktiebolaget Karlstads Mekaniska Werkstad v. ITC,* 705 F.2d 1565 (Fed. Cir. 1983): *Certain Welded Stainless Steel Pipe and Tube.* No. 337-TA-29 (1979) (ITC jurisdiction questioned).

[n26] Footnote 26. Letter from President Ronald Reagan to Hon. Paula Stern, Chairwoman. ITC dated January 4, 1985.

[n27] Footnote 27. *Certain Alkaline Batteries,* No. 337-TA-165 (1984).

[n28] Footnote 28. *Certain Softballs and Polyurethane Cores therefore,* No. 337-TA-190 (1985) (ITC does not use rigid formula in determining industry requirement). Certain Battery Operated Toy Vehicles No. 337-TA-122 (1982), *aff'd. sub nom. Schaper Mfg. Co. v. ITC,* 717 F.2d 1368 (Fed. Cir 1983) (where complainant's product also made outside the U.S.; no domestic industry): *Certain Products with Gremlins Depictions,* No. 337-TA-201 (9186), *compare, Certain Ultra-Microtone Freezing Attachments.* Investigation No. 337-TA-10 (1976) (finding of domestic industry when only domestic act is the importation of goods from abroad) with *Certain Writing Instuments and Nibs Therefor.* Investigation No. 337-TA-129 (1984) (two patents, two possible industries, only one meets statutory definition) *see Note* at 137, n.72.

[n29] Footnote 29. Brunsvold at 513 (citations omitted): *Note* at 137, n. 72.

In the leading case on the question of injury, the Court of Appeals for the Federal Circuit held that even though proof of injury in a patent case can be less than other Section 337 cases it is still necessary to show that the infringer holds, or threatens to hold a significant share of the market or has made significant sales. *Texton v. ITC.,* 753 F.2d 1019, 1029 (1985), *see also, Certain Optical Waveguide Fibers,* No. 337-TA-189 (June 19, 1985). (no injury finding); *Certain Combination Locks,* No. 337-TA-45 (1979) (no injury finding); *Certain Attache Cases,* No. 337-TA-49 (1979) (no injury finding).

[n30] Footnote 30. *See e.g., Certain Methods for Extracting Plastic Tubing,* No. 337-TA-110 (1982) a: 10-11. *See also. ITC Staff Paper* at 9-10. *Note* at 137, n. 74.

[n31] Footnote 31. 19 U.S.C. 1337(a) .

[n32] Footnote 32. *Certain Roller Units.* No. 337-TA-49 (1979); *Certain Chain Door Locks,* No. 337-TA-5 (1976).

[n33] Footnote 33. *ITC Staff Paper* at 12.

[n34] Footnote 34. *Id.* at 22 (Commission considers complainant's anticompetitive behavior and the industry's likely pricing behavior in the absence of imports).

[n35] Footnote 35. 19 U.S.C. 1337(d) : *S. Rep. No.* 1298, 93d Cong., 2d Sess. 193, 197 (1974).

[n36] Footnote 36. 19 C.F.R. 210.14(a)(4)(1984) : *see e.g.,* 47 Fed. Reg. 39. 746 (1982).

[n37] Footnote 37. *Certain Automatic Crankpin Grinders.* No. 337-TA-60. 205 U.S.P.Q. 71 (Int'l Trade Comm. 1979).

[n38] Footnote 38. *Certain Inclined Field Acceleration Tubes and Components Thereof.* No. 337-TA-67 (1980).

[n39] Footnote 39. The European Patent Convention countries provide process patent protection against infringement by use of a protected process overseas. *See, e.g.,* 1977 Patent Act, Ch. 37 Section 601(1)(c) (United Kingdom) (reprinted in *Industrial Property Laws and Treaties,* UNITED KINGDOM--Text 2-001); *see also, Note* at 141-145; 1980 Patent law Section 9 (Federal Republic of Germany) (reprinted in *Industrial Property Laws and Treaties.* GERMANY (FEDERAL REPUBLIC OF--Text 2-002); Article 64(2) of the European Patent Convention (reprinted in *Industrial Property Laws and Treaties,* MULTILATERAL TREATIES--Text 2-008). *See also,* Community Patent Convention, Article 29(b) (reprinted in *Industrial Property Laws and Treaties,* MULTILATERAL TREATIES--Text 2-001). *Contra* (insofar as pharmaceuticals are concerned) Law on Inventions and Trademarks (1975) (Mexico) (processes for obtaining, modifying, or applying products and mixtures relating to the chemical-pharmaceutical industry, or medicines are not patentable, but can be granted a certificate of invention for 10 years wherein the owner must grant a compulsory license with a right to receive royalties) (reprinted in *Industrial Property Laws and Treaties,* MEXICO--Text 1-001); Patents Law of 1967. Section 102 (Israel) (reprinted in 21 *Laws of the State of Israel,* Jerusalem. 1967) (a compulsory license can be issued if the process is for the manufacturing of a product for sale as a medicine).

Article *Quarter* of the Paris Convention for the Protection of Industrial Property, to which the United States of America is party, provides: "When a product is imported into a country of the Union where there exists a patent protecting a process of manufacture of the said product, that are accorded to him by the legislation of the country of importation, on the basis of the process patent, with respect to products manufactured in that country."

[n40] Footnote 40. Patent Law of 1959. Section 2(3)(iii) (Japan) (Law No. 121. April 13, 1959, as last amended by Law No. 83, August 24, 1982) (reprinted in *Industrial Property Laws and Treaties, JAPAN--Text 2-001); see also,* Patent Act of Canada, VI Can. Rev. Stat., Chap. P-4 (1970) (reprinted in *Industrial Property; 1970. p. 166); see also, Dole Refrigerating Products Ltd. v. Canadian Ice Machine Co.,* 17 Fox Pat. C. 125 (Exch. CT. 1957).

[n41] Footnote 41. 130 Cong. Rec. H. 10527 (daily ed. October 1, 1984). Hearings in the House of Representatives are found in Innovation and Patent Law Reform, *supra* n. 4. In the Senate, the hearings are contained in National Productivity and Innovation Act of 1983 : Hearings Before the Subcommittee on Patents, Copyrights and Trademarks of the Senate Committee on the Judiciary, 98th Cong., 1st Sess. (1983).

The first bill to expand the remedies for process patent infringement was introduced as early as 1852. Cong. Globe, 32nd Cong., 1st Sess. 1549-51, 1566-73 (1852) and 32nd Cong., 2d Sess., 127, 128, 528, 534-36 (1853). This measure was opposed in part because of concerns about the potential liability of "innocent infringers" purchasing goods on the open market (remarks of Mr. Hall (at 1549)). Similar bills were introduced in the 94th Congress. *See,* e.g., S. 2255. Those bills failed when patent law recodification efforts stalled. *See also* S. 2504, 93rd Cong., 1st Sess., proposed section 27(e).

During the 98th Congress, other bills relating to process patent reform were:

H.R. 3577 (Moorhead). 98th Cong., 1st Sess.; H.R. 4526 (Kastenmeier), 98th Cong., 1st Sess.; S. 1841 (Thurmond), 98th Cong., 2nd Sess.; S. 1535 (Mathias), 98th Cong., 2nd Sess.

[n42] Footnote 42. An additional concern about H.R. 6286 was raised by the United States Trade Representative concerning a potential conflict between the bill and the General Agreement on Tariff and Trade (GATT). *See* Innovation and Patent Law Reform (memorandum of Alice Zalik) at 2432. This issue was further analyzed by the Committee on the Judiciary during the 99th Congress. The expert views received by the Committee led it to conclude that process patent reform should not be limited to imports.

Hearings on Intellectual Property and Trade, *supra* note 13, at 172 (statement of Prof. Robert Hudec), 42, (letter from Prof. Robert Hudec to Robert W. Kastenmeier), and 426 (letter from Professor John Jackson, University of Michigan, to Robert W. Kastenmeier).

[n43] Footnote 1. "Extension of Patent Protection of a Process to the Products obtained by that Process; Proof of Infringement of a Process Patent." Memorandum by the International Bureau of WIPO, March 12, 1986, pp. 3-4.)

[n44] Footnote 2. "Process Patents," Hearings on S. 1543 before the Senate Judiciary Subcommittee on Patents, Copyrights and Trademarks, 99th Congress, 1st Session, p.12.)

[n45] Footnote 3. Ibid., p. 43.

[n46] Footnote 4. Senate Report 98-663, 98th Congress, 2nd Session, p. 6.

[n47] Footnote 5. Statement of Thomas D. Kiley, Esq., Vice President, Corporate Development, Genentech, Inc., before the House Judiciary Subcommittee on Courts, Civil Liberties and the Administration of Justice, February 19, 1986 (Hearing on "Intellectual Property and Trade." 99th Congress, Serial Number 60).

[n48] Footnote 6. Letter from Jan Jancin, Jr., President, ABA Section of Patent, Trademark and Copyright Law, to Senator Mathias, March 10, 1986. Printed in "Process Patents," Hearing on S. 1543 before the Senate Judiciary Subcommittee on Patents, Copyrights and Trademarks, 99th Congress, 1st Session, pp. 266-8.