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## PROCESS PATENT AMENDMENTS ACT OF 1987

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

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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 becomes 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 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 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 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. 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 continu-

ous 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 commercial 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.<sup>1</sup> 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.<sup>2</sup> Process patents, however, have been granted only partial protection against acts of infringement.<sup>3</sup> This is so because, unlike product patents,

<sup>1</sup> 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).

<sup>2</sup> 66 Stat. 92, 773; 35 U.S.C. 100(b) (reprinted in *Industrial Property Laws and Treaties*, United States of America—Text 2-001).

<sup>3</sup> *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).

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 metals<sup>4</sup> 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.<sup>5</sup> 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*.<sup>6</sup>

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.<sup>7</sup> 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.<sup>8</sup> 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.<sup>9</sup>

<sup>4</sup> *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*).

<sup>5</sup> 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).

<sup>6</sup> "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).

<sup>7</sup> 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").

<sup>8</sup> *In re Amtorg Trading Corporation*, 75 F.2d 826, 931-832 (1935) (citations omitted), *cert. denial* 276 U.S. 576 (1935).

<sup>9</sup> DeLio & Worth, *supra* note 3, at 286-344.

<sup>10</sup> *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).

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.<sup>10</sup> 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.<sup>11</sup> 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.<sup>12</sup>

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.<sup>13</sup> 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.<sup>14</sup> The most

<sup>10</sup> 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).

<sup>11</sup> President's Commission on Industrial Competitiveness. *Preserving America's Industrial Competitiveness*, at 328-9, 343 (1985).

<sup>12</sup> 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)).

<sup>13</sup> 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").

<sup>14</sup> 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 *habe 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

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.<sup>15</sup> 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.<sup>16</sup> The ITC may extend this period up to 18 months for complex cases.<sup>17</sup> 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.<sup>18</sup>

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.<sup>19</sup> The exclusion orders can extend to non-respondents if a pattern or practice of abuse has been shown.<sup>20</sup> In cases where personal jurisdiction exists, the ITC may also issue cease and desist orders.<sup>21</sup> 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.<sup>22</sup> 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 ef-

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fills 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.

<sup>15</sup> *Id.* As of September 1983, the Commission had instituted 165 Section 337 actions.

<sup>16</sup> 19 U.S.C. 1337(b)(1).

<sup>17</sup> 19 U.S.C. 1337(f)(1).

<sup>18</sup> 19 C.F.R. 210.12 (1984).

<sup>19</sup> 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 (Int'l 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).

<sup>20</sup> U.S.C. 1337 (d).

<sup>21</sup> *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.

<sup>22</sup> *ITC Staff Paper* at 8-9.

forts 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.<sup>23</sup>

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.<sup>24</sup>

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.<sup>25</sup> For the first time in memory, President Reagan on January 4, 1985, overturned the ITC decision to exclude “grey market goods” on policy grounds.<sup>26</sup> Disagreeing with a written opinion by the ITC,<sup>27</sup> 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

<sup>23</sup> 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.

<sup>24</sup> 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).

<sup>25</sup> 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).

<sup>26</sup> Letter from President Ronald Reagan to Hon. Paula Stern, Chairwoman. ITC dated January 4, 1985.

<sup>27</sup> *Certain Alkaline Batteries*, No. 337-TA-165 (1984).

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.<sup>28</sup> It also appears difficult to show the separate requirement of "injury" if one's business is still showing a profit.<sup>29</sup> 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,<sup>30</sup> 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.<sup>31</sup> 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.<sup>32</sup> 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.<sup>33</sup>

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.<sup>34</sup> This consideration

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<sup>28</sup> *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 Instruments 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.

<sup>29</sup> *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).

<sup>30</sup> 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.

<sup>31</sup> 19 U.S.C. 1337(a).

<sup>32</sup> *Certain Roller Units*. No. 337-TA-49 (1979); *Certain Chain Door Locks*, No. 337-TA-5 (1976).

<sup>33</sup> *ITC Staff Paper* at 12.

<sup>34</sup> *Id.* at 22 (Commission considers complainant's anticompetitive behavior and the industry's likely pricing behavior in the absence of imports).

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.<sup>35</sup> Moreover, the ITC, by law and regulation, must consult on this question with other federal agencies and outside groups.<sup>36</sup>

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.<sup>37</sup> The other involved the use of basic research equipment in nuclear structure physics.<sup>38</sup>

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 Community<sup>39</sup> and Japan,<sup>40</sup> pro-

<sup>35</sup> 19 U.S.C. 1337(d); *S. Rep. No. 1298*, 93d Cong., 2d Sess. 193, 197 (1974).

<sup>36</sup> 19 C.F.R. 210.14(a)(4)(1984); see e.g., 47 Fed. Reg. 39, 746 (1982).

<sup>37</sup> *Certain Automatic Crankpin Grinders*, No. 337-TA-60, 205 U.S.P.Q. 71 (Int'l Trade Comm. 1979).

<sup>38</sup> *Certain Inclined Field Acceleration Tubes and Components Thereof*, No. 337-TA-67 (1980).

<sup>39</sup> 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."

<sup>40</sup> 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—

vide 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).<sup>41</sup> 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.<sup>42</sup>

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

*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).

<sup>41</sup> 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., 2d Sess.; S. 1535 (Mathias), 98th Cong., 2d Sess.

<sup>42</sup> 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).

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 Professor 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 subsequently 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 attorney 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 infringement 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 relation 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 likelihood 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 efficiency 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 report 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(1)(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(1)(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(1)(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**

Sec.

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.*

\* \* \* \* \*

**§ 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.*

\* \* \* \* \*