

# THE PROCESS PATENT AMENDMENTS ACT OF 1988: CLOSING A LOOPHOLE IN UNITED STATES PATENT LAW

## I. INTRODUCTION

Recent technological advances, particularly in biotechnological and chemical processes, raise important international trade issues for the protection of intellectual property rights. The ability of the United States to compete in worldwide markets is largely dependent upon its technological developments. These developments directly contribute to economic growth by providing new and improved products and new manufacturing processes that are less expensive and more efficient. Inadequate protection of intellectual property rights, particularly for patents covering manufacturing processes, has led to pirating of these processes by foreign manufacturers.<sup>1</sup> The growing trade deficit between the United States and its foreign trading partners has led to a bipartisan effort in Congress to address foreign piracy and thus increase the incentive for United States companies to invest in research and development.

The Omnibus Trade and Competitiveness Act of 1988<sup>2</sup> (the Omnibus Trade Act) incorporated the Process Patent Amendments Act<sup>3</sup> (the Process Patent Act). This allowed United States companies to restrict the importation of goods made abroad using United States patented manufacturing processes. Prior to the Process Patent Act, any United States business that wanted to manufacture a product in the United States using a patented manufacturing process was required to obtain a license from the patent owner, or risk infringing the patent

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1. See generally Clark, *The Future of Patent-Based Investigations Under Section 337 After the Omnibus Trade and Competitiveness Act of 1988*, 38 AM. U.L. REV. 1149 (1989).

2. Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107 (1988) (this Comment specifically addresses amendments to 19 U.S.C. § 1337 and 35 U.S.C. §§ 154, 271, 287, and 295).

3. The Process Patent Amendments Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107, 1563-67 (1988) (as codified in 35 U.S.C. §§ 154, 271, 287, and 295).

and suffer legal penalties. However, the business could import the same product made overseas without obtaining a license from the patent owner and without infringing the patent. Thus, United States patent law left companies holding process patents unable to prevent the importation of goods made abroad with United States patented processes.<sup>4</sup> This lack of process patent protection encouraged manufacturing outside of the United States and the concurrent loss of domestic jobs. The scope of the problem became apparent with the release of a survey by the United States International Trade Commission (ITC) in which respondents estimated their aggregate worldwide losses due to inadequate intellectual property protection to be 23.8 billion dollars or approximately 300,000 jobs in 1987.<sup>5</sup>

This Comment will analyze the impact of the amendments within the Omnibus Trade and Competitiveness Act on both United States patent laws and the Tariff Act of 1930. The Comment will assess the ramifications of these amendments on both United States industries and the international community.

## II. THE PROCESS PATENT AMENDMENTS ACT

### A. Background

United States patent law allows the patenting of either products or processes.<sup>6</sup> Prior to the Process Patent Act, United States manufacturers who held a patent on a process, but not on the product made with that process, were vulnerable to the importation of the goods made abroad with their United States patented processes.<sup>7</sup> This vulnerability arose from a loophole in United States patent law that allowed claims of patent infringement only for goods made, used, or sold within the *territory* of the United States.<sup>8</sup> Thus, if a patented product entered United

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4. *Floor Remarks on Intellectual Property Provisions of H.R. 3*, 35 Pat. Trademark & Copyright J. (BNA) No. 878, at 579 (Apr. 28, 1988) [hereinafter *Floor Remarks*].

5. *Id.* at 581.

6. A. MILLER & M. DAVIS, *INTELLECTUAL PROPERTY: PATENTS, TRADEMARKS, AND COPYRIGHTS* 23-27 (1983).

7. Gould, *Protecting Owners of U.S. Process Patents from the Importation of Pharmaceuticals Made Abroad by Use of the Patented Process: Current Options, Proposed Legislation, and a GATT Solution*, 42 FOOD DRUG COSM. L. J. 347 (1987).

8. Before the Process Patent Amendments Act, the federal patent statutes

States territory, the patentee could sue for infringement under United States patent law. Yet, the law did not allow a patentee to sue for infringement to prevent the importation of products made overseas with a United States patented process.<sup>9</sup> For example, Allied-Signal spent fifteen years and one hundred million dollars developing a patented process for manufacturing amorphous metals only to find that German and Japanese companies were using Allied's process to make and legally import these metals into the United States.<sup>10</sup>

To close this loophole in United States patent law, the Ninety-Eighth and Ninety-Ninth Congresses proposed legislation that would have made the importation of products manufactured abroad by United States patented processes an act of patent infringement.<sup>11</sup> The chief opponents of the legislation were the generic drug industry and United States retailers. The opponents argued that the legislation introduced a new liability on domestic importers, retailers, and purchasers for the illegal activities of foreign manufacturers and suppliers.<sup>12</sup> To ameliorate the retailers' and generic drugmakers' objections, the Process Patent Act, passed by the One Hundredth Congress, contains various limitations on the remedies available to United States patent holders against domestic infringers.<sup>13</sup>

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specified that a patent grants to an inventor the exclusive right to make, use, or sell the invention only in the United States. 35 U.S.C. § 154 (1982). Section 9002 of the Process Patent Amendments Act amends § 154 to specify that a patent on a process includes the right to exclude the unauthorized use or sale of any product either within the United States or imported into the United States that had been made by the patented process. Process Patent Amendments Act of 1988 § 9002, 35 U.S.C. § 154 (1988).

9. Before the Process Patent Amendments Act, patent infringement included the unauthorized manufacture, use, or sale of a patented invention within the United States. 35 U.S.C. § 271(a) (1982). Section 9003 of the Process Patent Amendments Act amends § 271 by adding § 271(g) which specifies that anyone importing, using, or selling a product made by a process patented in the United States shall be liable as an infringer. Process Patent Amendments Act of 1988 § 9003, 35 U.S.C. § 271(g) (1988).

10. Rhein, *Setting the Stage for Stronger U.S. Patents*, CHEMICAL WK., May 6, 1987, at 16.

11. Gould, *supra* note 7 at 347.

12. Rhein, *U.S. Ready to Pass Law Protecting Process Patents*, CHEMICAL ENGINEERING, Sept. 14, 1987, at 29.

13. Comment, *The Process Patent Amendments Act of 1988: Solving an Old Problem, But Creating New Ones*, 1989 B.Y.U.L. REV. 567 (1989).

### *B. Provisions Within the Act*

The Process Patent Act includes several provisions which are intended to lighten the patent holder's burden of proving foreign process patent infringement and to limit the remedies against United States parties, who often play an indirect role in such infringement.<sup>14</sup> This attempt to balance protection for both process patent holders and domestic infringers allowed for the passage of the Process Patent Act, but the overall result may be less effective than initially anticipated.

#### (1) The Presumption of Patent Infringement

To obtain relief against infringing imports made from a process patented in the United States, a complainant or patent holder must prove that the patent has been infringed. However, proving that a particular process was used by the manufacturer of a product may be impossible if the foreign manufacturer is not subject to service of process in the United States.<sup>15</sup> To circumvent this problem the Process Patent Act creates a rebuttable presumption that a process is being infringed if: (1) there is "a substantial likelihood that the product was made by the patented process"<sup>16</sup> and (2) the patent holder "has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine."<sup>17</sup> Thus, the burden of establishing that the product was not made by the patented process rests on the defendant even if the defendant is an importer, or a subsequent purchaser.<sup>18</sup>

Rebutting the presumption of infringement is particularly difficult for an importer or retailer who did not use the patented process but bears liability for its infringement.<sup>19</sup> The primary rationale behind the presumption of infringement is that an importer, because of its contractual relationship with the manufacturer, will be able to exert some influence on the manufac-

14. *Id.* at 568.

15. Gould, *supra* note 7, at 357.

16. Process Patent Amendments Act of 1988 § 9005, 35 U.S.C. § 295 (1988).

17. *Id.*

18. Gould, *supra* note 7, at 357.

19. Comment, *supra* note 13, at 569.

turer to produce the necessary information and will be in a better position than the patentee to obtain the information.<sup>20</sup> David Haarz, representing the National Retail Merchants Association, objected to this provision, pointing out that this measure would "require innocent retailers to choose between patent liability and the 'costly and time-consuming task of undertaking a fact-finding mission to ensure themselves that goods purchased from every one of their suppliers, domestic as well as foreign, were not produced pursuant to a process protected by a United States patent.'"<sup>21</sup> To impose liability on the retailer and purchaser, where none had existed before, would result in higher business costs which would be passed along to the consumer.<sup>22</sup>

The overall effect of the Process Patent Act's rebuttable presumption stance will depend on the court's interpretation of two clauses.<sup>23</sup> These two clauses are (1) the "substantial likelihood" that the product was made by the patented process and (2) plaintiff's "reasonable effort" to determine if the product was made by the patented process. The elements necessary to show these two factors have not yet been developed and must await case law in this area. Thus the extent of the presumptive infringement provision of the Process Patent Act is subject to court interpretation.

## (2) Limitations on Remedies

The Process Patent Act, like existing patent laws in Europe and Japan, imposes liability on domestic importers, retailers, and users of products made overseas with a pirated process. But unlike foreign patent laws, the Process Patent Act has safeguards and equity provisions aimed at meeting the retailers' and generic drug manufacturers' concerns.<sup>24</sup>

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20. Gould, *supra* note 7, at 357.

21. *Effects of Process Patent Bills on Retailers Disputed at Hearings*, 1987 Daily Rep. for Executives (BNA) No. 84, at A-15 (May 4, 1987).

22. *Id.*

23. Process Patent Amendments Act of 1988 § 9005(a), 35 U.S.C. § 295 (1988).

24. Rhein, *supra* note 10, at 16.

## (a) Inventory Exemptions for Retailers

Earlier proposals of the Act included a number of provisions designed to protect retailers from liability for goods in stock or on order. One of the more controversial proposals, eliminated from the final Process Patent Act, was the inclusion of provisions granting retailers a six- to eighteen-month period to sell existing stocks while paying patent holders a reasonable royalty fee.<sup>25</sup> The Commissioner of the Patent and Trademark Office testified before the Senate that the imposition of reasonable royalties resembled compulsory licenses, which had no place in United States patent law.<sup>26</sup> The Administration's opposition to these proposals ultimately caused their defeat.

Another related proposal, also eliminated from the final Process Patent Act, was an exemption from liability for importers who had binding commitments to purchase infringing goods prior to receiving notice of infringement from the patent holder.<sup>27</sup> Representative Moorhead,<sup>28</sup> in remarks before the House on April 20, 1988, said:

[O]ne of the most important compromises was reached when the Senate agreed to delete its language that would have allowed an infringer to sell products 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 patent owner would never be certain as to what was "partially or wholly manufactured, before the party had notice of infringement." An infringer could put together "a binding commitment" with the

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25. *Id.*

26. *Witnesses Argue Over Accommodations to Retailers in Process Patent Bills*, 4 Int'l Trade Rep. (BNA) No. 18, at 615 (May 6, 1987) [hereinafter *Witnesses*].

27. Comment, *supra* note 13, at 570.

28. Representative Carlos J. Moorhead is a Republican congressman elected from the 22nd district of California. He is a member of the Judiciary Committee on Intellectual Property.

foreign manufacturer that could last for years . . . . At best this language was mischievous and at worse it created a giant loophole.<sup>29</sup>

Both of these proposals were rejected in the final version of the Process Patent Act because they neutralized the incentives for importers to avoid infringement. The final version of the Act, however, connects remedies and notice; the patent holder must prove that the infringer had notice of the infringement before he may receive damages.<sup>30</sup> The Process Patent Act allows infringing retailers to escape liability while they sell all their existing inventory and any product in transit to them at the time that they receive notice of infringement.<sup>31</sup> However, the "person subject to liability shall bear the burden of proving any possession or transit."<sup>32</sup> This provision tries to eliminate any undue hardship to importers or retailers who make commitments without knowledge of infringement by their manufacturers or suppliers.<sup>33</sup>

#### (b) Notice requirement

The Process Patent Act has made United States manufacturers less vulnerable to the importation of goods made abroad with their United States patented processes. However, it has introduced a new liability on domestic importers, retailers, and purchasers for the patent infringement acts of foreign manufacturers and suppliers. In an effort to eliminate undue hardships on retailers, unfamiliar with the manufacturing processes involved in the goods that they sell and import, the final version of the Process Patent Act does not trigger liability until the infringer has "notice" of infringement.<sup>34</sup>

Since notice of infringement is necessary to initiate a suit against importers of products made from pirated United States processes, it was necessary for the Process Patent Act to define

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29. *Floor Remarks*, *supra* note 4, at 581-82.

30. *Comment*, *supra* note 13, at 571.

31. Process Patent Amendments Act of 1988 § 9004(b)(2), 35 U.S.C. § 287(b)(2) (1988).

32. *Id.*

33. *New Process Patent Bills Would Limit Imports, Focus of Dispute is Liability of Retailers*, 4 Int'l Trade Rep. (BNA) No. 10, at 340 (March 11, 1987).

34. *Floor Remarks*, *supra* note 4, at 581.

the standard for proving sufficient notice. A great deal of controversy over the definition of notice plagued the earlier versions of the Process Patent Act. For instance, an early Senate version had required "that the patent holder set forth such information as is reasonably necessary to fairly explain the patent holder's belief that no commercially feasible process other than his was likely to have been used."<sup>35</sup> This standard of proof was impractical and was eventually dropped since it was acknowledged that a patent holder should not be forced "to explain to foreign and domestic competitors how to avoid infringing their patent with a list of all commercially feasible processes, patented and unpatented, known to them for producing the product."<sup>36</sup>

Another version of the Process Patent Act had defined notice as "factors which are sufficient to establish that there is a substantial likelihood that the product was made by an infringing process."<sup>37</sup> The Reagan administration expressed reservations about requiring the patent holder to enumerate enough factors to establish a substantial likelihood of infringement. A "substantial likelihood" standard was thought to be too stringent in that it would require the complainant to practically prove his case to the infringer to meet the elements of legitimate notice.<sup>38</sup> Donald Quigg, the Commissioner of Patents and Trademarks, testified before the Senate that provisions such as this could turn process patents into "second class patents."<sup>39</sup>

The final version of the Process Patent Act amended the standard for notice to "actual knowledge or receipt by a person of a written notification, or a combination thereof, of information sufficient to persuade a reasonable person that it is likely that the product was made by a process patented in the United States."<sup>40</sup> This standard for notice lessened the burden of the previously worded version of the standard. This makes it easier

35. *Id.* at 582.

36. *Id.*

37. *Senate Judiciary Subcommittee Okays Plan to Curb Foreign Piracy of Patents*, 1987 Daily Rep. for Exec. (BNA) No. 92, at L-2 (May 14, 1987).

38. *Id.*

39. *Witnesses*, *supra* note 26, at 614.

40. Process Patent Amendments Act of 1988 § 9004(b)(5)(A), 35 U.S.C. § 287(b)(5)(A) (1988).

for the patent holder to bring an action against the infringer without being barred by the defense of lack of notice.

Patent infringement cases are tried in courts of equity. The definition of notice allows equity courts to balance the requirements of notice with the degree to which the infringer knew, or should have known, what processes were being used.<sup>41</sup> Because actual knowledge is within the definition of notice given in the Process Patent Act, no notice is required from the patent holder if the United States party has knowingly dealt in infringing merchandise.<sup>42</sup> For instance, section 9004(b)(1) specifically excludes the requirement of notice for 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.<sup>43</sup>

In addition, section 9004(b)(5)(D) provides that "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."<sup>44</sup>

If the importer, retailer, or purchaser did not know what manufacturing process was used to produce the product, then the Process Patent Act provides that the patent holder should provide the infringer with a written notice of infringement. That notice must: (1) charge the person with infringement, (2) specify the patented process alleged to have been used, (3) provide the reasons for a good faith belief that the process was used, and (4) include any information that is reasonably necessary to explain fairly the patent holder's belief unless that information

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41. *Floor Remarks*, *supra* note 4, at 581.

42. *Id.*

43. Process Patent Amendments Act of 1988 § 9004(b)(1), 35 U.S.C. § 287(b)(1) (1988).

44. *Id.* § 9004(b)(5)(D), 35 U.S.C. § 287(b)(5)(D).

is a trade secret.<sup>45</sup> Today, it is unclear whether filing an action for infringement constitutes sufficient notice. An earlier version of the Process Patent Act specified that filing an action for infringement constituted sufficient notice and even required that the pleadings contain sufficient information to satisfy the notice standard.<sup>46</sup>

(c) Request for disclosure

The Process Patent Act requires a court to consider the good faith of both the defendant and the plaintiff in determining the remedy to an infringement action.<sup>47</sup> Factors which are specified as evidence of good faith revolve around a provision in the Process Patent Act allowing an importer to make a "request for disclosure" to a manufacturer of a product of the same type that the importer is selling or desires to sell.<sup>48</sup> A request for disclosure is defined as:

[A] written request made to a person then engaged in the manufacture of a product to identify all process patents owned by or licensed to that person, as of the time of the request, that the person then reasonably believes could be asserted to be infringed if that product were imported into, or sold or used in, the United States by an unauthorized person.<sup>49</sup>

Requests such as these must be made before the requestor has imported, used, or sold goods manufactured with an infringing process and before that person has received a notice of infringement with respect to the product.<sup>50</sup> Furthermore, the person requesting the disclosure must then submit the patents identified pursuant to the request to the manufacturer or, if unknown, to the supplier of the goods that the person desires to sell. Along with the identified list of process patents, that person must also ask the manufacturer or supplier for a written

45. *Id.* § 9004(b)(5)(B), 35 U.S.C. § 287(b)(5)(B).

46. Comment, *supra* note 13, at 572.

47. Process Patent Amendments Act of 1988 § 9004(b)(3)(A), 35 U.S.C. § 287(b)(3)(A) (1988).

48. *Id.* § 9004(b)(3)(B), 35 U.S.C. § 287(b)(3)(B).

49. *Id.* § 9004(b)(4)(A), 35 U.S.C. § 287(b)(4)(A).

50. *Id.* § 9004(b)(4)(A)(ii), 35 U.S.C. § 287(b)(4)(A)(ii).

statement declaring that none of the processes claimed in those patents was used in the manufacture of the product.<sup>51</sup>

The request for disclosure provision was apparently added to the Process Patent Act in an effort to give importers and distributors information that could assist them to avoid infringement.<sup>52</sup> A prompt response to this request becomes an element considered by the court as evidence of the plaintiff's good faith.<sup>53</sup> Similarly, the failure to respond to a request for disclosure is evidence of an absence of good faith unless there are mitigating circumstances.<sup>54</sup> "Mitigating circumstances include the case in which, due to the nature of the product, the number of sources for the product, or like commercial circumstances, a request for disclosure is not necessary or practicable to avoid infringement."<sup>55</sup>

A number of companies have complained that this request for disclosure is an unnecessary burden on patent owners. The request for disclosure requires that they supply information about their patent rights that can be easily obtained by the other party from public files.<sup>56</sup> Many companies, particularly large companies with thousands of patents, felt that this section of the Process Patent Act was an undue burden on them, even when the person requesting the disclosure had to pay a fee to cover the cost of compliance.<sup>57</sup> Patent holders also objected to the requirement that the product manufacturer who receives a request for disclosure must identify all patents owned by or licensed to that person.<sup>58</sup> This requirement failed to recognize that licensing arrangements are private contractual agreements, the very existence of which constitutes sensitive business

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51. *Id.* § 9004(b)(4)(A)(iii), 35 U.S.C. § 287(b)(4)(A)(iii).

52. Comment, *supra* note 13, at 573.

53. Process Patent Amendments Act of 1988 § 9004(b)(3)(B)(ii), 35 U.S.C. § 287(b)(3)(B)(ii) (1988).

54. *Id.* § 9004(b)(3)(B)(iii), 35 U.S.C. § 287(b)(3)(B)(iii).

55. *Id.*

56. *Floor Remarks, supra* note 4, at 579.

57. Process Patent Amendments Act of 1988 § 9004(b)(6), 35 U.S.C. § 287(b)(6) (1988). This section of the Process Patent Act limits the amount of reimbursement that can be charged to a person making a request for disclosure. The amount "may not exceed the cost of a commercially available automated patent search of the matter involved, but in no case more than \$500." *Id.*

58. *Id.* § 9004(b)(4)(A), 35 U.S.C. § 287(b)(4)(A).

information.<sup>59</sup> The final version of the Process Patent Act provides that when a request for disclosure is received by a person with a patent license (exclusive or nonexclusive), the recipient of the request may choose to either respond to the request or pass on the request to the patent owner for disclosure.<sup>60</sup> This is in response to the patent holder's legitimate concern regarding the necessity of identifying licensing arrangements.

The drafters of the Process Patent Act also provided an alternative for companies that do not want to be burdened by responding to requests for disclosure. The alternative is to mark the number of the process patent on all products sold in the United States that are made by the patented process. Manufacturers who have marked all of their products before a request for disclosure is received do not have to respond to the request.<sup>61</sup> This practice is similar to the patent marking option that is available for product patent owners.<sup>62</sup>

#### *D. Annual Reports*

The chief opponent to the passage of this legislation was the generic drug industry, which argued that the Process Patent Act "would make it more difficult to import certain chemical ingredients needed to produce generic equivalents of off-patent drugs."<sup>63</sup> Partially in response to this opposition, Congress included section 9007 of the Process Patent Act to monitor the effect of the amendments.<sup>64</sup> Section 9007 requires an annual report by the Secretary of Commerce to Congress concerning any adverse effects of the amendments on legitimate sources of supply for domestic industries.<sup>65</sup> Since it will probably take several years to assess the overall effect of the Process Patent

59. *Floor Remarks*, *supra* note 4, at 583-84.

60. Process Patent Amendments Act of 1988 § 9004(b)(4)(B), 35 U.S.C. § 287(b)(4)(B) (1988).

61. *Id.* § 9004(b)(4)(C), 35 U.S.C. § 287(b)(4)(C) (stating that only products made after the enactment of the Process Patent Act must be marked with the number of the process patents used in their manufacture).

62. *Floor Remarks*, *supra* note 4, at 579.

63. Gould, *supra* note 7, at 347.

64. Process Patent Amendments Act of 1988 § 9007(a), 35 U.S.C. § 271(a) (1988).

65. *Id.* § 9007(b), 35 U.S.C. § 271(b).

Act, the reports are to continue for five years.<sup>66</sup> The first report, submitted February 23, 1990, was merely a statement by the Secretary indicating that no complaints had been received from domestic industries.<sup>67</sup> The Patent and Trademark Office (PTO) has again requested that any industries wishing to comment on any adverse effects on supplies send their comments to the Secretary of Commerce before January 31, 1991, to be included in the second year's report.<sup>68</sup>

### III. THE BOUCHER BILLS

#### A. Background

Passage of the Process Patent Act made the importation of a product manufactured by a United States patented process an act of infringement. Increased protection of process patents has fueled a debate on what has been perceived as a narrow interpretation of process claims by the United States Court of Appeals for the Federal Circuit (CAFC).<sup>69</sup> The debate has focused on the court's interpretation of obviousness and the application of the decision in *In re Durden*<sup>70</sup> to biotechnology inventions. In *In re Durden* the CAFC held that the use of a novel starting material did not render an otherwise obvious chemical process patentable.<sup>71</sup> The resulting debate and how it relates to the

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66. *Comment Sought on Adverse Effects of Recent Process Patent Amendments*, 39 Pat. Trademark & Copyright J. (BNA) No. 962, at 174 (Jan. 4, 1990).

67. Telephone interview with H. Dieter Hoinkes, Office of Legislation and International Affairs of the Patent and Trademark Office (Jan. 19, 1991).

68. *PTO, Process Patents*, 41 Pat. Trademark & Copyright J. (BNA) No. 1007, at 83 (Nov. 22, 1990).

69. *American Type Culture Collection Hosts Biotech Patent Conference*, 38 Pat. Trademark & Copyright J. (BNA) No. 932, at 107 (May 25, 1989). See also, Myers & Sibley, *Biotechnology in the Courts*, 40 SIM INDUSTRIAL MICROBIOLOGY NEWS 189, 195 (1990) stating that:

Patent applications are filed with and examined by an administrative agency: the United States Patent & Trademark Office (PTO) . . . . Decisions involving patents by the PTO or a District Court may be appealed to the U.S. Court of Appeals for the Federal Circuit (CAFC), and from there are appealed to the United States Supreme Court.

70. 763 F.2d 1406 (Fed. Cir. 1985).

71. *Id.* at 1410.

fledgling biotechnology field is illustrated in the complex set of lawsuits involving the various erythropoietin (EPO) patents.<sup>72</sup>

*B. Amgen, Inc. v. Chugai Pharmaceutical Co.*<sup>73</sup>

United States patent laws allow the patenting of both products and processes. Amgen, Inc. held a product patent<sup>74</sup> covering both the DNA encoding EPO and the genetically altered cells that express recombinant EPO.<sup>75</sup> However, Genetics Institute (along with its joint venture partner Chugai Pharmaceutical Co.) held a patent<sup>76</sup> covering both a process for purifying nonrecombinant EPO and the product homogeneous EPO.<sup>77</sup> Chugai made recombinant EPO in Japan (using genetically altered cells similar to those patented by Amgen) and imported it into the United States. At the same time, Amgen made and sold recombinant EPO in the United States.<sup>78</sup> Consequently Amgen brought a patent infringement action against Chugai, and Chugai countersued Amgen for patent infringement.<sup>79</sup> The court found that Amgen's sale of homogeneous recombinant EPO infringed Genetics Institute's product patent because the recombinant EPO was indistinguishable from the homogeneous nonrecombinant EPO covered in Genetics Inst-

72. Erythropoietin is a hormonal substance that stimulates the production of red blood cells. 5 OXFORD ENGLISH DICTIONARY 383 (2d ed. 1985).

73. 706 F. Supp. 94 (D. Mass. 1989).

74. *Id.* at 97.

75. DNA is the genetic material that, by the sequence of its component parts, provides a coded message to a cell to produce a specific protein (e.g., EPO). When DNA from one source (e.g., human) is combined with the genetic material of another source (e.g., bacterial), recombinant DNA has been produced. This recombinant DNA can be used to produce the protein from the original source in the genetically altered cell. Recombinant EPO is the product of a genetically altered bacteria.

76. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 706 F.2d 94, 96 (D. Mass. 1989).

77. Homogeneous EPO refers to purified EPO that has been separated from all other substances. The characteristics of homogeneous EPO are described in Genetics Institute's patent and are indistinguishable from the characteristics of recombinant EPO.

78. Myers & Sibley, *Biotechnology in the Courts*, 40 SIM INDUSTRIAL MICROBIOLOGY NEWS 189, 191 (1990).

79. *Chugai Pharmaceutical Co.*, 706 F. Supp. at 95.

itute's patent.<sup>80</sup> In addition, the court found that Chugai had not infringed Amgen's patent because its patent did not contain claims on their process of manufacturing recombinant EPO.<sup>81</sup>

Amgen's problem arose when Amgen canceled its process claims in response to the patent examiner's opinion, formulated in light of the appeals court decision in *In re Durden*,<sup>82</sup> that the claim for the process of making EPO from a genetically altered cell was obvious.<sup>83</sup> However, whether *In re Durden* required Amgen to cancel its process claim (a decision that Amgen made before 1988), or whether it was just more expedient at the time is unknown.<sup>84</sup> "The scope of every patent is limited to the invention described in the claims contained in it."<sup>85</sup> Thus, when Amgen sought an exclusion order against the recombinant EPO made by Chugai in Japan<sup>86</sup> it had nothing to enforce against Chugai. There is no extraterritorial enforcement of United States patent laws.<sup>87</sup> Thus, Amgen's product patent for the genetically altered cells that express recombinant EPO was irrelevant to the use of similar cells in Japan. The Process Patent Act would have entitled Amgen to an exclusion order against Chugai's importation of recombinant EPO if Amgen's patent had contained claims for the process of making EPO from genetically altered cells.<sup>88</sup>

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80. *Id.* at 104.

81. *Id.* at 94.

82. 763 F.2d 1406 (Fed. Cir. 1985).

83. Myers & Sibley, *supra* note 78, at 192.

84. *Id.* at 199. Although it has been argued that *In re Durden* has prevented the protection of commercial interests in processes for the production of recombinant products, one should note that Genentech obtained claims for a process expressing a DNA sequence encoding for human tissue plasminogen activator in 1989 in U.S. Patent No. 4,853,330.

85. *Chugai Pharmaceutical Co.*, 706 F. Supp. at 99 (quoting *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510 (1917)).

86. *Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532 (Fed. Cir. 1990).

87. A. MILLER & M. DAVIS, *supra* note 6, at 132-33.

88. *U.S. Int'l Trade Comm'n*, 902 F.2d at 1533. Interestingly, Congress passed the Omnibus Trade Act during the course of the proceedings by the International Trade Commission on Amgen's complaint alleging that Chugai Pharmaceutical had violated section 337 of the Tariff Act of 1930. Because the Omnibus Trade Act stated that the amended section 1337 would apply to all pending ITC investigations, Amgen's complaint fell under section 1337(a)(1)(B)(ii). *Id.* at 1534.

### C. Text of the Boucher Bills<sup>89</sup>

The rulings in *In re Durden*<sup>90</sup> and *Amgen v. Chugai*<sup>91</sup> are viewed by some as obstacles to the development of the biotechnology industry in the United States.<sup>92</sup> This perception has led to the introduction of the Boucher Bills (H.R. 3957 and H.R. 5664).<sup>93</sup>

H.R. 3957 was introduced February 6, 1990, to amend United States patent laws. Its purpose was to (a) limit *In re Durden* by providing that "a process shall not be considered obvious . . . if an essential material used in the process is novel . . . and otherwise nonobvious . . . ,"<sup>94</sup> and (b) extend the Process Patent Act by making the importation of a product made using a biotechnological material patented in the United States an act of patent infringement.<sup>95</sup> The bill defines biotechnological material as ". . . a biologically engineered organism that is essential for the production of a product. Such term includes any host cell, DNA sequence, or vector."<sup>96</sup> On Septem-

89. The Boucher Bills refer to two resolutions sponsored by Rep. Rick Boucher, a Democrat from Virginia. These two resolutions were H.R. 3957 and H.R. 5664, *infra* note 88.

90. 763 F.2d 1406 (Fed. Cir. 1985) (the use of a novel starting material did not render an otherwise chemical process patentable).

91. 706 F. Supp. 94 (D. Mass. 1989) (the importation of a product made in Japan using genetically altered cells patented in the United States was not an infringement of the patented genetically altered cells).

92. *House Panel Examines Biotech Patent Legislation*, 40 Pat. Trademark & Copyright J. (BNA) No. 999, at 462 (Sept. 27, 1990) [hereinafter *House Panel*].

93. H.R. 3957, 101st Cong., 2d Sess. (1990); H.R. 5664, 101st Cong., 1st Sess. (1990).

94. H.R. 3957, 101st Cong., 2d Sess. § 1 (1990). Section 1 would amend 35 U.S.C. § 103 by adding at the end of the section the following new paragraph:

A process of making a product shall not be considered obvious under this section if an essential material used in the process is novel under section 102 and otherwise nonobvious under section 103.

95. *Id.* § 2(a),(b) (1990). Section 2(a) of the bill would amend section 337(a)(1)(B) of the Tariff Act of 1930 (19 U.S.C. 1337(a)(1)(B)) to explicitly grant the ITC jurisdiction to exclude products made abroad through the use of a biotechnological material covered by a valid and enforceable U.S. patent. Section 2(b) would add a new section 271(h) to Title 35 U.S.C. that would make such imports patent infringements.

96. H.R. 3957, 101st Cong., 2d Sess. § 2(b)(2)(e) (1990).

ber 18, 1990, Representative Boucher<sup>97</sup> introduced a revised, scaled-down version of H.R. 3957.<sup>98</sup> The new bill (H.R. 5664), entitled Process Patent Amendments Act of 1990, differs from H.R. 3957 by eliminating the provisions regarding the exclusion of imports made using patented biotechnological material.<sup>99</sup> This scaled-down version of the Boucher Bill (H.R. 5664) has won the general endorsement of the PTO and representatives of the biotechnology industry. Robert Armitage of the Upjohn Company said that his company favors H.R. 5664. He claimed that H.R. 5664's per se rule of nonobviousness for those process claims involving novel essential materials would reduce the search and examination burden before the PTO.<sup>100</sup> However, there is little chance that the bill will be passed until after Amgen and Chugai Pharmaceutical have settled their legal differences. Furthermore, the bill would affect the outcome of only a fraction of patent applications because some of the processes that would be mandated as nonobvious under H.R. 5664 would also be found nonobvious under existing law.<sup>101</sup>

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97. Representative Rick Boucher is a Democratic congressman elected from the 9th district of Virginia. He is a member of the Judiciary Committee on Intellectual Property.

98. *House Panel, supra* note 92, at 463 (Sept. 27, 1990).

99. H.R. 5664, 101st Cong., 2nd Sess. § 2 (1990). This section would amend 35 U.S.C. § 103 by adding the following paragraph to it:

When a process of making or using a machine, manufacture, or composition of matter is sought to be patented in the same application as such machine, manufacture, or composition of matter, such process shall not be considered as obvious under this section if such machine, manufacture, or composition of matter is novel under section 102 and nonobvious under this section. If the patentability of such process depends upon such machine, manufacture, or composition of matter, then a single patent shall issue on the application.

Section 2 of H.R. 5664 is similar, although more limited in scope, than section 1 of H.R. 3957. *See supra* note 94. The major change made in H.R. 5664 was the elimination of section 2 of H.R. 3957, which would have excluded imports made using United States patented biotechnological materials. Section 2 of H.R. 3957 would have amended both the Tariff Act of 1930 (H.R. 3957 § 2(a)) and Title 35 of the United States Code (H.R. 3957 § 2(b)). *See infra* note 102 and accompanying text. The elimination of proposed amendments to section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) was particularly welcomed by the administration, since section 337 is currently the subject of extensive negotiations within the General Agreement on Tariffs and Trade (GATT).

100. *House Panel, supra* note 92, at 464.

101. Myers & Sibley, *supra* note 78, at 201.

## IV. SECTION 337 OF THE TARIFF ACT OF 1930

*A. Background*

Section 337 of the United States Tariff Act of 1930 (Section 337)<sup>102</sup> provides another mechanism for excluding imports made with pirated processes from the United States marketplace. Section 337 empowers the United States International Trade Commission (ITC) to investigate alleged "unfair methods of competition and unfair acts in the importation of articles into the United States."<sup>103</sup>

Patent infringement was first held to be an unfair act under section 316 of the Tariff Act of 1922 (the predecessor of Section 337).<sup>104</sup> Since 1925, patent infringement has been consistently considered an unfair act under the tariff laws.<sup>105</sup> In fact, the majority of Section 337 investigations have been patent infringement cases.<sup>106</sup> Prior to 1988 and the passage of the Process Patent Act, Section 337 investigations represented the only domestic relief available to companies whose process patents had been infringed.<sup>107</sup> Section 337a of the Tariff Act,<sup>108</sup> which was amended by the Omnibus Trade Act, protected process patents by treating the infringement of a patented process the same as an infringement of a patented product.<sup>109</sup> At that time, process patent rights were given protec-

102. Tariff Act of 1930, ch. 497, title III § 337, 46 Stat. 703 (1930) (currently codified in 19 U.S.C. § 1337 (1988)).

103. 19 U.S.C. § 1337(a)(1)(A).

104. Tariff Act of 1922, ch. 356, § 316(a), 42 Stat. 943 (1922) (current version at 19 U.S.C. § 1337 (1988)). See Clark, *supra* note 1, at 1157.

105. Clark, *supra* note 1, at 1156.

106. Tarrif Act of 1922, ch. 356, § 316(a), 42 Stat. 943 (1922) (current version at 19 U.S.C. § 1337 (1988)).

107. Gould, *supra* note 7, at 354.

108. Act of July 2, 1940, ch. 515, 54 Stat. 724 (1940), *repealed by* Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, title I, § 1342(c), 102 Stat. 1107, 1215.

109. *Id.* Although no longer in effect, section 337(a) declared:

The importation hereafter for use, sale, or exchange of a product made, produced, processed, or mined under or by means of a process covered by the claims of any unexpired valid United States letters patent, whether issued heretofore or hereafter, shall have the same status for the purposes of section

tion under section 337a that was not available under United States patent law.<sup>110</sup> Passage of the Process Patent Act has corrected this dichotomy.<sup>111</sup>

In 1988, Congress enacted sweeping changes in section 337 of the Tariff Act of 1930 as part of the Omnibus Trade Act.<sup>112</sup> There are four major changes that have lessened the burden for domestic industries in pursuing actions before the ITC:

(1) the elimination of the economic injury requirement in intellectual property cases,<sup>113</sup>

(2) the broadened definition of domestic industry beyond its former judicially created definition to include non-production related activities (e.g., significant plant or equipment investment, significant labor or capital, or substantial investment in research and development, or licensing activities),<sup>114</sup>

(3) the elimination of the requirement to show that an industry in the United States is "efficiently and economically operated;"<sup>115</sup> and,

(4) the shortening of the deadline to ninety days for the Commission to decide whether to grant temporary relief.<sup>116</sup>

Although the implementation of the Section 337 amendments will make procedures more expeditious and less costly, these amendments will also allow foreign owners of United States intellectual property rights to use the statute for the first time provided that they satisfy the less-stringent definition of domestic industry.<sup>117</sup> However, it will take the experience

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337 of the Tariff Act of 1930 as the importation of any product or article covered by the claims of any unexpired valid United States letters patent.

110. Gould, *supra* note 7, at 354.

111. Process Patent Amendments Act, Pub. L. No. 100-418, 102 Stat. 1107, 1563-67 (1988), as codified in 35 U.S.C. §§ 154, 271, 287, and 295.

112. *AIPLA Annual Meeting Turns to International Considerations*, 37 Pat. Trademark & Copyright J. (BNA) No. 905, at 52 (Nov. 10, 1988) [hereinafter *AIPLA Annual Meeting*].

113. Clark, *supra* note 1, at 1152.

114. *AIPLA Annual Meeting*, *supra* note 112, at 52.

115. Clark, *supra* note 1, at 1152.

116. *AIPLA Annual Meeting*, *supra* note 112, at 52.

117. *Id.*

of several cases under the new statute to determine the impact of this legislation.

### *B. The Administrative Process*

Section 337 protects intellectual property rights from infringing imports by providing a remedy for unfair methods of competition (e.g., patent infringement).<sup>118</sup> When a complaint is filed with the ITC, an administrative law judge holds a preliminary hearing to examine the issues of the case and make an initial determination whether Section 337 has been violated.<sup>119</sup> The full ITC either accepts that initial determination or decides to review it.<sup>120</sup> Once the ITC makes its decision and recommends relief, the President of the United States has sixty days to intervene and disapprove of the ITC's actions for policy reasons.<sup>121</sup> If the President approves the ITC's decision or does not respond within sixty days, the decision becomes final.<sup>122</sup>

The responsibility of enforcing exclusion orders issued by the ITC lies with the Secretary of the Treasury.<sup>123</sup> This duty has been delegated to the United States Customs Service, which automatically enforces all exclusion orders issued.<sup>124</sup>

### *C. GATT Considerations*

An international dispute has arisen over whether Section 337 conflicts with United States obligations under the General Agreement on Tariffs and Trade (GATT). This dispute arose from a patent dispute between Akzo, a Netherlands company,

118. Comment, *Section 337 and GATT in the Akzo Controversy: A Pre- and Post-Omnibus Trade and Competitiveness Act Analysis*, 9 NW. J. INT'L L. & BUS. 382, 385 (1988).

119. Clark, *supra* note 1, at 1155.

120. *Id.*

121. *Id.* See also 19 U.S.C. § 1337(g) (1988).

122. Comment, *supra* note 118, at 385.

123. 19 U.S.C. § 1337(e) (1988). "The Commission shall notify the Secretary of the Treasury of its action [exclusion order] under this subsection directing such exclusion from entry, and upon receipt of such notice, the Secretary shall, through the proper officers, refuse such entry. . . ." *Id.*

124. *U.S.T.R.'s Proposed Patent Law Reforms Concerning Infringing Imports*, 39 Pat. Trademark & Copyright J. (BNA) No. 967, at 272 (Feb. 8, 1990) [hereinafter *U.S.T.R.'s Proposed Reforms*].

and Du Pont.<sup>125</sup> Du Pont sought an exclusion order prohibiting the importation of Akzo's aramid fibers, produced abroad by a process for which Du Pont held a United States patent.<sup>126</sup> In 1985, the ITC held that Du Pont's process patent had been infringed and issued a limited exclusion order.<sup>127</sup> In *Akzo N.V. v. United States International Trade Commission*,<sup>128</sup> the Court of Appeals for the Federal Circuit (CAFC) affirmed ITC's Section 337 exclusion order. Akzo then filed a complaint with the European Economic Community (EEC).<sup>129</sup> In response to this complaint, a GATT panel was established to examine claims that differences in procedure under Section 337<sup>130</sup> of the Tariff Act of 1930 accorded imported products less favorable treatment than that accorded domestic products in conflict with GATT.<sup>131</sup> The GATT panel found Section 337 discriminatory for the following reasons:

- (1) United States patent owners have a choice of forum (i.e., United States district courts or the ITC) in which to challenge imported products, whereas there is no choice of forum for litigating against domestic products;
- (2) Section 337 imposes fixed time limits on ITC determinations, whereas United States district courts do not

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125. Comment, *supra* note 118, at 387.

126. Clark, *supra* note 1, at 1178.

127. Abbott, *GATT Dispute Settlement Panel*, 84 AM. J. INT'L L. 274, 275 (1990).

128. 808 F.2d 1471 (Fed. Cir. 1986), *cert. denied*, 402 U.S. 909 (1987).

129. Abbott, *supra* note 127, at 275.

130. The panel considered not only Section 337 itself, but also Section 337(a) (19 U.S.C. § 1337(a) (1988)) which extended the application of Section 337 to imported products manufactured using a process patented in the United States. The findings of the panel are limited to Section 337 as it stood in October 1987, when the panel was established; however, the panel's findings are also applicable to Section 337(a). See Abbot, *supra* note 127, at 275.

131. The GATT panel found that certain aspects of Section 337 did provide less favorable treatment to imports than to products of domestic origin and are inconsistent with GATT Article III. Article III provides that:

The products of the territory of any contracting party imported into the territory of any accorded treatment no less favorable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution, or use. . . .

General Agreement on Tariffs and Trade, *opened for signature* Oct. 30, 1947, 61 Stat. A3. T.I.A.S. No. 1700, 55 U.N.T.S. 187 [hereinafter GATT].

- have fixed time limits;
- (3) counterclaims cannot be raised in Section 337 proceedings, whereas they can in United States district court;
- (4) general exclusion orders are available under Section 337, whereas no comparable remedy is available against infringing products of United States origin;
- (5) ITC's exclusion orders are automatically enforced by United States Customs Service; and,
- (6) producers or importers of products manufactured abroad may have to defend their products both before the ITC and the United States district court.<sup>132</sup>

The GATT panel further found that both the automatic enforcement of exclusion orders by the United States Customs Service and the issuance of general exclusion orders may sometimes be justified to secure compliance with United States patent laws. Thus, these issues were excepted from GATT obligations pursuant to Article XX.<sup>133</sup>

Initially the United States criticized the reasoning of the panel and repeatedly blocked the adoption of the panel report.<sup>134</sup> Finally in November 1989, the United States withdrew its opposition and the GATT Council adopted the report.<sup>135</sup> However, in a memorandum to the United States Trade Representative, President Bush stated that pending enactment of legislation amending Section 337, the Administration would

132. *U.S.T.R.'s Proposed Reforms*, *supra* note 124, at 272.

133. Article XX provides for general exceptions to all GATT provisions, including Article III. *See* GATT, *supra* note 131. Article XX provides in pertinent part that:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: I. (d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, . . . the protection of patents, trademarks and copyrights. . . .

*Id.*

134. Abbott, *supra* note 127, at 279.

135. *Id.*

continue to enforce Section 337 without change.<sup>136</sup> Yet, if the United States does not implement the GATT Council's recommendations within a reasonable period of time, the United States may face retaliation against United States goods by a suspension of GATT concessions leading to higher tariffs for certain items.<sup>137</sup> Thus, patent owners contemplating bringing Section 337 actions must realize that the future of patent-based Section 337 investigations is uncertain.

#### V. EXCLUDING IMPORTS MANUFACTURED WITH PIRATED UNITED STATES PROCESSES

A patent gives the patentee the exclusive right to make, use, or sell his invention.<sup>138</sup> Acts of patent infringement are defined by federal law,<sup>139</sup> and both United States and foreign nationals are subject to suit for patent infringement in federal district court. However, potential jurisdictional and enforcement problems have often led to the use of Section 337 for enforcement of patent rights against infringing imports.<sup>140</sup> A Section 337 investigation, considering patent infringement as an unfair act,<sup>141</sup> follows the same body of statutory and judicially derived patent law as would be applied in any district court patent litigation.<sup>142</sup> Although in many respects ITC patent infringement investigations are similar to district court infringement actions, there are several distinct differences in the two actions.<sup>143</sup>

First, a patent infringement action must be brought against the infringer, which requires in personam jurisdiction.<sup>144</sup> Although the ITC needs in personam jurisdiction for a cease and

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136. *U.S.T.R.'s Proposed Reforms*, *supra* note 124, at 271.

137. *Id.* at 273.

138. 35 U.S.C. § 154 (1988).

139. 35 U.S.C. § 271 (1988).

140. *U.S.T.R.'s Proposed Reforms*, *supra* note 124, at 272.

141. Clark, *supra* note 1, at 1156.

142. *Id.* at 1157.

143. *U.S.T.R.'s Proposed Reforms*, *supra* note 124, at 272.

144. Comment, *supra* note 118, at 387. In personam jurisdiction is jurisdiction over the person. Thus the court can subject an individual to its decision-making power only if the individual is personally served with process within the tribunal's territory or if the individual consents to the court's jurisdiction. See *id.* at 387, n.48.

desist order,<sup>145</sup> the question of personal jurisdiction is irrelevant to the exclusion of goods pursuant to Section 337.<sup>146</sup> Thus, if various importers bring the infringing goods into the country through different ports, the patentee might have to file a patent infringement action for injunctive relief in the district court for each port. Because the ITC has *in rem* jurisdiction over the imports, a Section 337 petitioner can avoid potential jurisdiction problems.<sup>147</sup> In addition, an ITC exclusion order that is automatically enforced by the United States Customs Service enables petitioners to avoid the burden of enforcing district court injunctions against a variety of importers and decreases the policing costs for the petitioner.<sup>148</sup>

Secondly, ITC relief can be considerably faster than comparable federal court determinations.<sup>149</sup> The Commission must, by statute, conclude its investigation and make a determination within a year,<sup>150</sup> unless the case is declared to be a "more complicated case." Even if the case is declared "more complicated," the investigation must be completed within eighteen months.<sup>151</sup> By contrast, federal court patent litigation can drag

145. *Id.* at 387.

146. *Sealed Air Corp. v. United States Int'l Trade Comm'n*, 645 F.2d 976 (C.C.P.A. 1981).

An exclusion order operates against goods, not parties. Accordingly, that order was not contingent upon a determination of personal or "in personam" jurisdiction over a foreign manufacturer. The Tariff Act of 1930 (Act) and its predecessor, the Tariff Act of 1922, were intended to provide an adequate remedy for domestic industries against unfair methods of competition and unfair acts instigated by foreign concerns operating beyond the *in personam* jurisdiction of domestic courts.

147. Comment, *supra* note 118, at 387. *In rem* jurisdiction is jurisdiction over the thing (i.e., imported goods) within its territory. Since the Commission's jurisdiction operates on the thing, its decision does not bind the parties but settles the dispute over the property. *See id.* at 387, n.50.

148. *Id.*

149. Abbott, *supra* note 127, at 277.

150. 19 U.S.C. § 1337(b)(1) (1988). "The Commission shall conclude any such investigation, and make its determination under this section, at the earliest practicable time, but not later than one year (18 months in more complicated cases) after the date of publication of notice of such investigation." *Id.*

151. 19 U.S.C. § 1337(b)(1) (1988). "The Commission shall publish in the Federal Register its reasons for designating any investigations as a more complicated investigation." *Id.*

on for years.<sup>152</sup> The accelerated proceedings of the ITC can decrease the time of uncertainty about the rights involved and can help minimize the injury.<sup>153</sup>

Third, the nature and scope of the remedies available from the courts and the ITC are different.<sup>154</sup> For example, unlike federal district court patent litigation, damages are not awarded to a successful plaintiff in a Section 337 investigation.<sup>155</sup> ITC-imposed remedies are limited to exclusion orders and cease and desist orders.<sup>156</sup> An exclusion order can be limited in scope (i.e., cover specified goods from identified parties) or, when appropriate, it can be general (i.e., encompass the importation of all goods within the scope of the order even if the importer and manufacturer of the infringing goods were not parties to the case before the ITC).<sup>157</sup> Thus, a United States firm may obtain a total cessation of all infringing imports from a single case.<sup>158</sup> In addition to, or in lieu of an exclusion order, the Commission may issue a cease and desist order. Cease and desist orders prohibit specified activities relating to goods covered by the order (e.g., importation or sale of infringing goods).<sup>159</sup>

Finally, the public interest plays a role in Section 337 actions that is not present in district court patent litigation. Even if the ITC determines that there has been a Section 337 violation, it can decide not to provide a remedy if the ITC determines that a remedy would be against public interest.<sup>160</sup> Furthermore, the President can nullify a Section 337 remedy for policy reasons, whereas it is unconstitutional for him to review judicial decisions.<sup>161</sup>

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152. Comment, *supra* note 118, at 406.

153. *Id.* at 406-07.

154. *U.S.T.R.'s Proposed Reforms, supra* note 124, at 273.

155. Liebeler & Lowry, *Changing § 337, for Better or for Worse*, 7 *THE COMPUTER LAW*. 1 (July, 1990).

156. *U.S.T.R.'s Proposed Reforms, supra* note 124, at 271.

157. *Id.* at 273.

158. Comment, *supra* note 118, at 407.

159. *U.S.T.R.'s Proposed Reforms, supra* note 124, at 273.

160. 19 U.S.C. §§ 1337(d)-(f) (1988).

161. *Id.* § 1337(j).

## VI. CONCLUSION

The Omnibus Trade and Competitiveness Act of 1988<sup>162</sup> had a significant impact on process patentees' options in prohibiting the importation of goods made abroad with their patented processes. The Process Patent Act<sup>163</sup> (contained within the Omnibus Trade Act) amended United States patent law to make the importation of products made outside of the United States with United States patented manufacturing processes an act of infringement. Since patent infringement is actionable in federal courts, the Process Patent Act created a new forum in which process patent holders could challenge imported products.

Prior to 1988, the only option available to the process patent owner was to file a claim with the ITC under Section 337 of the Tariff Act of 1930. Although Section 337 proceedings have both advantages and disadvantages over United States district court infringement actions, the major impact of the Process Patent Act was to allow process patent owners not only a choice of forum (i.e., federal courts or the ITC) but also the option of filing concurrent claims with the United States district court and the ITC.

The Omnibus Trade Act also made sweeping changes in Section 337 of the Tariff Act of 1930. These changes make exclusion orders from the ITC under Section 337 a less costly and more attractive option for patent holders. However, the increased availability of Section 337 actions to the domestic patent owner will undoubtedly increase the visibility of Section 337 actions to the international community and accentuate the necessity for finding an effective GATT-consistent Section 337-type mechanism. However, even if Section 337 actions become discontinued in response to the GATT panel's criticism, the enactment of the Process Patent Act has ensured a right of action in the federal courts for process patent owners against infringing imports.

*Elizabeth R. Hall*

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162. *See supra* note 2.

163. *See supra* note 3.