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# Protecting the High-Tech Frontier: The Need for Stronger Process Patent Laws

Bruce Kramer

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# PROTECTING THE HIGH-TECH FRONTIER: THE NEED FOR STRONGER PROCESS PATENT LAWS

On July 28, 1987, President Reagan addressed an audience of more than 1,000 scientists, businessmen, and government officials at a federal conference concerning the commercial applications of superconductivity. Calling recent laboratory breakthroughs historic, the President pointed out that "for the promise of superconductivity to become real, it must bridge the gap from the laboratory to the marketplace; it must make the transition from a scientific phenomenon to an everyday reality, from a specialty item to a commodity." To help accomplish the goal of commercializing superconductivity, President Reagan announced an eleven-point initiative. One part of the plan involves strengthening U.S. patent laws to increase protection for new manufacturing processes. Specifically, the proposed patent law changes would allow companies to recover damages when imported products are made via patented processes.

The reason for the concern over process patents is the tremendous economic potential of superconductivity and other areas of high technology. Superconductivity, the ability of a material to lose all of its electrical resistance and thus carry a current without any dissipation of energy, is a scientific phenomenon that will change the world.<sup>5</sup> However, until recently, scientists had been able to achieve superconductivity only when the superconducting material was kept at extremely low temperatures. The low temperature requirement made superconductivity prohibitively expensive for virtually all practical applications. Now, though, a number of discoveries have elevated the temperature at which superconductivity can be achieved.<sup>6</sup> These temperature increases have brought within reach advanced technologies ranging from fusion energy to magnetically levitated trains.<sup>7</sup> The practical applications will result in an economic boon to whomever

<sup>&</sup>lt;sup>1</sup> For the full text of Ronald Reagan's remarks, see Federal Conference on Commercial Applications of Superconductivity, 23 WEEKLY COMP. PRES. DOC. 867 (July 28, 1987) [hereinafter cited as Federal Conference]. For reports on the conference and the federal government's support for superconductivity development, see Crawford, White House Spotlights New Superconductors, 237 SCIENCE 593 (1987); Hartley, No Resistance to Superconductivity, 132 Sci. News 848 (1987); Greenwald, Frenzied Hunt for the Right Stuff, TIME. Aug. 10, 1987, at 26.

<sup>&</sup>lt;sup>2</sup> Federal Conference, supra note 1, at 869.

<sup>3</sup> Id.

<sup>4</sup> Id.

<sup>&</sup>lt;sup>5</sup>A number of articles have been written about the potential impact of superconductivity. For various perspectives on the subject, see e.g., Lemonick, Superconductors!, TIME, May 11, 1987, at 64; Wilson & Port, The New World of Superconductivity, Bus. Wk., Apr. 6, 1987, at 98 [hereinafter cited as Wilson & Port]; Hartley, High Temperature Superconductivity: What's Here, What's Near and What's Unclear, 132 Sci. News 106 (1987).

<sup>&</sup>lt;sup>6</sup>The pace of discovery has been amazingly rapid, especially when one considers the feeling of hopelessness that had previously prevailed in the scientific community in regard to the prospects of high temperature superconductivity. For articles chronicling the advances through superconductivity temperature barriers, see e.g., Lemonick, Superconductivity Heats Up, TIME, Mar. 2, 1987, at 62; Smith & Davis, Our Life Has Changed, Bus. Wk., April 6, 1987, at 94; Cook, Seeking the Perfect Wire, U.S. News & WORLD REP., May 11, 1987, at 66; Rogers, Getting Warmer..., Newsweek, July 6, 1987, at 42.

<sup>&</sup>lt;sup>7</sup> Wilson & Port, supra note 5, at 99.

can successfully bring superconductivity out of the laboratory and into the marketplace.8

And superconductivity is not the only technology which holds great promise for the future. Biotechnology has already begun to yield commercial products and should play a major role in improving world health. Fiber optics will continue to make communications technology more efficient. Ceramics will see increased use in high temperature applications such as jet engines. New polymers will result in strong yet lightweight products. Many high technological innovations will also improve the quality of life in the future.

But difficulties exist in transforming these technological possibilities into realities. Aside from scientific and engineering problems, legal obstacles stand in the way of technological development. One major legal impediment is the lack of protection afforded by U.S. process patent laws. All too often, foreign companies infringe on process patents obtained by American companies. For example, Sohio developed a process to manufacture ceramic heat seals for turbine engines and obtained a patent on it, but Japanese competitor Kyocera soon entered the market with a similar process. Other major companies which claim their process patents have been violated include Allied-Signal, Corning Glass Works, Schering-Plough, Merck, and DuPont. Odeter foreign companies from infringing on U.S. process patents in the future, it is clear that action must be taken to strengthen process patent protection.

#### PROCESS PATENT LAW

In order to determine what changes would help improve protection for process patent holders, it is necessary to understand what process patent law is and how it reached its current state of development. An inventor may obtain a patent on "any new and useful process . . . or any new and useful improvement thereof. . . ."<sup>13</sup> A process may be defined as "an operation or series of steps leading to a result or a product rather than the product itself."<sup>14</sup> In *Cochrane v. Deener*,<sup>15</sup> the Supreme Court defined "process" as follows:

A process is a mode of treatment of certain materials to produce a given

<sup>&</sup>lt;sup>8</sup> For a business viewpoint on superconductivity, see Ramirez, Superconductors Get Into Business, FORTUNE, June 22, 1987, at 114; Levine, Venture Capital's New Gold Rush, Bus. WK., October 5, 1987, at 66.

<sup>&</sup>lt;sup>9</sup>Bronson, Loophole Closing Time, FORBES. May 4, 1987, at 144 [hereinafter cited as Bronson]. <sup>10</sup> Id.

<sup>11</sup> Rhein, Jr., Patent Pirates May Soon Be Walking the Plank, Bus. Wk., June 15, 1987, at 62.

<sup>1335</sup> U.S.C. § 101 (1982). This section lays out which types of inventions are patentable.

<sup>&</sup>lt;sup>14</sup>1 E. LIPSCOMB. LIPSCOMB'S WALKER ON PATENTS § 2:4 (3d ed. 1984). The statutory definition of a process is listed in 35 U.S.C. § 100(b): The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter or material.

<sup>1594</sup> U.S. 780 (1877). The case dealt with a patent on a process for sifting flour. http://ideaexchange.uakron.edu/akronlawreview/vol21/iss4/4

result. It is an act, or series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing. If new and useful, it is just as patentable as is a piece of machinery.<sup>16</sup>

However, the problem with process patents is not in obtaining them but rather in enforcing them. A process patent holder has the exclusive right to use or sell the process during the seventeen-year lifetime of the patent.<sup>17</sup> Anyone who uses the process within the United States during the term of the patent and without the permission of the patent holder has infringed on the patent.<sup>18</sup> Thus, a peculiar problem arises with process patents. A foreign manufacturer can use a patented process in an overseas plant and sell the resulting product back in the United States, assuming the product itself is not patented.<sup>19</sup> Of course, if the product is under patent, the aggrieved patent holder can sue for infringement on the product patent.<sup>20</sup> Often, though, the patented process is a new and improved method of manufacturing a product that is unpatented or whose patent has expired. Then, the process patent holder has no remedy under patent law.<sup>21</sup> Even if the product is patented, the process patent holder cannot obtain damages for the infringed process patent.<sup>22</sup>

Enka B.V. of Arnhem, Holland v. E.I. DuPont de Nemours<sup>23</sup> points out the problem of the process patent holder. Akzo, a competitor of DuPont, produced Arnitel, an industrial fiber similar to DuPont's patented Hytrel.<sup>24</sup> While DuPont could sue for infringement of its product patents,<sup>25</sup> the District Court held that in regard to DuPont's process patents, there would be no basis for an action against Akzo under 35 U.S.C. Section 271.<sup>26</sup> The court reasoned that since Akzo produced Arnitel in Holland, there was no infringement on DuPont's process patents in the United States.<sup>27</sup> The court noted the Supreme Court's statement in Deepsouth Packing Co. v. Laitram Corp.<sup>28</sup> that "it is not an infringe-

<sup>&</sup>lt;sup>16</sup> Id. at 788. See also O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853) (distinguishing a principle of nature from a process); Corning v. Burden, 56 U.S. (15 How.) 252 (1853) (producing a result "by chemical action, by the operation or application of some element or power of nature, or of one substance to another" is a process); Tilghman v. Proctor, 102 U.S. 707 (1880) (chemical process patent valid); Telephone Cases, 126 U.S. 1 (1887) (valid claim for a method of using electricity not for electricity itself).

<sup>1735</sup> U.S.C. § 154 (1982).

<sup>1835</sup> U.S.C. § 271(a) (1982).

<sup>&</sup>lt;sup>19</sup> 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, Importation].

<sup>&</sup>lt;sup>20</sup>35 U.S.C. § 271(a) (1982).

<sup>21</sup> Id.

<sup>22</sup> Id.

<sup>23 519</sup> F. Supp. 356 (D. Del. 1981), aff'd, 810 F.2d 1148 (Fed. Cir. 1987).

<sup>24</sup> Id. at 361.

<sup>25</sup> Id. at 362.

<sup>26 [</sup>d.

<sup>27</sup> Id.

<sup>&</sup>lt;sup>28</sup>406 U.S. 518 (1972).

ment to make or use a patented product outside of the United States."<sup>29</sup> From this statement, the District Court determined that the territorially limited protection given U.S. patents would not allow DuPont to sue in federal district court under 28 U.S.C. Section 1338 for process patent infringements occurring outside the United States.<sup>30</sup>

Because there is no remedy under patent law for process patent infringements occurring outside the United States, it might seem like there is no use in obtaining a process patent. The alternative to obtaining a process patent is keeping the process a secret.<sup>31</sup> However, trade secret protection is relatively weak in that it does not prevent use of the secret by independent inventors or those who discover the secret legally.<sup>32</sup> Because of improvements in analytical techniques, products resulting from secret processes are becoming more susceptible to reverse engineering, which can reveal the process by which the product was made.<sup>33</sup> Thus, the inventor must examine the individual circumstances surrounding the product and process and weigh the advantages and disadvantages of patent and trade secret protection in order to determine which route to take.<sup>34</sup> In this balancing test, it is important to remember that while a process patent does not protect the patent holder from infringement occurring outside the United States, it does offer protection against infringement within the United States.<sup>35</sup>

#### **EXISTING PROTECTION**

If an inventor does secure a process patent, the question still remains as to how the patent holder can deal with infringement on the patent outside the United States. Currently, an aggrieved process patent holder may seek relief before the U.S. International Trade Commission (ITC) under Section 337 of the Tariff Act of 1930.<sup>36</sup> The patent holder would claim that the importation of the product resulting from the process constitutes an unfair practice in import trade.<sup>37</sup> Section 337a of the Tariff Act states that, for purposes of Section 337, the importation of a product made "by means of a process covered by

<sup>&</sup>lt;sup>29</sup> Enka B.V. of Arnhem, Holland, 519 F. Supp. at 362 (citing Deepsouth Packing, 406 U.S. at 527).

<sup>&</sup>lt;sup>30</sup> Id. The reason DuPont cannot sue under § 1338 is because the court lacks subject matter jurisdiction in such instances.

<sup>&</sup>lt;sup>31</sup> Leuzzi, Process Inventions: Trade Secret or Patent Protection, 66 J. PAT. OFF. SOCY 159 (1984) [hereinafter cited as Leuzzi].

<sup>&</sup>lt;sup>32</sup> Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 490 (1974).

<sup>33</sup> Leuzzi, supra note 31, at 168.

<sup>34</sup> Id. at 159.

<sup>35 35</sup> U.S.C. § 271(a) (1982).

<sup>&</sup>lt;sup>36</sup> 19 U.S.C. § 1337(a) (1982). This section states:

Unfair methods of competition and unfair acts in the importation of articles into the United States, or in their sale by the owner, importer, consignee, or agent of either, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, or to prevent the establishment of such an industry, or to restrain or monopolize trade and commerce in the United States, are declared unlawful. . . .

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the claims of any unexpired valid United States letters patent, shall have the same status . . . as the importation of any product or article covered by the claims of any unexpired valid United States letters patent." Thus, process patent holders can use Section 337a to exclude imports made by the patented process in a manner similar to excluding importation of patented products.

Because Section 337 is currently the process patent holder's only recourse when goods produced by the process in a foreign country are imported into the United States,<sup>39</sup> it has become "an increasingly important weapon in the arsenal available to American industries seeking to reduce foreign competition."40 Section 337 provides several possible remedies for the aggrieved process patent holder. One remedy allows the patent holder to obtain a temporary exclusion order which prevents importation of products resulting from the process during the ITC investigation, unless the importer posts a bond set by the ITC and prescribed by the Secretary of the Treasury.41 A second remedy is a permanent exclusion order, which halts importation of products resulting from foreign use of a patented process, unless public health and welfare or competitive conditions in the United States outweigh the need for protection.<sup>42</sup> A permanent exclusion order results after the ITC determines from an investigation that a violation of Section 337 has occurred.<sup>43</sup> The final remedy is a cease and desist order, which is served on any person violating or believed to be violating Section 337.44 A cease and desist order differs in effect from exclusion orders in that it is directed only at the party or parties infringing on the process patent, while exclusion orders act in rem, affecting all importers.<sup>45</sup>

Unfortunately, the Section 337 remedies only allow the aggrieved party to limit the damage to what has already occurred by preventing further importation of the offending goods.<sup>46</sup> In this sense, Section 337 remedies act like injunctions.<sup>47</sup> While Section 337 remedies are better than nothing and are even

<sup>38</sup> Tariff Act of 1930, § 337(A).

<sup>&</sup>lt;sup>39</sup> Note, *Importation, supra* note 19, at 129. See also Safran, *Protection of Inventions in the Multinational Marketplace: Problems and Pitfalls in Obtaining and Using Patents*, 9 N.C.J. INTL L. & COM. REG. 117, 127-28 (1983) (contrasting contributory infringement and active infringement inducement with actual infringement). Safran points out that while actual infringement of a process must occur in the United States to come within the scope of 35 U.S.C. § 271(a), active infringement inducement and contributory infringement do not need to occur within the United States to fall under the purview of 35 U.S.C. § 271(b) and (c), respectively.

<sup>&</sup>lt;sup>40</sup> Ablondi & Vent, Section 337 Import Investigations — Unfair Import Practices, 4 LOY. L.A. INT'L & COMP. L.J. 27, 27-28 (1981) [hereinafter cited as Ablondi & Vent].

<sup>&</sup>lt;sup>41</sup> 19 U.S.C. § 1337(e) (1982). The ITC held in Certain Luggage Products, Investigation No. 337-TA-39 (1978), that this remedy "is an extraordinary measure and should only be issued under the most compelling circumstances."

<sup>42 19</sup> U.S.C. § 1337(d) (1982).

<sup>43</sup> Id.

<sup>44 19</sup> U.S.C. § 1337(f) (1982).

<sup>&</sup>lt;sup>45</sup>Brunsvold, Analysis of the United States International Trade Commission as a Forum for Intellectual Property Disputes, 60 J. PAT. OFF. SOCY 505, 507 (1978) [hereinafter cited as Brunsvold].

<sup>46</sup> Id. at 508.

advantageous in some ways,<sup>48</sup> they still do not provide monetary relief for the damage already done.<sup>49</sup> Thus, while domestic manufacturers have increasingly relied on Section 337 to fight unfair trade in recent years,<sup>50</sup> more needs to be done to turn the tide in the trade war.

#### LEGISLATING ADDITIONAL PROTECTION

With the trade deficit mounting, Congress is under pressure to take corrective action. A major focus of Congressional efforts is process patent protection. Congress has tried to deal with the process patent problem on a number of occasions in recent years. However, it has not been able to reach a consensus, and as a result, process patent reform remains a live issue.

### Process Patent Bills in the 100th Congress

Because Congress realizes that it is the branch of government that can solve the process patent problem,<sup>54</sup> a number of bills have been proposed in the 100th Congress. Out of all the bills, two have emerged from the fray and are currently under consideration. These bills are H.R. 1931,<sup>55</sup> which replaced H.R. 1718<sup>56</sup> as the House bill revising existing process patent law, and S. 1200,<sup>57</sup> which replaced S. 568,<sup>58</sup> S. 573,<sup>59</sup> and S. 635<sup>60</sup> as the Senate bill amending current process patent law.

H.R. 1931 and S. 1200 are similar in many ways and even identical in some respects. Both seek to amend 35 U.S.C. Section 154 by specifically giving owners of process patents "the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process." Under existing patent law, the patentee only has "the right to exclude others from making, using, or selling the invention throughout the United

<sup>&</sup>lt;sup>48</sup> Note, Importation, supra note 19, at 152.

<sup>49</sup> Brunsvold, supra note 45, at 508.

<sup>50</sup> Ablondi & Vent, supra note 40, at 42.

<sup>&</sup>lt;sup>51</sup> Roberts, *Process Protection Tops Agenda for Patent Law Reform*, L.A. Daily J., Apr. 8, 1987, at 1, col. 2 [hereinafter cited as Roberts].

<sup>&</sup>lt;sup>52</sup> For a recap of the Congressional attempts at process patent reform during the last three Congresses, see H.R. Rep. No. 60, 100th Cong., 1st Sess. 11-12 (1987) [hereinafter cited as H.R. Rep.]. This report accompanies H.R. 1931, the House of Representatives' latest bill on process patents.

<sup>53</sup> H.R. REP., supra note 52, at 11-12.

<sup>54</sup> Id. at 6.

<sup>55</sup> H.R. 1931, 100th Cong., 1st Sess. (1987).

<sup>&</sup>lt;sup>56</sup>H.R. 1781, 100th Cong., 1st Sess. (1987).

<sup>&</sup>lt;sup>57</sup> S. 1200, 100th Cong., 1st Sess. (1987).

<sup>58</sup> S. 568, 100th Cong., 1st Sess. (1987).

<sup>&</sup>lt;sup>59</sup> S. 573, 100th Cong., 1st Sess. (1987).

<sup>60</sup> S. 635, 100th Cong., 1st Sess. (1987).

States,"62 which limits the scope of process patent protection to infringements taking place within the United States. The proposed language in the House and Senate bills attacks the heart of the process patent problem by extending the coverage of 35 U.S.C. Section 154 to include imported products resulting from infringement of the process patent outside the United States. The amendment necessarily targets the imported products resulting from the patented process rather than the overseas infringing process itself, because of the well-recognized doctrine that one nation's laws should not govern conduct occurring in other countries — to do otherwise would conflict with fundamental principles of national sovereignty.<sup>63</sup>

In protecting the rights of process patent owners, it is necessary to determine who is liable for infringement. The House and Senate bills amend 35 U.S.C. Section 271 by adding a subsection (g) which states in part that "[w]hoever 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." 64

Because a number of parties would be liable as infringers but not all would be equally culpable from an equitable standpoint, the bills specify which parties the aggrieved patent holder should look to first. H.R. 1931 states that "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 Act for infringement on account of the importation or other sale of that product."65 S. 1200 provides that "no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use or sale of that product."66 The House bill forces the patent holder to look to the importer and wholesaler first because they are the "more involved" parties.<sup>67</sup> The Senate bill allows the patent holder to look in the first instance to the commercial user of the product also. The Senate Judiciary Committee differentiated between non-commercial users like "the patient who consumes a drug product or a home gardener who sprays a pesticide"68 and commercial users who use "a product produced by an allegedly infringing process in the production of another product. . . . "69 The bills also prevent the process patent holder

<sup>6235</sup> U.S.C. § 154 (1982).

<sup>63</sup> H.R. REP., supra note 52, at 13 (imported products).

<sup>64</sup> H.R. 1931, 100th Cong., 1st Sess. § 3 (1987); S. 1200, 100th Cong., 1st Sess. Title I § 102 (1987).

<sup>65</sup> H.R. 1931, 100th Cong., 1st Sess. § 3 (1987).

<sup>66</sup> S. 1200, 100th Cong., 1st Sess. Title I § 102 (1987) (emphasis added).

<sup>67</sup> H.R. REP., supra note 52, at 13.

<sup>68</sup> S. REP. No. 83, 100th Cong., 1st Sess. 48 (1987) [hereinafter cited as S. REP.].

<sup>69 11</sup> 

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from looking initially to the retailer who sells the product resulting from the patented process. Again, the rationale is the lesser degree of involvement by the retailer as compared to the importer or wholesaler.<sup>70</sup>

The House and Senate bills deny process patent liability altogether after the product resulting from the patented process is "materially changed by subsequent processes"<sup>71</sup> or becomes an insignificant component of another product.<sup>72</sup> The bills deny liability by considering the product not to have been made by the patented process and thus not infringing for purposes of the process patent law.<sup>73</sup> It is important to understand that the House and Senate Judiciary Committees intended limits to be placed on what constitutes a material change by subsequent processes or an insignificant component of another product.74 Hypothetical examples can clarify these limits. Considering an imported chemical X produced by a patented process and materially changed to produce a new chemical Y, the House committee states:

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.

<sup>&</sup>lt;sup>70</sup>H.R. REP., supra note 52, at 13; S.REP., supra note 68, at 48. The retail involvement factor may be further explained as follows:

Retailers buy and sell thousands of different products. For the most part, these are finished products, any one of which may have hundreds of components. Retailers have no way of knowing the source of many of these components, particularly for complex products. Generally, the merchandise has passed through several steps in the chain of distribution; from the manufacturer, to a wholesaler, then possibly to a distributor, and only then to the retailer. Process Patent Legislation: Hearing on S. 568, S. 573, and S. 635 Before the Subcomm. on Patents, Copyrights and Trademarks of the Senate Comm. on the Judiciary, 100th Cong., 1st Sess. 69 (1987) (statement of the National Retail Merchants Association) [hereinafter cited as Hearing].

<sup>&</sup>lt;sup>71</sup>H.R. 1931, 100th Cong., 1st Sess. § 3 (1987); S. 1200, 100th Cong., 1st Sess. Title I § 102 (1987).

<sup>72</sup> The House bill uses "minor or nonessential" for the test of insignificance. H.R. 1931, 100th Cong., 1st Sess. § 3 (1987). "[T]rivial and nonessential" is the Senate version of insignificance. S. 1200, 100th Cong., 1st Sess. Title I § 102 (1987).

<sup>&</sup>lt;sup>73</sup>H.R. 1931, 100th Cong., 1st Sess. § 103 (1987); S. 1200, 100th Cong., 1st Sess. Title I § 102 (1987).

<sup>&</sup>lt;sup>74</sup>H.R. Rep., supra note 52, at 13-14; S.Rep., supra note 68, at 49-51. These limits are "critical to understanding the scope of this legislation." S.Rep., supra note 68, at 49. To resolve what could be a potentially difficult determination, courts would use a two-phased test:

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

<sup>2.</sup> A product will be considered to have been made by a patented process if the additional processing steps which are not covered by the patent do not change the physical or chemical properties of the product in a manner which changes the basic utility of the product by the patented process. However, a change in the physical or chemical properties of a product, even though minor, may be "material" if the change relates to a physical or chemical property which is an important feature of the product produced by the patented process. Usually, a change in the physical form of a product ... or minor chemical conversion . . . would not be a "material" change. *Id.* at 50. http://ideaexchange.uakron.edu/akronlawreview/vol21/iss4/4

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.<sup>75</sup>

The Senate committee also provides hypothetical examples to illustrate the intended limits:

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

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

If there are commercially viable non-infringing processes to have arrived at X, the connection between the patented process for producing chemical X and the ultimate product, chemical Y, is broken, and Y would be a non-infringing product.<sup>76</sup>

Using these hypothetical examples as guidelines, a court would determine whether an infringement had taken place.

Even if the court resolves in the affirmative the difficult question of whether infringement exists, damages may still be limited or even denied. 35 U.S.C. Section 287 states that when an item is not marked so as to give notice that it is under patent, "no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringe-

<sup>&</sup>lt;sup>75</sup>H.R. REP. supra note 52, at 13-14. Note the similarities in the House examples and the Senate two-phased test, supra note 74.

<sup>&</sup>lt;sup>76</sup>S.Rep., supra note 68, at 50. The hypothetical cases apply the two-phased test, supra note 74. Published by IdeaExchange@UAkron, 1988

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ment and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice." The House and Senate bills add to Section 287 a notice provision specifically covering process patent infringement. The notice provision applies to all infringers except those who used the patented process, are related by ownership or control to the one who used the patented process, or had knowledge before the infringement that a patented process was used to make the product involved in the infringement. The requirement of notice in process patent cases is necessary for parties like retailers because the products they receive are not marked as patented with respect to the process. Notification must be in writing and of a nature such that a party would become aware of the likelihood that a product was made by a patented process.

After notification, no remedies for infringement would be available for any product which was already in the possession of, or in transit to, the infringer before the infringer had notice.<sup>81</sup> The Senate bill also denies remedy to any product "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. . . ."<sup>82</sup> These allowances to infringers are tempered by the limitation that products maintained or ordered above normal levels are subject to remedy,<sup>83</sup> which avoids the harsh result of rewarding bad faith infringers while trying to protect innocent infringers for their infringement prior to notice.

In addition to modifying existing sections of the U.S. Code, the House and Senate bills would add a Section 295 to Title 35 creating in some infringement actions a rebuttable presumption that the product in question was made by the patented process.<sup>84</sup> The presumption takes effect if the court finds "that a substantial likelihood exists that the product was made by the patented process, and . . . that the claimant has made a reasonable effort to determine

<sup>7735</sup> U.S.C. § 287 (1982).

 $<sup>^{78}</sup>H.R.\ 1931,\ 100th\ Cong.,\ 1st\ Sess.\ \S\ 4(a)(3)\ (1987);\ S.\ 1200,\ 100th\ Cong.,\ 1st\ Sess.\ Title\ I\ \S\ 103(a)(3)\ (1987).$ 

<sup>&</sup>lt;sup>79</sup> H.R. 1931, 100th Cong., 1st Sess. § 4(a)(3) (1987); S. 1200, 100th Cong., 1st Sess. Title I § 103(a)(3) (1987).

<sup>&</sup>lt;sup>80</sup> H.R. 1931, 100th Cong., 1st Sess. § 4(a)(3) (1987); S. 1200, 100th Cong., 1st Sess. Title I § 103(a)(3) (1987). Prior to actual notification, S. 1200 sets out a complex procedure by which a process patent holder ascertains that the patent has been infringed. *Id.* This procedure includes a "request for disclosure" made by the patent holder to the alleged manufacturer to identify all process patents owned by or licensed to the manufacturer that the manufacturer believes could potentially result in an infringement. *Id.* The request for disclosure has been criticized because "there is no justification for putting a burden on patent owners to advise their competitors whether they might file a lawsuit in hypothetical situations" and the cost of answering a request for disclosure could be substantial. *Hearing, supra* note 70, at 113 (statement of Richard C. Witte, Proctor & Gamble Co., on behalf of Intellectual Property Owners, Inc., Chemical Manufacturers Association, and National Association of Manufacturers). The request for disclosure has been characterized as "fundamentally unfair," taking away property rights of one private party for the benefit of other private parties. *Id.* at 100 (statement of Robert C. Kline, President, American Intellectual Property Law Association).

<sup>83</sup> H.R. 1931, 100th Cong., 1st Sess. § 4(a)(3)(1987); S. 1200, 100th Cong., 1st Sess. Title I § 103(a)(3) (1987). http://ickgae1939.pn.1900th/Cong.lu/Istr3045wse5(a)/(1987); S4/1200, 100th Cong., 1st Sess. Title I § 104(a) (1987). 10

the process actually used in the production of the product and was unable so to determine. . . ."85 The House Judiciary Committee explained the need for the presumption as follows:

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 actually made by another method.<sup>86</sup>

#### Additional Discussion of the Process Patent Bills

The House and Senate bills represent a delicate balancing of competing interests. Foreign piracy of American technology hinders the ability of the United States to compete in the marketplace.<sup>87</sup> The lack of protection afforded process patents "is a loophole that should be closed."<sup>88</sup> The major stumbling block is that the process patent problem has become "a line drawing exercise" in determining how much protection innocent infringers like retailers should receive.<sup>89</sup>

In dealing with retailers, the House and Senate bills provide some protection by forcing process patent holders to look to retailers secondarily after importers and wholesalers. However, the bills have cut back other protection for retailers which had been present in previously proposed process patent legislation. In S. 568, retailers could have potentially received what amounted to an eighteen-month grace period after notification of infringement. This provision was criticized as "compulsory licensing" which has no place in U.S. patent law. The grace period "tilts the playing field against the patent owner ... by stripping him of any remedy for a period of eighteen months against infringers . . . who have been notified of their transgression." Because of

<sup>85</sup> H.R. 1931, 100th Cong., 1st Sess. § 5(a) (1987); S. 1200, 100th Cong., 1st Sess. Title I § 104(a) (1987).

<sup>&</sup>lt;sup>86</sup> H.R. Rep., supra note 52, at 16. See also S.Rep., supra note 68, at 57. The Senate Judiciary Committee noted that users and sellers could exert pressure on importers, who in turn could exert pressure on the manufacturer. Id.

<sup>&</sup>lt;sup>87</sup> Hearing, supra note 70, at 96 (statement of Robert C. Kline, President, American Intellectual Property Law Association).

<sup>88</sup> Roberts, supra note 51, at 1, col. 2 (quoting Michael Blomer of the American Patent Law Association).

<sup>89</sup> Id. (quoting Michael Blomer of the American Patent Law Association).

<sup>90</sup> See supra notes 65-70 and accompanying text.

<sup>91</sup> S. 568, 100th Cong., 1st Sess. § 2(c)(3) (1987).

<sup>&</sup>lt;sup>92</sup> Hearing, supra note 70, at 35 (statement of Donald J. Quigg, Assistant Secretary and Commissioner of Patents and Trademarks).

the patent unfairness of compulsory licensing, a grace period should not be included in process patent legislation, and the current House and Senate bills do not include it.

One interesting but vexing problem with process patent legislation has been the policy struggle between concerns of the pioneer and generic drug manufacturing industries.<sup>94</sup> A good policy argument exists in protecting a pioneer pharmaceutical manufacturer's huge investment in research and development and thus spurring the effort to discover new drugs.<sup>95</sup> Strong process patent laws would eliminate "the opportunity for copiers to avoid infringement and effectively obtain free use of U.S. research and development expenditures."<sup>96</sup> On the other hand, process patent legislation would result in the generic drug industry losing "significant access to overseas suppliers,"<sup>97</sup> thus impairing "the balance of competitive power between the generic and pioneer industries."<sup>98</sup> Competition from the generic companies is valuable to society because it makes drugs more affordable.<sup>99</sup> Process patent legislation must carefully weigh the competing policy interests of new drugs versus lower prices.

Opposition by the generic drug industry has created problems for process patent legislation in the past.<sup>100</sup> Although the generic drug industry seems to have viewed recent process patent legislation in a more favorable light,<sup>101</sup> law-makers should be wary of renewed opposition. If opposition does arise, perhaps Congress should consider reducing the scope of the legislation to avoid the possibility of another consensus-breaking confrontation. Giving special consideration to a particular industry is not unprecedented in patent law; the Drug Price Competition and Patent Term Restoration Act of 1984<sup>102</sup> is an example of custom-tailored patent legislation dealing with the same industry that has created difficulties in process patent legislation. By taking an industry dispute out of the legislative debate, the chances of the remaining bill to become law increase. However, protection of the pioneer drug industry and, in particular,

<sup>&</sup>lt;sup>94</sup> For an excellent discussion of the policy battle, see 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. 346, 348-50 (1987) [hereinafter cited as Gould].

<sup>95</sup> Id. at 348.

<sup>&</sup>lt;sup>96</sup> Hearing, supra note 70, at 56 (statement of Gerald J. Mossinghoff, President, Pharmaceutical Manufacturers Association).

<sup>97</sup> Gould, supra note 94, at 348.

<sup>98</sup> Id.

<sup>99</sup> Id.

<sup>100</sup> Id. at 347.

<sup>&</sup>lt;sup>101</sup> See Hearing, supra note 70, at 81-89 (statement of Alfred B. Engelberg, Patent Counsel, Generic Pharmaceutical Industry Association).

<sup>&</sup>lt;sup>102</sup> For a discussion of how the act fits into the overall policy battle between the pioneer and generic drug industries, see Gould, supra note 94, at 349-50.

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the biotechnology industry<sup>103</sup> is becoming increasingly important, and it would be best if the process patent legislation could pass intact.

#### Conclusion

The importance of stronger process patent protection must not be underestimated. It would help reduce the trade deficit<sup>104</sup> and protect American jobs.<sup>105</sup> Additionally, improving process patent laws would ultimately yield technologically superior products because "[b]etter protection fosters research and development."<sup>106</sup>

Besides the economic and technological advantages of stronger process patent laws, a sense of equity demands the increased protection. Consider the unfair outcome of Corning Glass Works' infringement claim against Sumitomo Electric Industries regarding Corning's process patent for manufacturing optical waveguide fibers.<sup>107</sup> Corning, which had spent almost twenty years and more than \$200 million on research and development for the technology, could not convince the court of economic damage because its plants were running at full capacity at the time.<sup>108</sup> The House Judiciary Committee recognized the harsh result which can occur from lack of process patent protection when it concluded:

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.<sup>109</sup>

The pace of technological advancement is accelerating. In response to this reality, other countries have passed process patent legislation. It is time the United States strengthened its process patent protection, too.

BRUCE KRAMER

<sup>&</sup>lt;sup>103</sup> See Hearing, supra note 70, at 24-32 (statement of Richard D. Godown, President, Industrial Biotechnology Association).

<sup>104</sup> Roberts, supra note 51, at 1, col. 2.

<sup>&</sup>lt;sup>105</sup> Hearing, supra note 70, at 106 (statement of Richard C. Witte, Proctor & Gamble Co., on behalf of Intellectual Property Owners. Inc., Chemical Manufacturers Association, and National Association of Manufacturers). "By protecting the owners of U.S. patents from free riders who have no R&D expenses, we can protect many thousands of jobs in the United States in industries that manufacture for the U.S. market and export markets." *Id.* at 106-07.

<sup>&</sup>lt;sup>106</sup>Bronson, supra note 9, at 145 (quoting Richard Agnich, General Counsel, Texas Instruments).

<sup>107</sup> Id. at 144.

<sup>108 [</sup>d

<sup>109</sup> H.R. REP., supra note 52, at 11.

<sup>110</sup> See S.Rep., supra note 68, at 31-35. A U.S. process patent holder could try to procure patents in as many countries as possible to protect the process. However, such protection would be "unrealistically expensive and largely ineffective because of the impossibility of obtaining adequate protection in all of the countries in which a process might be used." Hearing, supra note 70, at 37 (statement of Donald J. Published Assistant Secretary and Commissioner of Patents and Trademarks).