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## The Effectiveness of International Enforcement of Intellectual Property Rights, 37 J. Marshall L. Rev. 985 (2004)

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# THE EFFECTIVENESS OF INTERNATIONAL ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

ALLISON CYCHOSZ\*

“[A] country without a patent office and good patent laws [is] just a crab, and can’t travel any way but sideways or backways.”  
Mark Twain<sup>1</sup>

At a time when international patent law harmonization is at the forefront of international trade discussions, it is necessary to recognize not only the need for harmonization, but also the great need for international patent law enforcement. While harmonization has continued, the progress of international patent law enforcement has taken a backseat. Patent laws are useless without effective enforcement mechanisms. Until sufficient enforcement measures are adopted, patent holders will continue to see unchecked abuses against their valid patents.

This article focuses on the need for stronger enforcement of intellectual property (“IP”) rights at the international level, particularly on biotechnology patents and the current Human Genome Project (“HGP”). Part I of this article examines the development of the HGP and international patent law. Part II considers whether the current international enforcement mechanisms have been effective in protecting IP rights. Finally, Part III proposes changes to the current system to create stronger patent enforcement.

## I. BACKGROUND OF THE HUMAN GENOME PROJECT AND PATENT RIGHTS.

### A. *History of the Human Genome Project*

The HGP was created in response to the influx of new

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1. MARK TWAIN, *A CONNECTICUT YANKEE IN KING ARTHUR’S COURT* 64 (Harper & Brothers Publishers 1906) (1889).

technologies that emerged in the 1980s.<sup>2</sup> The National Institute of Health (“NIH”) and the Department of Energy (“DOE”) initiated the HGP in the United States (“U.S.”) in 1988.<sup>3</sup> The project was originally estimated to span up to fifteen years and cost three billion dollars.<sup>4</sup>

The HGP is an international effort to map the entire human genome sequence.<sup>5</sup> It started as a publicly funded, non-profit effort to create a public database of the 100,000 human genes to enable scientists all around the world to advance their research.<sup>6</sup> With each gene in the entire sequence identified, scientists would no longer have to search for the proverbial needle in a haystack when researching a particular disease.<sup>7</sup> With the identification of

2. Ari Patrinos & Daniel Drell, *Introducing the Human Genome Project: Its Relevance, Triumphs and Challenges*, at [http://www.ornl.gov/TechResources/Human\\_Genome/publicat/judges/drell.html](http://www.ornl.gov/TechResources/Human_Genome/publicat/judges/drell.html), ¶ 5 (last visited Feb. 20, 2004). Robert Mullan Cook-Deegan, *Origins of the Human Genome Project*, at <http://www.fplc.edu/risk/vol5/spring/cookdeeg.htm>, ¶¶ 9-15 (last visited Feb. 20, 2004). The government wanted to help the scientific community while also considering the potential for creation of jobs and wealth through technology. *Id.* ¶ 6.

3. Amy E. Carroll, Comment, *A Review of Recent Decisions of the United States Court of Appeals For the Federal Circuit: Comment: Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 AM. U. L. REV. 2433, 2434-35 (1995); Cf. Tim Symanietz, *Ethics, Business and the Human Genome Project*, at <http://www.ndsu.nodak.edu/instruct/mcclean/plsc431/students99/symanietz.htm>, ¶ 1 (1999) (last visited Feb. 20, 2004) (stating the HGP began in 1990). The NIH and DOE have several major goals including,

identify[ing] all the estimated 100,000 genes in the human genome[,] [m]ap[ping] the three billion chemical bases that make up human DNA[,] [s]tor[ing] this mapped information in databases worldwide[,] [d]evelop[ing] even better tools for sequencing and analysis[,] [and] [a]ddress[ing] the many ethical, legal and social issues that come with this project.

*Id.*

4. Symanietz, *supra* note 3.

5. Clare Saliba, *Cracking the Code* (Apr. 6, 2000), at <http://users.rcn.com/clarems/News/about031800.htm>. (last visited Apr. 2, 2004). The Human Genome Project was the intellectual “baby” of the United States and the United Kingdom. *Id.* It was an international effort to map and sequence the entire genome consisting of 3 billion letters and 100,000 genes making up the human genetic code. *Id.*

6. *Id.*

7. Symanietz & Drell, *supra* note 3, ¶ 2. All humans have genomes, which are the genetic instructions located on the twenty-three pairs of chromosomes in our bodies. Patrinos, *supra* note 2, ¶ 6. These chromosomes are 99.9% identical from one person to another. *Id.* The DNA molecules are made up of four parts, or building blocks, adenine, cytosine, guanine and thymine. *Id.* These four building blocks pair up, forming the DNA double helix. *Id.* Each human cell contains approximately six billion pairs, “three billion from each parent.” *Id.* However, it is estimated that merely one out of every thousand base pairs makes us different from each other. *Id.* “[W]hat we share dwarfs

the responsible genes, scientists have begun research to counteract and cure many diseases.<sup>8</sup> The HGP has resulted in a better understanding of the human genetic make-up, and has advanced the potential for drug discovery and development.<sup>9</sup>

In the U.S., the HGP was initially funded by the federal government, but in 1992 funding began to shift from government funded research facilities to privately funded institutes supported by private investments and public stock offerings.<sup>10</sup> In order for the shift from public to private funding to occur, private investors needed a way to recoup their investments in the project.<sup>11</sup> Research companies could not be expected to pour out enormous amounts of cash without some assurances of return.<sup>12</sup> As a result,

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what distinguishes us." *Id.*

8. Patrinos & Drell, *supra* note 2, ¶¶ 13-15. The HGP will allow scientists to identify the complete human DNA sequence so that scientists would "no longer have to do a needle in the haystack type of search for small genes[.]" Symanietz, *supra* note 3, ¶ 2. Another benefit of having the entire DNA sequence predetermined is enabling scientists to more effectively perform further research on the importance of the seemingly unimportant DNA contained in every human, i.e. the repeated DNA and the non-protein encoding DNA. *Id.* See Carl F. Cranor, *Are Genes Us?*, (1994) (discussing benefits of genetic mapping). For example, the gene found on chromosome four is responsible for Huntington's disease. *Id.* at 27. Chromosome nineteen has already been identified as contributing to the genetic defect of myotonic dystrophy as well as the aberrant triplet repeats which are known to be present at the onset "of at least nine diseases, including Huntington's disease." Patrinos & Drell, *supra* note 2, ¶ 13. Chromosome sixteen genes have been identified as contributing to "Batten's disease, polycystic kidney disease, Crohn's disease, forms of breast and prostate cancer and Fanconi's anemia, as well as many others." *Id.* In addition, "the DNA repair genes HHR23A, XRCC1 and ERCC2 as well as genes involved in olfactory receptors, Alzheimer's disease and one form of migraine headache have been discovered on chromosome 19." *Id.*

9. Patrinos & Drell, *supra* note 2, ¶ 10. The goal of the HGP is to document the entire sequence of human DNA, as well as to provide the necessary information to spearhead research to begin to understand what makes us individuals. *Id.* ¶ 7. The HGP will also provide critical information to begin to understand the origins of diseases. *Id.* These discoveries will contribute to the research being done in the fields of biology and biotechnology, opening the door to new treatments for diseases. *Id.*

10. Cook-Deegan, *supra* note 2, ¶¶ 27-29, 36. By the end of 1993, private investors contributed over \$100 million to the project. *Id.* at ¶ 36.

11. Timothy Linkkila & Timothy Tracy, *Biotechnology Process Patents: Is Special Legislation Needed?*, at <http://www.fplc.edu/risk/vol5/spring/lin&trac.htm>, ¶ 1 (last visited Feb. 20, 2004). The field of biotechnology is still relatively young. *Id.* ¶ 2. It has been estimated that the cost of discovering a new drug and bringing it to market, on average, exceeds \$359 million. *Id.*

12. Gerald Mossinghoff, *Progress in the Pharmaceutical Industry*, at <http://usinfo.state.gov/products/pubs/intelprp/progress.htm>, ¶¶ 2-3 (last visited Jan. 29, 2003). The amount of investment capital necessary for research and development to introduce a useful, effective pharmaceutical drug is astounding. The cost of developing a new drug, on average, can exceed \$500

patent protection has become the essential tool to ensure economic and scientific success for pharmaceuticals.

### B. History of Patents in the U.S.

Patent protection in the U.S. begins with the Constitution.<sup>13</sup> Article 1, Section 8 of the Constitution states: "Congress shall have the power . . . To promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors, the exclusive Right to their respective Writings and Discoveries."<sup>14</sup> A patent is an exclusive government grant used to encourage investment in research and development.<sup>15</sup> A holder of a patent has the right to exclude others and exploit the fruits of his labor until the patent expires; in return, the government then makes public the information or the invention.<sup>16</sup> This disclosure ignites inventive activity for others to build upon the work of the patent holder.<sup>17</sup> Without patents, companies would have a difficult time recouping their investments and would be discouraged from making public their new found knowledge and inventions.<sup>18</sup>

In 1980, Chief Justice Burger handed down a decision which held the door wide open for patents.<sup>19</sup> In his discussion Burger

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million. *Id.* ¶ 2. These astounding figures are rarely, if ever, seen in any other field where the cost of discovery and development is so high, and the cost to reverse engineer a product is so low. *Id.* ¶ 3.

13. U.S. CONST. art. I, § 8, cl. 8.

14. *Id.*

15. Thomas G. Field Jr., *Intellectual Property: The Practical and Legal Fundamentals*, at [www.fplc.edu/tfield/plfip.htm](http://www.fplc.edu/tfield/plfip.htm), III A1 (last visited Jan. 29, 2004). There are three kinds of patents in the U.S.—utility, design and plant. *Id.* at III A2. Utility patents include "machines, industrial processes, compositions of matter and articles of manufacture." *Id.* "Design patents protect ornamental features, rather than the function, of articles such as containers or light fixtures." *Id.* "Plant patents reward discovery of previously uncultivated plants or the breeding of novel plants." *Id.* See also *Protection of Intellectual Property Rights: The WTO TRIPS Agreement*, at <http://usinfo.state.gov/topical/econ/ipr/ipr-wtotrips.htm> (last visited Jan. 29, 2004) [hereinafter *Protection of International Property Rights*] (discussing the benefits of patent protection): Strong patent protection is the cornerstone of attracting corporate investment. *Id.* Patent protection rewards innovation; promotes the discovery of more cost efficient production methods; encourages the discovery of new products and technology; stimulates local, as well as national, economies; creates jobs, and encourages the discovery of information which could potentially benefit the entire human race. *Id.*

16. Field, *supra* note 15, at III A3-4.

17. *Id.* Patents encourage investment and competitiveness. *Id.*

18. Lila Feisee, *Anything Under the Sun Made By Man*, (Apr. 11, 2001) at [www.bio.org/news/041101.html](http://www.bio.org/news/041101.html). The biotech industry spends an exorbitant amount of capital to fund research and development, more than any other industry. *Id.* Therefore, it is even more prevalent within the biotech industry to facilitate the use of patents to recover the enormous investments required to develop a pharmaceutical. *Id.*

19. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

declared, “[e]verything under the sun is patentable.”<sup>20</sup> In response to this landmark decision, Congress enacted laws to expand patent protection.<sup>21</sup> Despite the vast opportunity to patent new inventions, there are still several requirements before a patent application is granted.

### C. *General Requirements for a Patent Grant*

There are several requirements before a patent will be granted.<sup>22</sup> In order for an applicant to be issued a patent, the subject matter must be new, useful, and nonobvious.<sup>23</sup> The novelty requirement is the easiest to overcome,<sup>24</sup> and merely

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20. *Id.* at 309. See also Jennifer Van Brunt, *Next Move In the Patent Game*, Signals Magazine, (April 4, 2001) available at <http://www.signalsmag.com/signalsmag.nsf/0/5BFF0C004DB8303F88256A390080AA36?Open> (stating that before *Diamond v. Chakrabarty*, the Supreme Court was hostile toward patent claims until 1952, when Congress revised and codified the law). With the new changes, patent holders did not do well in court leading to doubts about the benefits of patents and, in turn, levels of U.S. innovation declined. *Id.* In the late 1970s, trade imbalances led President Carter and Congress to seek stronger protection, which led to the creation of the Court of Appeals for the Federal Circuit (“CAFC”) in 1982. *Id.* The CAFC has exclusive appellate jurisdiction for patent cases and is subject to infrequent review by the Supreme Court. *Id.* Before *Chakrabarty*, researchers could patent the use of an organism, such as those used to create antibiotics; researchers could also patent the process of creating an antibiotic, such as fermentation, but not the organism itself. *Id.* *Chakrabarty* was the first decision that allowed the patenting of a living thing; even today, some countries still do not allow it. *Id.* See also Feisee, *supra* note 18 (recognizing that after *Chakrabarty*, the biotech industry skyrocketed). Now there are over 1,300 biotech companies with over 150,000 employees. *Id.* Directly and indirectly, the biotech industry has created over half a million jobs and has generated almost \$50 billion in revenues. *Id.*

21. See Stevenson-Wydler Technology Innovation Act of 1980, 15 U.S.C. § 3701 (2000) (making technology transfer an integral part of federal laboratories). See also Bayh-Dole Act, 35 U.S.C. § 200 (2000) (giving small businesses the right to retain title to inventions created using federal funds). See also The Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, § 12(a), 100 Stat. 1785 (amending 15 U.S.C. §§ 3701) (authorizing federal laboratories to cooperate with public and private organizations). See also Saliba, *supra* note 5 (explaining that locating a gene is only half the battle). Simply knowing that a gene exists is not enough; a researcher must identify a gene and be able to explain a use for that gene. *Id.* Otherwise, a patent will not be granted. *Id.*

22. See 35 U.S.C. § 115 (2000) (outlining the oath required by patent applicants). See also Field, *supra* note 15 (explaining what is necessary for a U.S. patent application).

23. 35 U.S.C. §§ 102-103 (2000). See also *id.* § 112 (2000) (describing the requirements for the written description of an invention); *id.* § 101 (2000) (describing who may obtain a patent); *id.* § 100 (2000) (defining an invention).

24. Kate Murashige, *Overview of Potential Intellectual Property Protection for Biotechnology*, at <http://www.fplc.edu/risk/vol5/spring/murashig.htm> (last visited Jan. 29, 2003). The novelty requirement is easy for a patent applicant to overcome since the subject matter merely must not have existed elsewhere

requires that the subject matter must not have been known or described in a printed publication somewhere.<sup>25</sup> The utility requirement simply means that the subject matter must be useful to the general consuming public or the research community.<sup>26</sup> Finally, for the nonobvious requirement, the U.S. Patent and Trademark Office ("PTO") may deny the grant if the differences between the applicant's invention and a previous invention are obvious.<sup>27</sup>

#### D. Benefits of Patents

The main benefits of a patent are twofold. Patents allow a return on investments made, while at the same time giving the public access to new data.<sup>28</sup> Often, a company does not profit from the research and development or from the patent itself, but does profit from the practical application of resulting discoveries.<sup>29</sup> For example, by having a limited monopoly on a gene sequence linked to a disease, such as cancer, a company would have a great advantage to discovering the drugs to combat that disease.<sup>30</sup>

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before. *Id.*

25. See Feisee, *supra* note 18 (recognizing that an element found in its natural form cannot be patented). *Id.* However, if the element changes so that it is a purified element, or different from that found in nature, then a patent may be granted. *Id.*

26. Rebecca Eisenberg, *Technology Transfer and the Genome Project: Problems with Patenting Research Tools*, at <http://www.piercelaw.edu/risk/vol5/spring/Eisenber.htm> (last visited Jan. 30, 2003). See also Murashige, *supra* note 24 (explaining that anybody can receive a utility patent for a new and useful machine or process or the improvement of an existing machine or process). "Claims of relevance in biotechnology can be directed to proteins, DNA molecules, cells, mice, antibodies, methods of treatment, methods of recombinant production, oligosaccharides, oligonucleotides and so forth. They can also be directed to assay devices, chromatographic columns, methods to conduct electrophoresis, panels of peptides and methods of diagnosis." *Id.* See also *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966) (holding that "[u]nless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross [sic] what may prove to be a broad field").

27. *Introduction to Understanding Patents*, at <http://www.lib.umich.edu/ummu/pattm/whatis.html> (last visited Jan. 29, 2003).

28. See Eisenberg, *supra* note 26 (explaining that the reason for granting patents for research discoveries is to provide the companies, which invest in the development of pharmaceuticals, with a means of reaping the rewards of its investments). Patents also provide some protections against free riders who have not shared in the high costs of the development process. *Id.*

29. See Cook-Deegan, *supra* note 2 (showing that the potential for profit lies not in the patent but in applying the new discoveries for practical uses). The creation of an effective pharmaceutical is the most effective way of recouping corporate investment. *Id.*

30. Symanietz, *supra* note 3. See also Feisee, *supra* note 18 (noting that the biotech industry has created nearly 100 drugs and vaccines helping more than 270 million people across the globe). Currently, there are another 350 drugs

Patent protection is critical to recover the tremendous amount of capital needed for the research and development to bring a pharmaceutical product to the market.<sup>31</sup> Moreover, it is imperative that the patent last long enough to allow the biotech company to recoup its investment.

Intellectual property rights are most prevalent in the pharmaceutical industry.<sup>32</sup> The research and development involved in bringing an effective new drug to the market is astounding. Typically, the pharmaceutical industry investigates over 15,000 chemical and molecular compounds before discovering perhaps three which are suitable for human use, and developing only one which would go on to become a profitable pharmaceutical.<sup>33</sup>

In recent years it has become quite obvious that patents have played a large role in a private research institute's "race to sequence the human genome."<sup>34</sup> The rapid increase in patent applications evidences this large role of patents. In 1991, the PTO received about 4,000 patent requests for sequenced data, and that number increased to 500,000 in 1996.<sup>35</sup>

#### *E. International Patent Controversy*

An international controversy sparked in 1991 when the NIH filed for hundreds of patents on gene sequences.<sup>36</sup> After the PTO rejected the applications, the NIH abandoned the effort, but the attempt sparked a world wide controversy.<sup>37</sup> The U.S. became embroiled in the controversy for three reasons: the U.S. is a leader of the HGP research, the biotech industry in the U.S. is enormous,

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that are in the clinical trial stage and may be ready for release soon. *Id.*

31. Mossinghoff, *supra* note 12.

32. Joseph Papovich, *Intellectual Property in the TRIPS Era*, at <http://usinfo.state.gov/journals/ites/0598/ijee/ipustr.htm> (last visited Jan. 29, 2003). The US began suffering from chronic trade deficits in the 1980s. *Id.* It became apparent that these deficits could be alleviated by exporting those products in which the U.S. has a great comparative advantage. *Id.* One area the U.S. has its strongest advantage over other countries is in intellectual property. *Id.* It became clear to the U.S. that U.S. intellectual property exportation was not as high as it should be due to the high rate of counterfeit U.S. intellectual property in other countries. *Id.*

33. *Africa Shuns US Move Allowing Access to Cheaper AIDS Drugs*, (Aug.-Sep. 2000) at [www.twinside.org.sg/title/twr120f.htm](http://www.twinside.org.sg/title/twr120f.htm).

34. Symanietz, *supra* note 3.

35. *Id.*

36. Feisee, *supra* note 18. "[I]n the year 2000, the NIH obtained 120 U.S. patents, filed 189 applications and executed 185 licenses and 109 cooperative research and development agreements (known as CRADAS) with the private sector." *Id.*

37. Cook-Deegan, *supra* note 2. This created the race to sequence the human genome. *Id.* Each country had to secure a patent to beat the other researchers in other countries so that it may get credit for and use what they had discovered. *Id.*



and the U.S. is well known for its strong patent system.<sup>38</sup>

#### F. History of International Patent Law

The discussion of international enforcement of IP rights started long before the HGP. The first global discussion took place at the Paris International Convention for the Protection of Industrial Property ("Paris Convention") in 1883.<sup>39</sup> The Paris Convention set forth several provisions for international patent applications, the first of which was national treatment that ensures the equal treatment of both domestic and foreign inventors in the application process.<sup>40</sup> A second provision gives each applicant in a member country the same filing date for subsequent applications in other member states.<sup>41</sup>

Although the Paris Convention made great steps toward a global system of patent protection, there was no international body to enforce these accomplishments.<sup>42</sup> Such an organization was established over eighty years later with the creation of the World Intellectual Property Organization ("WIPO") in 1967.<sup>43</sup> WIPO is one of sixteen specialized agencies of the U.N. administering twenty-one international treaties dealing with different aspects of IP protection.<sup>44</sup> WIPO has the responsibility for receiving an application once a pharmaceutical company has filed a national patent, publishing reports regarding what national patents have been filed as well as initiating patent registration procedures in member countries.<sup>45</sup>

International discussions of IP enforcement have been ongoing. After five years of debate, the Patent Law Treaty ("PLT") was adopted on June 1, 2000.<sup>46</sup> The PLT is aimed at facilitating easier and cheaper access to patent protection.<sup>47</sup> Over forty-seven countries have signed on to the PLT.<sup>48</sup> The PLT outlines in greater

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38. Carroll, *supra* note 3, at 2438-39.

39. *Id.* at 2456.

40. *Id.*

41. *Id.*

42. See Robert J. Pechman, Note, *Seeking Multilateral Protection for Intellectual Property: The United States "TRIPS" Over Special 301*, 7 MINN. J. GLOBAL TRADE 179, 181 n.4 (1998) (explaining that the Paris Convention left the enforcement of IP rights up to each nation).

43. *Id.* at 180 n.2.

44. Anthony Sabatelli & J.C. Rasser, *Impediments to Global Patent Law Harmonization*, 22 N. KY. L. REV. 579, 594-98 (1995). See WIPO, *Member States*, at <http://www.wipo.int/members/members/index.html> (last visited Jan. 30, 2003) (listing the member states). There are 179 signatory states. *Id.*

45. Carroll, *supra* note 3, at 2457.

46. Patent Law Treaty, June 1, 2000, at <http://www.wipo.int/lea/docs/en/wo/wo038en.htm>. (last visited Jan. 29, 2003).

47. *Id.*

48. *PTO Seeks Comments on International Patent Law Harmonization*, Patent, Trademark & Copyright Law Daily, at

detail the requirements for filing a patent application, however, the PLT fails to address any enforcement issues with regard to patent infringement.<sup>49</sup>

Other global forums, outside of WIPO, have discussed enforcing international IP rights.<sup>50</sup> The discussion surfaced in the 1986 Uruguay Round of the General Agreement on Trade and Tariffs ("GATT").<sup>51</sup> As a result, the Trade-Related Aspects of Intellectual Property Rights ("TRIPS") was included in GATT.<sup>52</sup> TRIPS required all WTO members to pass and enforce copyright, patent and trademark laws and provided a dispute settlement mechanism to protect patent holder's rights.<sup>53</sup> TRIPS allows for a twenty-year term of patent protection from the time of filing.<sup>54</sup> TRIPS defines patentable subject matter as any new invention, whether product or process, that involves an inventive step and is capable of industrial application.<sup>55</sup> Additionally, TRIPS prohibits discrimination by a member country against foreign patents.<sup>56</sup>

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<http://subscript.bna.com/SAMPLES/ptd.nsf/> (Mar. 22, 2001).

49. Patent Law Treaty, June 1, 2000, at <http://www.wipo.int/lea/docs/en/wo/wo038en.htm>. (last visited Jan. 29, 2003). See also Patent Cooperation Treaty, Sept. 3, 1975, 27 U.S.T. 7645 (making it possible to seek patent protection for an invention in each member country by filing a single international patent).

50. Murashige, *supra* note 24. The European Patent Convention of 1978 was a first step for European nations to harmonize the patent application process. *Id.* However, patent rights still had to be enforced in each country individually. *Id.*

51. WTO, *Trading Into the Future*, at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm6_e.htm) (last visited Jan. 29, 2003). TRIPS sets out the minimum rights that member countries must grant patent holders. *Id.* Many countries see the guidelines as the only rights which need to be granted, but the main objective was to set the minimum requirements with the intention that each country go beyond those requirements to further protect patent holders. *Id.* See WTO, *Trade Related Aspects of Intellectual Property Rights, Uruguay Round Agreement*, [hereinafter TRIPS], Apr. 15, 1994, at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_01\\_e.htm](http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm) (last visited Jan. 29, 2003) (laying out the caveats of the agreement).

52. TRIPS, *supra* note 51. TRIPS became U.S. law in 1994. *Id.* TRIPS is an agreement that is part of the World Trade Organization ("WTO"). *Id.*

53. *The Work of the USTR - Intellectual Property*, at [www.ustr.gov/sectors/ustrwork.shtml](http://www.ustr.gov/sectors/ustrwork.shtml) (last visited Jan. 29, 2003).

54. TRIPS, *supra* note 51, at art. 33.

55. *Id.* at art. 27. See also *id.* at art. 28 (defining the rights conferred to a patent holder); *Id.* at art. 41 (outlining the general obligation for enforcement by member countries); *Id.* at art. 44 (stating when an injunction should be granted to prevent the importation of goods infringing patent holder's rights); *Id.* at art. 64 (outlining the dispute settlement procedure).

56. *Id.* at art. 41. TRIPS is the most effective multilateral treaty on IP rights yet. Protection of International Property Rights, *supra* note 15. It establishes a set of minimum standards for IP protection, enforces IP rights by requiring signatory nations to provide national procedures and enforcement and it provides a binding settlement dispute mechanism for complaints against WTO members that do not comply. *Id.*

### G. TRIPS In Depth

TRIPS took great strides in protecting patent holders' rights. Yet, TRIPS left some controversial loop holes. Article 31 of TRIPS allows the use of patent subject matter without the authorization of the patent holder. This practice is better known as compulsory licensing. Compulsory licensing is a government issued license for the product to be produced domestically while providing the patent holder with reasonable compensation.<sup>57</sup>

This is the most controversial article of TRIPS because its terms are so vague. Article 31, section (b) provides that use of the subject matter may be had without permission if the party seeking use has made an attempt to obtain authorization from the patent holder "on reasonable commercial grounds and that such efforts have not been successful within a reasonable period of time."<sup>58</sup> This language has caused much debate since it is impossible to determine what "reasonable commercial grounds" and "reasonable period of time" mean.<sup>59</sup> How long does a State need to negotiate with a patent holder before it can make a determination that discussions should cease? Is one week, one month, six months, or one year reasonable? How much compensation should a State offer a patent holder before it can determine that an agreed upon price cannot be had? Are what a citizen can afford, what the government can afford, the cost to make the drug, or the profits lost to the patent holder reasonable?

Each of these questions are valid, but TRIPS leaves them unanswered. Section (b) permits the Member State to forego the "reasonable" provisions of negotiation in the case of a national emergency, leaving the patent holder merely with the right of notification that it, in fact, has no rights.<sup>60</sup> Section (f) further states that such use shall be *predominantly* for the domestic market.<sup>61</sup> It does not require that the use be limited solely to the domestic market.

This has been interpreted to apply to developing countries that do not have either the technology or resources to manufacture the drug within its borders. These countries are limited because TRIPS prevents a developing country from granting a compulsory license to a foreign manufacturer since this would interfere with a patent in a foreign country.<sup>62</sup> Therefore, the compulsory license

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57. Divya Murthy, Comment, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health*, 17 AM. U. L. REV. 1299, 1307 (2002).

58. TRIPS, *supra* note 51, at art. 31.

59. *Id.*

60. *Id.*

61. *Id.*

62. Murthy, *supra* note 57, at at 1335.

may not be useful in some cases.<sup>63</sup>

### H. *The Doha Declaration*

These issues have thus far culminated in the Doha Ministerial in November 2002, which resulted in the Declaration on the TRIPS Agreement and Public Health ("Declaration").<sup>64</sup> The Declaration is a ministerial interpretation of TRIPS. It seeks to clarify a number of these issues and primarily provides interpretive meaning to imprecise obligations of TRIPS. Therefore, it will likely be persuasive authority in future dispute resolutions under TRIPS.<sup>65</sup>

#### 1. *Compulsory Licenses*

The Declaration opened the door for compulsory licensing of patented pharmaceuticals. In pertinent part the Declaration states,

[e]ach member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency.<sup>66</sup>

As a result, the Declaration allows the countries to define, on their own terms, what constitutes a national emergency. The countries are free to determine the grounds upon which a compulsory license will be granted and for what purpose.

#### 2. *Foreign Production*

As previously discussed, Article 31 section (f) of TRIPS prevents a country with a compulsory license from seeking the manufacture of that drug in a foreign country. Developing nations sought language in the Declaration that would permit them to do so since some nations lack the capacity to produce the drugs domestically.<sup>67</sup>

The Declaration was not able to effectively address this issue and instead deferred it to the Council of TRIPS.

We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face

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63. Alan Sykes, *Public Health and International Law: TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 CHI. J. INT'L L. 47, 55 (2002).

64. WTO, *The Doha Declaration Explained*, at <http://www.wto.org/english/tratop-e/dda-e/dohaexplained-e.htm> (last visited Mar. 24, 2004).

65. *Id.* at 54.

66. See Sykes, *supra* note 63, at 54 (quoting the Declaration on the TRIPS Agreement and Public Health, adopted November 14, 2001).

67. *Id.* at 54-55.

difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.<sup>68</sup>

If compulsory licensing is to be used effectively to combat epidemics, the countries that do not have manufacturing facilities should be allowed to obtain the drugs from a foreign country. If the main goal is to stamp out these diseases, then there should be no barriers applicable only to the least developed countries, which coincidentally, are where many epidemic diseases are located.

The one place where TRIPS limits compulsory licensing to protect patent rights is the one place where it should not be limited. The purpose of the restriction is to protect patent rights in foreign countries and to prevent the exportation of cheaper pharmaceuticals. However, when there is a national emergency for public health, the least developed countries should not lose the benefit of compulsory licensing for the "idea" of patent protection.

Patents are infringed upon in so many ways, and compulsory licensing is not narrowly construed enough to provide patent holders with any control or certainty as to how it will be used. This is especially true now that the Declaration allows each country to determine, without any direction, what constitutes a national emergency. It seems to be an irrelevant measure to limit the benefits of compulsory license to those who can manufacture it domestically, when the main purpose is to combat these epidemics that are predominant in countries which do not have the manufacturing capabilities.

### *I. Enforcement of Patent Protection in the U.S. and Internationally*

Even with these effective steps toward globalization of IP rights, there still remains a major issue with patent enforcement. TRIPS dispute settlement procedures apply only to WTO member-states, and they can be time consuming and arduous.<sup>69</sup> Even if the WTO General Council makes a determination in a case, no effective enforcement procedures exist to ensure that a member country will comply.<sup>70</sup> For example, if a U.S. pharmaceutical

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68. *Id.* at 54 (quoting the Declaration on the TRIPS Agreement and Public Health, November 14, 2001).

69. See WTO, *Trading Into the Future, Large Flow Chart*, at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/disp2\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp2_e.htm) (last visited Jan. 29, 2003) (illustrating the steps and the time required to work a claim through the settlement process).

70. WIPO, *TRIPS Agreement Arbitration Procedures*, at <http://arbiter.wipo.int/arbitration/procedures/index.html> (last visited Jan. 29, 2003). TRIPS allows for mediation or arbitration in its dispute settlement process. *Id.* However, only willing parties can be brought before the general council. *Id.* If

company has a patent infringement dispute with a company in Argentina, the U.S. company could not file for a hearing in the WTO.<sup>71</sup> That company is forced to rely upon the violating country for protection of its IP rights.<sup>72</sup> Relying upon another country, even a WTO member country, can prove extremely difficult in enforcing patent rights.<sup>73</sup>

The United States Trade Representative ("USTR") is empowered by Congress to enforce laws worldwide to control IP infringement.<sup>74</sup> The USTR uses the Special 301, which is also known as the Omnibus Trade Act of 1974.<sup>75</sup> The USTR annually creates a list of countries on its "Watch List" to warn investors that their patent rights may not be adequately protected.<sup>76</sup> Free trade and tariff preferences are used to encourage other countries to provide adequate protection.<sup>77</sup>

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a member country refuses to appear there is no alternative. *Id.* Also, the mediation process is not enforceable, and a party may abandon the mediation process if it so chooses. *Id.* Under the arbitration process, a decision may be binding upon a member country, however, enforcement mechanisms are lacking in effect. *Id.*

71. See TRIPS, *supra* note 51, at art. 50 (stating that Members of TRIPS shall make settlement procedures available to patent holders, however, patent holders are not conferred the right to take the matter to the WTO).

72. Harold C. Wegner & Stephen Maebius, *The Global Biotech Patent Application*, 666 PLI/PAT 87 (2001). In TRIPS transition countries where enforcement of pharmaceutical patent is nonexistent, such as India, it remains difficult to stop the infringement of patent rights. *Id.* at 125-26.

73. *Id.* at 126. American pharmaceutical companies know all too well how difficult it was to enforce a patent in Japan. Proving that the use of a research tool was violating a patent is difficult enough but, often, the lack of meaningful discovery made the system useless. *Id.* And even if it was proven, and the company won in court, the patented material could still be exported into yet another country. *Id.* at 127.

74. 19 U.S.C. § 2171 (2000).

75. See Omnibus Trade Act of 1974, 19 U.S.C. § 2242 (1974) (creating the Special 301).

76. Greg Aharonian, *Global Intellectual Property Revenue Losses for US Companies*, at [http://www.eff.org/IP/ip\\_theft\\_losses.stats](http://www.eff.org/IP/ip_theft_losses.stats) (1998) (last visited Apr. 1, 2004). The USTR estimated that approximately \$1,908,660,000 was lost in the pharmaceutical market alone due to theft of U.S. company patent rights. *Id.* The December 2000 Special 301 report of the USTR identified several countries that violate intellectual property rights. *Id.* Among those on the "Priority Watch List" (those countries who warrant close monitoring to determine if Special 301 action is needed) is the United Arab Emirates (UAE). *Id.* The UAE agreed to prevent the marketing of unauthorized copycat drugs but "unfortunately, marketing approval for some copycat drugs was granted nevertheless. . . Argentina has failed to grant exclusive marketing rights for pharmaceuticals, despite being obliged to do so under the TRIPS Agreement." *Id.*

77. See 19 U.S.C. § 2411 (2000) (outlining the actions the USTR may take against a country identified in the Special 301 Report).

## II. THE NEED FOR STRONGER GLOBAL PATENT PROTECTION

### A. *The Undermining of International Patents*

The international market has been infected with patent infringement. There are a myriad of ways in which a patent can be infringed in the international market and a host of countries that permit or even encourage patent infringement.<sup>78</sup>

#### 1. *International Patent Infringement Statistics*

Both countries and individual companies suffer extreme losses from patent infringement.<sup>79</sup> Patent infringement causes lost sales, distortions in trade flows and diminished capital to fund new research and development.<sup>80</sup> A recent study illuminated the excessive amount of sales lost to patent infringement. The results showed that pharmaceuticals pirated in just five countries amounted to \$192 million, while legitimate sales by U.S. companies were only \$162 million.<sup>81</sup> On a global scale, it has been estimated that over \$200 billion a year are lost to pirated IP rights as a whole.<sup>82</sup> As evident, pirating is a lucrative black-market industry.

#### 2. *Methods of Infringing Patent Rights*

Patent infringers have no incentive to follow international law or to protect patent holders rights since there are several

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78. See Wegner & Maebius, *supra* note 72, at 125-29 (discussing the infringement of patent holder's rights and the difficulty of enforcing IP rights).

79. Stefan Kirchanski, *Protection of U.S. Patent Rights in Developing Countries: U.S. Efforts To Enforce Pharmaceutical Patents in Thailand*, 16 LOY. L.A. INT'L & COMP. L.J. 569, 575 (1994). The U.S. economy suffers when IP rights are infringed. *Id.* at 569. When U.S. patent owners are not compensated for the use of their patent materials, the U.S. can lose sales, which creates a decrease in international trade when decreasing the U.S. foreign trade deficit is crucial. *Id.* In just seven years, from 1980-1987, the "U.S. trade deficit increased from \$31 billion to \$170 billion." *Id.* at 574. The yearly payment on the interest on the trade deficit in the 1990's was estimated to be around \$100 billion. *Id.* at 575. Therefore, enforcing U.S. patent rights abroad is critically important to the U.S. economy. *Id.*

80. Angela Beam, Comment, *Piracy of American Intellectual Property in China*, 4 D.C.L. J. INT'L L. & PRAC. 335, 336-37 (1995). See also Sabatelli & Rasser, *supra* note 44, at 582-91 (discussing the need for global patent harmonization).

81. Kirchanski, *supra* note 79, at 575.

82. *Testimony Before the Subcomm. on Int'l Econ. Policy and Trade of the U.S. House Int'l Relations Comm.*, 106th Cong. (October 13, 1999) (statement of Raymond Kelly, Commissioner, U.S. Customs Service). Also, approximately 750,000 jobs are lost annually as well due to theft of IP rights. *Id.* See also Carroll, *supra* note 3, at 2470. One investigation revealed that in 1986, U.S. businesses lost \$23.8 billion due to pirated goods. *Id.* This estimated loss was equal to 15% of the U.S. trade deficit. *Id.*

methods for getting around current international patent laws.

a. Parallel Importing

The first method patent infringers use is parallel importing.<sup>83</sup> Parallel importing occurs when the patent holder gives permission to produce a patented good in one country, but it is then exported into a second country without the patent holder's permission.<sup>84</sup> Generally, the patent holder has the right to control the importation of the patented goods into other countries.<sup>85</sup>

Typically, parallel importing occurs when there is a great disparity in market conditions between two countries.<sup>86</sup> The patented goods are generally imported from a country with a lower priced market and into a country with a higher priced market.<sup>87</sup> The ultimate result is free profits for the patent infringer at the expense of the patent holder.

The practice of parallel importing is most apparent in the pharmaceutical industry, which provides necessary medication to the lower market economies at more affordable prices.<sup>88</sup> Therefore, when these pharmaceuticals are exported, from the lower to higher market economies, the only party that profits is the patent infringer.<sup>89</sup> While the pharmaceutical company is trying to recoup the cost of its research, the parallel importer is reaping the profits.

In the U.S. and in the European Union ("E.U."), parallel importing is considered patent infringement.<sup>90</sup> However, the E.U.

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83. See *Intellectual Property: Parallel Import of Pharmaceuticals*, at <http://www.phrma.org/intnatl/intellprop/parallel.phtml> (last visited Nov. 11, 2002) (discussing parallel imports and pharmaceuticals).

84. *Id.* Laurinda L. Hicks & James R. Holbein, *Convergence of National Intellectual Property Norms in International Trading Agreements*, 12 AM. U.J. INT'L L. & POL'Y 769, 778-80 (1997) (directing the reader's attention to the portion of the article entitled "Overview of Main Intellectual Property Treaties and Conventions").

85. Hicks & Holbein, *supra* note 84, at 778-80.

86. *Id.*

87. *Id.*

88. *Id.* The EU permits parallel importation of goods within its member countries, allowing the movement of pharmaceuticals from one nation to another resulting in the parallel importation of pharmaceuticals. *Id.* For instance, lower priced pharmaceuticals are purchased in Greece and then imported to another EU member state for sale at a higher price. *Id.* As a result, Greece is experiencing shortages of some medications. *Id.*

89. *Id.* The government and its citizens that receive the parallel imports are at high risk since the conditions in which the pharmaceuticals are stored and shipped are not controlled and can cause public health concern. *Id.*

90. Wegner & Maebius, *supra* note 72, at 114-15. See also, Lee Ann Askew, Comment, *The ECJ, the ICJ and Intellectual Property: Is Harmonization the Key?* 7 TULSA J. COMP. & INT'L L. 375, 375-862 (2000) (discussing the E.U. and the European Court of Justice as well as the U.N. and the International Court of Justice).



only prohibits parallel importing into the E.U.<sup>91</sup> Member countries of the E.U. can parallel import within the E.U. and the patent holder's rights are considered to be exhausted.<sup>92</sup>

#### b. Exhaustion of Rights

Another method of limiting the rights of patent holders is the doctrine of exhaustion of rights.<sup>93</sup> The doctrine dictates that once a patent holder has produced the protected goods, and has entered them into the stream of commerce, the patent holder's rights have been exhausted.<sup>94</sup> The patent holder no longer has the right to prevent the further distribution of that good in the market place.<sup>95</sup> In effect, the exhaustion of rights limits the control the patent holder has over its own goods.<sup>96</sup>

#### c. Free Riding

Yet another method that negates international patent law is "free riding."<sup>97</sup> Free riding is a method of patent infringement by a nation as well as its citizens.<sup>98</sup> Free riding is the taking of patented property without paying for its use.<sup>99</sup> It is most prevalent in the pharmaceutical industry where research and development costs are extreme.<sup>100</sup> Free riding patent infringers can easily copy the drug and benefit from a windfall profit without bearing any of the costs of development.<sup>101</sup>

### 3. Several Countries Have Been Identified As Lacking Patent Enforcement

Several countries are well known for their weak, or even

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91. Wegner & Maebius, *supra* note 72, at 115.

92. *Id.* at 114.

93. WTO, *Parallel Imports, Grey Imports and Exhaustion of Rights*, at [http://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm#parallelimports](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#parallelimports) (last visited Jan. 29, 2003).

94. Hicks, *supra* note 84, at 810-11.

95. *Id.*

96. *Id.*

97. See Sabatelli & Rasser, *supra* note 44, at 607-08 (explaining that many countries, excluding the US, have an automatic publication requirement whereby an application for a patent is automatically published about eighteen months after filing regardless of whether an application was approved or not, effectively making public the information when the patent applicant may or may not have any legal protection).

98. Nicolas S. Gikkas, *International Licensing of Intellectual Property: The Promise and the Peril*, 1 J. TECH. L. & POL'Y 6, 29 (1996). Governments that allow its citizens to take, use and sell intellectual property without compensating the owner are considered free riding governments. *Id.*

99. *Id.*

100. *Id.*

101. *Id.*

nonexistent, patent laws for pharmaceuticals.<sup>102</sup> In fact, some countries incorporate patent infringement into their economic planning.<sup>103</sup> Here in the U.S., the Special 301 list is used to create a list of those countries that violate IP rights.<sup>104</sup> The Special 301 list has three categories for those countries that deny adequate IP protection: priority foreign countries, priority watch list and watch list.<sup>105</sup> The priority foreign country watch list identifies countries “that have the most onerous or egregious acts, policies, or practices that have the greatest adverse impact” on IP rights.<sup>106</sup> The priority watch list identifies “countries whose acts, policies and practices meet some, but not all, of the criteria for priority foreign

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102. *Id.* at 30. Among those countries are India, Thailand, Brazil and Taiwan. See also Beam, *supra* note 80, at 341-49 (explaining the legislative framework for China’s IP rights and discussing the lack of IP rights in China’s legal system due to traditional Chinese culture); William C. Revelos, *Patent Enforcement Difficulties in Japan: Are There Any Satisfactory Solutions for the United States?*, 29 GEO. WASH. J. INT’L L. & ECON. 503 (1995) (discussing the recent surge in lawsuits filed in the US against Japanese companies as well as explaining how the Japanese court system works in comparison to the US court system). A recent example of the surge of lawsuits is the \$127 million award in a U.S. patent case covering auto focus technology for Honywell Camera Company against Minolta. *Id.* at 506. See also Kirchanski, *supra* note 79, at 576-82 (discussing the negative consequences of lacking IP enforcement for developing countries); *Industry Policy in Denmark*, at [www.dkpto.dk/publications/reports/indu\\_policy/kap03.htm](http://www.dkpto.dk/publications/reports/indu_policy/kap03.htm) (last visited Jan. 29, 2003)

(discussing the IP system and enforcement of IP rights in Denmark and explaining that almost 20% of the country’s enterprises have experienced trouble with parallel imports, affecting a large portion of that country’s trade and industry); Sabatelli & Rasser *supra* note 44, at 584-88 (discussing how national patent rights and international trade principles clash).

103. Gikkas, *supra* note 98, at 30. These countries include: Taiwan, Singapore, Hong Kong and Korea. *Id.*

104. See Pechman, *supra* note 42, at 196-97 (explaining the view that Special 301 may violate GATT); see also Kirchanski, *supra* note 79, at 587 (noting that Special 301 is a provision of the Omnibus Trade and Competitiveness Act of 1988 which was intended to provide the USTR with a “credible threat of U.S. retaliation against any trading partners that fail to reform their intellectual property laws”).

105. 19 U.S.C. § 2242 (2000). See Kirchanski, *supra* note 79, at 588 (describing the utilization of the priority watch list).

106. Kira Alvarez, *Identification of Countries that Deny Adequate Protection, or Market Access, for Intellectual Property Rights Under Section 182 of the Trade Act of 1974*, at <http://www.wifcon.com/newsarctrade01.htm>. (published May 8, 2001). See also Beam, *supra* note 80, at 350 (observing that China has twice been placed on the priority foreign country watch list, each time resulting in China and the US entering into a bilateral agreement providing for greater protection of IP rights in China); E. Anthony Wayne, *Intellectual Property Rights Policy and Enforcement*, at <http://www.state.gov/e/eb/rls/rm/2002> (Apr. 23, 2002). By leveraging the Special 301, the U.S. persuaded Slovenia to “pass legislation protecting test data submitted to obtain marketing approval for pharmaceuticals.” *Id.*

country identification.”<sup>107</sup> The watch list identifies countries “that warrant special attention because they maintain intellectual property practices or barriers to market access that is of particular concern.”<sup>108</sup>

### B. *The Ineffectiveness of International Patent Enforcement*

Effective enforcement of international patent protection is crucial not only in developing national economies, but for fostering research and development of new, life saving pharmaceuticals.<sup>109</sup> Thieves of patented goods operate with relative impunity due to the lax enforcement measures currently in place in the international market.<sup>110</sup> National enforcement measures are generally ineffective against infringement. Remedies are relatively innocuous and are not expeditiously applied nor implemented in any meaningful way.<sup>111</sup> Even member states to the international treaties, designed to enforce IP rights, often find excuses for non-compliance or outright disregard for the treaty’s provisions, as evidenced by the U.S. Special 301 report.<sup>112</sup>

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107. U.S. Department of State, *Intellectual Property Rights Protection: Background Fact Sheet*, at <http://usinfo.state.gov/topical/econ/ipr/ipr-background.htm> (last visited Jan. 29, 2003).

108. *Id.* See also Brendan Daly, *USTR Announces Results of December, 2000 Special 301 Out-of-Cycle Reviews*, at <http://www.ustr.gov/releases/2001/01/01-11.html> (Jan. 19, 2001). In 2000, the United Arab Emirates (“UAE”) received no listing on the Special 301 list, however, they were identified as a source of “unauthorized copies of patented pharmaceuticals.” *Id.* The only reason the UAE was not listed on the Special 301 report was that the UAE gave assurances that it would reverse any market approvals it had granted previously. *Id.* Also among those listed on the Special 301 Report are countries that fail to meet the standards required under the TRIPS Agreement. *Id.* The list included Argentina, India, Brazil and Vietnam as countries which are required to provide a minimum level of patent protection under the TRIPS Agreement, but fail to do so. *Id.*

109. See Carroll, *supra* note 3, at 2464-74 (discussing the debate on patent rights divide between northern and southern countries’ views on patent rights and the positions of developing countries on the enforcement of IP rights). See also Wegner & Maebius, *supra* note 72, at 128 (explaining the trend for businesses to apply only in the US and requesting secrecy of the application thus allowing a patent holder to maintain a patent while the information is sealed from the public).

110. Kelly, *supra* note 82. See also Jennifer Mills, Comment, *Alternative Dispute Resolution in International Intellectual Property Disputes*, 11 OHIO ST. J. ON DISP. RESOL. 227, 229-30 (1996) (discussing the fundamental problems of international intellectual property disputes).

111. See WIPO, *Advisory Committee on the Enforcement of Intellectual Property Rights*, [hereinafter *WIPO Advisory Committee*] International Anti-Counterfeiting Coalition, at <http://www.unece-ipr.org/WIPOEnfRFCresponse.doc> (Sept. 2001) (discussing the ineffectiveness of criminal procedures and penalties of most member states).

112. See Daly, *supra* note 108 (addressing the reasoning of several countries’ non-compliant status).

### 1. *TRIPS and WIPO Enforcement Mechanisms*

Both TRIPS and WIPO have received criticism for being too vague and ambiguous in the area of IP protection.<sup>113</sup> TRIPS provides for mechanisms of enforcement, but these are not implemented by member countries.<sup>114</sup> TRIPS fails to specify how IP disputes are to be decided,<sup>115</sup> nor does the treaty have any disciplinary powers to deter infringement or to enforce IP rights.<sup>116</sup>

However, TRIPS does specifically address exhaustion of rights and parallel imports in Article 6 of the TRIPS Agreement.<sup>117</sup> Article 6 provides that none of its provisions may apply to parallel imports or exhaustion of rights.<sup>118</sup> Therefore, even if a member country is violating a provision of the agreement in any way by allowing parallel imports, that country may not be disputed against.<sup>119</sup>

Also, TRIPS cuts the effectiveness of its enforcement mechanism by allowing continual extensions of the compliance period for developing countries.<sup>120</sup> As a result, several developing

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113. Hicks & Holbein, *supra* note 84, at 782. *See also*, Wegner & Maebius, *supra* note 72, at 126. (explaining that ambiguities exist within the current international law of patents, and questioning whether using research tool patents in biotechnology is a violation of the patent holder's rights); Pechman, *supra* note 42, at 193 (discussing the dispute settlement mechanism of TRIPS); Sabatelli & Rasser, *supra* note 44, at 607-12 (discussing the current attempts at patent law harmonization and the impediment to those attempts); Mills, *supra* note 110, at 229-39 (discussing the strengths and weaknesses of the GATT and WIPO treaties); Shozo Uemura, *WIPO Programs and Activities for the Reduction of Patent Costs*, at <http://www.law.washington.edu/casrip/Symposium/Number5/pub5atcl20.pdf> (last visited Jan. 29, 2003) (providing and discussing nine treaties which are among the main international efforts to harmonize global patent protection).

114. *WIPO, Advisory Committee*, *supra* note 111. TRIPS provides for border measurers to stop the flow of counterfeit goods; however, the provision is written in a manner that permits member countries "to comply on paper, but not in practice." *Id.* at 2. "The vast majority of WTO member states make border enforcement available through an 'application' process, whereby the right holder files an application with the competent authorities." *Id.*

115. Pechman, *supra* note 42, at 193. *See also* Sabatelli & Rasser, *supra* note 44, at 609-10 (explaining that WIPO focuses too heavily on procedural issues and not enough on the substantive issues dealing with the right of the patent holder).

116. Hicks & Holbein, *supra* note 84, at 782.

117. *See* TRIPS, *supra* note 51, at art. 6.

118. *Id.*

119. *Id.*

120. *Id.* at art. 66 (providing least developed nations a 10 year delay in implementing TRIPS' minimum protections for patent holders). *Id.* at art. 65, art. 67 (outlining the grace periods for TRIPS enforcement); TRIPS, *supra* note 51, at art. 30 (providing developing member states the opportunity to "provide limited exceptions to the exclusive rights conferred by a patent."); James Rogan, *Official Outlines U.S. Goals for Global Patent System*, at <http://usinfo.state.gov/topical/econ/ipr/ipr-rogan26.htm> (Mar. 26, 2002)

countries that are signatory states to TRIPS provide little, if any, patent protection.<sup>121</sup> These extensions provide no real incentive for developing countries to conform with minimum standards espoused in TRIPS.<sup>122</sup>

The WTO dispute settlement procedures are ineffective. The WTO has little, if any, power to compel a party to comply with the panel's findings.<sup>123</sup> The WTO dispute panel prefers that the member, found to be in violation of GATT, comply with its provisions.<sup>124</sup> However, if the panel cannot compel the member country to comply, it will allow the offending country to provide compensation to the injured party. The offending country is not required to change the current status of its laws, which remain in violation of GATT.<sup>125</sup> Therefore, it is unlikely that such an enforcement mechanism, such as the WTO dispute settlement panels, will actually be effective in enforcing its own provisions.

## 2. *Special 301 is Evidence of the Ineffectiveness of Current Enforcement Mechanisms*

Every year the USTR identifies countries that violate IP rights internationally.<sup>126</sup> The ineffectiveness of international enforcement of IP rights is evidenced by the rising number of countries included in the list each year.<sup>127</sup>

Among those countries identified as failing to enforce IP rights, even at the minimum standard of TRIPS, is Argentina.<sup>128</sup> Argentina has a tenuous history for the protection of pharmaceuticals.<sup>129</sup> Its patent protection for pharmaceuticals has "steadily deteriorated over the last two years."<sup>130</sup> In fact, Argentina provides no patent protection for pharmaceuticals even though it is explicitly required to do so under TRIPS.<sup>131</sup>

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(explaining that developing countries were given an extra four years to comply with TRIPS and those that did not comply by 2000 were given another five years). Least developed countries were given until 2006 and then extended until 2016 for compliance with TRIPS. *Id.*

121. Sabatelli & Rasser, *supra* note 44, at 613.

122. Pechman, *supra* note 42, at 195.

123. *Id.*

124. *Id.* at 205.

125. *Id.*

126. *Id.* at 196 (explaining the history of the Special 301).

127. *See* Daly, *supra* note 108.

128. *Id.* Other countries which are identified as having sub-standard patent protection for pharmaceuticals are India, Israel, Brazil, Qatar and Vietnam. *Id.*

129. Daly, *supra* note 108.

130. *Id.*

131. *Id.*

### 3. *Current Judicial Enforcement Mechanisms Are Too Costly and Time Consuming*

Most of the enforcement mechanisms provided in the international treaties rely on each member's own judicial system to enforce the patent holder's rights.<sup>132</sup> These systems have proven ineffective.<sup>133</sup> It is nearly impossible for patent holders to prove infringement.<sup>134</sup> This is due, in part, to a lack of meaningful discovery in patent infringement cases.<sup>135</sup> It is virtually impossible for a patent holder to discover how its patented research tools and products are being used and then prove this to a court.<sup>136</sup>

Assuming that the act of infringement could be proven to a court's satisfaction, getting to that initial point is too costly for most patent holders.<sup>137</sup> Enforcing patent rights is often too time consuming for all but the most profitable patent holders.<sup>138</sup> Even the TRIPS panel process can take thirty-three to thirty-seven months, not including the appeals process.<sup>139</sup>

The current mechanisms to enforce the minimum standards of TRIPS on a signatory member are inadequate along with the current framework for the enforcement of international IP rights. Without enforcement, countries will have to harmonize and strengthen IP rights of their citizens, otherwise research efforts will prove worthless.

### III. REVISING CURRENT ENFORCEMENT MEASURES

There is a universal need for patent protection; however, getting all concerned parties to agree on how to protect those rights is difficult. As patent grants become exceedingly more important, WIPO and TRIPS must take leadership action to ensure that progress does not stall. This can be accomplished by making some strong, yet simple, revisions to the current patent enforcement system. However, for patent enforcement to truly be effective, an independent patent tribunal should be created.

In order to make strong patent enforcement become a reality,

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132. For GATT, see Mills, *supra* note 110, at 234. When an individual patent holder has a dispute with a foreign nation that patent holder is forced to deal with a foreign legal system which often times is confusing since it involves complex issues as to the choice of law involved, whether equitable remedies are available and what damages are available. *Id.* at 237.

133. *Id.*

134. Wegner & Maebius, *supra* note 72, at 126.

135. *Id.*

136. *Id.*

137. *Id.* at 129.

138. *Id.*

139. See WTO, *The Panel Process Flow Chart*, at [http://www.wto.org/english/thewto\\_e/whatise/tif\\_e/disp2\\_e.htm](http://www.wto.org/english/thewto_e/whatise/tif_e/disp2_e.htm) (last visited Jan. 29, 2003) (depicting the panel process from beginning to end and the time each step takes to complete).

a few changes need to be made.<sup>140</sup> First, the interpretations that the Doha Declaration provides should be more narrowly tailored to ensure that incentives remain to develop life saving drugs. Second, compulsory licenses should be more narrowly construed and their use limited. Third, TRIPS needs to become a more effective treaty by enforcing the rights of patent holders itself, instead of leaving it up to member countries. Fourth, an agency of WIPO should be created to enforce patent holder's rights. Further, those countries that do provide adequate patent protection should crackdown on patent infringers. Finally, developing countries should not be given such lengthy time extensions for compliance with TRIPS.

### A. The Doha Declaration

#### 1. A Response

The Declaration opens the door wider for countries to use compulsory licensing, placing pharmaceutical companies on notice that, if they undertake research and development of drugs for tropical diseases, those most likely to be deemed national emergencies, they risk losing any potential profit from a successful drug. Therefore, compulsory licensing may actually negate any preexisting incentive to develop these drugs.<sup>141</sup>

The interpretations that the Declaration provides should be more narrowly tailored. For example, the term "national emergency" should be defined using factors such as the percentage of the population affected, how easily the disease can spread, and the severity of the symptoms. A respected organization, such as the World Health Organization ("WHO"), should be consulted to determine when a national health emergency exists.<sup>142</sup> This would allow an independent body to make the decision on previously determined grounds, resulting in a more fair, unbiased decision.

Furthermore, adequate compensation for a compulsory license should take into account the research and development that was required to produce that drug.<sup>143</sup> After all, this is the primary concern when developing a pharmaceutical, and the main cost that must be recovered. The country should not have to pay full compensation, but the research and development costs should at least be considered.

Additionally, Article 31, which requires a product to be used

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140. See Edward Fiorito, *Highlights of Selected Recommendations of the Advisory Commission on Patent Law Reform*, 1 TEX. INTELL. PROP. L.J. 11, 18 (1992) (discussing advisory commission on patent law reform's recommendation for patent enforcement and patent harmonization).

141. *Id.* at 66.

142. Murthy, *supra* note 57, at 1341.

143. Sykes, *supra* note 63, at 68.

predominantly for the domestic market, should be changed to mandate the entire production be used for addressing the national emergency within the domestic market only. Compulsory licensing should be limited in scope in order to provide a balance between patent rights and public health.<sup>144</sup>

Governments might be more successful if they cease the use or threat of compulsory licensing and, instead, offer protections to patent holders in exchange for discounted drugs to be used for their poorest citizens.<sup>145</sup> Governments can offer to impede the sale of these discounted drugs to their wealthier citizens.<sup>146</sup> These governmental measures would provide the patent holder with at least minimal protection while, at the same time, affording the citizens of that country access to essential medicines.

## 2. *Doha Interpretation*

As evidenced, compulsory licenses are appropriate under certain circumstances, however, it must be kept in mind that these are exceptions, not the norm.<sup>147</sup> Therefore, when the TRIPS Council considers how to address the issue of countries without domestic production capabilities, many factors should be kept in mind: "infrastructure, financing, elimination of impediments such as tariffs and internal taxes and training."<sup>148</sup> Also, in order to protect the IP rights of patent holders, which TRIPS was designed to do, the licenses should be limited and carefully drawn.<sup>149</sup>

Before a compulsory license for manufacture of a product in a foreign market should be used, a government should still try to obtain the pharmaceutical from the patent holder. If sufficient quantities at a price comparable to that obtainable under a compulsory license can be obtained from the patent holder, the compulsory license should not be used.

More information for an effective solution would be helpful. A study should be conducted to determine exactly the global situation with respect to diseases plaguing the developing countries as well as what pharmaceuticals would be needed to combat those diseases. It should be determined which of those pharmaceuticals are patented and which can not be afforded by the citizens of those countries requiring assistance. This would allow everyone to see what effect patents have on access to pharmaceuticals and which ones must be addressed by the

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144. Murthy, *supra* note 57, at 1342-46.

145. Sykes, *supra* note 63, at 67-68.

146. *Id.*

147. "Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health," available at <http://www.ustr.gov/sectors/doha-trips-graph6.PDF> (last visited May 20, 2003).

148. *Id.*

149. *Id.*



Council.

If countries lacking the manufacturing facilities to produce pharmaceuticals under a compulsory license are permitted to seek foreign manufacture, then the TRIPS Council should monitor the use of the license in each case as well as the results achieved.<sup>150</sup> Therefore, there should be a reporting requirement for the country to provide necessary information to the Council regarding the nature of the national emergency, the pharmaceutical subject to the compulsory license, where the drug is manufactured, in what quantities and whether there is any evidence that the drugs are not reaching the domestic market.<sup>151</sup>

The entire output of the manufacturing facility should be required for domestic use only in the country that has the compulsory license.<sup>152</sup> The drug should be exported to and used solely by the member in need. Furthermore, the member with the compulsory license should ensure this is executed without any of the product shipped to another country.

These measures would ensure that countries lacking the manufacturing capability can still obtain the pharmaceuticals necessary during a national emergency while also limiting its scope and protecting the patent holder. Such limitations would balance the right to access necessary medications and the right of the patent holder.

## *B. Counteracting Infringement Methods*

### *1. Differential Pricing*

Differential pricing would allow the patent holder to sell pharmaceuticals in every country at an affordable price. The wealthier countries pay more, allowing the patent holder to recover the research and development costs of that drug where it can be afforded. The poorer countries pay what they can in order to cover the marginal costs of manufacturing the drug plus a very minimal profit. The patent holder would at least recoup some profit.<sup>153</sup> However, for this to work, there must be a collective action among developing countries to protect the patent holder from parallel imports.

### *2. Exhaustion of Rights*

Although amendments to TRIPS are difficult to execute, it benefits both developing and developed countries when the rights

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150. *Id.*

151. *Id.*

152. *Id.*

153. Sykes, *supra* note 63, at 64.

of a patent holder are not exhausted after the first sale.<sup>154</sup> Patent holders should be given the right and the power to fight patent infringement throughout the world. The income pharmaceutical companies potentially lose through compulsory licensing may be less prevalent if other forms of patent infringement could be stopped or deterred.

### C. *Stronger Patent Protection*

The long history of little, if any, patent protection in the developing and under developed countries has discouraged pharmaceutical companies from developing drugs to be marketed in those areas. If developing countries strengthen IP protection within their borders, the pharmaceutical companies have a greater incentive to willingly enter those markets.

Although the market in developing countries seems minimal compared to the world market, stronger patent protection may be the necessary incentive necessary to the development and low pricing of drugs in those countries.

Drugs that treat serious and widespread conditions are precisely the drugs that are the most valuable to society, and thus the types of drugs on which more research and development has the greatest potential payoff. A policy that requires the developers of such drugs to sacrifice their intellectual property rents in the name of a 'national emergency' or some similar moniker will simply discourage research in the areas where it has the most potential to yield high returns.<sup>155</sup>

In one study, a survey conducted in a range of industries sought to determine what percentage of inventions would not have been developed if not for IP protection.<sup>156</sup> The empirical data showed that for most industries, fourteen percent of the products would not have been developed.<sup>157</sup> However, the response for the pharmaceutical industry was sixty percent.<sup>158</sup>

### D. *Changes are Needed to Make TRIPS More Effective*

Currently, the enforcement of IP rights under TRIPS is weak because TRIPS does not clearly define the settlement of patent right disputes.<sup>159</sup> Instead, TRIPS leaves it to the signatory

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154. *Id.* at 67.

155. *Id.* at 62.

156. *Id.* at 60-61.

157. *Id.*

158. *Id.*

159. Pechman, *supra* note 42, at 193. *See also*, Mills, *supra* note 110, at 234. GATT also does not have an established court system to settle disputes and instead disputes are often settled with panel discussions. *Id.* Once the panel reaches a decision it recommends that the member nation conform to the panel's decision, however, these decisions are not binding on a member nation.

countries to determine enforcement of the minimum treaty standards.<sup>160</sup> However, TRIPS establishes that the treaty's purpose is to enforce property rights of patent holders in order to prevent any restraint or adverse affects on international trade or on the transfer of technology.<sup>161</sup>

In order to fulfill that goal, TRIPS needs to implement an effective method to enforce the property rights of patent holders internationally.<sup>162</sup>

TRIPS has several provisions calling for fair enforcement procedures without unreasonable delay, however, there is no mechanism in place to enforce these provisions on the member nations.<sup>163</sup> Therefore, if member countries refuse to comply with TRIPS, a WIPO agency should have the power to take over the enforcement of IP rights until that member country is in compliance.<sup>164</sup> Thus, countries that readily sign and agree to comply with TRIPS and all of its provisions, must be accountable to the WIPO agency.

Therefore, TRIPS should take over the enforcement of IP rights until individual nations implement their own effective systems. Once the member states establish proper enforcement measures, TRIPS can then allow the countries to enforce their own IP rights.

#### *E. An Independent Tribunal Should Be Created To Enforce Patent*

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*Id.*

160. TRIPS Agreement art. 41, § 1 (providing that members are to ensure that IP rights under TRIPS are enforced).

161. TRIPS Agreement art. 8, § 2.

162. Claude E. Barfield & Mark A Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185, 188 (1999). An effective enforcement system for IP rights would prevent parallel imports. *Id.* A patent holder should be allowed to prevent the distribution of goods across borders. *Id.* See also WIPO, *Advisory Committee*, *supra* note 111. One way to do this is via border enforcement. *Id.* Currently, TRIPS' border enforcement measures are not enforced. *Id.* The patent holder must file an application with the nation's authorities to use the border enforcement measure, requiring the patent holder to supply all necessary information. *Id.* That means that the patent holder must supply the authorities with all details of the counterfeit goods including when they will be coming in, how much and what transportation is being used. *Id.* Authorities should be allowed to take the initiative themselves to create truly effective border enforcement. *Id.*

163. See TRIPS, *supra* note 51, art. 41, § 2 (calling for fair and equitable proceeding, and the prevention of unnecessary or costly delay). See also TRIPS, *supra* note 51, art. 41, § 1 (requiring the procedures under member nations' laws which ensure effective action against infringement of IP rights).

164. Sabatelli & Rasser, *supra* note 44, at 610. Currently, WIPO "essentially ratifies the status quo" since articles 21 and 23, which address the interpretations and enforcement of patent claims, have such broad language and most of the signatory countries would not need to take action to comply with it. *Id.*

### *Holder's Rights*

In order for TRIPS to take over enforcement of IP rights, there must be a tribunal to implement a settlement system. Therefore, there should be an independent court created under WIPO for the settlement and enforcement of patent disputes.<sup>165</sup>

#### *1. The Settlement of Patent Disputes*

There are several aspects of current dispute settlement procedures in many problematic nations. In fact, a few countries already acknowledge that their own judiciary is not up to the task of prosecuting IP crimes.<sup>166</sup> Thailand, the Philippines and Panama, and especially China, have begun to create specialized courts to deal with IP crimes.<sup>167</sup> These countries have realized that their current judiciary needs to provide better enforcement, better trained judges,<sup>168</sup> and fewer delays.<sup>169</sup>

China has taken the creation of a specialized patent tribunal system very seriously. This is evidenced by the extensive efforts made to ensure effective enforcement of IP rights. China created a series of specialized courts to implement the new laws it adopted to protect IP rights.<sup>170</sup> China realized the need for strong IP protection in order to participate in the world economy. Therefore, China has taken a strong stand against patent and all other forms of IP infringement.

The Intellectual Property Right Tribunal in China has jurisdiction over the protection of IP rights in order to safeguard

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165. Mills, *supra* note 110, at 235. Currently, WIPO, which is under the jurisdiction of the International Court of Justice, has few mechanisms for the enforcement of IP rights. *Id.* Recently, WIPO has opened an arbitration center which addresses these issues. *Id.* The arbitration center allows for arbitration, mediation and even expedited forms of arbitration and mediation. *Id.* A party can start with mediation, which is non binding, and, under the expedited form, if a dispute is not settled within a certain time frame, the dispute will automatically be directed to an expedited arbitration, which is binding. *Id.* at 235-36. However, WIPO has no real means in which to enforce these binding results. *Id.* at 237.

166. Peter Fowler, *Intellectual Property and the Global Marketplace: A Panel Discussion*, at <http://usinfo.state.gov/journals/ites/0598/ijee/ippanel.htm> (last visited Jan. 29, 2003).

167. *Id.*

168. Mills, *supra* note 110, at 231. The lack of experience for a judge on a patent case causes delay as well as inconsistent results. *Id.* Therefore, having judges that already have the necessary technical expertise would speed up the process and provide more consistent, educated results. *Id.*

169. *Id.*

170. See "The organization, functions and powers of the People's courts," available at <http://www.chinaiprlaw.com/english/courts/court1.htm> (last visited Apr. 28, 2003) (describing China's court system). See also, Naigen Zhang, *Intellectual Property Law in China: Basic Policy and New Developments*, 4 ANN. SURV. INT'L & COMP. L. 1, 4 (1997) (describing Chinese patent law in detail).

the rights of patent holders and “to guarantee a party to fully expect the right of action.”<sup>171</sup> The IP Tribunal has appellate jurisdiction from the People’s Courts. Among other issues, the Court may hear patent infringement cases that, though not crimes, potentially may harm the patent owner.<sup>172</sup>

China’s legal remedies under its patent law are extensive.<sup>173</sup> The parties are first encouraged to settle the matter on their own. However, where they cannot agree, the parties may institute legal proceedings in the People’s Court or they can request that the China Patent Office handle the matter.<sup>174</sup> If those authorities find the claim to be well founded, it may order the infringer to immediately stop.<sup>175</sup> If the patent holder is not satisfied, the holder can bring an action to the People’s Court.<sup>176</sup>

Chinese law recognizes the need for quick action. When a request is made to stop patent infringement, if the patent holder is likely to be harmed, the Court issues a ruling within forty-eight hours.<sup>177</sup> The Court offers remedies that provide the patent holder with real recourse for patent infringement.<sup>178</sup> China requires that illegal income from patent infringement be confiscated.<sup>179</sup> The infringing party may also be fined up to three times the amount of the illegal income along with a fine of up to 50,000 Renminbi.<sup>180</sup> The infringer may also be prosecuted where the infringement constitutes a crime.<sup>181</sup> Additionally, calculated damages are recoverable, which include the losses suffered by the patent holder in addition to the infringer’s profits.<sup>182</sup>

An international dispute resolution process should take its cue from China, and other countries, to eliminate the excessive costs, undue delay and lack of knowledge currently plaguing the judicial systems of some countries.<sup>183</sup> Several ways to combat the

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171. “Judicial Protection of IPR in China,” available at <http://www.chinaiprlaw.com/english/courts/sichuan.htm> (last visited Apr. 28, 2004).

172. *Id.*

173. “Chapter 7: Protection of Patent Right,” available at <http://www.chinaiprlaw.com/english/laws/laws4.htm> (last visited Apr. 28, 2003).

174. *Id.* See also, Zhang, *supra* note 170, at 4 (explaining that the Chinese Patent Office has the ability to settle disputes before they reach the court system, and also has the power to issue orders for the cessation of patent infringement).

175. “Chapter 7: Protection of Patent Right,” *supra* note 173.

176. *Id.*

177. “Bid to Fortify IPR Protection,” available at <http://www.chinaiprlaw.com/english.laws/laws9.htm> (last visited Apr. 28, 2003).

177 “Chapter 7: Protection of Patent Right,” *supra* note 173.

179. *Id.*

180. *Id.*

181. *Id.*

182. *Id.*

183. Pechman, *supra* note 42, at 182-83.

excessive delays exist.<sup>184</sup> A firm trial date, as well as strict deadlines for each stage of the trial, must be set early in the proceeding.<sup>185</sup> An overall maximum time limit for a case settlement must also be established.<sup>186</sup>

## 2. *A Specialized International Intellectual Property Tribunal*

This Comment proposes that a specialized international intellectual property tribunal should be created in order to combat IP infringement worldwide. A specialized tribunal, if effective, would allow patent holders to efficiently defend their rights and hold patent infringers responsible for pirating acts.

The International Criminal Court ("ICC") is an example of an effective independent international court. The U.N. established the ICC in 1998 to prosecute crimes against humanity such as genocide.<sup>187</sup> The International Court of Justice ("ICJ"), the arena for prosecuting international crimes, had no criminal jurisdiction for prosecuting individuals.<sup>188</sup> The ICC, put into force in 2002, is currently not hearing cases until the Court is fully established and operational.<sup>189</sup> Though created under the direction of the U.N., the ICC operates independently of the U.N.<sup>190</sup>

A primary purpose behind creating the ICC was to allow prosecutions against individuals.<sup>191</sup> As it was, the International Court of Justice at The Hague was capable of only handling cases among states, not among individuals.<sup>192</sup> As a result, many states refused to prosecute its own citizens and crimes went unpunished.

Similarly, the current system for international patent disputes is only capable of handling disputes among states, not individuals. This carries the same result, individual states refuse to prosecute their own citizens and crimes go unpunished. Patent infringers should be brought to justice by the national court system, however, these nations are often unwilling or unable to act.<sup>193</sup> As stated earlier, many states benefit from patent

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184. *Id.* at 183. The current dispute settlement procedures under WIPO are unnecessarily long and arduous, creating a complex and lengthy process. *Id.*

185. Fiorito, *supra* note 140, at 18.

186. See Pechman, *supra* note 42, at 196 (discussing that Congress has set such deadlines requiring that disputes be settled within eighteen months even if a settlement is underway).

187. "Rome Statute of the International Criminal Court," available at [http://www.un.org/law/icc/statute/99\\_corr/estatute.htm](http://www.un.org/law/icc/statute/99_corr/estatute.htm) (last visited Apr. 28, 2003).

188. International Criminal Court, at <http://www.icc-cpi.int/php/show.php?id=history> (last visited May 10, 2003).

189. *Id.* ¶ 4.

190. *Id.* ¶ 9.

191. Article I of the "Rome Statute of the International Criminal Court," *supra* note 187 (last visited Apr. 28, 2003).

192. *Id.*

193. Pechman, *supra* note 42, at 182.

infringement and may not gain any benefit from enforcing the rights of patent holders against pirates living within the state's borders.

*F. The Need for Stronger National Enforcement Against Patent Infringement*

There is an urgent need for those countries with proper IP enforcement to fully implement those procedures against patent infringement. Strong civil or criminal penalties are ineffective deterrents for career IP criminals.<sup>194</sup>

Often unconvicted patent infringers are allowed to retain the counterfeited goods.<sup>195</sup> These goods are placed back in the international market and the crime continues.<sup>196</sup> Conversely, counterfeit goods should immediately be destroyed, whether or not the defendant is convicted.<sup>197</sup> This prevents counterfeited goods from reentering the marketplace and benefits both the public and the patent holder.<sup>198</sup>

Those defendants convicted of patent infringement should lose their business license in that country as well as their licenses for importing and exporting goods.<sup>199</sup> A civil fine is often not enough to punish a patent infringer who makes a substantial profit. Therefore, a more effective way to deter patent infringement is to focus on preventing that patent infringer from continuing to commit IP crimes.<sup>200</sup>

*G. Developing Countries Should Be Required to Conform to TRIPS*

The TRIPS articles allowing extensive compliance delays for developing countries must be limited.<sup>201</sup> Though understandable that developing countries need extended time to bring their systems up to TRIPS standards,<sup>202</sup> granting such extensive delays

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194. *WIPO, Advisory Committee, supra* note 111.

195. *Id.* TRIPS requires the mental state of willfulness in order for a defendant charged with patent infringing to be convicted, therefore, the goods may in fact be counterfeit even though the defendant may not be convicted. *Id.*

196. *Id.*

197. *Id.*

198. *Id.*

199. *Id.*

200. *Id.*

201. *See* TRIPS, *supra* note 51, at art. 65 (allowing a developing country to delay compliance for four years after application to WTO agreement); *see also*, TRIPS, *supra* note 51, at art. 66, § 1 (providing for a ten year compliance delay for least developed countries).

202. Mills, *supra* note 110, at 232-33. Generally, developed nations provide higher safeguards for patent protection than do developing nations. *Id.* Therefore, more time is needed for the developing nations to bring their patent

hinders patent holder's rights, constricts international trade, and hampers the development of the country itself.<sup>203</sup> Such extensions should only be provided in exchange for firm timetables of compliance, as well as periodic progress reports.<sup>204</sup>

Developing countries need incentives to bring their patent enforcement systems up to TRIPS standards. Economic aid helps a country develop its own economy to a point where the protection of IP rights is beneficial.<sup>205</sup> The economic aid should not only focus on developing the country's economy, but also on cutting the cost of developing its IP system as well.<sup>206</sup> Finally, economic aid also helps to curtail the increased cost of goods that inevitably results from the granting of patents.<sup>207</sup>

Furthermore, developing countries need training to assist in the transition and implementation of TRIPS.<sup>208</sup> Training programs should advise developing countries on the best way to implement as well as enforce a new IP system.<sup>209</sup> All of these provisions encourage developing countries to bring IP systems up to TRIPS standards, benefiting patent holders as well as the developing country itself.

#### IV. THE FOUNDATION HAS BEEN LAID

A harmonized enforcement system for IP rights benefits all. It provides more certainty for patent holders as well as security for foreign investment. It helps to limit the amount of piracy occurring worldwide, which helps reduce the price of patented goods as well as the cost of the patent system itself.<sup>210</sup>

A few modifications to the current IP enforcement system will have a potent affect in helping patent holders enforce their rights. The foundation for a harmonized patent system has been laid with the WTO, the U.N., WIPO and TRIPS. We ought to build upon that foundation, further the development of an international IP

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systems up to TRIPS standards. *Id.*

203. Sabatelli & Rasser, *supra* note 44, at 616-17. *See also* Pechman, *supra* note 42, at 193 (explaining that concessions granted to developing countries may hinder efforts of the implementation of TRIPS standards in those countries).

204. Sabatelli & Rasser, *supra* note 44, at 617.

205. Kirchanski, *supra* note 79, at 600.

206. *Id.* The patent systems in developing countries would be relatively inexpensive since most developing countries currently do not protect IP rights. *Id.* Therefore, a developing country which brought itself up to TRIPS standards would likely have few patents to begin with. *Id.*

207. *Id.*

208. WIPO, *Advisory Committee*, *supra* note 111.

209. *Id.*

210. Sergio Amenabar & Gustavo Leonardos, WIPO PATENT AGENDA REQUEST FOR COMMENTS, at <http://patentagenda.wipo.int/rfc/rfc1/0023.html> (Feb. 15, 2002).



system, and ensure the rights of patent holders. While there are no executed plans, good materials coupled with strong construction methods are the salient tools to ensure success.<sup>211</sup>

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211. Rogan, *supra* note 120, ¶ 38.