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Nathan E. Stacy

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# THE EFFICACY AND FAIRNESS OF CURRENT SANCTIONS IN EFFECTING STRONGER PATENT RIGHTS IN DEVELOPING COUNTRIES

*Nathan E. Stacy, Ph.D.*<sup>†</sup>

## I. INTRODUCTION

The world economy has changed in recent years, with manufacturing jobs shifting to nations with lower salaries.<sup>1</sup> While the United States has been living with this trend for many years, recently more and more white-collar jobs have also been moving to other markets.<sup>2</sup> This has been accompanied by the largest trade deficit in history, leading to concerns that the long-term economic stability of the United States may be at risk.<sup>3</sup> One optimistic point throughout all of the negative news concerning the trade

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<sup>†</sup> J.D., University of Tulsa College of Law, Tulsa, Oklahoma, Anticipated May 2006; B.S. Chemistry, Oklahoma State University, Stillwater, Oklahoma, May 1982, Ph.D. Inorganic Chemistry, Purdue University, West Lafayette, Indiana, May 1987. The author thanks his parents, Carl and Virginia Stacy, for their support and encouragement, especially when he decided to return to school to study law. The author especially thanks his wife Teresa Lynn Patterson for her love, encouragement, support and most of all patience making it possible to pursue a law degree. The author is also grateful to the staff of the Tulsa Journal of Comparative & International Law for their support, suggestions, and editorial assistance while preparing this comment, especially Erin Bender, Matt Wiebe, Amanda Hunt, Krista Hodges-Eckhoff, Emily Maxwell, Tim Hansen, Jill Parker and Lori Kingston.

1. See generally L.A. Lorek, *Levi Straus to Ship S.A. Jobs Overseas*, SAN ANTONIO EXPRESS-NEWS, Sept. 26, 2003, at 1A (discussing the reasons for Levi Straus closing two San Antonio sewing plants, including the lower costs of overseas labor); see also Ken Moritsugu, *Jobless Recovery Lasting Longer than Expected; Companies are Trying to Find Ways to Produce More with Fewer Workers*, THE BRADENTON HERALD, Aug. 10, 2003, at 4 (explaining that the so called "jobless recovery" is due to both the use of higher technology in the production of goods and services, and the shifting of more types of jobs overseas).

2. Associated Press, *IBM Jobs Moving Overseas*, DESERET MORNING NEWS, Dec. 16, 2003, at E01 (reporting on the movement of 4,700 programming jobs to India).

3. See generally Bruce Arnold, *Causes and Consequences of the Trade Deficit: An Overview*, CONGRESSIONAL BUDGET OFFICE MEMORANDUM, Mar. 2000 (noting that the largest trading deficit is with China).

deficit has been the export of intellectual property.<sup>4</sup> This is the primary motivation for strengthening intellectual property rights in the world, as a loss of these rights will directly harm the economic interests of the United States.<sup>5</sup>

#### *A. Importance of Strong Intellectual Property Protection*

This comment will focus on the importance of strong patent rights in protecting the economic strength of the United States. In addition, the economic benefits and liabilities that countries obtain through the protection of these intellectual property rights will be discussed. The comment will examine this subject in the context of the three most populous countries on the planet: China, India, and the United States.<sup>6</sup>

The second section will give an overview of what comprises "intellectual property," including patents, copyrights, and other forms of intellectual property. In the third section, the current organizations for the enforcement of intellectual property rights will be examined, including the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO). This section will focus on the purposes of these organizations, a brief overview of the history of their formation including the treaties that formed each, and the enforcement mechanisms inherent in each organizational structure. The dissatisfaction of the developed nations, especially the United States, with the lack of enforcement mechanisms inherent in (or used by) the WIPO, will be discussed. The resulting enforcement mechanisms included in the Agreement on Trade Related Aspects of Intellectual Property Services (TRIPS Agreement), implemented under the auspices of the WTO, will be examined.

The fourth section will discuss the difficulties in the development of patent rights in the least developed countries (LDCs) and developing countries (DCs). The perception of unfairness in the balance of intellectual property laws between the developed and the developing nations will be discussed, looking at some of the arguments raised by the LDCs and DCs against strong intellectual property protection, including

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4. See generally J. Thomas McCarthy, *Intellectual Property – America's Overlooked Export*, 20 U. DAYTON L. REV. 809 (1995).

5. *Id.* at 813; see also GRAEME B DINWOODIE, INTERNATIONAL AND COMPARATIVE PATENT LAW (2002). "[A]s the leading exporter of intellectual property in the world, the United States is a strong advocate for treaty membership and implementation." *Id.* at 233.

6. See CIA, THE WORLD FACTBOOK, available at <http://www.cia.gov/cia/publications/factbook/index.html> (listing the populations of these countries as China: 1.287 Billion, India: 1.050 Billion, United States: 290 Million) (last visited Sept. 14, 2004).

the problem of “biopiracy.” Historical examples showing the importance of intellectual property rights in the development of industries in developed countries will be presented.

In the fifth section, changes made at the national levels in each of the countries in response to the treaties or enforcement actions will be discussed. A case study from the WTO, focusing on a dispute resolution between the United States and India, will be used to illustrate these changes.

The sixth section will examine some examples of individual enforcement actions in the courts of the three countries. The seventh and final section will discuss whether the current mechanisms in the TRIPS Agreement are effective at requiring changes to strengthen international property laws. An argument will be made that the changes made as a result of this implementation, while difficult for LDCs and DCs in the short term, will lead to beneficial effects in the longer term.

## II. OVERVIEW OF INTELLECTUAL PROPERTY RIGHTS

“Intellectual property” is the right to products generated by the creativity of a person.<sup>7</sup> The importance of intellectual property rights (IPRs) to the well being of the United States has been accepted as important since its formation, as stated in the Constitution, “[t]he Congress shall have power . . . [t]o 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>8</sup> This clause recognizes two of the three most crucial types of intellectual property: copyrights and patents. Along with these two rights, the third most important type of intellectual property is the use of trademarks.<sup>9</sup> In addition to these important rights, a number of less important intellectual property rights have developed over the years. These include trade secrets, mask works, and industrial designs.<sup>10</sup>

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7. BLACK'S LAW DICTIONARY 813 (7th ed. 1999).

8. U.S. CONST. art. III, § 9, cl. 8.

9. See ALEXANDER POLTORAK & PAUL LERNER, ESSENTIALS OF INTELLECTUAL PROPERTY, ch. 1 (2002). The author discusses “The Big Three: Patents, Trademarks, and Copyrights.” *Id.* at 1.

10. See *id.* at ch. 2.

### A. Patent Rights

A patent gives “the right to prevent others from making, using, selling, offering for sale . . . or importing”<sup>11</sup> the protected invention for a period of years.<sup>12</sup> Three types of patents are defined in United States patent law: design patents, plant patents, and utility patents.<sup>13</sup> A design patent is granted for “any new, original and ornamental design for an article of manufacture.”<sup>14</sup> A plant patent is granted for any invented or discovered plant that one is able to asexually reproduce, so long as the plant is not found in an uncultivated environment.<sup>15</sup> By far, the most important type of patent is the utility patent.<sup>16</sup> A utility patent is granted to anyone who “invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”<sup>17</sup>

This comment will focus on the protections available for patent rights. However, it is important to have a definition of the remaining types of intellectual property for comparison to the rights granted by a patent. A trademark is used to identify a source of goods and can be any word, symbol, or combination.<sup>18</sup> A trademark can be registered at the state or national level,<sup>19</sup> and trademarks can also be used without registration, so long as it is identified as a trademark.<sup>20</sup>

### B. Copyrights

A copyright grants the owner exclusive rights to reproduction, preparation of derivative works, distribution, public performance, and

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11. *Id.* at 2.

12. See U.S. PATENT & TRADEMARK OFFICE, U.S. DEPT. OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURES § 2701 (8th ed. Aug. 2001, revised Feb. 2003) (discussing patent term for utility and plant patents); see also *id.* at § 1502.01 (discussing patent term for design patents).

13. POLTORAK & LERNER, *supra* note 9, at 2.

14. 35 U.S.C. § 171 (2003).

15. 35 U.S.C. § 161 (2003).

16. U.S. Patent & Trademark Office, U.S. Dept. of Commerce, *U.S. Patent Statistic, Calendar Years 1963-2003*, available at [ftp://ftp.uspto.gov/pub/taf/us\\_stat.pdf](ftp://ftp.uspto.gov/pub/taf/us_stat.pdf) (last visited Oct. 14, 2004) (indicating that in 2001, 166,039 utility patents were granted, compared to 16,872 design patents and 584 plant patents).

17. 35 U.S.C. § 101 (2003).

18. POLTORAK & LERNER, *supra* note 9, at 23.

19. *Id.* at 24.

20. *Id.*

transmission of the work.<sup>21</sup> It lasts for at least seventy years.<sup>22</sup> To obtain a copyright, it is only necessary for the creator to appropriately mark the copyright status on the work,<sup>23</sup> and under certain circumstances, deposit a copy with the Library of Congress.<sup>24</sup>

### C. *Less Important Forms of Intellectual Property Rights*

Other forms of intellectual property include trade secrets, mask works, and industrial designs.<sup>25</sup> Trade secrets consist of information that is not generally known, and may include technical information, formulations, business methods, and other information.<sup>26</sup> In *Ruckelshaus v. Monsanto*, the Supreme Court confirmed that trade secrets are a protected property right in which companies are given the right to use or disclose their trade secrets at their own option.<sup>27</sup> While numerous common law doctrines in the United States make theft of trade secrets a civil offense,<sup>28</sup> prior to the *Economic Espionage Act of 1996*,<sup>29</sup> no federal criminal penalties existed for theft of trade secrets from companies.<sup>30</sup> The act was specifically designed to protect United States corporations' trade secrets from theft for the benefit of foreign nationals.<sup>31</sup>

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21. 17 U.S.C. § 106 (2003).

22. See generally 17 U.S.C. §§ 301-305 (2003).

23. 17 U.S.C. §§ 401-406 (2003); see also POLTORAK & LERNER, *supra* note 9, at 31.

24. 17 U.S.C. § 407 (1988).

25. See POLTORAK & LERNER, *supra* note 9.

26. See ROGER M. MILGRIM, MILGRIM ON TRADE SECRETS, vol. 1 – 2, § 2.01, 1 (Matthew Bender 2003); see also RESTATEMENT OF TORTS: INTERFERENCE WITH BUSINESS RELATIONS § 757 cmt. b (1939) (defining a trade secret as “any formula, pattern, device or compilation of information which is used in one’s business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it”) [hereinafter RESTATEMENT].

27. 467 U.S. 986 (1984). “The economic value of that property right lies in the competitive advantage over others that Monsanto enjoys by virtue of its exclusive access to the data, and disclosure or use by others of the data would destroy that competitive edge.” *Id.* at 1012.

28. RESTATEMENT, *supra* note 26, at cmt. a. “The theory that has prevailed is that the protection is afforded only by a general duty of good faith and that the liability rests upon breach of this duty; that is, breach of contract, abuse of confidence or impropriety in the method of ascertaining the secret.” *Id.*

29. 18 U.S.C. § 1831 (1996).

30. See James M. Fischer, *An Analysis of the Economic Espionage Act of 1996*, 25 SETON HALL LEGIS. J. 239, 248-56 (2001).

31. 18 U.S.C. § 1831, *supra* note 29, at § 1831(a) (discussing that the law is aimed at “[w]hoever, intending or knowing that the offense will benefit any foreign government, foreign instrumentality, or foreign agent. . .”).

Intermediate between patent and copyright are mask works. Mask works are the stencils used in the creation of semiconductor chips, and they pose a number of unique problems in intellectual property protection.<sup>32</sup> As useful products they cannot be protected either under copyright or design patent laws.<sup>33</sup> They are often obsolete by the time a patent could be issued,<sup>34</sup> and they often would fail the non-obviousness requirement<sup>35</sup> for a utility patent.<sup>36</sup> To prevent the loss of this expertise to intellectual theft, Congress specifically passed a law in 1984<sup>37</sup> to recognize these assets and allow for their registration.<sup>38</sup>

The final type of intellectual property consists of industrial designs.<sup>39</sup> Industrial designs have many of the same problems as mask works. For example, they may be unique, but generally, they cannot pass the non-obviousness test, and they have a very short commercial lifespan.<sup>40</sup> The solution to this problem was a registration process similar to that used for the mask works. Typically, the design is registered with the copyright protection office.<sup>41</sup>

### III. ORGANIZATIONS ENFORCING INTERNATIONAL INTELLECTUAL PROPERTY RIGHTS

#### A. *World Intellectual Property Organization (WIPO)*

The purpose of the World Intellectual Property Organization is to protect the rights of creators and owners of intellectual property around the world.<sup>42</sup> The Paris Convention for the Protection of Industrial

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32. See POLTORAK & LERNER, *supra* note 9, at 41.

33. *Id.*

34. *Id.* at 42.

35. 35 U.S.C. § 103 (2003).

36. 18 U.S.C. § 1831, *supra* note 29; *see also* POLTORAK & LERNER, *supra* note 9, at 41.

37. 17 U.S.C. § 901 (2003).

38. 18 U.S.C. § 1831, *supra* note 29; *see also* POLTORAK & LERNER, *supra* note 9, at 41.

39. POLTORAK & LERNER, *supra* note 9, at 42.

40. *Id.*

41. *Id.* at 43.

42. WIPO, *An Organization for the Future*, at

[http://www.wipo.int/about-wipo/en/gib.htm#P23\\_2347](http://www.wipo.int/about-wipo/en/gib.htm#P23_2347) (last visited Sept. 25, 2004) (“The World Intellectual Property Organization (WIPO) is an international organization dedicated to helping to ensure that the rights of creators and owners of intellectual property are protected worldwide and that inventors and authors are, thus, recognized and rewarded for their ingenuity.”).

Property in 1883 created WIPO.<sup>43</sup> The Paris Convention went into effect in 1884, and an International Bureau was set up by the fourteen Member States to administer the treaty.<sup>44</sup> Copyright protection was added to the administrative duties of the International Bureau in 1893, when the International Bureau for the administration of the Berne Convention for the Protection of Literary and Artistic Works was combined with the International Bureau administering the Paris Convention to become the United International Bureau for the Protection of Intellectual Property (BIRPI).<sup>45</sup> In 1970, the adoption of the Convention Establishing the World Property Organization made BIRPI into WIPO,<sup>46</sup> and in 1974 WIPO became an agency of the United Nations.<sup>47</sup>

### 1. The Treaty Foundation for the WIPO

The Paris Convention is the founding treaty of the WIPO and defines industrial property as “patents, utility models, industrial designs, trademarks, service marks, trade names, and indications of source or appellations of origin.”<sup>48</sup> The patent protection afforded such property is defined in the treaty as equal to the protection afforded the nationals of the country in which the protection is sought.<sup>49</sup> While specific remedies for trademark infringement are clearly delineated in the Paris Convention,<sup>50</sup> remedies for patent infringement are only defined as the rights afforded a national in the country in which enforcement is sought.<sup>51</sup> In fact, the Paris Convention does not extend patent protection equal to that afforded nationals. It has an article that can force compulsory licensing of the invention in the country in which protection is sought for either failure to use the invention, or failure to work the invention in that country.<sup>52</sup> These points mean that lack of harmonization of patent laws can be used to lower the protection an inventor in one country will have in another country. For example, through the tailoring of patent laws a country can ensure

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43. *Id.*

44. *Id.*

45. *Id.*

46. *Id.*

47. *Id.*

48. Paris Convention for the Protection of Industrial Property, June 2, 1934, art. 1(2), 53 Stat. 1748, 828 U.N.T.S. 108, 115 [hereinafter Paris Convention].

49. *Id.* at art. 2.

50. *Id.* at arts. 7bis-10bis.

51. *See id.*

52. *Id.* at art. 5.



that it has freer access to the patents of another country that generates greater numbers of patents.<sup>53</sup>

This problem is apparent to practitioners, and has led to numerous efforts to force this harmonization, including clauses contained in the treaty that formally organized WIPO.<sup>54</sup> In the treaty, one of the purposes of the WIPO was to harmonize national legislation on intellectual property.<sup>55</sup> Numerous arguments have been made for the necessity of harmonization,<sup>56</sup> but opponents from both developed and developing countries have tried to resist normalization. From the point of view of the developed countries, especially the United States, the efforts at harmonization are an attempt to weaken patent protections.<sup>57</sup> From the point of view of the developing countries, normalization of patent laws will lead to stronger patent protection. Since most of the patents are from the United States, they felt that this is just another example of the United States' attempts at hegemony over the rest of the world.<sup>58</sup>

## 2. Developed Nations' Dissatisfaction with WIPO

The dissatisfaction of developed countries with the enforcement mechanisms available through WIPO, the weakness of the protections afforded patents under the Paris Convention, and the lack of harmonization in patent laws led to the inclusion of the Trade Related Aspects of Intellectual Property Rights (TRIPS) in the General Agreement on Trades and Tariffs (GATT).<sup>59</sup> The developing countries, on

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53. Kate H. Murashige, *Harmonization of Patent Laws*, 16 HOUS. J. INT'L L. 591, 595 (1994).

54. Convention Establishing the World Intellectual Property Organization, Jul. 14, 1967, 21 U.S.T. 1749, T.I.A.S. No. 6932.

55. *Id.* at art. 4 (i).

56. See generally Edward G. Fiorito, *The WIPO "Basic Proposal" for Harmonization of Patent Laws Viewed from the U.S. Practitioners Point of View*, 19 AM. INTELL. PROP. L. ASS'N. Q. J. 24 (1991); see also Murashige, *supra* note 53.

57. Fiorito, *supra* note 56, at 32-33 (noting that the U.S. stood by itself in continuing to demand that the best mode requirement be met).

58. VANDANA SHIVA, *PROTECT OR PLUNDER? UNDERSTANDING INTELLECTUAL PROPERTY RIGHTS* 11 (Zed Books Ltd., 2001) (arguing that patents are "instruments of conquest").

59. NUNO PIRES DE CARVALHO, *THE TRIPS REGIME OF PATENT RIGHTS*, 24-25 (2002). "It is true that the Paris Convention had already a few provisions obliging Member States to adopt border measures and effective legal remedies, but those are of a general nature and ultimately depend on the existence of national law provisions." *Id.* at 25; see also *id.* at 43-44 n.152 (pointing out that the failures of the developing countries to participate in earlier WIPO negotiations that would have raised patent protections "were the factor[s] that

the other hand, wished to keep all discussion and negotiation of intellectual property in the WIPO.<sup>60</sup> GATT, which contains the TRIPS Agreement and establishes the World Trade Organization (WTO), was signed into law in the United States in 1994.<sup>61</sup>

### B. World Trade Organization (WTO)

The WTO was established on January 1, 1995, by the Uruguay Round of Negotiations of the GATT.<sup>62</sup> The primary purpose of the WTO is to “help trade flow as freely as possible – so long as there are no undesirable side-effects.”<sup>63</sup> Within this context, the organization provides a negotiating forum for nations to sort out their trade disputes,<sup>64</sup> and provides a neutral procedure to settle these differences.<sup>65</sup> The initial GATT treaty that led to the WTO was first signed in 1948, leading to a de facto organization given the same name as the treaty.<sup>66</sup>

The rest of this discussion will focus on Article 4 of the Uruguay Round of GATT, known as the TRIPS Agreement.<sup>67</sup> In what seems like a non-sequitur, the most fundamental goal of the TRIPS Agreement is not to enhance intellectual property rights.<sup>68</sup> This is secondary to its true purpose of promoting free trade by increasing the strength of intellectual property rights.<sup>69</sup> This is illustrated by two factors. First, protecting the

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convinced the major trading partners that GATT, unlike WIPO, could provide a more persuasive negotiating environment – hence the pursuance of intellectual property negotiations in the GATT”); Monique L. Codray, *GATT v. WIPO*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 121 (1994).

60. DE CARVALHO, *supra* note 59, at 43.

61. Louis S. Sorell et al., *Changes to U.S. Patent Law Under GATT: Summary and Practice Recommendations*, 426 PRACTISING L. INST. 95 (1995).

62. WORLD TRADE ORGANIZATION, UNDERSTANDING THE WTO 2 (2003), available at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/understanding\\_e.pdf](http://www.wto.org/english/thewto_e/whatis_e/tif_e/understanding_e.pdf) (last visited Sept. 14, 2004) [hereinafter UNDERSTANDING THE WTO].

63. *Id.* at 10.

64. *Id.* at 11.

65. *Id.* at 12.

66. *Id.* at 10.

67. General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A3, 55 U.N.T.S. 187; Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994); Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, 33 I.L.M. 81 [hereinafter TRIPS Agreement].

68. DE CARVALHO, *supra* note 59, at 31 (“The first paragraph of the Preamble identifies the most fundamental goal of the TRIPS Agreement: to reduce distortions and impediments to international trade.”).

69. *Id.* at 35.

author's "moral rights" to their work, as mentioned in the Berne Convention,<sup>70</sup> "does not necessarily promote free trade," and is not required by the TRIPS Agreement.<sup>71</sup> Second, the TRIPS Agreement only mentions inventors once, and then only to specify that the inventor will reveal the best mode of the invention.<sup>72</sup> Although the primary purpose of the TRIPS Agreement is not to strengthen individual patent rights, the protection of individual property rights is the secondary purpose of TRIPS.<sup>73</sup> In the preamble, the agreement states that patent rights are individual rights.<sup>74</sup> The purpose of this is to emphasize that governments are to pass the laws necessary in each of the Member States to allow private citizens to pursue their own actions against infringers.<sup>75</sup>

### 1. Treaty on the Trade Related Aspects of Intellectual Property (TRIPS)

The TRIPS Agreement consists of seventy-three articles in seven parts, covering basic obligations, intellectual property rights, enforcement of rights, acquisition of rights, dispute resolution, a transitional period until full implementation, and the implementation of institutional arrangements for overseeing the agreement.<sup>76</sup> The TRIPS Agreement covers a number of intellectual property rights in addition to patents, including copyrights, trademarks, geographical indications, industrial designs, integrated circuits, and trade secrets.<sup>77</sup> This discussion of the TRIPS Agreement will focus on those articles that are most relevant to protecting, obtaining, and enforcing patent rights in Member States of the WTO.

As defined in Part I, the first and foremost obligation of Member States is to implement the agreement in national legislation.<sup>78</sup> Since Article 1 includes the Paris Convention and Berne Convention by reference, these treaties are now included in a framework that has

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70. Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, art. 11bis(2), 99 Stat. 27, S. TREATY DOC. NO. 99-27.

71. DE CARVALHO, *supra* note 59, at 35.

72. *Id.* at 36.

73. *Id.* at 32.

74. TRIPS Agreement, *supra* note 67, at 84.

75. DE CARVALHO, *supra* note 59, at 33.

76. TRIPS Agreement, *supra* note 67, at 83.

77. *Id.*

78. *Id.* art. 1, cl. 1, at 84-85.

enforcement power.<sup>79</sup> As in the Paris and Berne Conventions, the TRIPS Agreement requires Member States to treat nationals of other Member States no less favorably than its own citizens.<sup>80</sup> The agreement also prevents nations from arranging side agreements to treat each others' citizens more favorably than those of other Member States.<sup>81</sup>

Part I also contains a clear statement of the objective of the TRIPS agreement in Article 7:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.<sup>82</sup>

While the obligations are clearly defined, the agreement still leaves the freedom for nations to adopt measures they feel are of national importance, so long as they are consistent with the TRIPS Agreement.<sup>83</sup>

One issue that could not be agreed upon in the Uruguay Round of negotiations was the concept of exhaustion of patent rights.<sup>84</sup> Under many circumstances, patented products may be sold at a lower price in one country than another.<sup>85</sup> This motivates importation of products from countries with a lower price to countries with a higher price; this is defined as parallel importation.<sup>86</sup> In the absence of trade barriers, the only control a producer has over this is the existence of patent rights in the country of importation.<sup>87</sup> Since patent rights are national rather than international, the owner should be able to enforce the rights in the target country to prevent importation; however, they are often blocked by the doctrine of exhaustion of patent rights.<sup>88</sup> The doctrine of exhaustion of patent rights

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79. *Id.* art. 2, cl.2, at 85; see also DINWOODIE, *supra* note 5, at 233 (noting that “[a]s a general matter, countries are expected or required to bring their laws into compliance with treaty obligations before joining”).

80. TRIPS Agreement, *supra* note 67, art. 3, at 85.

81. *Id.* art. 4, at 86.

82. TRIPS Agreement, *supra* note 67, art. 7, cl. 1, at 86-87.

83. See *id.*

84. *Id.* art. 6, at 86.

85. David Perkins et al., *Exhaustion of Intellectual Property Rights*, 574 PRACTISING L. INST. 41, 45 (1999).

86. *Id.* at 46.

87. *Id.*

88. *Id.*

originated in the United States and the United Kingdom in similar ways, and basically states that once a product is sold under a patent, the buyer has the right to use, sell, or dispose of the product in any way he or she wishes, including exportation to any other country.<sup>89</sup> The importance of this subject is highlighted by the current disputes over attempts to import lower cost pharmaceuticals from Canada.<sup>90</sup> The importance of the exhaustion of patent rights and the inability of the negotiators to agree on inclusion of the topic in TRIPS nearly guarantee it will become a point of contention in future trade disputes.

One of the most important changes from previous conventions, made a part of the TRIPS Agreement, focuses on defining what can be protected as intellectual property.<sup>91</sup> The requirements for a patent are defined in section five of part II.<sup>92</sup> The TRIPS Agreement details the requirement as follows: "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."<sup>93</sup> This wording, including "inventive step," and "industrial application," follows the wording of the European Patent Convention.<sup>94</sup> To ensure standardization, the TRIPS Agreement explicitly equates these terms with "non-obvious" and "useful,"<sup>95</sup> matching the wording used in the United States.<sup>96</sup> In addition to these requirements, Member States are permitted to exclude certain items from patentability, including items that may be harmful to public health or morality,<sup>97</sup> medical and diagnostic procedures,<sup>98</sup> and animals or plants under most circumstances.<sup>99</sup>

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89. *Id.* at 48.

90. See generally Karl Ross, *Bush Rebuffs Canada Drug Plan; Gov. Bush Rejects Miami-Dade Mayor Alex Penelas' Attempts to Begin a State Program to Import Less-Expensive Canadian Prescription Drugs*, THE MIAMI HERALD, Dec. 25, 2003, at 1; Sarah Lueck, *Senate Supports Wider Importing of Canada Drugs*, WALL ST. J., June 23, 2003, at A10.

91. TRIPS Agreement, *supra* note 67, pt. II, at 87-99.

92. *Id.* arts. 27-34, at 93-97.

93. *Id.* art. 27, cl. 1, at 93-94.

94. European Patent Convention, Oct. 5, 1973, art. 52(1).

95. TRIPS Agreement, *supra* note 67, pt. II, at 87.

96. 35 U.S.C. § 101 (2003) (requiring that an invention must be "new and useful" for patentability); see also 35 U.S.C. § 103 (2003) (requiring that an invention must be "non-obvious" for patentability).

97. TRIPS Agreement, *supra* note 67, art. 27, cl. 2, at 94.

98. *Id.* art. 27, cl. 3(a), at 94.

99. *Id.* art. 27, cl. 3(b), at 94.

## 2. Enforcement Mechanisms in the TRIPS Agreement

The major rights conferred on a patent holder under the TRIPS Agreement are the ability to prevent others from practicing or importing materials in violation of the terms of the patent and to license or sell the patent to others.<sup>100</sup> While these rights are analogous to the rights given patent holders in the United States,<sup>101</sup> the TRIPS Agreement contains a number of conditions under which patent holders can be deprived of their patent rights.<sup>102</sup> The first of these conditions is the limited use of the patented product under Article 30, provided such a use does not “unreasonably prejudice the legitimate interests of the patent owner.”<sup>103</sup> An example of this is the regulatory review exception permitted for pharmaceuticals in Canada, which allows any amount to be produced to prove the ability of the future manufacturer of a generic drug to meet quality and technical specifications, so long as the product is not sold or stockpiled for future sales.<sup>104</sup>

A more problematic exception to patent holders’ rights is provided in Article 31,<sup>105</sup> which allows for compulsory licensing of patents under a number of conditions.<sup>106</sup> DCs and LDCs have strongly fought for the right to force compulsory licenses, but they harm both patentees and the nations in which they are granted.<sup>107</sup> The patentees’ rights are harmed by giving up the right to turn down a licensee, while the presence of compulsory licenses as an option kills research in areas in which they are granted.<sup>108</sup> While they cannot be granted for trivial purposes, some LDCs will be allowed to issue licenses across borders to enable generic firms in more developed countries to make drugs for major health crises, such as the AIDS pandemic in southern Africa.<sup>109</sup> The TRIPS Agreement does require adequate compensation for the patent owner, a limited term for

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100. *Id.* art. 28, at 94.

101. 35 U.S.C. § 271 (2003).

102. TRIPS Agreement, *supra* note 67, arts. 30-31, at 95-97.

103. *Id.* art. 30, at 95.

104. DE CARVALHO, *supra* note 59, at 220 n. 567.

105. TRIPS Agreement, *supra* note 67, art. 31, at 95-96.

106. DE CARVALHO, *supra* note 59, at 230; *see also id.* at 60 (noting that a compulsory license is a license granted by a government to a firm other than the patent owner to work the patent locally, or to obtain a lower price for the goods).

107. *Id.* at 231.

108. *Id.*

109. *WTO'S Compulsory License Rules*, FOOD & DRUG LETTER, No. 688 (Nov. 21, 2003).

the compulsory license, and non-exclusivity for the compulsory licensee, all of which tend to discourage the use of compulsory licenses.<sup>110</sup>

In addition to the requirement that all subject matter be patentable, the second most important change that the TRIPS Agreement provides over previous patent conventions is the establishment of clear procedures for the enforcement of intellectual property rights.<sup>111</sup> These articles do not stop at the general requirement of the Paris Convention that "nationals of each of the countries of the Union shall . . . enjoy in all other countries of the Union the advantages that their respective laws now grant . . . to nationals."<sup>112</sup> In the Paris Convention, the format of the legal proceedings for the protection and enforcement of intellectual property was expressly reserved to the Member States.<sup>113</sup> In the TRIPS Agreement, however, the format of the entire proceeding is clearly laid out, including fundamental requirements that the procedures "be fair and equitable [and] . . . shall not be unnecessarily complicated or costly."<sup>114</sup> Also, the decisions must be in writing and provided to the parties "without undue delay."<sup>115</sup> While the TRIPS Agreement specifically states that it does not require the creation of an extra-judicial system for intellectual property cases, nor the allocation of scarce judicial resources to these types of cases,<sup>116</sup> it does impose a number of complex requirements. These requirements include formalities concerning procedures,<sup>117</sup> evidence,<sup>118</sup> and remedies.<sup>119</sup>

The procedural requirements include much of what would be considered due process in developed countries, including: timely and complete written notice of the proceedings and their basis, the right to present evidence to substantiate claims, and procedures to protect confidential information.<sup>120</sup> The evidentiary requirements include required disclosure of evidence by the opposing party upon the presentation of a

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110. TRIPS Agreement, *supra* note 67, art. 31(d), (g), & (h), at 95.

111. *Id.* pt. III, at 99-105.

112. Paris Convention, *supra* note 48, art. 2(1).

113. *Id.*

114. TRIPS Agreement, *supra* note 67, art. 41, cl. 2, at 99.

115. *Id.* art. 41, cl. 3, at 99.

116. *Id.* art. 41, cl. 5, at 99-100.

117. *Id.* art. 42, at 100.

118. *Id.* art. 43, at 100.

119. *Id.* arts. 44-46, at 100-101.

120. TRIPS Agreement, *supra* note 67, art. 42, at 100.

prima facie case,<sup>121</sup> and the ability of authorities to make a determination in the absence of voluntary presentation of evidence.<sup>122</sup>

The relief mechanisms defined by TRIPS are analogous to those in U.S. Civil Procedure.<sup>123</sup> These include injunctive relief, which may be granted at the discretion of the Member State.<sup>124</sup> Additionally, damages may be ordered by the Member State's court, including adequate compensation for the infringement, and potentially including appropriate attorney's fees and disgorgement of profits.<sup>125</sup> The TRIPS Agreement also includes an article that allows judicial authorities to seize and dispose of property made in violation of another's intellectual property rights.<sup>126</sup>

The requirements above detail the general options that private entities have in enforcing their patent rights in Member States, which are required to be incorporated into national laws by the structure of the WTO itself.<sup>127</sup> If a Member State does not implement the provisions, private entities are left without enforcement options because intellectual property rights are defined as private rights by the agreement.<sup>128</sup> The TRIPS Agreement should be seen as a starting point for the protection of intellectual property rights, but "sets only minimum standards that remain far below those embodied in U.S. intellectual property law."<sup>129</sup>

#### IV. DIFFICULTIES IN THE DEVELOPMENT OF PATENT RIGHTS IN DEVELOPING COUNTRIES

Despite the improvements the TRIPS Agreement brings to the development of patent rights, enforcement in many developing countries is very difficult.<sup>130</sup> There are many reasons for these difficulties; the four primary reasons will be discussed here: the cultural differences between the developed and developing nations, the lack of judicial and legislative structures in LDCs and DCs, the focus on economic self interests by both

121. *Id.* art. 43, cl. 1, at 100.

122. *Id.* art. 43, cl. 2, at 100.

123. *See generally* FED. R. CIV. P. 64-71 (covering provisional and final remedies).

124. TRIPS Agreement, *supra* note 67, art. 44, at 100.

125. *Id.* art. 45, at 101.

126. *Id.* art. 46, at 101.

127. *Id.* art. 1, cl. 1, at 84-85.

128. *Id.* Pmbl., at 84.

129. TERENCE P. ROSS, INTELLECTUAL PROPERTY LAW: DAMAGES AND REMEDIES § 12.02 [2] (2003).

130. *See generally* Ronald J.T. Corbett, *Protecting and Enforcing Intellectual Property Rights in Developing Countries*, 35 INT'L LAW. 1083 (2001).



the developed nations and the developing nations, and the perceived unfairness of the intellectual property laws.

Intellectual property is a new concept in many of the developing nations that have joined the WTO, and are obligated to implement the TRIPS Agreement.<sup>131</sup> In Latin American nations, as in many developing nations, intellectual property is not viewed as a private asset, but as either "information with commercial value or the heritage of humanity."<sup>132</sup> In formally communist countries, such as the People's Republic of China (PRC), the entire "concept of having individual rights in intangibles such as intellectual property is a new one."<sup>133</sup> In all fairness, even in developed nations it is often difficult for the average citizen to grasp the importance of the protection of intellectual property rights.<sup>134</sup>

In addition to cultural differences, implementation of the TRIPS Agreement has been difficult for the LDCs because they often lack many of the bureaucratic and judicial structures necessary for implementation.<sup>135</sup> Not only are the average citizens of LDCs unaware of intellectual property rights and the vast array of complex structures that need to be implemented, including patent offices, changes in laws, additional enforcement, but many of the law enforcement officials, judges, and civil servants are unaware as well.<sup>136</sup> For example, LDCs may be overwhelmed

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131. See generally ROSS, *supra* note 129.

132. Kimberly A. Czub, *Argentina's Emerging Standard of Intellectual Property Protection: A Case Study of the Underlying Conflicts Between Developing Countries, TRIPS Standards, and the United States*, 33 CASE W. RES. J. INT'L L. 191, 220 (2001).

133. Corbett, *supra* note 130, at 1085.

134. See Tobias Young, *Petaluma Man Upset over Paying \$4,000 in Music Suit; Daughter's Downloading Led to Being Targeted by Recording Industry*, SANTA ROSA PRESS DEMOCRAT Feb. 14, 2004, at A1 (discussing the filing of suits by the recording industry for illegitimate file sharing; in the article, the author makes the point that many of the persons who downloaded the music, including the parents of children who downloaded music, did not know that they were breaking the law); see also Andrew Sullivan, *The Way We Live Now: 6-11-00: Counter Culture; Dot-communist Manifesto*, N. Y. TIMES, June 11, 2003, § 6, at 30 (discussing the author's confession to downloading music from NAPSTER, then going on to state that he felt no remorse, since both the record companies and the artists are "rich enough already"); for a response see Andrea Wolper, *Tech 2010*, N. Y. TIMES, July 11, 2003, § 6, at 8 ("Andrew Sullivan doesn't give a thought to how musicians and writers are supposed to survive as long as we don't actually live in a communist society. . . . Or perhaps he is advocating only stealing from musicians who are already rich -- because people bought their albums.").

135. DE CARVALHO, *supra* note 59, at 60.

136. *Id.*

by the cost and complexity.<sup>137</sup> Many of the LDCs and even DCs were far from implementing their obligations by January 1, 2000, which may imply that there could have been some overreaching on the part of negotiators during the Uruguay Round.<sup>138</sup> However, the greatest difficulty has been overcoming political opposition.<sup>139</sup>

Many DCs, it is felt that strengthening patent rights only transfers wealth from the DCs to the developed countries, since the majority of intellectual property rights currently reside in the developed nations.<sup>140</sup> Developing nations often have large industries dedicated to pirating good. Thus, enforcement of rights will clearly have a detrimental effect on these industries and for the economy in the short term.<sup>141</sup> For example, Argentina has one of the worst records of intellectual property theft of pharmaceuticals in the world, with around \$500 million per year copied from multinational corporations.<sup>142</sup> However, Argentineans point out that adoption of stronger protection for intellectual property rights in Chile resulted in the disappearance of the local pharmaceutical industry.<sup>143</sup> Politicians in these nations are not likely to want enforcement of intellectual property rights, since “[r]igorously protecting intellectual property rights may be viewed as favoring foreign interests over domestic business interests and the welfare of citizens.”<sup>144</sup> For example, studies show that the price of pirated pharmaceuticals are fifty six percent lower in Argentina, than for the same product produced under the patent and sold in the United States.<sup>145</sup>

#### A. *The Doha Declaration*

It was in this context that the Doha Declaration was agreed upon.<sup>146</sup> The Doha Declaration was intended to assist LDCs and DCs in economic development and participation in international trade.<sup>147</sup> It was recognized

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137. *Id.*

138. *Id.* at 61.

139. *Id.*

140. DINWOODIE, *supra* note 5, at 369.

141. Corbett, *supra* note 130, at 1085.

142. Czub, *supra* note 132, at 192.

143. *Id.* at 210.

144. Corbett, *supra* note 130, at 1085.

145. Czub, *supra* note 132, at 201.

146. WTO, MINISTERIAL DECLARATION, Doha, Nov. 20, 2001, WT/MIN(01)/DEC/1, available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.pdf](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.pdf) (last visited Sept. 14, 2004).

147. *Id.* cl. 2.

in this agreement that implementing the obligations under the WTO agreements was very difficult for LDCs and DCs, and that further assistance would be required.<sup>148</sup> The Declaration had specific clauses focusing on the TRIPS Agreement, and its effects on LDCs and DCs.<sup>149</sup> These specifically focused on the need for both access to medicines in LDCs and DCs, research into new medicines,<sup>150</sup> and the issues specific to the concern of LDCs and DCs with respect to biopiracy.<sup>151</sup> The Doha Declaration expressed a number of concessions made by the developed countries to the LDCs and DCs, including lowering the requirements for compulsory licensing of patents in order to allow local pharmaceutical manufacturers to make lower cost versions for an indigenous population.<sup>152</sup> While the Doha Declaration has assisted in resolving, or at least clarifying, a number of issues in TRIPS for LDCs and DCs, it has been criticized as leaving a number of gaps.<sup>153</sup> Examples of these gaps include: a postponement of the discussion of options for LDCs that need lower cost medicines but have no manufacturing infrastructure of their own,<sup>154</sup> “what constitutes a national emergency” under which production of drugs by compulsory licenses is allowed,<sup>155</sup> and the lack of a binding precedent, since the document does not carry any weight in the dispute resolution process.<sup>156</sup> The declaration, while not completely solving problems in TRIPS, was a significant step forward in relations between developed countries and the LDCs and DCs.<sup>157</sup> As the author noted, “[t]he international intellectual property system can only be successful if it creates benefits for all.”<sup>158</sup>

Perhaps the most important point for citizens of developed countries to keep in mind is the total magnitude of the losses from the theft of intellectual property in LDCs and DCs and the direct risks to health and safety as a result of stolen intellectual property. In 1998, losses due to the theft of copyrighted material were around \$10 billion, with twenty five

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148. *Id.* cl. 3.

149. *Id.* cls. 17-19.

150. *Id.* cl. 17.

151. *Id.* cl. 19.

152. Nabila Ansari, *International Patent Rights in a Post-Doha World*, 11 CURRENTS: INT'L TRADE L.J. 57, 63 (2002).

153. *See generally id.* at 57-68.

154. *Id.* at 64.

155. *Id.*

156. *Id.*

157. *Id.* at 67.

158. Ansari, *supra* note 152, at 67.

percent occurring in the People's Republic of China (PRC).<sup>159</sup> Additionally, losses from software piracy were estimated at \$11 billion in 1998.<sup>160</sup> In many countries, purchased copies of software are the exception rather than the rule. For example, in Russia, Vietnam, Indonesia and the PRC, over ninety percent of all business application software is pirated.<sup>161</sup> Theft of intellectual property may also cause significant risks to health and safety. As one report stated:

[C]ounterfeit items are so prevalent it is difficult to purchase legitimate, non-bootlegged, goods for products such as CDs and DVDs in Chinese markets. Recently, Cohen said, Chinese exporters have begun producing counterfeit aircraft parts, counterfeit car parts, and indeed whole counterfeit cars and motorcycles. Counterfeit pharmaceuticals have left several Americans hospitalized because of toxic reactions.<sup>162</sup>

History shows that nations will resist stronger intellectual property protection until it is in their best interests to do so, as shown by the actions of Switzerland in the nineteenth century.<sup>163</sup> In 1866 and 1882, patent laws were rejected by popular referenda,<sup>164</sup> but public opinion changed as increasing outside competition with the technologically advanced and the watch industry developed.<sup>165</sup> In 1887, Swiss voters approved a patent law but limited it to mechanical devices because they found it advantageous to continue to use chemical technology developed by the more advanced Germans.<sup>166</sup> This continued until the German Reich threatened significant trade sanctions unless German technology was protected.<sup>167</sup> Even then, the Swiss patent laws were only changed to allow the patenting of chemical process technology, leaving their ability to make compounds by different processes intact.<sup>168</sup>

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159. Corbett, *supra* note 130, at 1084.

160. *Id.*

161. *Id.*

162. U.S. Department of State, *Rampant Counterfeiting in China is Costing U.S. Billions*, International Information Programs (Feb. 3, 2003) (on file with the author).

163. DINWOODIE, *supra* note 5, at 304.

164. *Id.*

165. *Id.*

166. *Id.*

167. *Id.*

168. *Id.*

*B. Controversies on the Importance of Patent Rights*

Perhaps one of the most critical trends for developed nations to watch is an anti-globalization movement that apparently promotes patent rights not being granted at all due to inherent unfairness.<sup>169</sup> The core of this argument seems to be that since intellectual property rights are valuable, they are inherently bad for the overall population and only good for a small minority of intellectual property rights holders.<sup>170</sup> However, this argument itself is subverted in the text by the author's recognition of two points. First, "[i]ntellectual property rights already constitute an increasingly large share of property in the advanced market economies, especially the United States. Activities surrounding intellectual property are fast becoming the core economic functions in advanced capitalist economies."<sup>171</sup> When this is taken with the previously mentioned losses from theft of intellectual property, the overall importance of protecting intellectual property rights is further emphasized.<sup>172</sup> Second, although subversive to his thesis, the author makes a general statement on the relative importance of intellectual property as a factor in the global redistribution of wealth:

I do not pretend that intellectual property is the only cause of the increasingly unequal distribution of income around the world. During the same decades that intellectual property rights have been strengthened, in the United States the rights of unions have been weakened; cheap imported goods have displaced millions of decently paying working-class jobs; and the tax codes have radically tilted in favor of the wealthy.<sup>173</sup>

Since the theft of intellectual property rights often leads to the generation of lower cost imitation goods,<sup>174</sup> this will be harmful to employment, contributing to the job loss of which he complains.<sup>175</sup>

A more cogent argument is made against the unfair practice termed "biopiracy."<sup>176</sup> The term is used to describe the patenting of medicines

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169. See generally MICHAEL PERELMAN, *STEAL THIS IDEA: INTELLECTUAL PROPERTY RIGHTS AND THE CORPORATE CONFISCATION OF CREATIVITY* (2002).

170. PERELMAN, *supra* note 169, at 5.

171. *Id.* at 3.

172. See *infra* pp. 20-21.

173. PERELMAN, *supra* note 169, at 7.

174. Paris Convention, *supra* note 48, art. 2; see also Perkins et al., *supra* note 85.

175. See generally Lorek, *supra* note 1.

176. SHIVA, *supra* note 58, at 49.

found in indigenous cultures.<sup>177</sup> As the argument goes, a large western based corporation, such as the United States, will send scientists into LDCs or DCs to find indigenous knowledge that can be used in the development of new drugs or foods; they take that knowledge back and patent it with no regard for the ownership rights of the peoples from which it came.<sup>178</sup> At that point, the company can either buy the entire supply of the material, depriving the indigenous population of its benefit, or attempt to force the native population to stop using the material in citing their use as a violation of the company's newly developed rights to the material.<sup>179</sup>

Normally, a patent cannot be granted for material that has been previously discovered or published (prior art); however, the patent law of the United States allows inventions from information commonly known in other countries, but not in publications, to be patented.<sup>180</sup> This geographical limitation would seem to promote the constitutional purpose of patents by promoting the introduction and use of technology known in other parts of the world in the United States, but this was not the original purpose of the patent laws in the United States.<sup>181</sup> Prior to the introduction of the geographic limitation on prior art in 1836, evidence of prior use from any location was acceptable for invalidation of a patent.<sup>182</sup> This is currently the case in Europe, where evidence of previous use in some part of the world can be introduced as prior art, even if not in a publication.<sup>183</sup> The difference in evolution between the two patent systems must be noted. The European Patent Organization (EPO) is an intergovernmental organization that was created in 1977, subsequent to

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177. *Id.* at 4.

178. *Id.* at 49.

179. *See id.* at 57-61 (discussing the discovery and western patenting of insecticide products from *neem*, a native plant of India, where the usage of the plant for these purposes is widespread and well-known; in India, the sudden popularity of *neem* in the west has resulted in a significant price increase, and a significant decrease in supply, seriously impacting the availability of the plant for the indigenous population).

180. 35 U.S.C. § 102(a)-(b) (2003).

181. *See* Margo A. Bagley, *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, 87 MINN. L. REV. 679, 684 (2003) ("From its earliest days, the Intellectual Property Clause has been understood to prohibit the grant of patents (1) to non-inventors and (2) for inventions in the public domain, even if the grant of a patent might have expedited the introduction of beneficial technology within U.S. borders.").

182. *Id.* at 697; *see also* *Shaw v. Cooper*, 32 U.S. 292, 298 (1833) (stating that "there was nothing in the act confining such use to the United States; and that, if the invention was previously known in England or France, it was sufficient to avoid the patent, under that act").

183. Bagley, *supra* note 181, at 686-87.

the signing of the European Patent Convention (EPC) in Munich in 1973.<sup>184</sup> Since the EPC was intended to harmonize patent requirements in Europe across numerous international boundaries, it can be inferred that it is inconsistent with the goal to bar evidence of use in one country from preventing patentability in another. The United States patent system, on the other hand, has always been focused on a single nation.

An example of the differences is clearly shown in the fight over patent rights in the use of *Azadirachta indica* (known as *neem*), a plant native to India.<sup>185</sup> *Neem* is a very common and important tree to the indigenous population of India, where it is used in numerous applications, including insecticides, cosmetics, and native medicines.<sup>186</sup> W.R. Grace acquired the United States patent right to *neem* from its western "discoverer," Robert Larson, and pursued patent protection in Europe, with the United States government as a co-inventor.<sup>187</sup> In Europe, a consortium called the "Neem Team," consisting of two non-governmental organizations from India and the Health and Environment Minister of Belgium, challenged the European patent in front of the EPO, claiming the patent was not valid on the basis of prior art.<sup>188</sup> The EPO agreed with this argument, and on the basis of the prior public use, set aside the patent.<sup>189</sup> Under similar facts the patent was upheld in the United States because the evidence of the previous foreign use, in the absence of publications, was deemed inadmissible.<sup>190</sup> This is the "loophole" in the United States patent law that makes "biopiracy" possible; arguments have been made that the legislature should eliminate the geographical restriction for prior art.<sup>191</sup>

Strong arguments against the removal of the geographical restriction have also been made.<sup>192</sup> These arguments center on the unavailability of products from traditional knowledge; as one author has stated:

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184. *Information about the EPO, available at*

[http://www.european-patent-office.org/epo\\_general.htm#organ](http://www.european-patent-office.org/epo_general.htm#organ) (last visited June 17, 2004) (arguing that "the EPO is the outcome of the European countries' collective political determination to establish a uniform patent system in Europe").

185. *See SHIVA, supra* 58, at 57-61.

186. *Id.* at 58.

187. *Id.*

188. Bagley, *supra* note 181, at 681-82.

189. *Id.* at 682.

190. *Id.* at 681.

191. *See id.*

192. *See generally* Craig Allen Nard, *In Defense of Geographic Disparity: A Response to Margo A. Bagley, Patently Unconstitutional: The Geographic Limitation on Prior Art in a Small World*, 88 MINN. L. REV. 222 (2003).

[T]he driving force behind the clause was the enhancement of public welfare. Section 102 of the patent code is consistent with utilitarianism because the geographic distinction provides an incentive to invest in and commercialize products derived from traditional knowledge--products that otherwise would most likely remain undeveloped or out of reach for a vast majority of potential beneficiaries.<sup>193</sup>

This author noted that pharmaceutical companies would be reluctant to invest large sums of money in commercializing products for which they could not recoup their investment due to a lack of patent rights, "thus depriving all consumers."<sup>194</sup> The pharmaceutical companies do bring a significant amount to the commercial development of products based on native plants, which is not present in the "raw" knowledge of their use by indigenous healers, such as testing and refining.<sup>195</sup> Safety, efficacy, and dosage testing are required for approval for use of any pharmaceuticals in the United States.<sup>196</sup> An example of this is found in the "accelerated" approval of AZT, a drug marketed as Retrovir and used for the treatment of acquired immunodeficiency syndrome (AIDS).<sup>197</sup> The FDA spent eight years, at a cost of \$600,000, evaluating AZT.<sup>198</sup> In that study, nineteen patients died on placebos, while only one died taking AZT, proving the efficacy of the drug.<sup>199</sup> While the costs from the FDA approval process alone are large and likely beyond the reach of many developers in third world countries, the total costs of research and commercialization for a new drug are staggering, recently reaching \$900,000,000 per drug.<sup>200</sup> The overall statistics for the development of new drugs illustrate the critical nature of having as many new drugs as possible in the developmental "pipeline":

Only one of 5,000 screened compounds is approved as a new medicine. Of these 5,000 compounds, 250 enter preclinical testing, five proceed to clinical testing and one is approved by the FDA. Only three of 10

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193. *Id.* at 224-25.

194. *Id.* at 226.

195. *Id.* at 229.

196. DIXIE FARLEY, FOOD & DRUG ADMIN., BENEFIT VS. RISK: HOW FDA APPROVES NEW DRUGS 1 (January 1995), available at <http://www.fda.gov/fdac/special/newdrug/benefits.html> (last visited Sept. 14, 2004).

197. *Id.*

198. *Id.*

199. *Id.*

200. See *Cutting Edge Information; Drug Development Costs Reach All-Time High*, BIOTECH WEEK 143 (Dec. 3, 2003).



marketed drugs generate enough revenue to match or exceed research and development (R&D) costs.<sup>201</sup>

Further support for the proposition that these products would be unavailable if some exclusive rights are not given to those who bring them to market is actually found in the arguments of one of the most strongly committed supporters of the rights of indigenous peoples against biopiracy, Vandana Shiva.<sup>202</sup> In her discussion of the “discovery” of *neem* by Robert Larson, she reports that Larson first observed the usefulness of the tree in 1971 and began importing *neem* to the United States at that time.<sup>203</sup> She then mentions that “[o]ver the next decade, he conducted safety and performance tests upon a pesticidal *neem* extract called Margosan-O and in 1985 received clearance for the product from the US Environmental Protection Agency (EPA).”<sup>204</sup> Considering the costs of government approvals, and the decade he spent testing the product, it would appear unlikely that he would have made this investment without some expectation of exclusivity for the product. The constitutional arguments made against retaining the geographic limitations also break down when the unavailability of products to western consumers is considered.<sup>205</sup> The author’s arguments are strongly based on the free availability of information in the modern world.<sup>206</sup> In the 1850 case of *Gayler v. Wilder*, shortly after the legislature added the geographic limitation to the determination of prior art, the Supreme Court discussed the reason for this rule in dicta:

If the foreign invention had been printed or patented, it was already given to the world and open to the people of this country, as well as of others, upon reasonable inquiry. They would therefore derive no advantage from the invention here. It would confer no benefit upon the community, and the inventor therefore is not considered to be entitled to the reward. But if the foreign discovery is not patented, nor described in any printed publication, it might be known and used in remote places for ages, and the people of this country be unable to profit by it. The

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201. Alan F. Holmer, *Have Pharmaceutical Companies Been Unfair to American Consumers?*, INSIGHT MAGAZINE 47 (Sept. 1, 2003) (quoting from a speech given by FDA Commissioner Mark McClellan to the Commonwealth Club in San Francisco on June 9, 2004).

202. See SHIVA, *supra* note 58.

203. *Id.* at 58.

204. *Id.*

205. See generally Bagley, *supra* note 181.

206. *Id.* at 718.

means of obtaining knowledge would not be within their reach; and, as far as their interest is concerned, it would be the same thing as if the improvement had never been discovered. It is the inventor here that brings it [sic] to them, and places it in their possession. And as he does this by the effort of his own genius, the law regards him as the first and original inventor, and protects his patent, although the improvement had in fact been invented before, and used by others.<sup>207</sup>

This argument is as relevant today as it was in 1850, although with a slightly different slant. For example, much of the traditional knowledge is not available for use in this country without approval from the relevant government agencies, and the companies that expend the money to get these approvals should be given the right to recoup their investment.<sup>208</sup>

Perhaps the loss of availability of these drugs for the populations of the developed countries is the price that has to be paid for political fairness to the LDCs and DCs of the world. This would balance the rights of companies in the developed countries to drugs developed at great expense in research labs against the rights of DCs to their traditional medicines.<sup>209</sup> While this is one possible outcome, it is an isolationist conclusion that stands in opposition to the open world trade structure envisioned by the WTO and leads to losses for both groups.<sup>210</sup> In the long term, strengthening of patent rights around the world will most likely lead to the balancing of rights, as will be discussed later in this comment. However, this will take a significant period of time, and interim solutions seem to be necessary. One possible interim approach that appears to be promising is the contractual protection of traditional knowledge through "bioprospecting agreements."<sup>211</sup> There are two ways to implement these types of arrangements: through amending the patent laws of developed countries to require "lawful acquisition of genetic resources and an

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207. 51 U.S. 477, 497 (1850).

208. See generally Nard, *supra* note 192.

209. See Bagley, *supra* note 181, at 688 ("[T]he policy ramifications of the § 102 limitation are significant . . . the United States fiercely condemns the pirating of U.S. intellectual property by trading partners . . . [y]et, the § 102 geographical limitation facilitates the 'pirating' of unpatented, unpublished, traditional knowledge and genetic resources from developing countries, exacerbating feelings of ill will.").

210. See UNDERSTANDING THE WTO, *supra* note 62, at 10.

211. See Nard, *supra* note 192, at 233.

equitable compensatory arrangement,<sup>212</sup> or to have voluntary agreements between western companies and organizations in developing nations.<sup>213</sup>

### C. *Controversies on the Importance of Patent Rights*

In examining the mechanisms for the development of more universal patent rights, the utilitarian reasons for having patent rights in the first place, including their historical importance, should be examined.<sup>214</sup> This subject is discussed below, using patent rights in the United States as an example, and the discussion focuses on three topics: the debate on the value of patent rights, patent rights as a boost to creativity in the early twentieth century, and modern concepts of patent rights.

Patent rights proponents, including inventors and assignees, hold as accepted wisdom that technological innovation is critical to social progress – a doctrine that is not necessarily held true by all societies or organizations.<sup>215</sup> Even if technological innovation is believed to be socially beneficial, does the issuance of a legal right to exclude others from practicing an invention actually encourage the advancement of technology?<sup>216</sup> This question is the critical controversial point in determining the importance of patent rights. Some authors have proposed the thesis that patent rights actually decrease innovation.<sup>217</sup> The negative response to patent rights by these authors is summarized by Vandana Shiva:

IPRs are essentially a market distortion, a government sanctioned monopoly and subsidy. IPRs put territorial borders around technologies and other inventions so that firms can capture higher profits. In the long

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212. *Id.*

213. *Id.* (pointing out that this later approach is exemplified by an agreement between the Instituto Nacional de Bioveridad (INBio), a nonprofit organization in Costa Rica, and Merck, a pharmaceutical company in the United States. In this agreement, INBio will deliver 10,000 genetic specimens to Merck, along with information of their use by indigenous peoples of the region, and Merck will pay \$1.35 million up front and royalties on products developed from the samples).

214. See DINWOODIE, *supra* note 5, § 2.02, at 49-53.

215. *Id.* at 49 (“This thesis is not universally accepted, and is expressly rejected by some groups that venerate traditional cultural values and beliefs and/or, perhaps less kindly, others whose members are in a position to derive personal benefit from maintenance of the *status quo.*”); see generally The Foundation on Economic Trends, *About FOET*, available at <http://www.foet.org/AboutFET.htm> (last visited Sept. 14, 2004) (noting this organization, founded by Jeremy Rifkin, a major anti-biotechnology activist, is focused on the harm that unchecked new developments may have on society and the environment).

216. See *id.*

217. See SHIVA, *supra* note 58, at 4-5.

term, a strong IPR system can result in price discriminations and many market-distorting practices like patent pooling, tied-up sales, cross licensing and refusal to licence [sic].<sup>218</sup>

In contrast to this view, corporations take the view that without patent rights, investment in research would be pointless.<sup>219</sup> A recent press release from Koninklijke Philips Electronics N.V., on the issuance of their 100,000th patent summarized this view:

Without patent[s] and the laws that protect them, Philips could not have built up its impressive record as an innovation leader. Philips spends billions of dollars a year on research and development. Through patent and other Intellectual Property Rights (IPR), the company can safeguard the fruits of its tremendous effort in R&D. 'If there were no protection for our IPR, other companies could use our inventions at no cost at all. That would all but kill the incentive to spend money on R&D', says Ruud Peters, CEO of Intellectual Property & Standards (IP&S) in Philips. 'Historically, countries that have protected their inventors with a well-functioning system of patent law have fared better than countries that have failed to do so.'<sup>220</sup>

The press release goes on to make the point that the majority of income from the development of intellectual property rights is reinvested in research and development activities.<sup>221</sup> While a press release can usually be considered an idealistic viewpoint, or the "face that the company wants the world to see," the views on intellectual property expressed by Philips are by no means unique.<sup>222</sup> The right to exclude others from using a patent provides companies with incentives to invent new technologies and to invest the funds required to bring these technologies to the marketplace.<sup>223</sup> A study done for the patent law institute in 1990 showed that even patent rights in fields only indirectly related to core businesses, such as those in electronics and computer related fields, could have value for the chemical,

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218. *Id.* at 5.

219. Press Release, Koninklijke Philips Electronics N.V., Philips Reaches Milestone of 100,000 Patents (2004) (on file with the author).

220. *Id.*

221. *Id.*

222. See generally POLTORAK & LERNER, *supra* note 9. "Whatever its other characteristics, however, intellectual property *does* have economic value – often, great economic value – although this value is often overlooked, underestimated, and underreported." *Id.* at xiii.

223. DINWOODIE, *supra* note 5, at 50.

biotech, and pharmaceutical industries.<sup>224</sup> These types of patents support the primary goals of the business, such as plant control systems, molecular modeling, and neural networks.<sup>225</sup> Companies with product patents in these fields showed an average pretax return on investment of 19.7%, while companies without showed an average of 13.8%.<sup>226</sup> The effects for process patents and overall earnings were similar, with companies having patent rights showing significant benefits over those companies without such rights.<sup>227</sup>

### 1. Historical Perspective on Patent Rights

In addition to short term benefits for companies and individuals, over the long term strong patent rights can have extraordinarily beneficial effects on all of society. This is illustrated by the stories of the inventor-entrepreneurs of the late nineteenth and early twentieth centuries, such as Thomas Edison and Alfred Nobel.<sup>228</sup>

The clearest example of the importance of patent rights, and its effects on society, is shown by the life and career of Thomas Edison.<sup>229</sup> Edison had only three months of formal schooling and was only twenty-one years old in 1870 when he invented a ticker tape machine for stockbrokers.<sup>230</sup> With the \$40,000 he earned for the invention, he established a small lab in Newark, and went on to invent the incandescent light bulb in 1878.<sup>231</sup> His company, the Edison Electric Light Company, designed and built the first power station in New York City in 1882.<sup>232</sup> The developments he created were made possible by the money earned from the patents, and they created entire industries, including the electric power, motion picture, and phonographic recording industries.<sup>233</sup>

Alfred Nobel made similar contributions to society.<sup>234</sup> Nobel was only twenty-nine years old when the fundamental event that shaped his life

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224. See generally Charles A. Weigel, Jr., *The Importance of Patent Protection of Electronic and Computer Technology to the Chemical, Biotech, and Pharmaceutical Industries*, 292 PRACTISING L. INST. 459 (1990).

225. *Id.* at 470-72.

226. *Id.* at 467.

227. *Id.* at 468.

228. See DINWOODIE, *supra* note 5, at 50.

229. *Id.*

230. *Id.*

231. *Id.*

232. *Id.*

233. *Id.*

234. See DINWOODIE, *supra* note 5, at 50.

took place: in 1864, his younger brother and four others were killed in an explosion at his father's nitroglycerin factory in Stockholm, Sweden.<sup>235</sup> He promptly started working to find a safer alternative to the use of liquid nitroglycerin, experimenting with mixtures of nitroglycerin and various binders.<sup>236</sup> He patented his invention in 1867, calling the mixture "dynamite."<sup>237</sup> The patent earned a fortune, and Nobel continued to innovate, earning 355 patents in his lifetime.<sup>238</sup> Upon his death in 1896, Nobel stipulated that the bulk of his estate be placed into a fund to give annual prizes for the most significant advancements "in physics, chemistry, physiology or medicine, and literature, and toward the promotion of international peace."<sup>239</sup>

## 2. The Purpose of Patent Rights

One author has stated that the greatest value of patent rights at this time is as a source of shareholder confidence in a corporation's ability.<sup>240</sup> The purpose of scientific discovery in this case is not the love of discovery, but the sustenance of the corporation and the support of thousands or tens of thousands of jobs.<sup>241</sup> The contribution back to the community is encouraged, but "is not at the center of what drives financial backers to invest in a firm or what drives the firm to channel that investment into R&D . . . . Where ownership rights are clear, investors are confident."<sup>242</sup>

While the theory above could perhaps be called the "investment theory" of patent rights, other theories of the utilitarian purpose of patent rights have focused on the reward and the prospect theories.<sup>243</sup> In the reward theory, patents are "granted to individuals who contribute to economic and technological progress by inventing and disclosing the inventions."<sup>244</sup> While this would seem like a plausible theory, most patents are never exploited, thus their value cannot be considered relevant.<sup>245</sup> Additionally, all patents are judged using the same standards, without

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235. *Id.*

236. *Id.*

237. *Id.*

238. *Id.*

239. *Nobel, Alfred Bernard*, HISTORYCHANNEL.COM, available at

[http://www.historychannel.com/perl/print\\_book.pl?ID=103970](http://www.historychannel.com/perl/print_book.pl?ID=103970) (last visited Sept. 14, 2004).

240. See DINWOODIE, *supra* note 5, at 50-51.

241. *Id.* at 51.

242. *Id.*

243. See DE CARVALHO, *supra* note 59, at 2.

244. *Id.*

245. *Id.* at 2-3.

consideration of the scientific field, or how important the technical subject matter is that they cover.<sup>246</sup> Finally, the patent laws of many countries clearly state that the purpose of patents is to accomplish social goals and not to reward individuals.<sup>247</sup>

#### V. ACTIONS IN RESPONSE TO INTERNATIONAL PRESSURES IN INTELLECTUAL PROPERTY DISPUTES

Although the value of patent rights is hotly debated, especially by residents of the LDCs and DCs, protection of these rights is a requirement for membership in the WTO.<sup>248</sup> To implement these protections, nations must change their laws to be in compliance with the minimum requirements expressed in TRIPS.<sup>249</sup> The TRIPS Agreement requires that Member States notify the WTO when their laws or regulations are changed to effect the obligations.<sup>250</sup> In this section, the changes made in order made to comply with the TRIPS Agreement in the United States, India, and China will be discussed. The international pressures required to change their national patent laws to conform to the TRIPS Agreement will be examined. In addition, some examples of the treatment of foreign nationals in the national courts of these countries will be analyzed, since appropriate legislation does not guarantee fair or equal treatment.

The United States and China were both signatories to the original GATT treaty, which took effect on January 1, 1948.<sup>251</sup> Since then, the United States has continuously been a member of GATT; China left the organization after the communist revolution in 1949, at which time it broke all outside business ties.<sup>252</sup> Both India and the United States became members of the WTO when the treaty went into effect on January 1,

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246. *Id.* at 3.

247. *Id.*

248. See TRIPS Agreement, *supra* note 67.

249. See *supra* Part III.B.1 (discussing the TRIPS Agreement requirements).

250. TRIPS Agreement, *supra* note 67, at 346.

251. See *id.* at 1.

252. Charlene Barshefsky, China's WTO Accession in American Postwar Strategy, Address Before the Bretton Woods Committee (May 16, 2000), available at <http://hongkong.usconsulate.gov/uscn/trade/general/ustr/2000/0516a.htm> (last visited Sept. 26, 2004).

1995.<sup>253</sup> However, China did not re-accede to membership in the WTO until December 11, 2001.<sup>254</sup>

*A. Changes in Patent Law as a Result of the WTO*

The requirement to change patent laws to harmonize them with the GATT treaty was not confined to LDCs and DCs; the United States also required changes in order to comply.<sup>255</sup> Four major changes were required in the domestic patent laws of the United States to conform to TRIPS: the patent term was changed from seventeen years from date of issue to twenty years from date of filing, inventive activities in any WTO country can now be used to establish priority, the scope of infringement was broadened and now includes “offers for sale” and importation of infringing goods.<sup>256</sup> In comparison to changes required in many other countries, those in the United States may seem minor, but they triggered significant controversy, especially the change in patent term.<sup>257</sup> The primary purpose of this change was to prevent what are termed “submarine” patents.<sup>258</sup> A submarine patent is one that has been filed (or the continuation of a previously filed patent) but not issued, which resurfaces at a later date with a seventeen year term, perhaps just as a technological field has developed.<sup>259</sup>

The patent term change was part of the Uruguay Round Agreements Act, which implemented the general requirements for WTO membership in United States law.<sup>260</sup> Under the new system, a patent that takes a significant period of time to issue, for any reason whatsoever, will lose patent protection at an earlier date than under the previous term.<sup>261</sup> Later legislation mitigated this rather harsh result by allowing time to be added

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253. WTO, *Understanding the WTO: The Organization, Members and Observers*, available at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) (last visited Sept. 14, 2004).

254. *Id.*

255. See generally Sorell et al., *supra* note 61.

256. *Id.* at 97-98.

257. *Id.* at 98.

258. *Id.* at 101.

259. *Id.* at 119 n.3.

260. Adam Isaac Hasson, *Domestic Implementation of International Obligations: The Quest for World Patent Harmonization*, 25 B.C. INT'L & COMP. L. REV. 373, 380 (2002); see also 19 U.S.C. 3511 (1994).

261. Sorrell et al., *supra* note 61, at 105-06.



to the patent term for delays out of the control of the inventor, including delays in processing, appeals, and interferences, among others.<sup>262</sup>

In contrast to the United States, both India and China made significant changes to their patent laws in order to bring them into compliance.<sup>263</sup> Indian patent laws, prior to the enactment of the WTO in 1995, provided no coverage for plants, pharmaceuticals, agricultural chemicals, or products made by chemical processes.<sup>264</sup> This dates back to the Patent Act of 1970, in which the president of a large Indian pharmaceutical manufacturer lobbied then Prime Minister, Indira Gandhi, to block product patents for pharmaceuticals.<sup>265</sup> The purpose of this was not to supply the Indian population with large amounts of lower cost copies of drugs patented in the developed countries, but to enable the Indian pharmaceutical firms to produce these copies for export to other world markets in which there was little or no patent protection on the drugs.<sup>266</sup> A clear example is found in the copies of HIV/AIDS drugs made by the major Indian pharmaceutical manufacturer, CIPLA. CIPLA makes these drugs and exports them at a very low price of \$350/year/patient, and is still able to make a profit at these very low rates because the company completely lacks research and development costs.<sup>267</sup> While these drugs were being exported at that cost in early 2001, the treatments were not available in India below a cost of \$1,320/year/patient until later that year.<sup>268</sup> Even at the lower cost, very few of India's AIDS patients were receiving the therapy because the government would not pick up the cost of the

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262. See generally William Slate, *The Sky is Not Falling: The Effects of Term Adjustment Under the American Inventor's Protection Act on Patent Prosecution*, 4 YALE SYMP. ON L. & TECH. 7 (2001).

263. See generally Susan Finston, *India: A Cautionary Tale on the Critical Importance of Intellectual Property Protection*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 887 (2002); see also George K. Foster, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and Its Aftermath*, 3 UCLA J. INT'L L. & FOREIGN AFF. 283 (1998); Kenneth Parks, et al., *India Modifies Patent Laws*, 7 NO. 3 J. PROPRIETARY RTS. 33 (1995); *WTO Requests Amendment to India Patent Laws*, 10 NO. 3 J. PROPRIETARY RTS. 23 (1998); David Hill & Judith Evans, *Chinese Patent Law: Recent Changes Align China More Closely with Modern International Practice*, 27 GEO. WASH. J. INT'L L. & ECON. 359 (1994); Jiwen Chen, *Better Patent Law for International Commitment – The Amendment of Chinese Patent Law*, 2 RICH. J. OF GLOBAL L. & BUS. 61 (2001).

264. Parks et al., *supra* note 263, at 33.

265. Finston, *supra* note 263, at 888-89.

266. *Id.* at 892.

267. *Id.* at 893.

268. *Id.*

drugs.<sup>269</sup> In 1995, the implementation of the Uruguay Round of the GATT, which created the WTO, inherently forced a change of Indian patent laws.<sup>270</sup> The changes required were to introduce protection for agricultural chemicals and pharmaceuticals, but India was able to delay their implementation on the basis of the WTO rules for implementation of the TRIPS standards by developing nations.<sup>271</sup> This gave India until December 31, 2004 to actually implement the recommendations.<sup>272</sup> In the intervening years, however, India would be required to set up a “mailbox,” for patent applications to be sent for registration after which they are given a priority date, and, upon request, exclusive marketing rights for the last five years prior to the 2004 deadline.<sup>273</sup>

### *B. The Dispute Resolution Process at the WTO*

India did not complete these requirements, and a request for consultation was brought in the WTO’s Dispute Settlement Body by the United States in 1996, demanding that India make the needed changes to its patent laws: “India’s legal regime appears to be inconsistent with India’s obligations under the TRIPS Agreement, including but not necessarily limited to Article[s] 27, 65, and 70 of the Agreement.”<sup>274</sup>

The path of the dispute will be discussed in some detail here as it provides an excellent example of the dispute resolution process available through the WTO, including: the time required for the resolution, the responses of the parties, and the actions taken at the national levels in response to the outcome of the dispute. The importance of the negotiations to merchants in other parts of the world was confirmed by a request from the European Union to join in the consultations with India: “[t]he European pharmaceutical and agro-chemical industry has important export interests in the Indian market. The actual amount of these interests is, at this stage, difficult to evaluate because the Republic of India does not provide for either patent protection or the above-mentioned filing and marketing systems.”<sup>275</sup> India responded to the request, and formally

269. *Id.* at n.27, p. 893.

270. Parks, *supra* note 263.

271. *Id.*

272. *Id.*; see also TRIPS Agreement, *supra* note 67, at 348.

273. Foster, *supra* note 263, at 295; see also TRIPS Agreement, *supra* note 67, at 348.

274. WTO, *India – Patent Protection for Pharmaceutical and Agricultural Products: Request for Consultations by the United States*, WT/DS50/1 (July 9, 1996).

275. WTO, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products: Request to Join Consultations, Communication from the European Communities*, WT/DS50/2 (July 22, 1996).

permitted the European Union to participate in the discussions.<sup>276</sup> India, the United States, and the European Union met on July 29, 1996, but were unable to come to any sort of an agreement, leading the United States to formally request that a panel from the Dispute Settlement Body (DSB) of the WTO be designated to look into the issue.<sup>277</sup> This panel was formally established by the DSB, and notifications were sent to the United States and India, with the European Union reserving the right to participate as a third party.<sup>278</sup>

### 1. The Findings of the WTO Panel

On the issue of Article 70.8 of the TRIPS Agreement, India argued that it had set up a de-facto mailbox system for the registration of patents; however, there was no evidence to show that they had informed the TRIPS Council, or any other international body of this fact.<sup>279</sup> The United States argued that as international agreements require legislation to be binding in India, a lapse in legislation prevented the establishment of a legally defensible mailbox system in India; thus, the result would be automatic rejection of pharmaceutical and chemical patents.<sup>280</sup> India made the argument that the entire point of the transitional period was to allow LDCs the time needed to build consensus for unpopular changes to the patent laws without requiring immediate changes, and that by forcing the unpopular actions, the United States was circumventing the purpose of the delay,<sup>281</sup> thus eliminating any advantage that the extra time gave the government in selling an unpopular change to its people.<sup>282</sup>

On the additional issue of Article 70.9 of the TRIPS Agreement, which would require a developing country to grant an exclusive marketing right for a new product during the final five years of the transition period

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276. WTO, *India - Patent Protection for Pharmaceutical and Agricultural Products: Acceptance by India of the Request to Join Consultations by the European Communities under Article 4.11 of the DSU*, WT/DS50/3 (July 29, 1996).

277. WTO, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products: Request for the Establishment of a Panel*, WT/DS50/4 (Nov. 8, 1996).

278. WTO, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products: Constitution of the Panel Established at the Request of the United States*, WT/DS50/5 (Feb. 5, 1997).

279. WTO, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products: Report of the Panel*, WT/DS50/R, at pt. II.F (Sept. 5, 1997) [hereinafter *WR/DS50/R*].

280. *Id.* at pt. IV.2.3.

281. *Id.* at pt. IV.2.9.

282. *Id.*

prior to patentability, India stated that no particular product was found to have had full marketing approval in the United States prior to the dispute.<sup>283</sup> Since this is a necessary condition for the granting of the exclusive rights by the non-patenting nation, it was their contention that this excused the development of a mechanism.<sup>284</sup>

The European Union, having been permitted by India to participate in the proceedings, was allowed to submit testimony to the Panel.<sup>285</sup> They expressed surprise at India's claim that they had fulfilled their obligations under Article 70.8 by setting up the mailbox system, since no mechanism had been published.<sup>286</sup> The Panel also disagreed with India's contention that since no patent filings were made under the system, India was justified in postponing the development of any mechanism for granting exclusive marketing rights under 70.9.<sup>287</sup> They specifically asked what the administrative instructions were for the system, where they were published, and what guarantees were in place to resolve disputes in Indian Courts.<sup>288</sup> The European Union's testimony made their opinion of the current mechanisms clear: "[i]n answering these questions, India would have to admit that simple administrative instructions did not fulfil[l] the requirements laid down in Articles 70.8 and 70.9."<sup>289</sup>

The Panel's findings also focused on Articles 70.8, and 70.9, although some procedural issues were included by necessity.<sup>290</sup> The Panel reaffirmed the view that if a developing country were to take advantage of the transitional period in Article 66 of the TRIPS Agreement, the country was required to set up a mailbox system, wherein the patent could be sent, and the inventor could obtain priority as of the date the application was received.<sup>291</sup> The panel found that any mechanism for registering filing dates must have a legally sound basis, or be inoperable, which would risk

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283. *Id.* at Part IV.2.27.

284. *Id.*

285. WT/DS50/R, *supra* note 279, pt. V.3.1.

286. *Id.* at pt. V.3.2.

287. *Id.*

288. *Id.*

289. *Id.*

290. *Id.* at pt. VII.5.8-5.22 (noting that the United States claimed that if India had established a mailbox system, their failure to publish it was a violation of Article 63 of the TRIPS Agreement, requiring member states to clearly publish their procedures, laws, and regulations, and to inform the TRIPS Council; the panel agreed with the United States on this point).

291. WT/DS50/R, *supra* note 279, Part VII.5.27.

losing novelty for the patents filed.<sup>292</sup> Therefore, any country that wished to take advantage of the transitional period was required to have an established legal mechanism for the granting of patent rights at the end of the transition period in place by the operational date of the WTO agreement, i.e. January 1, 1995.<sup>293</sup> One of the points most strongly emphasized by the panel is that the legal insecurity of having an informal system could place restraints on the actions of parties, since under Indian patent law, any pharmaceutical or agricultural chemical is automatically rejected.<sup>294</sup> The panel also agreed with the contention that India had violated the transparency requirements in Article 63 by not publishing details of its mailbox system, and not informing the Council for TRIPS of the legal basis for handling such applications after the expiration of the Patents (Amendment) Ordinance of 1994.<sup>295</sup> As for the obligation to set up a mechanism to grant exclusive marketing rights for five years prior to the patent under Article 70.9 of the TRIPS Agreement, the panel found that India was obliged to have the mechanism in place by January 1, 1995 when the WTO agreement went into effect.<sup>296</sup> In conclusion, the panel recommended that the DSB request that India bring its patent laws into compliance with the TRIPS Agreement with respect to transitional rights for pharmaceutical and agricultural patents.<sup>297</sup>

## 2. The Appeal of the Ruling to the Appellate Body

As would be expected in any very contentious legal proceeding, India promptly appealed the ruling.<sup>298</sup> Three members of a permanent seven-member panel called the Appellate Body (AB) hear appeals from rulings in the DSB.<sup>299</sup> The Appellate Body can "uphold, modify or reverse the Panel's legal findings and conclusions."<sup>300</sup> Once they have made their decision, the DSB can accept or reject the report, but rejection is only possible by consensus.<sup>301</sup> The AB reviewed the evidence presented in the initial Panel proceeding, and upheld the Panel's findings that India was not

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292. *Id.* at pt. VII.5.28.

293. *Id.* at pt. VII.5.31.

294. *Id.* at pt. VII.5.35-5.36.

295. *Id.* at pt. VII.5.46-5.50.

296. *Id.* at pt. VII.5.63.

297. WT/DS50/R, *supra* note 279, pt. VIII.6.2.

298. WTO, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997) [hereinafter WT/DS50/AB/R].

299. UNDERSTANDING THE WTO, *supra* note 62, at 57.

300. *Id.*

301. *Id.*

in compliance with Articles 70.8 and 70.9 of the TRIPS Agreement.<sup>302</sup> However, the AB overturned the finding that India was in violation of the transparency requirements of Article 63 because that issue had not been raised in the initial complaint.<sup>303</sup>

### 3. Changes in Indian Patent Law as a Result of the Resolution

The final decision of the AB was issued on December 19, 1997 and adopted by the full DSB on January 16, 1998.<sup>304</sup> After the decision was adopted, India and the United States met and decided that fifteen months from the time of their April 21, 1998 meeting, was a reasonable period of time to pass the legislation needed for implementation of the TRIPS Agreement obligations.<sup>305</sup> This initial report was followed up by a series of status reports and communications from India and between the various parties, discussing the efforts to pass the legislation required,<sup>306</sup> leading to the final report of passage of a permanent bill on the issue on March 26, 1999.<sup>307</sup> The initial letter requesting consultation was issued in July of 1996, as discussed above, so the entire procedure and final passage of the bill in the Indian Parliament took around three years.

302. WT/DS50/AB/R, *supra* note 298, at pt. IX.97.

303. *Id.* (noting that the issue for which a violation of Article 63 was raised was not in existence at the time the complaining letter was sent out; thus, even though the issue was not known at the time, it was not allowed to be brought up later, even as a response).

304. WTO, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products: Status Report by India*, WT/DS50/10 (Nov. 12, 1998) [hereinafter WT/DS50/10].

305. *Id.*

306. *See* WTO, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products: Status Report by India*, WT/DS50/10/Add.1 (Jan. 14, 1999); *see also* WTO, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, Recourse to Article 21.5 of the DSU*, WT/DS50/11 (Jan. 20, 1999) (expressing that the United States doubts that the temporary ordinance proposed will meet India's obligations under TRIPS); WTO, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, Request by the European Communities and its Member States Regarding Consultations by the United States* WT/DS50/12 (Feb. 4, 1999) (requesting that the European Union wished to join in any consultations regarding this issue); WTO, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products: Status Report by India*, WT/DS50/10/Add.2 (Feb. 5, 1999) (noting that a bill to replace the temporary ordinance the United States and Europe are objecting to will be introduced in the next session of Parliament); WTO, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products: Status Report by India*, WT/DS50/10/Add.3 (March 9, 1999) (noting passage of ordinance and introduction of bill into the next session of Parliament).

307. WTO, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products: Status Report by India*, WT/DS50/10/Add.4 (April 16, 1999).

#### 4. Recent Changes in Chinese Patent Law

The development of modern concepts of patent rights in China did not essentially start until the open door policy was implemented in the late 1970s, after the death of Chairman Mao.<sup>308</sup> In 1979, a drafting group was established to study other patent law systems and make recommendations on the establishment of a new patent law system in China.<sup>309</sup> The People's Congress adopted a new patent law on March 6, 1984.<sup>310</sup>

Outside efforts to ensure adequate intellectual property protection in China have taken a significantly different approach from those for India, in that they started earlier and took place much more unilaterally.<sup>311</sup> Negotiations from the trade dispute resulted in the implementation of a "memo of understanding" between China and the United States in 1992.<sup>312</sup> Pressure was not applied by a multilateral international organization, such as the WTO, but directly by the United States threatening the use of the "Special 301" rule in U.S. trade laws.<sup>313</sup> As a result of the memo of understanding, China agreed to modify its patent laws by January 1, 1993, "to make product patents available for all chemical inventions, including pharmaceuticals and agricultural chemicals, provide a term of protection of 20 years for the date of filing of a patent application, and impose conditions on the grant of compulsory licenses."<sup>314</sup> While these changes were significant in the amount of protection they afforded inventors, they did not necessarily take patent protection in China to the level expected in other nations.<sup>315</sup> However, in 2000, China implemented a much stronger revision to prepare for membership in the WTO.<sup>316</sup> This revision took

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308. See Robert G. Oake, Jr., A Primer on Chinese Patent Law (on file with the author).

309. *Id.*

310. *Id.*

311. See generally Qaio Dexi, *A Survey of Intellectual Property Issues in China-U.S. Trade Negotiations Under the Special 301 Provisions*, 2 PAC. RIM L. & POL'Y J. 259 (1993); see also John Gero & Kathleen Lannan, *Trade and Innovation: Unilateralism v. Multilateralism*, 21 CAN.-U.S. L.J. 81 (1995); Myles Getlan, Comment, *TRIPS and the Future of Section 301: A Comparative Study in Trade Dispute Resolution*, 34 COLUM. J. TRANSNAT'L L. 173 (1995).

312. Dexi, *supra* note 311, at 259.

313. See Getlan, *supra* note 311, at 178-179 (providing an excellent overview of the "Special 301" provisions of the United States Omnibus and Competitiveness Act of 1988; the article in general compares the Special 301 provisions with the enforcement provisions of the TRIPS Agreement, concluding that TRIPS will be a far more effective tool).

314. Memorandum of Understanding on the Protection of Intellectual Property, Jan. 17, 1992, U.S.-P.R.C., *Explanation of the Agreement*, DEP'T ST. BULL., Jan. 17, 1992.

315. See Louis S. Sorrell, *A Comparative Analysis of Selected Aspects of Patent Law in China and the United States*, 11 PAC. RIM L. & POL'Y J. 319, at 322-23 (2002).

316. See *id.*

effect on July 1, 2001, and included changes such as harmonizing Chinese patent law with the TRIPS Agreement, streamlining the approval process, and strengthening patent rights.<sup>317</sup> China has implemented a first to file system, like much of the world outside of the United States, but using novelty, non-obviousness, and utility requirements that are roughly analogous to the United States' standards.<sup>318</sup> The most significant differences are in subject matter and infringement proceedings. Unlike the United States, patentable subject matter in China excludes plants and "methods for the diagnosis or for the treatment of diseases."<sup>319</sup> In China, infringement proceedings can take two distinct paths, either going into the courts or through an administrative proceeding that has no analogous counterpart in the United States.<sup>320</sup> In addition to these differences, Chinese law is inquisitorial, i.e. based on administrative principles rather than common law principles, making the lack of experience of the judges more difficult to overcome because no case has precedential value.<sup>321</sup> Despite all of these problems, China seems sincere in its attempts to implement strong intellectual property rights, and motivated to move forward: "China's accession to the World Trade Organization (WTO) brings a sense of urgency for [the] Chinese to improve their understanding about intellectual property rights and patents."<sup>322</sup>

## VI. THE USE OF LEGAL PROTECTIONS FOR PATENTS AT THE NATIONAL LEVEL

While the development of mechanisms for the protection of patent rights is important, all of the actual proceedings to stop misappropriation must still take place at the private litigation level.<sup>323</sup> In this section, a few private enforcement actions that have taken place in the United States, China, and India are examined to determine what differences are seen. It should be noted that this is not a statistical sampling to determine if the different nations' courts treat foreign nationals with less fairness.

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317. *See id.*

318. *Id.* at 326.

319. *Id.* at 327.

320. *Id.* at 328-29.

321. *See Sorrell, supra* note 315, at 331.

322. *Patent Law to Take on New Significance*, PEOPLE'S DAILY, Nov. 14, 2001 (quoting Tian Lipu, Deputy Director of State Intellectual Property Office).

323. DE CARVALHO, *supra* note 59, at 33 ("[T]he role of governments is to pass legislation and create the institutions that enable private citizens to protect themselves against infringement, rather than enforcing private rights on behalf of citizens.").



### A. *United States*

The following cases are from U.S. courts and were pharmaceutical patent infringement cases between American companies and Indian companies. In the first, *Pharmacia & Upjohn Company v. Ranbaxy Pharmaceuticals*,<sup>324</sup> an Indian company attempted to make a small change within a claimed formulation and start importing a look alike drug into the United States.<sup>325</sup> Since the change was within the claims of the patent, the court granted a preliminary injunction against Ranbaxy.<sup>326</sup> Ranbaxy then attempted to invalidate the patent on a double patenting argument over a previous Pharmacia application. Even with a rather obscure and complex argument, the judge was able to discern the issues and find in favor of the patent.<sup>327</sup>

In the second patent infringement case, *Dr. Reddy's Laboratories, Ltd. v. Aaipharma Inc.*,<sup>328</sup> an American company attempted to use patent rights obtained on structural information of a pharmaceutical, which it had discovered after a previous patent term had expired, to block a generic manufacturer in India from entering the United States market.<sup>329</sup> In addition to using the patent rights against the company, the American company obtained a sample of the product the Indian company would be shipping. The American company turned it over to the initial patent holder for testing, upon which the initial patent holder made a claim to the FDA that the product was not functionally equivalent, a requirement for permission to manufacture a generic drug.<sup>330</sup> The Indian firm brought suit, alleging damages from the extra testing required, and the American firm attempted to claim immunity from suit for turning data over to a government agency.<sup>331</sup> The judge saw through all of these attempts and denied the American firm's attempt to have the case dismissed.<sup>332</sup>

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324. 85 FED. APPX. 205, available at 2003 WL 23016042 (Fed. Cir. 2003) (unpublished opinion).

325. *Id.* at 207-08.

326. *Id.* at 209.

327. *Id.* at 214.

328. 66 U.S.P.Q.2d 1878, available at 2002 WL 31059289 (S.D.N.Y. 2002) (not reported in F. Supp. 2d).

329. *Id.* at 3.

330. *Id.* at 11.

331. *Id.* at 12.

332. *Id.* at 14.

### B. India

Since India will not allow the patenting of pharmaceuticals or chemicals until January 1, 2005, only cases on infringement of analogous intellectual property rights could be examined. In the first, *Schneider Electric Industries, S.A. v. Telemacanique & Controls, Ltd.*,<sup>333</sup> an Indian firm sought to invalidate a design patent as actually being a utility type patent, so the local firm could continue making copies of the foreign company's design, outside of a previous licensing agreement.<sup>334</sup> The Indian court issued an injunction against the Indian firm to prevent it from continuing to copy the foreign firm's design.<sup>335</sup> In a trademark case, *Rainforest Café v. Chidabram*,<sup>336</sup> the defendant who was operating a restaurant based on the unlicensed (and poor quality) use of the plaintiff's theme claimed that since the plaintiff had no restaurants in India at that time, there was no goodwill built up for the defendant to destroy.<sup>337</sup> The court found that the worldwide reputation of the restaurant chain was sufficient, and that the obvious imitation of the logo had just enough changes so as to appear to be deliberately designed to create a defense.<sup>338</sup> An injunction was issued to bar further operation of the imitator.<sup>339</sup>

### C. China

In a Chinese case, *Shengzen Triangle Science & Technology Industrial Company, Ltd. v. Compaq Computer Corp.*,<sup>340</sup> a Chinese company attempted to enforce an unused patent on a design for a laptop computer against Compaq for its sales of the Armada series of laptops in China.<sup>341</sup> In their decision, the judges found that not all of the elements required by the

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333. *M/s Schneider Electric Industries S.A. v. Telemecanique & Controls (India) Ltd.*, Delhi High Court, Suit No. 1919/1999 (Nov. 27, 2000).

334. *Id.*

335. *Id.* ("I am satisfied that the plaintiff has made out a case for grant of interim injunction and accordingly IA.8522/99 is allowed and that till the disposal of the suit, the defendants, their agents, servants and assignees are restrained from manufacturing and advertising . . . products of the plaintiff").

336. *Rainforest Café, Inc. v. Rainforest Café & Ors.*, Delhi High Court, Suit No. 72/2000 (April 12, 2001).

337. *Id.*

338. *Id.* (issuing an injunction against further operation of the imitator).

339. *Id.*

340. *Shengzen Triangle Science & Technology Industrial Company, Ltd. v. Compaq Computer Corp. of the United States*, Chinalaw Database of Chinese Judicial Cases, Dec. 8, 2000 (The Higher People's Court of Beijing Municipality).

341. *Id.*

claims were present in Compaq's computer, and ruled for the defendants.<sup>342</sup>

In all three countries it should be noted that the judges, at least in these cases, appear to have based their decisions on sound principles using the intellectual property law in their jurisdictions as the appropriate tool to reach their final decision. This tends to indicate that the most important consideration is to provide the judges with the clearest set of tools possible so that the decisions are consistent, and strongly support intellectual property rights.

## VII. CONCLUSION: THE NEED FOR STRONG LAWS TO PROTECT INTELLECTUAL PROPERTY RIGHTS

This comment focuses on the tools available to acquire and enforce patent rights in markets around the world. These tools are the treaties that have created the major intellectual property organizations, including WIPO,<sup>343</sup> and the TRIPS Agreement within the WTO.<sup>344</sup> The lack of power within the WIPO to force the normalization of national Intellectual Property laws directly led the developed countries to negotiate the TRIPS Agreement, placing enforcement of changes to national laws to protect IPRs into a structure that tied these changes to overall trade considerations.<sup>345</sup> The obligation to normalize intellectual property laws then became an obligation of membership in the WTO.<sup>346</sup>

This obligatory normalization has been perceived as an attempt by the developed nations to force their own views on the LDCs and DCs of the world.<sup>347</sup> The greatest concerns of the LDCs and DCs are the loss of industries dedicated to imitating goods patented in developed countries,<sup>348</sup>

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342. *Id.*

343. *See supra* Part III.A (discussing WIPO).

344. *See supra* Part III.B (discussing the TRIPS Agreement).

345. *See supra* Part III.A.2 (discussing the reason for including the TRIPS Agreement in the WTO).

346. *See supra* Part III.B.1 (discussing the obligation of Member States).

347. *See supra* Part III.A.1; *see also supra* Part III.B.2 – IV (discussing the difficulties that LDCs and DCs have in implementing their obligations under the TRIPS Agreement).

348. *See supra* at Part IV (discussing the effects that stronger IPRs would have on industries, using the example of the disappearance of the Chilean pharmaceutical industry when stronger IPRs were adopted).

the potential lack of available medicines for their population,<sup>349</sup> and the perceived theft of indigenous knowledge.<sup>350</sup>

The developed countries have also identified the protection of IPRs as fundamental to their survival in a time when more and more production is being shifted to countries with lower labor costs.<sup>351</sup> While the balance of power seems to be wholly on the side of the developed nations, the losses from the theft of intellectual property are staggering,<sup>352</sup> and also includes dangers from poorly made imitations.<sup>353</sup> Even the patenting of indigenous knowledge is not as unfair as it would seem. Without some measure of exclusivity to reward the development of products based on this knowledge, it would not be available to the developed countries, due to the detailed and expensive approval processes.<sup>354</sup>

The implementation of the TRIPS Agreement within the WTO structure has led to significant changes in the patent laws of LDCs and DCs to protect and enforce the ownership of IPRs.<sup>355</sup> However, there has been great reluctance in India to implement the provisions, since, as in Chile, the likely initial outcome is the demise of a thriving pharmaceutical industry dedicated to imitating products patented by the drug companies of the developed countries.<sup>356</sup> The lack of progress in implementation of the TRIPS Agreement in India led the United States to bring an action in the Dispute Settlement Body of the WTO.<sup>357</sup> This action illustrated the power of the WTO dispute resolution process: within three years of the initial filing of the action, the laws of India changed to implement the necessary provisions.<sup>358</sup> In China, the actions taken to force improvements in the protection of IPRs were taken much earlier, and were unilateral on the part of the United States.<sup>359</sup> However, China also made further

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349. See *supra* Part IV.A (discussing the Doha agreement, which was implemented in an attempt to relieve some of the immediate pressure on the LDCs and DCs).

350. See *supra* Part IV.B (discussing biopiracy).

351. See *supra* Part I (discussing off-shoring of jobs).

352. See *supra* Part IV.A (discussing the amounts lost from the theft of intellectual property).

353. See *supra* Part IV.A (pointing out that counterfeit pharmaceuticals have caused health problems).

354. See *supra* Part IV.B (discussing costs of pharmaceutical development).

355. See *supra* Part V.A (detailing the timeframe of changes to the laws of the United States, India, and China).

356. See *supra* Part V.A (discussing the Indian Pharmaceutical industry).

357. See *supra* Part V.B.1 (discussing the dispute resolution process of the WTO).

358. See *supra* Part V.B.2.

359. See *supra* Part V.B.3 (discussing the changes in Chinese patent law).

changes to improve its patent laws in preparation for joining the WTO in 2001.<sup>360</sup>

In all three nations, a brief examination of cases showed that the courts enforced the patent laws as written, and that, when given the tools, the judges did not hesitate to use them to prevent infringement.<sup>361</sup>

Strong intellectual property protection not only benefits the developed countries, but also the LDCs and DCs.<sup>362</sup> As one author has noted, one only has to look at the difference in progress between the information technology and pharmaceutical industries in India to see the importance of IPRs.<sup>363</sup> In the information technology industry, where IPRs were not opposed by an entrenched constituency, over 250,000 persons are employed, and the sector is actually taking business from Western firms.<sup>364</sup> In the pharmaceutical sector, where patent rights are nonexistent, no new drugs are being developed, and India is losing many of its most talented scientists to the West.<sup>365</sup> This is a tragedy in a country that could use that talent to develop new drugs for endemic diseases,<sup>366</sup> and one that could be mitigated by stronger protection of patent rights.

The historical lessons of Edison and Nobel show that the protection of patent rights can give young scientists and engineers the motivation and funding to develop new products leading to entirely new industries and changing the face of nations and the world.<sup>367</sup>

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360. See *supra* Part V.B.4.

361. See *supra* Part VI (discussing cases brought before the courts of the individual nations).

362. See Finston, *supra* note 263, at 887.

363. *Id.* at 888.

364. *Id.*

365. *Id.* at 890.

366. *Id.* at 891-92.

367. See *supra* Part IV.B.1 (discussing Edison and Nobel).