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## Why Can't the Poor Access Lifesaving Medicines? An Exploration of Solving the Patent Issue

*Samantha Shoell\**

### INTRODUCTION

At this very moment there is an HIV/AIDS health crisis facing developing countries. The HIV/AIDS crisis has caused, and continues to cause, the deaths of millions of people.<sup>1</sup> According to statistics, 95% of the world's AIDS sufferers live in the poorest countries in the world.<sup>2</sup> In Thailand, AIDS is the leading cause of death, and an estimated one million people have the HIV virus.<sup>3</sup> In addition, at least 580,000 Brazilians are infected with HIV.<sup>4</sup> However, Africa is the continent most affected. In 1997, Africa housed 21 million of the 30.6 million people infected worldwide.<sup>5</sup> It is estimated that in South Africa, Zimbabwe, and Botswana almost one quarter of the adult population is infected with AIDS.<sup>6</sup> For the year 2000, in South Africa, the “[y]oung people who died of natural causes . . .

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1. See Kofi Annan, *No Letting Up on AIDS*, WASH. POST, Nov. 29, 2001, at A33. Kofi Annan, the Secretary General of the United Nations, says, “[e]very day more than 8,000 people die of AIDS. Every hour almost 600 people become infected. Every minute a child dies of the virus.” *Id.* In addition, “[a]bout 3 million AIDS deaths are expected this year.” David Brown, *AIDS Is Up Sharply in Eastern Europe*, WASH. POST, Nov. 29, 2001, at A29.

2. See Alan Cassels, *The Battle Against the Pharmaceutical Giants: Drugs, Patents, and Health: the Achilles Heel of the WTO?*, CCPA MONITOR (June 2001), available at <http://www.policyalternatives.ca/publications/articles/article287.html> (last visited Oct. 14, 2002).

3. See Herman Reinhold, *Patients v. Patents*, 19 NEWSL., (A.B.A. Section of Intell. Prop. Law), 2001, at 1.

4. See *id.*

5. See *id.* This number has increased to a total of 40 million people living with AIDS. See Annan, *supra* note 1.

6. As to the statistic on South Africa, see Jon Jeter, *Challenging S. Africa's AIDS Policy*, WASH. POST, Oct. 19, 2001, at A25. As to the statistics on Zimbabwe and Botswana, see Reinhold, *supra* note 3, at 1.

outnumbered the old.”<sup>7</sup> Death causes anguish, but premature death is especially devastating for any hope of economic development. Many businesses in Africa hire three workers for every two jobs because AIDS-related deaths are so rampant.<sup>8</sup> According to Joe Sills, a co-chairman of a taskforce studying employment during the current crisis, it costs a fortune for a corporation to train their middle management because “these people drop like flies from AIDS.”<sup>9</sup> As of October 19, 2001, “AIDS has become the leading cause of death in South Africa,” and by 2010 between five and seven million people will die as a result.<sup>10</sup> Undoubtedly, developing countries, especially those in Africa, are suffering from a HIV/AIDS crisis that will continue into the future.

WTO Director-General Mike Moore, voiced the thoughts of many when he said, “[u]rgently, more needs to be done to save the lives of millions of poor people.”<sup>11</sup> Part of the problem is that “[t]he poor cannot afford expensive medicines.”<sup>12</sup> In one year a single drug therapy may cost between \$4,800 and \$7,100 wholesale, and multiple drug therapy may cost between \$11,000 and \$15,000.<sup>13</sup> Moreover, the standard of care for a patient is a “triple drug therapy.”<sup>14</sup> Although costly, AIDS infected citizens in “developed nations can receive an array of medicines to delay the onset of symptoms.”<sup>15</sup> However, the poor

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7. Jeter, *supra* note 6.

8. See John Donnelly, *Activists Hope Firms' Involvement Boosts Battle Against AIDS in Africa*, BOSTON GLOBE, Sept. 4, 2001, at D1.

9. *Id.*

10. Jeter, *supra* note 6.

11. Mike Moore, *Yes, Drugs for the Poor – and Patents as Well*, INT'L. HERALD TRIBUNE, Feb. 22, 2001, at [http://www.wto.org/wto/english/news\\_e/news01\\_e/tn\\_dg\\_iht\\_feb2001\\_e.htm](http://www.wto.org/wto/english/news_e/news01_e/tn_dg_iht_feb2001_e.htm) (last visited Oct. 14, 2002). Another part of the problem facing HIV/AIDS suffers is that many developing countries lack the infrastructure to bring care and medicines to patients. See *New Medical Facility Will Train Health Providers From All of Africa*, 11 AIDS READER 364, at <http://www.medscape.com/viewarticle/410408>. See also Barton Gellman, *An Unequal Calculus of Life and Death*, WASH. POST, Dec. 27, 2000, at A18. A Roche distributor states that, “‘huge quantities’ of medicine donated to Zimbabwe reached expiration and had to be destroyed.” Although there are many problems, this comment will limit its discussion to the access of HIV/AIDS medicines. *Id.*

12. Moore, *supra* note 11.

13. See Reinhold, *supra* note 3, at 4.

14. *Id.* at 4.

15. Sara M. Ford, Note, *Compulsory Licensing Provision Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV. 941, 951

in developing countries cannot afford HIV/AIDS medicines.<sup>16</sup> In Zimbabwe, the cost of keeping an AIDS patient alive for a year is twenty-four times the average income.<sup>17</sup> In South Africa, physicians “do not mention those remedies to their [AIDS] patients because they know that the patients cannot afford the drugs.”<sup>18</sup> The poverty in these nations “means that neither the poor nor their governments can afford to purchase the essential medicines, or ensure their proper use in well-run health systems.”<sup>19</sup> Unfortunately, the inability to afford even a “single drug therapy” causes many in developing countries to suffer and die.

The cost of HIV/AIDS medicines is extremely high for a number of reasons. A study from Tufts University released in 2001 explains that the factors contributing to the high cost of a new prescription drug include: research, development, and inflation.<sup>20</sup> Due to these factors, the corporate boards of pharmaceutical companies, with the approval of public authorities, have not lowered the price of AIDS medicines.<sup>21</sup> Additionally, because the economies of most developing countries are weak, “there may be insufficient foreign currency reserves to pay the royalties and provide essential services.”<sup>22</sup> Because of the high medicine prices and poverty in developing countries, Kofi Annan, Secretary General of the United Nations, set up the Global Fund for AIDS, Tuberculosis, and Malaria.<sup>23</sup> To effectively reduce the rate of HIV infections in poorer African and Asian countries the “fund will require \$7 billion to \$10 billion.”<sup>24</sup>

If and when the Global Fund reaches \$7 to \$10 billion, and

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(2000).

16. Paul Blustein and Barton Gellman, *HIV Drug Prices Cut for Poorer Countries*, WASH. POST, March 8, 2001, at A1.

17. Moore, *supra* note 11.

18. Ford, *supra* note 15, at 951.

19. Jeffrey D. Sachs, *Macroeconomics and Health: Investing in Health for Economic Development*, Report of the Commission on Macroeconomics and Health, World Health Organization, Geneva, at 86 (Dec. 20, 2001).

20. *RX Drugs: New Study Estimates Development Costs at \$802M*, AM. HEALTH LINE: NAT. J. GROUP, Dec. 3, 2001.

21. See Gellman, *supra* note 11.

22. Stefan Kirchanski, *Protection of U.S. Patent Rights in Developing Countries: US Efforts To Enforce Pharmaceutical Patents in Thailand*, 16 LOY. L.A. INT'L & COMP. L.J. 569, 576 (1994).

23. See *Senate Approves Funding of International Anti-AIDS Efforts*, REUTERS MEDICAL NEWS, Oct. 25, 2001.

24. *Id.*

the “adequate donor financing is available, drug pricing by pharmaceutical companies (especially for drugs under patent) can be a significant obstacle.”<sup>25</sup> Brazil’s Health Minister Jose Serra states that, “[t]he drugs’ prices are about 10 times their cost.”<sup>26</sup> He continues by insisting that the high cost is not necessary to finance investment and research.<sup>27</sup> Rather, he states that the “trouble is, the patent for AIDS drugs represents a pure monopoly condition in what’s become a global epidemic.”<sup>28</sup> In other words, through patent protection, pharmaceutical companies are able to set high prices to recoup production costs and to maintain profit margins, especially in their rich-country markets.<sup>29</sup> In addition, in the year 2005, members of the World Trade Organization will be required to implement a “harmonized” patent system that will provide consistent patent protection in each country.<sup>30</sup> However, developing countries without capabilities to produce generics under a compulsory license and with only the finances from the Global Fund, which has only reached \$2 billion, are bound by patents to pay expensive prices for medicines or let their populations die.

This comment will explore the problem presented by the nexus of patents, high cost drugs, and poor developing countries. Part I explains the history of patent law and Trade-Related Aspects of International Property Rights (TRIPS). Part II of this comment delves into the different interpretations of TRIPS presented by both the developing and developed countries. It also examines the effects of the Declaration presented at the World Trade Organization (WTO) ministerial meeting. Part III discusses a solution based upon both the developing and developed countries’ ultimate goals.

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25. Sachs, *supra* note 19, at 87.

26. Roy Wadia, *Brazil’s AIDS Policy Earns Global Plaudits*, (Aug. 16, 2001), at <http://www.cnn.com/2001/WORLD/americas/08/14/brazil.AIDS/index.html> (last visited Oct. 15, 2002).

27. *Id.*

28. *Id.*

29. See Sachs, *supra* note 19, at 87.

30. *Id.* at 87.

## I. HISTORY OF TRIPS

### A. THEORY OF INTELLECTUAL PROPERTY PROTECTION

Ideas and knowledge, or intellectual property, is “bought and sold because of the information and creativity [it] contain[s].”<sup>31</sup> The value of vaccinations, medicines, and other inventions lies in the innovation, research, and testing involved.<sup>32</sup> “However, in the absence of legal protection, there is nothing to prevent someone from copying the invention and using it.”<sup>33</sup> As a result, the copier’s competition diminishes the inventor’s ability to enjoy, use, and sell the invention for profit.<sup>34</sup> In addition, the copier has “the advantage of being able to compete without bearing the investment, time or effort necessary for the discovery.”<sup>35</sup> Therefore, the inventor loses profit and is not encouraged to search for and discover new inventions to benefit society.<sup>36</sup> Intellectual property law was created to eliminate copying, allowing the inventor to recoup costs and make a profit as an incentive to make new discoveries.<sup>37</sup>

Patent law, a subset of intellectual property law, provides similar legal protection for “intangible” items that was formerly afforded only to manual labor and tangible items.<sup>38</sup> A patent is a contract between the government and the inventor.<sup>39</sup> The government provides “the inventor a monopoly to the enjoyment of his or her invention in return for disclosure of the invention to the public.”<sup>40</sup> The monopoly that is created for the inventor restricts copying and provides a means for the inventor to recoup his original investment and make a profit.<sup>41</sup> Allowing for the recuperation of the original investment is also

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31. *Intellectual Property: Protection and Enforcement*, at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm6_e.htm) (last visited Oct. 14, 2002).

32. *See id.*

33. David Benjamin Snyder, Comment, *South Africa’s Medicines and Related Substances Control Amendment Act: A Spoonful of Sugar or a Bitter Pill to Swallow?*, 18 DICK. J. INT’L L. 175, 178 (1999).

34. *See id.*

35. *Id.*

36. *See id.* at 179.

37. *See id.* at 178-79.

38. *See* Kirchanski, *supra* note 22, at 570.

39. *See* Snyder, *supra* note 33, at 179.

40. *Id.*

41. *Id.* at 178-179.

an incentive for the inventor to make new discoveries.<sup>42</sup> In addition, disclosure assists other inventors in searching and thinking about what is covered by the patent, which helps them create additional advances and new discoveries benefiting society.<sup>43</sup> Aside from the incentives and assistance that patent law provides, it is important to understand that patent law does not deny society anything that it enjoyed freely prior to the grant of the patent.<sup>44</sup> Moreover, patent protection ends after a certain time, after which anyone may manufacture the product.<sup>45</sup>

## B. PATENT PROTECTION PRIOR TO TRIPS

On a national level, patent law was first granted in Renaissance Italy based on two ideas: “(1) [i]t is morally right to give an inventor the exclusive right to exploit the fruits of his own mind; and (2) protection allows him to recoup costs incurred in research, providing an incentive to create useful new products for society.”<sup>46</sup> In accordance with these provisions, many countries enacted patent laws by the 1870s.<sup>47</sup> In addition, international trade expressed a need for international patent law. In 1878, an “international congress gathered to discuss the prospects of an agreement to extend protection to foreigners.”<sup>48</sup> As a result of this discussion, the Paris Convention was created in 1883.<sup>49</sup> The Paris Convention gave foreign inventors national treatment equal to what a domestic inventor would receive and the exclusive right to file for the patent in multiple countries within one year without having to race would-be copiers who may be locals of each country.<sup>50</sup> Although the Paris Convention provided patent

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42. *Id.* at 179.

43. *Id.*

44. *See, e.g.*, Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND, 33 I.L.M. 81 (1994) [hereinafter TRIPS] (stating patent expires after 20 years).

45. For example, TRIPS patent protection expires after 20 years. *Id.* at Art. 33.

46. George K. Foster, Comment, *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, 285 (1998).

47. *See id.*

48. *Id.* at 285-86.

49. *See id.* at 286.

50. *See id.*

protection, it lacked both a standard degree of protection among all the member states, as well as enforcement provisions to ensure a remedy if a member state violated a provision.

With recent advances in medical technology, the U.S. needed more protection than the Paris Convention could offer. Notably, the U.S. economy was and is “increasingly moving away from basic manufacturing to high-technology industries.”<sup>51</sup> In the last twenty years, the U.S. has developed almost one half of the commercial pharmaceutical drugs in the world.<sup>52</sup> The process to create, develop, and commercialize a drug is extremely expensive. In 1990, the U.S. government estimated that “a single new drug took ten to twelve years to come to market at a cost of \$359 million.”<sup>53</sup> The pharmaceutical industry receives 40% of its income from exporting drugs.<sup>54</sup> However, “foreign companies that copy and reproduce patented pharmaceuticals take away \$5 billion in sales from pharmaceutical companies.”<sup>55</sup> If not for lost revenues, the pharmaceutical industry would have another \$720 to \$900 million to invest in research and development.<sup>56</sup> This investment could result in the discovery of additional vaccines and medicines.<sup>57</sup> Due to this lost revenue, the pharmaceutical companies “began a sustained campaign to make expanded patent protection a priority of U.S. trade policy.”<sup>58</sup> In other words, pharmaceutical companies campaigned for more order, predictability, and enforcement to be introduced into an internationally-agreed-upon trade rule.<sup>59</sup>

### C. TRIPS

As a result of the campaign, the U.S. government invited representatives from the Pharmaceutical Manufacturers

51. See John A. Harrelson, Note, *TRIPS, Pharmaceutical Patents, And The HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion*, 7 WIDENER. L. SYMP. J. 175, 183 (2001).

52. See *id.*

53. *Id.* at 184.

54. *Id.* at 183.

55. *Id.* at 184.

56. *Id.* See also Foster, *supra* note 46, at 298 (citing International Trade Commission figures which state that if it were not for lost revenues from copiers, that “innovators would invest \$720 to \$900 million more annually” in research and development).

57. See Foster, *supra* note 46, at 298.

58. *Id.* at 298.

59. See *Intellectual Property: Protection and Enforcement*, *supra* note 31.

Association to attend the Uruguay Round negotiations.<sup>60</sup> On April 15, 1994, 117 countries signed the Uruguay Round Agreement, which was conducted under the umbrella of the General Agreement on Trade and Tariffs, now succeeded by the World Trade Organization (WTO).<sup>61</sup> This agreement included the Trade-Related Aspects of International Property Rights (TRIPS), which became effective January 1, 1995.<sup>62</sup> TRIPS offers the “protection conferred in the Paris Convention (as Article 2 expressly requires member to adhere to that accord), but go[es] much further in almost every respect.”<sup>63</sup>

As noted above, the Paris Convention lacked a standard degree of protection and enforcement.<sup>64</sup> TRIPS addressed those issues.<sup>65</sup> Prior to TRIPS, few developed countries had strong intellectual property protection laws;<sup>66</sup> and many developing countries “maintained weak intellectual property protection because, among other things, they felt strong patent protection would protect foreigners at the expense of local producers.”<sup>67</sup> TRIPS became the starting point to harmonize the patent laws of both developed and developing signatory nations.<sup>68</sup> In addition, TRIPS allows intellectual property rights to be enforced by trade sanctions.<sup>69</sup> As a result, intellectual property rights and trade “were formally linked on a global basis.”<sup>70</sup> Also, pharmaceutical drugs, which many countries did not recognize as patentable, became patentable subject matter.<sup>71</sup>

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60. See Foster, *supra* note 46, at 299.

61. Harrelson, *supra* note 51, at 175-76.

62. *Id.* at 179.

63. Foster, *supra* note 46, at 289.

64. See *supra* Part I.B., para. 2.

65. See Foster, *supra* note 46, at 289 (explaining that Article 27 obligates all members to make patents 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”).

66. See *id.* at 288. “Most regional agreements required simply that the members adhere to the Paris Convention; the only one that went beyond this—the European Patent Convention—did not extend beyond Europe and thus could not address inventors’ global concerns.” *Id.*

67. Harrelson, *supra* note 51, at 179.

68. See *id.*

69. *Id.* at 176.

70. *Id.* at 175.

71. See *id.* at 179. There are also transition periods for the developing and least developed countries. *Pharmaceutical Patents and the TRIPS Agreement* (July 11, 2000) at [http://www.wto.org/english/tratop\\_e/trips\\_e/pharma\\_ato186\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm) [hereinafter *Pharmaceutical Patents*].

Although many developing countries had “reservations about strengthening intellectual property rights, [they] signed the TRIPS agreement because international trade was of major importance to their economic growth.”<sup>72</sup> In other words, only after signing TRIPS would the developing countries be able to participate in the WTO, which is essential in order to realize economic growth.<sup>73</sup> Furthermore, it is believed that strong intellectual property protection laws “stimulate[] economic growth and enhance[] social welfare.”<sup>74</sup> Growth may be stimulated by increasing investments due to the exclusivity provided by patent protection.<sup>75</sup>

The TRIPS agreement attempts to balance long-term social objectives with short-term social objectives.<sup>76</sup> Article 7 of TRIPS notes that the objectives are to contribute to the promotion of technological innovations and transfer in a manner conducive to social and economic welfare.<sup>77</sup> Enforcing intellectual property rights aids the patentee in recovering development costs and receiving profit.<sup>78</sup> Protection also encourages inventors to create new drugs because they can expect to earn future benefits from their creativity.<sup>79</sup> In addition to receiving protection, TRIPS mandates in Article 29, paragraph 1, disclosure of the patented material.<sup>80</sup> Disclosure allows other inventors to study the drug while it is patented, thereby avoiding the re-invention of the wheel.<sup>81</sup> As a result, the time between developing new drugs is minimized, potentially saving more lives and maximizing health. Additionally, patent protection does not deny society vaccines or medicines that it enjoyed freely prior to the grant of the patent.

Article 8 notes that social objectives allow for exceptions to

72. Harrelson, *supra* note 51, at 176.

73. *Id.*

74. Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELL. PROP. L. 41, 47 (1998).

75. See Snyder, *supra* note 33, at 188-89.

76. *Philosophy: TRIPS Attempts to Strike a Balance* (April 2001), at [http://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm01\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm01_e.htm) (last visited Sept. 16, 2001) [hereinafter *Philosophy*].

77. TRIPS, *supra* note 44, at art. 7.

78. See *supra* Part I.A.

79. *Philosophy*, *supra* note 76.

80. TRIPS, *supra* note 44, at art. 29, para. 1.

81. *Philosophy*, *supra* note 76.

the patent holder's rights when necessary to protect public health.<sup>82</sup> Members of TRIPS may make an exception during certain circumstances, one of these being a "national emergenc[y]."<sup>83</sup> However, the exception may only be used "provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner."<sup>84</sup> Therefore, other members may enforce their property protection rights through the Dispute Resolution Board of the WTO.<sup>85</sup> Ultimately, TRIPS contains a "carefully-negotiated balance between providing intellectual property protection—which is essential if new medicines and treatments are to be developed—and allowing countries the flexibility to ensure treatments reach the world's poorest and most vulnerable people."<sup>86</sup>

## II. TRIPS AND THE HIV/AIDS CRISIS

Due to the HIV/AIDS crisis facing developing countries and the lack of affordable medicines, critics argue that TRIPS lacks balance between its long and short-term social objectives and therefore should be completely eliminated.<sup>87</sup> Nonetheless, the support for TRIPS extends throughout a majority of the WTO countries.<sup>88</sup> The Chairperson of the first special discussion on Intellectual Property and Access to Medicines stated, "I think I can safely say that all members are determined to ensure that

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82. TRIPS, *supra* note 44, at art. 8.

83. *Philosophy*, *supra* note 76, (referring to TRIPS Article 8).

84. *Pharmaceutical Patents*, *supra* note 71.

85. To date there has not been a case regarding compulsory licensing of pharmaceutical patents brought in front of the Dispute Resolution Board. Harrelson, *supra* note 51, at 183. However, "[t]he United States has come under fire for initiating a WTO dispute settlement case against Brazil's patent legislation, which Washington says obliges holders of patents in Brazil to ensure that their products are 'worked' in Brazil (either produced locally or licensed for production in Brazil) in violation of TRIPS provision." *Pharmaceuticals: U.S. Commitment on TRIPS Limits Welcomed by WHO Director-General*, BNA'S HEALTH CARE DAILY REPORT, (May 18, 2001). This case was later dropped. *AIDS RX: U.S. Drops WTO Complaint Over Brazilian Generics*, American Health Line, NAT. J. GROUP, (June 27, 2001).

86. *WTO Members to Press On, Following 'Rich Debate' on Medicines*, WTO News: 2001 Press Release (June 22, 2001) (quoting WTO Director General Mike Moore), at [http://www.wto.org/english/news\\_e/pres01\\_e/pr233\\_e.htm](http://www.wto.org/english/news_e/pres01_e/pr233_e.htm) (last visited Sept. 16, 2001) [hereinafter *Members to Press On*].

87. See Moore, *supra* note 11.

88. See *Members to Press On*, *supra* note 86.

the TRIPS Agreement is part of the solution . . . [to meet] the public health crises in poor countries. That includes the HIV/AIDS crisis in my own continent of Africa.”<sup>89</sup> Therefore, instead of arguing whether TRIPS should be eliminated, countries have narrowed their arguments to the interpretation of TRIPS exceptions.<sup>90</sup>

#### A. VAGUE ARTICLES OF TRIPS NEED INTERPRETATION

The need for a definite interpretation of TRIPS exceptions motivated the African Group to request an item on the agenda of the regular meetings of the WTO Council on TRIPS.<sup>91</sup> As a result, the June 20, 2001, meeting included a special discussion on Intellectual Property and Access to Medicines.<sup>92</sup> At this meeting, the European Union (EU) and the developing countries offered papers that discussed the relation between TRIPS and access to medicines.<sup>93</sup> During the discussion of these papers, the developing countries requested an interpretation of TRIPS “which would allow governments to pursue health policies in the secure knowledge that they would not be violating TRIPS.”<sup>94</sup> It was also requested that this interpretation be underscored by a political declaration at the Fourth Ministerial Conference in Doha, Qatar, 2001.<sup>95</sup> No country at the meeting objected to such a declaration in Doha.<sup>96</sup> Soon after, drafts for the ministerial declaration were offered

89. *Id.*

90. *See supra* notes 86, 88-89 and accompanying text.

91. *See Governments Share Interpretations on TRIPS and Public Health*, WTO News: 2001 News Item (June 20, 2001) at [http://www.wto.org/english/news\\_e/news01\\_e/trips\\_drugs\\_010620\\_e.htm](http://www.wto.org/english/news_e/news01_e/trips_drugs_010620_e.htm) (last visited Oct. 16, 2002) [hereinafter *Governments Share Interpretations*].

92. *See id.*

93. *EU's paper*, TRIPS: Council Discussion on Access to Medicines (June 20, 2001), at [http://www.wto.org/wto/english/tratop\\_e/trips\\_e/paper\\_eu\\_w280\\_e.htm](http://www.wto.org/wto/english/tratop_e/trips_e/paper_eu_w280_e.htm) (last visited Sept. 25, 2002) [hereinafter *EU's paper*]; *Developing Country Group's Paper*, TRIPS: Council Discussion on Access to Medicines (June 19, 2001) (submitted by the Africa Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela), at [http://www.wto.org/english/tratop\\_e/trips\\_e/paper\\_develop\\_w296\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm) (last visited Sept. 16, 2001).

94. *Governments Share Interpretations*, *supra* note 91.

95. *Id.*

96. *See id.*

by the developing nations, developed nations, and Hong Kong.<sup>97</sup> These ministerial declaration drafts discussed each country's interpretation of the TRIPS provisions relating to the access of medicines, and were then received by the General Council Chairperson's consultants.<sup>98</sup>

## B. MINISTERIAL DECLARATION DRAFTS INTERPRETING TRIPS

The ministerial declaration draft composed by the developing countries addressed the "inability of large segments of the population to obtain medicines and treatments at prices they can afford."<sup>99</sup> They proposed that, "[n]othing in the TRIPS Agreement shall prevent Members from taking measures to protect public health."<sup>100</sup> Draft provisions included both parallel importing and compulsory licensing with other countries as approaches to meet the demand for medicines.<sup>101</sup> Additionally, the draft provisions stated that other countries should refrain from imposing or threatening to impose sanctions.<sup>102</sup> Ultimately, these draft provisions seek to define the qualifications of the exceptions in TRIPS, thereby granting a government the opportunity to obtain medicines legally.<sup>103</sup>

### 1. Parallel Importing

The first provision addressing an exception within TRIPS relates to parallel importing. Parallel imports are not counterfeit products or illegal copies.<sup>104</sup> Parallel import

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97. *Draft Ministerial Declaration, Proposal from a Group of Developed Countries*, TRIPS: Proposal (Oct. 4, 2001) (submitted by Australia, Canada, Japan, Switzerland and the U.S.), at <http://www.patentmatics.com/pub54.htm> (last visited Oct. 23, 2002) [hereinafter *Developed Countries*]; *Draft Ministerial Declaration, Proposal from a Group of Developing Countries*, TRIPS: Proposal (Oct. 4, 2001), at [http://www.wto.org/english/tratop\\_e/trips\\_e/mindecdraft\\_w312\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm) (last visited Nov. 7, 2001) [hereinafter *Developing Countries*]; *Members Discuss Drafts For Ministerial Declaration*, WTO News: 2001 News Item (Sept. 19-21, 2001) (Hong Kong China also circulated a draft), available at [http://www.wto.org/english/news\\_e/news01\\_e/trips\\_drugs\\_010919\\_e.htm](http://www.wto.org/english/news_e/news01_e/trips_drugs_010919_e.htm) [hereinafter *Members Discuss Drafts*].

98. See *Members Discuss Drafts*, *supra* note 97.

99. *Developing Countries*, *supra* note 97.

100. *Id.*

101. See *id.*

102. See *id.*

103. See *id.*

104. *Obligations and Exceptions*, Fact Sheet: TRIPS and Pharmaceutical Patents, at

products are marketed by the patent owner in one country, and imported to another country with approval of the country, but not the patent owner.<sup>105</sup> The concept of parallel imports is centered on the exhaustion of patent rights and protection.<sup>106</sup> Exhaustion occurs after the first sale, after the patent holder loses the right to royalties and after patent protection ends for the item sold.<sup>107</sup> After a patent becomes exhausted, “the initial purchaser may resell the goods without infringing on the patent held by the original seller.”<sup>108</sup>

Sellers who are not authorized by the patent owner may be in direct competition with the authorized sellers in that country.<sup>109</sup> Unauthorized sellers may be able to offer lower prices and eventually force the authorized sellers out of business for several reasons: First, the unauthorized seller can search a number of countries to find the lowest price and resell the product in the highest priced country.<sup>110</sup> On the other hand, the authorized seller must acquire the product in the country from the patent owner, at the price set by the patent owner.<sup>111</sup> Second, the unauthorized seller can capitalize on the currency fluctuations of other countries.<sup>112</sup> Third, the unauthorized seller gets the advantage of promotional and advertising campaigns paid for by the authorized seller without any cost.<sup>113</sup> Finally, the unauthorized seller’s duties and expenses end after the sale, whereas the authorized seller may be responsible for the expense of servicing the goods.<sup>114</sup>

Although unauthorized sellers may create direct competition, potentially causing injury to the authorized seller, application of the first sale doctrine is limited to each country. According to European Union law, the “first sale of a product in any European Union member country exhausts the patentee’s

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[http://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm) (last visited Oct. 16, 2002) [hereinafter *Obligations and Exceptions*].

105. *Id.*

106. See Hillary A. Kremen, Note, *Caveat Venditor: International Application of the First Sale Doctrine*, 23 SYRACUSE J. INT’L L. & COM. 161, 162 (1997).

107. *See id.*

108. *Id.*

109. *See id.* at 161.

110. *See id.* at 161-62.

111. *See id.*

112. *Id.* at 162.

113. *Id.*

114. *Id.*

rights.”<sup>115</sup> For example, if a patent protected drug is first sold in Spain at a reasonably low price, it can be resold in France, without the patentee’s consent, for a profit.<sup>116</sup> However, if a generic version of the same drug is bought in India, it cannot be resold in Spain without the patentee’s consent.<sup>117</sup>

Distinct from the European Union, the U.S. does not allow parallel imports. Rather, in *Boesch v. Graff*,<sup>118</sup> the U.S. Supreme Court addressed the issue of “whether a dealer residing in the United States can purchase in another country articles patented there, from a person authorized to sell them, and import them to and sell them in the United States, without the license or consent of the owners of the United States patent.”<sup>119</sup> The Court held that, although the laws of one country allow the selling of a product, this fact did not authorize the selling of “articles in the United States in defiance of the rights of patentees under a United States patent.”<sup>120</sup> In addition, Congress passed legislation in October of 2000 that “authorized the reimportation of patented pharmaceutical products from Canada into the United States, subject to approval from the Department of Health and Human Services.”<sup>121</sup> However, Donna Shalala, then Secretary of Health and Human Services, refused to authorize the reimports for fear that parallel imported “pharmaceuticals would not meet United States safety standards.”<sup>122</sup> Thus, each country determines its law regarding parallel import products.

TRIPS fails to definitively harmonize the concept of

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115. Rosemary Sweeny, Comment, *The U.S. Push for Worldwide Patent Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Collision*, 9 PAC. RIM. L. & POL’Y J. 445, 456 n.102 (2000).

116. *See id.*

117. *See id.* (citing Harold C. Wegner, *Parallel Imports of Patented Goods Killing the Technology Transfer Goose*, 14-18, 23 (Presentation at the Fordham University School of Law, Sixth Annual Conference on International Intellectual Property Law & Policy, Apr. 16-17, 1998)).

118. 133 U.S. 697 (1890).

119. *Id.* at 702.

120. *Id.* at 703.

121. Shubha Ghosh, *Pills, Patents, and Power: State Creation of Gray Markets as a Limit on Patent Rights*, 53 FLA. L. REV. 789, 793-794 (2001) (referring to Congressional Legislation Oct. 2000 on reimports, H.R. Conf. Ref. No. 106-984, at 39 (2001) (“Making appropriations for Agriculture Rural Development, Food and Drug Administration, and Related Agencies Programs for the Fiscal Year Ending Sept. 30, 2001, and for Other Purposes,” amending 21 U.S.C. 381 *et seq.*)).

122. *Id.* at 794.

exhaustion amongst member countries. Exhaustion is identified by Article 6, which states that, subject to provisions 3 and 4 which deal with non-discrimination, “nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”<sup>123</sup> If there are conflicts between nations concerning exhaustion, they are to be “resolved bilaterally between individual nations.”<sup>124</sup> Thus, as a matter of law, in the absence of a definition granted by TRIPS, parallel importation remains an “entirely domestic legal concern.”<sup>125</sup>

With respect to parallel importing, the developing countries’ draft states, “[e]ach Member retains the right to establish its own policy and rules regarding the exhaustion of intellectual property rights.”<sup>126</sup> The concept of parallel importing is attractive to many developing nations, including South Africa, because they lack “sufficient manufacturing resources [that prevent] compulsory licensing from being a viable solution to the high cost of pharmaceuticals.”<sup>127</sup> In addition, parallel importing coincides with GATT’s objective of limiting “restrictions on the free movement of goods.”<sup>128</sup> Thus, any limits or restrictions on parallel importing “collide with free trade, [and] the WTO should favor open trade.”<sup>129</sup> Consequently, developing countries prefer the concept of parallel importing to compulsory licensing as a means to obtain medicines for HIV/AIDS patients.

Although poorer populations are in desperate need for HIV/AIDS medicines, parallel importing may not be the best solution. The developed countries of the EU, U.S. and Switzerland warn that parallel imports into higher-priced markets could reduce profits and undermine “differential pricing.”<sup>130</sup> Differential pricing occurs when companies sell

123. *Obligations and Exceptions*, *supra* note 104.

124. Kremen, *supra* note 106, at 174.

125. Duane Nash, *South Africa’s Medicines and Related Substances Control Amendment Act of 1997*, 15 BERKELEY TECH. L.J. 485, 494 (2000).

126. *Developing Countries*, *supra* note 97.

127. Harrelson, *supra* note 51, at 177.

128. *Id.* at 195.

129. *Id.* The WTO was created to promote free trade by reducing and eventually limiting the restrictions on the movement of goods between countries. Due to exhaustion’s ability to limit the movement of a product from one country into another country, it can be described as colliding with free trade. *See id.*

130. *Governments Share Interpretations*, *supra* note 91.

drugs at lower prices to poorer markets.<sup>131</sup> Humanitarianism is cited as the main reason for lower prices.<sup>132</sup> Recently, price-cutting for poorer countries has become very common. As of April 5, 2001, the UN Secretary General Kofi Annan stated that six major drug companies agreed, "to keep cutting prices of AIDS treatments for the world's poorest nations."<sup>133</sup> In addition, pharmaceutical companies have negotiated with countries to reduce prices. For example, negotiations between Roche pharmaceutical company and Brazil cut the price of nelfinavir by 40 percent.<sup>134</sup> GlaxoSmithKline Plc handed over its rights on AZT, 3TC and Combivir to a South African generic drug firm.<sup>135</sup> Pfizer pharmaceutical company has agreed to donate to South Africa a powerful anti-fungal agent that nearly one in ten African AIDS patients require.<sup>136</sup> Boehringer Ingelheim is willing to give anti-HIV nevirapine, which blocks the transmission of the virus from infected mothers to their newborn babies, absolutely free to poor countries.<sup>137</sup> These examples show that price-cutting or differential pricing exists and is helping poorer countries receive HIV/AIDS medicines.

Although developing countries want to parallel import cheaper medicines into their markets, some developed countries fear that the low priced medicines will flow into developed countries' markets and undermine differential pricing.<sup>138</sup> This may cause a variety of problems. First, parallel importing of lower priced medicines into developed nations would reduce pharmaceutical companies' profits, thereby decreasing the incentive to continue research and

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131. See *WTO/WHO Seminar in Norway Examines Case for Using Tiered Pricing for Medicines*, BNA'S HEALTH CARE DAILY REPORT, Apr. 13, 2001.

132. Harrelson, *supra* note 51, at 194.

133. *Annan Renews Push for Lower AIDS Treatment Costs*, REUTERS NEWMEDIA, Oct. 5, 2001, available at <http://www.aegis.com/news/re/2001/RE011004.html>. "Nine months later, however, agreements have been reached with only three countries." Karl Vick, *Kenyan Orphanage Takes Initiative on AIDS Drugs*, WASH. POST, Feb. 22, 2001, at A12.

134. John Donnelly, *Brazil Wins Big Price Cut in AIDS Drug*, BOSTON GLOBE, Sept. 1, 2001, at A1.

135. Ben Hirschler, *Glaxo Gives up Rights to AIDS Drugs in South Africa*, REUTERS NEWMEDIA, Oct. 6, 2001, at <http://www.aegis.com/news/re/2001/RE011009.html>.

136. Gellman, *supra* note 11, at A18.

137. Laurie Garrett, *Drugmakers Aid In War on AIDS / Controversy Rages Over Distribution*, NEWSDAY, July 9, 2000, at A6.

138. *Governments Share Interpretations*, *supra* note 91.

development.<sup>139</sup> The market prices for most medicines are considerably high in developed countries.<sup>140</sup> As a result, there is “a major financial incentive . . . for distributors to buy the lower priced pharmaceuticals in developing countries and resell (i.e., parallel import) the pharmaceuticals in developed countries where the market price [is] considerably higher.”<sup>141</sup> However, these markets are where pharmaceutical companies receive the “bulk” of their profits.<sup>142</sup> Therefore, parallel importing lower priced drugs to developed nations would reduce pharmaceutical companies’ profits, resulting in the lack of funds needed for the research and development of new drugs.

Second, parallel importing of cheaper medicines from poor to rich countries could put “downward pressure on the global price, [and] then the core markets of the pharmaceutical industry are at risk.”<sup>143</sup> However, pharmaceutical companies are concerned “about maintaining profit margins in wealthy nations.”<sup>144</sup> As a result of this downward pressure, pharmaceutical companies may respond by equalizing prices for all nations, therefore reducing the profitability of parallel imports.<sup>145</sup> However, equalizing prices would end differential pricing and once again raise the price of medicines beyond the reach of developing nations.

Third, parallel importing could result in needed medicines not reaching the sick in developing nations. In order to resell a particular drug it must leave the developing country that it was supposed to help.<sup>146</sup> Therefore, the infected populations may not receive the medicines they desperately need.<sup>147</sup>

Finally, there is a substantial risk that parallel imports that arrive at developing nations are unsafe or counterfeit. Parallel imports may drastically lower prices and make medicines more accessible to poorer populations.<sup>148</sup> However, developing countries may not be able to ensure the safety of

139. Harrelson, *supra* note 51, at 194.

140. *See id.* at 196.

141. *Id.*

142. *Id.*

143. Gellman, *supra* note 11, at A18.

144. Reinhold, *supra* note 3, at 5.

145. *See* Harrelson, *supra* note 51, at 196.

146. Common sense explains that a drug can only be at one place at a time, and if it is in the developed country, then it is not helping the poor in the developing country.

147. *See generally* Harrelson, *supra* note 51.

148. *See* Snyder, *supra* note 33, at 196.

these imported medicines.<sup>149</sup> For example, “‘South Africa’s border guards are unable to staunch the flow of illegal immigrants, cocaine, endangered species and even rustled cattle,’ and that they would be even less effective against ‘counterfeit drugs that have expired and were supposed to be destroyed but were just repackaged.’”<sup>150</sup> Kenya, a developing country, recently banned imports due to the problems of “ascertaining whether parallel imports had been produced in accordance with good manufacturing practice, and [the manufacturer’s] inability to recall unsafe products.”<sup>151</sup> Although developing countries do not have the HIV/AIDS medicines they need, allowing parallel imports without means to ensure safety will only harm the poorer populations.

As a result of the potential injuries created by parallel importing, the developed nations’ ministerial declaration draft “encourage[s] Members, whatever the exhaustion regime that they may have chosen, to take measures to prevent pharmaceuticals provided to the poorest populations of the globe under discounted pricing schemes or supplied under aid-schemes from being diverted.”<sup>152</sup> In other words, because developed nations would like differential pricing to continue, the draft encourages all nations to prevent parallel importing.

## 2. Compulsory Licensing

The second draft provision addressing an exception within TRIPS relates to compulsory licensing. “A compulsory license is ‘an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state.’”<sup>153</sup> The government grants the license, of a particular patented product, to a manufacturer without consent of the patent holder.<sup>154</sup> Medicines made under a compulsory license could be referred to as generic because they are “drugs that are not

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149. *Id.* at 191-92. (stating that, Kenya, a developing country, “experimented with allowing parallel imports, recently banned them citing an abundance of unsafe and counterfeit drugs”).

150. *Id.* at 192 (quoting Donald G. McNeil, Jr., *South Africa’s Bitter Pill for World’s Drug Makers*, N.Y. TIMES, Mar. 29, 1998, at Section 3, p.1).

151. *Id.*

152. *Developed Countries*, *supra* note 97.

153. Nash, *supra* note 125, at 489 (quoting Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349 (1993)).

154. *Obligations and Exceptions*, *supra* note 104.

produced under patent.”<sup>155</sup> However, this term is usually reserved for drugs made outside patent protection by countries that do not have patent laws.<sup>156</sup>

Members who have signed TRIPS disallow the creation of generic drugs before the patent is exhausted except in the form of compulsory licensing.<sup>157</sup> Strict laws surrounding generic manufacture resulted from developed countries negotiating at the Uruguay Round. One of the *main goals* was “to secure a restriction on the application of compulsory licenses.”<sup>158</sup> Although the term compulsory licensing is not specifically mentioned, TRIPS discusses “other use[s] of the subject matter of a patent without the authorization of the right holder” in detail.<sup>159</sup> Compulsory licensing under the TRIPS agreement requires that a government fulfill a number of conditions prior to exercising the license.<sup>160</sup> One of which is first attempting to obtain a voluntary license.<sup>161</sup> Another condition is that “the right holder shall be paid adequate remuneration in the circumstances of each case.”<sup>162</sup>

However, there is no need to obtain, or even try to obtain, a voluntary license if the reason for the license falls under certain special conditions.<sup>163</sup> The special conditions in Article 31(b) include: national emergency, other circumstances of extreme urgency, public non-commercial use (government use), or anti-competitive practices.<sup>164</sup> Eventually, however, the

155. *What does “generic” mean?, at* [http://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm03\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm03_e.htm) (last visited Oct. 17, 2002). However, often a product is generic because the “patent has expired, or there never was a patent . . . [or] the drug is being copied outside [of] patent protection, for example in a country that still does not provide patent protection.” *Id.*

156. *Id.*

157. *See* TRIPS, *supra* note 44, at art. 31. *See also Pharmaceutical Patents, supra* note 71 (stating that, under TRIPS, patent rights are not absolute but can be subject to limits, including compulsory licenses).

158. McCabe, *supra* note 74, at 61.

159. *Obligations and Exceptions, supra* note 104 (citing TRIPS Agreement Article 31).

160. *Id.* (citing TRIPS Agreement Article 31(a)-(l)).

161. *Id.* (stating that these requirements include first trying to receive authorization from the patent holder, use must be limited to the scope and duration authorized, and pay the right holder adequate remuneration (citing TRIPS Agreement Article 31(a)-(l))).

162. *Id.* (citing TRIPS Agreement Article 31(h)).

163. *Id.* (citing TRIPS Agreement Article 31(b)).

164. *Id.*

patent holder should be notified and receive remuneration.<sup>165</sup>

The developing countries' draft, similar to TRIPS, states in the "case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, Members may grant compulsory licenses without prior efforts on the part of the user to obtain authorization from the right holder."<sup>166</sup> Thus, developing countries could use compulsory licensing to "decrease the price and make medical treatment more affordable [for HIV/AIDS patients]."<sup>167</sup> In addition, according to the U.S., EU, and Japan, developing countries' current problem with HIV/AIDS crisis is clearly a national emergency.<sup>168</sup> It seems that all parties agree that the HIV/AIDS crisis is an emergency and, therefore, developing countries should be able to manufacture generic medicines through a local compulsory license.

However, many developing countries have not issued compulsory licenses. The denying of licenses may be a result of pressure applied by developed countries because of fears arising from TRIPS ambiguities. Although TRIPS limits a country's issuance of a compulsory license to matters of extreme urgency and although TRIPS states that remuneration is eventually to be provided, TRIPS fails to specify what is extremely urgent and what amount of remuneration is adequate.<sup>169</sup> Thus, "seemingly minor health risks [may] be interpreted as extremely urgent, allowing for a wave of compulsory licenses for pharmaceuticals."<sup>170</sup> Also, seemingly sufficient remuneration may be considered adequate when in reality it "may imperil the pharmaceutical industry if widely

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165. *Id.* (stating that notification should occur either as reasonably as practical for national emergency, or promptly for government use) (citing TRIPS Agreement Article 31(b)-(h)).

166. *Developing Countries*, *supra* note 97.

167. Harrelson, *supra* note 51, at 189.

168. *Governments Share Interpretations*, *supra* note 91.

169. TRIPS Agreement Article 31(b) only states that in "circumstances of extreme urgency" may a Member use the subject matter of a patent without authorization. It does not give clarification as to what constitutes as an extreme urgency. However, listed as other reasons why a Member may waive the requirement of obtaining prior authorization are national emergency and cases of non-commercial use. TRIPS, *supra* note 44. Also, TRIPS Agreement Article 31(h) only states that the "right holder shall be paid adequate remuneration" by "taking into account the economic value of the authorization." *Id.* It does not give further detail or specific dollar amounts.

170. Ford, *supra* note 15, at 966.

employed.”<sup>171</sup> In other words, developed countries fear the broad and vague terms in TRIPS; which may allow a country to issue compulsory licenses for inadequate reasons and for insufficient royalties to support the patent holders.<sup>172</sup>

The fear of compulsory licenses has caused developed nations, primarily the U.S., to use pressure to discourage compulsory licensing.<sup>173</sup> Legal pressures that the U.S. uses consist of the Generalized System of Preferences and Section 301 of the Omnibus Trade and Competitiveness Act.<sup>174</sup> Thus, when disputes arise concerning compulsory licensing, countries are wary of damaging relations with an important trading partner<sup>175</sup> and negotiate an agreement. As a result, there has yet to be an argument related to compulsory licensing before the Dispute Resolution Board of the WTO.<sup>176</sup> For example, South Africa passed legislation stating that it permits the government to license companies to manufacture generic medicines.<sup>177</sup> However, the act “can be read to permit activity which is in violation of TRIPS.”<sup>178</sup> As a result, “United States Trade Representative Charlene Barshefsky announced the placement of South Africa on the Watch List for countries who provide inadequate intellectual property right protection.”<sup>179</sup> Similarly, the U.S. has “applied similar pressure to Argentina, Brazil, and India when they considered intellectual property bills that would authorize compulsory licensing of pharmaceuticals.”<sup>180</sup> As described, developed countries have pressured developing countries to limit and prevent compulsory licensing.

In addition, developed countries are pursuing, on a

171. See Nash, *supra* note 125, at 487.

172. See Ford, *supra* note 15, at 966.

173. *Id.* at 952-54 (referring to the pressure applied by the U.S. on South Africa because of the Medicines and Related Substances Control Amendment Act that allowed for compulsory licensing and parallel importing).

174. Sweeny, *supra* note 115, at 458-59 (referring to the pressure applied by the U.S. upon Thailand which caused Thailand to amend its Patent Act).

175. Ford, *supra* note 15, at 944.

176. Harrelson, *supra* note 51, at 183.

177. Medicines and Related Substances Control Amendment Act, No. 90 (1997) (S. Afr.).

178. Nash, *supra* note 125, at 494.

179. Snyder, *supra* note 33, at 176. Shortly afterwards, President Clinton, through an executive order, declared that the United States would not implement trade policies that would deprive access to AIDS medication in South Africa. See Harrelson, *supra* note 51, at 186.

180. Harrelson, *supra* note 51, at 186.

country-by-country basis, even stricter laws concerning compulsory licensing. In an attempt to eliminate the ability of nations to compulsory license, the U.S. has “attempted to negotiate changes in the patent laws of numerous nations.”<sup>181</sup> For example, Thailand’s Patent Act of 1992 arguably met all the requirements of TRIPS.<sup>182</sup> However, U.S. pressure resulted in amendments that “narrowed the situations in which compulsory licenses can be issued to produce generic versions of AIDS drugs locally.”<sup>183</sup> Also, the Jordan Free Trade Agreement “went beyond TRIPS and ‘raised standards.’”<sup>184</sup> According to Joe Papovich, Assistant U.S. Trade Representative for Intellectual Property, the U.S. is “seeking to persuade the Chileans and the Singaporeans to agree to the same provisions.”<sup>185</sup> Hence, in order to limit compulsory licensing, developed countries have pursued and pressured other countries into implementing stricter laws.

In response, developing nations argue that the political pressure applied by developed nations hinders their ability to address public health issues.<sup>186</sup> The developing countries’ ministerial declaration draft states that sanctions have the ability to “curtail the ability of developing . . . country Members to avail themselves of every possible policy option to protect and promote public health.”<sup>187</sup> Thus, the developing countries suggest that the developed nations should “exercise utmost restraint in initiating and pursuing dispute settlement proceedings relating to measures adopted . . . to protect and promote public health.”<sup>188</sup> Ultimately, developing countries desire to be secure in that the actions they take to promote public health will not be sanctioned.

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181. *Id.* at 183.

182. Sweeny, *supra* note 115, at 457.

183. *Id.* at 463.

184. Chris Rugaber, *Cooperation, Enforcement, TRIPS Case Will Help Protect IP Rights, Leader Says*, 188 BNA DAILY R. FOR EXECUTIVES, Oct. 1, 2001, at A20 (quoting President Eric H. Smith of the International Intellectual Property Alliance (IIPA)), *available at* <http://lists.essential.org/pipermail/ecommerce/2001q4/000604.html> (last visited Oct. 14, 2002).

185. *Id.*

186. *See Developing Countries, supra* note 97.

187. *Id.*

188. *Id.*

### 3. Issuing a Compulsory License to a Third Party

TRIPS is ambiguous as to whether a country may issue a compulsory license to a producer in another country. This third party producer would then manufacture and export the medicines back to the country that originally gave them the compulsory license.<sup>189</sup> Many developing countries, even if justified under an exception to compulsory license, are unable to make HIV/AIDS treatment drugs because “[t]hese drugs require a sophistication of manufacture that, without cooperation of the developers of the technology, is beyond the capacity of many developing countries.”<sup>190</sup> As a result, developing countries want to use compulsory licensing for import. Developing countries who are authorized to issue compulsory licenses but do not have the capabilities to do so, would appoint a producer in another country to supply them with medicines. In their ministerial declaration drafts, both the developing countries and Hong Kong mention appointing another country for the production and exportation of drugs as a means to address public health.<sup>191</sup> The developing countries supported their argument with Article 30 of TRIPS.<sup>192</sup> They claim that TRIPS authorizes such production and exportation because these measures “do not infringe the rights of the patent holder.”<sup>193</sup> Therefore, issuing compulsory licenses to another country to produce and export needed medicines should be allowed.

However, further broadening and relaxing of TRIPS restrictions on compulsory licensing to allow one country to issue a compulsory license to another is unlikely to be agreed

189. TRIPS is silent as to giving a compulsory license to another country to produce the medicines for a country that lacks the capabilities but is in extreme urgency. See TRIPS, *supra* note 44. However, under article 31, after fulfilling the stated requirements, Member states may allow for the use of the patent by the government or third parties authorized by the government. See TRIPS, *supra* note 44.

190. Harrelson, *supra* note 51, at 192.

191. *Developing Countries*, *supra* note 97. Hong Kong China also circulated a draft. See WTO News: 2001 News Items, *Members discuss drafts for ministerial declaration*, Sept. 19-21, 2001 (claiming countries cannot compulsorily license foreign companies, thus foreign governments will have to cooperate), at [http://www.wto.org/english/news\\_e/news01\\_e/trips\\_drugs\\_010919\\_e.htm](http://www.wto.org/english/news_e/news01_e/trips_drugs_010919_e.htm) (last visited Oct. 14, 2002).

192. *Developing Countries*, *supra* note 97.

193. *Id.*

upon by the developed nations.<sup>194</sup> Additionally, the TRIPS agreement is ambiguous as to the exact place of manufacture. Therefore, developed countries may seek to interpret TRIPS according to Article 31(f).<sup>195</sup> Article 31(f) states that a product made under a compulsory license should be “predominantly for the supply of the domestic market of the member authorizing such use.”<sup>196</sup> By interpreting the domestic market as both the authorizing and supply country, the article then seems to limit the location of production to the country authorizing a compulsory license.

In addition, developed countries fear that a drug created through a compulsory license will be a parallel import.<sup>197</sup> South Africa and other countries could issue a compulsory license that could force pharmaceutical companies to compete “at rock bottom prices, only to find that these drugs are then parallel imported into other nations where they undercut the prices of ‘authorized’ suppliers.”<sup>198</sup> Undercutting prices and profits would harm pharmaceutical companies and developed countries.<sup>199</sup> Thus, it is unlikely that developed countries will support compulsory licensing through an import country because it increases the chance of parallel importation of cheaper medicines.

### C. THE INTERPRETATION OF TRIPS

On November 14, 2001, the WTO adopted the Declaration on the TRIPS Agreement and Public Health.<sup>200</sup> The final

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194. See McCabe, *supra* note 74, at 61 (stating that “[g]iven the negotiating position of the developed countries, it is unlikely that they would agree to a relaxation of the restrictions on compulsory licenses”).

195. See *EU’s Paper*, *supra* note 93; see also TRIPS, *supra* note 44.

196. TRIPS, *supra* note 44.

197. See Nash, *supra* note 125, at 500.

198. *Id.*

199. See *supra* Part II.B.1 (explaining injuries from parallel imports).

200. *Declaration on the TRIPS Agreement and Public Health*, WTO (adopted 2001), available at

[http://www.wto.org/wto/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/wto/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) [hereinafter *Declaration on the TRIPS Agreement*] (last visited Oct. 14, 2002). The Declaration also extends the date for poor nations to comply with the patent rules to 2016. *Id.* at para. 7; see also, C. Rammanohar Reddy, *Agreement at Doha to soften TRIPS provisions*, HINDU, Nov. 14, 2001, available at 2001 WL 30300681. On June 27, 2002, the WTO council responsible for intellectual property approved a decision that extends the transition period for least-developed countries to 2016. *Council Approves LDC Decision with Additional Waiver*, WTO News: 2002 Press Releases, (June 28,

agreement was brought together by Brazil, on behalf of the developing countries, and the U.S., on behalf of the developed countries.<sup>201</sup> The declaration recognizes the importance of patents, yet reaffirms the right to issue a compulsory license during an emergency.<sup>202</sup> Prior to the declaration, developing countries had the right to issue compulsory licenses in the event of a health emergency, yet the definition of a national emergency was vague.<sup>203</sup> The declaration's interpretation of TRIPS reaffirms the right of a country to grant a compulsory license, allows each country to determine what constitutes a national emergency, and recommends that other countries should not prevent a country from taking measures to protect public health.<sup>204</sup> As a result of reaffirming the right to issue a compulsory license according to each country's definition of a national emergency without any insecurity or fear of sanctions, a developing country may be more likely to take action to promote public health such as issuing compulsory licensing itself. Daniel Berman, from Doctors Without Borders, explains that due to this declaration "it is doubtful that a wealthy country would dare file a dispute against a developing country for using . . . compulsory licensing."<sup>205</sup> Therefore, the declaration could be seen as an accommodating interpretation of the compulsory licensing provision.

However, upon closer examination, the declaration is not legally binding. The declaration was neither an amendment nor a modification.<sup>206</sup> As one U.S. official pointed out, the

2002), at [http://www.wto.org/english/news\\_e/pres02\\_e/pr301\\_e.htm](http://www.wto.org/english/news_e/pres02_e/pr301_e.htm) (last visited Oct. 14, 2002).

201. Frances Williams, *Declaration on Patent Rules Cheers Developing Nations*, FIN. TIMES (LONDON), Nov. 15, 2001, at 11.

202. *Declaration on the TRIPS Agreement*, *supra* note 200, at paras. 3-5.

203. See TRIPS, *supra* note 44, at art. 31(b); see also Melody Petersen, *U.S. Companies Largely Back Trade Decisions*, N.Y. TIMES, Nov. 15, 2001, at C3 (noting that the declaration made it clear that "each country has a right to grant compulsory licenses and to determine what constitutes a health emergency").

204. *Declaration on the TRIPS Agreement*, *supra* note 200, at paras. 4,5(c) and 7. It can be argued that this provision (TRIPS art. 31(b)) was added to allow the U.S. the necessary means to determine that the Anthrax incidences are a national emergency, therefore allowing compulsory licensing if needed.

205. *Activists Welcome WTO Accord on Drug Patents*, REUTERS MEDICAL NEWS, Nov. 13, 2001, available at [http://www.medformation.com/mf/news.nsf/ReutersNews/Activists\\_welcome\\_WTO\\_accord\\_on\\_drug\\_patents](http://www.medformation.com/mf/news.nsf/ReutersNews/Activists_welcome_WTO_accord_on_drug_patents) (last visited Oct. 14, 2002).

206. Although a political declaration is not binding law, if it was ever challenged in the Dispute Settlement Body, and upheld, it would receive the

declaration is “a political and not legal text’ and that ‘the statement does not add or subtract to TRIPS.’”<sup>207</sup> As a result, the declaration is not legally binding and does not have the legal force as an amendment or modification.

In addition, the declaration highlights the need to find a means that would allow countries without manufacturing capabilities to use compulsory licensing, but it does not assist those countries.<sup>208</sup> “[T]he TRIPS council has been given until the end of next year [2002] to find an ‘expeditious solution’ to the question of how countries without local drug industries can make ‘effective use of compulsory licensing.’”<sup>209</sup> Also, the declaration did not decide whether developing countries may issue compulsory licenses to producers in other countries to produce medicines for them.<sup>210</sup> Therefore, the declaration, although useful in interpreting compulsory licensing and providing limited security to developing countries with production capabilities authorized to use a compulsory license, is not legally binding, and it is unable to address the HIV/AIDS crisis in poorer developing countries that do not have production capabilities.

### III. ANOTHER SOLUTION

A declaratory interpretation of TRIPS alone is unable to address the issues of patent protection and the HIV/AIDS crisis. However, the interpretation presented by the WTO, coupled with a modification to TRIPS, will have more authority

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authority of law.

207. Reddy, *supra* note 200.

208. See Celia W. Dugger, *A Catch-22 on Drugs for the World's Poor*, N.Y. TIMES, Nov. 16, 2001, at W1.

209. Geoff Dyer, *Activists See Flaws in Drug Patent Proposal*, FIN. TIMES (LONDON), Nov. 16, 2001, at 13 (referring to *Declaration on the TRIPS Agreement*, *supra* note 200, at 6). Since the Declaration, proposals have been submitted by the U.S., EC, and a group of developing countries, Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand, and Venezuela. The EC proposal suggests four options, one of which is an amendment to Article 31 of TRIPS. However, the U.S. proposal recommends using the flexibility of Article 31 of TRIPS, rather than modifying TRIPS. The Developing Countries' Proposal considered deleting Article 31(f) of TRIPS or amending 31(k) of TRIPS; however the preferred solution is an authoritative interpretation of Article 30 of TRIPS. *Access to Medicines in Spotlight at TRIPS Council*, 6 BRIDGES WEEKLY, June 26, 2002, available at <http://www.ictsd.org/weekly/02-06-26/story3.htm> (last visited Oct. 14, 2002).

210. See Dugger, *supra* note 208.

and persuasion to solve the problem. To negotiate and resolve issues between disagreeing parties, it is necessary to look at each party's ultimate goals. It is apparent that the developed nations want stronger intellectual property protection, while developing nations desire medicines for their infected populations.

#### A. DIFFERENTIAL PRICING AND THIRD PARTY PRODUCERS

Differential pricing allows for lower prices in developing countries, developing countries gain access to medicines while drug companies maintain high prices in profitable markets.<sup>211</sup> Pharmaceutical companies have already begun to lower their prices and/or give patents to developing countries.<sup>212</sup> Michael Scholtz, who is now working for the World Health Organization after 21 years as a manager at Ciba-Geigy and SmithKline Beecham, says, "lost profits from a price cut in Africa would amount to no more than 'three days' fluctuation of exchange rates."<sup>213</sup> Therefore, differential pricing could be set and monitored to ensure lower prices. If the prices of medicines were set according to each developing country's gross domestic product (GDP), developing countries would be ensured a reasonable price. However, setting the price of medicines according to GDP may be problematic. The UN tried to control the pace of negotiations and the flow of drugs with five pharmaceutical companies.<sup>214</sup> One year later, "the effort had resulted in deals with only three countries – Uganda, Senegal and Rwanda – and promised to cover only a few thousand Africans."<sup>215</sup> Thus, past experience with the UN shows that controlling negotiations fails to produce quick results.<sup>216</sup>

Additionally, pharmaceutical companies are concerned that differentially priced medicines "will undermine their prices in the high-income markets."<sup>217</sup> Lowering their prices to cost will bring attention to the high profit margins gained in developing countries. As a result, populations within developed countries, who are paying ten times the amount of rock bottom prices,

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211. See Reinhold, *supra* note 3, at 6.

212. See discussion *infra* Part II.B.1.

213. Gellman, *supra* note 11.

214. See Blustien & Gellman, *supra* note 16, at A13.

215. *Id.*

216. See *id.*

217. Sachs, *supra* note 19, at 87.

may demand that their prices drop as well.<sup>218</sup> Also, if the differentially priced medicines are parallel imported into high-income markets then the pharmaceutical companies will lose profits.<sup>219</sup> Furthermore, in some low-income markets profits can actually be higher “as [a] result of a few high-priced sales to a narrow segment of rich customers as opposed to broad-based sales at close-to-production cost.”<sup>220</sup> Thus, pharmaceutical companies do not have an incentive to continue lowering their prices.

Rather than setting and monitoring price, competition may provide a better means to drive down prices. In many poorer countries, like South Africa, “consumers do not enjoy the strong competition found in more developed economies.”<sup>221</sup> Also, poorer countries do not have the capabilities to create their own competition.<sup>222</sup> Thus, exporting generics may be the means to develop competition and “drastically lower the price of drugs.”<sup>223</sup> If a country were to accept generic imports, pharmaceutical companies would have to compete with “generic versions often cost[ing] 80 to 90 percent less than the brand-name product.”<sup>224</sup> However, according to interpretations of TRIPS Agreement 31(f), generic drug producers of patented medicines should only be in those countries that already have a compulsory license due to their own emergency.<sup>225</sup>

However, if 31(f) was interpreted to allow a developing country to assign its compulsory license to another country that already retains its own compulsory license and has the capabilities to produce medicines, then competition may be created causing reduction in prices. In addition, restricting third party compulsory licensing to a producer in a country who is already in a state of emergency will direct the Global Funds to a country who is in need of economic stimulation. Hereinafter, a compulsory license from a country in a state of emergency without capabilities of production to a producer in another country who is also in a state of emergency will be

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218. See Gellman, *supra* note 11, at A13.

219. See Sachs, *supra* note 19, at 87-88.

220. See *id.* at 88.

221. Snyder, *supra* note 33, at 195.

222. See Harrelson, *supra* note 51, at 177.

223. Snyder, *supra* note 33, at 196.

224. See Stephen Buckley, *U.S., Brazil Clash Over AIDS Drugs*, WASH. POST, Feb. 6, 2001, at A1.

225. See discussion *supra* Part II.B.3.

known as “restricted third party compulsory licensing.”

Due to the creation of competition, third party compulsory licensing may be able to bring to developing countries medicines from the original producer. Dr. Mark Wainberg, former president of the International AIDS Society and a professor of medicine at McGill University, states “that it would be ‘far superior’ if developing countries obtained AIDS drugs from the pharmaceutical companies that originally developed them rather than from generic drug makers, ‘particularly companies without proven track records.’”<sup>226</sup> Critics are fearful that “generic drugs that are not manufactured at full strength may ‘fail the patient and may also foster the growth of drug resistant viruses.’”<sup>227</sup> Thus, due to the potential harm that could result to the patient and community, it would be best for developing countries to receive their medicines from the original producers.

However, it may be questioned whether pharmaceutical companies, even with the pressures of competition, would be able to lower their prices for poorer countries. According to Reuters Health, the government of the Ivory Coast “told various people that patented medicines from originating brand companies have been as cheap or cheaper than generic versions.”<sup>228</sup> Thus, noting the Ivory Coast as an example, pharmaceutical companies may be able to reduce prices low enough for the poor to afford. However, even if pharmaceutical companies in developed countries do not lower prices, restricted third party licensing provides a means for developing countries to receive access to medicines.<sup>229</sup>

## B. EXHAUSTION

Restricted third party compulsory licensing may create competition and reduce prices. However, it may not be

226. *Inside the Industry AIDS RX: Experts Question Quality of Foreign Generics*, AMERICAN HEALTH LINE, Apr. 25, 2001.

227. *Id.*

228. *AIDS Drugs: Easing Patent Laws Won't Help*, Thompson Says, AM. HEALTH LINE, May 17, 2001 (quoting Harvey Bale, the head of the International Federation of Pharmaceutical Manufacturers' Association). This article is a report of Tommy Thompson, the Health and Human Services Secretary, speaking at a meeting of the World Health Assembly.

229. Although restricted third party compulsory licensing may not provide developing countries with ‘far superior’ medicines, patients in developing countries “are probably more fearful of not having any medical attention than receiving imposter drugs.” Snyder, *supra* note 33, at 196.

accepted as a solution by the developed countries. Developed countries may fear that restricted third party compulsory licensing will increase parallel importing to developed countries, thus injuring pharmaceutical companies' profit margins.<sup>230</sup> Without stronger intellectual property protection laws, developed countries are less likely to agree to this solution.

Therefore, the TRIPS exhaustion article should be modified to solve for the parallel importing problem. The International Intellectual Property Institute suggests that if there were a global adoption of a national exhaustion scheme similar to the type used by the United States, "pharmaceutical companies would be protected against parallel importing."<sup>231</sup> As a result of eliminating parallel importing, except between countries that are both in states of emergencies, pharmaceutical companies may be more willing to agree to restricted third party compulsory licensing.<sup>232</sup> In addition, a global adoption of a national exhaustion scheme would not limit a capable country's ability to issue a compulsory license, to manufacture, and to use this ability as a negotiating tool.<sup>233</sup>

### C. THE NEGOTIATION AND BARGAIN

In order for developing countries in a state of emergency to gain the means to issue their compulsory license to third party producers in a country, they will need to negotiate and bargain with the developed countries. Also, in order for the developed countries to receive global adoption of a national exhaustion scheme, they will need to negotiate and bargain with the developing countries.

Unlike developed countries, developing countries' ultimate goals are not to have a national exhaustion scheme. Currently, "developing nations have opposed national exhaustion."<sup>234</sup>

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230. See *supra* notes 172 and 173 and accompanying text.

231. Harrelson, *supra* note 51, at 198.

232. Conversely, if the pharmaceutical companies do not need to fear the parallel importation of their drugs, or loss of profits, they may continue to lower their prices even farther as a result of humanitarian pressures.

233. Poor countries with the ability to manufacture may use this scheme as a negotiating tool to lower prices. Thailand, Brazil and China are such countries. Brazil threatened compulsory licensing and it prompted various pharmaceutical companies to reduce their prices. See Jennifer L. Rich, *Roche Reaches Accord on Drug with Brazil*, N.Y. TIMES, Sept. 1, 2001, at C1. China potentially has the power to do the same.

234. Harrelson, *supra* note 51, at 198.

However, their ultimate goals are to have medicines available to their infected populations. Thus, if restricted third party compulsory licensing were available, developing countries would favor a national exhaustion scheme.<sup>235</sup> Also, developed countries do not support compulsory licensing or even third party compulsory licensing for fear of parallel imports.<sup>236</sup>

However, if the developing countries supported a modification to the TRIPS agreement that defined the exhaustion scheme, the developed countries would be likely to support a modification of TRIPS to allow for restricted third party compulsory licensing. Also, restricting third party compulsory licensing limits the competition and following price reduction to only developing countries in extreme need. These restrictions may make it easier for pharmaceutical companies to explain the price reduction to the wealthy nations. WHO official Michael Sholtz suggests telling the consumer “[y]ou can have the same deal when you are living on a dollar a day.”<sup>237</sup> By using a large-scale publicized campaign, backed by public health agencies, the wealthy nations’ populations should be able to tolerate the price reduction to assist solving the HIV/AIDS crisis in developing countries.<sup>238</sup> Although convincing the wealthy population to tolerate the price difference may be difficult, the pharmaceutical companies may agree in order to gain a global adoption of a national exhaustion scheme. Ultimately, the developed and developing countries should be able to agree on a modification which allows for restricted third party compulsory licensing in exchange for a global adoption of a national exhaustion scheme. Through this modification, both developing and developed countries reach their ultimate goals.

#### D. MODIFICATION BEST MEANS

A modification to TRIPS should be used to allow for restricted third party compulsory licensing and exhaustion schemes. It has a greater likelihood of adoption than an amendment, and more legal standing than a declaration. As

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235. *See id.* (stating that “[t]he economic interests of developing countries would favor national exhaustion if tiered pricing and subsidies were available”). Along a similar path, parallel imports would provide developing countries cheaper medicines adjacent to their economic interests.

236. *See supra* notes 172, 173, 197-199 and accompanying text.

237. Blustien & Gellman, *supra* note 16.

238. *See id.*

noted earlier, a declaration is merely a political statement; yet a modification or an amendment to TRIPS has legal binding power.<sup>239</sup> A modification is easier to pass than an amendment. Article 71 appears to suggest that the "TRIPS Council has the authority to make modifications to the TRIPS Agreement without forwarding such modifications to the full Ministerial Conference of the WTO."<sup>240</sup> Since the TRIPS Council is smaller than the Ministerial Conference, it is more likely that support will be found within the TRIPS council.<sup>241</sup> Thus, a modification to TRIPS should be used to address the issues of restricted third party compulsory licensing and exhaustion schemes, rather than a declaration or an amendment.

### CONCLUSION

Patent law, through the implementation of TRIPS, secures profits for patentees from would-be copiers to provide funding for research and development, and allows for disclosure so inventors may continue to build on the knowledge of the patentee. However, the current HIV/AIDS crisis requires assistance. Although there are many pressing issues, providing HIV/AIDS medicines to developing nations is important. Ministerial drafts from both the developing and developed countries illuminate this dispute in detail. Using both drafts as guides, the declaration provides flexibility and security to countries that issue compulsory licenses. However, the declaration is not legally binding, nor does it provide a means for developing countries without manufacturing capabilities to receive medicines. Therefore, a modification to TRIPS is necessary. The modification should contain a means to transfer a compulsory license to a third party after meeting certain requirements as well as global exhaustion based upon a national scheme. A modification to TRIPS should provide low-priced medicines to the developing countries in exchange for an exhaustion scheme desired by developed countries.

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239. Unlike a declaration, a modification will be integrated into the TRIPS agreement and have legal power.

240. McCabe, *supra* note 74, at 63.

241. *Id.* at 64. A TRIPS council must forward amendments to the Ministerial Conference for consideration. As the Ministerial Conference is a larger body, proposed amendments are thus more likely to be rejected here. However, the Council has the authority to make modifications, and since it is a smaller body, the supporting countries should be able to obtain support.