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# TRIPS AND PUBLIC HEALTH: SOLUTIONS FOR ENSURING GLOBAL ACCESS TO ESSENTIAL AIDS MEDICATION IN THE WAKE OF THE PARAGRAPH 6 WAIVER

*Jessica L. Greenbaum*\*

Approximately thirty-three million people worldwide are infected with HIV.<sup>1</sup> Two-thirds of those infected live in sub-Saharan Africa.<sup>2</sup> In 2007, deaths caused by AIDS in sub-Saharan Africa represented seventy-five percent of AIDS-related deaths globally.<sup>3</sup> While the provision of antiretroviral therapy has expanded dramatically, less than one quarter of the estimated number of those in need of therapy in the sub-Saharan region receive it.<sup>4</sup> Eighty percent of those in clinical need of antiretrovirals worldwide cannot gain access to the life saving medication.<sup>5</sup>

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1. UNAIDS, 2008 REPORT ON THE GLOBAL AIDS EPIDEMIC 32 (2008), <http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/> [hereinafter 2008 UNAIDS REPORT]. See generally UNAIDS, FAST FACTS ABOUT HIV 1 (2008), [http://data.unaids.org/pub/FactSheet/2008/20080519\\_fastfacts\\_hiv\\_en.pdf](http://data.unaids.org/pub/FactSheet/2008/20080519_fastfacts_hiv_en.pdf) (“HIV stands for ‘human immunodeficiency virus.’ HIV is a virus that infects cells of the human immune system . . . and destroys or impairs their function. Infection with this virus results in the progressive deterioration of the immune system, leading to ‘immune deficiency.’”).

2. 2008 UNAIDS REPORT, *supra* note 1, at 39.

3. *Id.*

4. UNAIDS, AIDS EPIDEMIC UPDATE 2006, 10 (2006), [http://www.unaids.org/en/HIV\\_data/epi2006/default](http://www.unaids.org/en/HIV_data/epi2006/default) [hereinafter AIDS UPDATE 2006].

Lack of access to medication contributes to high death rates, particularly in sub-Saharan Africa.<sup>6</sup> Various factors contribute to the lack of access to medication, but one of the largest barriers is the exorbitant cost of antiretroviral therapy.<sup>7</sup> The high cost of medication is a result of both patent protection, which prevents the production of generic forms of antiretrovirals to be sold at lower costs, and also the inability of many underdeveloped countries to manufacture their own medication.<sup>8</sup> The competing interests of patent holders and developing countries surround the issue of affordable access to medication.<sup>9</sup> In 2003, the World Trade Organization (WTO) proposed a waiver to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), known as the “Paragraph 6 Waiver,” in order to create flexibility for developing countries and to allow easier importation of cheap generic medication.<sup>10</sup> On July 17, 2007, Rwanda became the first country to make use of the waiver.<sup>11</sup> The fact that only one

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5. UNAIDS, 2006 REPORT ON THE GLOBAL AIDS EPIDEMIC 155 (2006), <http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2006/default.asp> (follow “7 Treatment and care” hyperlink) [hereinafter 2006 UNAIDS REPORT].

6. AIDS UPDATE 2006, *supra* note 4, at 10.

7. 2008 UNAIDS REPORT, *supra* note 1, at 157.

8. *See id.* at 157; Carlos M. Correa, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, April 2004, at 1, [http://www.who.int/medicines/areas/policy/WTO\\_DOHA\\_DecisionPara6final.pdf](http://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf). [hereinafter Correa: Implementation] (“Many developing countries and least developed countries . . . cannot produce either active ingredients or formulations, due to lack of technology, equipment, human resources or economic viability of domestic production.”).

9. *See* John A. Harrelson, *TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion*, 7 WIDENER L. SYMP. J. 174, 175 (2001) (analyzing the level of patent protection that should be afforded to pharmaceuticals in developing countries).

10. General Council Decision, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 1, 2003), available at [http://www.wto.org/english/tratop\\_e/TRIPS\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/TRIPS_e/implem_para6_e.htm) [hereinafter Implementation of Paragraph 6].

11. Council for Trade-Related Aspects of Intellectual Property Rights, *Notification Under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of*

country has used the waiver since 2003 suggests that the waiver has not achieved its desired results.

It is now time to revisit the TRIPS agreement and determine how to guarantee global access to essential medications. Part I begins with an overview of the TRIPS agreement and describes the provisions that specifically aim to protect public health. This section includes a discussion of the history and development of the WTO, the creation of the TRIPS agreement, the availability of compulsory licensing, and the newer provisions and amendments such as the “Paragraph 6 Waiver” promulgated to address public health. Part II asserts three problems the WTO failed to recognize when it drafted the “Paragraph 6 Waiver” and concludes that such problems have made the waiver ineffective in its goal of enabling access to medication in developing countries. Included in this section is an analysis of the problems faced by Rwanda and Canada, the first countries to make use of the “Paragraph 6 Waiver.” Part III provides three suggestions that will solve the problems overlooked by the WTO and allow for a more effective implementation of the “Paragraph 6 Waiver.”

#### I: A LOOK AT THE DEVELOPMENT OF THE WORLD TRADE ORGANIZATION AND ITS EFFECT ON PUBLIC HEALTH

##### *A. Creation of the World Trade Organization and Trade Related Aspects of Intellectual Property Rights*

With technological innovations and increased mobility, countries throughout the world have become interconnected in ways never thought possible. In the 1980's, it became apparent that global trade regulations were outdated and that a more complex system was needed to control trade between countries.<sup>12</sup> In 1995, the WTO was formed as an international organization to monitor and enforce “the global rules of trade between nations.”<sup>13</sup> According to the WTO, “[i]ts main function is to ensure that

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*Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health-  
Rwanda*, IP/N/9/RWA/1 (July 19, 2007).

12. WORLD TRADE ORGANIZATION, UNDERSTANDING THE WTO 15 (2007), [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/tif\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/tif_e.htm).

13. WORLD TRADE ORGANIZATION, THE WORLD TRADE ORGANIZATION IN BRIEF 1 (2008), [http://www.wto.org/english/res\\_e/download\\_e/inbr\\_e.pdf](http://www.wto.org/english/res_e/download_e/inbr_e.pdf) (explaining that the WTO replaced the General Agreement on Tariffs and Trade (GATT) established after World War II in 1948). GATT reduced tariffs as a way to increase trade in goods between member countries. *Id.* at 3. GATT facilitated a stable multilateral trading system through

trade flows as smoothly, predictably and freely as possible.”<sup>14</sup> The WTO is governed by a multilateral trading system of agreements, negotiated and signed by a majority of its member states and ratified in each member’s home government. These agreements work as contracts binding all countries that are members of the WTO.<sup>15</sup> As of July 23, 2008, the WTO’s membership included 153 countries.<sup>16</sup>

The WTO regulates world intellectual property rights through the TRIPS agreement.<sup>17</sup> According to the WTO, “[TRIPS] attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations.”<sup>18</sup> TRIPS became effective on January 1, 1995, at the same time the WTO came into existence,<sup>19</sup> and according to the WTO it is considered to be “the most comprehensive multilateral instrument on intellectual property” rights.<sup>20</sup> TRIPS creates a minimum standard of intellectual property protection that all member states must seek to incorporate into their own national legislation.<sup>21</sup> Article 1 of

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rounds of trade negotiations. *Id.* As a result of the Uruguay Round of negotiations, which spanned from 1986 until 1994, the WTO became effective January 1, 1995. *Id.*

14. *Id.* at 1.

15. *Id.* at 2.

16. *Id.* at 8.

17. General Agreement on Tariffs and Trade: Multilateral Trade Negotiations, Apr. 15, 1994, Marrakesh Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Art. 1—Results of the Uruguay Round, 33 I.L.M. 84 (1994) [hereinafter TRIPS Agreement].

18. WORLD TRADE ORGANIZATION, FACT SHEET: TRIPS AND PHARMACEUTICAL PATENTS 1 (2006), [http://www.wto.org/english/tratop\\_e/trips\\_e/tripsfactsheet\\_pharma\\_2006\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf). [hereinafter TRIPS Fact Sheet].

19. WORLD TRADE ORGANIZATION, OVERVIEW: THE TRIPS AGREEMENT, [http://www.wto.org/english/tratop\\_e/TRIPS\\_e/intel2\\_e.htm](http://www.wto.org/english/tratop_e/TRIPS_e/intel2_e.htm) (last visited Sept. 17, 2008).

20. *Id.*

21. Obijiofor Aginam, *Between Life and Profit: Global Governance and the Trilogy of Human Rights, Public Health and Pharmaceutical Patents*, 31 N.C. J. INT’L. & COM. REG. 901, 909 (2006).

the TRIPS agreement states that WTO “[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”<sup>22</sup> While TRIPS only provides minimum standards of compliance, member states may enact legislation that provides for stronger protection.<sup>23</sup>

Article 27 of the TRIPS agreement states that, “patents shall be available for any inventions, whether products or process, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”<sup>24</sup> Patents give an inventor the legal right to prevent others from making, using, or selling a new invention for a specific period of time.<sup>25</sup> The protection encourages development and innovation as it allows patent owners to prosper and gain from their inventions.<sup>26</sup> Under TRIPS, member states must allow patent protection for at least twenty years from the date the patent application was filed.<sup>27</sup>

#### *B. Exceptions to Patent Protection Under TRIPS: Compulsory Licensing*

Under the TRIPS agreement, member states are not required to grant patents in certain limited circumstances.<sup>28</sup> Article 30 of the TRIPS agreement states, “[m]embers may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not

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22. TRIPS Agreement, *supra* note 17, art. 1.

23. *Id.*

24. *Id.* art. 27.1.

25. *Id.* art. 28.

26. TRIPS Fact Sheet, *supra* note 18, at 1-2.

27. TRIPS Agreement, *supra* note 17, art. 33.

28. *Id.* arts. 27, 8, and 30. Article 27 of the TRIPS agreement states that governments can refuse to grant patents under three circumstances that may relate to public health: first, inventions whose commercial exploitation needs to be prevented to protect human, animal, or plant life or health; second for diagnostic, therapeutic and surgical methods for treating humans or animals; and third for certain plant and animal inventions. *Id.* art. 27. The TRIPS agreement through Articles 8 and 40 says that governments can act to prevent patent owners and other holders of intellectual property rights from abusing intellectual property rights, “unreasonably” restraining trade, or hampering the international transfer of technology. *Id.* arts. 8, 40.

unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owner, taking account of the legitimate interests of third parties.”<sup>29</sup> This process is known as compulsory licensing.<sup>30</sup> The subsections of Article 31 of the TRIPS agreement contain a list of requirements that must be met prior to the use of a compulsory license, and as a result of such requirements it is only used in very limited circumstances.<sup>31</sup> Under Article 31(b), which describes compulsory licensing, “[t]he person or company applying for a license” to use the patented product “must have first attempted, unsuccessfully, to obtain a voluntary license from the right holder on reasonable commercial terms.”<sup>32</sup> Under Article 31(h), if a compulsory license is issued, the patent holder must still receive sufficient remuneration costs.<sup>33</sup> In addition, under Article 31(b), the requirement of attempting to obtain a voluntary license “may be waived by a member in the case of a national emergency or other circumstance of extreme urgency or in cases of public non-commercial [‘governmental’] use.”<sup>34</sup> There are also additional requirements that must be met in order to obtain a compulsory license. The right to produce the product cannot be given exclusively to the licensee.<sup>35</sup> This ensures that the patent-holder can also continue to produce the product.<sup>36</sup> In addition, Article 31(f) requires that compulsory licenses be granted “predominantly for the supply of the domestic market of the Member authorizing such use.”<sup>37</sup> This

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29. *Id.* art. 30.

30. TRIPS Fact Sheet, *supra* note 18, at 4.

31. *Id.* See also TRIPS Agreement, *supra* note 17, art. 31.

32. TRIPS Fact Sheet, *supra* note 18, at 4.

33. TRIPS Agreement, *supra* note 17, art. 31(h).

34. TRIPS Agreement, *supra* note 17, art. 31(b).

35. *Id.* art. 31(d).

36. TRIPS Fact Sheet, *supra* note 18, at 4 (explaining that one additional mechanism for flexibility, known as parallel importing, allows for importation of patented products without the authorization of the patent holder. This practice is also not specifically referred to in the TRIPS agreement, but is referred to in Article 6 as “exhaustion of rights.” Once a product is marketed for the first time with the consent of the patent owner, the patent owner has exhausted his or her rights and no longer has protection).

37. TRIPS Agreement, *supra* note 17, art. 31(f).

provision in particular created many problems which will be discussed below.

*C. Changes to the TRIPS Agreement: The Doha Declaration and the 2003 Decision on Implementation*

In the years that followed the adoption of TRIPS, tension surrounded compulsory licensing and questions were raised regarding the enforcement of the agreement.<sup>38</sup> Developing countries worried about their ability to comply with the strict provisions and deadlines.<sup>39</sup> In a response to the questions raised by TRIPS concerning public health, the WTO ministerial conference in Doha, Qatar, adopted the Declaration on the TRIPS Agreement and Public Health in November of 2001 (Doha Declaration).<sup>40</sup> The Doha Declaration stated that TRIPS “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”<sup>41</sup> The declaration was an important acknowledgement by the WTO that compulsory licensing may be difficult, not only because of the many requirements that must be met prior to their use, but also because members with insufficient or no pharmaceutical manufacturing capabilities may be unable to effectively use the provisions designed to provide access to medication.<sup>42</sup> While the Doha Declaration affirmed the right of member states to use compulsory licensing to obtain low-cost pharmaceutical products in a national emergency, members who exported drugs produced under compulsory licenses to countries without manufacturing capabilities could still be sanctioned for violating Article 31(f) of the TRIPS agreement.<sup>43</sup> In paragraph 6 of the Doha Declaration the WTO

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38. Aginam, *supra* note 21, at 912.

39. *Id.* at 902-03.

40. *See generally* World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration].

41. *Id.* ¶ 4.

42. Aginam, *supra* note 21, at 912.

43. Margo A. Bagley, *Legal Movements in Intellectual Property: TRIPS, Unilateral Action, Bilateral Agreements, and HIV/AIDS*, 17 EMORY INT’L L. REV. 781, 786 (2003); *see also* TRIPS Agreement, *supra* note 17, art. 31(f) (requiring that a country authorize a compulsory license for use predominantly in the *domestic* market).



acknowledged that “WTO members with insufficient or no manufacturing capabilities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.”<sup>44</sup> Paragraph 6 also called for “the Council for TRIPS to find an expeditious solution to this problem.”<sup>45</sup>

In 2003, the WTO addressed the paragraph 6 issue and further clarified the TRIPS agreement.<sup>46</sup> The 2003 General Council Decision on TRIPS and Public Health addressed and modified Article 31(f) of TRIPS, which originally stated that any use of compulsory licensing “shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.”<sup>47</sup> The 2003 General Council Decision, which became known as the Paragraph 6 Waiver because it addressed the concerns stated in paragraph 6 of the Doha Declaration, had a major impact on developing countries that could not manufacture drugs domestically. Prior to the Paragraph 6 Waiver, countries were unlikely to import generic medications because member countries with the ability to import generic pharmaceuticals under compulsory licenses could not export the drugs due to the “domestic market” requirement of Article 31(f). The Paragraph 6 Waiver specifically addressed the domestic use requirement by stating that any obligation under Article 31(f) “shall be waived with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of pharmaceutical product(s) and its export to an eligible importing Member(s).”<sup>48</sup> This answered the question raised by the Doha Declaration: exporting pharmaceuticals produced under a compulsory license to a member state without such manufacturing capability would be acceptable.

The Paragraph 6 Waiver contains three waivers.<sup>49</sup> First, “exporting countries’ obligations under Article 31(f) are waived.”<sup>50</sup> Second, “importing countries’ obligations on remuneration to the patent holder under compulsory licensing are waived” because remuneration is only required by

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44. Doha Declaration, *supra* note 40, ¶ 6.

45. *Id.*

46. Implementation of Paragraph 6, *supra* note 10.

47. *Id.*; TRIPS Agreement, *supra* note 17, art. 31(f).

48. Implementation of Paragraph 6, *supra* note 10, ¶ 2.

49. TRIPS Fact Sheet, *supra* note 18, at 6.

50. *Id.*

the exporting country.<sup>51</sup> Third, “exporting constraints are waived for developing and least-developed countries so that they can export within a regional trade agreement.”<sup>52</sup> Although all member countries of WTO are eligible to import under the Paragraph 6 Waiver, thirty-three developed countries have declared that they will not import because they do not want to undermine the intent of the provision and eleven more countries have said they will only import during extreme emergencies.<sup>53</sup> After the Paragraph 6 Waiver, several potential exporting countries implemented the waivers into their national legislation and now allow production for the export under compulsory license. As of 2006, Norway, Canada, India, and the EU had formally informed the TRIPS council of such changes in legislation.<sup>54</sup>

The Paragraph 6 Waiver was only an interim modification to the TRIPS agreement. A decision to make the Paragraph 6 Waiver an amendment was reached in December 2005.<sup>55</sup> The proposed amendment, identical to the waiver, will become part of the TRIPS agreement when two-thirds of WTO members accept it.<sup>56</sup> Though originally scheduled to occur by December 1, 2007, the TRIPS council agreed to extend the deadline to December 31, 2009.<sup>57</sup>

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51. *Id.*

52. *Id.*

53. *Id.*

54. *Id.*

55. TRIPS Fact Sheet, *supra* note 18, at 6.

56. *Id.*

57. WTO: TRIPS and Public Health: Members Accepting Amendment of the TRIPS Agreement, [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm) (last visited Oct. 30, 2008) (listing those members of the WTO that have accepted the amendment as of 6 August 2008: United States, Switzerland, El Salvador, Republic of Korea, Norway, India, Philippines, Israel, Japan, Australia, Singapore, Hong Kong, China, the European Communities, Mauritius, Egypt, Mexico, and Jordan). The TRIPS council consists of all WTO members. *Id.*

## II: THE PARAGRAPH 6 WAIVER: HAS THE WTO REALLY FOUND A BALANCE BETWEEN INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO PHARMACEUTICALS?

The WTO and others have heralded the Paragraph 6 Waiver as a major breakthrough for developing countries. The formal announcement by the WTO and proposed amendment to the TRIPS agreement that compulsory licensing and exporting of generic drugs under compulsory licensing are acceptable means of gaining access to cheap generic medications was supposed to save millions of lives threatened by disease. Then, why, in the five years since the formal announcement of the WTO's commitment to public health, has only one country notified the WTO of its intention to import pharmaceuticals from another member state with manufacturing capabilities?

### *A. Why Compulsory Licensing Will Still Not Work*

Although ninety percent of those infected with the HIV/AIDS virus live in developing countries,<sup>58</sup> almost eighty percent of these countries do not have the means necessary to produce anti-retroviral drugs.<sup>59</sup> One of the most effective ways for developing countries to obtain large amounts of medication is to import generics from another WTO member state capable of producing the specific medication. This process has now been made possible by the Paragraph 6 Waiver, however, there are several reasons why the waiver has not been as successful as the WTO had hoped. First, exporting countries must amend their own patent legislation to produce generic drugs solely for export to countries that need them.<sup>60</sup> In the face of a strong pharmaceutical lobby, this may be a difficult task for exporting countries to undertake.<sup>61</sup> Second, because compulsory licensing under the importing/exporting scheme was once prohibited by the TRIPS agreement, the effects of past sanctions for engaging in such practices has lingering effects which make developing countries reluctant to seek out exporting countries. Finally, under the current scheme of compulsory licensing

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58. World Health Organization, WHO Takes Major Steps Do [sic] make HIV Treatment Accessible (Apr. 22, 2002), <http://www.who.int/mediacentre/news/releases/release28/en/index.html>.

59. Aginam, *supra* note 21, at 913. See also Correa: Implementation, *supra* note 8, at 1.

60. Correa: Implementation, *supra* note 8, at 6.

61. Aginam, *supra* note 21, at 913.

proposed by the Paragraph 6 Waiver, remuneration costs to the patent holder are to be paid by the exporting country, creating little incentive for such countries to participate in the new compulsory licensing scheme.

The pharmaceutical industry has historically been the target of widespread criticism for its positions on intellectual property rights.<sup>62</sup> Much of the criticism stems from the fact that pharmaceutical companies tend to charge “high prices for treatments for diseases that heavily affect poor people that are unable to afford them.”<sup>63</sup> The global pharmaceutical industry is composed of only a few companies and concentrated mainly in the United States, the United Kingdom, Germany, and Switzerland.<sup>64</sup> The present industry makeup is due to high research and development (R&D) costs, which average around 500 million dollars per new drug, regardless of whether it ever enters the market.<sup>65</sup> While it may be true that the pharmaceutical industry needs to generate a large amount of money to develop new medication, the industry as a whole consistently brings in incredibly high profits. For example, “[i]n 24 of the 32 years between 1960 and 1991, the pharmaceutical industry held either the first or second position in Fortune magazine’s ranking of the most profitable sectors of the U.S. economy.”<sup>66</sup> The profitability of the pharmaceutical industry makes clear that the high costs of medications are not necessarily a direct result of high R&D costs. It is also likely that R&D costs are not as high as pharmaceutical companies report. The numbers often include “substantial marketing expenses that are only marginally relevant to therapeutic innovation.”<sup>67</sup>

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62. See Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 834-35 (2007).

63. *Id.* at 835 (quoting Graham Dutfield, *Introduction to TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE, AND SUSTAINABILITY* 6-7 (Christopher Bellmann, Graham Dutfield & Ricardo Melendez-Ortiz eds., Earthscan Publications 2003)).

64. Nitya Nanda & Ritu Lodha, *Access to Essential Medicines and Affordable Drugs: Making Essential Medicines Affordable to the Poor*, 20 WIS. INT’L L.J. 581, 581 (2002).

65. *Id.* at 581-82.

66. *Id.* at 583.

67. Yu, *supra* note 62, at 836.

The pharmaceutical industry has also been criticized for putting “pressure on developing nations to prevent the local manufacture or importation of cheaper versions of the drugs produced in countries where either they cannot be patented or where the patents are not respected.”<sup>68</sup> Despite the WTO’s strong commitment to promoting public health, pharmaceutical companies have not changed their position.<sup>69</sup> They maintain that “the pharmaceutical business is extremely risky, and the research and development (R&D) costs are always very high.”<sup>70</sup> To the companies who own pharmaceutical patents, the notion that a government can use their product without the permission of the patent holder seems unfair and counterproductive.<sup>71</sup> They argue that such policies stifle innovation and create a disincentive for pharmaceutical companies.<sup>72</sup> Pharmaceutical companies argue that long-term patent protection is necessary for the development of new medications.<sup>73</sup> However, the high profits generated by pharmaceutical companies make clear that “the actual need for incentives to invent . . . is much less than the industry has claimed.”<sup>74</sup>

There is some evidence that the idea of compulsory licensing alone has lowered costs of medication. The mere threat of a government right to issue a compulsory license forces companies with patents to lower prices.<sup>75</sup> For

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68. *Id.* at 835 (quoting Graham Dutfield, *Introduction to TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE, AND SUSTAINABILITY*, 6-7 (Christophe Bellmann, Graham Dutfield & Ricardo Melendez-Ortiz eds., Earthscan Publications 2003)).

69. *See id.*

70. *Id.*

71. *See* Lisa C. Pavento, Jamie L. Greene & John K. McDonald, *International Patent Protection for HIV-Related Therapies: Patent Attorney’s Perspective*, 17 EMORY INT’L L. REV. 919, 921 (2003).

72. *See generally id.* (discussing the perspective of pharmaceutical companies).

73. Yu, *supra* note 62, at 835-36.

74. *Id.* at 837.

75. Council for Trade-Related Aspects of Intellectual Property Rights, *Report on the Workshop on the WTO Decision on Access to Medicines at Affordable Prices for Countries with No or Insufficient Manufacturing Capacities*, ¶ 6(A), IP/C/W/439 (Feb. 23, 2005) [hereinafter TRIPS Report] (discussing that evidence confirmed prices of certain patented products were lower than the price before negotiations for the adoption

example, in Brazil the threat of using compulsory licensing was used to obtain concessions from major pharmaceutical companies.<sup>76</sup> Even when the Brazilian government did not issue a compulsory license, it used “the mere threat of issuing one to reduce the price of individual HIV/AIDS retroviral drugs by up to 75 per cent.”<sup>77</sup> Despite Brazil’s success, threats may not work elsewhere.<sup>78</sup> Also, it seems the effects are only temporary; prices tend to increase after threats subside or an application for a compulsory license is withdrawn.<sup>79</sup>

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of the WTO decision. In a few cases, members attending the workshop reported that drug prices had fallen to nearly one-tenth of the previous cost).

76. Yu, *supra* note 62, at 847; *see also* Tina Rosenberg, *Look at Brazil*, N.Y. TIMES, Jan. 28, 2001, § 6 (Magazine), at 26 (discussing the success of Brazil in producing copies of brand-name drugs and Brazil’s ability to force major drug companies to lower their prices just by threat of compulsory licensing. The price of medications fell by an average of seventy-nine percent. Furthermore, as a result of such practices the AIDS epidemic stabilized in the country, and the death rate nationally was cut by about fifty percent. “Brazil, by defying the pharmaceutical companies and threatening to break patents, among other actions, has made drugs available to everyone . . . . Its experience shows that doing this requires something radical: an alteration of the basic social contract the pharmaceutical companies have enjoyed until now.”).

77. Yu, *supra* note 62, at 847 (*quoting* Pedro Roffe with Ctistop Spennemann & Johanna von Braun, *From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health*, in *NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 15* (Pedro Roffe, Geoff Tansey & David Vivas-Eugui eds., 2006)); *see also* Rosenberg, *supra* note 76, at 26.

78. Yu, *supra* note 62, at 847 (“Brazil was successful because it also possessed two unique conditions that made its threat credible. First, the country has an indigenous capacity to develop and manufacture pharmaceuticals, and that capacity created ‘a strong negotiating capacity for obtaining low prices from patent holders.’ Second, Brazil contains a lucrative middle class market that U.S. pharmaceutical firms cannot afford to lose or alienate.”).

79. TRIPS Report, *supra* note 75, ¶ 6(A) (explaining the counter argument that experience of members at the workshop had shown prices of drugs increased when it became “clear that a generic manufacturer would no longer be interested in obtaining a compulsory license.”). *See also* Eyal Benvenisti & George W. Downs, *Distributive Politics and International Institutions: The Case of Drugs*, 36 CASE W. RES. J. INT’L L. 21, 46 (2004) (“[I]t seems more appropriate to view a price break as an isolated victory that is materially important in the short term, but institutionally irrelevant in the long term.”).

Because the mere threat of issuing a compulsory license is not adequate to lower prices in the long-term, it is important for the developing countries that cannot manufacture their own medications to feel that importing under compulsory licenses is a real option. However, there is a strong tension between pharmaceutical patent holders, often supported by powerful countries like the United States, and countries that want to use compulsory licensing to gain access to medication.<sup>80</sup> In February 2001, the tension led the United States to seek sanctions against Brazil and sent strong messages to countries seeking to use compulsory licensing.<sup>81</sup> At the WTO Dispute Settlement Body, the United States attempted to impose sanctions against Brazil due to one of Brazil's intellectual property law provisions that required holders of Brazilian patents to manufacture their products within Brazil.<sup>82</sup> This was known as the "local working" requirement.<sup>83</sup> Under the provision, if a company did not comply with the requirement, its patent would be subject to compulsory licensing after three years.<sup>84</sup> The United States argued the Brazilian law compromised the rights of patent holders and discriminated against United States patent owners.<sup>85</sup> The United States also argued that the Brazilian law violated Articles 27.1 and 28.1 of the TRIPS Agreement.<sup>86</sup> The United States' widely criticized action<sup>87</sup> created legitimate fear that countries could be subjected to reprisal in the form of sanctions, litigation, and trade restrictions due to the use of compulsory

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80. Aginam, *supra* note 21, at 909 ("[L]egitimate efforts by a few developing countries to pursue these measures in the face of high prevalence of HIV/AIDS among their populations were either blocked or legally challenged by some industrialized member states of the WTO, especially by the United States.").

81. Ellen t'Hoen, *Public Health and International Law: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 32 (2002).

82. *Id.*

83. *Id.*

84. *Id.* at 33.

85. *Id.* at 32-33.

86. *Id.* at 33.

87. t'Hoen, *supra* note 81, at 33.

licensing.<sup>88</sup> Many feared it would negatively impact Brazil's AIDS program and deter other countries from seeking Brazil's help when developing their own programs.<sup>89</sup> Despite the fact that the United States eventually withdrew the WTO panel against Brazil,<sup>90</sup> lingering effects remain throughout the international community and may contribute to the absence of countries making use of the Paragraph 6 Waiver.

Even if countries do not fear direct sanctions, the United States sent a strong message for its distaste of compulsory licensing. For example, at a WTO workshop,<sup>91</sup> one developing country explained that while its "Ministry of Health was pressing for the granting of a license on an urgent basis to import drugs needed for treatment of HIV/AIDS, other ministries . . . were reluctant to support the proposal, as they considered that granting of such licenses could have an adverse impact, in the long term, on the flow of foreign investment."<sup>92</sup> Such fear is not uncommon and stems from both the 2001 litigation in Brazil and trepidation over angering large companies based in powerful nations that hold patent rights. For developing countries that are still attempting to come into compliance with other, more simplistic provisions of the TRIPS agreement, engaging in the importation of generic

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88. See Tony Karon, *AIDS Drug Case Puts Our Idea About Medicine on Trial*, TIME, Mar. 5, 2001, available at <http://www.time.com/time/printout/0,8816,101494,00.html> (discussing a trial in Pretoria, South Africa, over the intellectual property rights of thirty-nine drug companies against authorities in South Africa who wanted the right to import the cheap generic medications).

89. *Id.* (discussing how Brazil's AIDS program serves as a model for some developing countries that are unable to produce medicines locally. Brazil was cooperating with developing countries, sharing technology and helping with the production of generic AIDS medications prior to U.S. action against Brazil).

90. t'Hoen, *supra* note 81, at 33.

91. TRIPS Report, *supra* note 75, ¶ 1.

To assist countries in the effective implementation of the Decision, the Commonwealth Secretariat arranged a Workshop . . . in Geneva on 12-14 October 2004, for discussions on measures that could be taken at national and regional levels. The basis for the discussions was provided by case studies undertaken in nine Commonwealth developing countries by national experts with experience of work in the area of intellectual property rights and/or regulation and distribution of pharmaceutical products at the national level.

*Id.*

92. *Id.*



medication produced under a compulsory license may not be worth the risk of potential sanctions or trade reprisals.

Exporting countries also face significant challenges in creating legislation that not only meets the requirements imposed by the WTO and provides a humanitarian benefit to developing member countries, but that also benefits its own country. Part of the problem is that exporting countries do not have a strong incentive to enact legislation because currently they must remunerate or compensate the patent holder.<sup>93</sup> Guidelines do not exist for a legislative and institutional framework that could be adopted at the national level by countries with the capacity to produce pharmaceuticals under a compulsory license with intent to export.<sup>94</sup> This includes guidelines regarding how much remuneration should be paid. At the above mentioned WTO Workshop, it was suggested that “each country should have the freedom to determine the appropriate level of remuneration to be paid, taking into account . . . ‘the economic value to the importing member of the use of the patent right that has been authorized.’”<sup>95</sup> The lack of guidelines regarding remuneration may lead exporting countries to pay prices that are either too high - and thus not worth any potential gains they would receive as a result of producing the low cost medication - or too low - and thus not a fair compensation value to the patent holder.

*B. Implementation of Paragraph 6: For the First Time in Four Years,  
Rwanda Tests the Water and Canada Tries to Help*

The Paragraph 6 Waiver requires that developing countries notify the WTO of their intention to become an eligible importing member as well as which products they intend to import and the quantity of any drugs they intend to import.<sup>96</sup> The WTO announced that Rwanda was the first member

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93. Council for Trade-Related Aspects of Intellectual Property Rights, *Implementation of Paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, Annex to the Protocol Amending the Trips Agreement, *Article 31bis* ¶ 2, IP/C/41 (Dec. 6, 2005).

94. TRIPS Report, *supra* note 75, ¶ 3(C).

95. *Id.* (suggesting that “[i]f the exporting countries were to take into consideration the economic value of production to the importing country, it may be necessary for the exporting country to receive information from the importing country regarding factors as to how the medicines will be supplied.”).

96. Implementation of Paragraph 6, *supra* note 10, ¶ 2.

state to notify them of intent to use the waiver in July 2007.<sup>97</sup> Rwanda notified the WTO that it “wanted to purchase 260,000 packages of a triple-drug anti-retroviral therapy, enough to treat 21,000 people for one year.”<sup>98</sup>

Canada was one of the first countries to enact legislation for the sole purpose of exporting generic drugs to developing countries and its experience is indicative of the problems presented by compulsory licensing and the Paragraph 6 Waiver.<sup>99</sup> In May 2004, Canada amended its national law, creating Canada’s Access to Medicines Regime (CAMR).<sup>100</sup> The law became effective in May 2005.<sup>101</sup> According to the Canadian government, the purpose of the law is to, “provide a way for the world’s developing and least-developed countries to import high-quality drugs and medical devices at a lower cost to treat the diseases that bring suffering to their citizens to allow generic manufacturers to produce and export medication to developing countries.”<sup>102</sup> Before Canada will issue a compulsory license the law first requires a generic company to obtain the permission, called a voluntary license, from the patent holder.<sup>103</sup> This voluntary license requirement makes the law even more rigorous than the standards for compulsory licensing

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97. WTO, TRIPS AND PUBLIC HEALTH, Patents and Health: WTO Receives First Notification Under ‘Paragraph 6’ System, July 20, 2007, [http://www.wto.org/english/news\\_e/news07\\_e/public\\_health\\_july07\\_e.htm](http://www.wto.org/english/news_e/news07_e/public_health_july07_e.htm).

98. Unnati Gandhi, *Generic Drug Problem Strangled by Red Tape*, THE GLOBE AND MAIL (Canada), Sept. 15, 2007, at F10.

99. For an excellent discussion of the problems associated with Canada’s Access to Medicines Regime, the effect of these problems on other developing nations, and potential solutions for improving access to medication under TRIPS see generally Christina Cotter, *The Implications of Rwanda’s Paragraph 6 Agreement with Canada for Other Developing Countries*, 5 LOY. U. CHI. INT’L L. R. 177, 185-86 (2008).

100. Holger P. Hestermeyer, *Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines*, ASIL INSIGHT, Dec. 10, 2007, <http://www.asil.org/insights071210.cfm>.

101. *Id.*

102. GOVERNMENT OF CANADA, CANADA’S ACCESS TO MEDICINES REGIME, WELCOME (2007), [http://www.camr-rcam.gc.ca/index\\_e.html](http://www.camr-rcam.gc.ca/index_e.html).

103. Unnati Gandhi, *Supplying Generic AIDS Drugs Called Pricey Process*, THE GLOBE AND MAIL (Canada), May 8, 2008, at A5 [hereinafter Gandhi: *Pricey Process*].

under TRIPS.<sup>104</sup> Once the company owning the patent grants a voluntary license, the generic manufacturer must then obtain a compulsory license from the Canadian Commissioner of Patents.<sup>105</sup> After these requirements are met, the generic manufacturer can formally begin a bidding process with the government of a developing nation.<sup>106</sup>

For over a year, the Toronto-based generic drug manufacturer Apotex, Inc. sought to obtain a voluntary license from manufacturers GlaxoSmithKline, Shire, and Boehringer Ingelheim, each of which owns patents on three components of a triple-fixed-dose, anti-viral AIDS drug known as Apo-TriAvir that Apotex wanted to produce under CAMR.<sup>107</sup> Despite efforts to negotiate, the pharmaceutical companies refused to give Apotex a voluntary license.<sup>108</sup> It wasn't until after Rwanda sent its notification to the WTO, that the companies changed their mind and consented to the use of their patented drugs.<sup>109</sup> On September 19, 2007, the Canadian Commissioner of Patents, Murray Lewis, granted Apotex a compulsory license<sup>110</sup> and on October 4, 2007, Canada notified the WTO.<sup>111</sup>

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104. See Cotter, *supra* note 99, at 185-86.

105. See *id.* at 186; Gandhi: *Pricey Process*, *supra* note 103, at A5.

106. Gandhi: *Pricey Process*, *supra* note 103, at A5.

107. Cotter, *supra* note 99, at 185-86. See also Gandhi: *Pricey Process*, *supra* note 101; Jillian C. Cohen-Kohler, Laura C. Esmail & Andre Perez Cosio, *Canada's Implementation of the Paragraph 6 Decision: Is It Sustainable Public Policy?*, 3:12 GLOBALIZATION AND HEALTH, at 2 (2007), available at <http://www.globalizationandhealth.com/content/3/1/12>.

108. Cotter, *supra* note 99, at 186.

109. Kaiser Daily HIV/AIDS Report, *Canadian Drug Company Awarded Rwandan Contract to Provide Combination Antiretroviral*, May, 12, 2008, [http://www.kaisernetwork.org/daily\\_reports/print\\_report.cfm?DR\\_ID=52061&dr\\_cat=1](http://www.kaisernetwork.org/daily_reports/print_report.cfm?DR_ID=52061&dr_cat=1) [hereinafter Kaiser Daily]. GlaxoSmithKline gave consent to Apotex to use lamivudine and zidovudine in August 2007 and Boehringer Ingelheim gave consent in July 2007 to allow Apotex to use nevirapine. *Id.*

110. *Canada Issues Compulsory License for HIV/AIDS Drug Export to Rwanda*, in *First Test of WTO Procedure*, 11 BRIDGES WEEKLY TRACE NEWS DIGEST 32, (Sept. 26, 2007), available at <http://ictsd.net/i/news/bridgesweekly/6556>.

111. Council for Trade-Related Aspects of Intellectual Property Rights, *Notification Under Paragraph 2(c) of the Decision of 30 August 2003 on the Implementation of*

Finally, after meeting obligations under CAMR and TRIPS, Apotex was able to begin negotiations with Rwanda and on May 7, 2008, Rwanda accepted Apotex's bid.<sup>112</sup> In a press release dated September 23, 2008, Apotex announced that, "[t]he first shipment of seven million tablets, which will help save the lives of 21,000 people is scheduled to leave from Toronto on September 24th, 2008."<sup>113</sup>

Over four years after CAMR was enacted, the first pills may finally be on the way to help those in critical need of the medication. Four years? Despite the obvious humanitarian objectives of the Canadian government, it is clear that CAMR is too complicated and imposes requirements that are too stringent.<sup>114</sup> For example, the effect of the voluntary license requirement is to allow pharmaceutical patent holders to stop the process at any time.<sup>115</sup> Elie Betito, Director of Public and Government Affairs for Apotex, explained that "nothing will be final until the drugs are delivered, [and] the patent-holding companies can still withdraw permission for the sale to take place 'even on the day we are shipping.'"<sup>116</sup> CAMR has also been criticized by both developing countries and the generic pharmaceutical industry for being too complex.<sup>117</sup>

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*Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, IP/N/10/CAN/1 (Oct. 8, 2007) (announcing Canada's notification to the WTO of its intention to export on October 4, 2007).*

112. Gandhi: *Pricey Process*, *supra* note 103, at A5.

113. Press Release from Elie Betito, Director of Public and Government Affairs, Apotex, to City/International Editors, Canadian-Made Life Saving HIV/AIDS Drug Heading to Africa (Sept. 23, 2008) [hereinafter Apotex Press Release] (on file with author). A second shipment of seven million doses of the drug is expected to take place in September 2009. *Id.*

114. *See generally* Cotter, *supra* note 99 (explaining the criticism of CAMR from both developing countries and the generic drug industry); Cohen-Kohler, Esmail, & Cosio, *supra* note 107 (discussing the problems of access to medication from the viewpoint of various stakeholders in CAMR).

115. Tanya Talaga, *AIDS Drugs Fiasco a Tale of Red Tape; Generic Pills Could Finally Reach African Patients After Years Lost While Canadian Officials Squabbled*, THE TORONTO STAR, Aug. 9, 2007, at A1, available at <http://www.thestar.com/article/244582>.

116. Kaiser Daily, *supra* note 109.

117. According to Jack Kay, Apotex President:

The experience between Rwanda and Canada is further proof that the current system proposed by the Paragraph 6 Waiver is fraught with problems. While the problems do not appear to be in the language of TRIPS or in the language of the Paragraph 6 Waiver, there are still steps the WTO can take to improve the process and ensure that the underlying goal of access to medication is achieved.

### III: HOW TO SOLVE THE PROBLEM WITH A THREE PART PLAN: REAL PROTECTION, MODEL LEGISLATION, AND GLOBAL COMPENSATION

#### *A. Real Protection Against Sanctions and Reprisal*

Despite the WTO attempts to assure developing countries that using compulsory licensing to address public health crises such as HIV/AIDS is acceptable, developing countries still fear reprisal.<sup>118</sup> A specific commitment by developed countries like the United States should be issued so that those countries facing health crises can feel safe in their ability to use the TRIPS compulsory licensing schemes. Unfortunately, a specific commitment in the form of a public announcement - such as what occurred when the United States withdrew litigation against Brazil - has not been effective. More effective means should involve the threat of sanctions from other international organizations, such as the United Nations or even from the WTO, towards countries who engage in trade reprisal. This may prove difficult because it is hard to determine when trade reprisals are a response to compulsory licensing. If sanctions and pressure are placed on powerful countries, perhaps this would be enough to deter countries from trade reprisal and assure developing countries that they need not worry. Fear from developing countries will also begin to dissipate over time as more countries use the TRIPS waiver.

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While we are extremely pleased to be able to make this important and historic contribution, there is a reason no other company has tried to provide medicines under this regime. It is too complex and has to be repeated for every request that comes in from a country. For Canada to truly be able to provide help, the regime must be changed. Apo-TriAvir will save lives the moment the patients have access to it but it is now up to the federal government to fix CAMR.

Apotex Press Release, *supra* note 113; *see also* Cotter, *supra* note 99, at 186-88.

118. *See* t'Hoën, *supra* note 81, at 33; *see also* TRIPS Report, *supra* note 75, at 439.

*B. Model Legislation and Benefits for Developed Countries Capable of Producing Medication*

Lack of cooperation of exporting countries remains a major obstacle. Since 2003, only four developed countries have notified the WTO that they have implemented the waivers and will allow for the production of medication exclusively for export under a compulsory license.<sup>119</sup> Because Article 31(f) of TRIPS, prior to the Paragraph 6 Waiver, specified that compulsory licenses were to be issued “predominantly” for the domestic market, most national laws did not allow compulsory licensing for the supply of export markets.<sup>120</sup> Furthermore, as Carlos Correa notes, “[i]mplementation of [Doha] through appropriate amendments to national laws, as necessary, should not be regarded as a matter of mere convenience or political choice. The Decision creates international obligations that must be complied with in good faith.”<sup>121</sup> Thus, all members of the WTO with manufacturing capabilities should make amendments to their current national law with respect to the ability to issue compulsory licenses for exporting purposes, even if they do not intend to export. However, as evidenced by the faulty legislation enacted in Canada, member states need assistance with this process.

To help members come into compliance, the WTO should propose model legislation that individual governments can adopt. The WTO is better equipped than individual member states to fully understand and incorporate the needs of all parties involved in the Paragraph 6 scheme.<sup>122</sup> Model legislation would make it easier for interested exporting countries to help developing countries obtain critically needed medication at low costs. Currently, no such guidelines exist.

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119. TRIPS Fact Sheet, *supra* note 18, at 8.

120. Carlos M. Correa, *TRIPS and Access to Drugs: Toward a Solution for Developing Countries without Manufacturing Capacity*, 17 EMORY INT’L L. REV. 389, 399 (2003).

121. Correa: Implementation, *supra* note 8, at 8.

122. See generally Cohen-Kohler, Esmail, & Cosio, *supra* note 107 (discussing the continuing problems of access to medication from the viewpoint of various stakeholders with respect to CAMR).

*C. Protecting Innovation: A WTO Fund to Compensate Pharmaceutical Patent Holders*

A further disincentive for developed countries with manufacturing capabilities to export generic medications is that they are left with the burden of compensating the patent holder.<sup>123</sup> Article 31(h) of the TRIPS agreement requires that adequate remuneration be paid to the patent holder taking into account the economic value of the authorization to use the patent.<sup>124</sup> The Paragraph 6 Waiver states that the *exporting* country must pay remuneration or compensation to the patent holder; however, the agreement defines neither “adequate remuneration” nor “economic value.”<sup>125</sup> Exact amounts and methods for determining remuneration vary but presumably a fair system would compensate patent holders for the loss of their patent rights while maintaining the system’s cost effectiveness for countries issuing the compulsory licenses.<sup>126</sup>

One of the main reasons why a developed country wants to become an eligible exporting country is the potential economic benefits. A generic company in an exporting country creates revenue, jobs, and generally benefits the economy. Requiring the exporting country to compensate the patent holder is illogical because any benefits a country might gain by having its own generic company be able to produce certain medications for the purpose of exporting could be outweighed by the amount the country has to compensate the patent holder.<sup>127</sup> Likewise, it is also illogical for the importing country to be responsible for remuneration to the patent holder because this would outweigh the benefits of importing cheap generic medications under compulsory licensing. It would be unacceptable to allow the patent holder who loses sole rights to ownership of the patent to be uncompensated. This could have the stifling effect so many pharmaceutical companies claim. The WTO should create a fund to solve this problem.

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123. See TRIPS Fact Sheet, *supra* note 18, at 6.

124. Daniel R. Cahoy, *Confronting Myths and Myopia on the Road from Doha*, 42 GA. L.R. 131, 150 (2007); see TRIPS Agreement, *supra* note 17, art. 31(h).

125. Cahoy, *supra* note 124, at 150.

126. See generally *id.* at 152-53.

127. See generally *id.* at 148-53 (discussing the importance of remuneration and the underlying compensation problems at the heart of the Doha Agreement and 2003 Waiver). For a good discussion of the importance of remuneration and the underlying compensation problems at the heart of the Doha Agreement and 2003 Waiver see generally Cahoy, *supra* note 124, at 131.

Developed member countries should generate money for the fund. This action is justified under the WTO's goals of promoting harmony and creating innovation because this will allow developing countries to "catch up" faster and allow them to come into compliance with other provisions of WTO at a faster rate.

In 2007, the estimated annual funding devoted to AIDS and available for spending on low and middle income countries was ten billion dollars.<sup>128</sup> The Global Fund to Fight AIDS, Tuberculosis and Malaria is one of the largest contributors of funding.<sup>129</sup> By the end of December 2005, the Global Fund had received 4.7 billion dollars in contributions. Pledges will bring the cumulative total to 8.6 billion dollars by the end of 2008.<sup>130</sup> By December 2005, the Global Fund had put 384,000 people on antiretroviral therapy for HIV.<sup>131</sup> These incredible numbers show how much money is being used to help fund AIDS prevention and treatment. This money is given directly to governments of developing countries. If the WTO creates the proposed fund for the sole purpose of compensating pharmaceutical patent holders, more people could be treated.

Money from any such fund must go directly to the pharmaceutical patent holder. The fund will allow the exporting country to produce generic medications at an even lower cost than they might have charged originally because remuneration costs will not be a factor. The ability to charge lower costs for the production of generic medication while still making a profit would allow importing countries the ability to purchase a larger quantity of medication for the same price and thus the funding they receive from humanitarian groups such as the Global Fund will go further.

#### CONCLUSION

Thousands of people die from AIDS every day in countries that do not have the resources to manufacture cheap generic medication. While the WTO has approved the use of compulsory licensing to manufacture and to import generic medications, only one country has attempted to use the Paragraph 6 Waiver in the five years since the WTO's announcement. It is clear that WTO's current attempt at "striking a balance between the long term social objective of providing incentives for future inventions and

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128. 2006 UNAIDS REPORT, *supra* note 5, at 224 (follow "10 Financing the response to AIDS" hyperlink).

129. *Id.* at 240.

130. *Id.* at 241.

131. *Id.*



creation, and the short term objective of allowing people to use existing inventions” is weighted in favor of the long term objective of protecting innovation and to the detriment of those people who desperately need existing inventions.<sup>132</sup>

This is a problem that can be solved. First, by ensuring that developing countries do not fear reprisal or sanctions, they will be encouraged to either seek out developed countries with manufacturing abilities or issue compulsory licenses to manufacture medications themselves. Next, the WTO can help potential exporting countries by creating model legislation that will allow them to issue compulsory licenses for the sole purpose of exporting cheap generic medications so that countries do not feel that the task of creating such legislation is not worth the trouble it could potentially cause. Finally, a “TRIPS” fund should be created that could be used for remuneration of patent holders to ensure that the pharmaceutical industry is adequately compensated, and to ensure the WTO’s broader long-term goal of providing incentives for future inventors. All WTO member states and humanitarian organizations should contribute to this fund. If all of these goals are accomplished a true balance can be found between the long term benefits of protecting innovation and the short term benefits to be gained from new invention. Most importantly, millions of people suffering from AIDS will gain access to life saving medication.

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132. TRIPS Fact Sheet, *supra* note 18, at 1.