

3-1-2007

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### Recommended Citation

Karen Godnick, *Profitability versus the Public Interest: Is International Patent Law Hindering Third World Countries Access to HIV/AIDS Medications*, 10 RICH. J.L. & PUB. INT. 86 (2007).

Available at: <http://scholarship.richmond.edu/pilr/vol10/iss2/5>

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**PROFITABILITY VERSUS THE PUBLIC  
INTEREST: IS INTERNATIONAL PATENT LAW  
HINDERING THIRD WORLD COUNTRIES  
ACCESS TO HIV/AIDS MEDICATIONS?**

BY KAREN GODNICK\*

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## INTRODUCTION

Patent law has been described as “the Price of Life”.<sup>1</sup> This can most strikingly be seen when applied to developing countries’ access to HIV/AIDS drugs. Since the explosion of the HIV/AIDS epidemic in the 1980’s,<sup>2</sup> the disease referred to as the “Modern Black Death”<sup>3</sup> has devastated large parts of populations in several developing countries.<sup>4</sup> Because of several reasons, including strong patent protection advocated and implemented by developed countries through TRIPS and the resulting high price of medicines, these developing countries cannot afford the price of the HIV/AIDS drugs. The majority of medicines used to treat this disease are patented.<sup>5</sup> As of 2005 there are an estimated 38.6 million people living with HIV/AIDS.<sup>6</sup> In developing and transnational countries 6.8 million people are in immediate need of HIV/AIDS drugs. Of these, only 1.65 million are actually receiving them.<sup>7</sup> Eliminating patent laws will not solve this global epidemic. Allowing compulsory licensing in developing countries dealing with large number of affected persons, and strengthening parallel importation laws, can help. However, the larger issue is not simply how to treat the disease, but how to contain it and prevent its spread.

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<sup>1</sup> Erika Mullenbach, *The Influence of Disease on the Evolution of U.S. Patent Law and Policy Towards Foreign Patent Laws in the Late Twentieth to Early Twenty-First Century*, 7 TUL. J. TECH. & INTELL. PROP. 227, 228 (Spring 2005) (quoting Lynn Woods, *Government AIDS Effects Target Drug Makers, Pharmaceuticals Act to Stop Backlash Against Their IP Rights*, BUS. WITHOUT BORDERS, Aug. 18, 2000, at col. 1).

<sup>2</sup> Avert.org, *The History of AIDS: 1981 – 1986*, [http://www.avert.org/his81\\_86.htm](http://www.avert.org/his81_86.htm).

<sup>3</sup> Mullenbach, *supra* note 1, at 235 (citing David P. Fidler, *Racism or Realpolitik? U.S. Foreign Policy and the HIV/AIDS Catastrophe in Sub-Saharan Africa*, 7 J. GENDER RACE & JUST. 97, 100 (2003)).

<sup>4</sup> *Id.*

<sup>5</sup> Christopher T. Nidel, *Public Health, Hypocrisy, and Brown-Skinned People*, 59 FOOD & DRUG L.J. 355 (2004).

<sup>6</sup> AVERT.ORG, *Worldwide HIV & AIDS Statistics*, available at [www.avert.org/worldstats.htm](http://www.avert.org/worldstats.htm) (last visited Oct. 22, 2006).

<sup>7</sup> *Id.*

This paper will examine the history of AIDS and international patent law, the ways in which they intertwine and overlap, the international patent law agreements that affect HIV/AIDS drugs distribution (specifically TRIPS §31, Doha and the 2003 Declaration, and the 2005 Amendment to TRIPS), compulsory licensing and other options available to fight the HIV/AIDS epidemic, and finally analyze public and private sector partnerships.

### I. AN OVERVIEW OF THE HIV/AIDS EPIDEMIC

Of the almost 40 million people suffering from HIV and AIDS worldwide, 95 % of them live in developing countries.<sup>8</sup> The disease has killed more than 20 million people around the world, is the leading cause of death in Africa, and is the fourth leading cause of death worldwide.<sup>9</sup> Three million people die of AIDS every single year.<sup>10</sup> There are 5 million infections annually, which comes out to one person every six seconds.<sup>11</sup> 1,900 children under the age of 15 are infected every day. Only 15-20,000 of these children are being treated, while 600,000 are in need of urgent medical help.<sup>12</sup> In Africa, 12 million children have lost a parent to AIDS.<sup>13</sup>

Despite the huge number of affected people, the average country in Africa only spends about \$10 a year per person on health care. Yet a years supply of medicine might cost as much as \$12,000.<sup>14</sup> While there is no cure for AIDS, there are several effective

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<sup>8</sup> The Global Fund, Fighting AIDS, *available at* <http://www.theglobalfund.org/en/about/aids>.

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> UNITAID, A Global State of Emergency, *available at* <http://www.unitaid.eu/EN-Un-etat-d-urgence-mondial.html>.

<sup>13</sup> *Id.*

<sup>14</sup> Theodore C. Bailey, Innovation and Access: The Role of Compulsory Licensing in the Development and Distribution of HIV/AIDS Drugs, 2001 U. ILL. J.L. TECH. & POL'Y 193 (Spring 2001) (citing Gumisai Mutume, Trade: Drug Companies Ease Up on South Africa, INTER PRESS SERVICE, Sept. 12, 1999, *available at* 1999 WL 2737954).

treatments that can prolong the length and quality of life for those affected.<sup>15</sup> But because most of these medicines are patented, lack of competition creates strong barriers to accessing these medicines.<sup>16</sup> It has been estimated that a total of \$7-10 billion a year is needed to adequately address the HIV/AIDS epidemic.<sup>17</sup>

In addition to the huge lack of funding in developing countries, there are several other issues regarding treatment that need to be addressed. Should treatment become available to those in need, a constant supply of the same drug is essential in preventing resistance, and thus to not spread the disease any further. Most HIV and AIDS drugs work by attaching to enzymes the virus needs to mutate. However, the virus quickly mutates and becomes resistant within weeks. Because of this, most treatments focus on the “combination therapy” approach, which tries to “overwhelm” HIV the disease with two or three drugs. However, even this approach eventually loses its effectiveness.<sup>18</sup> Should the drugs fail, or if they are not taken properly, the virus will mutate. This causes the drugs to become less effective, until they finally stop working.<sup>19</sup> Further, medicines need to be taken on a very specific regimen, at specific times of the day and with or without food.<sup>20</sup> Once a person begins an anti-AIDS treatment, the drugs need to be taken regularly for the rest of their life.<sup>21</sup>

While patents on HIV/AIDS medication will eventually expire, counting on this to occur in order to secure lower prices for drugs is an ill-conceived notion. The problem is

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<sup>15</sup> Bailey, *supra* note 14.

<sup>16</sup> Nidel, *supra* note 5.

<sup>17</sup> The Global Fund, *supra* note 8.

<sup>18</sup> New Protease Inhibitor Could Thwart AIDS Resistance To Current Drugs, SCIENCE DAILY.COM, February 4, 1999, available at <http://www.sciencedaily.com/releases/1999/02/990204082547.htm>.

<sup>19</sup> AIDS Meds.com, Things You Should Know Before Starting Treatment, <http://www.aidsmeds.com/lessons/StartHere5.htm> (last visited Oct. 22, 2006).

<sup>20</sup> *Id.*

<sup>21</sup> UNAIDS, 2006 Report on the Global AIDS Epidemic, Ch. 7, Treatment and Care, available at [http://www.unaids.org/en/HIV\\_data/2006GlobalReport/default.asp](http://www.unaids.org/en/HIV_data/2006GlobalReport/default.asp).

that “patent expiration is, at best, a reasonable guess since there are many strategies for extending patents and many regulatory incentives for granting extended periods of market exclusivity.”<sup>22</sup> There are several reasons drugs often do not come off patent when projected. One, some drugs have several different patents. Two, manufacturers can extend their patents by obtaining new ones. Three, even without new patents, it is still possible to gain exclusive rights for longer periods of time. Four, often times manufacturers develop newer medications with fewer side effects and greater success rates by the time their old patents expire.<sup>23</sup>

It could be argued that older medicines could still be effective, and thus using the generic versions of these drugs once they come off patent would be a viable solution. The problem with this argument is that with HIV and AIDS treatment there is a great need for continuity. Resistance to drugs is a key concern with older drugs because when there is a wide range of medicines available to the public more mutated strands develop. Should large numbers of mutated strands be created, old nor new medicine is going to stop its spread. Further, if a person develops a resistance to a drug it is likely they will become resistant to the whole class of drugs. Therefore access to different, and often patented drugs, again becomes crucial for survival.<sup>24</sup>

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<sup>22</sup> C Daniel Mullins, Francis Palumbo & Bruce Stuart, *Projections of Drug Approvals, Patent Expiration and Generic Entry to 2004*, Business Briefing: Pharmagenetics 2005.

<sup>23</sup> *Id.*

<sup>24</sup> Kamala Sarup, Expensive H.I.V. Drugs Further Instability in South Asia, *worldpress.org* (July 7, 2005), <http://www.worldpress.org/Asia/2112.cfm>

## II. THE RISE AND INTERTWINEMENT OF INTELLECTUAL PROPERTY RIGHTS AND THE HIV/AIDS EPIDEMIC

### a. A QUICK HISTORY OF INTERNATIONAL PATENT RIGHTS

Starting in the 1980's, the global economy experienced a substantial rise in the importance of intellectual property rights and their relation to technology.<sup>25</sup> This led to the drafting, and implementing in 1995, of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. TRIPS required all World Trade Organization (WTO) members to enact legislation establishing a minimum level of intellectual property protection and harmonization of laws.<sup>26</sup> Under TRIPS, patents may be granted as long as the invention is new, substantially different from previous inventions, and can be industrially exploited.<sup>27</sup> It is argued that patent monopolies “encourage[] innovation and research.”<sup>28</sup> While this may result in higher prices for consumers, the development of new products and production processes is deemed to be a greater benefit to society.<sup>29</sup>

The goal of TRIPS, as set out by the WTO Ministry of Foreign Affairs, is “to balance the long-term goal of stimulating research and the development of new products with the short-term goal of ensuring market access on reasonable terms for products and production processes that have already been patented.”<sup>30</sup> Further, “[t]he WTO has recognized that, for the poorest nations, the costs of protecting intellectual property rights can outweigh the benefits.”<sup>31</sup>

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<sup>25</sup> Thomas A. Haag, TRIPS Since Doha: How Far Will the WTO Go Towards Modifying the Terms for Compulsory Licensing?, 84 J. PAT. & TRADEMARK OFF. SOC'Y 945 (December 2002).

<sup>26</sup> See generally TRIPS, Annex 1C.

<sup>27</sup> *Id.* at §5, art. 27(1).

<sup>28</sup> WTO Ministry of Foreign Affairs, <http://www.dep.no/ud/english/topics/trade/wto/doha/032121-120019/dok-bn.html>.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

Those in favor of strong intellectual property rights argue that without sufficient protection, pharmaceutical companies are reluctant to invest in developing countries. Proponents also argue that protecting intellectual property rights promotes research and development.<sup>32</sup> Creating drugs is extremely expensive – the cost of development from the start of research to market launch was estimated to be \$802 million as of 2001.<sup>33</sup> A new drug can also fail at any time while in development, usually resulting in a total loss of the company's investment.<sup>34</sup> The pharmaceutical industry stresses that only one in every four thousand drugs researched and developed is granted government approval and can thus be marketed.<sup>35</sup> Because of their huge investments, pharmaceutical companies are eager to reap all the financial benefits of their creations. These companies have successfully patented many of their developed drugs, and have made huge sales and profits from them.<sup>36</sup> The question thus becomes how to balance the interests of pharmaceutical companies against the needs of developing countries.

#### **b. A QUICK HISTORY OF HIV/AIDS AND ITS TREATMENT**

Before the 1980's not much is known about the history of AIDS. The origin of the disease is a mystery, but by 1980 HIV had spread to at least five continents (North America, South America, Europe, Africa, and Australia).<sup>37</sup> In June of 1981 the Center for Disease Control published the first report on this previously unknown virus.<sup>38</sup> While this

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<sup>32</sup> *Id.*

<sup>33</sup> Press Release, Tufts Center for the Study of Drug Development, Pegs Cost of a New Prescription Medicine at \$802 million (Nov. 30, 2001), *available at* <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6> (last visited Oct. 23, 2006).

<sup>34</sup> Lisa C. Pavento, Jamie L. Greene & John K. McDonald, *International Patent Protection for HIV-Related Therapies: Patent Attorneys' Perspective*, 17 EMORY INT'L L. REV. 919 (Summer 2003).

<sup>35</sup> Bailey, *supra* note 14.

<sup>36</sup> *Id.*

<sup>37</sup> J.M. Mann, *AIDS: A worldwide Pandemic*, CURRENT TOPICS IN AIDS, vol. 2 (edited by M.S. Gottlieb, D.J. Jeffries, D. Mildvan, A. J. Pinching, T.C. Quinn, John Wiley & Sons) (1989).

<sup>38</sup> Avert.org, The History of AIDS: 1981 – 1986, [http://www.avert.org/his81\\_86.htm](http://www.avert.org/his81_86.htm).



report is often referred to as the “beginning” of AIDS, it is more accurately described as the beginning of awareness.<sup>39</sup> In November of 1983 the first meeting of the world’s countries was held to discuss the global AIDS crisis.<sup>40</sup> At this time the World Health Organization (WHO) reported that AIDS was present in the United States, Canada, fifteen European countries, Haiti, Zaire, seven Latin American countries, Australia and Japan.<sup>41</sup>

Once the reality of the nature and extent of the HIV/AIDS virus set in, the patent race was on. Drugs used to treat the disease have been, and still are, the focus of intense research and development programs in the pharmaceutical industry.<sup>42</sup> In 1991, for example, sixty-four firms were working on developing over eighty different drugs, spending over \$19 million a year.<sup>43</sup>

### c. THE COST TO SOCIETY

The “age old debate questioning the fundamental societal value of intellectual property rights” has arisen in the context of issuing compulsory licenses to developing countries in order for them to supply their AIDS stricken populations with generic drugs.<sup>44</sup> This problem is particularly troublesome considering that, while fewer than five percent of medicines on the WTO Model List of Essential Medicines<sup>45</sup> are patented,

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<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> Bailey, *supra* note 14.

<sup>43</sup> *Id.*

<sup>44</sup> Haag, *supra* note 25.

<sup>45</sup> Duncan Matthews, WTO Decision on Implementation of Paragraph 6 of The Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?, 7 J. INT’L ECON. L. 73 (March 2004) (citing World Health Organization Intellectual Property Rights, Innovation and Public Health: Report by the Secretariat (Geneva: WHO, 56th World Health Assembly Provisional Agenda Item 14.9, A56/17, 12 May 2003)).

many new drugs designed to combat the HIV/AIDS virus are patented.<sup>46</sup> It is argued that “the premium prices of patented drugs make them unobtainable for the sickest and weakest in the developing world and that these prices are unjustifiably expensive in view of the shockingly high rates of HIV infection.”<sup>47</sup>

### **III. TRIPS: AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS**

As mentioned previously, the WTO responded to the need for global intellectual property rights by implementing TRIPS in 1995. One of the main considerations of this Agreement was the special needs of developing countries – especially in regards to the health issues devastating their populations.

#### **a. BACKGROUND**

TRIPS came into effect on January 1, 1995.<sup>48</sup> It was revolutionary in that it not only harmonized patent law, but connected it with international trade.<sup>49</sup> TRIPS is a minimum standards agreement, allowing Members to mandate higher standards of protection if they so desire. Member states are also free to determine the appropriate implementation methods for the Agreement within their national laws and practice.<sup>50</sup> TRIPS sought to promote increased research and development through a worldwide patent protection system.<sup>51</sup> In spite of these goals, TRIPS specifically recognized “the special needs of the least-developed country Members in respect of maximum flexibility

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<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> *See generally* TRIPS

<sup>49</sup> Mullenbach, *supra* note 1, at 228.

<sup>50</sup> *See generally* TRIPS

<sup>51</sup> Jessica J. Fayerman, Comment, The Spirit of TRIPS and the Importation of Medicines Made Under Compulsory License After the August 2003 TRIPS Council Agreement, 25 *NW. J. INT’L L. & BUS.* 257, 267 (Fall 2004).

in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.”<sup>52</sup>

#### **b. ARTICLE 27: PATENTABLE SUBJECT MATTER**

Article 27 is important for two reasons. One, it expressly recognizes the conflict between intellectual property protection and public health in §27(2) by stating that:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.<sup>53</sup>

Two, while it contains an exception for “diagnostic, therapeutic and surgical methods for the treatment of humans and animals”<sup>54</sup> to promote free use of new medical treatments, it does not allow for the refusal to patent pharmaceutical drugs.<sup>55</sup> This seeming dichotomy between the two sections of Article 27 is resolved somewhat in Article 31.

#### **c. ARTICLE 31: OTHER USE WITHOUT AUTHORIZATION OF THE RIGHT HOLDER**

Article 31 is the most important provision of TRIPS concerning developing countries and their fight for access to affordable pharmaceuticals. This is because it allows for compulsory licensing under certain circumstances. It states that the requirement of a patent “may be waived by a Member in the case of a national emergency

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<sup>52</sup> TRIPS, Annex IC.

<sup>53</sup> TRIPS, 27(2)

<sup>54</sup> TRIPS 27(3)(a)

<sup>55</sup> John A. Harrelson, *TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion*, 7-SPG Widener L. Symp. J. 175, 180 (2001) (citing George K. Foster, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and its Aftermath*, 3 UCLA J. INT’L L & FOR. AFF. 283, 283-84 (1998)).

or other circumstances of extreme urgency or in cases of public non-commercial use.”<sup>56</sup>

However, this is not blanket authority to allow compulsory licenses. The Article sets out a number of required conditions before and during the process of compulsory licensing.<sup>57</sup>

For example, “the scope and duration of such use shall be limited to the purpose for which it was authorized,”<sup>58</sup> “such use shall be non-exclusive,”<sup>59</sup> and “such use shall be non-assignable.”<sup>60</sup>

The problem with this provision is that it has the practical effect of preventing generic drug imports to countries without significant manufacturing industries.<sup>61</sup> It states “[a]ny such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.”<sup>62</sup> Few developing countries meet the level of production needed to produce significant amounts of generic drugs. Thus the only real option for these countries is to import from other countries who have the ability to manufacture generic drugs.<sup>63</sup> However, should the country in need of drugs find another Member state to export generic versions, this act of exporting would be a violation of Section 31(f)’s requirement “predominantly for the supply of the domestic market.”<sup>64</sup> Therefore no Member country would realistically act as an exporter because it would then be in violation of TRIPS.

Article 31 was so riddled with complications that it was essentially useless. The lack of formal guidelines stipulating what qualifies as a “national health crisis” and what

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<sup>56</sup> TRIPS 31(b)

<sup>57</sup> TRIPS 31

<sup>58</sup> TRIPS 31(c)

<sup>59</sup> TRIPS 27(d)

<sup>60</sup> TRIPS 27(e)

<sup>61</sup> Matthews, *supra* note 45, at 78.

<sup>62</sup> TRIPS 27(f)

<sup>63</sup> Matthews, *supra* note 45, at 78.

<sup>64</sup> *Id.* at 82. See generally, TRIPS §31(f).

things could be considered an “other circumstance[] or extreme urgency”<sup>65</sup> opened it up to a wide variety of interpretations as to its key provisions. Thus not only did WTO countries disagree over the provisions’ applications and practical effects, but just using the system itself in most circumstances seems to be in violation of TRIPS itself.

#### **IV. THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH**

In November of 2001 the Ministerial Conference of the WTO gathered to discuss Article 31 of TRIPS, specifically provision (f) which required the supply be predominantly for the domestic market.<sup>66</sup> Before this Conference, developing countries expressed concern that pressure from Western countries prevented them from using the TRIPS flexibilities, especially the compulsory licensing provision.<sup>67</sup> While globally the AIDS epidemic was recognized as a serious health crisis, there was no consensus regarding the role patents and TRIPS should play. Those in favor of strong patent protection tried to suggest other issues were to blame for the epidemic, such as inadequate health care structures.<sup>68</sup> While this is admittedly part of the problem, public campaigns by Non-Governmental Organizations (NGO’s), the WHO, and the United Nations helped the Council, and the world, view access to essential medicines as a right to health.<sup>69</sup>

The Conference issued a November 14, 2001 Ministerial Declaration recognizing “the particular vulnerability of the least-developed countries and the special structural

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<sup>65</sup> See TRIPS, 27(b)

<sup>66</sup> Doha Declaration

<sup>67</sup> Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433, 492-93 (Spring 2006).

<sup>68</sup> *Id.* at 495 (citing Amir Attarran & Lee Gillespie-White, *Do Patents on Antiretrovirals Drugs Constrain Access to AIDS Treatment in Africa?*, 286 JAMA 1886, 1890-91 (2001)).

<sup>69</sup> *Id.* at 293 (citing Susan Sell, *Private Power, Public Law* 39-55 (2003)).

difficulties they face in the global economy.”<sup>70</sup> The Declaration stated the Counsel’s commitment “to addressing the marginalization of least-developed countries in international trade and to improving their effective participation in the multilateral trading system.”<sup>71</sup> Further, the Declaration stated:

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS . . .

. . .

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health . . .

5. Accordingly . . . we recognize that these flexibilities include:

. . .

b. *Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.*

c. *Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.*

d. *The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge*

6. *We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.*<sup>72</sup> (emphasis added)

The Doha Declaration thus implied no Member state was barred by TRIPS from doing taking any necessary action to address national health crises, of which AIDS was

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<sup>70</sup> Doha (3)

<sup>71</sup> Doha (3)

<sup>72</sup> Declaration on TRIPS

specifically mentioned.<sup>73</sup> The Declaration was met “with great enthusiasm and hailed as a leap toward correcting the social injustice allegedly resulting from the high price of patented drugs.”<sup>74</sup>

In paragraph six Doha recognized the inherent problem with Article 31(f) because Member countries without manufacturing capacities would not be able to use compulsory licenses. The Ministers directed the TRIPS Council to come up with a solution to this “Paragraph 6 Problem” by the end of 2002.<sup>75</sup> Thus started a series of negotiations. The Declaration was not legally binding, but simply an interpretive statement issued by the WTO.<sup>76</sup> However, it was regarded as persuasive authority in the event of a trade dispute.<sup>77</sup> This brought to the negotiation table two distinct groups. One was the pharmaceutical industry, who felt that Doha made too many concessions for developing countries and ultimately undermined the TRIPS policy rationale.<sup>78</sup> The other was world leaders and lobbying groups who thought Doha a good balance between international intellectual property rights and the needs of developing countries.<sup>79</sup>

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<sup>73</sup> Vishal Gupta, Note, *A Mathematical Approach to Benefit-Detriment Analysis as a Solution to Compulsory Licensing of Pharmaceuticals Under the TRIPS Agreement*, 13 CARDOZO J. INT’L & COMP. L. 631, 642 (Fall 2005).

<sup>74</sup> Haag, *supra* note 25, at 952.

<sup>75</sup> *Id.* at 951-52.

<sup>76</sup> See Understanding the WTO: The Agreements: Intellectual Property: Protection and Enforcement, at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm).

<sup>77</sup> *Id.*

<sup>78</sup> Fayerman, *supra* note 51 (citing Peter N. Fowler & Alice T. Zalik, *A U.S. Government Perspective Concerning the Agreement on the Trade-Related Aspects on Intellectual Property: Past, Present, and Near Future*, 17 ST. JOHN’S J. LEGAL COMMENT. 401 (2003)).

<sup>79</sup> *Id.* at 262 (citing Sara DeForge, Comment, *A Tough Pill to Swallow: The United States’ Passive Efforts in Curtailing Intellectual Property Rights in Favor of Humanity*, 4 LOY. L. & TECH. ANN. 75, 79 (2004)).

**V. IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION: THE  
DECISION OF THE WTO GENERAL COUNCIL ON AUGUST 30, 2003**

On August 30, 2003, after several rounds of negotiations, the WTO finally approved a waiver to Article 31(f) of the TRIPS Agreement.<sup>80</sup> This waiver allowed for pharmaceuticals manufactured via compulsory licenses to be exported to developing countries lacking sufficient production capabilities.<sup>81</sup> Thus, Member states were allowed to effectively and legally export generic medicines to those countries unable to make the drugs themselves.<sup>82</sup> The waiver conditioned compulsory licenses as long as “used in good faith to protect the public . . . not [as] instrument to pursue industrial or commercial policy objectives.”<sup>83</sup>

The waiver included all patented products or products manufactured by a patented process needed for public health problems stated in paragraph 1 of Doha.<sup>84</sup> Therefore a Member state could, as a result of a national emergency or other circumstance of extreme urgency, legally use the compulsory licensing system to produce generic versions of HIV/AIDS drugs.<sup>85</sup> One area of concern with compulsory licenses is parallel importing. This is when a product is placed in the market in one country and is subsequently exported to a second country without the permission of the right holder, usually at a higher price than originally bought for. To safeguard against this the waiver required that generic compulsory licensed drugs be a different shape and color than patented drugs.

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<sup>80</sup> 2003 WTO General Council Implementation of Paragraph Six of the Doha Declaration

<sup>81</sup> *Id.*

<sup>82</sup> Ministry of Foreign Affairs, Trade Related Aspects of Intellectual Property Rights, *available at* <http://www.dep.no/ud/english/topics/trade/wto/doha/032121-120019/dok-bn.html> (last updated July 14, 2006).

<sup>83</sup> Mullenbach, *supra* note 1, at 245 (quoting *WTO Votes to Bypass Patents on Medicines; Cheap Generics Go to Poor Nations*, WASH. POST, Aug. 31, 2003, at A16).

<sup>84</sup> Matthews, *supra* note 45, at 95.

<sup>85</sup> *Id.*



Also, procedures were put in place for the TRIPS Council to periodically review licensing arrangements to check for abuse.<sup>86</sup>

Procedurally, the Decision is quite complicated. In order to begin a compulsory licensing scheme, the importing country must attempt to obtain a voluntary license from the patent holder on reasonable commercial grounds for a reasonable period.<sup>87</sup> Should this fail, the importing country must access its generic industry's capacity to produce such drugs locally. If that is found insufficient, the country must provide the WTO with a detailed description of why this is so.<sup>88</sup> Then the importing country must contact an exporting country, which must in turn obtain a voluntary license. Should that not be possible, the exporting country must receive a compulsory license from its government on a single-country basis, with due compensation.<sup>89</sup>

As beneficial as the Declaration appears to developing countries, there are several issues which make actual implementation quite difficult. As mentioned previously, the importing country must comply with strict and complicated procedural requirements which can be quite burdensome to an already overwhelmed developing country. Further, there was still staunch opposition to this Declaration by developed countries.<sup>90</sup> While any country in need could act as an importer, a list of developed Member countries have pledged never to use the system, and did so at the signing of the Declaration.<sup>91</sup> Another

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<sup>86</sup> *Id.* at 96.

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> *See generally* Implementation of Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health

<sup>90</sup> Matthews, *supra* note 45, at 95.

<sup>91</sup> These states include: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom, and the United States.

list of Members<sup>92</sup> stated that if they were to use the system, it would only be in a situation of national emergency or other urgent situation – thus implying that other Members might use the system more liberally.<sup>93</sup> In addition, recent applicants to the EU, including the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia, have all agreed to act as importers only in situations of national emergency or other extreme urgency situations. Once these countries become official members of the EU they have pledged to never act as importers.<sup>94</sup>

One could argue that the fact that certain countries pledged not to act as importers does not pose a real problem because the countries did not say that they would never act as exporters. However, importing is the essential component of compulsory licensing. The system is based on the premise that a country has a large enough problem to justify importing medicines from other countries. Exporting is just the means by which this is accomplished. Thus, by specifically pledging not to act as importers, the countries are essentially pledging to never act as exporters either. If they fundamentally disagree with the proposition that there will ever be an emergency so great that a country should look to other countries to import drugs from, they are certainly not going to act as an exporter for another country to do just that.

Another problem with this waiver is the cost of procedural requirements (specifically altering packaging, pill size and color). This added financial burden may create negative effects regarding the availability of essential medicines in developing countries. These provisions may reduce incentives for drug companies to make generic

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<sup>92</sup> These states include: Hong Kong, China, Israel, Kuwait, China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and the United Arab Emirates.

<sup>93</sup> Matthews, *supra* note 45, at 95.

<sup>94</sup> *Id.* at 96.

drugs because it is less cost-effective.<sup>95</sup> Further, all the regulations impose heavy administrative burdens on countries which have several other pressing problems. In addition, the Council's decision to periodically review compulsory licenses could further result in lengthy delays and costs.<sup>96</sup>

## VI. THE DECEMBER 6, 2005 AMENDMENT TO THE TRIPS AGREEMENT

On December 6, 2005 the WTO Council met again to discuss the issue brought about by the Doha Declaration – Article 31(f) of the TRIPS Agreement. In the first time a core WTO agreement has been amended, the Council made permanent the waiver of Article 31(f) from August 30, 2003. Therefore any Member country may now legally export pharmaceutical products made under a compulsory license, making it easier for developing countries to access essential medicines. This Amendment will be formally built into the TRIPS Agreement once 2/3 of Member countries ratify the change.<sup>97</sup> Members have until December 1, 2007, and the waiver will remain in effect until then.<sup>98</sup> Director-General Pascal Lamy said, “[t]he agreement to amend the TRIPS provisions confirms once again that members are determined to ensure the WTO’s trading system contributes to humanitarian and development goals . . . .”<sup>99</sup>

This decision came a week after WTO members agreed to allow least-developed countries a longer transition period to provide protection for intellectual property rights in general by extending the deadline to July 1, 2013.<sup>100</sup> Yet, even with all the protections and exceptions the WTO is making for least-developed countries, there is no guarantee

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<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> WTO Press Release, Members OK Amendment to Make Health Flexibility Permanent, Dec. 6, 2005, available at [http://www.wto.org/English/news\\_e/pres05\\_e/pr426\\_e.htm](http://www.wto.org/English/news_e/pres05_e/pr426_e.htm).

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

<sup>100</sup> *Id.*

that these countries will actually be able to obtain the patented medicines. As with the 2003 exception, the 2005 Amendment contains lists of countries who pledge not to ever act as importers, and even more countries pledging only to do so in cases of extreme national emergency.<sup>101</sup>

That pharmaceutical companies, and not those working towards allowing compulsory licensing such as Non-Governmental Organizations (NGO), were pleased with the amendment<sup>102</sup> says quite a bit. Médecins Sans Frontières (Medicine Without Borders), an NGO, disapproved of the decision because it was “based on a mechanism that has failed to prove it can increase access to medicines.” It further said that the original 2003 decision was “overly cumbersome and inefficient” because it is based on a “drug-by-drug, country-by-country decision-making process,” and in adopting it the WTO was “ignoring the day-to-day reality of drug production and procurement.”<sup>103</sup>

## VII. PHARMACEUTICAL COMPANIES AND THE ROLE OF US LOBBIES

WTO Members may, but are not required to, grant intellectual property protection in excess of what TRIPS requires.<sup>104</sup> As one of the most influential TRIPS Members, the United States has attempted several bilateral and multilateral treaties with countries to prevent them from granting compulsory licenses.<sup>105</sup> The US economy is moving from manufacturing to high-technology industries, and therefore protecting intellectual property rights is an important concern.<sup>106</sup> The pharmaceutical industry constitutes a large

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<sup>101</sup> *Id.*

<sup>102</sup> Tove Iren S. Gerhardsen, TRIPS Health Amendment Evokes Harsh NGO Reaction, Industry Caution, <http://www.ip-watch.org/weblog/index.php?p=169&res=1024&print=0> (Dec. 12, 2005)

<sup>103</sup> *Id.*

<sup>104</sup> See generally TRIPS

<sup>105</sup> Harrelson, *supra* note 55, at 183 (citing Robert Weissman, *In Focus: AIDS and Developing Countries: Democratizing Access to Essential Medicines*, at <http://www.foreignpolicy-infocus.org/briefs/vol4/v4n23aids.html> (Aug. 1999)).

<sup>106</sup> *Id.*

part of the industrial base of the US, and receives 40% of its income from the export of pharmaceuticals.<sup>107</sup> Further, almost half of all commercial pharmaceutical drugs developed in the last twenty years were developed in the US.<sup>108</sup>

Because of the above mentioned, the US often threatens trade sanctions upon countries who attempt to use compulsory licensing.<sup>109</sup> This is done under the authority of Section 301 Powers,<sup>110</sup> which allow the President to designate countries practicing unfair foreign trade practices that negatively affect US trade and investment in goods and services.<sup>111</sup> It “is the principal statutory authority under which the United States may impose trade sanctions against foreign countries that maintain acts, policies and practices that violate, or deny U.S. rights or benefits under, trade agreements, or are unjustifiable, unreasonable or discriminatory and burden or restrict U.S. commerce.”<sup>112</sup> Further, pharmaceutical companies often actively fund political campaigns and public action committees.<sup>113</sup> This gives them the ability to influence government policy in regards to their interests, specifically patent protection.<sup>114</sup>

One example of the use of §301 powers and the effect of pharmaceutical companies on US government policy is South Africa. In 1998 it’s government passed a law allowing the manufacture of generic HIV and AIDS drugs. This prompted the pharmaceutical industry to complain to the US government, which in turn put South Africa on the

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<sup>107</sup> *Id.* at 183.

<sup>108</sup> *Id.*

<sup>109</sup> *See, e.g.,* Harrelson, *supra* note 55, at 184.

<sup>110</sup> The Trade Act of 1974, 19 U.S.C. § 2411 (1974)

<sup>111</sup> Harrelson, *supra* note 55, at 184 n.90.

<sup>112</sup> Jean Heilman Grier, Section 301 of the 1974 Trade Act, at <http://www.osec.doc.gov/ogc/occic/301.html>.

<sup>113</sup> Harrelson, *supra* note 55, at 184-84.

<sup>114</sup> *Id.*

“Section 301” watch list, one step above trade sanctions.<sup>115</sup> However, developing country rights activists strongly protested, and in September of 1999 the US government responded to this pressure by taking South Africa off the list,<sup>116</sup> although they continue to monitor them closely for violations of TRIPS.<sup>117</sup> Pharmaceutical representatives made several strong statements against the actions of South Africa. For example, Jeffrey Trehwitt, a spokesman for the Pharmaceutical Research and Manufacturers of America, said the new South African laws “are attacks on legitimate patent protection, which is the lifeblood of this industry . . . . This could set a very, very bad precedent that could undermine legitimate patent protection around the world. The potential harm from these recent developments can be expected to reach into many other developing countries.”<sup>118</sup>

However, despite reluctance to be involved in the compulsory licensing debate, pharmaceutical companies are feeling pressured. Investors frequently urge companies to improve access to medicines in developing countries.<sup>119</sup> Investors want to put money in companies that balance sensitivity to the global AIDS epidemic and the enforcement of patent rights.<sup>120</sup> In response to these pressures some companies have donated drugs to developing countries for free.<sup>121</sup> Complicating matters, however, is the fact that many sub-Saharan countries in great need refuse to accept these medicines. Problems of political commitment, shortcomings in local healthcare systems, and problems with

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<sup>115</sup> *Id.* at 185 (citing Karl Vick, African AIDS Victims Losers of A Drug War: U.S. Policy Keeps Prices Prohibitive, Wash. Post, Dec. 4, 1999, at A1).

<sup>116</sup> *Id.* at 185 n. 93.

<sup>117</sup> *Id.* (citing Simon Barber, Stars and Stripes: To Whom are the Battle of Seattle NGOs Accountable?, Business Day (South Africa), Jan. 20, 2000, at 2, available at 2000 WL 7449976).

<sup>118</sup> *Id.* (citing Mike McKee, Tripping over TRIPS: A Court Battle in South Africa Over AIDS Drug Imports Could Threaten the Most Comprehensive Multilateral Trade Agreement on IP Rights to Date, The Recorder (San Francisco), Sept. 1999, at S20).

<sup>119</sup> Matthews, *supra* note 45, at 98.

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

distribution all cannot be solved by free medicine. This could be why countries are refusing to accept the free drugs.<sup>122</sup> This illustrates that simply giving medicine away is not the answer to the AIDS crisis. More needs to be more done within developing countries themselves. Should these countries feel as though once they accept the medicine they will also receive help to distribute it, medical and health services for their public to ensure the proper use of those medications, and other such help it seems logical to conclude they would accept the drugs.

**VIII. CURRENT OPTIONS: COMPULSORY LICENSING AFTER THE 2003 DOHA  
DECLARATION AND THE 2005 TRIPS AMENDMENT**

**a. THE GOOD VS. THE BAD ABOUT COMPULSORY LICENSES**

**b. THE GOOD**

There are several positive aspects to compulsory licenses and their ability to help combat the HIV/AIDS crisis in developing countries. For one, the price of most AIDS-related drugs could be reduced anywhere from 50-90% by generic drug versions manufactured via compulsory licenses.<sup>123</sup> The problem with this approach is that if the average country only spends about \$10 a person on health care, the lowered costs of these medicines still will not be low enough to be affordable.

Another positive aspect is that pharmaceutical companies could still make a profit, and thus continue to have incentives to research and develop new drugs. One 1999 UK study found that lowering prices on drugs to developing countries would seriously threaten profits or research and development of pharmaceutical companies. This is

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<sup>122</sup> *Id.*

<sup>123</sup> Someshwar Singh, Compulsory Licensing Good for US Public, Not Others, Third World Network, <http://www.twinside.org.sg/title/public-cn.htm> (citing Aids, Health, Trade and Compulsory Licensing, The Corner House (Eng.) (Oct. 1999)).

because lower prices equal increased sales from developing countries in addition to the steady stream of drugs needed in the developed countries where people can pay full price.<sup>124</sup> Also, the compulsory licensing program calls for patent owners to receive “adequate remuneration.”<sup>125</sup> Therefore, reasonable fees paid for compulsory licenses, combined with the amount of profit pharmaceutical companies are making already, should not cause significant financial harm. Generic versions further expand profit margins because they open markets in regions of the world that otherwise would not be considered.

However, the real value of compulsory licensing is not actual use, but instead threat of use.<sup>126</sup> Compulsory licenses are a tool for developing countries to use in negotiations with pharmaceutical companies to try and secure reasonable prices for HIV/AIDS medications.<sup>127</sup> Forcing pharmaceutical companies to face a choice between a compulsory license or making a deal, makes its threat a valid and useful bargaining chip for developing countries – many of whom who have nothing else on their side. In fact, “the mere threat of compulsory license[] may often be as, of not more, effective in achieving public policy objectives than actual use.”<sup>128</sup>

### **c. THE BAD**

However, compulsory licenses themselves cannot solve the whole problem. In reality, while compulsory licensing is an option for developing countries, it is rarely used. Many countries are hesitant to use the system out of respect for the international patent

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<sup>124</sup> *Id.*

<sup>125</sup> TRIPS, §31(h)

<sup>126</sup> Matthews, *supra* note 45, at 81.

<sup>127</sup> *Id.*

<sup>128</sup> *Id.* (citing Jerome H. Reichman & Catherine Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America (Case Study for UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development, 2002)*).



system, as well as to not anger Western companies who could provide their country with new investment and technology.<sup>129</sup> It has been said that the “velvet handcuffs of international custom and comity are [so] strong” they prevent any action by developing countries that could result in angering those who could possibly give money and resources.<sup>130</sup> Developing countries are starved for foreign capital, and their desire to attract foreign investment understandably makes them wary of applying for compulsory licenses. Pressure from the US and other countries and groups with great power often successfully prevent countries from using the compulsory licensing system.<sup>131</sup> While the 2005 TRIPS Amendment is a step in the right direction for these countries, the WTO needs to make a stronger stand on the issue and ensure developing countries are realistically able to use the system should they decide to without significant harm.

Second, as mentioned previously, HIV/AIDS drugs need to be taken on a very specific schedule, the interruption of which can cause mutations and resistance.<sup>132</sup> Therefore, the fact that compulsory licensing is not a long term solution renders it unrealistic as a viable solution. Further, licenses are granted for specific quantities and specific durations.<sup>133</sup> Because developing countries often have infrastructure problems, most of them simply do not have the internal systems in place to adequately navigate through all the red tape required in applying and receiving compulsory licenses. Even countries which have industries in place to produce generic drugs quite possibly do not have enough government organization to make application feasible.

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<sup>129</sup> Fayerman, *supra* note 51, at 265.

<sup>130</sup> *Id.* at 265-66 (citing Amir Attaran, *Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution*, 17 EMORY INT’L L. REV. 743, 750 (2003)).

<sup>131</sup> Matthews, *supra* note 45, at 95.

<sup>132</sup> AIDSmeds.com, Things You Should Know Before Starting Treatment, <http://www.aidsmeds.com/lessons/StartHere5.htm> (last visited Oct. 22, 2006).

<sup>133</sup> *See generally* TRIPS §31

Third, using compulsory licenses to combat public health issues may harm the potential of creating more innovative national policies. If a country without manufacturing capabilities can rely on other countries to import medicines from, there is no incentive for that country to create its own industry to sustain itself in the long-term. Further, because Western countries and industries strongly oppose compulsory licensing, using the system discourages direct foreign investment and the transfer of technology.<sup>134</sup> Without help from wealthier countries in the form of investment or technology developing countries will lack the ability to create their own manufacturing capabilities even if they wish to do so.

Fourth, the added costs of changing packaging, color, and size under TRIPS<sup>135</sup> might have a negative effect on developing countries. These costs could reduce incentives for generic-drug companies who might decide it is not cost-effective to make special pills just for compulsory licenses.<sup>136</sup> These companies may determine it is not economically viable to spend so much making special looking pills for a low profit.

Fifth, there are huge administrative costs and burdens associated with obtaining a compulsory license.<sup>137</sup> Should a country decide to use the system, it must contact and make specific arrangements with an exporting country for specific quantities of drugs and for specific time periods. Then the WTO must be notified, and administrative proceedings must be undertaken, to assure compliance with TRIPS. Further, the country

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<sup>134</sup> Matthews, *supra* note 45, at 80.

<sup>135</sup> See generally TRIPS §31

<sup>136</sup> Matthews, *supra* note 45, at 96.

<sup>137</sup> See generally TRIPS §31

will have to undergo WTO scrutiny to determine if it is, in fact, using the system properly. All of this results in long delays and is quite costly.<sup>138</sup>

Sixth, intellectual property protection benefits developing countries in a number of ways quite possibly more in line with the purposes of TRIPS than compulsory licensing. Pharmaceutical companies, who are consistently on the Fortune 500 List,<sup>139</sup> are businesses out to make money. They thus require strong incentives to research and develop new and improved medicines, especially for diseases that primarily affect individuals in developing countries.<sup>140</sup> It is argued that “the first step in combating a public health crisis is to ensure that the essential medicines exist before the pricing of such drugs becomes an issue.”<sup>141</sup>

#### **d. IS DOHA ENOUGH?**

Doha is important not only because it provided a basis for compulsory licensing, but because it was an “important catalyst” to alert the world of the magnitude of the HIV/AIDS epidemic.<sup>142</sup> It helped spur action by corporate donors and public-private initiatives, and increased donations to international organizations dealing with the HIV/AIDS epidemic.<sup>143</sup> Doha essentially helped shift attention away from perceived losses of the pharmaceutical industry and instead put a face on the global crisis for many.

Doha’s importance lies in the fact that it reaffirmed and emphasized that a line needed to be drawn between protecting intellectual property rights and social welfare. It

<sup>138</sup> Matthews, *supra* note 45, at 96.

<sup>139</sup> See Fortune 500, available at [http://money.cnn.com/magazines/fortune/fortune500/full\\_list/](http://money.cnn.com/magazines/fortune/fortune500/full_list/) (last visited Oct. 31, 2006).

<sup>140</sup> Fayerman, *supra* note 51, at 270.

<sup>141</sup> *Id.* (quoting Keith E. Maskus, *Ensuring Access to Essential Medicines: Some Economic Considerations*, 20 WIS. INT’L L.J. 563, 568 (2002)).

<sup>142</sup> Matthews, *supra* note 45, at 75.

<sup>143</sup> *Id.*

specifically stated that “the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.”<sup>144</sup> It spurred change in the national patent laws of many countries, including the US.<sup>145</sup> Basically, “least-developed and developing nations gained affirmations of the right to use compulsory licenses on independent terms, while developed nations received affirmations of the importance of patent protection.”<sup>146</sup>

However, there are several problems with Doha and its resulting Amendment to TRIPS. For one, the scope of diseases for which compulsory licensing is applicable has yet to be defined.<sup>147</sup> For example, there is nothing that says a national emergency has to be a result of an epidemic.<sup>148</sup> Further, each Member state is free to decide what qualifies as “public health crisis.”<sup>149</sup> Pharmaceutical companies and those in favor of strong intellectual rights protection are already wary of the compulsory licensing scheme; the lack of clear definitions in regards to when the system is legally applicable complicates the situation even more. In order to balance both social rights and patent protection under compulsory licensing, there needs to be clear definitions of what is applicable and what is not. If this is not done, inconsistent application of provisions will result, causing greater tension among those for and against the system.<sup>150</sup> It is simply unreasonable to believe a majority of countries will, in actual practice, support this system without clarification.

Compulsory licensing, whether clearly defined or not, poses the very real risk that pharmaceutical companies will decide it is economically infeasible to spend millions of

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<sup>144</sup> Doha, paragraph 4

<sup>145</sup> Mullenbach, *supra* note 1, at 242-43.

<sup>146</sup> Gupta, Note, *supra* note 73, at 633 (citing Arnaldo Lacayo, *Seeking a Balance: International Pharmaceutical Protection Public Health Crisis, and the Emerging Threat of Bio-Terrorism*, 33 U. MIAMI INTER-AM. L. REV. 295, 317 (2002)).

<sup>147</sup> Matthews, *supra* note 45.

<sup>148</sup> *See generally* TRIPS § 31

<sup>149</sup> Gupta, *supra* note 73, at 647.

<sup>150</sup> *Id.*

dollars in research and development on medicines for diseases and specific stands of diseases primarily affecting developing countries when they will get very little in return.<sup>151</sup> If the companies realize a strong probability exists that their patents will get compulsory licensed, and they will thus receive little if any compensation for their work, they might be inclined to not spend time on developing the drugs to begin with.<sup>152</sup> Further, individual countries are allowed complete discretion over restrictions and punishments applicable to parallel importation.<sup>153</sup> It is not unreasonable for this to make pharmaceutical companies wary that their lower cost or compulsory licensed drugs will be resold in different markets. This may cause companies to air on the side of caution when deciding how much time and money to invest in the development of HIV/AIDS drugs.

Finally, the United States and other key Western powers actively fight against Doha and compulsory licensing. Many countries have already signed agreements not to participate in the compulsory licensing system,<sup>154</sup> and there is no reason for this to change in the future. Developing countries may feel pressure to sign onto such agreements in order to avoid losing access to developed markets.<sup>155</sup> While the HIV/AIDS epidemic is in need of immediate attention in developing countries, their governments may decide that overall it would be better not to isolate themselves from Western markets.

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<sup>151</sup> TRIPS requires “adequate remuneration” (TRIPS Article 31bis). Matthews, *supra* note 45, at 105.

<sup>152</sup> Matthews, *supra* note 45, at 105.

<sup>153</sup> Gupta, *supra* note 73, at 649.

<sup>154</sup> Matthews, *supra* note 45, at 105.

<sup>155</sup> *Id.* at 105-106

## IX. CURRENT OPTIONS: OTHER SOLUTIONS

Unfortunately there is no easy answer to the global HIV/AIDS epidemic. As illustrated above, the compulsory licensing system is a step by the international community in the right direction. It has alerted the world to the very real issue of AIDS and for the need of an international movement to combat the problem. However it alone is simply not enough. There are too many ambiguities in the system, and too much opposition to the way it currently works. Therefore, other solutions need to be considered.

### a. PARALLEL IMPORTATION AND TIERED DRUG PRICING

An alternative way to provide HIV/AIDS drugs to developing countries without going through the compulsory licensing system is simply for pharmaceutical companies to provide cheaper drugs for those countries in need of them.<sup>156</sup> Tiered drug pricing is a system in which drug companies charge different prices in different markets, thus allowing those less-able to pay to have a lower cost. This ultimately means that “pharmaceutical companies can maintain their price and profit structures in wealthy countries while allowing the developing world access to needed medicines.”<sup>157</sup> This system is attractive for pharmaceutical companies because they can retain their ability to license their products to someone of their choosing. Further, it allows them to maintain full control over the product they invested so much time and money developing.<sup>158</sup>

The problem with this is the doctrine of the exhaustion of rights, which is when an intellectual property owner loses, or exhausts, certain rights after the first use of his

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<sup>156</sup> *Id.* at 99.

<sup>157</sup> Fayerman, *supra* note 51, at 272 (citing Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha “Solution.”* 3 CHI. J. INT’L L. 47, 63 (2002)).

<sup>158</sup> *Id.*

patent.<sup>159</sup> The relevant TRIPS Agreement provision states that a patentee's rights are exhausted as soon as the patented product is put on the market with his consent.<sup>160</sup> Doha affirmed this in saying each Member is "free to establish its own regime for such exhaustion without challenge."<sup>161</sup> Thus, in the context on parallel imports, once the right holder agrees to put their product into a certain market, their rights to that product are lost. Once a pharmaceutical company agrees to and provides a developing country with lower priced drugs, they have no control over what happens to the drugs once delivered. Therefore it would be completely legal for the developing country to resell the drugs in a higher priced market. There would be nothing the pharmaceutical company could do to stop that country's actions because their rights would be already exhausted.<sup>162</sup>

The possibility of parallel importing undermines the willingness of pharmaceutical companies to make deals with developing companies on lower drug costs. Because of this there needs to be some sort of international consensus on the exhaustion of rights to combat this problem. The best course of action would be to amend the TRIPS Agreement to reflect a change in parallel importation laws, such as imposing minimum standards so all countries have a basic level of protection. If accomplished, it would go a long way in assisting developing countries ability to negotiate with pharmaceutical companies.

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<sup>159</sup> Wikipedia, [http://en.wikipedia.org/wiki/Exhaustion\\_of\\_rights](http://en.wikipedia.org/wiki/Exhaustion_of_rights).

<sup>160</sup> TRIPS, art. 6

<sup>161</sup> Doha, 5(d)

<sup>162</sup> Matthews, *supra* note 45, at 99.

## **b. OTHER AREAS OF POSSIBILITIES**

### **1. FORGIVENESS OF DEBT**

Another option, and one proposed by the World Bank and the International Monetary Fund, is debt relief.<sup>163</sup> This entails forgiving debts of the poorest countries with conditions such as surplus money must be spent on buying essential patented medicines.<sup>164</sup> To ensure the actual purchase of medicine, the money would be transferred to the Bank, and it would then purchase the necessary drugs.<sup>165</sup>

While this sounds like a plausible solution, it does not guarantee health will necessarily improve in developing countries. While it would supply money for certain drugs, it does not guarantee enough money to buy all the supplies developing countries actually need to combat the HIV/AIDS crisis. Further, unless there is nationwide continuous treatment, there is nothing to stop the spread of infection. Nor is this a long-term solution, which is both needed to provide incentives for pharmaceutical companies to continue research and development of new drugs, and what those affected by HIV/AIDS needed to be effectively treated.<sup>166</sup>

### **2. INCENTIVES**

A third potential possibility is to provide pharmaceutical companies with financial incentives to gain cooperation on lowering drug prices. These companies are in the business of making money, thus presenting them with financial incentives is a sure way

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<sup>163</sup> Jillian Clare Cohen and Patricia Illingworth, *Pharmaceutical Patents and International Commitments: The Inherent Tensions and Implications for Public Health*, May 30-June 1, 2003, *available at* <http://www.cpsa-acsp.ca/paper-2003/cohen-illingworth.pdf>.

<sup>164</sup> Matthews, *supra* note 45, at 100 (quoting Marco M. Slotbloom, *The Exhaustion of Intellectual Property Rights: Different Approaches in EC and WTO Law*, 6(3) *J. World Intell. Prop.* 421, 423 (2003)).

<sup>164</sup> Cohen, *supra* note 164.

<sup>165</sup> *Id.*

<sup>166</sup> *Id.* (citing J. Sachs, *Submission to the Senate Subcommittee on African Affairs*, Washington, Feb. 24, 2000)).



to at least get their attention. The best example of this is tax breaks.<sup>167</sup> Countries, by offering tax incentives, may spawn innovation in research and development, as the US does successfully with the Orphan Drug Bill.<sup>168</sup>

This way, even if it would not necessarily be profitable for pharmaceutical companies to research and develop drugs specifically dealing with the HIV/AIDS crisis, or to provide countries in need with lower prices medicines, they would still benefit in the way of tax cuts. While it seems implausible that this alone can solve the problem, it is a step in the right direction. An international agreement on tax incentives would be a win-win situation for both pharmaceutical companies and countries in need. In dealing with such a large epidemic it is important to not rely on one method alone to create change, but to institute a number of small changes which together create a powerful solution.

### **c. COULD THESE SOLUTIONS BE ENOUGH?**

One could argue that these solutions, if combined, could be enough to combat the HIV/AIDS epidemic until drugs come off patent protection. Once off patent, drugs enter a capitalist market with competition, which naturally lowers prices. Also, generic drugs do not need to factor research and development costs into their prices. However, as explained earlier, older drugs are simply not as effective as newer drugs. Issues of resistance make using older drugs more of a problem than a solution. The HIV disease changes often.<sup>169</sup> Thus, “when this happens, the drug no longer controls virus growth

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<sup>167</sup>The Orphan Drugs Bill, H.R. 4014 (2002)

<http://www.usmedicine.com/article.cfm?articleID=562&issueID=45>

<sup>168</sup> Bill Boosts Orphan Drug Research Grant Program, U.S. Medicine, Dec. 2002,

<http://usinfo.state.gov/products/pubs/intelprp/industry.htm> (This U.S. law, administered by the Food and Drug Administration, deals with medications used to treat diseases and conditions that rarely occur. Since there is little financial incentive for the pharmaceutical industry to develop such medications, "orphan drug status" gives a manufacturer specific financial incentives to develop and provide such medications.)

<sup>169</sup> Merrill Hayden, Drug resistance and HIV, Yahoo! Health.com,

<http://health.yahoo.com/topic/hiv/resources/article/healthwise/tm6300>, June 17, 2005.

(replication) or protects the immune system” and it is necessary to change medications.<sup>170</sup> By the time drugs come off patent there is a likely possibility most are resistant to them, and hence the drugs are essentially worthless to a large portion of the HIV/AIDS infected population.

#### **X. PUBLIC-PRIVATE PARTNERSHIPS – THE FUTURE**

After examining current patent law regarding the HIV/AIDS crisis, including compulsory licensing, tougher parallel importation laws and tax incentives, it becomes clear that these alone cannot solve the global problem. The option this paper will suggest is public-private partnerships. These partnerships offer the best overall solution. For one, not only are they able to work well under current international patent law without using compulsory licensing, but these organizations are able to encourage pharmaceutical companies with financial incentives. Second, the organizations address several other issues involved in the HIV/AIDS crisis. These include the need for health care systems within developed countries, access to educated and informed medical personnel and capable distribution systems.

Public-private partnerships are comprised of international organizations, international companies, non-governmental organizations, private organizations, and countries. The greatest strength of organizations such as these is their ability to coordinate contributions and programs, thus increasing efficiency for all involved. This also allows for cost-sharing, a benefit which all appreciate. Another unique aspect of these partnerships is their dedication to working with organizations that already have established infrastructures and are currently involved in affected communities. A central organizational structure reduces administrative problems and decreases time delays.

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<sup>170</sup> *Id.*

Further, because it allows each organization to provide “unique expertise and core competencies” the overall result is well-rounded organizations able to competently address several different areas of concern effectively and in conjunction.<sup>171</sup>

This paper will briefly summarize the works and benefits of three main organizations: UNAIDS, The Global Fund to Fight AIDS, Tuberculosis and Malaria, and UNITAID.

#### **a. MAIN ORGANIZATIONS**

##### **b. UNAIDS**

UNAIDS is a Joint United Nations program which includes the efforts and resources of ten UN organizations.<sup>172</sup> UNAIDS was established in 1994 by a resolution of the UN Economic and Social Council and officially launched in January 1996.<sup>173</sup> It is co-sponsored by such organizations as the World Bank and the World Health Organization.<sup>174</sup> While based in Geneva, the UNAIDS secretariat works in more than 75 countries worldwide.<sup>175</sup>

UNAIDS is “committed to strengthening support to nationally owned and led responses.”<sup>176</sup> Because of all their co-sponsors, UNAIDS is able to ensure better coordination among the UN, governments, civil society, donors, and the private sector.<sup>177</sup> Thus its most important role is that of an organizer to ensure that all the different groups of sectors which need to work together do. “Together we are committed to making the

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<sup>171</sup> USAID, HIV/AIDS Public-Private Partnerships, *available at* [http://www.usaid.gov/our\\_work/global\\_health/aids/Partnerships/partnerships\\_brief.html](http://www.usaid.gov/our_work/global_health/aids/Partnerships/partnerships_brief.html).

<sup>172</sup> UNAIDS, About, <http://www.unaids.org/en/AboutUNAIDS/default.asp>.

<sup>173</sup> UNAIDS, Governance, <http://www.unaids.org/en/AboutUNAIDS/Governance/default.asp>.

<sup>174</sup> Also: UNHCR, UNICEF, WFP, UNDP, UNFPA, UNODC, and UNESCO.

<sup>175</sup> About, *supra* note 173.

<sup>176</sup> UNAIDS in Action, <http://www.unaids.org/en/Coordination/default.asp>.

<sup>177</sup> *Id.*

money work for those who are in the most need today – while ensuring long term solutions are in place for tomorrow.”<sup>178</sup>

UNAIDS develops, disseminates and monitors the implementation of HIV/AIDS policies all around the world.<sup>179</sup> It guides developing countries in creating effective programs to deal with social, political, culture, medical, health, and economic issues.<sup>180</sup> It encourages policies which not only include national governments, but community and faith based organizations and groups of people which include those living with HIV/AIDS.<sup>181</sup> It understands that in order for its policies to be effective it needs to be “dynamic, comprehensive, [and] informed by evidence and information gathered through experience, and oriented towards acknowledging and encouraging the role of different stakeholders.”<sup>182</sup> UNAIDS tends to focus on what it finds the crucial issues confronting the HIV/AIDS epidemic: HIV prevention, testing, and the “vulnerability of young people who are increasingly and disproportionately affected by HIV.”<sup>183</sup>

The really great thing about this organization is it’s connections to key international organizations such as the World Bank and the World Health Organization. This allows UNAIDS to have more influence than a less connected group. Also, its key issues not only focus on the treatment of HIV/AIDS, but its prevention – the one thing that compulsory licensing is simply not equipped to deal with. Prevention is a long term goal, and in order for this to be realistic there needs to be more done to help developing countries than just simply donating drugs.

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<sup>178</sup> *Id.*

<sup>179</sup> *Id.*

<sup>180</sup> UNAIDS, Policy, <http://www.unaids.org/en/Policies/default.asp>.

<sup>181</sup> *Id.*

<sup>182</sup> *Id.*

<sup>183</sup> *Id.*

**c. THE GLOBAL FUND TO FIGHT AIDS,  
TUBERCULOSIS, AND MALARIA**

The Global Fund is a partnership between governments, civil society, the private sector, and affected communities.<sup>184</sup> The purpose of the Global Fund “is to attract, manage and disperse resources to fight AIDS . . . [it] do[es] not implement programs, relying instead on the knowledge of local experts.”<sup>185</sup> The main objective of the Global Fund is to work as a financing mechanism. The group works with “closely with other multilateral and bilateral organizations involved in health and development issues to ensure that newly funded programs are coordinated with existing ones.”<sup>186</sup> The Global Fund tries to incorporate their work with local, existing financial institutions when possible to help developing countries build their own working systems instead of relying on other countries.<sup>187</sup>

The Global Fund was created in 2001 to finance programs for epidemics in developing countries.<sup>188</sup> It only finances programs that will not replace or reduce any other sources of funding.<sup>189</sup> It seeks to “complement the finance of other donors and to use its own grants to catalyze additional investments by donors and by recipients themselves.”<sup>190</sup> Since 2001, the Global Fund has ensured \$4.7 billion worth of financing through 2008. Through its first two rounds of grants, it has committed \$1.5 billion to support 154 programs in 93 countries.<sup>191</sup>

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<sup>184</sup> How the Global Fund Works, <http://www.theglobalfund.org/en/about/how/>.

<sup>185</sup> *Id.*

<sup>186</sup> *Id.*

<sup>187</sup> *Id.*

<sup>188</sup> See generally The Global Fund, <http://www.theglobalfund.org/en/>

<sup>189</sup> *Id.*

<sup>190</sup> How the Global Fund Works, *supra* note 185.

<sup>191</sup> *Id.*

Over the past five years, Global Fund resources have made a real impact upon the HIV/AIDS epidemic. Because of it, 1.8 million people are projected to have access to antiretroviral treatment.<sup>192</sup> More than a million orphans will have medical services, education, and community care.<sup>193</sup> Further, 62 million people will have access to voluntary counseling and testing services.<sup>194</sup>

This partnership is key to the fight against HIV/AIDS because of the financial contributions and organization it provides worldwide for those in need. As mentioned before, a problem with compulsory licensing is that while it is a step in the right direction, it offers no long term realistic solution. The Global Fund works with developing countries to create effective economic programs, thus providing much needed financial support while also providing much needed, and important, overall infrastructure support. Partnerships like the Global Fund have far reaching effects because of its ability to integrate all levels of government and society.

#### **d. UNITAID**

UNITAID launched its partnership on September 16, 2006 at the Opening Session of the United Nations General Assembly.<sup>195</sup> It was originally created by France, Brazil, Chile, Norway, and the United Kingdom to create an international drug purchase facility to be financed with predictable and consistent resources.<sup>196</sup> Currently there are 44 countries working on implementing UNITAID financial mechanisms.<sup>197</sup> In addition, UNITAID is supported by many key global institutions such as the World Health

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<sup>192</sup> The Global Fund, Fighting AIDS, <http://www.theglobalfund.org/en/about/aids/default.asp>.

<sup>193</sup> *Id.*

<sup>194</sup> *Id.*

<sup>195</sup> UNITAID's Core Principals, <http://www.unitaid.eu/EN-Inutaid-unis-pour-soigner.html>.

<sup>196</sup> *Id.*

<sup>197</sup> *Id.*

Organization, UNAIDS, The Global Fund, NGO's, private foundations (like the Clinton and Gates Foundations), and especially by the World Trade Organization.<sup>198</sup> In a statement by the WTO it said, "[t]he World Health Organization welcomes the official launch of UNITAID . . . WTO shares the key public health objectives of UNITAID as it seeks to assist developing countries in purchasing medicines . . . ."<sup>199</sup>

UNITAID seeks to implement a financing mechanism around the world that will increase the supply of HIV/AIDS medicines while lowering their prices, without compromising their quality.<sup>200</sup> Because the program creates stable and continuing financial contributions, UNITAIDS can guarantee long term financial help for large-scale treatment programs.<sup>201</sup> Its goal is to achieve universal access to healthcare by 2010.<sup>202</sup> The purpose of UNITAID is not to replace any other organization, but offer others an innovative financing system.<sup>203</sup>

UNITAID is based on a new idea: it proposes a levy tax on airline travel with proceeds going into a fund used to purchase medicine from pharmaceutical companies.<sup>204</sup> Thus, it assures a long-term solution to the need for funding. "Air transport is one of the industries that benefits most from globalization with an average annual growth of 5% . . . [u]sing differentiated rates according to the travel classes ensures that efforts are distributed fairly among passengers."<sup>205</sup>

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<sup>198</sup> *Id.*

<sup>199</sup> WTO, Media Center, WTO Welcomes Launch of UNITAID, <http://www.who.int/mediacentre/news/statements/2006/s15/en/index.html>

<sup>200</sup> UNITAID's Core Principals, *supra* note 196.

<sup>201</sup> *Id.*

<sup>202</sup> *Id.*

<sup>203</sup> *Id.*

<sup>204</sup> UNITAID, Innovating Financing Mechanism, <http://www.unitaid.eu/EN-Mode-de-financement-innovant.html>.

<sup>205</sup> *Id.*

UNITAID has the ability to be an incredible help in the fight against HIV/AIDS. Because it will be able to guarantee long term and predictable profit, it will have substantial leverage with pharmaceutical companies. “UNITAID will negotiate multi-year large-volume procurement programs with the pharmaceutical companies to obtain significant cost reductions. Meanwhile UNITAID will boost the marketing of generic drugs by accelerating their WHO pre-qualification and facilitating their distribution in developing countries.”<sup>206</sup> Thus, pharmaceutical companies will have an incentive to increase the production of essential HIV/AIDS drugs for use in developing countries.<sup>207</sup>

**b. WHY THESE ORGANIZATIONS OFFER A REAL  
SOLUTION AND CAN WORK WITHIN THE  
PATENT SYSTEM**

It is estimated that it will be at least another next two decades before there is a substantial decline in HIV and AIDS infections.<sup>208</sup> Therefore, long term solutions are the only realistic option. The Doha Declaration and the subsequent 2005 amendment to TRIPS to allow compulsory licensing are crucial to the global fight against HIV and AIDS. However, these alone will not be enough to solve the problem because they offer only short term solutions without any permanent effects. The unique thing about public-private partnerships is that they can work within the already established international patent system without the need for compulsory licenses. Further, because of the wide range of organizations represented, these partnerships can address a much wider array of

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<sup>206</sup> UNITAID/IDPF Added Value, <http://www.unitaid.eu/EN-Valeur-ajoutee-Unitaid-FIAM.html>.

<sup>207</sup> *Id.*

<sup>208</sup> Associated Press, Bush: AIDS ‘Can Be Defeated’, MSNBC, <http://www.msnbc.msn.com/id/15971729/> December 1, 2006.



issues involved in the HIV/AIDS crisis then simply providing medication to some of those in need.

The large amount of money these partnerships can raise is far more helpful to the global fight on HIV and AIDS than individual compulsory licenses. These foundations can make deals with pharmaceutical companies so both sides win. The pharmaceutical companies make more money because of the increased demand, and developing countries can receive lower cost drugs because of that increase in sales. All of this can occur without the need to violate established patent laws, or anger developed countries. While the threat of a compulsory license is in itself a motivator for companies to reduce prices on their patented medicines, the sheer amount of profit they could make by negotiating deals on large orders from organizations like the three mentioned above is much more of an incentive. In the case of public-private partnerships everyone wins. Pharmaceutical companies are allowed to maintain control of their patents and make a profit from them, and developing countries are allowed access to the essential medicines their populations so desperately need at lower prices without any huge administrative or financial burdens.

In order to fully take advantage of the benefits public-private partnerships offer, there should be more integration among them. One of the unique benefits of such organizations is their ability to pull together several different groups. Expanding on that notion, large global partnerships like the three mentioned above should pool their resources and work together. This was assure no overlap in their activities, and better serve the overall purpose of benefiting those in need. One option would be for private agreements between the organizations. Because they represent a wide variety of organizations it is realistic to assume the partnerships would want to maintain a high level

of individual control. However, with agreements it would be possible to carve out special areas which each partnership could agree to concentrate on, and assure that all their other activities function in conjunction with each other. Further, private agreements between the organizations would increase their bargaining power in regards to pharmaceutical companies. Should they all pool their resources and funding, pharmaceutical companies will have no choice but bargain with groups because of the sheer amount of business represented.

Another benefit of private agreements among partnerships is that this would allow more resources to be used on other areas needing attention, such as the need for developing countries to have access to food, clean water, adequate health care, distribution systems, and overall national infrastructures to deal with the large scale of the HIV/AIDS epidemic. All of these organizations by themselves focus on creating programs to deal with issues such as these, and have been successful. By pooling their resources and working together, the number of programs could dramatically increase. It is likely each partnership has a specialty in regards to these types of programs. Through agreement, each partnership could agree to work primarily on their specialty, with economic and administrative help from the other partnerships. This would increase productivity while lowering costs and associated administrative and time delays.

### **CONCLUSION**

Overall, in order to effectively fight the global war on HIV/AIDS, there needs to be a balance between the public interest and the need to incentivize pharmaceutical companies research and development with profits. Allowing compulsory licensing alone will not solve the problem for several reasons. For one, it is a short term solution that

offers no real incentives for pharmaceutical companies. Second, it offers no realistic solution to the other issues which need to be addressed, such as the need for food, water, health services, distribution centers and so on within the HIV and AIDS infected countries. There need to be other systems in place to motivate pharmaceutical companies and create and build up structures within developing countries to create long-term change.

The TRIPS Agreement was implemented in order to “promote effective and adequate protection of intellectual property rights,” and recognized “the underlying policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives” as well as “the special needs of the least-developed Member states in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.”<sup>209</sup> There are valid arguments, discussed previously, that advance the idea that compulsory licensing is contrary to the above stated goals. That while there is a need to protect and help developing countries, this should not be done at the expense of the purpose of TRIPS – to protect intellectual property rights. The Doha Declaration and the 2005 TRIPS Amendment were needed to provide leverage for developing countries and public-private partnerships against pharmaceutical companies in their quest for lower drug costs, but they were not meant to impeded on the foundations of patent law.

Compulsory licenses cannot be the only avenue through which countries deal with their medical crises, including the HIV/AIDS epidemic. While compulsory licenses can help in some ways, they are far from a permanent fix. Partnerships provide a much more

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<sup>209</sup> TRIPS

stable opportunity through which to provide essential medicines, money, and other help needed to deal with the HIV/AIDS issues in developing countries. This viable alternative to compulsory licenses provides a secure, realistic, and reasonable solution to the HIV/AIDS epidemic devastating developing countries.