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## Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem

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# INADEQUACY OF TRIPS & THE COMPULSORY LICENSE: WHY BROAD COMPULSORY LICENSING IS NOT A VIABLE SOLUTION TO THE ACCESS TO MEDICINE PROBLEM

## INTRODUCTION

Erectile dysfunction, cancer, and HIV/AIDS are not generally thought of as falling within the same class of medical illness. Erectile dysfunction is often characterized as a non-life-threatening condition,<sup>1</sup> while cancer is labeled a life-style disease,<sup>2</sup> and HIV/AIDS as an epidemic.<sup>3</sup> Yet, medications for all three health problems have had their drug patents broken by a compulsory license under the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”).<sup>4</sup> The goal of TRIPS is to provide access to essential medications in cases of national public health emergency by granting a compulsory license of a patented medication.<sup>5</sup> The drafters’ intent was to balance intellectual property (“IP”) rights with access to affordable medications.<sup>6</sup> Yet the vagueness of TRIPS and its compulsory license provisions, specifically Articles 30 and 31, has caused much controversy and opposition.<sup>7</sup> Consequently, TRIPS has not been utilized to its fullest nor has it been utilized as its drafters intended. It is doubtful, for example, that the drafters of TRIPS intended erectile dysfunction to be covered under the Article 31 public health emergency exception to

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1. See *Erectile Dysfunction Treatment*, REVITA: ANTI-AGING CENTER, <http://www.revitaantiagingcenter.com/erectile-dysfunction-treatment/> (last visited Feb. 20, 2013).

2. See *Cancer is a Preventable Lifestyle Disease*, TIME FOR WELLNESS (Mar. 16, 2010), <http://www.timeforwellness.org/blog-view/cancer-is-a-preventable-lifestyle-disease-115>.

3. See David Gratzner, *The WTO’s Drug Problem*, MANHATTAN INSTITUTE FOR POLICY RESEARCH (Jan. 21, 2003), <http://www.manhattan-institute.org/html/miarticle.htm?id=3276>.

4. See Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9 PLOS MED., Jan. 2012, at 1, 4.

5. See Gratzner, *supra* note 3.

6. See *id.*

7. See *id.*

patent rights, which allows third parties to manufacture a patented medication without the consent of the patent owner.<sup>8</sup> At the other end of the spectrum, HIV/AIDS is explicitly covered under this exception.<sup>9</sup> Furthermore, as the number of cancer deaths increases, it has become less clear whether life-style disease medications should be covered.<sup>10</sup> Thus, as these three brief examples illustrate, the scope of compulsory licenses must be better defined to properly balance the countervailing goals of IP rights with access to medicines, and to allow TRIPS to more successfully achieve these dual goals.

Balancing countervailing goals is never an easy feat, especially in international IP where countries vary in economic, social, and cultural terms.<sup>11</sup> It follows, then, that providing access to affordable medicines has been a challenge for the international community, which must balance improving global health against the IP rights of patent holders of life-saving medications.<sup>12</sup> Both interests are supported by parties having deeply entrenched goals with different primary priorities and different approaches.<sup>13</sup> On the one hand, developing countries and non-profit organizations have a primary focus of ensuring access to affordable medicines for those in poverty.<sup>14</sup> Developing countries often lack the capabilities and infrastructure to create IP, such as patentable drugs, and are thus primarily IP importers, and lack an incentive to protect IP.<sup>15</sup> These countries favor weaker IP rights,<sup>16</sup> which allow market entry of generic drug

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8. *See id.*

9. *See id.*

10. *See* Kevin Outtersson, *Disease-Based Limitations on Compulsory Licenses Under Articles 31 and 31bis*, 1–2, 17–21 (B.U. Sch. Law, Working Paper No. 09–26, 2009).

11. *See* Daniel C.K. Chow & Edward Lee, *INTERNATIONAL IP: PROBLEMS, CASES, AND MATERIALS* 197 (2006).

12. *See* Brittany Whobrey, *International Patent Law and Public Health: Analyzing TRIPS' Effect on Access to Pharmaceuticals in Developing Countries*, 45 *BRANDEIS L.J.*, 623–624 (2007).

13. *See* Alexandra G. Watson, *International IP Rights: Do TRIPS' Flexibilities Permit Sufficient Access to Affordable HIV/AIDS Medicines in Developing Countries?*, 32 *B.C. INT'L & COMP. L. REV.* 143, 149–150 (2009).

14. *See* Whobrey, *supra* note 12, at 623–624.

15. Chow, *supra* note 11, at 12.

16. *See* Whobrey, *supra* note 12, at 625.

manufacturers and increased market competition.<sup>17</sup> Market entry and competition lower drug prices, resulting in increased availability of affordable medications.<sup>18</sup> On the other hand, developed countries and the pharmaceutical industry primarily focus on protecting their valuable IP, namely patented medications.<sup>19</sup> Developed countries are primarily IP exporters<sup>20</sup> and thus seek stronger IP rights to ensure protection both abroad and domestically.<sup>21</sup> Similarly, pharmaceutical companies assert that strong IP rights are required to recoup their research and development costs—which can exceed \$800 million for each successful drug—and to incentivize future innovation.<sup>22</sup>

Although neither concern over global health nor IP are new issues in the international community, they were initially contemplated as separate and competing interests and were only brought together for the first time under TRIPS. International commitment to global health was highlighted as early as the 1940s with the formation of the United Nations,<sup>23</sup> the World Health Organization,<sup>24</sup> and the World Bank Group<sup>25</sup> and has been reaffirmed repeatedly, appearing in the Millennium Development Goals<sup>26</sup> established by the United Nations Millennium Declaration<sup>27</sup> in September 2000. Likewise, protection of IP rights through international initiatives is not a novel concept;

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17. *See id.*

18. *See id.*

19. *See* Chow, *supra* note 11, at 453.

20. *Id.* at 12.

21. *See id.* at 8–9.

22. *Id.* at 10–11, 453.

23. *UN at a Glance*, UNITED NATIONS, <http://www.un.org/en/aboutun/index.shtml> (last visited Sept. 22, 2011).

24. *About WHO*, WORLD HEALTH ORGANIZATION, <http://www.who.int/about/en/> (last visited June 13, 2013).

25. *HIV/AIDS Prevention Additional Financing*, THE WORLD BANK, <http://www.worldbank.org/projects/P144537/hiv-aids-prevention-additional-financing?lang=en> (last visited Feb. 20, 2013).

26. *Background*, UNITED NATIONS MILLENNIUM DEVELOPMENT GOALS, <http://www.un.org/millenniumgoals/bkgd.shtml> (last visited Sept. 22, 2011).

27. Millennium Declaration, G.A. Res. 55/2, U.N. Doc. A/RES/55/2 (Sept. 18, 2000), *available at* <http://www.un.org/millennium/declaration/ares552e.pdf>.

it is rooted in the 1883 Paris Convention,<sup>28</sup> which was echoed with the formation of the World Intellectual Property Organization (“WIPO”)<sup>29</sup> in 1967 and the Patent Cooperation Treaty<sup>30</sup> in 1970. However, in 1994, when the World Trade Organization (“WTO”)<sup>31</sup> adopted TRIPS,<sup>32</sup> the two competing interests clashed. TRIPS linked IP to trade, and trade affects access to medications.<sup>33</sup> Though the TRIPS negotiations pitted developing and developed countries against each other,<sup>34</sup> all 153 WTO member countries adopted TRIPS on April 15, 1994, which attempted to create strong international IP rights by setting basic standards.<sup>35</sup> However, in an attempt to balance strong IP rights with access to essential medicines, TRIPS included certain flexibilities intended to support global health, particularly compulsory licensing and parallel importation,<sup>36</sup> which will be discussed *infra* in Part I.B.

This Note will analyze whether TRIPS has successfully balanced its two competing goals of protecting IP and improving access to medicines. The analysis will illustrate several impediments to TRIPS in the approximately fifteen years after its

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28. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305, *available at* [http://www.wipo.int/export/sites/www/treaties/en/ip/paris/pdf/trtdocs\\_wo020.pdf](http://www.wipo.int/export/sites/www/treaties/en/ip/paris/pdf/trtdocs_wo020.pdf).

29. *About WIPO*, WORLD IP ORGANIZATION, [http://www.wipo.int/about-wipo/en/what\\_is\\_wipo.html](http://www.wipo.int/about-wipo/en/what_is_wipo.html) (last visited Sept. 22, 2011).

30. Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231, *available at* <http://www.wipo.int/pct/en/texts/pdf/pct.pdf>.

31. *The WTO*, WORLD TRADE ORGANIZATION, [http://www.wto.org/english/thewto\\_e/thewto\\_e.htm](http://www.wto.org/english/thewto_e/thewto_e.htm) (last visited Feb. 20, 2013).

32. Agreement on Trade-Related Aspects of IP Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS].

33. Chow, *supra* note 11, at 25.

34. See Watson, *supra* note 13, at 149–150.

35. *The WTO*, *supra* note 31; *Fact Sheet: TRIPS and Pharmaceutical Patents Obligations and Exceptions*, WORLD TRADE ORGANIZATION, [http://wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm](http://wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm) (2011) [hereinafter *TRIPS Fact Sheet*]. Currently there are 193 WTO member countries which have all adopted TRIPS. Tina S. Bhatt, Note, *Amending TRIPS: A New Hope for Increased Access to Essential Medicines*, 33 BROOK. J. INT'L L. 597, 600 (2008).

36. *The WTO*, *supra* note 31; *TRIPS Fact Sheet*, *supra* note 35.

implementation and will highlight special challenges concerning access to chronic disease medications. This analysis will show that TRIPS is an ineffective solution for the access to medicine problem. The Note will then suggest recommendations for amending TRIPS to better achieve its two policy goals, as well as suggest a supplemental market approach to TRIPS that will best ensure access to both communicable (i.e., infectious) and non-communicable (i.e., chronic) disease medications.

In light of the treaty's deficiencies, the amendment to TRIPS proposed here will require a three-tier pricing system and will also prohibit parallel importation. A supplementary market approach will be an alternative to compulsory licensing. The market approach for all practical purposes must be advantageous to pharmaceutical companies and developed countries, while still providing needed medications to developing countries. Under this approach, compulsory licensing should have a limited scope and interpretation, as the market alternative should be the dominant route to distribute medications. Part I will discuss the timeline and background of international IP initiatives and will end with a discussion of the relevant provisions of TRIPS. Part II will identify problems and recent impediments to TRIPS. Part III will survey special challenges in the area of chronic diseases. Finally, Part IV will propose recommendations to strengthen TRIPS and to better promote its dual goals in the face of increased hostility and dissatisfaction of all involved parties.

## I. BACKGROUND

### *A. International IP Initiatives: Road to TRIPS*

The first international IP agreement was the Paris Convention of 1883.<sup>37</sup> Although it was a major step to address IP on a global scale, the Paris Convention lacked substantive standards for IP, and left member countries to structure their domestic IP laws as desired.<sup>38</sup> For example, the Paris Convention did not impose a standard definition of patentable subject mat-

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37. Chow, *supra* note 11, at 25.

38. *Id.* at 270.

ter, resulting in inconsistencies where some countries excluded pharmaceuticals and biotechnology from patent protection.<sup>39</sup> Lack of enforcement capabilities presented additional limitations to the Paris Convention.<sup>40</sup> A more significant attempt at international harmonization occurred in 1967 with the creation of WIPO, a specialized agency under the United Nations.<sup>41</sup> However, like the Paris Convention, WIPO lacked a global enforcement mechanism.<sup>42</sup> In 1994, the WTO adopted TRIPS, which is currently the leading international IP treaty and links IP to trade.<sup>43</sup>

The key improvement that makes TRIPS a stronger treaty than past international IP regimes is its enforcement capability, established through “an elaborate Dispute Settlement Body” under the WTO.<sup>44</sup> Due to this improvement, TRIPS is not a “toothless organization” and has “real powers to impose [trade] sanctions” on member countries that do not comply with the minimal substantive IP standards set forth in TRIPS.<sup>45</sup> Further, TRIPS includes minimal standardized substantive

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39. *Id.*

40. *Id.* at 26.

41. See Margot Kaminski, *The Origins and Potential Impact of the Anti-Counterfeiting Trade Agreement (ACTA)*, 34 YALE J. INT'L L. 247, 248 (2009).

42. See Chow, *supra* note 11, at 26. The WIPO international harmonization effort was much larger, containing 175 member countries, compared to only eleven member countries bound by the Paris Convention. See Kaminski, *supra* note 41, at 248; Chow, *supra* note 11, at 64.

43. Chow, *supra* note 11, at 25, 58.

44. *Id.* at 26.

When one member challenges another's actions as violating a specific WTO agreement or principle, the issue is brought before the Dispute Resolution Body (DRB). The DRB holds proceedings and issues decisions . . . . If a country loses a dispute and does not cooperate and abide by the DRB's decisions, the WTO has the power to authorize trade sanctions against the losing party.

Whobrey, *supra* note 12, at 628; TRIPS is a non-self-executing treaty, as articulated in Article 1.1, meaning each member country must enact domestic legislation to comply with the standards set forth in TRIPS. Chow, *supra* note 11, at 289; see TRIPS, *supra* note 32, art. 68 (establishing the TRIPS Council to monitor compliance by member countries with TRIPS and to interpret its provisions); see also Chow, *supra* note 11, at 292.

45. Chow, *supra* note 11, at 26, 58.

rights for patent protection,<sup>46</sup> lacking in past international IP agreements. For example, TRIPS prohibits denying patents “based on the field of technology” and thus requires all member countries to protect pharmaceutical and biotechnology patents.<sup>47</sup> It also requires patent protection for a minimum of twenty years in member countries.<sup>48</sup> Attempting to balance these stronger IP standards, TRIPS also includes exceptions, called TRIPS flexibilities, in order to appease the competing interest of global health.<sup>49</sup>

### *B. Relevant Provisions of TRIPS: TRIPS Flexibilities*

#### 1. General Public Health Provisions

Article 28 of TRIPS lays out the exclusive rights of patent holders, namely, the exclusive right to make, use, offer for sale, sell, or import the patented good.<sup>50</sup> The patent holder also has the exclusive right to assign, transfer, or license the patent.<sup>51</sup> The compromise and balance between strong IP rights and attempts to promote public health is seen generally in Article

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46. See *id.* at 271. Substantive minimum standards of patent protection in TRIPS include, but are not limited to:

[First,] countries must allow for the patenting of processes and may not deny patents based on the field of technology . . . . [Second,] TRIPS also delineates what exclusive rights a patent must entail and for how long, and puts limitations on when countries may enact exceptions or compulsory licenses to patents . . . . [Third, TRIPS] also requires countries to afford judicial review of any revocation or forfeiture of a patent.

*Id.*; see TRIPS, *supra* note 32, art. 27–34 (setting the minimal terms for patent protection).

47. Chow, *supra* note 11, at 271; TRIPS, *supra* note 32, art. 27(1). Prior to TRIPS over forty countries had no patent protection for pharmaceutical products. Josephine Johnston & Angela A. Wasunna, *Patents, Biomedical Research, and Treatments: Examining Concerns, Canvassing Solutions*, 37 HASTINGS CENTER REPORT (SPECIAL REPORT), no.1, S1, S5 (2007).

48. TRIPS, *supra* note 32, art. 33.

49. See Bhatt, *supra* note 35, at 600. See also *TRIPS Fact Sheet*, *supra* note 35; Chow, *supra* note 11, at 336.

50. TRIPS, *supra* note 32, art. 28(1).

51. *Id.* art. 28(2).

8(1) and Article 27(2).<sup>52</sup> Article 8(1) demonstrates that public health was a concern during the drafting of TRIPS, where it allows member countries to “adopt measures necessary to protect public health, nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”<sup>53</sup> Article 27(2) excludes patentability of inventions that are “necessary to protect the *ordre public* or morality,” including those inventions that protect human life or health.<sup>54</sup>

## 2. Compulsory Licensing

Article 30 and Article 31 more clearly state the exceptions to the IP rights held by a patent owner and attempt to address the access to medicine concern of developing countries. These exceptions are often referred to as the “TRIPS flexibilities.”<sup>55</sup> Article 30 allows member countries to provide “limited exceptions” to a patent holder’s exclusive rights,<sup>56</sup> “provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”<sup>57</sup> Article 31 offers a more detailed exception to a patent holder’s exclusive rights, specifically the compulsory license exception.<sup>58</sup> This exception requires a third party to first attempt to negotiate a voluntary license with the patent holder before requesting a compulsory license through the third party’s government.<sup>59</sup> However, Article 31 allows third parties to bypass the voluntary license negotiation in cases of “a national emergency or other circumstances of extreme urgency<sup>60</sup> or in cases of public non-commercial

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52. *See id.* art. 8(1), 27(2).

53. *Id.* art. 8(1).

54. *Id.* art. 27(2).

55. Bhatt, *supra* note 35, at 600.

56. TRIPS, *supra* note 32, art. 28, 30 (Article 28 refers to the patent holder’s exclusive rights).

57. *Id.* art. 30.

58. *See id.* art. 31.

59. *Id.* art. 31(b).

60. *See* discussion *infra* Part II.A.3. TRIPS does not define “national emergency” or “extreme urgency”—a deficiency that will be discussed below.

use.”<sup>61</sup> This emergency compulsory license exception is limited to requiring compulsory licenses to be “authorized predominantly” for domestic use.<sup>62</sup>

### 3. Parallel Importation

In addition to the compulsory license, another significant TRIPS flexibility is the concept of parallel importation alluded to in Article 6.<sup>63</sup> Parallel importation results from price discrimination, where a particular product is sold at different prices in different countries, and is based on the concept of exhaustion.<sup>64</sup> Exhaustion, or the first sale doctrine, states that after a sale the prior possessor of a product relinquishes all rights to the product and the new possessor is able to distribute and import it at will.<sup>65</sup> Opponents of exhaustion, including pharmaceutical companies, contend that it “decreases profitability and removes the incentive to sell drugs to poor countries at lower prices.”<sup>66</sup> Further, there is a concern that some corrupt governments of developing countries may resell the discounted drugs received at higher profits to other countries, rather than provide the discounted drugs to their citizens in need.<sup>67</sup> TRIPS neither bans nor authorizes parallel importation.<sup>68</sup>

## *C. Response to TRIPS: International Clarification of TRIPS*

### 1. The Doha Declaration

After developing countries raised concerns as to the scope of interpretation of the TRIPS flexibilities and its relation to the issue of access to medicines, the WTO issued a Declaration on TRIPS and Public Health at a conference in Doha, Qatar in

61. TRIPS, *supra* note 32, art. 31(b). TRIPS requires “adequate remuneration” be paid to the patent holder in cases where a government does in fact grant a compulsory license. *Id.* art. 30(h).

62. *Id.* art. 31(f).

63. *See id.* art. 6.

64. Chow, *supra* note 11, at 428.

65. *Id.* at 419.

66. Whobrey, *supra* note 12, at 633.

67. *Id.*

68. *See* TRIPS, *supra* note 32, art. 6 (“[N]othing in this Agreement shall be used to address the issue of exhaustion . . .”).

2001.<sup>69</sup> The Doha Declaration<sup>70</sup> reaffirmed the need to balance grave “public health problems afflicting many developing . . . countries”<sup>71</sup> with “intellectual property protection[, which] is important for the development of new medicines.”<sup>72</sup> Further, paragraph four of the Doha Declaration states that TRIPS “should be interpreted and implemented in a manner supportive of WTO member’s right to protect public health and, in particular, to promote access to medicines for all” and that the flexibilities were provided “for this purpose.”<sup>73</sup> The Doha Declaration also affirms that each member country can determine the circumstances for granting compulsory licenses, the circumstances constituting a national emergency, and can establish its own policy on exhaustion.<sup>74</sup> It specifically states that a public health crisis may include, but is not limited to, those “relating to HIV/AIDS, tuberculosis, malaria and other epidemics.”<sup>75</sup>

Lastly, the Doha Declaration recognizes a problem created by Article 31(f) of TRIPS regarding the use of compulsory licenses.<sup>76</sup> Article 31(f) restricts compulsory licenses to manufacturing goods “predominantly” in the domestic country.<sup>77</sup> However, many developing countries do not have the manufacturing, infrastructure, or expertise to domestically produce pharmaceutical products and thus these countries would not be able to use the compulsory license flexibility.<sup>78</sup> Paragraph six of the Doha

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69. Chow, *supra* note 11, at 459.

70. World Trade Organization, Ministerial Declaration of 14 November 2001: Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Public Health Declaration].

71. *Id.* ¶ 1 (specifically recognizing public health concerns in “HIV/AIDS, tuberculosis, malaria and other epidemics”).

72. *Id.* ¶ 3.

73. *Id.* ¶ 4.

74. *Id.* ¶ 5.

75. *Id.* ¶ 5(c).

76. Vishal Gupta, *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, 643 (2005).

77. TRIPS, *supra* note 32, art. 31(f).

78. Doha Public Health Declaration, *supra* note 70, ¶ 6. *See also* Chow, *supra* note 11, at 461. “[A]bout 80% of developing countries lack a functional pharmaceutical sector capable of producing [antiretroviral medications used to treat HIV/AIDS].” Aileen M. McGill, *Compulsory Licensing of Patented*

Declaration recognizes this issue and requests the WTO Council for TRIPS<sup>79</sup> to propose a solution.<sup>80</sup>

## 2. Paragraph Six Decision

On August 30, 2003, the WTO General Council reached a solution to the problem recognized in paragraph six of the Doha Declaration.<sup>81</sup> This solution, known as the “Implementation Decision” or “Paragraph 6 Decision,” created a waiver for Article 31(f) of TRIPS by which a country that lacks manufacturing capabilities may now import a specific pharmaceutical product.<sup>82</sup> However, the Paragraph 6 Decision contains a number of restrictions on this waiver, complicating the importation process.<sup>83</sup> In 2005, the WTO General Council voted to amend TRIPS to permanently include the Implementation Decision as Article 31*bis*.<sup>84</sup> The amendment will take effect after acceptance by two-thirds of the member countries.<sup>85</sup>

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*Pharmaceuticals: Why A WTO Administrative Body Should Determine What Constitutes a Public Health Crisis Under The Doha Declaration*, 10 WAKE FOREST INTELL. PROP. L.J. 69, 93 (2009).

79. TRIPS *supra* note 32, art. 68 (establishing the Council for TRIPS to monitor the operation of TRIPS and members’ compliance with their obligations, and affords members the opportunity to consult the Council on related matters).

80. Doha Public Health Declaration, *supra* note 70, ¶ 6.

81. Decisions of General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 and Corr. 1, 43 I.L.M. 509 (Aug. 30, 2003) [hereinafter Implementation Agreement].

82. *Id.* ¶ 2.

83. *Id.* The waiver applies only “for the purposes of production of a pharmaceutical product. . . .” *Id.* It also imposes several notification requirements and labeling requirements. *Id.* ¶ 2(b)(iii).

84. *TRIPS and Public Health: Members Accepting Amendment of the TRIPS Agreement*, WORLD TRADE ORGANIZATION, [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 updated Jan. 5, 2012); *see also* Chow, *supra* note 11, at 464.

85. *TRIPS and Public Health*, *supra* note 84. The deadline to accept the amendment has been pushed back to December 31, 2013. *Id.* As of February 16, 2013, forty-three of the 155 members have approved the amendment, including the United States. *Id.*; *Understanding the WTO: The Organization Members and Observers*, WORLD TRADE ORGANIZATION, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) (last visited May 10, 2012) (listing all 155 members and observers of the WTO).

## II. PROBLEMS AND IMPEDIMENTS TO TRIPS & ACCESS TO MEDICINES

A survey of a multitude of factors highlights the problems and impediments to successful use of TRIPS. These include: complicated procedural requirements, actual use of compulsory licensing, definitional ambiguities, limitations inherent in developing countries, retaliation by pharmaceutical companies and developed countries, and legal challenges to compulsory license laws and grants. As a result of these factors TRIPS has not been used to its fullest ability and has also not been used as its drafters intended. Consequently, the dual goals of balancing IP rights with access to essential medicines have not been fully achieved.

### A. Problems

#### 1. Complicated Procedural Requirements

Compulsory licensing is a complicated process requiring a number of procedural hurdles to be met prior to issuing the compulsory license.<sup>86</sup> “Even if a developing country is ultimately successful in authorizing a compulsory license . . . the delays in authorization due to [the mandatory] judicial review [or other independent review] may discourage licensees from producing generic versions . . . as they will have less time to recover start-up costs.”<sup>87</sup> Further, the Paragraph 6 Decision is not a

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86. See generally Donald Harris, *TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J. INTELL. PROP. L. 367, 390–392 (2011). TRIPS Article 31(a)—(l) states a long list of procedural requirements a country must satisfy prior to compulsory licensing, which include: “use [of the license] shall be considered on its individual merit,” “scope and duration of the use must be limited to the authorized purpose,” “judicial or other independent review of the use authorization,” use is “contingent on adequate remuneration” to the patent holder, which “must take into account the economic value of the authorization” and is “subject to judicial or other independent review.” Cynthia M. Ho, *A New World Order for Addressing Patent Rights and Public Health*, 82 CHI.-KENT L. REV. 1469, 1488 (2007) [hereinafter *A New World Order*]. But see *id.* (“Despite the long list of procedural requirements . . . compliance with these requirements has not generally been an issue.”).

87. Brent Savoie, *Thailand’s Test: Compulsory Licensing in an Era of Epidemic Transition*, 48 VA. J. INT’L L. 211, 239 (2007).

streamlined procedure and is time-consuming, expensive, and has been rarely used.<sup>88</sup> In addition, many countries have not enacted domestic legislation to incorporate the Paragraph 6 Decision, making it non-operational.<sup>89</sup> Canada was the first and only country to use the Paragraph 6 Decision to export a generic AIDS drug to Rwanda after issuance of a compulsory license.<sup>90</sup> However, due to the complicated process (cumbersome to both the eligible exporting and importing countries), lack of incentives, huge costs, time commitment, and challenges in recovery costs, the director of public affairs for the generic drug firm stated that it would not use the Paragraph 6 system again.<sup>91</sup> Fears that the procedures for the Paragraph 6 Decision

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The longer the issuance of compulsory licenses is delayed after patented drugs enter the marketplace, the less time licensees have to recover their start-up costs and the more difficult it is to achieve effective competition among multiple generic substitute suppliers. Thus, if compulsory licensing is to be successful, expeditious licensing procedures are a necessity.

F. M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Nations*, 5 J. INT'L ECON. L. 913, 924 (2002).

88. See generally *A New World Order*, *supra* note 86, at 1492–1493 (providing an overview of the procedures and requirements prior to allowing compulsory licensing of drugs for export under the Paragraph 6 Decision); Harris, *supra* note 86, at 389–392; Holger Hestermeyer, *HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES* 261–272 (2007) (offering a more detailed overview of the Paragraph 6 Decision and its procedural requirements).

89. *A New World Order*, *supra* note 86, at 1491–1492. Norway, Canada, India, and the EU are the only potential exporting countries that have formally informed the TRIPS Council that they have enacted domestic legislation to comply with the Paragraph 6 Decision. *TRIPS and Health: Frequently Asked Questions— Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORGANIZATION, [http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm) (2006).

90. Harris, *supra* note 86, at 389–390.

91. *Id.* at 389–391. It took more than four years to ship generic AIDS medications to Rwanda, where two years were spent negotiating between the generic drug manufacturer and the patent holders. *Id.* Concerns over the compulsory license being issued for too short a term—making it difficult for the generic drug maker to recover costs for investing in the manufacture of the medicines—further complicates the issue. *Id.* The scope and duration of a compulsory license is limited by Article 31(c), where the compulsory license must be terminated when the circumstances for the issuance of the compul-

are “so complicated that it will remain virtually unused until the WTO reforms the system to make it less cumbersome and more streamlined” were presented during the TRIPS Council’s October 2010 meeting.<sup>92</sup>

## 2. Actual Use of Compulsory Licensing

Few countries have made use of the TRIPS flexibilities.<sup>93</sup> Over the approximately fifteen years that Article 31 has been in force, only a handful of countries have issued compulsory licenses under its authority, and only one country has issued a compulsory license under the 2003 Paragraph 6 Decision.<sup>94</sup> The disuse of the TRIPS flexibilities and the United States’ and pharmaceutical companies’ negative reactions to South Africa’s 1997 attempt to provide cheaper HIV/AIDS medications led to clarification of TRIPS in the Doha Declaration.<sup>95</sup> Eight years after Doha, and fifteen years after the signing of TRIPS, only fifty-two countries have issued compulsory licenses.<sup>96</sup> Some

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sory license ceases. Hestermeyer, *supra* note 88, at 250. However, an important caveat is that the “legitimate interests of the beneficiary of the license must be adequately protected.” *Id.* This caveat is important because “the beneficiary of a license has to make investments before it can work the license and it would be difficult to find a beneficiary willing to do so if the license is liable to be terminated at any given moment.” *Id.*

92. Harris, *supra* note 86, at 391–392. Concerns over the limited use of the Paragraph 6 mechanism were also discussed at the March 2010 TRIPS Council meeting. *Id.* at 391; see also William New, *WTO Paragraph 6 Meeting Aims At Improved Use Of Health Waiver*, IP WATCH (Oct. 16, 2010, 5:20pm), <http://www.ip-watch.org/weblog/2010/10/16/wto-paragraph-6-meeting-aims-at-improved-use-of-health-waiver/>.

93. *But see* Savoie, *supra* note 87, at 237 (stating that although compulsory licensing has not been utilized extensively, there is a recent trend towards increased issuance of compulsory licenses by developing countries).

94. See generally Harris, *supra* note 86, at 387–390.

95. Savoie, *supra* note 87, at 234; see generally Pier DeRoo, *Public Non-Commercial Use: Compulsory Licensing of Pharmaceutical Drugs in Government Health Care Programs*, 32 MICH. J. INT’L L. 347, 354–359 (2011) (providing a detailed overview of South Africa’s 1997 attempt at National Emergency Compulsory Licensing for HIV/AIDS medications and the negative reactions that followed).

96. Ellen F. M. ‘t Hoen, *THE GLOBAL POLITICS OF PHARMACEUTICAL MONOPOLY POWER: DRUG PATENTS, ACCESS, INNOVATION AND THE APPLICATION OF THE WTO DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH* xv-xvi (2009). “Between 2001 and end 2007, 52 developing and least-developed countries have issued post-Doha compulsory licenses for production or import of generic

countries, particularly Brazil, threaten using compulsory licenses as a negotiation tool to lower drug prices.<sup>97</sup> However, it is the actual use of compulsory licenses that achieves the lowest prices, not mere threats.<sup>98</sup>

Since compulsory licensing is infrequently used, TRIPS has not effectively reduced the price of drugs on a broad scale, which is essential to increasing access to medicines.<sup>99</sup> Newer, more effective drugs are six times more expensive than older treatments where the patents have expired.<sup>100</sup> Further, when compulsory licensing is used, TRIPS limits generic manufacturers to producing only the quantities predefined in each compulsory license.<sup>101</sup> This limitation “curbs the large-scale produc-

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versions of patented medicines, given effect to government use provisions, and/or implemented the non-enforcement of patents.” *Id.* at xvi; *see, e.g., Examples of Health—Related Compulsory Licenses*, CONSUMER PROJECT ON TECHNOLOGY, <http://www.cptech.org/ip/health/cl/recent-examples.html> (last visited Oct. 3, 2011) (listing examples of countries and their issuance of health related compulsory licenses); *see also* Dep’t of Indust. Pol’y & Promotion, *Discussion Paper—Compulsory Licensing*, GOV’T OF INDIA MINISTRY OF COMMERCE & INDUS., at 3 (Aug. 24, 2010), *available at* <http://dipp.nic.in/English/Archive/ArchiveFeed.aspx>; *see also* DeRoo, *supra* note 95, at 358–359.

97. *See* Harris, *supra* note 86, at 387–388. Brazil’s use of its compulsory licensing provision as a negotiation tool has lowered HIV mortality rates by 50% in the 536,000 HIV infected Brazilians. Chow, *supra* note 11, at 454.

98. Tove Iren S. Gerhardsen, *Brazil Takes Steps To Import Cheaper AIDS Drug Under Trade Law*, IP WATCH (May 7, 2007, 1:50pm), <http://www.ip-watch.org/weblog/2007/05/07/brazil-takes-steps-to-import-cheaper-aids-drug-under-trade-law/?res=1280&print=0>. Negotiations between Thailand and Merck, and between Brazil and Merck, for the HIV/AIDS drug efavirenz show that the pharmaceutical companies offered their lowest prices after receiving a compulsory license. *Id.*

Brazil had achieved a price for efavirenz of \$580 per patient per year earlier when it had threatened to use compulsory license. But this was too expensive compared with the price for generics (Thailand was offered \$244 per patient per year after it issued a [compulsory license]), and thus Brazil has paid too much for too many years. . . .

*Id.* Also, when few or no licenses are actually issued, repeated, hollow threats of use erode the negotiating power of the compulsory license. *Id.*

99. Bhatt, *supra* note 35, at 600.

100. *AIDS, Drug Prices and Generic Drugs*, AVERT, <http://www.avert.org/generic.htm> (last visited Feb. 17, 2013) [hereinafter AVERT] (discussing, specifically, pricing of HIV/AIDS drugs).

101. *Id.*

tion that is required to deliver drugs cheaply.”<sup>102</sup> Also, some argue the price of drugs after a compulsory license does not justify the massive intrusion on patent rights because the price is not low enough and is still out of reach for the poor.<sup>103</sup> Moreover, actually granting a compulsory license is not necessary to lower the price of drugs.<sup>104</sup> Market competition and negotiations between large pharmaceutical companies and generic drug manufacturers have proven to lower drug prices. For example, a price war and social pressure, not issuance of a compulsory license between the pharmaceutical company and the generic drug makers, led to AIDS medications being reduced from about \$10,000 per person per year in 1996 to \$295 in 2001.<sup>105</sup>

Further, compulsory licenses have been predominantly issued for health related emergencies of HIV/AIDS, and thus their use has been very limited in scope.<sup>106</sup> In addition, despite compulsory licenses for HIV/AIDS drugs, 14.6 million people globally still lacked access to antiretroviral drugs at the end of 2009, which translates to a mere 36% coverage rate.<sup>107</sup> In the 2011 Millennium Development Goals Report, the WHO stated that it had not reached its 2010 target for universal access to HIV/AIDS treatment.<sup>108</sup> 91% of pregnant women in need of antiretroviral drugs live in largely impoverished sub-Saharan Af-

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102. *Id.*

103. Watson, *supra* note 13, at 154.

104. *See generally* AVERT, *supra* note 100.

105. *Id.*

106. *See* ‘t Hoen, *supra* note 96, at xvi–xvii; DeRoo, *supra* note 95, at 359. *But see* DeRoo, *supra* note 95, at 359–362 (discussing the Thai experience in the January 25, 2007, compulsory licensing of Plavix, a heart disease medication, under the public non-commercial use provision of TRIPS); *but see, e.g.*, Beth Jinks & Suttinee Yuvejwattana, *Thailand to Buy Generic Plavix in India, Snubs Sanofi (Update1)*, BLOOMBERG (July 5, 2007 12:13 PM), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aQ3E3cABtPXU>.

107. *The Millennium Development Goals Report 2011*, UNITED NATIONS, at 41 (2011), [http://www.un.org/millenniumgoals/pdf/\(2011\\_E\)%20MDG%20Report%202011\\_Book%20LR.pdf](http://www.un.org/millenniumgoals/pdf/(2011_E)%20MDG%20Report%202011_Book%20LR.pdf) [hereinafter MDG Report 2011]. *But see* AVERT, *supra* note 100 (“Around 8 million people in low- and middle-income countries are currently receiving drugs to treat HIV/AIDS.”).

108. MDG Report 2011, *supra* note 107, at 41.

rica.<sup>109</sup> Of course, other diseases still run rampant in low and middle-income countries. For example, 90% of malaria deaths still occur in sub-Saharan Africa, and 85% of new tuberculosis cases occur in Asia and Africa.<sup>110</sup>

### 3. Definitional Ambiguities & Ambiguities in Scope

Ambiguities in the interpretation of TRIPS due to the lack of substantive guidelines or definitions also hinder its effective use by increasing the risk of litigation.<sup>111</sup> The Doha Declaration merely stated that individual countries have “the right to determine what constitutes a national emergency or other circumstances of extreme urgency” in deciding to grant a compulsory license, and thus did little to ameliorate the different interpretive approaches of developed and developing countries.<sup>112</sup>

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109. *Id.* at 42.

110. *Id.* at 42, 46. *But see id.* at 47 (“[U]p to 6 million lives have been saved since 1995, thanks to an effective international strategy for the diagnosis and treatment of tuberculosis.”).

111. Gupta, *supra* note 76, at 640, 647, 649. *See also* Hestermeyer, *supra* note 88, at 247 (stating that members may take different views as to the interpretation, but also that a member relying on one interpretation risks litigation from another member relying on a different interpretation); *see also* Gupta, *supra* note 76, at 637 (“Though TRIPS sets forth minimum standards, patent protection is not equivalent in each member state since each state can independently interpret these standards.”).

[M]uch about the interpretation of Article 31 of the TRIPS Agreement remains in doubt and while the right to access to medicine is a useful argument to support a broader, more flexible interpretation, it is merely one argument amongst several. It remains uncertain to what extent it would carry the day in a dispute settlement proceeding. Faced with the uncertainty about the interpretation . . . and pressure exerted by developed countries . . . developing countries have largely foregone imposing such licenses to alleviate health concerns. Indeed, in the wake of the TRIPS Agreement many countries have limited the provisions on compulsory licensing in their laws.

Hestermeyer, *supra* note 88, at 239–253. *But see* Johnston & Wasunna, *supra* note 47, at S17 (noting that a lack of definitions allows member countries to have flexibility to interpret TRIPS to meet their own social and cultural values).

112. *A New World Order*, *supra* note 86, at 1485. Controversy over the scope of a public health crisis exists even after Doha, in which the United States

The flexible scope of compulsory licenses lends to abuse which further instills resistance and suspicion from pharmaceutical companies.<sup>113</sup> For example, Egypt's compulsory license for Pfizer's Viagra tarnishes the reputation of compulsory licensing because erectile dysfunction is clearly a less dire situation and one likely not intended to be covered by the public health exception of TRIPS.<sup>114</sup> Such excessive abuse and over-use of compulsory licensing likely encourages pharmaceutical companies to aggressively resist valid uses of compulsory licenses to prevent over-expansion of scope.<sup>115</sup> In addition to ambiguity in the scope of intended diseases, conflicting interpretations exist in the type of pharmaceutical products intended for compulsory licensing.<sup>116</sup>

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argues that the agreement's officially-listed "HIV/AIDS, tuberculosis, malaria and other epidemics," are the only possible emergencies, in contrast to the developing countries that argue for a broader interpretation. *Id.* at 1485 n.72. *See also* Gupta, *supra* note 76, at 646–647 ("the absence of guidelines, limits or direction as to the definition of [public health problem] will lead to inconsistent application of the provision and further tension," as well as include diseases "not within the Declaration drafter's intent."). Thailand's compulsory license for the heart disease drug, Plavix, was criticized for not satisfying the national emergency requirement, although it was ultimately granted under the "public, noncommercial use" exception. *See, e.g., A New World Order, supra* note 86, at 1486 n.76; *see also* Hestermeyer, *supra* note 88, at 246–247 (arguing that though "access to medicine supports a broad interpretation . . . [n]evertheless, the provision is not very attractive for Members in such a situation, as they are reluctant to label their situation one of emergency because of the effect that would inevitably have on likely investors and tourists.").

113. *See generally* McGill, *supra* note 78, at 87–97 (arguing inconsistencies in countries' interpretation of when to grant compulsory licenses leads to negative consequences).

114. *Id.* at 89–90. Pfizer responded by stopping construction of a manufacturing facility in Egypt and many pharmaceutical companies have avoided investing in Egypt. *Id.*; Egypt's aggressive compulsory licensing has contributed to a decrease in foreign direct investment "from \$948 million in 1987 to \$509.4 million in 2001-02." *Id.*

115. Toni Johnson, *The Debate Over Generic-Drug Trade*, COUNCIL ON FOREIGN REL., <http://www.cfr.org/drugs/debate-over-generic-drug-trade/p18055> (last updated Aug. 3, 2011) ("Some experts . . . contend that drug companies fought so strongly over the licensing of HIV/AIDS drugs because they foresaw that the 'national emergency' line would not end at infectious diseases.").

116. Gupta, *supra* note 76, at 647. Developed countries define "products within the pharmaceutical sector" as products "required by a WTO Member while dealing with public health problems." *Id.* In contrast, developing coun-

The scope of countries that should benefit from compulsory licensing remains another area of contention.<sup>117</sup> Not limiting the scope of applicable nations may create a chilling effect on the types of drugs pharmaceutical companies choose to invest in and develop to avoid the potential for a compulsory license, which hurts developing nations most in need of help.<sup>118</sup> Interpreting the morality exclusion in Article 27(2) also proves difficult, as there is no universally accepted definition.<sup>119</sup>

In addition to causing differing interpretations between countries, the lack of concrete definitions allows countries to alter their position to fit their self-interest and creates potential for abuse.<sup>120</sup> For example, despite the United States' narrow interpretation of TRIPS flexibilities, the United States contradicted itself during the 2001 anthrax scare by suggesting use of a compulsory license for Cipro, a drug that combats the effects of

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tries include "all medications and vaccines, including active pharmaceutical substances used in the prevention and treatment of disease and health care, as well as diagnostic products and products used to administer medicines and vaccines." *Id.*

117. *See id.* at 648. Doha and the Paragraph 6 Decision in referencing "countries with insufficient or no manufacturing capabilities," does not explicitly require that those countries must lack the "resources to purchase medicines from the manufacturer." *Id.* This ambiguity may qualify "small, wealthy nations such as Luxembourg or Singapore" who simply choose not to manufacture certain drugs, even though it may not have been the drafters' intention. *Id.* Other countries interpret Doha and the TRIPS flexibilities as applying to only "developing nations not capable of economically implementing such manufacturing technology . . . . Additionally, it remains unclear exactly what insufficient manufacturing capacity actually means." *Id.*; *see also* Watson, *supra* note 13, at 154 (expressing fear that "middle-income nations will take advantage of compulsory licensing to the detriment of poorer developing countries . . . . Brazil is not Rwanda, which cannot afford to pay.").

118. Gerhardsen, *supra* note 98 (Merck stating that Brazil should not be granted a compulsory license for efavirenz "as the world's 12th largest economy, Brazil has a greater capacity to pay for HIV medicines than countries that are poorer or harder hit by the disease.").

119. Johnston & Wasunna, *supra* note 47, at S10, S17. "[E]valuating patent applications by weighing their impact on *ordre public* and morality will require expertise that is generally not represented in patent offices." *Id.* Arguably, "*ordre public* is not limited to national security but extends to the protection of human, animal or plant life or health and may be applied to inventions that may lead to serious prejudice to the environment." *Id.*

120. *See* McGill, *supra* note 78, at 88.

anthrax.<sup>121</sup> On a related note, as India's government and pharmaceutical industry's capabilities grow, the future of India's willingness to grant compulsory licenses and produce cheap generic drugs for export to other developing countries is questionable.<sup>122</sup> Indian companies may opt to serve their self-interest and become "innovator companies" to compete globally with other large pharmaceutical companies.<sup>123</sup>

The vagueness of Article 30, which allowed a narrow interpretation to be given by the WTO dispute resolution panel, is a further impediment to increasing access to medicines.<sup>124</sup> Calculating adequate remuneration for payment to the patent holder when a compulsory license is issued is another obstacle to successful use of TRIPS flexibilities and is further complicated by the requirement to take the economic value of the authorization into account, as TRIPS does not provide guidance to determine what is 'adequate' and what is the authorization's 'value.'<sup>125</sup> The WTO members' inability to reach a decision regard-

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121. *A New World Order*, *supra* note 86, at 1471 n.7, 1485 n.70 (noting the hypocrisy of the United States, which has challenged compulsory licenses for HIV/AIDS drugs while 25 million people dying from AIDS lack access in Africa, and, at the same time, has suggested use of a compulsory license to address anthrax that was clearly not an actual epidemic where only eleven confirmed cases were cited).

122. *See* Johnston & Wasunna, *supra* note 47, at S18.

123. *Id.* "Since 1970, [Indian] domestic firms have increased in number and since 1999, about 8-10 of these have developed sufficient in house R&D capacity to be able to develop new drug molecules as well as produce bulk drugs. Indeed, some of these large Indian companies have become multinationals themselves." WARREN KAPLAN & RICHARD LAING, LOCAL PRODUCTION OF PHARMACEUTICALS: INDUSTRIAL POLICY AND ACCESS TO MEDICINES, HEALTH, NUTRITION, AND POPULATION FAMILY (HNP) OF THE WORLD BANK'S HUMAN DEVELOPMENT NETWORK (DISCUSSION PAPER) 15 (Joy de Beyer & Alexander S. Preker eds., 2005), available at [http://www.who.int/medicines/technical\\_briefing/tbs/KaplanLocalProductionFinal5b15d.pdf](http://www.who.int/medicines/technical_briefing/tbs/KaplanLocalProductionFinal5b15d.pdf).

124. *See* Hestermeyer, *supra* note 88, at 235 (arguing that the scope of Article 30 exceptions are "notoriously vague," which could have allowed the *Canada—Patent* Panel to interpret it broadly in light of a right to access to medicines, but it failed to do so). *See generally id.* at 234–239; WTO panel decisions are not binding to subsequent decisions. *A New World Order*, *supra* note 86, at 1482 n.54. Nevertheless, subsequent parties and panels usually rely on the prior decision. *Id.*

125. Hestermeyer, *supra* note 88, at 247–249; TRIPS, *supra* note 32, art. 31(h); Chow, *supra* note 11, at 452–453 (listing possible methods to determin-

ing parallel importation created a “fundamental flaw” of ambiguity.<sup>126</sup> In regard to compulsory licensing under the Paragraph 6 Decision, drugs made for export must be distinguishable by special labels, colors, or shapes to prevent trade diversion.<sup>127</sup> However, lack of monitoring guidelines and repercussions makes the re-exportation issue troubling.<sup>128</sup>

#### 4. Limitations Inherent in Developing Countries

Another impediment to the successful use of the TRIPS flexibilities and the successful achievement of its dual goals is the endemic and inherent characteristics of developing countries. Taking advantage of TRIPS flexibilities requires technical expertise, intergovernmental coordination, and legal sophistication, which are often lacking in developing governments.<sup>129</sup> Thus, TRIPS flexibilities often do not benefit the least developed countries most in need of help, and rather help middle income countries such as India and Brazil.<sup>130</sup> Developing countries also lack proper disease diagnosis capabilities, which hinders their ability to request proper quantities and types of medications in a compulsory license.<sup>131</sup> Developing governments

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ing adequate remuneration). “For example, Thailand considers a royalty rate of 0.5% of the total sales to be compliant.” *A New World Order*, *supra*, note 85 at 1488 n.90.

126. Hestermeyer, *supra* note 88, at 234. *See generally id.* at 230–234 (discussing parallel importation and the different interpretations amongst countries).

127. Implementation Agreement, *supra* note 81, ¶ 2(b)(iii).

128. Gupta, *supra* note 76, at 648–649.

129. Johnston & Wasunna, *supra* note 47, at S18–S19.

130. AVERT, *supra* note 100. “But the problem is that these options are limited to countries with political clout and financial stability and autonomy. As is all too often the case, it is the poorest countries already struggling to manage their HIV epidemics that are the least likely to benefit from the current system.” *Id.* *See also* Gerhardsen, *supra* note 98 (relating a statement by Merck that Brazil should not be granted a compulsory license for efavirenz “as the world’s 12th largest economy, Brazil has a greater capacity to pay for HIV medicines than countries that are poorer or harder hit by the disease.”).

131. *See* MDG Report 2011, *supra* note 107, at 44.

More African children are receiving the recommended medicines for malaria, but accurate diagnosis remains critical. Prompt diagnosis and treatment are needed to prevent life-threatening complications

have been criticized for mass military spending when there are existing public health issues, and so they may need to reevaluate their priorities.<sup>132</sup> Developing countries and their citizens may choose to spend funds on food rather than medication, even if costs are reduced, if insufficient funds exist to cover both costs.<sup>133</sup> Additionally, some developing governments are corrupt and may resell medications at higher prices, rather than distributing the drugs to their citizens.<sup>134</sup> A “scrupulous clean hands approach” must be practiced to ensure drugs are actually distributed at the lowest profitable prices, and unfortunately such practices have been questionable.<sup>135</sup> Further, lobbying pressure and conflicting interests may create abusive overuse of compulsory licensing where, for example, “the chairman of a large generic drug manufacturer was also the Chairman of the Health Committee in Egypt’s upper house of

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from malaria. However, accurate diagnosis is critical. The majority of childhood fevers, for example, are not due to malaria, and should not be treated with antimalarial drugs . . . [P]atients [may be] receiving antimalarial medicines who do not, in fact, have the disease.

*Id.*

132. See Savoie, *supra* note 87, at 244 (Thailand has been criticized for granting a compulsory license for Plavix after increasing “military spending by thirty percent, to over one billion dollars, while cutting public health expenditures by twelve million dollars.”).

133. Margo A. Bagley, *Legal Movements in IP: Trips, Unilateral Action, Bilateral Agreements, and HIV/AIDS*, 17 EMORY INT’L L. REV. 781, 794 (2003) (noting that drug costs are not the only factor impacting access to essential medicines).

134. Whobrey, *supra* note 12, at 633.

The incentives created by parallel importation encourages governments to favor profits over people, and since many governments in developing countries are unstable and may be prone to corruption, the general public in [least-developed countries] sees neither the critical medications nor realizes any benefits or improvements from the sale of the drugs.

*Id.*

135. Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 247, 254 (2009). “The level of compensation was questionable in the Thais’ treatment of Plavix, the compulsory license on Viagra in Egypt was tainted by the appearance of impropriety and self dealing, and complaints about ‘shadow pricing’ in some Latin American countries merit serious attention.” *Id.*

Parliament at the time the [Viagra] compulsory license was issued [in Egypt].”<sup>136</sup>

### *B. Impediments & Threats*

#### 1. Retaliation by Pharmaceutical Companies

Developing countries are cautious in using compulsory licenses to avoid alienating powerful pharmaceutical companies and business repercussions.<sup>137</sup> Pharmaceutical companies “bring jobs and investments to developing countries.”<sup>138</sup> After Thailand issued a compulsory license for Abbott’s HIV drug, Kaletra, Abbott stated it would not sell certain drugs in Thailand and withdrew seven new drug applications from Thailand.<sup>139</sup> Pharmaceutical companies have also stated that compulsory licenses destroy the incentive to research and develop drugs to treat diseases affecting developing countries.<sup>140</sup>

#### 2. Retaliation by Developed Countries

In addition to retaliation by pharmaceutical companies, developing countries also fear retaliation by developed countries. The possibility of trade sanctions imposed by developed countries against developing countries eliminates the benefits of granting a compulsory license because any costs saved by the

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136. Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 283, 306–07 (2008).

137. See Harris, *supra* note 86, at 392–393. The forcefulness of the pharmaceutical industry’s response in Thailand and Brazil “may have a discouraging effect on smaller economies considering similar public health actions but lack the legal or political resources to defend themselves on the global stage.” Gerhardsen, *supra* note 98.

138. Harris, *supra* note 86, at 392. Brazil’s decision to grant a compulsory license for Merck’s HIV/AIDS drug could divert investments from Brazil. Gerhardsen, *supra* note 98.

139. Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands from Fiction Under TRIPS*, 34 N.C. J. INT’L L. & COM. REG. 317, 444 (2009) [hereinafter *Patent Breaking or Balancing?*].

140. Watson, *supra* note 13, at 153; see Johnston & Wasunna, *supra* note 47, at S17.

cheaper medications are offset by other economic sanctions.<sup>141</sup> For example, the United States' Special 301 Watch-List Reports lists countries with inadequate IP protection and allows imposition of trade sanctions against the offenders.<sup>142</sup> Threat of trade sanctions by the United States, which is Thailand's biggest export market, forced Thailand to stop producing a generic version of the HIV drug, didanosine, and amend its domestic laws to restrict compulsory licenses and parallel importation.<sup>143</sup> Increase in border protection measures to prevent harmful counterfeit drugs may also be another form of retaliation by developed countries and is a barrier to access to medicines.<sup>144</sup> The 2003 European Union border regulations have led to the seizure of significant quantities of drugs, most of which originated in India and was bound for developing countries such as Nigeria and Ecuador.<sup>145</sup>

Developed countries also deviate outside of TRIPS to bind developing countries to more extensive patent protections

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141. *Patent Breaking or Balancing?*, *supra* note 139, at 447–48. “On why Brazil has not issued a CL before [2007], [t]he most obvious reason is the fear of an open conflict with the United States.” Gerhardsen, *supra* note 98. “The Thai case, and the recent 301 list report (IPW, US Policy, 30 April 2007), indeed shows that despite the Doha Declaration and all the commitments made, the US is ready to be extremely aggressive . . .” *Id.*

142. *Patent Breaking or Balancing?*, *supra* note 139, at 448–49; Watson, *supra* note 13, at 151–153 (Brazil, South Africa, and Thailand have all at some point been placed on the 301 Watch-List).

143. Johnston & Wasunna, *supra* note 47, at S19.

144. See Harris, *supra* note 86, at 393; see generally Catherine Dounis, *Enforcing IP Rights Via EU Border Regulations: Inhibiting Access to Medicine or Preventing Counterfeit Medicine?*, 36 BROOK. J. INT'L L. 717 (2011).

145. Seuba Xavier, *Border Measures Concerning Goods Allegedly Infringing IP Rights: The Seizures of Generic Medicines in Transit 1* (International Centre for Trade and Sustainable Development, Geneva, Switzerland, Working Paper, 2009), available at [http://www.iprsonline.org/New%202009/Seuba\\_Border%20Measures.pdf](http://www.iprsonline.org/New%202009/Seuba_Border%20Measures.pdf).

In February 2009 a shipment of second-line generic ARV drugs was confiscated by Dutch customs authorities. The 49kg of abacavir sulfate tablets produced by an Indian company, Aurobindo, were bound for a treatment programme in Nigeria. The tablets were later released but the seizure highlighted tensions between the European Union's rules on IP rights and World Trade Organization rules concerning the production of generic medicines.

AVERT, *supra* note 100.

through bilateral and regional free trade agreements (“FTAs”).<sup>146</sup> Often these FTAs limit the use of TRIPS flexibilities, impose stricter IP standards, and contain data exclusivity provisions.<sup>147</sup> Appropriately, such agreements are commonly called “TRIPS-plus free trade agreements.”<sup>148</sup> Despite the negative effect on access to medicines, developing countries agree to FTAs to appease and build a relationship with a powerful developed country hoping to gain benefits in other trade areas.<sup>149</sup> Further, developing countries have less leverage to negotiate favorable terms in FTAs where the agreements are often between only two countries of unequal negotiating powers and thus the developing country lacks the support of other countries.<sup>150</sup> As of early 2013, the United States has FTAs with twenty countries.<sup>151</sup> Recently, on October 1, 2011, the United States signed the Anti-Counterfeiting Trade Agreement (“ACTA”) which has been highly criticized for exceeding TRIPS limitations to a significant degree, violating human rights, and severely affecting access to medicines.<sup>152</sup>

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146. See generally Hestermeyer, *supra* note 88, at 289–292 (discussing the challenges posed by FTAs and BITs). TRIPS imposes only minimum standards of IP protection and explicitly allows countries to impose stricter IP regimes “as long as it does not contravene” TRIPS. Bagley, *supra* note 133, at 792.

147. Harris, *supra* note 86, at 393–394. Provisions exceeding TRIPS standards are usually referred to as TRIPS-plus provisions. Hestermeyer, *supra* note 88, at 289.

148. Bhatt, *supra* note 35, at 617–618.

149. *Id.* at 618. As of 2003, there were at least twenty-three bilateral and regional FTAs containing TRIPS-plus provisions and which affect more than 150 developing countries. Bagley, *supra* note 133, at 792–93.

150. See Hestermeyer, *supra* note 88, at 291.

151. *Free Trade Agreements*, OFF. U.S. TRADE REPRESENTATIVE, <http://www.ustr.gov/trade-agreements/free-trade-agreements> (last visited Apr. 11, 2013) (listing the current FTAs in which the United States is a party).

152. See Ante, *ACTA will be Signed Saturday*, FOUND. FOR FREE INFO. INFRASTRUCTURE (Sep. 27, 2011), <http://acta.ffii.org/?p=779>; see generally Guadalupe A. Lopez, *From Trips to ACTA: Establishing the Intent to Uphold Access to Medicine in the Face of Ambiguity*, NAT'L L. REV. (Apr. 22, 2011), <http://www.natlawreview.com/article/trips-to-acta-establishing-intent-to-uphold-access-to-medicine-face-ambiguity>. See *Anti-Counterfeiting Trade Agreement (ACTA)*, OFFICE OF THE U.S. TRADE REPRESENTATIVE, <http://www.ustr.gov/acta> (last visited Nov. 4, 2011) (listing signing members

## 3. Legal Challenges

Legal challenges to domestic implementation of compulsory licensing laws and to compulsory license grants also hinder the effectiveness of TRIPS, as such challenges delay access to essential medicines and add costs to seeking a compulsory license. In 1997, with the support of the U.S. government, forty pharmaceutical companies sued the South African government claiming that the South African Medicines and Related Substances Control Amendment Act of 1997 violated TRIPS.<sup>153</sup> Similarly, in 2000, the United States challenged the compulsory licensing provisions of the Brazilian Industrial Property Law in a petition to the WTO Dispute Settlement Body.<sup>154</sup> As of 2012, Indian generic manufacturers Cipla and Natco face separate patent infringement lawsuits in the Delhi High Court by Bayer Pharmaceuticals for its patented cancer drug Nexavar.<sup>155</sup>

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and access to full text of ACTA); see *ACTA Fact Sheet*, OFFICE OF THE U.S. TRADE REPRESENTATIVE, <http://www.ustr.gov/acta-fact-sheet-march-2010> (Mar. 2010) (providing information on the goals of ACTA); see *ACTA: Meeting U.S. Objectives*, OFFICE OF THE U.S. TRADE REPRESENTATIVE, <http://www.ustr.gov/about-us/press-office/fact-sheets/2011/september/acta-meeting-us-objectives> (Oct. 2011) (explaining that “ACTA is consistent with existing U.S. law and does not require the enactment of implementing legislation.”).

153. McGill, *supra* note 78, at 87–88. The Act attempted to allow generic production of patented antiretroviral HIV drugs. *Id.* However, public outcry eventually forced the pharmaceutical companies to withdraw the suit. *Id.* The United States also placed South Africa on its Special 301 Watch List and attempted to challenge the Act’s validity before a WTO panel before withdrawing due to public pressure. Watson, *supra* note 13, at 152.

154. Chow, *supra* note 11, at 454–546. Again, the United States withdrew the WTO challenge in exchange for Brazil’s agreement to hold negotiations with the United States prior to granting any compulsory license. *Id.*

155. Varun Chhonkar, *Nexavar: Compulsory license will severely impact global pharma companies*, PATENT CIRCLE (Aug. 11, 2011, 12:23 PM), <http://patentcircle.blogspot.com/2011/08/nexavar-compulsory-license-will.html>. Bayer’s lawsuit, filed in March 2010 against Cipla for its marketing of a generic version of Nexavar, is currently pending in the Delhi High Court. *Id.* In May 2011, Bayer also filed an infringement lawsuit against Natco in response to Nacto’s compulsory license request. *Id.*; see HIGH COURT OF DELHI, *Status of Cases: Orders/Judgments of [CS(OS)1090/2011]*, [http://delhihighcourt.nic.in/dhc\\_case\\_status\\_oj\\_list.asp?pno=577484](http://delhihighcourt.nic.in/dhc_case_status_oj_list.asp?pno=577484) (last visited Dec. 20, 2011) (for court documents and status of the case —*Bayer Corporation & Anr vs. Natco Pharma Limited*); see HIGH COURT OF DELHI, *Status of Cases: Orders/Judgments of [CS(OS)523/2010]*,

### III. SPECIAL CHALLENGES IN ACCESS TO CHRONIC DISEASE MEDICATIONS

A current shift in focus from infectious disease compulsory licensing to chronic disease compulsory licensing poses new implications for patent holders and those who seek access to such medicines.<sup>156</sup> “Compulsory licensing practices, however, continue to expand from responding to purely national emergencies toward addressing everyday health care.”<sup>157</sup> As the U.N. Secretary General Ban Ki-moon noted:

Commonly known as chronic or lifestyle-related diseases, the main non-communicable diseases are cardiovascular diseases, diabetes, cancers and chronic respiratory diseases. While the international community has focused on communicable diseases such as HIV/AIDS, malaria and tuberculosis, the four main non-communicable diseases have emerged relatively unnoticed in the developing world and are now becoming a global epidemic.<sup>158</sup>

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[http://delhihighcourt.nic.in/dhc\\_case\\_status\\_oj\\_list.asp?pno=535397](http://delhihighcourt.nic.in/dhc_case_status_oj_list.asp?pno=535397) (last visited Dec. 20, 2011) (court documents and status of the case —*Bayer Corporation & Anr. Vs. Cipla Ltd.*); see generally *Indian Pharma Patent Cases*, PATENT DAILY, <http://patentdaily.wordpress.com/indian-pharma-patent-cases/> (last visited Dec. 20, 2011) (listing a summary of pharmaceutical patent infringement lawsuits filed in India).

156. See generally Savoie, *supra* note 87.

157. DeRoo, *supra* note 95, at 354.

158. U.N. Secretary-General, *Prevention and Control of Non-communicable Diseases*, at 1, U.N. Doc. A/66/83 (May 19, 2011).

In 2008, 36 million people died from non-communicable diseases, representing 63 per cent of the 57 million global deaths that year [and 80 per cent of those deaths occurred in the developing world]. In 2030, such diseases are projected to claim the lives of 52 million people . . . . While non-communicable diseases have traditionally afflicted mostly high income populations, current evidence shows that the spread of such diseases is associated with increasing levels of development. Death and disease from non-communicable diseases now outstrip communicable diseases in every region except Africa, where the rate of such diseases is quickly rising. By 2030, non-communicable diseases are projected to cause nearly five times as many deaths as communicable diseases worldwide, including in low- and middle-income countries.

Developing countries are beginning to view “cancer as no less serious than HIV/AIDS.”<sup>159</sup> Thailand’s 2007 compulsory license for the blood thinner Plavix (used to treat heart disease) was likely motivated by data estimating thirty thousand cancer deaths annually compared to twenty-one thousand AIDS related deaths in Thailand in 2006.<sup>160</sup> Similarly, the Indian generic drug maker, Natco, cited over 24,000 Indian deaths per year in its compulsory license application for Bayer’s liver and kidney cancer drug, Nexavar.<sup>161</sup>

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*Id.* at 2; see David Brennan, former chief executive of AstraZeneca, Address on Behalf of AstraZeneca to the World Health Assembly (May 17, 2011), available at [http://www.ifpma.org/fileadmin/content/Events/Other\\_IFPMA\\_Events/17\\_May\\_2011/David\\_Brennan\\_Speech\\_Luncheon\\_17May2011.pdf](http://www.ifpma.org/fileadmin/content/Events/Other_IFPMA_Events/17_May_2011/David_Brennan_Speech_Luncheon_17May2011.pdf) (WHO research shows that 90% of deaths from non-communicable diseases are in developing countries, and will increase by 17% by 2015. Africa is seeing the greatest increase by 27% compared to Europe’s 6% increase); see generally *Raising the Priority of Non-communicable Diseases in Development Work at Global and National Levels*, WORLD HEALTH ORGANIZATION, [http://www.who.int/nmh/events/2010/ncd\\_facts\\_20100913.pdf](http://www.who.int/nmh/events/2010/ncd_facts_20100913.pdf) (2010) [hereinafter *Raising the Priority*].

159. *The 10 burning questions on the Government Use of Patents on the four anti-cancer drugs in Thailand*, THE MINISTRY OF PUBLIC HEALTH AND THE NATIONAL HEALTH SECURITY OFFICE THAILAND, at 2, [http://www.moph.go.th/hot/Second\\_white\\_paper\\_on\\_the\\_Thai\\_CL\\_%5BEN%5D.pdf](http://www.moph.go.th/hot/Second_white_paper_on_the_Thai_CL_%5BEN%5D.pdf) (Feb. 2008).

160. Johnson, *supra* note 115. In 2005, heart disease was estimated to be the second leading cause of death in Thailand. Porapakkham et al., *Estimated causes of death in Thailand, 2005: implications for health policy*, POPULATION HEALTH METRICS (May 18, 2010), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2885317/ppd/1478-7954-8-14.pdf>.

161. OFFICIAL JOURNAL OF THE PATENT OFFICE, No. 32/2011, at 13349, Dec. 8, 2011 (India), available at [http://dontradeourlivesaway.files.wordpress.com/2011/09/official\\_journal\\_12\\_082011\\_part\\_i.pdf](http://dontradeourlivesaway.files.wordpress.com/2011/09/official_journal_12_082011_part_i.pdf) [hereinafter *Natco CL Request*]. “In 2008 approximately 20,144 cases of [liver cancer] were reported in India, and more than 18,043 Indians died of [liver cancer].” *Id.* at 13347. “In 2008, about 8,900 Indians were diagnosed with kidney cancer, and about 5,733 died from the disease.” *Id.* at 13348. Natco argues that Bayer’s life-saving product is exorbitantly priced and of limited availability in India, and Indians “should be able to access this drug irrespective of their caste, creed, affordability etc.” *Id.* at 13352. Natco states that it can price the generic version “31 times cheaper than Bayer’s sorafenib tosylate [commonly known as Nexavar] or 3% of the price at which Bayer sells the drug in India.” James Love, *Update on the So-*

Developing countries, despite evidence of growing deaths from chronic disease within their populations, face special challenges in using compulsory licenses to combat chronic diseases as compared to infectious disease compulsory licensing. First, the Doha Declaration uses language of epidemics and infectious disease.<sup>162</sup> Second, lack of public attention and misconception that chronic disease affects only wealthy countries removes pressure on pharmaceutical companies to provide such medications at affordable prices for populations in developing countries.<sup>163</sup> Further, because chronic diseases can be combated by non-pharmaceutical means, it may be more difficult for developing countries to cite compulsory license use as necessary.<sup>164</sup> Lastly, expanding the scope of compulsory licenses to chronic diseases will likely be met by even stronger resistance from pharmaceutical companies because the inclusion of “chronic, non-communicable diseases like cancer hits at the

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*rafenib Tosylate Compulsory Licensing Case in India*, KNOWLEDGE ECOLOGY INT’L (Oct. 10, 2011, 4:32 PM), [http://lists.keionline.org/pipermail/ip-health\\_lists.keionline.org/2011-October/001392.html](http://lists.keionline.org/pipermail/ip-health_lists.keionline.org/2011-October/001392.html).

162. Doha Public Health Declaration, *supra* note 70, ¶ 5(c) (“[I]t 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.”).

163. See McGill, *supra* note 78, at 88; see Savoie, *supra* note 87, at 239. Advocacy efforts supporting compulsory licenses have focused on access to HIV/AIDS medications. *Id.* Pharmaceutical companies are likely to avoid the public relations nightmare faced when they attempted to sue South Africa after its passage of the Medicine and Related Substance Control Amendment Act of 1997, intended to begin generic product of HIV drugs. *Id.*; see generally MDG Report 2011, *supra* note 107 (failing to include chronic disease as a development, but including infectious diseases); see *Preventing Chronic Diseases a Vital Investment*, WORLD HEALTH ORGANIZATION, [http://www.who.int/chp/chronic\\_disease\\_report/contents/part1.pdf](http://www.who.int/chp/chronic_disease_report/contents/part1.pdf) (2005) at 4, 8–10 (explains ten widespread misunderstandings about chronic disease and the reality).

164. See *Raising the Priority*, *supra* note 158, at 3–4 (noting that chronic diseases are preventable by life-style changes such as tobacco use, diet, physical activity, and alcohol use). In contrast, the “WHO recommends that countries use a combination of antimalarial medicines to reduce the risk of drug resistance” as the best treatment for the infectious disease of malaria. *What is the best treatment against malaria? Why combine drugs?*, WORLD HEALTH ORGANIZATION, <http://www.who.int/features/qa/26/en/index.html> (2009) (last visited May 10, 2012).

heart of the drug industry's profit model."<sup>165</sup> For example, a dramatic decline in foreign direct investment and research establishments was seen in Thailand after it granted a compulsory license for a heart disease medication in 2007.<sup>166</sup>

#### IV. RECOMMENDATION & PROPOSAL

The shortcomings of TRIPS reveal that compulsory licensing is an ineffective solution to the problem of access to essential medicines. The impediments of TRIPS further illuminate the likely inability of TRIPS to effectively cope with the increasing global threat of chronic diseases. Drug prices need to be reduced in order to increase access to medicines. However, broad-range compulsory license use is not a viable solution because it jeopardizes the research and development structure of pharmaceutical companies.<sup>167</sup> Pharmaceutical companies argue that strict patent laws and high drug prices are necessary to recoup large research and development costs ("R&D").<sup>168</sup> Thus, to low-

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165. Johnson, *supra* note 115. See also Savoie, *supra* note 87, at 241 ("Medications for chronic diseases play a much larger role in pharmaceutical portfolios than do medications for infectious diseases such as HIV/AIDS."). Pharmaceutical companies focus drug discovery on chronic disease because "patients look forward to months, even years, of treatment" and hence prolonged profits whereas infectious disease often only requires short-term therapy. Steven J. Projan, *Why is Big Pharma Getting Out of Antibacterial Drug Discovery?*, 6 CURRENT OPINION MICROBIOLOGY 427, 428 (2003).

166. McGill, *supra* note 78, at 91 ("Gross private investment growth fell from 10.6% to .5% in 2007, its lowest since 2000" largely due to the \$10 billion decline in foreign direct investment in 2007).

167. DeRoo, *supra* note 95, at 354. "Given that pharmaceutical companies make a marginal profit of less than 20% across all their products the view that pharmaceuticals are 'grossly overpriced' is at best naïve and for the development of novel [products] it is fatal." Projan, *supra* note 165, at 428.

168. Johnson, *supra* note 115.

Research and development averages between ten and fifteen years in the United States and is included as part of the twenty-year patent—meaning the average drug patent, once on the market, lasts about eleven years, according to the lobby group PhRMA. R&D for 2010 was about \$67 billion, growing less than \$11 billion between 2006 and 2010 . . . . Few drugs ever recoup their R&D costs, notes PhRMA, and even fewer ever reach the incredible earning potential of a drug such as Lipitor, which made nearly \$11 billion in sales in 2010 but expired in the United States in 2011. Overall, drug compa-

er drug prices, the current business model of recouping R&D costs through profits should be adjusted. A new business model to recoup R&D costs, while lowering prices, should be approached through funding and incentives.<sup>169</sup> R&D models built on public-private partnerships<sup>170</sup> that help in financing and product development may help promote efficiency, access, innovation, and information sharing.<sup>171</sup> Alternative sources of funding R&D through partnership efforts, rather than expanding the scope of compulsory licenses, should be used to lower drug prices and increase access.<sup>172</sup> If alternative sources of funding are used, rather than the current business model of using profits to recoup R&D costs, then pharmaceutical companies should be more willing to lower drug prices and reduce resistance to compulsory licenses. A funding approach that relies less on recouping R&D costs will also encourage development of drugs that may primarily benefit developing countries<sup>173</sup> because, despite the lower profit potential, a greater

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nies are spending less on research and bringing fewer drugs to market than a decade ago.

*Id.* But see Bob Young & Michael Surrusco, *Rx R&D Myths: The Case Against The Drug Industry's R&D "Scare Card,"* PUBLIC CITIZEN, July 2001 (arguing that the pharmaceutical industry's claim that extraordinary profits are needed "to fund expensive, risky and innovative research and development [R&D] for new drugs" is misleading).

169. See Brennan, *supra* note 158 (relating a statement of interest made by the CEO of AstraZeneca regarding working together to create "commercially sustainable business models" that enable healthcare access to more people).

170. See Frederick M. Abbott, *IP and Public Health: Meeting the Challenge of Sustainability* 32 (GLOBAL HEALTH PROGRAMME, GENEVA, SWITZERLAND, WORKING PAPER NO. 7/2011, Nov. 15, 2011). Such public-private organizations include the Bill & Melinda Gates Foundation, Drugs for Neglected Diseases initiative ("DNDi"), and the Medicines Patent Pool ("MPP"). *Id.*

171. See generally *id.*

172. See James Love, *Will the UN backtrack on accessible medicine?*, CENTER FOR HEALTH HUMAN RIGHTS & DEVELOPMENT, <http://www.cehurd.org/2011/10/will-the-un-backtrack-on-accessible-medicine/> (Oct. 31, 2011) ("Developing countries cannot improve access to cancer drugs unless they grant more compulsory licenses on patents, or undertake more fundamental and radical changes in the way research and development . . . for cancer drugs is financed.").

173. See DRUGS FOR NEGLECTED DISEASES INITIATIVE, <http://www.dndi.org/overview-dndi.html> (last visited Dec. 20, 2011). DNDi is

percentage of revenues will constitute pure profit and will not count against R&D expenses.<sup>174</sup> Such a result will hopefully close the “10/90 research gap,” a disparity resulting from only 10% of the worldwide R&D being devoted to health problems that affect the poorest 90% of the world’s population.<sup>175</sup>

Further, compulsory licenses should be limited in scope to increase legitimacy, decrease resistance and fear of retaliation, and decrease abuse. If the scope of compulsory licenses is better defined, then all players would have proper notice. More specifically, if pharmaceutical companies are re-assured that a compulsory license would not open a floodgate and destroy a wide-array of patents, they will be more willing to acquiesce.<sup>176</sup> Similarly, better guidance will help the least developing countries to invoke legitimate compulsory licenses and prevent abusive use of compulsory licensing, such as Viagra in Egypt and Cipro in the United States.<sup>177</sup> Minimizing discretionary use will bring legitimacy to the compulsory license process.<sup>178</sup> However,

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a public-private partnership that promotes research and development for neglected diseases that often afflict developing populations. *Id.*

174. See generally *Research and Development*, WORLD HEALTH ORGANIZATION, <http://www.who.int/trade/glossary/story079/en/index.html> (last visited Dec. 20, 2011).

175.

The 10/90 research gap refers to the finding that only 10% of the US\$55 billion global spending on health research is devoted to diseases or conditions that account for 90% of the global burden of disease. For each year of potential life lost in the industrialized world, more than 200 times as much is spent on health research as is spent for each year lost in the developing world.

*Id.*

176. Johnson, *supra* note 115 (“[D]rug companies fought so strongly over the licensing of HIV/AIDS drugs because they foresaw that the ‘national emergency’ line would not end at infectious diseases.”); *Nexavar to Storm India: Compulsory License Plea Filed*, BIOSPECTRUM, <http://www.biospectrumasia.com/content/020911IND17008.asp> (Sept. 2, 2011) (last visited May 10, 2012) (“[E]xtensive use of compulsory licenses will in the long-term undermine and threaten the patent system.”).

177. See McGill, *supra* note 78, at 88–96 (arguing that the “[c]itizens of the most underdeveloped countries have suffered as a result of the discretionary allowances of the Doha Declaration.”).

178. *Id.* at 75 (“Unchecked discretion for compulsory licensing has made compulsory licenses a dirty word for economic development and erected a

some flexibility in scope is necessary to allow adaptation of compulsory licenses to changing global disease threats.<sup>179</sup>

TRIPS should therefore be amended to require WTO panels to take a more active role in compulsory license applications, as opposed to allowing complete discretion on the part of national governments.<sup>180</sup> Since approving generic production of a patented medication already may take several years—due to the various obstacles discussed above—WTO panel decisions will not significantly prolong the process.<sup>181</sup> To determine whether a compulsory license is necessary and the claimed disease is a true national public health emergency,<sup>182</sup> the WTO panel should use an analysis akin to U.S. courts' strict scrutiny test as applied to laws infringing on U.S. citizens' Constitutional rights.<sup>183</sup> The WTO panel should consider the national disease burden as well as the country's ability to cope, the marketed price of the patented medication compared to the proposed

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barrier between generic drugs and the least developed countries that need them.”).

179. *See id.* at 83 (arguing that “a pre-determined list of diseases that may benefit from compulsory licensing is not in the public's best interest; diseases that threaten public health mutate, evolve, and present unforeseeable degrees of gravity, mortality, contagiousness, and treatability.”).

180. *See id.* at 97 (“An administrative body through the WTO with representatives from both developed and developing countries may be in a better position to determine when countries may issue a compulsory license” and give developing countries a louder voice).

181. *See Cipla Launches Nexavar Generic at 1/10th of Bayer's Price*, MONEY CONTROL, [http://www.moneycontrol.com/news/business/cipla-launches-nexavar-generic-at-110thbayer39s-price\\_450770.html#](http://www.moneycontrol.com/news/business/cipla-launches-nexavar-generic-at-110thbayer39s-price_450770.html#) (Apr. 8, 2010) (last visited May 10, 2012) (“Bayer has succeeded in blocking the launch of [the] generic version [of the patented drug Nexavar] for two years by filing a writ petition in Delhi High Court . . .”).

182. *See Reichman, supra* note 135, at 254 (noting an argument for “[n]arrowly tailored licenses that focus on real public health needs and avoid the appearance of impropriety, and that also ensure consumers actually obtain lower prices.”).

183. *See United States v. Carolene Products Co.*, 304 U.S. 144, 155 n.4 (1938). U.S. courts apply strict scrutiny where a fundamental U.S. Constitutional or a fundamental right is infringed. *Strict Scrutiny*, LEGAL INFORMATION INSTITUTE (Aug. 19, 2010), [http://www.law.cornell.edu/wex/strict\\_scrutiny](http://www.law.cornell.edu/wex/strict_scrutiny). To pass strict scrutiny, the policy must be justified by a compelling government interest, narrowly tailored, and be the least restrictive means for achieving the interest. *Id.*

price of the generic, the consumer's ability to pay, and market availability of the patented drug.<sup>184</sup> The panel should also weigh the harm to the pharmaceutical company's profit and future floodgate impact.<sup>185</sup>

In addition to a strict scrutiny analysis by a WTO panel prior to the compulsory license, TRIPS Article 31(b)<sup>186</sup> should be amended to require good-faith prior negotiations even during a public health emergency. This will also hopefully reduce the burden and amount of cases that reach the proposed WTO panel. Pharmaceutical companies and developed countries would be less resistant to compulsory licenses if they felt they had a say in license determinations. In fact, because negotiations prior to compulsory licensing are already in practice and expected,<sup>187</sup> such an amendment would not be a drastic departure from current practice. A timeline for deal-making negotiations should be clearly established in TRIPS, limiting parties' negotiation period to a set number of days before a compulsory license can be filed with the proposed WTO panel.<sup>188</sup> After the deadline for negotiations expires, the WTO panel would then be compelled to step in and conduct its strict scrutiny analysis. Further, to prevent a party from stalling or refusing to negotiate, negotiations must be conducted in good faith, and the WTO

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184. See Reichman, *supra* note 135, at 254; see generally Natco CL Request, *supra* note 161.

185. See generally Brennan, *supra* note 158; See also *Public Policy Position: Compulsory Licensing*, MERCK (July 2008), [http://www.merck.com/about/views-and-positions/compulsory\\_licensing2009.pdf](http://www.merck.com/about/views-and-positions/compulsory_licensing2009.pdf).

186. TRIPS, *supra* note 32, art. 31(b).

187. See Chow, *supra* note 11, at 454–546. The United States withdrew the WTO challenge to Brazil's compulsory licensing provisions of the Brazilian Industrial Property Law in exchange for Brazil's agreement to hold negotiations with the United States prior to granting any compulsory license. *Id.* See also Natco CL Request, *supra* note 161, at 13358.

188. See *Natco Pharma Applies for India's First Compulsory License*, ALL ABOUT PATENTS (Aug. 2, 2011, 9:14 PM), <http://patentsind.blogspot.com/2011/08/natco-pharma-applies-for-indias-first.html>. Indian patent law requires a three year waiting period after a patent is granted before a compulsory license may be filed. *Id.* See also Natco CL Request, *supra* note 161, at 13354.

panel should consider in its analysis whether good faith negotiations occurred.<sup>189</sup>

The narrowed scope of the compulsory license should be balanced with a market approach to provide access to a broad range of medicines. Global pharmaceutical companies should be encouraged to compete with generic drug makers through government incentives and sell needed patented medication using a three-tier pricing system.<sup>190</sup> To encourage pharmaceutical companies to compete with generic drug manufacturers, governments should incentivize local manufacture by the global pharmaceutical company.<sup>191</sup> The demand for generic drugs exists in developing countries, hence there is a marketplace and thus a profit potential as well.<sup>192</sup> Local manufacture and

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189. Natco's December 6, 2010, letter requesting a license was turned down "point blank, without any discussion whatsoever" in a refusal letter sent three weeks later, on December 27, by patentee Bayer. *Id.* at 13358–59.

190. See Watson, *supra* note 13, at 154–57.

191. See generally KAPLAN & LAING, *supra* note 123. It is important to note that because generic production occurs only in countries that have manufacturing capability, global pharmaceuticals need only locally manufacture in middle-income developing countries where generic competitors exist. *Id.* Middle-income developing countries presumably have more political stability than low-income developing countries and so the risk of local manufacture is less, although inherently present. *Id.* Governments of middle-income developing countries, like India, Thailand, and Brazil, also have more ability to provide incentives for local manufacture. *Id.*

192. See THE WORLD MEDICINES SITUATION, WHO/EDM/PAR/2004.5 (2004), at 31–41.

The global generic medicines market is worth over US\$ 80 billion, about 30% of total sales . . . . In high-income countries, "originator" (patented) pharmaceuticals account for two-thirds of sales and the share of these in total sales grew substantially from 1990 to 2000. In low-income countries, these ["originator" (patented)] pharmaceuticals account for only about one-third of total sales. Generic pharmaceuticals represent almost two-thirds of total sales in low-income countries and about 60% of sales in middle-income countries. Branded generics are much more important than unbranded generics in sales. Some countries in transition have experienced a rapid change in the composition of their pharmaceutical sales, with generics rapidly being replaced by originator brands or by pharmaceuticals made under licence from originators.

*Id.* at 31.

competition by global pharmaceutical companies with generic drug manufacturers would reduce the problem of patent infringement, eliminate the need for broad scope compulsory licenses, and provide for a wider range of drugs accessible to developing countries. Local manufacture will also give pharmaceutical companies greater control of their product as well as provide developing countries with safer drugs.<sup>193</sup> Global pharmaceuticals should be free to then open factories in developing countries and compete with local generic manufacturers, thus offering healthy market competition.<sup>194</sup> However, since generic drugs are sold more cheaply, global pharmaceuticals will have to develop a differential pricing system to effectively compete with the generic drug makers.<sup>195</sup>

Pharmaceutical companies should differentially price drugs in low-income developing countries, middle-income developing countries, and developed countries according to the national median urban income in the respective country category.<sup>196</sup>

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193. See Johnson, *supra* note 115.

[I]mporting inexpensive patented drugs and generics from other countries will erode safety standards . . . . And some experts note a massive influx of generic drugs could help mask increases in the counterfeit drug trade, already a multibillion dollar industry and expected to see a 90 percent jump in global sales from 2005 to 2010. The U.S. Food and Drug Agency estimates counterfeit drugs represent as much 30 percent of all drugs sold in some developing countries, but amount to less than 1 percent of drugs in the developed world.

*Id.* The majority of private manufacturers in India are “small-scale and have problematic quality assurance systems and procedures.” KAPLAN & LAING, *supra* note 123, at 15.

194. See McGill, *supra* note 78, at 90–91. Global pharmaceuticals have previously built manufacturing facilities in developing countries. See *id.* Pfizer was in the process of constructing a manufacturing facility in Egypt before Egypt granted a compulsory license for Viagra. *Id.* Some companies have also set up research establishment in Thailand and more would have been built had Thailand not been aggressive in its compulsory licensing. *Id.*

195. See generally Whobrey, *supra* note 12 (suggesting a 2-tier pricing structure based on GDP).

196. See generally PRASHANT YADAV, DIFFERENTIAL PRICING FOR PHARMACEUTICALS: REVIEW OF CURRENT KNOWLEDGE, NEW FINDINGS AND IDEAS FOR ACTION, U.K. DEPARTMENT FOR INTERNATIONAL DEVELOPMENT (2010), *available at* <http://www.accesstomedicineindex.org/sites/www.accesstomedicineindex.org/f>

Prices set at the urban population's income levels, rather than the rural population, will be more economically feasible for global pharmaceutical companies.<sup>197</sup> Further, a three-tier pricing system will allow pharmaceutical companies to balance lower prices in developing countries with the higher prices in developed countries. Because the majority of sales occur in developed countries, lower prices in developing countries will not be a significant burden on profits.<sup>198</sup> Such reduced profits should be considered as "additional" profits that otherwise would not exist, instead of being negatively viewed as "reduced" profits. Moreover, to incentivize pharmaceutical companies to employ a three-tier pricing system, TRIPS must be amended to prohibit parallel importation and diversion of drugs. Governments and international organizations should regulate and police the re-importation issue, and the WTO should impose trade sanctions on repeat offenders.

Governments of both the developed and the developing countries should provide more incentives to global pharmaceutical companies to invest in a local factory.<sup>199</sup> Such incentives could

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iles/yadav\_differential\_pricing\_for\_pharmaceuticals.pdf; see generally Jayashree Watal, *Workshop on Differential Pricing and Financing of Essential Drugs*, WORLD TRADE ORGANIZATION (Apr. 2001), [http://www.wto.org/english/tratop\\_e/trips\\_e/wto\\_background\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/wto_background_e.pdf).

197. See YADAV, *supra* note 196, at 5 ("It is important to note that differential pricing is not a panacea to ensuring access. For patients with affordability levels lower than the marginal cost of manufacturing, donor subsidies and government support will continue to be required.")

198. See Kevin Outterson, *Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries*, 32 AM. J.L. & MED. 159, 160 (2006) (80% to 90% of global sales of patented pharmaceuticals occur in the thirty wealthiest countries in the OECD. Patented pharmaceuticals could be offered at generic prices to middle and low income countries, which include more than 84% of the world's population, with only a small reduction in global R&D cost recovery). "In 1999, the 15% of the world's population who live in high-income countries purchased and consumed about 90% of total medicines, by value. . . . The market share of the USA alone rose from 18.4% of the world total in 1976 to over 52% in 2000." THE WORLD MEDICINES SITUATION, *supra* note 192, at 31.

199. See, e.g., TURKISH HEALTHCARE INDUSTRY REPORT 4 (Aug. 2010), available at <http://www.invest.gov.tr/en-US/infocenter/publications/Documents/HEALTHCARE.INDUSTRY.pdf> (introducing incentives to attract foreign investors to Turkey).

include: tax breaks, free land to build the factory, or government funds to build the factory.<sup>200</sup> Both developed and developing country governments can provide tax breaks to pharmaceutical companies in return for selling medicine at reduced prices for developing populations. Developed governments can base tax incentives on a gradient system, where tax deduction increases as the quantity of reduced priced drugs supplied to developing countries increases. Developing governments can give tax breaks for a set number of years to the pharmaceutical company. Thus, any burden is shared by all, the pharmaceutical companies, the developed countries, and the developing countries.

The pharmaceutical company would be allowed to make and keep more of the profits from selling their drug in the local market while using workers and labor from the local country.<sup>201</sup> This suggested solution would allow the global pharmaceutical company to make a profit, while providing a public service of increasing access to safe medicine and stimulating the local economy by using their labor. As a result, a pharmaceutical company's public relations image will also improve. By driving the generic drug makers out of business, global pharmaceuticals will not have to worry about enforcing their patent rights as the market will take care of it. Although, in this suggested solution, global pharmaceuticals would be making less profit in developing countries than in developed countries, they would still be making a profit and not incurring a loss, particularly when pricing is based on the urban population coupled with government and market incentives. Further benefits include improved goodwill and reputation, increased control, as well as reduced parallel importation and illegal competition.

Differential pricing is only feasible when coupled with official support, such as amending TRIPS to prohibit parallel importation.<sup>202</sup> Potential for diversion of drugs from one market to an-

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200. See Watson, *supra* note 13, at 156.

201. See KAPLAN & LAING, *supra* note 123, at 15 ("India's rich natural resources and manpower have not been fully exploited."); see *id.* at 32 (noting, however, that few developing countries would have the PhD level skills and technical staff for many of the jobs required in the pharmaceutical industry).

202. See YADAV, *supra* note 196, at 6. "Despite its theoretical appeal and some notable successes, the use of differential pricing as a tool to improve access to medicines is not widespread. The primary causes include risks of

other eliminates the incentive for companies to engage in differential pricing, leading to a single, world-wide uniform pricing scheme.<sup>203</sup> Banning parallel exports will increase the supply available to needy consumers because it removes the demand by distributors.<sup>204</sup> Only the intended needy consumers will have access, and thus, as the drug will not be siphoned by distributors, the number of such consumers who will actually have access to the drug will increase. Re-importation should be policed and regulated.<sup>205</sup> Countries should implement domestic legislation to comply with this amendment to ban parallel importation, and countries in violation should be punished with trade sanction. Further, violating countries would be harmed by backlash from pharmaceutical companies who would likely opt not to locally manufacture their product.<sup>206</sup> Further, violating countries will also likely suffer a decrease in foreign direct investment.<sup>207</sup>

Any solution will need to address the realities and challenges of compulsory licensing, including the differing priorities of IP and public health interests. An easy solution does not exist and every solution comes with its own set of additional challenges. For example, any amendment to TRIPS—whether to limit the scope of compulsory licenses by better defining “public health emergency,” creating WTO panels that employ strict scrutiny to assess the validity of a compulsory license request, requiring good faith prior negotiations, or banning parallel importation—is a difficult task. In fact, there has only been one amendment

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physical arbitrage (lower priced product flowing back to the high income markets) . . .” *Id.*; see Watson, *supra* note 13, at 157.

203. See generally A. Bryan Baer, *Price Controls Through the Back Door: The Parallel Importation of Pharmaceuticals*, 9 J. INTELL. PROP. L. 109 (2001) (arguing a uniform pricing scheme would likely be set at a high price based on affordability and profit potential from developed countries).

204. See *id.* at 134.

205. See Watson, *supra* note 13, at 157.

206. See McGill, *supra* note 78, at 90 (describing how Pfizer responded to the Viagra compulsory license by halting construction of a manufacturing plant in Egypt).

207. See McGill, *supra* note 78, at 90–92. Foreign direct investment (“FDI”) in Thailand declined by \$10 billion in 2007 as a backlash to widespread compulsory licensing of pharmaceuticals. *Id.* Similarly, FDI in Egypt dropped from \$948 million in 1987 to \$509.4 million in 2001–02. *Id.*

to TRIPS in the approximately fifteen years since its inception.<sup>208</sup> An amendment to TRIPS requires acceptance by two-thirds of the WTO member countries, and the amendment will only affect those member countries having accepted the amendment.<sup>209</sup> Furthermore, once an amendment is adopted, domestic legislation must be drafted and adopted in the individual countries.<sup>210</sup> Moreover, amending TRIPS to better define “public health emergency” is in itself a delicate task, where a balance between removing ambiguity and retaining enough flexibility to adapt to changes is important. Defining and limiting “public health emergency” will eliminate ambiguity, decrease abuse, and decrease resistance from developed countries and the global pharmaceutical industry. However, even a more concrete definition requires enough flexibility to withstand changes in time and adapt to changes in trends. In addition, a market approach to supplement amendments to TRIPS also poses difficulties. For example, much coordination would be necessary among WTO member country governments, global pharmaceutical companies, and local generic manufacturers to prevent parallel importation, encourage local manufacture and healthy competition, and create a three-tier pricing scheme. Coordination and internal restructuring within the global pharmaceutical industry would also be required, which will likely be a time consuming and complicated process.

## CONCLUSION

TRIPS has been important in making strides toward access to essential medicines for developing populations. Despite noble efforts, however, many still lack access to life-saving medications. The spirit of TRIPS and its dual goal of improving medical access while preserving patent rights should be continued and enhanced. Legitimacy cannot be sacrificed for effi-

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208. *How to Accept the Protocol Amending the TRIPS Agreement*, WORLD TRADE ORGANIZATION, [http://www.wto.org/english/tratop\\_e/trips\\_e/accept\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/accept_e.htm) (last visited Mar. 29, 2013) [hereinafter *Amending TRIPS*].

209. *See Members Accepting Amendment of the TRIPS Agreement*, WORLD TRADE ORGANIZATION, [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 updated Nov. 5, 2012).

210. *Amending TRIPS*, *supra* note 208.

ciency and, accordingly, compulsory license use should be limited in scope to true public health emergencies with the help of WTO panel decisions. Market forces, such as government incentives, international cooperation and public-private partnerships between advocacy groups and pharmaceutical companies should be used as the dominant route to improving access to medicines and preserving patent rights.

Collaboration with pharmaceutical companies is the most commercially viable solution for balancing TRIPS' dual goals. Working against pharmaceutical companies by merely broadening compulsory license use is not realistically viable, as the many obstacles to compulsory license use has shown. With chronic diseases on the rise, TRIPS and pharmaceutical business models need to be adjusted to combat new global concerns. There is still a long road ahead to improving global access to medications and, although TRIPS was a major step, it cannot be the end of the road. New measures and methods need to be created and adopted to treat the expanding global threat of diseases.

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