

# IS ARTICLE 31BIS ENOUGH? THE NEED TO PROMOTE ECONOMIES OF SCALE IN THE INTERNATIONAL COMPULSORY LICENSING SYSTEM

## I. INTRODUCTION

Every year, millions of people die from diseases that ravage populations in the developing world. The leading causes of death from infectious diseases are HIV/AIDS,<sup>1</sup> tuberculosis,<sup>2</sup> and malaria.<sup>3</sup> Additionally, non-communicable (non-infectious) diseases, such as cancer and heart disease are taking an increasingly mortal toll on developing world populations.<sup>4</sup> The most distressing aspect of this problem is that vaccines and medications exist for the prevention or treatment of these diseases. However, due to the extreme poverty of the developing world,<sup>5</sup> the need for adequate food, water, and shelter supplants the ability to afford and provide life-prolonging medications. Consequently, each passing day that these needed medications are not readily available, millions more people throughout the developing world suffer and die.

These developing countries are often ill-equipped to provide affordable medical assistance to their citizens, primarily for two reasons: (1) international agreements that seek to protect private enterprises—notably through patent protection, and (2) insufficient manufacturing capacity to produce the

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1. 92% of all HIV/AIDS infections occur in the developing world, causing 3 million deaths per year. World Health Organization [WHO], *Report on Infectious Diseases 2002, Scaling up the Response to Infectious Diseases: A Way out of Poverty*, at 14, WHO/CDS/2002.7 (2002), available at <http://www.who.int/infectious-disease-report/2002/pdfversion/Ch0Introduction.pdf>.

2. 84% of all tuberculosis infections occur in the developing world, causing 1.9 million deaths per year. *Id.*

3. Nearly 100% of all malaria infections occur in the developing world, causing more than one million deaths per year. *Id.*

4. More than 7 million people now die each year from cancer and more than half of all cancer cases occur in developing countries. The estimated number of new cases is supposed to rise to 15 million a year by 2020, with approximately 60% of these occurring in the less developed parts of the world. WHO, *Global Strategy on Diet, Physical Activity and Health: Cancer* (2003), available at <http://www.who.int/dietphysicalactivity/media/en/gsfscancer.pdf>. Heart disease and stroke kill more than 17 million people worldwide each year with 80% of the deaths occurring in lower and middle income countries. In developing countries, cardiovascular disease represents three-quarters of the deaths from non-communicable diseases and already accounts for 10% of the developing world's burden for disability. Stephen Leeder et al., *A Race Against Time: The Challenge of Cardiovascular Disease in Developing Countries*, at 12 (2004), available at [http://www.earth.columbia.edu/news/2004/images/raceagainsttime\\_FINAL\\_0410404.pdf](http://www.earth.columbia.edu/news/2004/images/raceagainsttime_FINAL_0410404.pdf).

5. "1.3 billion people live on less than \$1 a day, 3 billion live on under \$2 a day, 1.3 billion have no access to clean water, 3 billion have no access to sanitation and 2 billion have no access to power." James Wolfensohn, President, The World Bank Group, Address to the Board of Directors: The Other Crisis, at 3 (Oct. 6, 1998), available at <http://www.worldbank.org/html/extdr/am98/jdw-sp/am98-en.pdf>.

medications.<sup>6</sup>

The most important institution governing international patent protection is the World Trade Organization (WTO), which administers the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS").<sup>7</sup> One goal of the TRIPS Agreement was to alleviate the barriers imposed on Members from patent protection when a legitimate public need arises.<sup>8</sup> This was accomplished through the inclusion of language allowing for countries to issue compulsory licenses.<sup>9</sup> A compulsory license is issued by the government and allows a competitor of the patent owner to manufacture, produce, process, or sell the patented invention without the patent owner's permission in order to address a public need and thereby lower the associated costs.<sup>10</sup>

While the WTO compulsory licensing provisions gave developing countries the ability to avoid the costs associated with patent recognition of pharmaceuticals, the second problem, insufficient manufacturing capacity, still existed.<sup>11</sup> The developing world pressured WTO Members to devise a solution to this barrier.<sup>12</sup>

In 2001, the WTO Members convened in Doha, Qatar with a goal of solving the developing countries' problem of access to pharmaceuticals.<sup>13</sup> There they pronounced what has become known as the Doha Declaration, which stated a commitment by the Members to improve the public health crises and access to medication issues in the developing world.<sup>14</sup> The tangible effects of this meeting were formalized on December 6, 2005, in a proposed amendment to TRIPS known as Article 31*bis*.<sup>15</sup> The fundamental implication of Article 31*bis* is allowing developed countries to issue compulsory licenses to domestic generic pharmaceutical manufacturers, thereby permitting the domestic manufacturers to

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6. See Thomas A. Haag, *TRIPS Since Doha: How Far Will the WTO Go Toward Modifying the Terms for Compulsory Licensing?*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 945, 948-51 (2002).

7. ROGER E. SCHECHTER & JOHN R. THOMAS, *INTELLECTUAL PROPERTY THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS* 522 (2003). See also Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf) [hereinafter TRIPS].

8. See SCHECHTER & THOMAS, *supra* note 7, at 523.

9. See *Id.*; TRIPS, *supra* note 7, art. 31.

10. See SCHECHTER & THOMAS, *supra* note 7, at 523. "Compulsory licenses are an essential government instrument to intervene in the market and limit patent and other intellectual property rights in order to correct market failures. The authority to issue a compulsory license is important, even when the right isn't exercised, because it may temper the exercise of market power or the abuse of a patent." Consumer Project on Technology, *Frequently Asked Questions about Compulsory Licenses*, [www.cptech.org/ip/health/cl/faq.html](http://www.cptech.org/ip/health/cl/faq.html) (last visited Apr. 14, 2008).

11. Haag, *supra* note 6, at 951.

12. *Id.*

13. *Id.*

14. See WTO, Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2, available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.pdf](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf) [hereinafter Doha Declaration].

15. See WTO, Implementation of Paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Dec. 6, 2005, IP/C/41, available at [http://www.wto.org/english/news\\_e/news05\\_e/trips\\_decision\\_e.doc](http://www.wto.org/english/news_e/news05_e/trips_decision_e.doc) [hereinafter Article 31*bis*].

export medications to developing countries.<sup>16</sup>

While Article 31*bis* seeks to assist developing countries in acquiring needed medications, its concessions do not go far enough. There are a number of deficiencies within the new regulations, but none greater than the lack of ability for developing countries to realize economies of scale. Economies of scale, generally, lead to lower unit costs.<sup>17</sup> The terms of Article 31*bis* make realizing economies of scale almost impossible due to its relationship requirements between countries, along with the administrative guidelines it imposes. This comment seeks to highlight these economies of scale deficiencies while also proposing that the theories underlying the existence of Article 31*bis* and economies of scale can be maintained if a few requirements are eliminated or altered.

The next section of this comment will argue that the industrialized nations of the world owe a human rights duty to the developing world. This duty encompasses ensuring that the citizens of developing countries are able to access life-prolonging medications.

The third section will examine the international patent system as it existed prior to the Doha Declaration. Specific attention will be paid to the evolution of “compulsory licensing” from the beginnings of patent law through the establishment of the TRIPS Agreement.

The fourth section of this comment will examine the evolution of compulsory licensing after the Doha Declaration, focusing specifically on the final language of Article 31*bis* and its economies of scale guidelines.

The fifth section will highlight the benefits of economies of scale by providing a history of the Brazilian HIV/AIDS program. Brazil has instituted a rather comprehensive and successful national program to fight the destabilizing effects of HIV/AIDS by providing anti-retroviral medications free-of-charge to all clinically diagnosed patients, regardless of income. It has done this through the threat of compulsory licensing under the original TRIPS Agreement, along with the ability to leverage economies of scale based on its population, and specifically, the large HIV/AIDS infected population.

The sixth section of this comment will apply the economies of scale provisions and language in Article 31*bis* to existing circumstances and show why they are ineffective.

Finally, this comment will propose a solution to the economies of scale deficiencies.

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16. *Id.*

17. *See infra* Part V.

## II. HUMAN RIGHTS RECOGNITION REQUIRES ENSURING ACCESS TO MEDICATIONS

Given the scarcity of resources in developing countries, the industrialized world has a humanitarian duty to see that individuals in developing countries are able to obtain as much assistance as possible, particularly in the areas of food, water, lodging, and medical treatment. Unfortunately, a humanitarian duty is not binding under international law, but rather exists as a moral duty that is required to effectively recognize and promote human rights. This humanitarian duty was first articulated in the Universal Declaration of Human Rights ("UDHR").<sup>18</sup> The Declaration states:

THE GENERAL ASSEMBLY proclaims THIS UNIVERSAL DECLARATION OF HUMAN RIGHTS as a common standard of achievement for all peoples and all nations, to the end that every individual and every organ of society, keeping this Declaration constantly in mind, shall strive by teaching and education to promote respect for these rights and freedoms and by progressive measures, national and international, to secure their universal and effective recognition and observance, both among the peoples of Member States themselves and among the peoples of territories under their jurisdiction.<sup>19</sup>

In other words, all peoples (including pharmaceutical companies) and all countries shall strive to promote and secure, on a domestic and international level, the universal and effective recognition and observance of the UDHR's articles. This applies among the peoples of Member States themselves, i.e. among all citizens of United Nations Members. One such article that should be recognized is Article 25, which states that:

(1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and *medical care and necessary social services*, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

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18. Universal Declaration of Human Rights, G.A. Res. 217A (III) (Dec. 12, 1948), available at <http://www.un.org/Overview/rights.html> [hereinafter UDHR]. The UDHR arose along with the United Nations in response to growing world despair following the existence of two World Wars in a thirty-year period. Though lacking the binding nature of a treaty, the UDHR sought to influence its declarants morally and politically to make humane decisions in world affairs. For an explanation of the UDHR's history, see Peter Bailey, *The Creation of the Universal Declaration of Human Rights*, <http://www.universalrights.net/main/creation.htm> (last visited Apr. 14, 2008).

19. UDHR, *supra* note 18, pmbl. (emphasis added by author).

(2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection. (emphasis added by author)<sup>20</sup>

Thus, by the words of the UDHR, which all of the developed countries signed as a condition of membership into the United Nations, a humanitarian duty exists that morally cognizant Member States should recognize by ensuring adequate access to food, water, shelter, and medications. Brazil has taken this idea to heart by proposing a resolution to the United Nations Commission on Human Rights for the promotion of access to medications in developing countries.<sup>21</sup> This resolution passed 52-0, with an abstention from the United States.<sup>22</sup>

### III. THE PARIS CONVENTION, TRIPS, AND THE EARLY YEARS OF COMPULSORY LICENSING

Patent protection desires to reward ingenuity and provide incentives for inventiveness.<sup>23</sup> As a result, the owner of a patent has the right to exclude others from making, using, or selling his invention.<sup>24</sup> This right of exclusion generally allows the patent owner to control price, supply, and usage in the marketplace.<sup>25</sup> These basic tenets of patent law have been in existence throughout the world for many years. These rights, however, were not recognized outside of a patentee's home country until relatively recently.<sup>26</sup>

The Paris Convention for the Protection of Industrial Property ("Paris Convention") was formed in 1883 and laid the foundation for the universal international recognition of intellectual property protection.<sup>27</sup> The primary reasoning for establishing international agreements was the realization that countries had little power to protect the hard-work and ingenuity of their citizens from infringement abroad.<sup>28</sup> As a result, the idea of "national treatment" was invoked, requiring each country to provide the same intellectual property rights and protections to foreigners as is afforded its own citizens.<sup>29</sup> Beyond national

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20. *Id.* art. 25.

21. U.N. Econ. & Soc. Council (ECOSOC), Comm. on Hum. Rights, *Access to Medication in the Context of Pandemics such as HIV/AIDS*, U.N. Doc. E/CN.4/2001/L.50 (Apr. 12, 2001).

22. *Id.*

23. See SCHECHTER & THOMAS, *supra* note 7, at 288.

24. *Id.* at 283.

25. See *id.*

26. See *id.* at 283-287 (discussing the history of patent recognition throughout the world).

27. See *id.* at 518; John Revesz, *Staff Paper: Trade-Related Aspects of Intellectual Property Rights*, Commonwealth of Australian Productivity Commission, at 5 (May 1999), available at [http://www.pc.gov.au/\\_data/assets/pdf\\_file/0009/7866/trips.pdf](http://www.pc.gov.au/_data/assets/pdf_file/0009/7866/trips.pdf) (discussing creation of Paris Convention). The Paris Convention, along with 23 other intellectual property treaties, is now administered by the World Intellectual Property Organization. For more information on the WIPO, please see their website at <http://www.wipo.int/portal/index.html.en>.

28. Revesz, *supra* note 27, at 5-6.

29. *Id.* "National treatment" later became a building block for many international agreements, most notably the WTO and TRIPS.

treatment, the Paris Convention was relatively lax in the requirements it imposed on signatory countries, serving more as guidelines rather than obligations.<sup>30</sup>

One such guideline instituted over time was a provision allowing countries to issue compulsory licenses over patent rights.<sup>31</sup> The acceptance of compulsory licensing as an appropriate means of expropriating one's intellectual property has had a difficult transition throughout history.<sup>32</sup> It initially arose in early domestic and international laws to address a patentee's risk of forfeiture resulting from restrictions on use.<sup>33</sup> This was later supplanted by the idea that forfeiture of a patent owner's rights in a country should only apply if the patentee failed to utilize his invention there *within a reasonable period of time*, also known as a "failure to work."<sup>34</sup>

This was often contested because of the economic inefficiencies involved with trying to work an invention in every possible country.<sup>35</sup> As a result, compulsory licensing evolved as a substitute to forfeiture and acted as a sanction for non-working.<sup>36</sup> The premise behind the sanctioning theory of a compulsory license is that a patent owner is still entitled to a portion of economic incentive for his intellectual investment, just not the full extent of what he would otherwise be able to gain if he had satisfactorily utilized his invention.<sup>37</sup>

Over time the circumstances subjecting a patent owner to a potential compulsory license expanded beyond a mere failure to work.<sup>38</sup> After a series of revisions and amendments, Article 5(A)(2) of the Paris Convention now states that "[e]ach country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."<sup>39</sup> This language of Art. 5(A)(2) suggests a very broad spectrum of patents subject to a compulsory license.

Considering that the use of a compulsory license lessens the value of an individual's ownership rights in her patent, there was often a strong resistance to expanding its applicable limits; however, many have recognized that a social value exists in utilizing, or threatening to utilize, compulsory licenses for public needs,

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30. See SCHECHTER & THOMAS, *supra* note 7, at 287.

31. See Jerome H. Reichmann & Catherine Hasenzahl, *Non-voluntary Licensing of Patented Inventions*, United Nations Conference on Trade and Development-International Centre for Trade and Sustainable Development Project on Intellectual Property Rights and Sustainable Development Issue Paper No. 5, at 10, (June 2003) available at [http://ictsd.net/downloads/2008/06/cs\\_reichman\\_hasenzahl.pdf](http://ictsd.net/downloads/2008/06/cs_reichman_hasenzahl.pdf).

32. See *id.*

33. *Id.*

34. *Id.*

35. *Id.*

36. *Id.*

37. Reichmann & Hasenzahl, *supra* note 31, at 10.

38. *Id.* at 11.

39. World Intellectual Property Organization (WIPO), Paris Convention for the Protection of Industrial Property, art. 5(a)(2), Mar. 20, 1883, available at [http://www.wipo.int/treaties/en/ip/paris/pdf/trtdocs\\_wo020.pdf](http://www.wipo.int/treaties/en/ip/paris/pdf/trtdocs_wo020.pdf). See also Reichmann & Hasenzahl, *supra* note 31, annex (showing evolution of Paris Convention language).

notably through preventing anti-competitive behavior.<sup>40</sup> Recently, this recognition has prompted a change in the international framework during discussions for the establishment of the General Agreement on Tariffs and Trade (“GATT”), which later became known as the World Trade Organization (WTO).<sup>41</sup>

Unlike the Paris Convention, agreements and declarations of the WTO establish minimum standards that Members are required to follow in regards to international trade, investment, and intellectual property protection.<sup>42</sup> Thus, during the 1994 Uruguay Round of negotiations, the Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS”) came into existence and provided the first set of mandatory guidelines for Members regarding the protection of intellectual property rights on an international level.<sup>43</sup> Section Five of the TRIPS Agreement outlines the framework for patent protection among Members.<sup>44</sup> It has been said that the “government” reserves more power to itself than to its citizens;<sup>45</sup> consequently, Article 31 of TRIPS permits governments to override patent rights that have been granted to their citizens.<sup>46</sup>

Article 31, titled *Other Use without Authorization of the Right Holder*, provides Members with the ability to issue compulsory licenses for almost any reasonable purpose.<sup>47</sup> Subsection (b) requires Members to make reasonable efforts to come to acceptable commercial terms with the patent owner, yet recognizes that such an outcome is not always possible.<sup>48</sup> Article 31 also allows a waiver of the previously stated negotiation requirement “in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.”<sup>49</sup> Requirements that are applicable to all compulsory licenses include that

40. See Reichmann & Hasenzahl, *supra* note 31, at 12.

41. *Id.* at 13.

42. *Id.* See also WTO, Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, annex 1C, available at [http://www.wto.org/english/docs\\_e/legal\\_e/28-dsu.pdf](http://www.wto.org/english/docs_e/legal_e/28-dsu.pdf).

43. See Reichmann & Hasenzahl, *supra* note 31, at 13.

44. TRIPS, *supra* note 7.

45. “[A] government big enough to give you everything you want is a government big enough to take from you everything you have.” Gerald Ford, Address to the Joint Session of the Congress, Aug. 12, 1974, available at <http://www.presidency.ucsb.edu/ws/index.php?pid=4694>.

46. SCHECHTER & THOMAS, *supra* note 7, at 523-24. See also TRIPS, *supra* note 7, art. 31.

47. SCHECHTER & THOMAS, *supra* note 7, at 523-24; Compare TRIPS, *supra* note 7, art. 31 (“Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder....”) with TRIPS, *supra* note 7, art. 30 (“Other uses” are those that “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.”).

48. TRIPS, *supra* note 7, art. 31(b) states that “such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable . . . .”

49. *Id.*

use “shall be non-exclusive;”<sup>50</sup> that any use “shall be authorized predominately for the supply of the domestic market of the Member authorizing such use;”<sup>51</sup> and that “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.”<sup>52</sup> Furthermore, Article 66 provided a transitional period for Least-Developed Country Members of ten years from the implementation date of the WTO and TRIPS, which was to end in 2005.<sup>53</sup> The 2005 transition period deadline was extended to 2016.<sup>54</sup>

While the language of Article 31 is recognized as giving Members the ability to issue compulsory licenses for national health needs,<sup>55</sup> those in the developing world have found themselves limited mostly by the language of subsection (f), authorizing compulsory licenses “predominately for the supply of the domestic market.”<sup>56</sup> Despite the legal language allowing them to do so, the capital, manufacturing capacity, and economic sustainability often do not exist within the developing countries in a sufficient manner to allow them to build the infrastructure needed.<sup>57</sup>

Other costs affecting the competitiveness of a local manufacturing operation include: labor costs for qualified personnel, costs of capital, construction costs, taxes and tariffs, costs for environmental safeguards, insurance, licensing, utilities, and costs of externally procured goods and services.<sup>58</sup> Additionally, countries and pharmaceutical manufacturers must invest in systems that ensure effectiveness and safety to avoid any health risks associated with impurities.<sup>59</sup>

One such system is a protocol of safeguards and procedures that all major pharmaceutical manufacturers have implemented, termed Good Manufacturing

50. *Id.*, art. 31(d).

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

52. *Id.* art. 31(h).

53. *Id.* art. 66.

54. Doha Declaration, *supra* note 14, ¶ 7.

55. *See id.* ¶ 5(c); *See also* Haag, *supra* note 6, at 951.

56. TRIPS, *supra* note 7, art. 31(f).

57. *See* Doha Declaration, *supra* note 14, ¶ 6. In a major WTO decision, Canada won the right to do efficacy and safety testing of generic pharmaceuticals for countries prior to a patent expiring within that country. The Panel stated in its decision that “[v]ery few countries had fully integrated brand name or generic drug industries within their borders. Even in large countries, generic producers frequently had to obtain ingredients such as fine chemicals from producers in other countries. Many countries had no generic industries at all and had to obtain generics (as well as brand name) products from other countries. Smaller countries that did have generic industries did not have domestic markets sufficiently large to enable those industries to operate on an economic scale. Those industries had to export in order to be able to manufacture in sufficient quantities to achieve economies of scale, so that domestic consumers could receive the benefits of cost-effective generic products.” WTO, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R, § (IV)(D)(4)(a) (Mar. 17, 2000), available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/7428d.pdf](http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf).

58. Andreas Seiter, *Pharmaceuticals: Local Manufacturing*, The World Bank HNP Brief #3, at 2 (Mar. 2005), available at [http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1109774792596/HNPBrief\\_3.pdf](http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1109774792596/HNPBrief_3.pdf).

59. *Id.* at 3.



Practice (“GMP”).<sup>60</sup> Adherence to GMP can add significantly to investment and operation costs, and could ultimately lead some to “cut corners” in avoidance of these costs.<sup>61</sup> The World Bank recommends that “[p]harmaceutical manufacturing should only be encouraged in countries that have an effective control agency to enforce GMP.”<sup>62</sup>

#### IV. DOHA TO ARTICLE 31BIS— THE WESTERN WORLD’S SOLUTION

Recognizing a need for reform of the compulsory licensing system and the public health crisis surrounding it, the WTO Members met for a round of negotiations in 2001 in Doha, Qatar.<sup>63</sup> At the end of the negotiations, the Ministerial Conference<sup>64</sup> released its “Declaration on the TRIPS Agreement and Public Health” (“Doha Declaration”).<sup>65</sup> The Doha Declaration established the WTO Members’ recognition of public health crises attributed to HIV/AIDS, malaria, tuberculosis, and other diseases exists in the developing world and that the then existing international patent system was insufficient to address the situation.<sup>66</sup> Paragraph 6 of this Declaration stated,

We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.<sup>67</sup>

In 2003, the General Council released a decision on the “Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health” (“Implementation of Paragraph 6”).<sup>68</sup> The Implementation of Paragraph 6 was a

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60. *Id.* GMP covers the layout and functionality of buildings, qualifications and training of personnel, cleanliness and sanitation, monitoring, supervision and many other aspects of quality control.

61. *Id.*

62. *Id.*

63. OXFAM INTERNATIONAL, PATENTS VERSUS PATIENTS: FIVE YEARS AFTER THE DOHA DECLARATION, OXFAM BRIEFING PAPER 95 at 1 (Nov. 2006), available at [http://www.oxfamamerica.org/newsandpublications/publications/briefing\\_papers/patents\\_patients/Doha5\\_Final\\_paper\\_101106\\_2.pdf](http://www.oxfamamerica.org/newsandpublications/publications/briefing_papers/patents_patients/Doha5_Final_paper_101106_2.pdf).

64. The Ministerial Conference is the top-level decision making body of the WTO and meets at least once every two years. All decisions are made by consensus of the whole of WTO membership. For more information on the structure and decision making processes of the WTO, see the WTO website at <http://www.wto.org>.

65. Doha Declaration, *supra* note 14.

66. *Id.*

67. *Id.* The Council for TRIPS is charged with oversight and administration of the TRIPS Agreement. See TRIPS, *supra* note 7, art. 68. The General Council is composed of representatives from each Member and oversees the operations of the WTO when the Ministerial Conference is not in session. For more information on the structure and decision making processes of the WTO, see the WTO website at <http://www.wto.org>.

68. WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 1, 2003) [hereinafter *Implementation of*

proposal for an amended set of guidelines to TRIPS Article 31(f)'s limitation of compulsory licenses to domestic markets and was temporarily put in place while negotiations over a finalized version continued.<sup>69</sup> The final amendment was proposed for Member acceptance on December 6, 2005 and addresses the limitations and confusion surrounding TRIPS Article 31(f).<sup>70</sup> This amendment leaves virtually every aspect of TRIPS intact but inserts a provision known as Article 31*bis* along with an explanatory annex to the TRIPS Agreement.<sup>71</sup>

Article 31*bis* sets forth a new set of guidelines for countries seeking to issue compulsory licenses for the import or export of pharmaceutical products. "Eligible importing Member(s)" under Article 31*bis* are those countries that are deemed to have insufficient or no manufacturing capacity, i.e. the majority of developing countries.<sup>72</sup> Those Members seeking to import pharmaceuticals through the new compulsory licensing scheme must submit an application to the TRIPS Council specifying the type of medication needed, the quantity needed, and that the country intends to issue a compulsory license locally if a patent exists in that country.<sup>73</sup>

An "eligible exporting Member"<sup>74</sup> will then issue a compulsory license domestically to provide for the needs of the requesting developing country.<sup>75</sup> The exporting Member is responsible for negotiating a favorable pricing scheme to sufficiently remunerate the patent owner.<sup>76</sup> Furthermore, the exporting Member and generic manufacturer must take sufficient measures to alter the color or design of the medication without sacrificing efficacy and price.<sup>77</sup> The purpose underlying this requirement is the fear that the lower priced exported medications will find their way back into the exporting Members or other industrialized economies.<sup>78</sup> This threat, known as parallel importing, is one of the biggest fears of the industrialized countries and their pharmaceutical industries. Therefore, all countries participating in the compulsory licensing system are required to take

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Paragraph 6].

69. See *id.* ¶ 11.

70. See Article 31*bis*, *supra* note 15, ¶ 2. Members have until Dec. 1, 2007 to accept the protocol. This acceptance date is subject to an extension by the Ministerial Conference. *Id.*

71. See *id.*

72. Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector. For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways: (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; or (ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply. *Id.* Appendix to the Annex to the TRIPS Agreement.

73. See *id.* Annex to the TRIPS Agreement, ¶ 2(a).

74. Defined as "a Member using the system . . . to produce pharmaceutical products for, and export them to, an eligible importing Member." *Id.* Annex to the TRIPS Agreement, ¶ 1(c).

75. *Id.* at Annex to the Protocol Amending the TRIPS Agreement, ¶ 1.

76. See Article 31*bis*, *supra* note 15, ¶ 2.

77. *Id.* Annex to the TRIPS Agreement, ¶ 2(b)(ii).

78. See *id.* Annex to the TRIPS Agreement, ¶¶ 3, 4.

adequate precautions to prevent parallel importing.<sup>79</sup>

Despite its seeming improvement to the obstacles that Members had in ensuring access to affordable medications, a number of deficiencies still exist within the new amendment. One problem concerns remuneration to the patent owner. Article 31bis does not state a formula for determining adequate remuneration, and as a result, there is sure to be much debate and litigation concerning the issue.<sup>80</sup> Another concern is the choice of a number of countries to “opt-out” as “eligible importing Member(s).”<sup>81</sup> There are a number of critics who believe this could potentially be harmful to those countries in the event of a future pandemic.<sup>82</sup> Should a major pandemic, such as avian flu, affect an “opt-out” Member to the extent that its pharmaceutical companies do not have the ability to provide the necessary medications, it is unable to seek affordable help elsewhere through the Article 31bis compulsory licensing system.<sup>83</sup> Furthermore, this provision prevents all members of the EU, regardless of development status, from utilizing the system in the event of a public health crisis.<sup>84</sup>

A third concern is the lack of safeguarding language to prevent industrialized countries from enacting stricter patent and compulsory licensing standards in their own bilateral trade agreements with developing countries.<sup>85</sup> TRIPS and Article 31bis provide a minimum set of guidelines that Members are obliged to follow; Members, however, always have the liberty to contract between themselves for more exacting standards.<sup>86</sup> Recently, the United States has been negotiating trade agreements with other countries and pushing what is known as “TRIPS-Plus.”<sup>87</sup> TRIPS-Plus seeks more stringent protections of intellectual property rights in the signatory countries than those currently recognized under the TRIPS Agreement.<sup>88</sup> In the context of patents, the U.S. has sought standards which stipulate that compulsory licenses may only be used domestically and for issues related to an anti-competitive matter, a public non-commercial use or an emergency of some

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79. *Id.* See also Letter from Pharmaceutical Research and Manufacturers of America, to Robert D. Zoellick, United States Trade Representative (Aug. 19, 2003) (discussing their goal of promoting anti-diversion in the compulsory licensing negotiations), available at <http://lists.essential.org/pipermail/ip-health/2003-September/005213.html>.

80. See Article 31bis, *supra* note 15, ¶ 2.

81. *Id.* Annex to the TRIPS Agreement, ¶ 1(b). These countries are Australia, Canada, the European Communities with its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.

82. See Press Release, Consumers International, Statement to TRIPS Council on Access to Medicine, in the Context of Avian Flu Pandemic and Other Emergencies (Oct. 25, 2005), available at <http://www.cptech.org/ip/health/tamiflu/ci10252005.html>; Letter from Michelle Childs, Head of European Affairs, Consumer Project on Technology, to Peter Mandelson, Director General of Trade, European Commission (Oct. 19, 2005), available at <http://www.cptech.org/ip/health/tamiflu/cptech-mandelson10192005.html>.

83. Article 31bis, *supra* note 15, ¶ 2.

84. *Id.*

85. See OXFAM INTERNATIONAL, *supra* note 63, at 1.

86. TRIPS, *supra* note 7, art. 1(1). See also OXFAM INTERNATIONAL, *supra* note 63, at 1.

87. OXFAM INTERNATIONAL, *supra* note 63, at 13.

88. *Id.* at 14.

kind, such as a pandemic or terrorist attack.<sup>89</sup> This represents a fundamental shift from TRIPS in which there are no restrictions on when a compulsory license may be issued provided that certain conditions are met.<sup>90</sup> Furthermore, not only do these agreements benefit the U.S., but because of the WTO's "most-favoured nation" policy, these rights extend to every other Member.<sup>91</sup>

The most glaring problem with the new regulations concerns efforts by developing countries to take advantage of economies of scale that will lower their purchasing prices and provide incentives for the creation of infant pharmaceutical manufacturing industries. Economies of scale can be viewed from the perspective of either the producer or the purchaser. From a producer perspective, increased production distributes fixed costs over a greater number of units, thereby reducing overall costs per unit.<sup>92</sup> Thus, the more that is produced and sold to consumers, the lower the average cost of producing that unit.<sup>93</sup> This acts as an incentive for producers to manufacture more units.<sup>94</sup> The purchaser benefits from economies of scale along the same premise, as purchasing more units decreases the per-unit cost.<sup>95</sup> Think of it as buying in bulk.

Paragraph 3 of Article 31*bis* states that:

3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.<sup>96</sup>

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89. *Id.*

90. *See supra* Section III.

91. OXFAM INTERNATIONAL, *supra* note 63, at 18-19. Most-Favoured-Country Treatment provides that "[w]ith regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members." TRIPS, *supra* note 7, art. 4.

92. DANIEL H. COLE & PETER Z. GROSSMAN, PRINCIPLES OF LAW AND ECONOMICS 305-06 (2005).

93. *Id.* at 305-06.

94. *Id.*

95. *Id.*

96. Article 31*bis*, *supra* note 15, ¶ 3 (emphasis added).

Thus, assuming all other requirements of Article 31*bis* have been satisfied, the language of paragraph 3 permits developing countries to realize economies of scale if three conditions are met: (1) countries seeking to utilize economies of scale must be a member of a WTO recognized regional trade agreement (“RTA”); (2) at least half of the members of that RTA must be on the United Nations list of least-developed countries; and (3) the country seeking the compulsory license is responsible for importing the medications, but may re-export them to qualifying members of the RTA.<sup>97</sup> The discussion below, *infra* Section Six, will demonstrate why these requirements are ineffective.

To date, WTO Members have been slow to implement local legislation reflecting the changes in Article 31*bis*. China, Canada, Korea, and a number of European countries were the first to enact legislative guidelines for the export of pharmaceuticals under a compulsory licensing scheme.<sup>98</sup> Most notably, the European Parliament of the European Union passed implementing legislation during the spring of 2006.<sup>99</sup> In the United States, the current statutory language permits the government to practice eminent domain of a patent for its own purposes.<sup>100</sup> No enacted legislation exists specifying the ability of the government to export to another country via a compulsory license, in the Senate, Patrick Leahy has proposed legislation that encompasses the fundamental provisions of Article 31*bis*.<sup>101</sup>

Until recently, no developing countries had requested a compulsory license under the Article 31*bis* system. However, standing up to international pressure, Thailand has asserted its rights under the TRIPS Agreement and Article 31*bis*.<sup>102</sup> In December of 2006, Thailand issued a compulsory license on the anti-AIDS drug Efavirenz, produced by Merck, in order to import a generic version from India.<sup>103</sup> By doing so, Thailand has slashed the price of the drug virtually in half from \$41 to \$22.<sup>104</sup> Now that a precedent has been set, other countries will hopefully follow.

## V. BRAZIL—A SUCCESSFUL MODEL OF ECONOMIES OF SCALE

Brazil has used economies of scale to its advantage as a producer and purchaser in lowering the cost of life-prolonging AIDS medications for its citizens

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97. *See id.*

98. Consumer Project on Technology, Legislation to Allow for the Export of Pharmaceuticals Produced under Compulsory License, <http://www.cptech.org/ip/health/cl/cl-export-legislation.html> (last visited Apr. 14, 2008) (listing countries and links to their legislation).

99. Council Regulation (EC) No. 816/2006 of 17 May 2006.

100. 28 U.S.C. § 1498.

101. *See* S. 3175, 109th Cong. (2006).

102. *See* Press Release, Medecins Sans Frontieres, MSF Welcomes Move to Overcome Patent on AIDS Drug in Thailand, (Nov. 30, 2006), *available at* <http://www.accessmed-msf.org/media-room/press-releases/press-release-detail/article/msf-welcomes-move-to-overcome-patent-on-aids-drug-in-thailand>.

103. *Id.*

104. *Id.*

and has been at the forefront of world countries in promoting access to pharmaceuticals for health and prosperity.<sup>105</sup> Brazil, with an approximate population of 168 million people, is the largest country in South America.<sup>106</sup> The per capita income is approximately \$3,460 per person per year.<sup>107</sup> The World Bank estimates that 52% of all reported HIV/AIDS cases in Latin America and the Caribbean are in Brazil, and an estimated 560,000 to 850,000 persons infected with HIV live in Brazil.<sup>108</sup>

In 1996, doctors at the World AIDS Conference announced that an anti-retroviral cocktail was found to slow down the effects of HIV/AIDS by reducing viral loads to an almost undetectable level.<sup>109</sup> Following the announcement, former Brazilian president José Sarney proposed a law guaranteeing state-of-the-art treatment to every Brazilian AIDS patient.<sup>110</sup> His law passed, and since the program's inception in 1997, the government has provided virtually all of Brazil's clinically diagnosed AIDS patients with the same triple-therapy cocktails used to keep the more affluent industrialized country citizens healthy.<sup>111</sup> The success of this program has transformed Brazil into the world's biggest proponent of competitive generic pricing of medications in the developing world, and specifically HIV/AIDS therapies.<sup>112</sup>

Brazil used a number of means to attain these results. Prior to 1996, Brazil did not grant patents on medications.<sup>113</sup> During that year, it passed a WTO compliant law to recognize patents on medications; however, the law provided that any medication already in commercial production anywhere in the world on May 14, 1997 would forever remain un-patentable in Brazil.<sup>114</sup> At the time this covered a number of first generation anti-retroviral medications, but was not applicable to more efficacious therapies that have and will come into existence.<sup>115</sup>

Faced with program-threatening prices on newer therapies, Brazil took a

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105. See Tina Rosenberg, *Look at Brazil*, N.Y. TIMES MAGAZINE, Jan. 28, 2001, available at [www.nytimes.com/library/magazine/home/20010128mag-aids.html](http://www.nytimes.com/library/magazine/home/20010128mag-aids.html).

106. For statistics on Brazil, see <http://www.worldbank.org> (follow "Countries" hyperlink; then follow "Brazil" hyperlink; then follow "Data & Statistics" hyperlink; then follow "Brazil Country Data Profile" hyperlink).

107. *Id.*

108. *Id.*

109. Effective HIV/AIDS treatment requires the use of three "lines" of therapies, each more potent than the previous. See U.S. DEPT. OF HEALTH AND HUMAN SERVICES, RECOMMENDED HIV TREATMENT REGIMENS, available at [http://www.aidsinfo.nih.gov/ContentFiles/RecommendedHIVTreatmentRegimens\\_FS\\_en.pdf](http://www.aidsinfo.nih.gov/ContentFiles/RecommendedHIVTreatmentRegimens_FS_en.pdf).

110. See Rosenberg, *supra* note 105.

111. *Id.*

112. *Id.* See also *supra* note 21 and accompanying text (discussing Brazil's resolution to recognize HIV/AIDS in the context of human rights).

113. Rosenberg, *supra* note 105.

114. *Id.* While the WTO generally required all signatories to be in compliance with its regulations and TRIPS at the time of signing, developing countries were given an additional four years, and least-developed countries were given an additional ten years. TRIPS, *supra* note 7, arts. 65, 66. Brazil is considered a developing country based on the United Nations criteria. See UN Country Classifications, *infra* note 140.

115. Rosenberg, *supra* note 105.

tough stance against the big pharmaceutical companies.<sup>116</sup> Initially, desiring not to abuse its power and relations with investors and foreign countries, Brazil sought to negotiate favorable prices with these companies to provide more affordable medications.<sup>117</sup> Reluctant to agree to the requested price reductions, many companies refused to compromise with the government.<sup>118</sup> In response, Brazil threatened to use compulsory licenses as permitted by the TRIPS Agreement.<sup>119</sup> Given the choice of providing medications at a cheaper price, or losing the business to a generic producer, this threat was often enough to persuade the pharmaceutical companies to lower their prices.<sup>120</sup> Interestingly enough, Brazil has never had to issue a compulsory license.<sup>121</sup> The threat alone has forced numerous pharmaceutical companies to make dramatic concessions in the costs of their medications, either through production or licensing.<sup>122</sup> As a result of its threats and leverage, in recent years Brazil has been able to drastically reduce the acquisition costs of such medications as Kaletra (Abbott Laboratories), Atazanavir (Bristol-Myers Squibb), Efavirenz (Merck), and Nelfinavir (Roche).<sup>123</sup>

Brazil's actions led to outrage throughout the pharmaceutical industry and industrialized countries of the world.<sup>124</sup> They see them as a threat to the basic rationale behind patent law, i.e. to promote innovation and to reward an inventor by allowing him to exclude others from using his invention without permission.<sup>125</sup> Furthermore, pharmaceutical companies claim that because of the high cost of research and development, it is necessary to charge high prices on medications, and that the use of compulsory licenses undermines their scientific progress.<sup>126</sup> Despite this pressure, Brazil has continued to fight for cheaper prices on generics, using its leverage as a major buyer to obtain prices much below those in the industrialized world.<sup>127</sup> Between 1996 and 2000, Brazil saw a drop of 9% in the prices of AIDS drugs with no Brazilian generic equivalent and 79% for those medications with an existing Brazilian generic equivalent.<sup>128</sup>

How can a country afford to subsidize medications for all of its AIDS patients? The evidence has shown that the benefits of the program help to pay for

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116. *Id.*

117. *Id.*

118. *Id.*

119. *Id.*

120. OXFAM INTERNATIONAL, *supra* note 63, at 24.

121. *Id.*

122. *Id.* Anti-retroviral therapies were at one point decreased from an average price of \$6,240 to \$1,336 per patient per year. *Id.*

123. *Id.* See also CPTECH Website, <http://www.cptech.org/ip/health/c/brazil> (describing the Brazilian government's negotiations with pharmaceutical multinationals).

124. *Id.* The CPTECH website contains documents from pharmaceutical companies, trade associations, and the U.S. government expressing displeasure with Brazil's actions.

125. See OXFAM INTERNATIONAL, *supra* note 63, at 20.

126. *Id.*

127. Rosenberg, *supra* note 105.

128. *Id.*

itself.<sup>129</sup> Brazil's initiative has halved the death rate from AIDS, prevented hundreds of thousands of new hospitalizations, cut the transmission rate, helped to stabilize the epidemic, and improved the overall state of public health in the country.<sup>130</sup> By reigning in the rapid decline that uncontrolled AIDS can cause in a population, Brazil has decreased the costs associated with the disease, while also helping to maintain its citizens as productive members of society that are able to contribute to its prosperity and advancement.<sup>131</sup> As aptly stated in the article "Look at Brazil":

Brazil is showing that no one who dies of AIDS dies of natural causes. Those who die have been failed—by feckless leaders who see weapons as more alluring purchases than medicines, by wealthy countries (notably the United States) that have threatened the livelihood of poor nations who seek to manufacture cheap medicine and by the multinational drug companies who have kept the price of antiretroviral drugs needlessly out of reach of the vast majority of the world's population.<sup>132</sup>

Despite the benefits realized by Brazil, the costs of medications are still extremely high and could destroy the program if not controlled.<sup>133</sup> Thus, Brazil has continued to use its leverage as a mass consumer to realize price reductions in these much needed pharmaceuticals.<sup>134</sup>

There is a fundamental difference between Brazil's ability to use the threat of compulsory licensing and the ability of other developing countries with similar health crises. Brazil's large population, and more importantly, its sick population, provide it with the ability to realize economies of scale as both a producer and a purchaser, thereby attaining medications at reasonably cheap costs. It does this through the threat of compulsory licensing; yet, the pharmaceutical companies concede in their negotiations because losing a portion of profits is better than

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129. *Id.*

130. *Id.* Treating AIDS helps to limit its spread because people with lower viral load are less contagious. Additionally, the availability of free life-saving medications entices individuals to visit hospitals and clinics for testing and treatment, not only of AIDS, but also of the concomitant diseases associated with it. Brazil actually had half of the 1.2 million HIV positive people in 2000 that the World Bank estimated it would have back in 1994. New cases have stabilized at about 20,000 per year. The death rate has been cut by approximately 50%, while the likelihood of hospitalization is a quarter of what it would have been otherwise. *Id.*

131. *Id.* In 2000, the Brazilian Health Ministry spent \$444 million on AIDS drugs. One study showed that they saved \$422 million between 1997 and 1999 from the decline in hospitalizations related to opportunistic infections. There have been no additional studies showing the economic impact of fewer infections and higher productivity. *Id.*

132. *Id.*

133. See OXFAM INTERNATIONAL, *supra* note 63, at 24. The price of new anti-retroviral therapies has steadily increased so that Brazil now pays, on average, \$2,500 per patient per year. *Id.*

134. Most recently, the Brazilian government negotiated a 51% reduction in the price of Tenofovir. See Press Release, Brazil Minister of Health Office, HIV drug will cost 51% less for Brazil (May 9, 2005), available at <http://lists.essential.org/pipermail/ip-health/2006-May/009546.html>.



losing them all.<sup>135</sup>

## VI. WHY THE ARTICLE 31BIS ECONOMIES OF SCALE PROVISION IS NOT EFFECTIVE

Article 31bis (3) possesses three major limiting factors: (1) that in order to realize economies of scale the importing members must be a member of a RTA; (2) that more than half of the countries to that RTA be on the United Nations list of least developed countries; and (3) that one country be responsible for the administration, importation, and re-exportation of medications to the other participating Members of the RTA.<sup>136</sup> These limitations create an extremely high hurdle for developing countries to overcome in order to realize the maximum extent of savings that can be obtained, such as in Brazil. Even in spite of Brazil's success, the sustainability of its successful program is in jeopardy by medication costs.<sup>137</sup> Without leverage and purchasing power, these countries will not be able to effectively address the major health issues that are affecting their viability.

The purpose of this section is to show that conditions exist throughout the world that make it necessary for all countries to be able to acquire drugs as cheap as reasonably possible, but the Article 31bis economies of scale provision raises a major impediment to that possibility. The first part of this section seeks to establish that outside of Africa, there are almost no countries able to avail themselves of the economies of scale provision in Article 31bis (3). The second part of this section seeks to show that even for those countries that qualify, the administrative language of Article 31bis (3) creates an additional barrier.

### A. Few Countries Satisfy the Economies of Scale Criteria

The most glaring problem with Article 31bis (3) concerns those RTA's that currently qualify to take advantage of economies of scale, thereby permitting the developing countries that are party to them to increase their purchasing power. For Article 31bis purposes, the WTO defines an eligible RTA as being a customs union, a free trade area, or a preferential agreement between developing countries.<sup>138</sup> Technically, this includes bilateral investment treaties that establish a

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135. See OXFAM INTERNATIONAL, *supra* note 63, at 24.

136. See *supra* notes 96-97 and accompanying text.

137. See Rosenberg, *supra* note 105.

138. See General Agreement on Tariffs and Trade, art. XXIV (Oct. 30, 1947), *available at* [http://www.wto.org/english/docs\\_e/legal\\_e/gatt47\\_e.pdf](http://www.wto.org/english/docs_e/legal_e/gatt47_e.pdf). The definitions for customs unions and free trade areas are as follows:

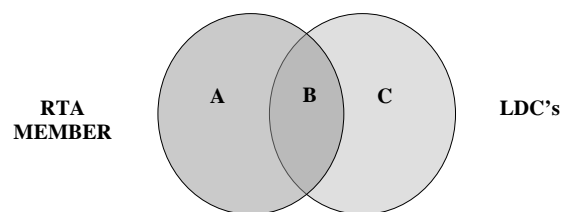
(a) A customs union shall be understood to mean the substitution of a single customs territory for two or more customs territories, so that

(i) duties and other restrictive regulations of commerce (except, where necessary, those permitted under Articles XI, XII, XIII, XIV, XV and XX) are eliminated with respect to substantially all the trade between the constituent territories of the union or at least with respect to substantially all the trade in products originating in such territories, and,

(ii) subject to the provisions of paragraph 9, substantially the same duties and other regulations of commerce are applied by each of the members of the union to the trade of territories not included in the union;

free trade agreement between two countries, but for the purposes of this paper, I will assume that two small developing countries do not acquire significantly more leverage than one.<sup>139</sup>

The United Nations broadly classifies developing economies as the countries of Africa, Latin America and the Caribbean, and Asia and the Pacific Rim (excluding Japan, Australia, New Zealand and the transitional economies of the former Soviet States).<sup>140</sup> This includes almost 150 countries.<sup>141</sup> Of these, the United Nations maintains a list of countries that are classified as least-developed countries (“LDCs”).<sup>142</sup> Applying the language of Article 31*bis*, a RTA would be required to look like the following:



**Art. 31*bis* (3)**  
A qualifying RTA if  $B \geq A/2$

**Diagram 1—Art. 31*bis* (3) qualifying RTA's**

(b) A free-trade area shall be understood to mean a group of two or more customs territories in which the duties and other restrictive regulations of commerce (except, where necessary, those permitted under Articles XI, XII, XIII, XIV, XV and XX) are eliminated on substantially all the trade between the constituent territories in products originating in such territories.

*Id.* See also WTO, *Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries*, L/4903 (Nov. 28, 1979), available at [http://www.wto.org/english/docs\\_e/legal\\_e/enabling\\_e.pdf](http://www.wto.org/english/docs_e/legal_e/enabling_e.pdf). A preferential agreement permits developing countries to reduce tariffs amongst themselves without having to extend the same to every Member as is generally required under the most favored nation principle. See *id.*

139. For instance, if Cambodia and Guatemala were to sign a bilateral investment treaty that is compliant with Article 31*bis*.

140. U.N., *List of Country Groupings and Sub-groupings for the Analytical Studies of the United Nations World Economic Survey and other UN Reports*, available at <http://unpan1.un.org/intradoc/groups/public/documents/un/unpan008092.pdf> [hereinafter U.N. Country Classifications].

141. Figure based on an actual count.

142. This list comprises of: Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Kiribati, Lao People's Democratic Republic, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Samoa, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, Sudan, Timor-Leste, Togo, Tuvalu, Uganda, United Republic of Tanzania, Vanuatu, Yemen, and Zambia. U.N. Office of the High Representative for the Least Developed Countries, Land Locked Developing Countries and Small Island Developing States [UN-OHRLLS], *List of Least Developed Countries*, <http://www.un.org/special-rep/ohrlls/ldc/list.htm> (last visited Apr. 14, 2008).

Therefore, of the thirty multi-party RTA's listed on the WTO website, only six qualify under the guidelines, i.e. at least fifty percent of their members are also on the United Nation's LDC list.<sup>143</sup> Five of those six qualifying RTA's include only countries on the African Continent. The sixth covers countries in the Pacific Rim. As a result, countries in South America, Central America, the Caribbean and Asia are currently not able to take advantage of the economies of scale provisions, though AIDS, tuberculosis, malaria, cancer and other deadly diseases are very real dangers to their societies. Appendix A provides a summary of the WTO listed RTA's and their membership in relation to the Article 31bis (3) guidelines.

Examples abound of developing countries in need of affordable medications for their citizens. For instance, the World Health Organization (WHO) estimates that the cost of second line AIDS therapies in Guatemala and Honduras are approximately \$6,500 per patient per year, whereas the price in many LDC countries is approximately \$1,000.<sup>144</sup> Given the World Bank's estimate of per capita income for Guatemala at \$2,400 and Kenya at \$530, the cost of second line AIDS therapies in Guatemala are almost two and a half times that of per capita income, while it is only twice that in Kenya.<sup>145</sup>

Malaria provides a further example that African countries are not alone in their need to curb the costs of life-prolonging patented medications. There are approximately 300 to 500 million cases of malaria worldwide each year, causing one to two million deaths annually.<sup>146</sup> The disease has had a significant impact on Asia and the Pacific Islands, resulting in millions of infections and tens of thousands of deaths annually.<sup>147</sup> As with most diseases, new strains have become more resistant to existing medications.<sup>148</sup> In order for countries to effectively

143. They are: CEMAC, COMESA, EAC, MSG, SADC, and UEMOA/WAEMU. WTO, *Regional trade agreements*, [http://www.wto.org/english/tratop\\_e/region\\_e/region\\_areagroup\\_e.htm](http://www.wto.org/english/tratop_e/region_e/region_areagroup_e.htm) (last visited Apr. 14, 2008) (providing a list of WTO-recognized RTAs and their member countries).

144. See Medecins Sans Frontieres, *Too Little for Too Few: Challenges for Effective and Accessible Antiretroviral Therapy*, XVI International AIDS Conference Briefing Document 7 (Aug. 2006), available at <http://www.accessmed-msf.org/resources/key-publications/key-publication-detail/article/too-little-for-too-few-challenges-for-effective-and-accessible-arvs/>.

145. For per capita income statistics, see The World Bank website at <http://www.worldbank.org> (follow "Countries" hyperlink; then follow "Data & Research" hyperlink for the respective country; then follow the country's "Data Profile" hyperlink).

146. See Medecins Sans Frontieres, *The Malaria Problem*, Feb. 14, 2005, [http://www.msf.org/msfinternational/invoke.cfm?objectid=2345243C-5C9F-40B8-B9F2A452FC23260F&component=toolkit.report&method=full\\_html](http://www.msf.org/msfinternational/invoke.cfm?objectid=2345243C-5C9F-40B8-B9F2A452FC23260F&component=toolkit.report&method=full_html).

147. *Id.* Aside from the effects of the disease itself, malaria so weakens the physiological system that it leads to increased susceptibility to other diseases, as well as anemia and poorer nutritional status. However, studies have shown that reducing malaria also reduces mortality associated with other diseases by up to 60%. *Id.*

148. Chantal M. Morel, et al., *Achieving the Millennium Development Goals for Health: Cost Effectiveness Analysis of Strategies to Combat Malaria in Developing Countries*, BRIT. MED. J. 1 (2005), available at <http://www.bmj.com/cgi/reprint/331/7528/1299.pdf>. See also MEDECINS SANS FRONTIERES, *MALARIA FACT SHEET*, available at [http://www.accessmed-msf.org/fileadmin/user\\_upload/diseases/other\\_diseases/malariafactsheetjun04.pdf](http://www.accessmed-msf.org/fileadmin/user_upload/diseases/other_diseases/malariafactsheetjun04.pdf) [hereinafter MALARIA].

combat malaria in high-risk areas, they should transition to artemisinin based combination treatments (“ACTs”) which are more effective, but more expensive than previous therapies and out-of-reach for a majority of poor patients.<sup>149</sup> A patented version of ACTs can cost over \$20, while a generic version available in Vietnam can be found for less than \$1.<sup>150</sup>

WHO recognized that area of South-East Asia (SEARO) which includes India, Bangladesh, Indonesia, Myanmar, Thailand, Sri Lanka, Democratic People’s Republic of Korea, Bhutan, Maldives, Nepal, and East Timor.<sup>151</sup> In this region there are twenty-one million clinically suspected cases of malaria annually, with an estimated 85% of the region’s population at risk for the disease.<sup>152</sup> Thailand was the only SEARO country that transitioned to the use of ACTs prior to 2002, and data has shown steadily decreasing incidences of malaria since the therapy’s introduction.<sup>153</sup> Based on the guidelines of Article 31*bis* (3), there is no existing RTA that will allow these eleven developing countries, six of which are LDCs, to realize economies of scale.

A similar situation exists in the WHO-recognized area of the Western Pacific Region (“WPRO”), which includes Vietnam, the Philippines, China, Cambodia, Republic of Korea, Laos, Malaysia, Papua New Guinea, the Solomon Islands, and Vanuatu.<sup>154</sup> While only 404,000 cases were confirmed in the region, it has been estimated that 2.28 million cases are “probable” or “suspected.”<sup>155</sup> Like Thailand, Vietnam transitioned to ACTs and has seen a 98% drop in malaria mortality between 1999 and 2002.<sup>156</sup> Based on the current Article 31*bis* (3) guidelines, the only existing RTA with the ability to realize economies of scale is the Melanesian Spearhead Group, consisting of Fiji, Papua New Guinea, the Solomon Islands, and Vanuatu. There is no existing RTA that will allow Vietnam, the Philippines, China, Cambodia, Republic of Korea, Laos, and Malaysia to take advantage of Article 31*bis* (3), though Cambodia and Laos are also least developed countries.

Recent occurrences in the Philippines also help highlight the advantages of and need to realize economies of scale. Heart disease, a non-communicable disease, is the number one cause of death in the Philippines.<sup>157</sup> Pfizer earns \$60 million a year by selling its heart drug Norvasc for more than twice the price it

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149. See Morel, *supra* note 148, at 2. See also MALARIA, *supra* note 148 (stating that newer medications are 10-100 times more expensive than older treatments).

150. MALARIA, *supra* note 148.

151. World Health Organization, Regional Office for Southeast Asia, SEAR Countries, <http://www.searo.who.int/EN/Section864/Section1007/Section1012.htm> (last visited Apr. 14, 2008).

152. MEDECINS SANS FRONTIERES, ACT NOW FOR ALL OF THE ASIA PACIFIC TO GET MALARIA TREATMENT THAT WORKS, CAMPAIGN FOR ESSENTIAL ACCESS TO MEDICATIONS 7 (2004), available at [http://www.msf.org/source/downloads/2005/malaria-asia/MSF2005\\_malaria\\_asia.pdf](http://www.msf.org/source/downloads/2005/malaria-asia/MSF2005_malaria_asia.pdf) [hereinafter ACT NOW].

153. *Id.*

154. *Id.*

155. *Id.*

156. *Id.*

157. Marwaan Macan-Markar, *Asian Governments Push Generic Drugs*, INTER PRESS SERVICE UN J. TERRA VIVA, Dec. 20, 2006, at 2.

charges other countries, even though more than 40% of Filipinos do not have affordable access to medications.<sup>158</sup> The Philippine government is currently trying to exert its rights under TRIPS to negotiate favorable generic pricing from Indian manufacturers, but is under intense pressure from Pfizer to extend Norvasc's patent rights.<sup>159</sup> Use of the generic form of Norvasc would reduce its price by almost 90%.<sup>160</sup> The Philippines is currently a member of three multi-party trade agreements.<sup>161</sup> Not one of those three trade agreements allows the Philippines or any of the agreement partners to make use of the economies of scale provision in Article 31bis because at least half of the members are not LDCs.

***B. Those Countries that do Qualify Must Overcome Administrative Impediments***

Despite the fact that most African countries fall within the above-described Article 31bis criteria for realizing economies of scale, there are still major administrative impediments that these countries must overcome. Paragraph (3) states:

[ . . . ]the obligation of that [importing] Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question.<sup>162</sup>

This language suggests that the only way in which multiple countries are able to utilize the economies of scale provision is if one Member applies for and imports the medications to then be re-exported to associate RTA Members that share the same health problem. This in effect makes one Member responsible for the overall coordination and administration of the system at a given time. After manufacturing occurs within the exporting Member, the medications must be shipped to the "lead" importing Member, who then must oversee distribution to associate Members, while also trying to avoid the diversion and corruption that industrialized nations fear so much.

Requiring a developing country that already has issues with infrastructure, control, corruption, and maintaining its border to be responsible for administration and re-exportation of medications to multiple countries significantly increases the chances of diversion. Furthermore, administration and re-exportation increases transaction costs for that country. Given the scarce resources that already exist, developing countries should not have to bear that risk singularly, when it can be spread out amongst multiple parties.

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158. *Id.*

159. *Id.*

160. *Id.*

161. They are the ASEAN Free Trade Area (AFTA), which includes all ASEAN members, the General System of Trade Preferences among Developing Countries (GSTP), and Protocol Relating to Trade Negotiations among Developing Countries (PTN). See *infra* Appendix A (listing all WTO recognized multi-party RTA's and their membership).

162. Article 31bis, *supra* note 15, at 4.

## VII. PROPOSED SOLUTION

Any solution to the world's public health crisis should strike a balance between the protection of incentives to develop life-prolonging pharmaceuticals and the humanitarian duty of countries to help improve the lives of others throughout the world. It would be too simplistic to suggest that patent rights should be completely disregarded in the context of access to medications in the developing countries. The development of pharmaceuticals is an expensive and time-consuming process, and it is important to protect the legitimate resources of the pharmaceutical companies that contribute these much needed medications to society. However, as suggested by the Universal Declaration on Human Rights, it is equally, if not more, important to foster a viable living situation for all throughout the world.

Therefore, developing countries and pharmaceutical multinationals should seek to compromise on affordable prices to the greatest extent possible. However, without the threat of a compulsory license, these multinationals will be hesitant to lower prices on life-prolonging medications to an affordable level. The provisions of Article 31*bis* are concededly a major step in the right direction towards creating an environment in which this threat actually exists. Yet, while developing countries are now able to access cheaper generic medications under the system, the economies of scale provision of paragraph (3) does not enable these countries to acquire them through cheapest means possible short of being free, the threat of a large-scale compulsory license.

The solution is also not to eradicate any guidelines on utilizing economies of scale. Rather, the goal of the WTO is to decrease barriers to trade and increase multilateralism throughout the world.<sup>163</sup> Members agree to this stated goal or else they would not seek to be included in the world's preeminent global trading "Club." Therefore, requiring RTA membership serves a purpose in incentivizing countries to utilize the multilateralism schema.

There are two aspects of Article 31*bis* (3) that should be sacrificed: (1) there should be no qualifier that at least half of the RTA members be on the UN's list of least developed countries, and (2) qualifying members of an RTA should be able to apply for a license as a purchasing bloc, while permitting importation into each requesting country by the exporting Member.

With respect to the first proposal, removing the LDC qualifier significantly increases the number of developing countries that are able to utilize economies of scale in their existing RTA's. By removing those few words, the number of eligible RTA's would increase to eighteen (18).<sup>164</sup> It is important to remember as well, that simply because an RTA qualifies, does not mean that each individual member would qualify as an "eligible importing Member."<sup>165</sup> Those countries

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163. See WTO, THE WORLD TRADE ORGANIZATION..., available at [http://www.wto.org/english/res\\_e/doload\\_e/inbr\\_e.pdf](http://www.wto.org/english/res_e/doload_e/inbr_e.pdf) (explaining purpose of WTO).

164. This figure is based on the author's analysis of those RTA's with a sufficient number of developing countries that have a need to use the WTO's compulsory licensing system. See *infra* Appendix A (listing these designations).

165. See *supra* note 72.

must still show that they lack the capacity to manufacture the needed medications domestically, and that the requested medications are intended for a public health crisis.

The second proposal would have two significant effects. First, it would actually lessen the chance of parallel importation, fraud, and diversion that concern industrialized countries and pharmaceutical companies. If the exporting Member, who should already have safeguards in place to prevent such occurrences, is responsible for exporting to each country that has requested medications as part of the trading bloc, then there exist more assurances that those medications will successfully enter those developing markets.

Second, by shifting the administrative burden to the exporting Member, much of the oversight would also be shifted to that Member. Administration and re-exportation increase transaction costs for that country. Shifting this burden to the exporting Member alleviates these additional costs for the developing country and places them on the Member that can more easily absorb them.

Given the above stated proposals, I suggest that Article 31*bis* (3) be amended to reflect the following language:

3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), Members of such Regional Trade Agreements shall be permitted to apply as a group for a single compulsory license applicable only to those Members that are able to show a lack of manufacturing capacity and a sufficient public health need. Those Members shall form a committee consisting of representation from each Member of the RTA for negotiating purposes and to ensure that all regulations are complied with in order to avoid diversion and promote safety.

It is worth noting one additional and important effect of relaxing the economies of scale provision. In fact, this could be the single greatest reason in the long-run to allow for the greater realization of economies of scale. In the *Annex to the TRIPS Agreement*, paragraph (6) encourages Members to share technology and promote the development of infant pharmaceutical industries in the developing countries. Without the ability to realize economies of scale, these infant industries will not be able to lower their per-unit production costs in order to be economically sustainable. The ability to lower per-unit production costs will allow them to serve a greater number of countries at an affordable output level. Not only does this allow countries to group together for purchasing power, but it provides an incentive to developing countries to create an infant pharmaceutical sector that can supply their “neighbors,” but which could only be sustainable

through the savings realized by economies of scale.

### VIII. CONCLUSION

The Members of the WTO, under pressure from the developing countries, realized in the late 1990s that a healthcare crisis was sweeping the world. One of the greatest impediments to solving this crisis is the cost of medications. The poverty in the developing world is so extreme that devoting any amount of one's income to medications is nearly impossible. This ultimately places the burden on the governments, lacking in funds themselves, to address the costly needs of their citizens. Because of this problem, the Members agreed to devise a solution.

After years of negotiation, Article 31*bis*, allowing for greater flexibility in the use of compulsory licenses, was proposed as an amendment to the TRIPS Agreement. Unfortunately, there are still a number of restrictions attached to this compulsory license provision. One such restriction is the limits placed on developing countries in their ability to realize economies of scale and lower the cost of generics to a relatively affordable level. As the language is currently drafted, there are virtually no developing countries outside of Africa that are able to realize economies of scale under Article 31*bis*. Furthermore, those countries that are able to realize economies of scale under Article 31*bis* must overcome some difficult administrative guidelines to do so. The WTO Members should reconvene and relax these provisions in order to allow all developing countries to realize greater savings and more affordable medications for their citizens.

*Mike Gumbel*



APPENDIX A<sup>166</sup>

Acronym	RTA Name	Members (LDC's in bold)	Art. 31 <i>bis</i> (3) Qualifying	Proposed Language Qualifying
AFTA	ASEAN Free Trade Area	Brunei, Darussalam, <b>Cambodia</b> , Indonesia, <b>Laos</b> , Malaysia, <b>Myanmar</b> , Philippines, Singapore, Thailand, Vietnam	No	Yes
ASEAN	Association of South East Asian Nations	Brunei, Darussalam, <b>Cambodia</b> , Indonesia, <b>Laos</b> , Malaysia, <b>Myanmar</b> , Philippines, Singapore, Thailand, Vietnam	No	Yes
BAFTA	Baltic Free Trade Area	Estonia, Latvia, Lithuania	No	No
BANGKOK	Bangkok Agreement	<b>Bangladesh</b> , China, India, Republic of Korea, <b>Laos</b> , Sri Lanka	No	Yes
CAN	Andean Community	Bolivia, Colombia, Ecuador, Peru, Venezuela	No	Yes
CARICOM	Caribbean Community and Common Market	Antigua & Barbuda, Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, <b>Haiti</b> , Jamaica, Monserrat, Trinidad & Tobago, St. Kitts & Nevis, St. Lucia, St. Vincent & the Grenadines, Surinam	No	Yes

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166. The table was compiled by cross-analyzing the WTO list of recognized RTAs, *see* World Trade Organization, Regional Trade Agreements, with the United Nations' list of Least Developed Countries, *see* United Nations, List of Least Developed Countries.

CACM	Central American Common Market	Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua	No	Yes
CEFTA	Central European Free Trade Agreement	Bulgaria, Croatia, Romania	No	No
CEMAC	Economic and Monetary Community of Central Africa	Cameroon, <b>Central African Republic</b> , <b>Chad</b> , <b>Congo</b> , <b>Equatorial Guinea</b> , Gabon	Yes	Yes
CIS	Commonwealth of Independent States	Azerbaijan, Armenia, Belarus, Georgia, Moldova, Kazakhstan, Russian Federation, Ukraine, Uzbekistan, Tajikistan, Kyrgyz Republic	No	No
COMESA	Common Market for Eastern and Southern Africa	<b>Angola</b> , <b>Burundi</b> , <b>Comoros</b> , <b>Democratic Republic of Congo</b> , <b>Djibouti</b> , Egypt, <b>Eritrea</b> , <b>Ethiopia</b> , Kenya, <b>Madagascar</b> , <b>Malawi</b> , Mauritius, Namibia, <b>Rwanda</b> , Seychelles, <b>Sudan</b> , Swaziland, <b>Uganda</b> , <b>Zambia</b> , Zimbabwe	Yes	Yes
EAC	East African Cooperation	Kenya, <b>Tanzania</b> , <b>Uganda</b>	Yes	Yes
EAEC	Eurasian Economic Community	Belarus, Kazakhstan, Kyrgyz Republic, Russian Federation, Tajikistan	No	No

EC	European Communities	Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom	No	No
ECO	Economic Cooperation Organization	<b>Afghanistan</b> , Azerbaijan, Iran, Kazakhstan, Kyrgyz Republic, Pakistan, Tajikistan, Turkey, Turkmenistan, Uzbekistan	No	No
EEA	European Economic Area	EC, Iceland, Liechtenstein, Norway	No	No
EFTA	European Free Trade Association	Iceland, Liechtenstein, Norway, Switzerland	No	No
GCC	Gulf Cooperation Council	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates	No	No
GSTP	General System of Trade Preferences among Developing Countries	Algeria, Argentina, <b>Bangladesh, Benin</b> , Bolivia, Brazil, Cameroon, Chile, Colombia, Cuba, Democratic People's Republic of Korea, Ecuador, Egypt, Ghana, <b>Guinea</b> , Guyana, India, Indonesia, Islamic Republic of Iran, Iraq, Libya, Malaysia, Mexico, Morocco,	No	Yes

		<b>Mozambique,</b> <b>Myanmar,</b> Nicaragua, Nigeria, Pakistan, Peru, Philippines, Republic of Korea, Romania, Singapore, Sri Lanka, <b>Sudan,</b> Thailand, Trinidad and Tobago, Tunisia, <b>United</b> <b>Republic of</b> <b>Tanzania,</b> Venezuela, Vietnam, Yugoslavia, <b>Zimbabwe</b>		
LAIA	Latin American Integration Association	Argentina, Bolivia, Brazil, Chile, Colombia, Cuba, Ecuador, Mexico, Paraguay, Peru, Uruguay, Venezuela	No	Yes
MERCOSUR	Southern Common Market	Argentina, Brazil, Paraguay, Uruguay	No	Yes
MSG	Melanesian Spearhead Group	Fiji, Papua New Guinea, <b>Solomon</b> <b>Islands, Vanuatu</b>	Yes	Yes
NAFTA	North American Free Trade Agreement	Canada, Mexico, United States	No	No

OCT	Overseas Countries and Territories	Greenland, New Caledonia, French Polynesia, French Southern and Antarctic Territories, Wallis and Futuna Islands, Mayotte, Saint Pierre and Miquelon, Aruba, Netherlands Antilles, Anguilla, Cayman Islands, Falkland Islands, South Georgia and South Sandwich Islands, Montserrat, Pitcairn, Saint Helena, Ascension Island, Tristan da Cunha, Turks and Caicos Islands, British Antarctic Territory, British Indian Ocean Territory, British Virgin Islands	No	No
PTN	Protocol relating to Trade Negotiations among Developing Countries	<b>Bangladesh</b> , Brazil, Chile, Egypt, Israel, Mexico, Pakistan, Paraguay, Peru, Philippines, Republic of Korea, Romania, Tunisia, Turkey, Uruguay, Yugoslavia	No	Yes
SADC	Southern African Development Community	<b>Angola</b> , Botswana, <b>Lesotho</b> , <b>Malawi</b> , <b>Mauritius</b> , <b>Mozambique</b> , Namibia, South Africa, Swaziland, Tanzania, <b>Zambia</b> , Zimbabwe	Yes	Yes
SAPTA	South Asian Preferential Trade Arrangement	<b>Bangladesh</b> , <b>Bhutan</b> , India, <b>Maldives</b> , Nepal, Pakistan, Sri Lanka	No	Yes

SPARTECA	South Pacific Regional Trade and Economic Cooperation Agreement	Australia, New Zealand, Cook Islands, Fiji, <b>Kiribati</b> , Marshall Islands, Micronesia, Nauru Niue, Papua New Guinea, <b>Solomon Islands</b> , Tonga, <b>Tuvalu</b> , <b>Vanuatu</b> , Western Samoa	No	Yes
TRIPARTITE	Tripartite Agreement	Egypt, India, Yugoslavia	No	No
UEMOA-WAEMU	West African Economic and Monetary Union	Benin, Burkina Faso, Côte d'Ivoire, <b>Guinea Bissau</b> , <b>Mali</b> , <b>Niger</b> , <b>Senegal</b> , <b>Togo</b>	Yes	Yes