

10-1-2002

# Seeking a Balance: International Pharmaceutical Patent Protection, Public Health Crises, and the Emerging Threat of Bio-Terrorism

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## Recommended Citation

Arnaldo Lacayo, *Seeking a Balance: International Pharmaceutical Patent Protection, Public Health Crises, and the Emerging Threat of Bio-Terrorism*, 33 U. Miami Inter-Am. L. Rev. 293 (2002)

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## COMMENT

### SEEKING A BALANCE: INTERNATIONAL PHARMACEUTICAL PATENT PROTECTION, PUBLIC HEALTH CRISES, AND THE EMERGING THREAT OF BIO-TERRORISM

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#### I. INTRODUCTION

The protection of intellectual property rights, and more particularly the patent rights claimed by the pharmaceutical industry, surfaced as an issue of international contention between developed and developing countries following the World Trade

Organization (WTO) Ministerial Meeting in Uruguay in 1994.<sup>1</sup> At the heart of the disagreement is the growing global awareness pertaining to the epidemic levels of HIV, AIDS, and other treatable, if not yet curable, diseases plaguing the developing world.<sup>2</sup>

The November 2001 Ministerial Meeting in Qatar met in the shadow of the failure of the Seattle WTO meeting, where no agreement as to the next round of trade liberalization talks was reached in part because of disagreements between the developing and developed States.<sup>3</sup> Also looming over the Qatar meetings was the new geopolitical reality born after the September 11th terrorist attacks on the United States and the bio-terrorism that followed.<sup>4</sup> On November 14, 2001, a resolution from Qatar emerged, directly addressing the issue of pharmaceutical intellectual property rights protection during a time of growing popular concern for both well-established and emerging public health threats.<sup>5</sup>

1. See David Dollar and Aart Kraay, *Spreading the Wealth*, FOREIGN AFFAIRS, Jan.-Feb. 2002, at 120, for a recent comprehensive discussion on the debate about globalization and trade and its effect on the developing world. This piece reflects the dissatisfaction and concern expressed by leaders from the developing world with regards to the pace of implementation for concessions made by their counterparts in the developed nations, pertaining to farming subsidies and other forms of trade protection that remain in place for the benefit of domestic industries. Many in the developing world question the fairness of the developed nations' actions (or lack thereof) in light of the pressure the developing countries are under to implement and enforce the agreements reached during the Uruguay Round, which resulted in the creation of the WTO. One of many such concessions made by the developing countries of the world is the implementation of intellectual property rights. The article argues that a growing protectionist movement in the rich countries is a dangerous phenomenon that threatens efforts to bring down trade barriers and the future welfare of the developing world's citizenry.

2. For a recent and comprehensive discussion on HIV/AIDS and other diseases that ravage people across the world, see *Challenges for Humanity: War on Disease and Amid the Unrelenting Spread of AIDS: Search for a Cure*, NATIONAL GEOGRAPHIC MAGAZINE 2 & 32 (Vol. 201, No. 2, Feb. 2002) [hereinafter *Challenges for Humanity*].

3. *Push Comes to Shove*, THE ECONOMIST, November 9, 2001, available at [http://www.economist.com/agenda/PrinterFriendly.cfm?Story\\_ID=852371](http://www.economist.com/agenda/PrinterFriendly.cfm?Story_ID=852371) (last visited Apr. 23, 2002). The article describes the WTO's gathering in Seattle in December 1999, as an "embarrassing failure, with acrimony between delegates and massive anti-globalization protests on the streets." The article goes on to describe how "the deep divisions between the poor and rich countries [again] threatened the possibility of a new trade round in the months leading to the Doha, Qatar meeting in November 2001."

4. Elizabeth Olson, *Drug Issue Casts a Shadow on Trade Talks*, N.Y. TIMES, Nov. 2 2001, at W1.

5. For the full text of the Doha, Qatar Declaration on the TRIPS Agreement and Public Health see Appendix A. See also World Trade Organization, Doha, Qatar Declaration, at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/min01\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm). (last visited Apr. 23, 2002) [hereinafter Declaration on the TRIPS Agreement and Public Health].

The Qatar resolution gives States tremendous latitude in addressing domestic health threats by legitimating the practice of developing States of invoking the WTO's Agreement on Trade Related Intellectual Property Rights (TRIPS) in times of public health crises for the purpose of obtaining needed pharmaceutical products.<sup>6</sup> The resolution's inclusion of a provision for the granting of compulsory licenses to produce generic drugs,<sup>7</sup> of a provision granting members the right to determine what constitutes a national emergency,<sup>8</sup> and a provision to delay implementation of intellectual property protection laws in the "least-developed" countries (LDCs)<sup>9</sup> is seemingly a victory for the developing world and its sick. Nevertheless, the question still remains whether the resolution's expansion of a State's right to invoke a "national emergency" at times of "urgency" relating to public health may ultimately serve as a chilling disincentive for the research and development of new drugs in the developed countries, which in the long term has the potential of indiscriminately disadvantaging all the peoples of the world.

This comment will examine the balance that the WTO's TRIPS Agreement attempts to strike between the long-term need for pharmaceutical research and development and the short-term need for access to affordable medicines particularly in the developing world. In particular, section II of the comment will explore the development of the World Trade Organization and the TRIPS Agreement as one of the legal texts comprising the overall agreement to form the WTO. Section III will explore the philosophical underpinnings to the TRIPS Agreement and its search for the balance described above. This exploration will focus on the role of patent protection in spurring innovation and advancement, the immediacy and magnitude of the public health crises affecting the peoples of the world, and the idea of striking a balance by providing flexibility through exceptions to the TRIPS Agreement. Section IV will break down the main arguments put forth by the developing nations and those put forth by the developed members

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6. See World Trade Organization, WTO's Agreement on Trade Related Intellectual Property Rights, available at [http://www.wto.org/english/docs\\_e/legal\\_e/final\\_e.htm](http://www.wto.org/english/docs_e/legal_e/final_e.htm) (last visited on Apr. 23, 2002) [hereinafter TRIPS]. This link will provide access to the full legal texts from the Uruguay Round Final Act from which the World Trade Organization was created. The TRIPS agreement can be found under Annex 1C.

7. Declaration on the TRIPS Agreement and Public Health, *supra* note 5, ¶ 5(b).

8. *Id.* ¶ 5(c).

9. *Id.* ¶ 7.

of the WTO. Finally, section V of the comment will look at how the events of September 11, 2001, and the anthrax scare that followed, changed the geopolitical framework of the debate, an alteration that resulted two months later in the Qatar Declaration on the TRIPS Agreement and Public Health.

## II. HISTORICAL FRAMEWORK

### A. *Free Trade and the World Trade Organization (WTO)*

From the divisiveness and destruction of World War II emerged the goal of creating a multilateral organization that would serve as the locus for efforts to revive and oversee the post-war world economy. In conjunction with the International Monetary Fund (IMF) and the International Bank for Reconstruction and Development (the World Bank), the International Trade Organization (ITO) was envisioned as one of three international institutions that would restore the economic world order, while working to avoid the tragic errors of the post-First World War period that, in the opinion of many, served to precipitate the second world conflict.<sup>10</sup>

The ITO ultimately fell victim to political opposition in the United States rooted in the suspicion and distrust of the nascent Cold War, but the fundamental objectives of the ITO continued to garner the attention of the world's trading nations.<sup>11</sup> With the goal of reducing trade barriers, twenty-three nations became signatories to the General Agreement on Tariffs and Trade (GATT) in 1947.<sup>12</sup> The GATT reflected many of the policy goals of the once-proposed ITO, and successfully served as the principal body of substantive international law governing member policies with respect to the trade of goods until the 1995 Uruguay Round Agreements, which resulted in the creation of the World Trade Organization (WTO).<sup>13</sup>

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10. See generally ALAN C. SWAN & JOHN F. MURPHY, CASES AND MATERIALS ON THE REGULATION OF INTERNATIONAL BUSINESS AND ECONOMIC REGULATION 467 (2d ed. 1999).

11. See *id.*

12. For a more complete history of the General Agreement on Tariffs and Trade (GATT) and its role as the foundation for the World Trade Organization, see World Trade Organization, *The WTO and GATT – Are they the same?* at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/fact6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact6_e.htm). (last visited Apr. 23, 2002).

13. SWAN AND MURPHY, *supra* note 10, at 467-68.

*B. The Agreement on Trade-Related Aspects of  
Intellectual Property Rights (TRIPS)*

The WTO built on the decades of experience and work resulting from the signing of the GATT and expanded the elements of international trade and economics that would be addressed multilaterally. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is one of approximately twenty-five legal texts composing the agreement establishing the WTO,<sup>14</sup> and as such, is subject to the WTO dispute settlement system.<sup>15</sup> The TRIPS Agreement covers intellectual property rights in general, and more specifically, subject matter relating to mechanisms of protection such as patents which serve the purpose of preventing others from making, using, or selling a new invention for a limited period of time.<sup>16</sup>

It is from within the framework of the TRIPS Agreement that the issue of international pharmaceutical patent protection must be explored. From the balance that TRIPS attempts to strike between the pharmaceutical companies who seek to protect their investments in research and development and the undeniable need for affordable drugs in the developing world, to the incorporation of numerous exceptions as to governments' obligations under TRIPS, the application of the multilateral agreement's provisions has been filled with contention and controversy.<sup>17</sup> The central role of TRIPS in the debate about the future of free trade was evinced most recently in the November 2001 WTO ministerial meeting in Doha, Qatar, where discussions on the topic resulted in a separate ministerial declaration on the TRIPS Agreement and

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14. Unlike the organizational structure established under GATT, where bilateral or multilateral side agreements were applicable only as to the parties to those agreements, the side agreements to the WTO contained in Annexes 1-4 are applicable as to every member of the WTO. The TRIPS Agreement is such an agreement and is contained in Annex 1C. For more on the WTO and its respective Annexes see SWAN AND MURPHY, *supra* note 10, at 473-74.

15. World Trade Organization, *Pharmaceutical Patents and the TRIPS Agreement* (July 11, 2000), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/pharma\\_ato186\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm). (last visited Apr. 23, 2002) [hereinafter *Pharmaceutical Patents and the TRIPS Agreement*].

16. World Trade Organization, *TRIPS and Pharmaceutical Patents WTO OMC Fact Sheet* (Apr. 2001), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/trips\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/trips_e.htm). (last visited Apr. 23, 2002) [hereinafter *WTO OMC Fact Sheet*].

17. World Trade Organization, *Governments Share Interpretations on TRIPS and Public Health* (June 20, 2001), available at [http://www.wto.org/english/news\\_e/news01\\_e/trips\\_drugs\\_010620\\_e.htm](http://www.wto.org/english/news_e/news01_e/trips_drugs_010620_e.htm). (last visited Apr. 23, 2002) [hereinafter *Interpretations on TRIPS*].

public health.<sup>18</sup>

### III. THE SEARCH FOR BALANCE - INTERNATIONAL PHARMACEUTICAL PATENT PROTECTION

#### A. *Short Term and Long Term Objectives Under TRIPS*

The WTO, in its fact sheet pertaining to pharmaceutical patents, proposes that the philosophy underlying the TRIPS Agreement is one that seeks to strike a balance between the long-term social objective of providing incentives for future inventions and creation, and the short-term objective of allowing people to use existing inventions and creations.<sup>19</sup> The interplay of these two, often contradictory, objectives reverberates along lines that divide the developed and developing world, and provides the backdrop for understanding a complex problem involving questions ranging from social justice and morality to economic and investment theory.<sup>20</sup>

The WTO fact sheet asserts that this elusive balance is sought through the application of policies that reflect three basic conceptual and philosophical tenets. The first of these holds that intellectual property protection encourages inventors and creators because they can expect to earn some future benefit from their creativity and investments.<sup>21</sup> The second aspect of this policy

18. Declaration on the TRIPS Agreement and Public Health, *supra* note 5.

19. *WTO OMC Fact Sheet*, *supra* note 16, at 1. (The WTO OMC fact sheet on TRIPS and Pharmaceutical Patents includes the following wording, "This fact sheet has been prepared by the Information and Media Relations Division of the WTO Secretariat to help public understanding. It is not an official interpretation of the WTO agreements or member's positions."). This type of language is representative that member nations each have their own interpretation of what protection they should afford foreign patent holders, and of what represents a "national emergency" or "other circumstances of extreme urgency." These differences in interpretation are central to the debate about the extent of restrictions imposed by the TRIPS Agreement and their effect on public health measures.

20. See Dollar & Kraay, *supra* note 1, at 131, for a general discussion of the multidisciplinary nature of the debate regarding the protection of intellectual property rights and the issue's place in the larger debate about globalization and free trade initiatives.

21. See discussion below on comments made by the Secretary General and the Deputy Secretary General of the WTO regarding the importance of intellectual property rights protection. See also Thomas H. Maugh II, *Vaccine for AIDS Shows Promise*, L.A. TIMES, Feb. 27, 2002, at A1; Steve Sternberg, *A Step Forward in the AIDS Vaccine Dance*, USA TODAY, Feb. 28, 2002, at 8D (describing an update on the advancement of efforts to create an HIV/AIDS vaccine in the United States at an expense of millions of dollars and years of research).

approach is that intellectual property protection can be engineered in such a manner as to service social goals. This approach holds that patented inventions should be disclosed in the public domain so that others can study the patented product during the patent's term; in short, the goal is to have the proverbial wheel improved but not necessarily reinvented. Lastly, the TRIPS agreement is effective only as far as signatory nations are willing and able to adopt and apply the provisions of the multilateral agreement.

With this practical consideration in mind, the third component of the philosophy underlying the TRIPS Agreement is the signatories' need for flexibility in catering to inventors so that they realize the protections granted within particular domestic social, political, and economic realms.<sup>22</sup>

### *B. Innovation and the Need for Patent Protection*

The TRIPS Agreement adopts a standard for patent protection that, at a minimum, mandates that the patent owner have the right "to prevent unauthorized persons from using the patented process and [from] making, using, offering for sale, or importing the patented product or a product obtained directly by the patented process."<sup>23</sup> Additionally, the TRIPS Agreement requires that the term of protection expire no earlier than twenty years from the date of filing the patent application.<sup>24</sup>

The need for this level of patent protection has been outlined by WTO Director-General Mike Moore, who describes why pharmaceutical companies need incentives to develop new drugs. Moore explains that the pharmaceutical industry puts the average cost of developing a new drug at around the \$500 million figure. It is his contention that without "a patent system that rewards companies for risking millions on research, anti-AIDS drugs would not exist."<sup>25</sup>

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22. WTO OMC Fact Sheet, *supra* note 16, at 1-2. (The Fact sheet prefaces its discussion of the three tenets by stating that this is "how the balance works."). The importance given to each of these tenets and whether they succeed in finding the balance is obviously questionable and the subject of much debate. It is arguable that the debate that consumed the pre-Doha consultations signifies a failure to find balance with the distribution as it stood. It seems like the third element is taking center stage as developing countries more aggressively assert the need for flexibility in implementation of intellectual property protection laws.

23. *Pharmaceutical Patents and the TRIPS Agreement*, *supra* note 15, at 2.

24. *Id.* at 3.

25. Mike Moore, *Yes, Drugs for the Poor – and Patents as Well*, INT'L HERALD



Moore's prediction about the dampening of innovation without patent protection is described using different language and statistics in a paper presented to the WTO and the World Health Organization (WHO) in April 2001, where the author writes that:

Research and innovation remain the prerequisite to obtaining new products. Without investments to support research, one cannot find candidates. Without applied research and investments to develop products, test them and prove that they are safe and effective, one cannot convert candidates into products. In this respect, intellectual property rights play a singularly important role in promoting development and availability of new products to treat diseases. Intellectual property rights are essential for turning ideas into candidates, turning candidates into safe and effective products, and for delivering products into the market.<sup>26</sup>

Decisions based on business calculations of risk and return are the precursors to the drawn-out process of research and development that eventually results in new and beneficial drugs. Situations where the risks outweigh the potential economic returns result in little or no research and development effort to address grave public health crises. This type of business decision-making is summed up by the WTO Deputy Director-General, Miguel Rodriguez, who notes that "there is no company that will invest the resources required for research and development without a promise of some degree of exclusivity in exploiting the results of its efforts."<sup>27</sup> He adds that the problem is further complicated by the fact that even with an effective intellectual property system in place, it is another uphill battle to provide incentives for research and development into the diseases that afflict the poor populations who reside in developing countries, where purchasing power is so limited.<sup>28</sup>

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TRIBUNE, Feb. 22, 2001, available at <http://www.iht.com> and [http://www.wto.org/english/news\\_e/news01\\_e/tn\\_dg\\_iht\\_feb2001\\_e.htm](http://www.wto.org/english/news_e/news01_e/tn_dg_iht_feb2001_e.htm). (last visited Apr. 23, 2002).

26. Richard Wilder, *Market Segmentation: Techniques, Actors and Incentives – The use of Intellectual Property Rights*, Presentation at the Workshop on Differential Pricing and Finance of Essential Drugs Hosted by the World Health Organization and World Trade Organization (Apr. 8-11, 2001), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/hosbjor\\_presentations\\_e/hosbjor\\_presentations\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/hosbjor_presentations_e/hosbjor_presentations_e.htm). (last visited April 23, 2002).

27. World Trade Organization, *An Appropriate Balance for Public Health* (Oct. 11, 2000), available at [http://www.wto.org/english/news\\_e/news00\\_e/tn\\_rodrig\\_sep00\\_e.htm](http://www.wto.org/english/news_e/news00_e/tn_rodrig_sep00_e.htm). (last visited Apr. 23, 2002).

28. *Id.*

### C. *The Immediacy and Magnitude of a Public Health Crisis*

Director-General Moore's presentation of the reasons why patent protection is essential to the development of new drugs is countered by the equally compelling (or greater) need for affordable drugs in the world's poorest countries. The Director-General notes that malaria, tuberculosis and AIDS kill six million people each year, with most of the deaths occurring in the developing world.<sup>29</sup> He describes how access to drug care is made impossible by the fact that keeping an AIDS patient alive for one year can cost up to \$15,000 – the equivalent of twenty four times the average annual income in Zimbabwe, where one in four adults is HIV-positive.<sup>30</sup>

The dire statistics presented by the Director-General of the WTO are further accentuated by facts incorporated into Richard Wilder's presentation at the April, 2001 Workshop on Differential Pricing and Financing for Essential Drugs. Wilder argues that the challenges of providing pharmaceutical products to patients in developing and least developed countries are immense. He cites as an example the drug regime "for treating patients afflicted with HIV/AIDS, which can encompass the administration of seventeen to thirty pills each day for the life of the patient."<sup>31</sup> The sheer costs associated with the treatment of HIV and AIDS creates a chasm between the developed and developing world. Accordingly, it is in the developing world, and most acutely on the African continent, that aggressive efforts must be undertaken to slow the spread of diseases that afflict the populations of many nations at epidemic rates.<sup>32</sup>

### D. *Flexibility through Exceptions to the TRIPS Agreement*

As described previously, the balance sought by the WTO in the TRIPS Agreement is underpinned by a philosophy that holds

29. Moore, *supra* note 25. See also *Challenges for Humanity*, *supra* note 2.

30. *Id.*

31. Wilder, *supra* note 26, at 1.

32. *Challenges for Humanity*, *supra* note 2, at 12. Additionally, the article reports on the status of other widespread ailments including influenza, diarrheal diseases, tuberculosis, malaria, and measles, which together with HIV/AIDS account for ninety percent of the deaths from infectious disease worldwide – some of which affect the world's nations indiscriminately, while others fall on either side of the separation between the developed and developing world.

that member nations must be given the flexibility they need in enacting intellectual property laws so as to make the process politically and socially viable.<sup>33</sup> This flexibility, as reflected in the mechanisms and exceptions described below, is the result of the efforts of the developing and least developed countries to incorporate their concerns into the debate following the creation of the WTO and about the growth of free trade initiatives.<sup>34</sup> From the contention that requiring countries to strictly enforce pharmaceutical patents enables drug companies in the developed world to charge exorbitant prices that the poor cannot afford, follows the push for flexibility in enacting intellectual property laws.<sup>35</sup> The following is a description of the language in the TRIPS Agreement, which creates exceptions to the provisions requiring patent protection.

Under Article 27 of the TRIPS Agreement dealing with patentable subject matter, member governments can refuse to grant patents for three reasons. Article 27(2) states that members "may exclude from patentability inventions, [when] prevention within their territory [for] commercial exploitation . . . is necessary to protect *ordre public* or morality, including to protect human, animal, or plant life, or health or to avoid serious prejudice to the environment[.]"<sup>36</sup> Similarly, a government can refuse patents under Article 27.3 (a) and (b) for diagnostic, therapeutic and surgical methods for the treatment of humans or animals, and for plant and animal inventions excluding those dealing with micro-organisms.<sup>37</sup>

The notion that the public good may, under certain circumstances, outweigh the right to have one's innovation and creation protected is further developed in Article 8 of the TRIPS Agreement. Article 8 reads as follows:

- (1) Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public

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33. There is danger in clumping all developing countries together in this discussion. While countries like India and Brazil harbor hopes of advancing their own infant research and development capabilities, the nations of the African sub-continent and most in the western hemisphere and Caribbean have the much more pressing need of addressing public health epidemics as their main concern in the debate about pharmaceutical patent protection and the TRIPS Agreement's implementation.

34. *Interpretations on TRIPS*, *supra* note 17, § 1.

35. Moore, *supra* note 25.

36. TRIPS, *supra* note 6.

37. *Id.*

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.

- (2) Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices, which unreasonably restrain trade or adversely affect the international transfer of technology.<sup>38</sup>

Shortly after its adoption, the language of Article 8 gave rise to a practice whereby countries began to invoke TRIPS as the basis for the argument that their domestic health crises necessitated the amending of their laws regarding intellectual property rights (or their immediate non-enforcement) in order to protect the public interest.<sup>39</sup>

In relation to Article 8, it is important to note that this section of the TRIPS Agreement holds another major concession made to the developing nations in its adoption. The developing countries had argued for a form of research "piggy-backing," which would allow for the further development of pharmaceutical products during the patent term. The theory for allowing this type of research on patented product was that the balance, which the TRIPS Agreement sought in principle, is better approached by allowing a form of forced collaboration between pharmaceutical companies, while simultaneously seeking to protect the patent through the minimum twenty year term.<sup>40</sup>

This concession to the developing countries is adopted in Article 8(2) and is commonly referred to as the "regulatory" or "Bolar" exception. Under this exception, some countries allow manufacturers of generic drugs to use the patented invention for research and development as they work their way through the pharmaceutical drug-approval process, without the patent owner's permission and before the patent protection expires. The idea behind this exception is that it speeds up the process of bringing generics to the local market after the patent term has expired.<sup>41</sup> This practice has been upheld by the WTO dispute resolution body in a deci-

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38. *Id.*

39. For general background information see Rachel Swarns, *AIDS Drug Battle Deepens in Africa*, N.Y. TIMES, March 8, 2001, at A1.

40. TRIPS, *supra* note 6. The second paragraph of article 8 has been construed broadly to allow for the "regulatory" or "Bolar" exception.

41. WTO OMC Fact Sheet, *supra* note 16, at 3.

sion where a Canadian law allowing this exception was held to be in conformity with the TRIPS Agreement.<sup>42</sup>

Another major concession to the TRIPS signatories from the developing world is Article 31, which encompasses what is described as "other use without authorization of the right holder."<sup>43</sup> This provision of the TRIPS Agreement grants member governments the right to legitimize compulsory licensing. This form of licensing allows a non-patent holder to produce the patented product or process absent the consent of the patent's rightful owner. Article 31 tries to limit the circumstances under which compulsory licensing can be utilized. Article 31(b) requires that under most circumstances, "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."<sup>44</sup> Additionally, Article 31(h) requires that after a compulsory license is issued without the consent of the patent's holder, "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."<sup>45</sup> As evinced by the language used in outlining the circumstances under which "other use without the authorization of the right holder" is permitted, the protection of patent rights is open to significant challenges even in countries agreeing to the provisions of the TRIPS Agreement in general.

This malleable language used in the drafting of Article 31 is especially important in the context of Article 31(b), parts of which were described above, but which in its entirety reads as follows:

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 emer-

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42. World Trade Organization, Canada – Patent Protection of Pharmaceutical Products (Mar. 17, 2000), at [http://www.wto.org/english/tratop\\_e/dispu\\_e/distabase\\_wto\\_members1\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/distabase_wto_members1_e.htm) (last visited Apr. 23, 2002). Click on the link for Canada "as respondent" and search for the document by date or document number, which for the original decision is WT/DS114/R.

43. TRIPS, *supra* note 6.

44. *Id.*

45. *Id.*

gency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as possible.<sup>46</sup>

The requirement that "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" is fraught with ambiguity and is highly problematic from the perspective of the patent right holder who, in all likelihood, cringes at the sight of the word "reasonable" appearing twice in one sentence.

Because of the ambiguity contained in the Article, it has been central to the debate about the enforcement of patent rights in the developing world, where arguably the level of infections from diseases like HIV and AIDS have created a "national emergency or other circumstances of extreme urgency" in many signatory countries. The implications of this argument will be discussed further following this section on exceptions to patent protection.

The issue of parallel or grey-market imports involves the unauthorized importation of a patented product from country A into country B, where both countries afford the patent holder protection, but the drug or product sells for less money in country A. In an instance of parallel importation, a separate company or individual would buy the product in country A, where it sells for less, and would then import it into country B where he could sell the same product at a higher price. It is worth noting that the products being imported in this fashion are not counterfeit or dangerous copies, but products of the same quality.<sup>47</sup>

Understandably, the developing and developed nations of the world each took a different perspective on the issue of parallel importation. The developing countries argue that parallel importation is essential to ensuring the lowest price possible for drugs of comparable quality and effectiveness; the European Union, Switzerland and the United States argue that parallel importation, and the accompanying danger of cheaper products flowing back into the developed countries' markets, has the potential of undermining efforts aimed at establishing an effective system for "dif-

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46. TRIPS, *supra* note 6.

47. For a thorough discussion on parallel trade, see Alberto Heimler, *The Pharmaceutical Industry and Parallel Trade, Market Segmentation: Techniques, Actors and Incentives - The Use of Intellectual Property Rights*, Presentation during the Workshop on Differential Pricing and Financing of Essential Drugs Hosted by the World Health Organization and World Trade Organization, (Apr. 8-11 2001), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/hosbjor\\_presentations\\_e/hosbjor\\_presentations\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/hosbjor_presentations_e/hosbjor_presentations_e.htm). (last visited Apr. 23, 2002).

ferential pricing," whereby companies sell at lower prices in developing countries.<sup>48</sup>

In addition to the connection drawn between parallel importation and differential pricing, the connection between parallel importation and the TRIPS Agreement involves Article 6 and the idea of patent exhaustion. The notion of exhaustion is that once a patent holder sells its product, its rights over the product's use or resale are exhausted, putting what happens to the product after the point of sale out of its control. Article 6 of the TRIPS Agreement deals with exhaustion, and states that "for the purposes of dispute settlement under [TRIPS], subject to the provisions of Article 3 and 4, nothing in the Agreement shall be used to address the issue of exhaustion of intellectual property rights."<sup>49</sup> The practical effect of this provision is that even where parallel or grey-market importation is undertaken in violation of the TRIPS Agreement in a signatory State which allows it, the WTO is powerless to address the dispute through its internal dispute settlement procedure, unless it involves an issue of discrimination under Article 3 or 4.<sup>50</sup>

A final note on the issue of exceptions to the TRIPS Agreement is that signatories that were designated as developing or as being least-developed countries were granted transition periods following the implementation of the TRIPS Agreement so that they could enact its provisions. Article 65(2), detailing the transitional arrangements, allows developing country members to "delay for a further period of four years the date of application . . . of the provisions of [the] Agreement."<sup>51</sup> This gave developing countries until January 1, 2000 to complete the transition. Under the provisions of Article 66(1), with respect to least-developed country members:

in view of [their] special needs and requirements . . . their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base . . . [are] not required to apply the provisions of [the TRIPS] Agreement . . . for a period of ten years from the date of application.<sup>52</sup>

These graduated transition periods are an additional component

48. *Interpretations on TRIPS*, *supra* note 17, at 3.

49. TRIPS, *supra* note 6.

50. *WTO OMC Fact Sheet*, *supra* note 16, at 5.

51. TRIPS, *supra* note 6.

52. *Id.*

of the concessions made to the developing and least-developed signatories so as to make the implementation of intellectual property protection laws politically, economically and socially possible. However, as will be discussed below, the transition periods would not prove long enough.

With these concessions to the developing world in its members' efforts to obtain flexibility in the implementation of the TRIPS Agreement's provisions, it is logical to examine which problems might result from this arrangement and to ask questions about whether the exceptions swallow the Agreement, rendering it inefficient or useless. The positions on opposite ends of the debate about intellectual property protection and the need for affordable drugs in the developing world shed light on these questions.

#### IV. TRIPS UNBALANCED – THE BATTLE LINES ARE DRAWN

Following the protest-plagued ministerial meeting of the WTO in Seattle, the agenda for the November 2001 meeting in Doha, Qatar began to take shape.<sup>53</sup> At the June 2001 TRIPS Council's Meeting, the jockeying for control of the agenda and the introduction of discussion topics came to a peak in relation to the issues of pharmaceutical patent protection and access to drugs. From this meeting emerged the basic positions of the developed and developing world in relation to the issues of compulsory licensing, parallel imports and other issues related to TRIPS and access to medicines. A follow-up meeting was held in September 2001, from which two papers emerged. In essence, these papers delineated the battle lines in the debate just a few weeks prior to the Qatar meeting.<sup>54</sup> These draft papers were submitted independently by two blocks of nations. The positions advocated by each are discussed below.<sup>55</sup>

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53. World Trade Organization, *WTO Members to Press on Following Rich Debate on Medicines* (June 22, 2001) at [http://www.wto.org/english/news\\_e/pres01\\_e/pr233\\_e.htm](http://www.wto.org/english/news_e/pres01_e/pr233_e.htm) (last visited Apr. 23, 2002) [hereinafter *Debate on Medicines*]. This article summarizes the Geneva TRIPS council discussion on intellectual property rights and access to medicines held on June 20, 2001. This meeting was the beginning of a process that was to last through the November meeting in Qatar, during which the positions of the members on the issue would be defined.

54. World Trade Organization, *Members Discuss Drafts for Ministerial Declaration* (Sept. 21, 2001) available at [http://www.wto.org/english/news\\_e/news01\\_e/trips\\_drugs\\_010919\\_e.htm](http://www.wto.org/english/news_e/news01_e/trips_drugs_010919_e.htm). (last visited Apr. 23, 2002).

55. The Developing Country Group's Paper on TRIPS and Public Health dated June 19, 2001 was submitted by the Africa Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan,



### A. *The Developing World's Position*

The Developing Country Group's Paper begins by asserting that the purpose of the discussion on TRIPS and public health at the TRIPS' Council should be to ensure that the TRIPS Agreement does not undermine the implementation of public health policies by members.<sup>56</sup> Additionally, the Paper states that while the TRIPS Agreement provides room for the implementation of public health policy measures, the flexibility afforded to members to modify the Agreement must be extended to situations where the provisions in TRIPS fail to address specific and pressing public health threats. Accordingly, the developing countries argue, the provisions of the TRIPS agreement must be read with deference to Articles 7 and 8, which seek to protect intellectual property rights without ignoring the need for policies that make needed drugs available to people.<sup>57</sup>

The Developing Country Group's paper also delves into the issue of compulsory licensing and discusses the benefits of allowing such licensing as a tool for assuring the prevention of abuses such as anticompetitive measures.<sup>58</sup> The Paper makes the argument that compulsory licensing fosters the development of pharmaceutical industries in the developing world, and that it is an essential mechanism for dealing with national emergencies and other circumstances of extreme urgency as described in Article 8.<sup>59</sup>

Additionally, the developing countries hold that domestic legislation pertaining to parallel importation, and the principle of exhaustion fall under the exclusive jurisdiction of the member countries and outside the realm of the WTO dispute settlement process under Article 6.<sup>60</sup> Lastly, the Paper makes reference to

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Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela. The European Union's Paper to the TRIPS Council for the Special Discussion on Intellectual Property and Access to Medicines was submitted the following day on June 20, 2001. See World Trade Organization, *Developing Country Group's Paper Submitted to the TRIPS Council for the Special Discussion on Intellectual Property and Access to Medicines* (June 19, 2001) available at [http://www.wto.org/english/tratop\\_e/trips\\_e/paper\\_develop\\_w296\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm); *EU's Paper Submitted to the TRIPS Council for the Special Discussion on Intellectual Property and Access to Medicines* (June 20, 2001), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/paper\\_eu\\_w280\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/paper_eu_w280_e.htm). (last visited Apr. 23, 2002) [hereinafter *Developing Country Group's Paper*].

56. *Developing Country Group's Paper*, *supra* note 55.

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

the possibility of extending the transitional period for the least developed countries, and introduces the idea that while nominally given flexibility through TRIPS, efforts need to be made to insure that the developing countries are able to exercise that flexibility in accordance with their needs.<sup>61</sup>

The developing countries back their arguments up with a listing of resolutions, recommendations, declarations and studies calling for policies that broaden access to essential drugs at low costs for all of the world's citizens.<sup>62</sup> Second, the developing countries resort directly to the text of Articles 7 and 8 of the TRIPS Agreement to substantiate their position.<sup>63</sup> In particular, they argue that Article 7 establishes that the protection and enforcement of intellectual property cannot be sought while ignoring the context and circumstances in which it is to be protected and enforced. They also propound that the language in Article 8 clearly establishes that nothing in the TRIPS Agreement will prevent members from adopting measures to protect public health.<sup>64</sup>

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61. See generally *Debate on Medicines*, *supra* note 53, for the proposition that while recognizing that the TRIPS Agreement grants flexibility, it is the concern of developing nations that the provisions granting flexibility are too narrowly interpreted by the developed countries and that in addition, developing countries come under undue pressure not to make full use of the flexibility that the TRIPS Agreement affords them.

62. *Developing Country Group's Paper*, *supra* note 55. The paper lists the following: Two May 2001 resolutions from the 54th World Health Assembly - the resolution "Scaling Up the Response to HIV/AIDS" (WHA 54.10), and the resolution "WHO Medicines Strategy" (WHA 54.11), which calls for making drugs available at lower prices for those in need; Resolution 2001/33 of the 57th Session of the U.N. Commission on Human Rights adopted in April 2001 and calling for an increase in access to medicines. . . especially for those who can least afford the costs; the Report of the Secretary General to the General Assembly of the U.N. for the Special Session on HIV/AIDS (document A/55/779, issued on 16 Feb. 2001), calling for the expansion of low-cost generic drug availability, and the reaffirmation of the importance of compulsory licensing and parallel importation to the increase in access to drugs; Statements from the XI Summit of the Heads of State and Government of the Group of Fifteen (G-15) in May 2001, where the heads of state called for noninterference of TRIPS in efforts to implement compulsory licensing and parallel importation legislation to ensure access to life-saving drugs at affordable prices to overcome hazards to public health and nutrition caused by HIV/AIDS and other diseases; and lastly, the recommendations of non-governmental organizations such as *Medecins sans Frontieres* (Doctors Without Borders), OXFAM, and Consumers International that the TRIPS Agreement not be applied in detriment to public health policies. See World Trade Organization, *Developing Country Group's Paper Submitted to the TRIPS Council for the Special Discussion on Intellectual Property and Access to Medicines*, ¶¶ 7-14.

63. TRIPS, *supra* note 6.

64. *Developing Country Group's Paper*, *supra* note 55, ¶¶ 1-6.

*B. The Developed World and its Pharmaceutical Industry Weigh-In*

On September 20, 2000, the European Commission (EC) and its member states proposed a paper reiterating the main objectives of EC development policy, including the elimination of communicable diseases within the framework of the existing goal of reducing poverty in developing countries. On February 21, 2001, the EC effectively adopted the paper entitled *Accelerated Action Targeted at Major Communicable Diseases Within the Context of Poverty Reduction*, as a program for accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction.<sup>65</sup>

The paper then shifts its attention to the issue of intellectual property rights and reiterates the EC's position that such rights are central to fostering creativity and innovation.<sup>66</sup> The paper argues that Articles 7 and 8 of the TRIPS Agreement give developing nations the flexibility and discretion they need to viably implement the Agreement.

On the issue of compulsory licensing, the EC notes that while "Article 31 does not itself contain tailor-made solutions to any specific problem raised in the debate on access to health, it does leave WTO members the freedom to determine the grounds for granting compulsory licenses . . . and it allows for swift action in case[s] of emergency or extreme urgency."<sup>67</sup> The EC goes as far as agreeing with the contention that levels of HIV/AIDS infections in certain developing countries reach the level of a national emergency or circumstance of extreme urgency. Lastly, the EC concedes that there may be room for discussion pertaining to the importation of goods manufactured under compulsory licenses in other countries. The EC holds reservations about the applicability of this reading of Article 31, but leaves the issue open to discussion in the paper.<sup>68</sup>

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65. *Id.* at ¶ 5. The EU's paper refers readers to the following web address for additional information regarding the topic, see [http://www.cc.cec:8082/comm/development/sector/social/health\\_en.htm](http://www.cc.cec:8082/comm/development/sector/social/health_en.htm).

66. *Id.* ¶¶ 7-8.

67. *Id.* ¶ 11.

68. *See id.* The paper again refers readers to the following web address for additional information on the EC's position: [http://www.cc.cec:8082/comm/trade/pdf/med\\_lic.pdf](http://www.cc.cec:8082/comm/trade/pdf/med_lic.pdf) (last visited Apr. 23, 2002).

V. THE BALANCE SHIFTS – SEPTEMBER 11TH,  
BIOTERRORISM AND THE QATAR DECLARATION ON  
THE TRIPS AGREEMENT AND PUBLIC HEALTH

The terrorist attacks on the United States on September 11, 2001, and the anthrax scare that followed, affected the debate about pharmaceutical patent protection to an extent that is yet to be determined, but which is clearly significant.<sup>69</sup> As the U.S. government and its constituents recovered from the initial shock of the September 11th attacks, a still unresolved crime began its assault on the American psyche. Anthrax spores in the form of powder made their way through post offices in numerous states to the Capitol building in Washington, D.C., to the National Broadcasting Corporation (NBC) building at Rockefeller Plaza in New York City, and to several other media outlets. Several people died from the coetaneous and inhaled form of the disease and thousands were treated with the antibiotic Cipro.<sup>70</sup>

The Center for Disease Control (CDC) in Atlanta and medical experts urged people to remain calm and insisted that anthrax was not easily transmitted. Regardless, people throughout the United States and the world bought Cipro in large quantities. The government was faced with the reality of a limited supply of the antibiotic, and a sole pharmaceutical company holding a valid patent for the drug of the hour.<sup>71</sup> Legislators in the U.S. and Canada began discussions about legislation designed to circumvent patents and to create a large and quickly available supply of the

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69. William Perry, *Preparing for the Next Attack*, FOREIGN AFFAIRS, Nov. 2001, available at 2001 WL 29745970, for a broad discussion of the threats facing the United States and its allies following the events of September 11, 2001. Of particular note is the discussion on increased likelihood that the next attack will involve nuclear or biological weapons.

70. See *The War Against the Spore*, THE ECONOMIST, Oct. 13, 2001, available at 2001 WL 7320583, for a discussion of the anthrax attacks in several U.S. states, that as of the writing of this paper remain an unresolved crime. See also David E. Rosenbaum, *Traces of Terror: The Bioterror Threat; Anthrax Scare at Bank; Lie Tests at Army Lab*, N.Y. TIMES, May 22, 2002, at A24, for a more recent update on the investigation into the anthrax attacks across the country in the Fall of 2001.

71. It is worth noting that the availability of the vaccine for anthrax involves a completely different set of issues. The U.S.'s only maker of the vaccine, Bioprot, was given clearance by the FDA to resume production of the vaccine after four years at the end of January, 2002, following a stop precipitated by FDA violations at Bioprot's production facilities. For more see Associated Press, *A Nation Challenged: The Vaccine Maker – Troubled Company is Allowed to Resume Making Vaccine*, N.Y. TIMES, Feb. 1, 2002, available at <http://www.nytimes.com>.

drug.<sup>72</sup>

The issue came to a head when Canada overrode the patent held by Bayer for Cipro and ordered the generic version from a Canadian company.<sup>73</sup> The Bush administration threatened similar action and Bayer finally agreed to sell the government bulk supplies at deep discounts. Pharmaceutical giants like Merck, Bristol-Myers Squibb, Bayer, Pfizer, Eli Lilly, and Johnson & Johnson responded to the endangerment of their patents with forceful lobbying and the promise to come to the nation's aid by helping the government build its stockpile of drugs, which may become necessary in the eventuality of a large-scale bio-terrorist attack.<sup>74</sup>

Against this backdrop the WTO ministerial meeting in Doha, Qatar was convened with the goals of discussing pressing issues left unresolved and of agreement on opening a new round of trade talks. At the heart of the unresolved issues was the debate on the TRIPS Agreement and public health. The recent actions undertaken by Canada, and threatened by the U.S., in relation to the overturning of patents, angered developing countries which had long been arguing for greater flexibility in addressing their own public health threats, which they argue amount to "national emergencies" or "other circumstances of extreme urgency" as per the language of the TRIPS Agreement's own provisions.<sup>75</sup>

72. Laurie Garrett, *The Nightmare of Bioterrorism*, FOREIGN AFFAIRS, Jan.-Feb. 2001, for a discussion of the subject pre-dating the attacks on the United States.

73. Olson, *supra* note 4.

74. Leslie Wayne & Melody Peterson, *A Muscular Lobby Tries to Shape Nation's Bioterror Plan*, N.Y. TIMES, Nov. 4, 2001, \_\_\_\_ 3, at 1.

75. Bipul Chatterjee, *India: Get TRIPS out of the WTO*, THE HINDU, Nov. 8, 2001, available at WL 29988351. This article coming out of India is significant because India has played a large role in articulating the position of the developing countries. The author of the article notes that the U.S. was at the time considering granting compulsory licenses to manufacturers who could produce Cipro so as to add to what Bayer, the patent holder, could produce. The article describes a U.S. double standard when it comes to intellectual property right protection; an issue which, according to the article, the U.S. fought to keep off the negotiating table during the Seattle meeting in 1999. The article also raises an interesting theory relating to the inclusion of TRIPS in the WTO. It is the article's contention that the TRIPS Agreement impedes the making of drugs available at low prices to poor countries and argues that TRIPS belongs under the auspice of the World Intellectual Property Organization and not the WTO. In support of this position, the author of the article asserts that TRIPS does not belong in the WTO because of the large discrepancies in experience with intellectual property law and policy among WTO members, the lack of consensus on the proper role and elements of intellectual property law, the politicized nature of intellectual property disputes, and the WTO's dispute resolution system's potential infringement of national sovereignty in cases involving disputes over implementation of intellectual property laws. As will be described, the role of TRIPS was at the center

One Brazilian trade negotiator admitted to the New York Times that the Canadian and American actions relating to Bayer and Cipro had provoked a lot of talk about the perceived double standard, and created pressure to strike a compromise at the bi-annual ministerial meeting in Qatar.<sup>76</sup> What follows is the text of the Declaration on the TRIPS Agreement and Public Health adopted on November 14, 2001, with discussion pertaining to key parts:

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.<sup>77</sup>

The first three points of the declaration provide an almost carbon copy of the opening points of the drafts completed by the developing country group and the European Union.<sup>78</sup> In particular, the opening statement concedes the gravity of the public health crises affecting the world's poor. The second point, in direct rejection of a position coming out of India calling for the rejection of the TRIPS Agreement as part of the WTO, affirms the place of the TRIPS Agreement at the center of any effort to resolve worldwide public health problems.<sup>79</sup> The third point is a mixed point, which reflects the developing world's concern with prohibitive pricing and the developed world's position that without intellectual property right protection, there will be a chilling effect on research and development.<sup>80</sup>

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that

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of the debate at Doha and what emerged was a reaffirmation of the TRIPS Agreement, but also a victory for the developing world.

76. Olson, *supra* note 4.

77. Declaration on the TRIPS Agreement and Public Health, *supra* note 5.

78. *Developing Country Group's Paper*, *supra* note 55.

79. Chatterjee, *supra* note 75.

80. *Interpretations on TRIPS*, *supra* note 17.

the Agreement can be and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
  - a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
  - b. Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
  - c. Each member has the right to determine what constitutes a national emergency or other circumstance of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent a national emergency or other circumstance of extreme urgency.
  - d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Article 3 and 4.<sup>81</sup>

The heart of the victory for the developing and least-developed countries of the world lies in points 4 and 5. Here, the developing world's position on the issues of compulsory licensing, exhaustion, interpretation and designation of national emergencies and other circumstances of extreme urgency triumphs over the concerns of the developed nation block.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to

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81. Declaration on the TRIPS Agreement and Public Health, *supra* note 5.

this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.<sup>82</sup>

Lastly, points 6 and 7 address the needs and concerns of the world's least developed nations.<sup>83</sup> From devising ways of helping the LDCs to better exploit the opportunity of compulsory licensing to the extension of the transition period for an additional decade, the Doha Declaration recognizes that these nations, often the same ones with the gravest health crises, are the least able to set up a viable intellectual property right protection system or the least in need of doing so at this time.

In summary, the Doha Declaration represents a clear victory for the developing and least-developed member countries. The concessions given to this block of countries is concrete: extensions on the transition period for least developed countries for another decade; the reaffirmation of the practice of granting compulsory licensing; recognition of the gravity of the HIV/AIDS, tuberculosis, and malaria epidemics in the developing world; greater latitude for interpretation and implementation of the TRIPS Agreement in light of the interest of protecting public health and the need to make medicines accessible to all; the power to unilaterally determine what constitutes a national emergency or other circumstance of extreme urgency; the affirmation that the above-listed epidemics represent such situations; and the opening for further instances of parallel importation under the theory of exhaustion for intellectual property rights.

The Declaration reflects almost entirely the goals of the devel-

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82. *Id.*

83. Declaration on the TRIPS Agreement and Public Health, *supra* note 5.



oping and least-developed countries as set out in their paper to the TRIPS Council.<sup>84</sup> Alternately, the developed countries walk away with a reaffirmation of the importance of intellectual property right protection for innovation and creativity and with a commitment to encourage their industries to transfer technology to the developing and least-developed countries of the world. WTO Director-General Mike Moore summarizes the results of this declaration and the other efforts of 2001 in his informal end-of-the-year report on the activities of the World Trade Organization. Moore states that:

the [WTO has] placed development issues and the interests of our poorer members at the heart of our work . . . while the Doha Development Agenda was launched out of mutual self-interest, for many resource-constrained member countries it was also a brave act of faith, trust, and hope. I believe members have already begun to deliver on this faith.<sup>85</sup>

## VI. CONCLUSION

In conclusion, the issue of pharmaceutical patent protection has been elevated to the heights of the global discussion on the future of the free trade initiative. The astronomical costs of research and development involved in bringing new and effective medicines to market and the epidemic levels of HIV/AIDS, tuberculosis, malaria, and other diseases are at the heart of this debate. The line of interests are unfortunately clear, with the developed countries seeking to protect their valuable pharmaceutical industries, and the developing countries struggling to meet the demands of their sick citizenry for more affordable medications. If the question were one of taking from the rich to give to the poor, a simple answer based on morality and social justice would suffice. Unfortunately, the reality is much more complex and potentially tragic.

The September 11th terrorist attacks on the United States and the anthrax-based bio-terrorism witnessed in the weeks following, made one thing clear – governments will act to respond to actual and potential national emergencies even to the point of ignoring the much valued rights of intellectual property holders.

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84. *Developing Country Group's Paper*, *supra* note 55.

85. World Trade Organization, *Moore Outlines Successes of 2001, Roadmap for 2002* (Dec. 20, 2001), available at [http://www.wto.org/english/news\\_e/pres01\\_e/pr265\\_e.htm](http://www.wto.org/english/news_e/pres01_e/pr265_e.htm) (last visited Apr. 23, 2001).

It is an extreme form of eminent domain that crosses borders and which has given the developing world the leverage it needed to push its agenda at the Qatar ministerial meeting of the WTO. What results is a declaration affirming the contentions of the developing and least-developed countries of the world that the epidemics which cripple their societies are national emergencies on par with the tragedy that befell the United States in September of 2001.

What remains to be seen is whether this affirmation and the actions yet to be taken by the countries in reaction to these epidemics will chill the research and development efforts of the developed world's pharmaceutical companies – not for the drugs which will be purchased on the developed world's streets, but for those drugs most needed in the developing world alone. If that proves to be the unintentional result, then a larger tragedy may be waiting to afflict the world's poor.<sup>86</sup>

ARNOLDO LACAYO\*

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86. For a discussion of the initial work undertaken by the TRIPS Council following the ministerial meeting in Qatar, see World Trade Organization, *Members Start Work on Doha Agenda Items*, available at [http://www.wto.org/english/news\\_e/news02\\_e/trips\\_reg\\_020307\\_e.htm](http://www.wto.org/english/news_e/news02_e/trips_reg_020307_e.htm) (last visited Apr. 23, 2002). The article discusses how the TRIPS Council has started discussions on proposals for dealing with compulsory licensing when member States lack domestic production capacity. The discussions will continue in June of 2002.

\* Juris Doctor Candidate, May 2003, University of Miami School of Law. I would like to express my immense gratitude to my wife, Monika, for her unconditional support and encouragement. I also wish to thank the editors and staff of the *University of Miami Inter-American Law Review* for their assistance and support. Finally, I would like to thank Professor Alan Swan for his guidance and advice.

## VII. APPENDIX

## MINISTERIAL CONFERENCE

DOHA, 9 - 14 NOVEMBER 2001

DECLARATION ON THE TRIPS AGREEMENT  
AND PUBLIC HEALTH

ADOPTED ON 14 NOVEMBER 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.
5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
  - (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
  - (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

- (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
  - (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.
6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
  7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.<sup>87</sup>

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87. The Qatar Declaration on the TRIPS Agreement and Public Health, *available at* [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/min01\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm) (Last visited April 23, 2002).