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## The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health

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# THE FUTURE OF COMPULSORY LICENSING: DECIPHERING THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

DIVYA MURTHY\*

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\* J.D. Candidate, 2003, American University, Washington College of Law; B.S., Pharmacy, 1998, Rutgers University. First and foremost, I would like to thank my parents, Keshava and Rajeshwari Murthy, and my sister, Vidya, for their constant and unwavering love and support throughout my law school career. I would also like to thank Matt Mitro for his advice, editing, and general support throughout the writing process. You know how much your help meant to me, thanks. In addition, I would like to thank Gina Raimond without whom this piece would never have been published. I hope you know your love, understanding, and most of all patience is something I will always treasure. Ryan Borho, I'm not sure what you did to help me with this piece, but I don't want you to feel left out, so thanks. Finally, I would like to extend my sincere appreciation to the members of the *International Law Review* for all their hard work.

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## INTRODUCTION

The extent to which patent protection should be extended to pharmaceuticals has always been and continues to be an issue that stirs public debate and discussion.<sup>1</sup> Developing countries and non-governmental organizations ("NGOs") argue that strict enforcement of pharmaceutical patent holders' rights has resulted in high prices, which render unaffordable to poor countries drugs critical to the treatment of epidemics.<sup>2</sup> The concern stems from the fact that the

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1. See generally Amol Sharma, *Fourth Ministerial Conference in Doha Developing Countries Seek Amendment to WTO Drug Patent Guidelines*, EARTH TIMES (reporting that access to life-saving patented pharmaceuticals remain "among the most contentious issues for discussion at the upcoming World Trade Organization (WTO) meeting in Doha, Qatar. . ."), at [http://www.earthtimes.org/nov/worldtradeorgfourthnov3\\_01.htm](http://www.earthtimes.org/nov/worldtradeorgfourthnov3_01.htm) (last visited July 11, 2002).

2. See, e.g., MÉDECINS SANS FRONTIÈRES CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES, A MATTER OF LIFE AND DEATH: THE ROLE OF PATENTS IN

patent holders' rights exclude others from selling or making their exact or substantially similar patented products for the term of the patent.<sup>3</sup>

This period of exclusivity provides the patent holder with the power to control the selling price of the patented product.<sup>4</sup> Critics contend that pharmaceutical companies, as patent holders, have abused this right in order to reap tremendous profits, despite a staggering loss of human life.<sup>5</sup> In response, proponents of strong patent rights assert that patents are not the major barrier to access to essential medicines; rather inaccessibility to critical medications results from inadequate infrastructure, absence of an effective drug distribution system, and poverty.<sup>6</sup>

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ACCESS TO ESSENTIAL MEDICINES (Nov. 2001) [hereinafter MÉDECINS SANS FRONTIÈRES] (arguing that if patent laws were relaxed, the suffering of millions of people due to infectious diseases worldwide would be lessened), at <http://www.accessmed-msf.org/upload/ReportsandPublications/291020011614133/DOHACOL.PDF> (last visited July 11, 2002); Rosemary Sweeney, *The U.S. Push for Worldwide Patent Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Collision*, 9 PAC. RIM L. & POL'Y J. 445, 447 (2000) (describing citizens of Thailand and NGOs as seeking relaxed patent laws in an effort to achieve a reduction in the cost of AIDS drugs).

3. See JOHN H. JACKSON ET AL., *LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS: CASES, MATERIALS AND TEXT* 844 (3d ed. 1995) (providing a general introduction to intellectual property rights and policies and explaining that the "granting of a patent confers upon the inventor a number of rights, including the right to prevent others from copying and selling the invention for a specified number of years").

4. See *id.* at 845 (stating that a patent holder "will tend to charge a monopoly price over the life of the patent, thus introducing the distortion of monopoly pricing into the economy").

5. See Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 3 (2001) ("In the health sector, where denial of affordable access to treatment or pharmaceuticals can have life-or-death consequences, the conditions, including price, that determine access to medicines are critical matters, especially for the low-income segments of the population"); Rosalyn S. Park, Note, *The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients*, 11 MINN. J. GLOBAL TRADE 125, 131 (2002) (displaying statistics of the disproportionate negative impact of drug patents on developing countries). The author contrasts an estimated \$3.5 to \$10.8 billion welfare loss experienced by developing nations, with a \$2.1 to \$14.4 billion gain to foreign pharmaceutical companies. *Id.*

6. See Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 JAMA 1886, 1886

Consider the example of sub-Saharan Africa, with nearly twenty-five million people infected with HIV/AIDS.<sup>7</sup> The situation has become one of the greatest public health challenges in the history of mankind.<sup>8</sup> This area of the world now contains more than seventy percent of the world's new AIDS cases.<sup>9</sup>

While the optimal way to address the AIDS/HIV crisis is to attack the root of the problem by reducing the rate of HIV infection,<sup>10</sup> the short-term solution lies with drug therapies that increase the life expectancy of those suffering from the disease.<sup>11</sup> The tragedy is that of the nearly 25 million people infected only about 25,000 people, at most, have access to life-prolonging medicines.<sup>12</sup>

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(2001) (concluding that patents and patent laws do not operate as the sole, major barriers to the treatment of AIDS in Africa). The authors stated:

[A] variety of de facto barriers are more responsible for impeding access to antiretroviral treatment, including but not limited to the poverty of African countries, the high cost of antiretroviral treatment, national regulatory requirements for medicines, tariffs and sales taxes, and, above all, a lack of sufficient international financial aid to fund antiretroviral treatment.

*Id.*

7. See JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, AIDS EPIDEMIC UPDATE: DECEMBER 2000 5 (2000) (stating statistics that show 25.3 million adults and children live with HIV/AIDS in Sub-Saharan Africa), *available at* [http://www.unaids.org/wac/2000/wad00/files/WAD\\_epidemic\\_report.PDF](http://www.unaids.org/wac/2000/wad00/files/WAD_epidemic_report.PDF) (last visited July 11, 2002).

8. See Former Vice President Al Gore, Remarks before the U.N. Security Council Session on AIDS in Africa (Jan. 10, 2000) (recognizing that AIDS in Africa has become "not just a humanitarian crisis," but also a "security crisis"), *at* [http://www.state.gov/www/global/oes/health/000110\\_gore\\_hiv-aids.html](http://www.state.gov/www/global/oes/health/000110_gore_hiv-aids.html) (last visited July 11, 2002).

9. See Bess-Carolina Dolmo, *Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South African Example*, 7 BUFF. HUM. RTS. L. REV. 137, 139 (2001) (stating the disproportionate number of AIDS cases in Sub-Saharan Africa compared with its relatively small population).

10. See *id.* at 140 (observing that the ability of a country to address HIV/AIDS lies with its ability to address the rate of infection). Death most often results from an individual's inability to receive adequate health care services. *Id.*

11. See *id.* (noting that top drug treatments and a high standard of living allow AIDS/HIV sufferers in the United States to live longer lives).

12. See WTO Trade Policy Review Body, *Overview of Developments in the International Trading Environment: Annual Report by the Director-General*, WT/TPR/OV/7 at 72 (Dec. 10, 2001) (stating that between 10,000 and 25,000 people have access to essential AIDS medicines). The report declares that a

Consequently, in a continent where the death count from AIDS threatens to rival that of the plague of 1937,<sup>13</sup> governments have sought to provide this access to pharmaceuticals by enacting legislation based on a legal theory known as compulsory licensing.<sup>14</sup> In essence, compulsory licensing is when a government compels the license of a patented product.<sup>15</sup> Developing country governments increasingly view this form of licensing as a necessary practice to ensure access to essential medications and to properly address the AIDS pandemic.<sup>16</sup>

The Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"),<sup>17</sup> part of the Uruguay Round of trade agreements

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general consensus has been reached by the World Health Organization ("WHO"), Joint United Nations Programme on HIV/AIDS ("UNAIDS"), and several other U.N. agencies, in identifying four components of a viable framework necessary for increased access to essential medicines. *Id.* Those components are the following: rational selection of pharmaceuticals; affordable prices of drugs; sustainable and adequate financing; and reliable health care and supply systems. *Id.* See also WHO, DRUG MANAGEMENT AND SUPPLY STRATEGIES (providing that one-third of the world population does not have access to medical supplies and ninety-five percent of those suffering from AIDS do not receive any form of HIV/AIDS treatment), *at* [http://www.who.int/medicines/teams/par/drug\\_management\\_and\\_supply\\_strat.html](http://www.who.int/medicines/teams/par/drug_management_and_supply_strat.html) (last visited July 11, 2002).

13. See *What is the United States' Role in Combating the Global HIV/AIDS Epidemic: Hearing before the House Subcomm. On Criminal Justice, Drug Policy and Human Resources, Comm. On Government Reform*, 106th Cong. 152 (1999) (statement of James Love, Director Consumer Project on Technology) (attempting to place in historical perspective the large number of AIDS related deaths expected to occur in Sub-Saharan Africa).

14. See *generally Paying for AIDS*, NEWSWEEK INT'L, Mar. 19, 2001 (discussing South Africa's 1997 Medicines Act amendment as an example of a law African governments are enacting to legalize compulsory licensing and parallel trade) *available at* 2001 WL 8109129.

15. See MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW § 19.2 (1998) (stating that compulsory licensing is a "governmental requirement that a patent owner permit another to perform otherwise infringing acts").

16. See Sara M. Ford, Note, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patients*, 15 AM. U. INT'L L. REV. 941, 946 (2000) (noting that developing countries are keen to utilize compulsory licensing as a means to provide essential medications to their citizens).

17. See Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND vol. 31, 33

establishing the World Trade Organization ("WTO"),<sup>18</sup> is the most comprehensive international agreement regarding intellectual property that is currently in force.<sup>19</sup> TRIPs outlines a framework for minimum intellectual property standards that bind all WTO Member ("Member") nations.<sup>20</sup> As part of this framework, TRIPs clearly authorizes Member countries to legislate exceptions to the rights of legitimate patent holders.<sup>21</sup> However, the text of TRIPs contained ambiguities that required clarification.<sup>22</sup> Specifically, WTO Members sought guidance in the area of compulsory licensing.<sup>23</sup>

One purpose of the fourth WTO Ministerial Conference held in Doha, Qatar in November 2001 ("Doha Conference" or "Doha") was to reduce any ambiguities relating to the compulsory licensing

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I.L.M. 81 (1994) [hereinafter TRIPs] (establishing minimum standards for the intellectual property laws of Members).

18. See Marrakesh Agreement Establishing the World Trade Organization, [hereinafter WTO Agreement], art. XI, XII, Apr. 15, 1994, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 1125, 1126 (1994) (requiring all ratifying Members to accept agreements settled at the Uruguay Round of trade negotiations). Between 1986 and 1994, the negotiators at the Uruguay round created an intergovernmental organization (the WTO) that would embody and establish the principles of the previous General Agreement on Tariffs and Trade relating to the trade in goods while adding agreements on trade in services, trade-related intellectual property, dispute settlement, and other supplemental agreements. See generally RAJ BHALA & KEVIN KENNEDY, WORLD TRADE LAW § 4 (a) - (b) (1st ed. 1998) (explaining the creation of the WTO and its mandate).

19. See CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPs AGREEMENT AND POLICY OPTIONS 1-22 (2000) [hereinafter CORREA, TRIPs POLICY] (noting that TRIPs is the current international agreement dealing with virtually all types of intellectual property rights).

20. See WTO Agreement art. II(2), 33 I.L.M. at 1144 (stating that TRIPs is a central component of the WTO Agreement and that TRIPs binds all Members); TRIPs art. 27-34 (outlining the essential components of WTO Member countries' patent laws).

21. See TRIPs art. 30, 33 (outlining that "[m]embers may provide limited exceptions to the exclusive rights conferred by a patent").

22. See WTO, DOHA PRESS PACK, NEGOTIATIONS, IMPLEMENTATION AND TRIPs COUNCIL WORK 24 (2001) [hereinafter DOHA PRESS PACK] (on file with author) (stating that the Doha Conference intended to clarify ambiguities relating to Members' use of the flexibilities codified in TRIPs).

23. See *id.* (stating that "[a]mong the flexibilities most often discussed is compulsory licensing").

provisions of TRIPs.<sup>24</sup> The ministerial text intended to discuss two major issues: the scope of the term “public health” and the ability of Members without adequate manufacturing capacities to seek the benefits of compulsory licensing (“third party compulsory license”).<sup>25</sup> The result of the meeting in Doha was a Declaration on the TRIPs Agreement and Public Health (“Declaration”).<sup>26</sup>

Accordingly, this Comment interprets the language of the Declaration and ascertains the meaning of the term “public health” in light of the Declaration. In the process, this Comment analyzes the weight that would be afforded to the Declaration by a WTO adjudicating body.

Part I of this Comment provides background information on drug development, compulsory licensing and the development of TRIPs. In addition, Part I details the events leading up to the Doha Conference. Part II examines the status of compulsory licensing pre- and post-Doha. The post-Doha status is determined by interpreting the term “public health” under TRIPs. Additionally, Part II examines third party licensing by interpreting the term “third party” under TRIPs. Part II also analyzes how the principle of territoriality affects the interpretation of the term “third party” under TRIPs. Finally, Part III recommends that WTO trade ministers further clarify the public health exception and third party production for export licenses through official interpretations, declarations and/or amendments.

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24. See *id.* (stating that the ministerial statement intended to “clarify what governments can do under the TRIPs Agreement, and to reduce their uncertainties about using the flexibilities that are built into the agreement”).

25. See *id.* at 24-25 (discussing the issues the ministerial declaration seeks to address). One issue was the scope of the proposed declaration. *Id.* at 24. The statement indicated that some Members would like the declaration to emphasize public health as a whole, while others would like the focus to be life-threatening epidemics. *Id.* The press statement also indicated that another issue under consideration is “how countries with limited manufacturing capabilities can take advantage of compulsory licensing.” *Id.* at 25.

26. See WTO Ministerial Conference, *Declaration on the TRIPs Agreement and Public Health*, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter *Declaration*] (on file with author) (recognizing the importance of rights protected under TRIPs as well as the need for developing nations to protect public health), available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) (last visited July 11, 2002).



## I. BACKGROUND

### A. DRUG DEVELOPMENT

Patent laws, like other branches of intellectual property law, are designed to encourage innovation by providing incentives to inventors.<sup>27</sup> Among these incentives, patent protection allows an inventor to recoup costs associated with the creation of a product.<sup>28</sup> In the case of pharmaceuticals, these costs include research, testing, clinical trials, and obtaining governmental regulatory approval.<sup>29</sup> Costs average in the hundreds of millions of dollars.<sup>30</sup> Yet, even after expending an exorbitant amount of money, a drug may ultimately prove unmarketable for various reasons.<sup>31</sup> In reality, revenues of even the largest of pharmaceutical companies precariously rely on only a

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27. See Gerald J. Mossinghoff, *Progress in the Pharmaceutical Industry*, INTRO TO INTELL. PROP. RTS. (on file with author) ("Strong patent protection for pharmaceuticals drives medical progress by providing economic incentives for innovation. Without international respect for pharmaceutical patents, medical innovation would suffer."), at <http://usinfo.state.gov/products/pubs/intelprp/progress.htm> (last visited Jan. 17, 2002). The author supports this assertion by referring to a 1988 study of twelve industries, in which Dr. Edwin Mansfield of the University of Pennsylvania concluded that "65 percent of pharmaceutical products would not have been introduced without adequate patent protection." *Id.* See also John M. Wechkin, Comment, *Drug Price Regulation and Compulsory Licensing for Pharmaceutical Patents: The New Zealand Connection*, 5 PAC. RIM L. & POL'Y J. 237, 238-239 (1995) (stating that patents are designed to foster human creativity and innovation).

28. See Wechkin, *supra* note 27, at 239 (indicating that patent holders rely on exclusive rights inherent in a patent to recoup their substantial investment).

29. See *id.* at 241-42 (discussing the various expenses resulting in the high cost of drug development).

30. See Mossinghoff, *supra* note 27 (speculating that pharmaceutical industry is unique in that actual process of discovering and developing drug is profoundly expensive, whereas cost of copying or reverse-engineering is minimal). Pharmaceutical companies spend, on average, \$500 million to develop one new medicine. *Id.*; Wechkin, *supra* note 27, at 241-42 (explaining that patents prevent "free riders" from benefiting without bearing the cost of prior research).

31. See Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 JURIMETRICS J. 295, 303 (1994) (stating that on average, only one out of 4,000 compounds that are discovered become marketable products).

few drugs.<sup>32</sup> Therefore, pharmaceutical companies seek the protection of patent laws as a means of ensuring their investments.<sup>33</sup>

Pharmaceutical companies have the dual goals of earning a profit and developing new drug entities that improve health and save lives.<sup>34</sup> While many critics point to the dangerous intersection of profits and improving health and saving lives, the evidence overwhelmingly indicates it is a successful marriage of goals.<sup>35</sup>

## B. COMPULSORY LICENSING GENERALLY

One benefit available to a patent holder is the ability to voluntarily issue a license for some or all of the rights of a product to another party.<sup>36</sup> In contrast, a compulsory license is a license for a patented product issued by the government to a third party without the patent holder's permission.<sup>37</sup> In return, the government grants the patent holder what it believes to be reasonable compensation.<sup>38</sup>

The justifications for issuing compulsory licenses include reducing an issuing country's dependence on imports, increasing the number of competitors in the marketplace, and protecting and developing

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32. See *id.* at 303-04 (emphasizing a pharmaceutical company's reliance on a limited number of products for the financial well being of the company).

33. See Michael Montagne, *Drug Advertising & Promotion: An Introduction* 22 J. DRUG ISSUES 195, 202 (1992) (discussing the role of health care as a business).

34. See Wechkin, *supra* note 27, at 239 (stating that patent protection is designed to protect the inventor's investment in research and development).

35. See Kenneth I. Kaitin, *The Role of the Research-Based Pharmaceutical Industry in Medical Progress in the United States*, 33 J. CLINICAL PHARMACOLOGY 412, 413-14 (1993) (highlighting that of the 196 new pharmaceuticals approved by the FDA from 1981 through 1990, the pharmaceutical industry created 92.4 percent while academia and government combined to produce 4.6 percent).

36. See ADELMAN ET AL., *supra* note 15, at 1229-32 (discussing the role of licenses within patent law).

37. See Seven Developing Nations Urge TRIPs Review to Ensure Compulsory Licensing for Drugs, 16 INT'L TRADE REP. (BNA), No. 23, at D7 (June 9, 1999) (discussing the differing interpretations of compulsory licensing within the framework of TRIPs).

38. See ADELMAN ET AL., *supra* note 15, § 19.2 (stating that the patent owner is compelled to license at a rate thought to be reasonable by the government).

local industry.<sup>39</sup> However, the reason that resonates with the highest moral tone, and is most often cited by developing countries and activists, is that compulsory licenses result in increased access to critical lifesaving medicines.<sup>40</sup>

While compulsory licensing provisions exist in U.S. patent laws, these exceptions are rare and only available in narrow and very fact-specific situations.<sup>41</sup> Developing countries have recently begun to enact legislation with provisions that allow for practices such as compulsory licensing and parallel importing of pharmaceuticals.<sup>42</sup> The pharmaceutical industry opposes such legislation because the industry views legislation in developing countries as supportive of patent infringement practices as the norm rather than the exception.<sup>43</sup>

### C. THE DEVELOPMENT OF AN AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

The 1883 Paris Convention for the Protection of Industrial Property ("Paris Convention"),<sup>44</sup> one of the first international

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39. See Wechkin, *supra* note 27, at 240 (discussing the various reasons in support of compulsory licensing).

40. See Ford, *supra* note 16, at 945-46 (noting the increased attention placed on compulsory licensing by the controversy over right to drug access for life-threatening diseases).

41. See Fisch, *supra* note 31, at 301 (observing that compulsory licensing provisions in U.S. patent law are rare and are used to redress antitrust violations, to prevent restrictions on use of air pollution control, and to encourage atomic energy inventions); see also Dolmo, *supra* note 9, at 153-54 (describing the ability of the National Institutes of Health ("NIH") to retain title to patents and to license inventions that result from NIH funding under the Federal Technology and Transfer Act of 1986).

42. See *Consumer Project on Technology, U.S. Dep't of State Report: U.S. Gov't Efforts to Negotiate the Repeal, Termination, or Withdrawal of Article 15(c) of the South African Medicines and Related Substances Act of 1965*, U.S. DEP'T OF STATE, Feb. 5, 1999 [hereinafter *State Dep't Report on South African Medicines Act*] (noting the effect of the new amendment, Article 15(c), on pharmaceutical patent rights), <http://www.cptech.org/ip/health/sa/stdept-feb51999.html> (last visited Aug. 4, 2002).

43. See Ford, *supra* note 16, at 966 (noting that legislation enacted with broad provisions on compulsory licensing would lead to a massive wave of licenses granted for essentially minor health risks and would have a resultant adverse impact on pharmaceutical industry profits).

44. See Paris Convention for the Protection of Industrial Property, Mar. 20,

agreements on intellectual property, allowed for disparate standards of patent protection among different countries.<sup>45</sup> Subsequent revisions of the Paris Convention led to the creation of the World Intellectual Property Organization (“WIPO”) in 1967.<sup>46</sup>

The creation of WIPO signaled recognition of the importance of developing common international standards for intellectual property law.<sup>47</sup> However, WIPO fails to constitute anything more than a forum for discussion.<sup>48</sup> While this forum was and continues to be important, manufacturers of patented products lacked sufficient patent protection in foreign countries, had no protection in some instances,<sup>49</sup> and lacked a means of redress.<sup>50</sup>

As research and development costs rose in the twentieth century,<sup>51</sup> trade liberalization resulted in intense competition in the open market

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1883, art. 4(C)(1), 828 U.N.T.S. 305, 315 (stating international intellectual property standards prior to the enactment of TRIPs).

45. See Carolyn S. Corn, Note, *Pharmaceutical Patents in Brazil: Is Compulsory Licensing the Solution?*, 9 B.U. INT’L L.J. 71, 71-75 (1991) (detailing the obligation of Paris Convention signatories to ensure that foreign patent holders have the same protection granted to citizens of the signatory country). The author also notes the Convention’s failure to set a commonly applicable framework for intellectual property laws. *Id.* See also John A. Harrelson, *TRIPs, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion*, 7 WIDENER L. SYMP. J. 175, 178-80 (2001) (citing the Paris Convention’s failure to harmonize patent laws among its member nations and questioning the usefulness of international patent protection that is inherently varied and domestically determined).

46. See Convention Establishing the World Intellectual Property Organization, July 14, 1967, 21 U.S.T. 1749, T.I.A.S. 6932 (establishing an international organization dealing with intellectual property laws and issues).

47. See generally Corn, *supra* note 45, at 73 (stating the goals of WIPO as maximizing participation of developing countries in an international patent system and promoting intellectual property protection).

48. See *id.* at 74 (noting that WIPO’s role is primarily one of guidance and persuasion because it has failed to delineate meaningful basic standards for intellectual property law and lacks enforcement power).

49. See *id.* at 74-5 (explaining that patented products in the international market regularly lose patent protection provided by the original granting nation). Corn notes Brazil’s failure, as of 1991 and prior to WTO, to provide any patent protection with regard to pharmaceuticals. *Id.*

50. See *id.* at 75 (noting the lack of remedies available to a manufacturer whose patent rights have failed to be adequately protected by a foreign nation).

51. See CORREA, TRIPS POLICY, *supra* note 19, at 3-4 (discussing the various

among manufacturers and developers.<sup>52</sup> Thus, intellectual property became a critical trade issue, and the international community simultaneously created the WTO<sup>53</sup> and drafted TRIPs.<sup>54</sup>

#### D. OBJECTIVES AND PRINCIPLES OF TRIPs

TRIPs Article 7 lists the objectives of TRIPs as to protect and enforce intellectual property rights so as to promote technological innovation, and to share information to the collective benefit of both producers and users.<sup>55</sup> The sharing and promotion of technological

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factors that necessitated the creation of TRIPs, such as technological advancements, globalization, and diminishing technological leadership of U.S. companies). The author explains that with increased technological sophistication came "high externalities in the production of knowledge," which consequently limited the usefulness of traditional research and development ("R&D"). *Id.* In other words, as the science-intensive sectors became more precise, research and development of a new invention required more time and money. *Id.* This factor in turn caused firms involved in the production of high-tech inventions to demand enhanced intellectual property protections as a means of recouping their R&D costs. *Id.* Together these reasons caused the vigorous push by industrialized countries to universalize standards of intellectual property protection. *Id.* See also Mossinghoff, *supra* note 27 (discussing the dramatic increase in R&D since 1985). The author's research shows that in 1985, the pharmaceutical industry had an R&D investment of approximately \$4,100 million. *Id.* That figure increased fourfold in ten years, rising to almost \$16,000 million. *Id.*

52. See CORREA, TRIPs POLICY, *supra* note 19, at 4 (explaining the problem associated with the declining technological capacity of U.S. firms). According to Correa, the 1980s saw the United States as the world leader in technology and manufacturing. *Id.* However, prompted by the "catching-up process" of innovative Asian countries with fast-emerging industrial bases, this supremacy dramatically declined in the 1990s. *Id.* As the Asian markets progressed and transformed into stronger competitors, U.S. businesses realized significant losses, particularly in the high-tech sector. *Id.* "The erosion of the technological leadership of U.S. firms in certain high-tech areas, coupled with the high U.S. trade deficit, was partially attributed to a too-open technological and scientific system which allowed foreign countries to imitate and profit from U.S. innovations." *Id.* Industrial lobbies dissatisfied with the patent regime under the Paris Convention started a campaign seeking enhanced intellectual property protection to prevent copycats and restore returns on R&D. *Id.*

53. WTO Agreement, *supra* note 18, art. I.

54. TRIPs, *supra* note 17, preamble. See Ford, *supra* note 16, at 948 (describing the events leading to the creation of the WTO and signing of the TRIPs agreement).

55. See TRIPs, *supra* note 17, art. 7.

The protection and enforcement of intellectual property rights should

innovation should be done in a manner conducive to social and economic welfare while providing an equal balance of rights and obligations.<sup>56</sup> TRIPs further seeks to provide certainty and predictability for transactions in the international market<sup>57</sup> by encouraging countries to enact patent laws with the same basic principles.

TRIPs Article 8 sets out the overall guiding principle for Members.<sup>58</sup> Member countries are authorized to adopt the necessary measures to protect public health when formulating their own national intellectual property legislation.<sup>59</sup> Furthermore, member countries are authorized to take appropriate measures to protect and promote areas that are vital to socio-economic and technological development.<sup>60</sup>

While this language seems to give broad, sweeping powers to Member Countries, the second part of Section I, Article 8 provides the context in which countries should interpret the language of necessary measures.<sup>61</sup> The second part defines appropriate measures as those that are needed to prevent patent holders from abusing their rights or resorting to practices that restrain trade or inhibit the transfer of technology.<sup>62</sup>

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contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

*Id.*

56. *See id.*

57. *See id.*

58. *See id.* art. 8(1) ("Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided such measures are consistent with the provisions of this Agreement.").

59. *See id.*

60. TRIPs, *supra* note 17, art. 8(1).

61. *See id.* art. 8(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.").

62. *See id.*

## E. LEADING UP TO DOHA: BAD PUBLIC RELATIONS AND CIPRO

While it is widely accepted that TRIPs provides for compulsory licensing,<sup>63</sup> the United States, until recently,<sup>64</sup> maintained that developing countries were violating TRIPs by enacting laws that allowed for the issuance of such licenses.<sup>65</sup> The cost of critical HIV/AIDS drugs became a controversial and contentious issue with the exponential increase in the number of HIV/AIDS cases and related deaths on the African continent.<sup>66</sup>

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63. See Frederick M. Abbott, *The TRIPs-Legality of Measures Taken to Address Public Health Crises: A Synopsis*, 7 WIDENER L. SYMP. J. 71, 72 (2001) (stating that the TRIPs Agreement "manifestly permits governments to authorize . . . compulsory licenses"). The author notes that, when Article 31 of TRIPs is read in conjunction with Article 2:1 of TRIPs and Article 5.A.2 of the Paris Convention, TRIPs clearly provides authority for the issuance of compulsory licenses. *Id.* at 74.

64. See *Testimony on the Protection of U.S. Intellectual Property Abroad, Particularly with Respect to Combating the Global HIV/AIDS Epidemic?: Hearing Before the House Subcomm. on Criminal Justice, Drug Policy and Human Resources, Comm. on Gov't Reform*, 106th Cong. 152 (1999) [hereinafter *Papovich Testimony*] (statement of Joseph Papovich, Assistant U.S. Trade Rep.) (testifying, in 1999, that the TRIPs Agreement allows for compulsory licensing in specific situations and that the United States would not object if such provisions were part of South African law), available at <http://www.house.gov/reform/cj/hearings/99.7.22/Papovich.htm> (last visited July 11, 2002); Press Release, Office of the U.S. Trade Rep., United States and Brazil Agree to Use Newly Created Consultative Mechanism to Promote Cooperation on HIV/AIDS and Address WTO Patent Dispute (June 25, 2001) [hereinafter *USTR 2001*], (stating that the Bush Administration would continue the policy of not raising objections to compulsory licensing provisions in developing countries' laws, if they were aimed at addressing HIV/AIDS), at <http://www.ustr.gov/releases/2001/06/01-46.htm> (last visited July 11, 2002).

65. See *State Dep't Report on South African Medicines Act*, *supra* note 42, at 5 (stating that the United States strongly criticized South Africa's Medicines Act as being "clearly inconsistent" with South Africa's obligations under TRIPs, and began taking actions in opposition to the Act prior to its 1997 enactment). This report, issued in 1999, but recounting actions taken at least as far back as 1997, also described the USTR's role as engaging South Africa in bilateral negotiations aimed at achieving the repeal, termination, or withdrawal of the offending provisions. *Id.* at 4.

66. See Mary K. Schug, Note, *Promoting Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa Within the Framework of International Intellectual Property Law*, 19 LAW & INEQ. 229, 235-36 (2001) (pointing out that most HIV-infected people in Sub-Saharan Africa go untreated because of the "staggering" prices of AIDS drugs); Dolmo, *supra* note 9, at 140 (noting that the annual HIV/AIDS drug cocktail cost of \$12,000 is "prohibitive" for most of the African

Logically, patents and their part in the prohibitive cost of medications became a very politically hot issue.<sup>67</sup> Supporting strong patent regimes quickly became equivalent to blocking HIV/AIDS sufferers' access to critical medications.<sup>68</sup> Consequently, when the pharmaceutical industry filed suit against the South African government in 2000 over a newly enacted domestic law that allowed for compulsory licensing of pharmaceuticals,<sup>69</sup> the accompanying media coverage created the perception that the big pharmaceutical companies and the U.S. government, as their greatest supporter, favored patents over lives.<sup>70</sup> The potentially devastating political liability sent top U.S. officials scrambling to reverse their position on the South African law.<sup>71</sup> The pharmaceutical industry soon followed

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population).

67. See Associated Press, *U.S. Defines Policy on AIDS Drugs for South Africa* (July 22, 1999) (briefly noting the various arguments put forth by White House officials, congressional members, trade representatives, the pharmaceutical industry, and consumer groups concerning the issue of U.S. trade policy and pharmaceutical patent protection in South Africa), available at <http://www.actupdc.org/africa/chatinka.html> (last visited July 11, 2002).

68. See OXFAM, *PATENT INJUSTICE: HOW WORLD TRADE RULES THREATEN THE HEALTH OF POOR PEOPLE* 2, 3 (2001) (arguing for changes in international intellectual property standards because a strict patent regime is a major contributing factor to the public health crises in developing countries), at <http://www.oxfam.org.uk/cutthecost/downloads/patent.pdf> (last visited Aug. 4 2002); MÉDECINS SANS FRONTIÈRES, *supra* note 2 (arguing that if patent laws were relaxed then the suffering of millions of people afflicted by infectious diseases worldwide would be lessened).

69. See Sarah Bosely, *At the Mercy of Drug Giants: Millions Struggle with Disease as Pharmaceutical Firms Go to Court to Protect Profits*, GUARDIAN, Feb. 12, 2001 (reporting that approximately forty pharmaceutical companies are engaged in an ongoing legal challenge to article 15(c) of South Africa's 1997 Medicines Act in a South African court), available at <http://www.guardian.co.uk/Archive/Article/0,4273,4134799,00.html> (last visited Aug. 4, 2002).

70. See *id.* (portraying the U.S. government and the pharmaceutical industry as taking legal actions to protect pharmaceutical patents at the expense of lives).

71. Compare Julian Borger, *Gore Accused of Working Against Cheap AIDS Drugs*, DAILY MAIL & GUARDIAN, Aug. 10, 1999 (reporting on Vice President Al Gore's efforts to lobby South Africa's government to ensure strong pharmaceutical patent protection), available at <http://www.mg.co.za/mg/news/99aug1/10aug-aids.html> (last visited July 11, 2002), with Ed Vulliamy & David Beresford *South Africa Beats U.S. Over Cost of AIDS Drugs*, DAILY MAIL & GUARDIAN, Sept. 21, 1999 (reporting that Vice President Gore intended to abandon "his attempts to



and dropped the suit in the spring of 2001.<sup>72</sup>

The misstep in the South African case changed the U.S.' general approach to dealing with similar compulsory licensing legislation in other developing countries.<sup>73</sup> Most notably, the United States dropped a complaint filed with the WTO Dispute Settlement Body against Brazil regarding its Intellectual Property Law,<sup>74</sup> choosing instead to pursue private bilateral negotiations.<sup>75</sup> Still, many developing countries were hesitant to enact such laws as steps to address HIV/AIDS in their respective countries.<sup>76</sup>

Then in the fall of 2001, the U.S. Secretary of Health and Human Services ("HHS") Tommy Thompson effectively destroyed any credibility left in the U.S. argument that compulsory licensing for pharmaceuticals was an undesirable option to address public health

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intimidate" South Africa's President Mbeki into changing South Africa's Medicines Act due to the effects of negative public relations on his presidential campaign), available at [http://www.mg.co.za/mg/news/99sep2/21sep-aids\\_drugs.html](http://www.mg.co.za/mg/news/99sep2/21sep-aids_drugs.html) (last visited July 11, 2002).

72. See Karen DeYoung, *Makers of AIDS Drugs Drop S. Africa Suit*, WASH. POST, Apr. 19, 2001, at A13 (reporting that the world's major pharmaceutical companies planned to drop their suit against the South African government due to the "public relations nightmare"), available at <http://www.washingtonpost.com/ac2/wp-dynA34439-2001Apr18?language=printer> (last visited July 11, 2002).

73. Compare USTR 2001, *supra* note 64 (stating that the Bush Administration will not object if WTO Member countries avail themselves of the flexibilities offered by TRIPs in order to address major health crises, such as HIV/AIDS), with *State Dep't Report on South African Medicines Act*, *supra* note 42, at 4 (detailing the U.S.' efforts, including those of the USTR and former Vice President Gore, to have the South African government repeal, withdraw, or terminate provisions of the Medicines Act).

74. See USTR 2001, *supra* note 64 (reporting that the United States and Brazil mutually agreed to transfer a disagreement over Brazil's patent law from the WTO formal litigation to a bilateral consultative forum).

75. See *id.* (noting that transferring the dispute from the WTO is intended to achieve a "more effective and less confrontational consideration of intellectual property issues").

76. See Gustavo Capdevila, *Trade: Developing World Demands Clear Rules on Access to Drugs*, INTER PRESS SERVICE (Geneva), June 20, 2001 (reporting the comments of European Union representative Carlo Trojan who stated that developing countries hesitate to use compulsory licensing provisions because they fear WTO litigation and sanctions), available at 2001 WL 4804341.

crises.<sup>77</sup> In the midst of an anthrax scare following the terrorist attacks on the United States of September 11, 2001, the HHS Secretary threatened the Bayer AG Corporation that the U.S. government would issue a compulsory license for Bayer's blockbuster antibiotic Cipro (ciprofloxacin), unless Bayer lowered its selling price for Cipro to the U.S. government.<sup>78</sup>

The reaction to Tommy Thompson's action was swift and critical.<sup>79</sup> Many countries simply recognized the inherent hypocrisy of the Secretary's position.<sup>80</sup> If the United States could assert the right to issue a compulsory license for a public health scare that resulted in less than a dozen deaths, then how could it maintain that developing countries should not take similar measures to address the HIV/AIDS crisis in their respective countries?<sup>81</sup>

In November 2001, the fourth WTO Ministerial Conference took place in Doha, Qatar.<sup>82</sup> With the South African case and the Cipro

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77. See generally *U.S. Threat to Cipro Patent Criticized*, INTELL. PROP. STRATEGIST, Nov. 2001, at 7 [hereinafter *Cipro Threat Criticized*] (indicating that Tommy Thompson's threat to override Bayer's Cipro patent places the United States in a difficult position to defend the request that developing countries should resist overriding patents).

78. See *id.* (describing Tommy Thompson's threat to override Bayer's patent on Cipro, in the wake of the anthrax scare, as a means to obtain lower prices for the drug).

79. See, e.g., Emma Young, *US Accused of Double Standards on Drug Patents*, NEW SCIENTIST, Nov. 2, 2001 (reporting that French Trade Secretary Francois Huwart believed that the U.S.' actions with regards to Cipro gave developing countries the legitimate impression that "double standards are in place"), at <http://www.newscientist.com/news/news.jsp?id=ns99991512> (last visited July 11, 2002).

80. See *id.* (implying that countries view the threat to override the Cipro patent as a double standard); *Cipro Threat Criticized*, *supra* note 77, at 7 (reporting that the threat to the Cipro patent has been viewed as a hypocritical action on the part of the U.S. government).

81. See *Cipro Threat Criticized*, *supra* note 77, at 7 (noting that the threat to Bayer's patent was characterized as hypocritical primarily because the United States purported to justify overriding a patent for a "scare," whereas the United States previously opposed similar actions by countries attempting to deal with AIDS crises).

82. See Young, *supra* note 79 (stating that developing countries' access to patented medicines will be a key issue at the fourth ministerial conference in Doha on November 9, 2001); Frances Williams, *Declaration on Patent Rules Cheers Developing Nations*, FIN. TIMES, Nov. 15, 2001, at 6 (on file with author).

incident occurring in the same year,<sup>83</sup> the United States was in a difficult position to object to the demands of developing countries.<sup>84</sup> Although the draft ministerial declaration submitted by the developed countries lacked any overt reference to compulsory licenses,<sup>85</sup> the final official declaration set relatively broad conditions under which a country could grant a compulsory license for pharmaceuticals.<sup>86</sup>

## II. ANALYSIS: THE LEGAL STATUS OF COMPULSORY LICENSING

### A. PRINCIPLES FOR INTERPRETING TRIPS

A WTO Appellate Body<sup>87</sup> ("AB") and more recently a WTO Panel<sup>88</sup> ("Panel") interpreted TRIPs in accordance with the principles

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(announcing the signing of the Declaration on Patent rules at the Doha Ministerial).

83. See DeYoung, *supra* note 72, at A13 (reporting on April 19, 2001 withdrawal of the pharmaceutical industries' lawsuit against the South African government); *Cipro Threat Criticized*, *supra* note 77, at 7 (reporting in November 2001 the Secretary of HHS's threat to issue a compulsory license for Cipro).

84. See Young, *supra* note 79 (suggesting that the world community would consider the United States hypocritical if it opposed relaxing restrictions on TRIPs standards for compulsory licenses in the wake of the Cipro incident).

85. See *Draft Ministerial Declaration, Proposal From a Group of Developed Countries*, IP/C/W/313 (Oct. 4, 2001) [hereinafter *Developed Countries Draft*] (lacking the term "compulsory license" within the text of the draft). The draft was proposed and submitted to the TRIPs Council by Australia, Canada, Japan, Switzerland, and the United States. *Id.*

86. See *Declaration*, *supra* note 26, para. 4-5 (stating that WTO Members have the right "to use, to the full, the provisions in the TRIPs Agreement, which provide flexibility for this purpose"). The purpose is to safeguard the Members' right to "protect public health and, in particular, to promote access to medicines for all." *Id.*

87. See *WTO Appellate Body Report, India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, para. 45 (Dec. 19, 1997) [hereinafter *India-Mailbox AB*] (stating that TRIPs should be interpreted in accordance with the principles outlined in Article 31 of the Vienna Convention on the Law of Treaties), available at <http://docsonline.wto.org> (last visited July 11, 2002).

88. See *WTO Panel Report, Canada-Patent Protection of Pharmaceutical Products*, WT/DS114/R, para. 7.13 (Mar. 17, 2000) [hereinafter *Canada-Generic*]

of interpretation contained in Article 31 of the Vienna Convention on the Law of Treaties ("VCLT").<sup>89</sup> VCLT Article 31(1) states that the words of a treaty must be given their ordinary meaning in their context and read in light of the treaty's object and purpose.<sup>90</sup> When determining the object and purpose of a treaty, the Panel interpretation should be tied closely to the actual text.<sup>91</sup> Selected material other than the text must also be considered for the purpose of providing context.<sup>92</sup> However, supplementary material should only be used to confirm the meaning derived from an Article 31 analysis

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(stating that "rules that govern the interpretation of WTO agreements are the rules of treaty interpretation stated in Articles 31 and 32 of the Vienna Convention"), available at <http://docsonline.wto.org> (last visited July 11, 2002).

89. See Vienna Convention on the Law of Treaties, May 23, 1969, art. 31(1), 1155 U.N.T.S. 331, [hereinafter VCLT] ("A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose"), available at <http://www.un.org/law/ilc/texts/treaties.htm> (last visited July 11, 2002).

90. See *id.* (defining treaty interpretation principles); *India-Mailbox AB*, *supra* note 87, para. 45 (stating that a treaty interpreter should examine the words of a treaty in accordance with the "ordinary meaning analysis" set out in Article 31 of Vienna Convention); *Canada-Generic*, *supra* note 88, para. 7.13 (stating that the starting point of an ordinary meaning analysis is VCLT Article 31(1)).

91. See *India-Mailbox AB*, *supra* note 87, para. 56 (indicating that the surrounding subparagraphs (b) and (c) constitute context for discerning the meaning of the word "means" as used in subparagraph (a) of Article 70.8 of TRIPs). The appellate body also reviewed other articles such as TRIPs Articles 65 and 1.1 for guidance. *Id.* paras. 58, 59.

92. See VCLT, *supra* note 89, art. 31(2), (3) (specifying the additional material outside of the treaty text that must be considered when conducting an ordinary meaning analysis). VCLT Article 31(2) states that under VCLT Article 31(1) the context "shall" include:

[I]n addition to the text, including its preamble and annexes: (a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty; (b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.

*Id.* art. 31(2). In addition to the context, as defined in VCLT Article 31(2), VCLT Article 31(3) states that the following "shall" be taken into account:

(a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation; (c) any relevant rules of international law applicable in the relations between the parties.

*Id.* art. 31(3).

or to clarify an analysis that results in an ambiguous meaning or "leads to a result that is manifestly absurd or unreasonable."<sup>93</sup>

A central issue in *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* ("India-Mailbox") was whether the Panel properly interpreted the word "means" in TRIPs Article 70.8(a).<sup>94</sup> Specifically, India appealed the Panel's finding that the good faith interpretation requirement of VCLT Article 31<sup>95</sup> mandated that the "legitimate expectations" of the parties to TRIPs be considered when interpreting the term "means."<sup>96</sup> The AB disagreed with the Panel and held that treaty interpreters should refer to the actual language of the treaty.<sup>97</sup> Furthermore, the AB held that the "legitimate expectations" of the parties are already reflected in the actual text of the TRIPs, and therefore, outside words and concepts

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93. See *Canada-Generic*, *supra* note 88, para. 7.13 (referring to VCLT Article 32 in discussing when a treaty interpreter should refer to supplementary material). The WTO Panel recognized that negotiating history is a type of supplementary material. *Id.* See also *India-Mailbox AB*, *supra* note 87, para. 48 (implying that in the appropriate circumstances negotiating history may be considered while interpreting TRIPs).

94. See *India-Mailbox AB*, *supra* note 87, para. 28(a) (describing the issue as the proper interpretation of the Article 70.8(a) requirement that a Member must provide "a means" by which applications for patents for inventions can be filed). This case was brought on an appeal by the Indian government seeking to overturn the lower Panel's decision. *Id.* para. 3. India argued that the lower panel's interpretation of the term "means" in TRIPs Article 70.8(a) was erroneous. *Id.* para. 28(a). The United States asserted that India's administrative practices failed to meet the requirements of TRIPs Article 70.8(a). *Id.* para. 1. See also TRIPs art. 70(8)(a) (requiring those Members granted a delay in enacting patent protection to establish a "means by which applications for such inventions can be filed").

95. See VCLT, *supra* note 89, art. 31(1) (requiring that a treaty be interpreted in "good faith").

96. See *India-Mailbox AB*, *supra* note 87, para. 33 (stating India's objection to the importation of a Members' "legitimate expectations" concerning TRIPs into the "good faith interpretation" principle). See also *WTO Panel Report, India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/R, para. 7.22 (Sep. 5, 1997) [hereinafter *India-Mailbox Panel*] (concluding that "when interpreting the text of the TRIPs Agreement, the legitimate expectations of WTO Members concerning the TRIPs Agreement must be taken into account"), available at <http://docsonline.wto.org> (last visited July 11, 2002).

97. See *India-Mailbox AB*, *supra* note 87, para. 45 (stating that a treaty interpreter's duty is "to examine the words of a treaty to determine the intentions of the parties").

should not be introduced into TRIPs.<sup>98</sup>

Although the AB holding seemingly contradicts the clear language of VCLT Article 31(2) and 31(3),<sup>99</sup> this is misleading because the AB's comments in *India-Mailbox* were specifically directed at supplementary material.<sup>100</sup> If confronted with material that is not a treaty and not supplementary, such as subsequent WTO agreements, the AB will likely follow VCLT Article 31 in its entirety and incorporate those documents into an interpretation of TRIPs.<sup>101</sup>

## B. COMPULSORY LICENSING UNDER THE TEXT OF TRIPs

At the time of its passage, TRIPs differed from other previously negotiated agreements because it set minimum international standards that were uniformly binding on all Members.<sup>102</sup> TRIPs Article 31 incorporates language that allows for practices such as compulsory licensing.<sup>103</sup> TRIPs Article 31(b) outlines the pre-

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98. See *id.* (emphasizing that the principles of interpretation outlined in the VCLT do not require nor do they "condone the imputation into a treaty of words that are not there or the importation into a treaty of concepts that were not intended").

99. See *supra* note 92 (quoting language from VCLT Article 31(2), (3) that mandates the consideration of material outside of the treaty text in order to determine a meaning under Article 31(1)).

100. See *India-Mailbox AB*, *supra* note 87, para. 33 (quoting the lower Panel decision that the term "legitimate expectations" as used in the AB report refers to the expectations of the parties negotiating TRIPs). Negotiating history falls within supplementary material. *Id.* at 48. See also VCLT, *supra* note 89, art. 32 (stating that supplementary material includes "preparatory work of the treaty").

101. See VCLT, *supra* note 89, art. 31(2), (3) (mandating that while performing a proper VCLT ordinary meaning analysis, certain additional agreements should be considered in order to provide context).

102. Compare Frederick M. Abbott, *Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework*, 22 VAND. J. TRANSNAT'L L. 689, 702-04 (1989) (discussing international intellectual property standards, prior to TRIPs, under the Paris and Berne Conventions), with CORREA, TRIPs POLICY, *supra* note 19, at 1-3 (offering a general overview of TRIPs and concluding that TRIPs provides a broader coverage of intellectual property rights than agreements prior to its enactment). The author also notes that TRIPs provides much stronger enforcement provisions. *Id.*

103. See TRIPs, *supra* note 17, art. 31 (stating Member nations may enact laws that allow "for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government" under specified conditions); see also Ford, *supra* note 16, at 960-

conditions to a Member's issuance of a compulsory license.<sup>104</sup> Under normal conditions, the licensee, whether a Member or third party entity, must engage the patent holder in negotiations before obtaining a compulsory license.<sup>105</sup> This requirement may be waived in the event of a national emergency or another extremely urgent situation.<sup>106</sup>

Significantly, TRIPS neglects to define the term "national emergency" anywhere within the text.<sup>107</sup> Such ambiguity in the language of TRIPS led to different interpretations of the specific exceptions and the conditions under which Members may pursue those exceptions.<sup>108</sup>

### C. UNDERSTANDING THE DOHA DECLARATION

At the time of the fourth ministerial conference, the WTO intended for the Doha Declaration to clarify certain ambiguous terms and phrases in TRIPS,<sup>109</sup> such as "national emergency."<sup>110</sup> To this end, both developing countries and developed countries submitted draft Declarations.<sup>111</sup> The final language more closely resembles the

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61 (discussing the ambiguity of Article 31 of TRIPS and the resultant interpretation that authorizes compulsory licensing).

104. See TRIPS art. 31(b) (outlining the actions a Member must take prior to authorizing another use under Article 31).

105. See *id.* (explaining that the party authorized for the "other use" must conduct negotiations on "reasonable commercial terms and conditions"). Furthermore, the party must allow a "reasonable period of time" to achieve a mutual agreement. *Id.*

106. See *id.* (stating that the licensee may waive negotiations "in the case of a national emergency or other circumstances of extreme urgency"). Even in the case of a waiver, the licensee should notify the patent holder of the authorization as promptly as possible. *Id.*

107. See *id.* arts. 1-73 (lacking a definition of the term "national emergency").

108. See Ford, *supra* note 16, at 963-67 (discussing the widely differing interpretations of Article 31 language by developing and developed countries).

109. See DOHA PRESS PACK, *supra* note 22, at 24 (stating that the objective of the ministerial declaration on TRIPS is to "clarify what governments can do under the TRIPS Agreement, and to reduce their uncertainties about using the flexibilities that are built into the agreement").

110. See *supra* notes 106-08 and accompanying text (providing examples of ambiguity within TRIPS).

111. See generally *Developed Countries Draft*, *supra* note 85 (offering a draft

desires of the developing countries,<sup>112</sup> and represents a significant shift in position for developed countries, such as the United States.<sup>113</sup>

The Doha Declaration contains its major conclusions in paragraphs 1 through 5.<sup>114</sup> Paragraphs 1 through 3 attempt to provide context to the issue of intellectual property protection for medicines and to recognize the need to balance private property and public welfare interests.<sup>115</sup> The first part of paragraph 4 outlines the permissible scope of Members' rights with regard to actions taken to protect public health.<sup>116</sup> The second part of paragraph 4 emphasizes that Members should interpret TRIPs in a manner to protect public health.<sup>117</sup> Paragraph 5 contains the most controversial provisions, those that provide Members with flexibilities in implementing

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declaration containing terminology and phrasing desired by countries representing the developed countries); *Draft Ministerial Declaration, Proposal From a Group of Developing Countries*, IP/C/W/312, WT/GC/W/450 (Oct. 4, 2001) [hereinafter *Developing Countries Draft*] (proposing a version of a declaration that contained the expectations and language of countries representing developing countries). The African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela submitted this draft declaration. *Id.*

112. See Williams, *supra* note 82, at 6 (reporting the final Declaration as a "victory for developing countries").

113. Compare *Declaration*, *supra* note 26, para. 4 (asserting that using permissive and broad language such as TRIPs "does not and should not prevent" Members from enacting measures to protect public health), with *Developed Countries Draft*, *supra* note 85 (stating only that TRIPs "contributes to the availability of medicines"). The Developed Countries Draft consistently uses the term "pandemic" rather than a term as encompassing as "public health." *Id.*

114. See *Declaration*, *supra* note 26, paras. 1-5 (acknowledging the importance of TRIPs to public health, and its flexibilities).

115. See *id.*, paras. 1-3 (emphasizing that both private and public interests are important considerations). The Declaration begins by recognizing that developing and least-developed countries are facing disastrous public health problems. *Id.* para. 1. Paragraph 2 stresses that TRIPs should be "part of the wider national and international action." *Id.* para. 2. Finally, paragraph 3 highlights the importance of intellectual property protection for the development of new medicines, but acknowledges concerns surrounding the higher prices. *Id.* para. 3.

116. See *id.* para. 4 (stating that "[w]e agree that the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health").

117. See *id.* (stating 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").



TRIPs.<sup>118</sup> Paragraph 6 leaves the issue of compulsory licenses and Members who lack adequate pharmaceutical manufacturing capacities unresolved.<sup>119</sup>

The opening three paragraphs of the Declaration describe the chief concerns of developing and developed countries, and form the framework for understanding the rest of the Declaration.<sup>120</sup> As stated in paragraph 1 and the second sentence of paragraph 3, developing countries are primarily concerned about the overwhelming public health epidemics in their countries and the high cost of the medications needed to treat afflicted populations.<sup>121</sup> On the other hand, developed countries want to emphasize the demonstrated value of patent protection and perhaps, more importantly, that diseases like HIV/AIDS necessitate a wider and more comprehensive effort.<sup>122</sup>

Paragraph 4 is a strong affirmative statement emphasizing that protecting public health, particularly promoting access to medicines, is a valid basis for Members to enact and exercise exceptions to

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118. See *Declaration*, *supra* note 26, para. 5 (outlining the flexibilities contained in TRIPs, such as the power to grant compulsory licenses and the determination of a national emergency).

119. See *id.* para. 6 (instructing the TRIPs Council to research a solution for those countries with inadequate pharmaceutical manufacturing capacities).

120. See *supra* note 115 and accompanying text (discussing the importance of paragraphs 1-3 of the Declaration).

121. See *Declaration*, *supra* note 26, paras. 1, 3 (noting the "gravity" of health problems in developing and least-developed Member countries, which help develop an understanding of the concern surrounding high drug prices).

122. See *id.* para. 2 (reminding Members of the role of intellectual property protections in the development of new medicines and that relaxing protections is only part of the solution to public health epidemics); see also *Developed Countries Draft*, *supra* note 85 (stating that an effective response to the challenges presented by pandemics consists of a "mix of complementary social, economic, health policies and practices, including education and prevention programmes"). The draft declaration goes on to state:

[a]mong the determinant factors for improving access to medicines are efficient infrastructure to distribute, deliver and monitor drug usage and provide necessary information and education; increased research and development particularly targeted at the major communicable diseases of relevance for developing countries; mechanisms to finance drug purchases, and affordable pharmaceuticals; and the implementation of effective and sustainable healthcare systems.

*Id.*

patent protection in their domestic legislation.<sup>123</sup> TRIPs Article 8, outlining the principles of the TRIPs, permits Members to “adopt measures necessary to protect public health.”<sup>124</sup> TRIPs Articles 30 and 31 relate to flexibilities,<sup>125</sup> and fail to provide any reference to TRIPs Article 8 or the acceptable bases upon which Members may exercise the provisions.<sup>126</sup> Applying the VCLT Article 31 principles of treaty interpretation,<sup>127</sup> the text of TRIPs Articles 30 and 31, read in light of article 8, may already permit countries to exercise TRIPs flexibilities to protect public health.<sup>128</sup>

Paragraph 4 obviates this analysis by specifically stating that Members have the right to use TRIPs flexibilities in order to protect the public health.<sup>129</sup> Developing countries exercising these provisions to address public health concerns can now depend on a clear interpretative statement, should future challenges be brought before

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123. See *Declaration*, *supra* note 26, para. 4 (indicating that Members may use all the provisions in TRIPs that provide for flexibility when attempting to protect public health, particularly to promote access to medicines); see also TRIPs, *supra* note 17, arts. 30-31 (failing to provide bases upon which a Member may exercise TRIPs’ flexibilities).

124. See TRIPs, *supra* note 17, art. 8 (outlining the guiding principles of TRIPs). The first principle indicates that Members should have some flexibility in shaping their domestic patent laws in order to address public health problems. *Id.*

125. See *id.* art. 30-31 (containing the exceptions to the exclusive rights of patent holders). Article 30 is titled “Exceptions to Rights Conferred.” *Id.* art. 30. Article 31 is titled “Other Use Without Authorization of the Right Holder.” *Id.* art. 31.

126. See TRIPs, *supra* note 17, arts. 30-31 (noting that TRIPs fails to provide bases upon which Members can obtain compulsory licenses). TRIPs Articles 30 and 31 do not make any reference to the principles outlined in TRIPs Article 8. *Id.* The “national emergency” and “extreme urgency” clause of TRIPs Article 31(b) is simply a basis for waiving licensing negotiations with the patent holder. *Id.* art. 31(b).

127. See VCLT, *supra* note 89, art. 31(1) (examining a treaty and its terms in light of its object and purpose).

128. See TRIPs, *supra* note 17, arts. 30-31 (acknowledging that Members may enact measures that violate a patent holder’s exclusive rights); *id.* art. 8 (stating as a guiding principle that Members may enact measures to address public health concerns).

129. See *Declaration*, *supra* note 26, para. 4 (affirming that Members may fully use the flexibilities in TRIPs for the “purpose” of protecting public health and promoting access to medicines).

the WTO.<sup>130</sup>

The Declaration, however, goes beyond a broad reference to TRIPs flexibilities.<sup>131</sup> Paragraph 5 explicitly states that Members may issue compulsory licenses.<sup>132</sup> Where the Declaration is concerned, Members should limit grounds for the issuance of such licenses to the protection of public health and promoting access to medicines<sup>133</sup> “in the light of paragraph 4.”<sup>134</sup>

Paragraph 5 also clarifies the term “national emergency” in TRIPs Article 31.<sup>135</sup> Under TRIPs, the most expeditious avenue for a country to issue a compulsory license is to claim a national emergency.<sup>136</sup> Both developing and developed countries sought to define the term “national emergency” because the text of TRIPs failed to provide interpretive guidance.<sup>137</sup> The Declaration provides Members the “right to determine what constitutes a national emergency,”<sup>138</sup> and expressly indicates that “public health crises,”<sup>139</sup>

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130. *See infra* notes 156-66 and accompanying text (analyzing the weight a Panel would accord the Declaration if a Member relied on it).

131. *See Declaration, supra* note 26, para. 5 (discussing compulsory licensing).

132. *See id.* para. 5(b) (stating that “[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted”).

133. *See Declaration, supra* note 26 at para. 4 (allowing Members to protect “public health” and “promote access to medicines”).

134. *See id.* para. 5 (prefacing the entire paragraph with an introductory clause stating “in the light of paragraph 4 above”).

135. *See id.* para. 5(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.”).

136. *See supra* notes 104-108 and accompanying text (discussing the preconditions to the issuance of a compulsory licensing outlined in TRIPs Article 31(b)).

137. *See TRIPs, supra* note 17, arts. 1-73 (failing to define the term “national emergency”).

138. *See Declaration, supra* note 26, para. 5(c) (clarifying the circumstances that constitute a national emergency).

139. *See id.* (specifying that “public health crises” would represent national emergencies).

such as HIV/AIDS, malaria, and “other epidemics,”<sup>140</sup> will be considered as national emergencies.<sup>141</sup>

Paragraph 5(a) also reminds Members that they should read “each provision of the TRIPs Agreement”<sup>142</sup> in light “of the Agreement as expressed . . . in its objectives and principles”<sup>143</sup> using the language of Article 31 of the VCLT.<sup>144</sup> This mode of analysis applies to the flexibilities within the TRIPs Agreement.<sup>145</sup>

Finally, while the Declaration notifies Members about how a WTO dispute settlement body may interpret the previously ambiguous terms and issues,<sup>146</sup> the Declaration does not restrict Members’ rights to use the dispute settlement procedure, with the exception of paragraph 5(d).<sup>147</sup> Consequently, Developed Member governments may still bring complaints before the Dispute Settlement Body regarding the very terms and issues addressed in the Declaration.<sup>148</sup>

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140. *See id.* (offering HIV/AIDS, tuberculosis, and malaria as representative examples of the epidemics included within the term “public health crises”).

141. *See id.* para. 5(c) (illustrating examples of national emergencies).

142. *See id.* para. 5(a) (providing guidance for interpreting international law and the TRIPs agreement).

143. *See id.* (highlighting that Members “shall” consider the principles and objectives of the Agreement in any interpretation of the TRIPs provisions).

144. *See VCLT, supra* note 89, art. 31 (outlining the general rule of interpretation).

145. *See Declaration, supra* note 26, para. 5 (prefacing statements on TRIPs flexibilities with subsection in 5(a) emphasizing public international law principles).

146. *See generally id.* paras. 1-5 (containing negotiated interpretations of terms and issues surrounding public health and TRIPs).

147. *See id.* para. 5(d) (barring Members from challenging other Members’ schemes dealing with the exhaustion of intellectual property rights).

148. *See DOHA PRESS PACK, supra* note 22, at 24-25 (stating that Members would protect their rights to dispute settlement procedures and would protest any significant restraint on the rights during negotiations).

D. WTO MEMBERS MAY ISSUE COMPULSORY LICENSES TO  
ADDRESS INTERNATIONALLY RECOGNIZED EPIDEMICS

The focus of the Declaration on addressing epidemics is narrower than the broad public health focus originally sought by developing countries.<sup>149</sup> Much of the public attention surrounding compulsory licensing and other TRIPs flexibilities concerning pharmaceuticals has concentrated on HIV/AIDS.<sup>150</sup> Developing countries sought a broader mandate to exercise TRIPs flexibilities for public health concerns as a whole.<sup>151</sup> The drafters intended the Declaration to clarify, remove uncertainties, and provide guidance in this area.<sup>152</sup> Unfortunately, the text fails to achieve this goal because of internal inconsistencies.<sup>153</sup>

Take for example country A, a poor, developing nation experiencing public health event B, the effective and expeditious resolution of which necessitates patented drug C. In addition, assume that the population of country A cannot afford drug C. Country A decides to issue a compulsory license for drug C. The patent holder's country could challenge country A's decision by asserting that public health event B is not the type of TRIPs public health event that allows for the issuance of a compulsory license.<sup>154</sup> In such a

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149. See *Developing Countries Draft*, *supra* note 111 (suggesting a broad focus to include virtually every illness classified as a "disease"). The draft declaration asserts that Members have an "obligation to protect and promote the fundamental human rights to life and the enjoyment of the highest attainable standard of physical and mental health, including the prevention, treatment, and control of epidemic, endemic, occupational and other diseases." *Id.*

150. See generally Schug, *supra* note 66, at 230 (focusing on HIV/AIDS when discussing issues surrounding TRIPs and public health); Ford, *supra* note 16, at 950 (using the South African HIV/AIDS crisis as a platform to discuss compulsory licensing issues).

151. See *supra* note 149 (noting the broadly inclusive language used by developing countries in defining what illnesses Members must address).

152. See *supra* note 109 (discussing the objectives of the Declaration).

153. Compare Declaration, *supra* note 26, paras. 1, 5(c) (modifying public health with the clause "HIV/AIDS, tuberculosis, malaria, and other epidemics") with *id.* para. 4 (stating simply that Members should have the ability to enact measures that "protect public health" and "promote access to medicines").

154. See *id.* paras. 1-5 (defining public health in several different ways).

situation, a WTO Panel would need to interpret the term “public health” within TRIPs.<sup>155</sup>

*1. Legal Status of the Declaration on the TRIPs Agreement and Public Health*

A WTO Panel interpreting TRIPs must look to the words of the treaty.<sup>156</sup> The Panel will consider secondary materials in its analysis only if a textual analysis yields an ambiguous result.<sup>157</sup> Therefore, to interpret the term “public health,” a Panel must first decide whether VCLT Article 31 mandates that the Declaration be considered part of the treaty text or simply supplementary material.<sup>158</sup>

The AB in *India-Mailbox* stated that negotiating history is inappropriate in a VCLT Article 31 analysis.<sup>159</sup> This same AB did not preclude the use of other WTO material as part of a VCLT Article 31 ordinary meaning analysis.<sup>160</sup> When interpreting GATT Article XX(b), the AB in *U.S.-Import Prohibition of Certain Shrimp and Shrimp Products* (“*Shrimp Turtle I*”) deliberately considered WTO material outside of the treaty text as part of a VCLT Article 31 ordinary meaning analysis.<sup>161</sup> This fact is important to determining

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155. See *id.* (allowing interpretation disputes to be brought before a WTO panel).

156. See *India-Mailbox AB*, *supra* note 87, para. 45 (noting the AB’s reasoning that the ordinary meaning analysis requires a treaty interpreter to look to words in the four corners of the treaty).

157. See VCLT, *supra* note 89, art. 32 (outlining that use of supplementary materials when interpreting a treaty is acceptable if a VCLT Article 31 analysis leaves the term’s meaning “ambiguous or obscure”).

158. See *Canada-Generic*, *supra* note 88, para. 7.13 (describing supplementary material as a secondary consideration when interpreting a treaty).

159. See *India-Mailbox AB*, *supra* note 87, para. 45 (stating that under a proper 31 analysis only expectations grounded in the treaty need consideration).

160. See *id.* (disallowing the importation of words and concepts from outside the treaty, without indicating what exactly the treaty includes).

161. See *WTO Appellate Body Report, United States - Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/RW (Oct. 12, 1998), para. 130 (looking outside of the GATT to other “modern international conventions and declarations” when performing a VCLT Article 31 ordinary meaning analysis of the term “exhaustible natural resources”) available at <http://docsonline.wto.org/DDFDocuments/t/WT/DS/58ABR.DOC> (last visited July 11, 2002).

the status of the Declaration because among the WTO material the AB in *Shrimp-Turtle I* considered was a decision of Ministers at Marrakesh.<sup>162</sup> Furthermore, the AB noted that it found this decision “most significant” to its interpretation of the WTO agreement.<sup>163</sup>

Finally, the WTO acknowledges that Panels are not experts in all subject matters and consequently, the Dispute Settlement Understanding (“DSU”) allows Panels to seek information from “any relevant source.”<sup>164</sup> As recently as 2001, the AB in *European Communities-Measures Affecting Asbestos and Asbestos-Containing Products* (“*EU Asbestos*”) affirmed the lower Panel’s consideration of non-WTO scientific experts, documentation, and relevant intergovernmental organizations’ findings when attempting to define a health risk.<sup>165</sup> As a result, a Panel would most likely consider the Declaration primary material and therefore essential in providing context for the purposes of a VCLT Article 31 ordinary meaning analysis.<sup>166</sup>

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162. See *id.* para. 154 (noting the Decision of Ministers at Marrakesh to establish a permanent committee relating to trade and environment).

163. See *id.* (stating that the decision to establish a trade and environment committee was “most significant” in clarifying the “objectives of WTO Members with respect to the relationship between trade and the environment”).

164. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, *Understanding on Rules and Procedures Governing the Settlement of Disputes*, vol. 31, 33 I.L.M. 81 (1994) (outlining the procedures a panel must undertake in order to gather technical advice and information). This Article specifies that a panel has the “right to seek information and technical advice from any individual or body it deems appropriate.” *Id.* It does not specify what weight a panel must accord to such technical information. *Id.*

165. See WTO Appellate Body, *European Communities - Measures Affecting Asbestos-Containing Products*, WT/DS135/AB/R (Mar. 12, 2001), paras. 159-62 [hereinafter *EU Asbestos*] (holding that Appellate Body should not overturn the decision of the Panel to consider various pieces of scientific evidence unless Panel clearly “exceeded the bounds of its discretion”), available at <http://docsonline.wto.org/DDFDocuments/t/WT/DS/135ABR.doc> (last visited July 11, 2002). France banned imports of asbestos based on grounds that measure protected citizens from health risks posed by asbestos. *Id.* para. 164.

166. See *supra* notes 156-165 and accompanying text (analyzing the weight AB or Panel would accord to Declaration in WTO dispute settlement process).

## 2. Article 31 Analysis of "Public Health"

Applying the principles outlined in VCLT Article 31(1), the Panel would first look at the "ordinary" meaning of the term "public health."<sup>167</sup> Although the *India-Mailbox AB* failed to provide detailed guidance on this step,<sup>168</sup> the Panel in *Canada-Patent Protection of Pharmaceutical Products* ("Canada-*Generic*") indicated that the common dictionary definition would be an appropriate point of reference.<sup>169</sup> The dictionary definition of public health encompasses the health of the community generally.<sup>170</sup> Finding the dictionary definition to be vague and indefinite, a reasonable Panel would determine the term's ordinary meaning by looking at its context and reading it in light of the object and purpose of TRIPs.<sup>171</sup>

In the contextual portion of a VCLT Article 31 analysis of "public health," a Panel would first look to the surrounding treaty provisions.<sup>172</sup> The inquiry would also examine the preamble or principles of TRIPs in order to incorporate the object and purpose of TRIPs into their interpretation.<sup>173</sup> Accordingly, public health event B,

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167. See VCLT, *supra* note 89, art. 31 (explaining the requirements of a "good faith" effort to interpret a treaty).

168. See *India-Mailbox Panel*, *supra* note 96, para. 7.25 (providing a one line statement on the interpretation of "means" without providing any reasoning for that conclusion); *India-Mailbox AB*, *supra* note 87, para. 55 (agreeing with Panel's conclusion that ordinary meaning of "means" was not definitive from the term itself).

169. See *Canada-Generic*, *supra* note 88, paras. 7.30, 7.54 (indicating that ordinary meaning of the words "limited" and "normal" is found in the dictionary).

170. See WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE: UNABRIDGED 1836 (1993) [hereinafter WEBSTER'S DICTIONARY] (defining public health as the "protection and improvement of community health").

171. See *India-Mailbox AB*, *supra* note 87, para. 55 (concluding that "means" should be read in light of context, object, and purpose of TRIPs because ordinary meaning from terms themselves was unclear).

172. See *id.* para. 56 (reasoning that surrounding subsections, (b) and (c), provide context for the meaning of term in subsection (a)); *Canada-Generic*, *supra* note 88, paras. 7.31, 7.32, 7.36 (determining the meaning of "limited exceptions" in TRIPs Article 30 by referencing the rights affected in TRIPs Article 28.1).

173. See *India-Mailbox AB*, *supra* note 87, para. 57 (noting that the Panel's definition of means was correct in part because it was consistent with the object and purpose of TRIPs). The AB quoted language from the TRIPs Preamble stating "adequate" and "effective" intellectual property protection as one of the objectives



from the above hypothetical, would have to cause a national emergency or disrupt sectors vital to the socio-economic welfare of the nation for country A to have a valid basis to issue a compulsory license.<sup>174</sup> However, while this reading may elucidate some characteristics of a valid public health event,<sup>175</sup> a proper VCLT Article 31 analysis would necessarily take into consideration certain documents relating to TRIPs and public health.<sup>176</sup>

Therefore, a reasonable treaty interpreter would justifiably expand the VCLT Article 31 inquiry to include other relevant WTO material,<sup>177</sup> especially directly applicable material such as the

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of TRIPs. *Id.* See also *Canada-Generic*, *supra* note 88, para. 7.26 (taking into account the principles of TRIPs as described in Articles 7 and 8).

Obviously, the exact scope of Article 30's authority will depend on the specific meaning given to its limiting conditions. The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes.

*Id.*

174. See TRIPs, *supra* note 17, arts. 7, 8, 31(b) (outlining pre-conditions to Members exercising flexibilities). Members should design their domestic laws to address both intellectual property interests and social and economic welfare. *Id.* art. 7. Members may use flexibilities to address public health events that adversely affect socio-economic sectors. *Id.* art. 8. In the event of a national emergency, a Member may authorize a license to a third party to quell the emergency. *Id.* art. 31(b).

175. See *id.* (reading the term "public health" in light of the instances when TRIPs permits Members to use flexibilities).

176. See *supra* note 92 and accompanying text (quoting language from VCLT that demonstrates that VCLT Articles 31(2) and 31(3) mandate consideration of agreements beyond the strict terms of the treaty, the preamble, and the annexes when performing an ordinary meaning analysis); *supra* notes 164-65 and accompanying text (discussing a Panel's potential use of material beyond treaty text for an ordinary meaning analysis).

177. See *supra* notes 161-62 and accompanying text (noting the incorporation of WTO material other than treaty text into a VCLT ordinary meaning analysis); see also JACKSON ET AL., *supra* note 3, at 311-12 (concluding that this incorporation is valid despite the fact that a Declaration at a Ministerial Conference does not technically fall within the five official ways to modify or set new trade rules or policy, according to the WTO charter, including official "interpretations"). A reasonable treaty interpreter may regard the Declaration as an agreement within the meaning of Article 31 of the Vienna Convention. *Id.* Compare Declaration, *supra* note 26, paras. 4-5 (setting forth negotiated language regarding the proper interpretation of certain TRIPs provisions), with VCLT, *supra* note 89, art.

Declaration.<sup>178</sup> Unfortunately this also presents some difficulties. Specifically, paragraphs 1 and 5(c) of the Declaration seemingly define a “public health” event as an epidemic,<sup>179</sup> but paragraph 4 makes no effort to narrow this focus to anything less than public health concerns as a whole.<sup>180</sup>

However, the Declaration reaffirms and reemphasizes the values expressed in TRIPs, that while the public good is important, ultimately TRIPs seeks to promote intellectual property protections.<sup>181</sup> As such, a Panel would adopt a narrower interpretation of “public health” and decide that the ordinary meaning of the term in its context, and in light of the object and purpose of TRIPs, denotes an epidemic.<sup>182</sup>

Finally, while a dictionary definition of epidemic serves as a starting point,<sup>183</sup> a Panel, acting similarly to the one in *EU Asbestos*,<sup>184</sup> would probably look to international health organizations such as the World Health Organization (“WHO”) for current scientifically accepted characteristics and examples of

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31(3)(a) (stating that “any subsequent agreement” that concerns treaty interpretation or the application of treaty provisions “shall be taken into account”).

178. See generally, *Declaration*, *supra* note 26 (guiding Members on how to interpret TRIPs provisions in order to address public health concerns).

179. See *supra* note 153 (discussing the modification of the term “public health” in paragraphs 1 and 5 of the Declaration).

180. See *id.* (noting the absence of representative diseases and the phrase “other epidemics” in paragraph 4 of the Declaration).

181. Compare TRIPs, *supra* note 17, art. 7 (commenting on the importance of the “protection and enforcement of intellectual property . . . in a manner conducive to social and economic welfare, and to a balance of rights and obligations”), and *id.* art. 8 (stating that “Members may . . . adopt measures necessary to protect public health . . . provided that such measures are consistent with the provisions of this Agreement”), with *Declaration*, *supra* note 26, paras. 1, 3 (recognizing the “gravity of the public health problems,” but also recognizing that “intellectual property protection is important for the development of new medicines”).

182. See *Declaration*, *supra* note 26, paras. 1, 5 (defining public health events with specific terms, including epidemic).

183. See generally WEBSTER’S DICTIONARY, *supra* note 170, at 762 (defining an epidemic as “affecting or tending to affect many persons within a community, area, or region at one time”).

184. See *EU Asbestos*, *supra* note 165, paras. 159-62 (finding the Panel’s consideration of non-WTO expert evidence permissible).

epidemics.<sup>185</sup> Public health event B would qualify as an epidemic if the population of country A suffers from a disease in proportions not normally occurring.<sup>186</sup>

Most significantly, “an epidemic is a temporary increase in prevalence” in disease.<sup>187</sup> Accordingly, the manufacture of medicines to address the epidemic, pursuant to a compulsory license, will also be temporary.<sup>188</sup> This result corresponds with the spirit of the TRIPs provisions permitting exceptions to patent protection.<sup>189</sup>

Assuming that public health event B is considered an epidemic, the next issue is whether country A, due to a lack of manufacturing capacity, could issue a compulsory license to pharmaceutical manufacturers outside its borders to produce drug C and supply country A.

#### E. COMPULSORY LICENSING FOR COUNTRIES LACKING ADEQUATE MANUFACTURING CAPACITIES: VIENNA CONVENTION ARTICLE 31 ANALYSIS OF THE TRIPs ARTICLE 31 “THIRD PARTY”

Paragraph 6 of the Declaration specifically recognizes that even if a public health event warrants a compulsory license, some Members do not have pharmaceutical manufacturers with the production

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185. See *supra* notes 164-165 and accompanying text (discussing the use of expert evidence to derive an accurate contemporary meaning of a term).

186. See generally World Health Organization, *Department of Communicable Disease Surveillance and Response, Hepatitis A*, WHO/CDS/CSR/EDC/2000.7 (2000) (defining an epidemic as “an outbreak of disease such that for a limited period a significantly greater number of persons in a community or region suffer from it than is normally the case”), available at <http://www.who.int/emc-documents/hepatitis/docs/whocdscsredc2007.pdf> (last visited July 11, 2002).

187. See *id.* (noting that the “outbreak of disease” is “temporary” in nature).

188. See TRIPs, *supra* note 17, art. 31(b) (stating that nations issue compulsory licenses for medicine in emergencies that require quick and temporary action).

189. See *id.* art. 30 (specifying that Members may provide “limited exceptions to the exclusive rights conferred by a patent”); *id.* art. 31(c) (stating that “the scope and duration of [other uses of the subject matter of a patent] shall be limited”); *id.* art. 31(g) (indicating that the compulsory license should be terminated when the “circumstances which led to it cease to exist”).

capability to meet the population's needs.<sup>190</sup> The WTO Ministers instructed the TRIPs Council to find a solution to this problem by the end of 2002.<sup>191</sup> This section argues that foreign drug manufacturers should be permitted to supply another Member country with pharmaceuticals, pursuant to the issuance of a compulsory license by that Member in need.<sup>192</sup>

TRIPs Article 31, although it does not use the term "compulsory license," is generally accepted as the primary TRIPs provision authorizing the issuance of compulsory licenses.<sup>193</sup> Under this provision, third parties approved by the government may undertake uses of patented subject matter,<sup>194</sup> including the manufacturing, marketing, and selling of such matter.<sup>195</sup> TRIPs Article 31, on its face, does not indicate that the term "third parties" should be construed to exclude foreign pharmaceutical manufacturers.<sup>196</sup>

The principle of territoriality, however, currently functions to exclude non-domestic manufacturers from inclusion within the term "third parties."<sup>197</sup> The principle of territoriality prevents any Member

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190. See *Declaration*, *supra* note 26, para. 6 (recognizing that "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").

191. See *id.* (providing a deadline for the solution).

192. See TRIPs, *supra* note 17, art. 31 (outlining specific restrictions on the use of patented products that are not authorized by the patent holder).

193. See, e.g., Abbott, *supra* note 63, at 73 (observing that TRIPs Article 31 provides the framework under which WTO Members can grant compulsory licenses).

194. See TRIPs, *supra* note 17, art. 31 (stating that "third parties authorized by the government" may make use of patented products other than those authorized by the patent holder).

195. See *id.* art. 28 (noting the patent holder's exclusive rights to the "making," "selling," or "offering for sale" of the patented product). TRIPs Article 31 permits a third party to perform these rights without the patent holder's permission. *Id.* art. 31.

196. See *id.* art. 31 (lacking a definition of the term "third parties" that specifically excludes foreign entities).

197. See *Communication from the European Communities and Their Member States to the TRIPs Council: Concept Paper for Approaches Relating to Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health*, para. 7 (Mar. 2002) [hereinafter *Communication from EU*] (asserting that WTO

country from interfering with the rights granted to a patent holder in another Member country.<sup>198</sup> Territoriality is grounded in the notion that every government has sovereignty within its borders or territories.<sup>199</sup> Members have retained their sovereign powers in the area of intellectual property rights by controlling the integration of TRIPs obligations into a Member's legal framework.<sup>200</sup> Significantly, an inventor must seek a patent from each Member country in which he desires protection.<sup>201</sup>

On the other hand, a Member granting a compulsory license suspends a patent holder's protections in that Member's country.<sup>202</sup>

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Members with insufficient manufacturing capacities cannot grant compulsory licenses to foreign manufacturers because of the principle of territoriality), at [http://europa.eu.int/comm/trade/csc/trips\\_doha.htm](http://europa.eu.int/comm/trade/csc/trips_doha.htm) (last visited July 11, 2002).

198. See *id.* (concluding that Members with insufficient manufacturing capacities cannot issue compulsory licenses to export to foreign entities). Such an action would interfere with patent protection granted in the exporting Member's country and violate the principle of territoriality. *Id.*

199. See FREDERICK ABBOTT ET AL., THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM: COMMENTARY AND MATERIALS 602 (1999) (commenting that "the sovereignty of each national government within its own territory [is the] paramount principle by which the international legal and political order was constituted").

200. See TRIPs, *supra* note 17, art. 1 (directing the nature and scope of obligations upon WTO Members under TRIPs).

Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their domestic law more extensive protection than is required by this Agreement . . . . Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

*Id.*

201. See ABBOTT ET AL., *supra* note 199, at 602 (stating that under the concept of territoriality, a "creator must obtain protection in each territory where protection is considered necessary"). Historically, intellectual property rights have been granted by and only have effect within the territories of a single nation-state. *Id.* See also John Gladstone Mills III, *A Transnational Patent Convention for the Acquisition and Enforcement of International Rights*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 83, 92 (2002) (maintaining that companies and inventors who desire patent protection for their products in foreign nations "must file and perfect a separate patent application in each country where their product is likely to be sold, licensed, or produced").

202. See *supra* notes 193-195 and accompanying text (discussing how a compulsory license allows a third party to exercise the exclusive rights that a patent holder obtained pursuant to the grant of a patent).

The current legal framework of TRIPs prohibits a Member government from granting a compulsory license to a manufacturer in a foreign Member's territory, because doing so interferes with the inventor's patent rights in that foreign Member country.<sup>203</sup> This type of interference constitutes a violation of the principle of territoriality.<sup>204</sup>

However, scholars have questioned the relevance of this principle in an increasingly international and interdependent economic and political environment.<sup>205</sup> Indeed, simply the assent of a nation-state to a binding international treaty or agreement sacrifices some of the nation's sovereign power.<sup>206</sup> Furthermore, multinational agreements on patents such as the Patent Cooperation Treaty ("PCT"),<sup>207</sup> regional patent systems such as the European Patent Office ("EPO"),<sup>208</sup> and international agreements such as TRIPs, demonstrate nations' willingness to cede certain sovereign powers in the area of patents.<sup>209</sup>

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203. See *Communication from EU*, *supra* note 197, para. 7 (stating that "Members can not [sic] grant a compulsory license [sic] to a foreign manufacturer, because the patent covering the product in the other country is independent from the patent in the former country").

204. See *id.* (noting the impermissibility of a Member granting a compulsory license to a foreign entity "by virtue of the principle of territoriality of patent protection").

205. See ABBOTT ET AL., *supra* note 199, at 603 (analyzing the continuing value of the principle of territoriality within the framework of international intellectual property rights agreements). Commentators observe that many present and future challenges to the principle of territoriality exist. *Id.* See also JOHN H. JACKSON, *THE JURISPRUDENCE OF GATT & THE WTO: INSIGHTS ON TREATY LAW AND ECONOMIC RELATIONS* 369-70 (2000) (questioning the emphasis placed on sovereignty in the current era, where international agreements abound).

206. See JACKSON, *supra* note 205, at 369 (suggesting that when countries agree to international treaties and agreements, they agree to give up some of their sovereign power to the international community).

207. Patent Cooperation Treaty, With Regulations, June 19, 1970, 28 U.S.T. 7645 [hereinafter PCT]. See also Mills, *supra* note 201, at 92 (observing that the Patent Cooperation Treaty provides an international system for filing patent applications).

208. Convention on the Grant of European Patents, Oct. 5, 1973, 13 I.L.M. 270 [hereinafter EPC].

209. See Mills, *supra* note 201, at 88 (discussing the powers of the PCT to establish priority dates, the EPC to grant regional patents, and TRIPs to set internationally binding minimum standards); see also Michael N. Meller, *Principles of Patentability and Some Other Basics for a Global Patent System*, 83

Consequently, the principle of territoriality is in a state of flux. A VCLT Article 31 analysis of the TRIPs Article 31 term “third party” supports a further paring down of the territoriality principle to include compulsory licensing to foreign entities.<sup>210</sup>

Applying Article 31 of the Vienna Convention, the term “third party” should be interpreted in accordance with its ordinary meaning, in its context, and in light of its object and purpose.<sup>211</sup> Using the dictionary definition as a starting point, a third party is “one who is not a party to a[n] . . . agreement . . . but who is somehow involved in the transaction.”<sup>212</sup> In the case of a patented product, the patent is the agreement between the government and the patent holder.<sup>213</sup> A foreign drug manufacturer meets this definition of a third party because, although not party to the patent, its right to access that patented product is restricted for the term of the patent.<sup>214</sup> Furthermore, reading the term “third party” in context, beginning with the surrounding provisions, a treaty interpreter would not find any restrictions limiting “other use” to domestic parties.<sup>215</sup>

Among the various conditions placed on “other use” under TRIPs Article 31, the most pertinent to this discussion may be TRIPs Article 31(f).<sup>216</sup> This subsection requires that patented products manufactured pursuant to Article 31 are directed “predominantly”

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J. PAT. & TRADEMARK OFF. SOC'Y 359 (2001) (discussing the importance of a uniform global patent system to global trade and the economy).

210. See VCLT, *supra* note 89, art. 31 (stating the guidelines for interpretation of treaties like TRIPs).

211. See *id.* (outlining the general rule of interpretation for international treaties).

212. See BLACK'S LAW DICTIONARY 1489 (7th ed. 1999) (providing the most current definition of a third party as understood within the legal system).

213. See ADELMAN ET AL., *supra* note 15, at 1 (characterizing the patent system as a “bargain” whereby the inventor discloses a technology in exchange for exclusive rights to that technology).

214. See TRIPs, *supra* note 17, art. 28 (stating the exclusive rights associated with the grant of a patent). A patent holder can prohibit a third party from “making, using, offering for sale, selling, or importing” the patented product. *Id.*

215. See *id.* arts. 28, 30, 31 (lacking any explicit or implicit limitations on the location of the party conducting the “other use” under TRIPs Article 31).

216. See *id.* art. 31(f) (specifying that the “other use” under TRIPs Article 31 “shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”).

towards supplying the domestic marketplace of the authorizing Member government.<sup>217</sup> In other words, the terms of the compulsory license should not allow the licensee to sell to other markets and go beyond the purpose that precipitated the issuance of the license.<sup>218</sup> Interpreted in this manner, TRIPs Article 31(f) places a general restriction on third party manufacturers, regardless of their domicile, to negotiate license terms that provide broad distribution rights.<sup>219</sup> Article 31(f), along with the other Article 31 conditions, provides protection against third party misuse of a compulsory license.<sup>220</sup>

Finally, a full contextual analysis under Article 31 of the Vienna Convention would be incomplete without considering the Declaration.<sup>221</sup> The Declaration indicates that its drafters expect that the exercise of flexibilities, such as compulsory licensing, will play an integral role in quelling epidemics that afflict the populations of developing and least developed Member countries.<sup>222</sup> Therefore, if the goal of TRIPs is to protect intellectual property “in a manner

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217. See *id.* (suggesting that a drug manufactured pursuant to a compulsory license must be for the Member country authorizing such use).

218. See TRIPs, *supra* note 17, art. 31(c) (explicitly stating that the “scope” of the other use “shall be limited to the purpose for which it was authorized”); see also *id.* art. 31(f) (suggesting that the purpose in granting a compulsory license must be to primarily provide the domestic market of the authorizing member with a supply of the patented product). Read together, a Panel could legitimately infer that as soon as a third party stops primarily supplying the domestic market, then the purpose for which the license was authorized has ceased to exist and the license should be terminated. *Id.* art. 31 (c), (f).

219. See *id.* art. 31(f) (restricting the possible markets for the patented product).

220. See TRIPs, *supra* note 17, art. 31 (setting forth various restrictions on “other use,” including a compulsory license). The proposed user must negotiate with the patent holder. *Id.* art. 31(b). The scope and duration of the license must be limited to the original purpose. *Id.* art. 31(c). The license shall be non-exclusive. *Id.* art. 31(d). The license shall be non-assignable. *Id.* art. 31(e). If the circumstances that justified a Member’s issuance of the license cease to exist, then the license shall be terminated. *Id.* art. 31(g).

221. See *supra* notes 156-166 and accompanying text (analyzing the legal status of the Declaration).

222. See Declaration, *supra* note 26, paras. 1-6 (suggesting how Members could issue compulsory licenses to address epidemics like HIV/AIDS, malaria, and tuberculosis); see also India-Mailbox AB, *supra* note 87, para. 45 (stating that the legitimate expectations of the parties to a treaty are evidenced in the text).



conducive to social and economic welfare,”<sup>223</sup> then the WTO should not place barriers on Members lacking adequate domestic manufacturing capacities to issue compulsory licenses to foreign pharmaceutical manufactures. Furthermore, Members should not assert the principle of territoriality against the aforementioned compulsory licenses.

### III. RECOMMENDATIONS

Patent laws, at their very cores, seek to promote the creation of new and innovative products and processes for the benefit of the public.<sup>224</sup> In the field of pharmaceuticals, patented products represent some of the most significant advances in science and medicine.<sup>225</sup> Indeed, pharmaceutical companies have been able to develop HIV/AIDS drug therapies that have been critical in transforming an AIDS diagnosis from a “death warrant”<sup>226</sup> to a “treatable disease.”<sup>227</sup> The grant of a patent is a bargained-for-exchange.<sup>228</sup> In exchange for informing the public of the invention, the government grants the patent holder certain exclusive rights for a fixed period of time.<sup>229</sup>

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223. See TRIPs, *supra* note 17, art. 7 (outlining the objectives of the TRIPs Agreement).

224. See Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1021-22 (1989) (characterizing patents as requiring the patentee to provide knowledge that will contribute to the public warehouse).

225. See *Papovich Testimony*, *supra* note 64 (noting the importance of patent protection to the emergence of medicines for AIDS and other catastrophic diseases).

226. See James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers*, 53 FLA. L. REV. 727, 733 (2001) (noting that “AIDS, contrary to the view that it is a death warrant, is a treatable disease.”).

227. See *id.* (noting that drug treatment has “quadrupled the median survival time” for those diagnosed with AIDS).

228. See Robert Weissman, *A Long, Strange TRIPs: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1071 (1996) (explaining the exchange as the inventor's immediate placement of the newly-created knowledge in the public domain for a limited period in which the patent holder can use the patented knowledge).

229. See TRIPs, *supra* note 17, arts. 28, 29 (describing the rights granted to

In drafting TRIPs, WTO Members recognized that under certain circumstances exceptions to the patent holder's exclusive rights would be necessary and appropriate.<sup>230</sup> The WTO met in Doha to provide guidance to Members because TRIPs failed to clearly define the circumstances that would justify a Member's authorization of an exception, such as a compulsory license.<sup>231</sup> The Declaration is a good first step in the new round of trade talks.<sup>232</sup> Negotiating trade ministers should keep in mind a number of recommendations when debating what changes should be made to TRIPs.

#### A. ISSUE AN OFFICIAL INTERPRETATION ON PUBLIC HEALTH

First, Members must consider either an amendment or official interpretive statement to incorporate the clarifications of TRIPs negotiated at Doha. The Declaration would most likely be considered primary material and used to provide context for a VCLT Article 31 ordinary meaning analysis of the term "public health".<sup>233</sup> An amendment or official interpretation, however, would be a stronger binding legal document.<sup>234</sup>

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patentees and what patentees must disclose in order to receive patents). The patent holder gains a period of exclusive use of the subject matter pursuant to the grant of a patent. *Id.*

230. See *id.* art. 30, 31 (outlining exceptions to patent rights); see also Weissman, *supra* note 228, at 1099 (stating that TRIPs Articles 30 and 31 are two important exceptions to the exclusive rights granted in TRIPs Article 28).

231. See DOHA PRESS PACK, *supra* note 22, at 24 (noting that one objective of the Doha Ministerial Conference was to clarify what measures Member governments could undertake under TRIPs).

232. See, e.g., Frances Williams, *WTO Agrees to Launch New Global Trade Round*, FIN. TIMES, Nov. 14, 2001 (providing account of concessions, negotiations, various deals, and compromises made by trade ministers in Doha in order to launch a new global trading round), available at [http://www.wto.ru/en/news.asp?msg\\_id=349](http://www.wto.ru/en/news.asp?msg_id=349) (last visited July 11, 2002); Paul Geitner, *WTO to Launch New Trade Talks*, PNLTV, Nov. 14, 2001 (reporting the decision of WTO Members to launch new trade negotiations), at <http://www.pnlv.com/NewsStories/Nov%2015%20WTO%20to%20Launch%20New%20Trade%20Talks.htm> (last visited July 11, 2002).

233. See *supra* notes 156-166 and accompanying text (analyzing the legal status of the Declaration).

234. See JACKSON ET AL., *supra* note 3, at 311 (stating that under the WTO, charter amendments and interpretations are two techniques for formulating new or amended trade rules).

An official interpretation, pursuant to Article IX (2) of the WTO charter,<sup>235</sup> might be the preferred choice. The streamlined amendment procedure set forth in Article X(6) of the WTO charter would not apply to changes that would potentially decrease patent protection,<sup>236</sup> such as those dealing with exceptions to exclusive rights. Consequently, the more rigorous procedure set forth in Article X(1) of the WTO charter would apply.<sup>237</sup>

In light of this, an official interpretation is preferable to an amendment because, while it does not carry the same weight as an amendment,<sup>238</sup> it is sufficient to formulate new policy.<sup>239</sup> A procedure-laden method is not the optimal choice for clarifying terms subject to rapid change and development, such as "public health."

#### B. DESIGNATE WHO AS THE OFFICIAL ORGANIZATION TO PROVIDE TECHNICAL ASSISTANCE ON TRIPS-RELATED HEALTH ISSUES

Second, without a more internally consistent and binding statement, developed countries may continue to file WTO legal challenges to domestic patent laws asserting a violation of TRIPS standards.<sup>240</sup> Developed countries might allege that developing countries exercised TRIPS flexibilities impermissibly by addressing

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235. See WTO Agreement, *supra* note 18, art. IX:2 (discussing the authority and procedure for interpretations).

236. See *id.* art. X:6 (stating that the formal acceptance process will be waived for TRIPS amendments that meet the criteria set forth in TRIPS Article 71); TRIPS, *supra* note 17, art. 71(2) (declaring that only amendments that increase protection for rights granted are eligible for adoption in accordance with paragraph 6 of Article X of the WTO charter).

237. See WTO Agreement, *supra* note 18, art. X:1 (outlining the full formal amendment procedure).

238. See *id.* art. IX.2 (suggesting that interpretations are of a lesser weight than amendments by stating that "[interpretations] shall not be used in a manner that would undermine Article X").

239. See JACKSON ET AL., *supra* note 3, at 311 (noting that interpretations are one way to enact new rules for trade policy).

240. See *supra* notes 153, 179-180 and accompanying texts (highlighting the internal inconsistencies of the Declaration).

public health concerns that are not widely accepted as epidemics.<sup>241</sup> While the WTO charter and AB decisions already acknowledge that Panels may seek the guidance of outside experts,<sup>242</sup> the WHO should be designated as the international organization from which Members should seek guidance when determining the presence of an epidemic.

#### C. AMEND TRIPS ARTICLE 31 TERM "THIRD PARTY" TO INCLUDE FOREIGN ENTITIES

Third, the ministers should consider amending TRIPS Article 31 to include language stating that in the case where the Member issuing a compulsory license lacks adequate manufacturing capacities, the term "third party" may include foreign entities. The inclusion of this type of language comports with the notion that Member governments recognize the need to cede certain sovereign powers in the area of patents, demonstrated by EPC and PCT systems.<sup>243</sup>

The text of TRIPS does not support an interpretation of the term "third party" that would exclude foreign pharmaceutical manufacturers.<sup>244</sup> In fact, a clear acknowledgment that "third party" includes foreign entities would be in accordance with the spirit of a Declaration seeking to help developing and least-developing Member countries overcome the epidemics that afflict their people.<sup>245</sup>

#### D. PROVIDE AN EXEMPTION TO TRIPS ARTICLE 31(F)

If Members insist on adhering to territoriality, then trade ministers should consider a system in which Members lacking manufacturing capacities issue compulsory licenses for importation of needed

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241. *See id.* (suggesting that internal consistencies may lead to varying interpretations and therefore, legal challenges).

242. *See supra* notes 164-165 and accompanying text (providing the authority for using non-WTO material in VCLT ordinary meaning analysis).

243. *See supra* notes 205-209 and accompanying text (discussing the current state of the concepts of sovereignty and territoriality in general, and specifically their future significance to patents).

244. *See supra* notes 190-223 and accompanying text (concluding that, in light of the changing significance of sovereignty as it relates to patents, the term "third party" in TRIPS Article 31 should include foreign entities).

245. *See supra* note 222 and accompanying text (concluding that the Declaration allows Members to use compulsory licenses to address epidemics).

pharmaceuticals, and exporting Members concurrently issue compulsory licenses for export.<sup>246</sup> According to this scenario, two compulsory licenses would be issued with each license having to separately meet the requirements of TRIPs Article 31.<sup>247</sup> In addition, TRIPs Article 31(f)'s limitation, requiring compulsory licenses to be used "predominantly for the supply" of the authorizing Member's territory, would apply.<sup>248</sup> Any compulsory license for export would be ineffective because TRIPs Article 31(f) would only allow for a "non-predominant proportion of the production" to be exported.<sup>249</sup>

Therefore, trade ministers should consider amending TRIPs to include an exemption clause that would suspend the TRIPs Article 31(f) requirement when a Member issues a compulsory license for export in order to supply another Member that lacks adequate pharmaceutical manufacturing capacities.<sup>250</sup> However, Members would still be required to undertake the other inquiries set forth in

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246. See *Communication from EU*, *supra* note 197, paras. 7, 8 (suggesting a compulsory licensing system for Members lacking adequate pharmaceutical manufacturing capacities where Members in need issue compulsory licenses for import and other Members willing to supply medicines issue compulsory licenses for export).

247. See *supra* note 220 and accompanying text (discussing the various TRIPs Article 31 limitations on the issuance of a compulsory license).

248. See Paul Vandoren, TRIPs in the Context of the Doha Ministerial Declaration, Speech at Hong Kong VIP Visitors' Programme (Jan. 6, 2002) (indicating that TRIPs Article 31(f) would function to limit compulsory licenses for export), at [http://europa.eu.int/comm/trade/speeches\\_articles/sp\\_vdo01.htm](http://europa.eu.int/comm/trade/speeches_articles/sp_vdo01.htm) (last visited July 11, 2002).

249. See *id.* (reasoning that Members lacking adequate production capacity could not truly benefit from compulsory licenses issued by foreign Members to their domestic manufacturers because TRIPs Article 31(f) would require that a predominant proportion of the manufactured product by the foreign Member's manufacturer be supplied to that Member's population). Thus, the foreign Member could "only export a non-predominant proportion of the production under compulsory license." *Id.* See also *Communication from EU*, *supra* note 197, para. 8 (stating that compulsory licenses for export would "not be workable because of the limitation under 31(f) of the TRIPs Agreement, which stipulates that 'a predominant part' of the production under a compulsory license must remain on the domestic market of the Member granting the license").

250. See *Communication from EU*, *supra* note 197, para. 21 (suggesting that an exception clause to TRIPs Article 31(f) should state "that Article 31(f) does not apply to compulsory licenses granted in view of supplying a poor country with a product needed to address serious public health problems").

TRIPs Article 31.<sup>251</sup> These inquiries include determining “adequate remuneration” for the patent holder,<sup>252</sup> whether sufficient efforts have been expended to obtain a voluntary license,<sup>253</sup> and whether a national emergency is present.<sup>254</sup>

Both the EU and public health groups have indicated the disadvantages of incorporating an exemption clause for TRIPs Article 31(f).<sup>255</sup> Their opinion is that the separate inquiries needed for both import and export compulsory licenses would be duplicative and inefficient.<sup>256</sup> In addition, another concern is that some Members

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251. *See supra* note 220 and accompanying text (outlining at least five other conditions that exist, in addition to TRIPs Article 31(f), relating to a Member’s issuance of a compulsory license).

252. *See* TRIPs, *supra* note 17, art. 31(h) (specifying that a patent holder, whose patent has been compulsory licensed, is entitled to “adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”).

253. *See id.* art. 31(b) (emphasizing that uses of a patented product unauthorized by the patent holder are only allowed if the Member government 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”).

254. *See id.* (indicating that mandated negotiations with the patent holder may be waived in the event of a national emergency).

255. *See Communication from EU, supra* note 197, para. 8 (pointing out the disadvantage behind a TRIPs Article 31(f) exemption clause); Press Release, Health Gap, U.S. Post-Doha Conditions Can Kill (Mar. 4, 2002) [hereinafter Post-Doha Conditions] (outlining the shortcomings of an informal U.S. solution that entails providing an exemption clause to TRIPs Article 31(f), but retains the remaining limitations in TRIPs Article 31(f)), at <http://allafrica.com/stories/printable/200203040443.html> (last visited July 11, 2002).

256. *See* Post-Doha Conditions, *supra* note 255 (concluding that a TRIPs Article 31(f) exemption clause would still require lengthy and costly administrative procedures for the issuance of compulsory licenses for export). Compulsory licenses for export would require Members to negotiate with the patent holder in an attempt to achieve a voluntary license on commercially reasonable terms. *Id.* Such negotiations involve bureaucratic and administratively burdensome procedures. *Id.* Furthermore, the exporting Member, that is the country not in need, would be required to make a determination of the public health need and manufacturing capacity in the Member issuing a compulsory license for import. *Id.* As result of the aforementioned issues, Members with manufacturing capacities to supply those Members who lack them may simply be deterred from issuing a compulsory license for export. *Id.*

may not approve an amendment to the text of TRIPs.<sup>257</sup> As a result, both the EU and public health groups have suggested a declaration providing a broader interpretation of TRIPs Article 30's exceptions to patent rights.<sup>258</sup>

#### E. ISSUE A FORMAL INTERPRETATIVE STATEMENT CLARIFYING TRIPs ARTICLE 30 EXCEPTIONS

The trade ministers should consider issuing a formal interpretative statement on TRIPs Article 30 allowing Members to supply patented pharmaceuticals to other Members that lack adequate manufacturing capacities but have issued a compulsory license for import.<sup>259</sup> The key difference between this recommendation and providing an exception to TRIPs Article 31(f) is that the former does not require the issuance of two separate compulsory licenses.<sup>260</sup> Consequently, the exporting Member exercising the TRIPs Article 30 exceptions is

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257. See Vandoren, *supra* note 248 (suggesting that a reluctance to amend TRIPs prevails among Members).

258. See *Communication from EU*, *supra* note 197, para. 19 (suggesting an interpretation of TRIPs Article 30's exceptions that would "allow production for export, to certain countries and under certain conditions, of products needed to combat serious public health problems"); Letter from Médecins Sans Frontières et al., to TRIPs Council 1 (Jan. 28, 2002) (urging the WTO to consider an interpretation of TRIPs Article 30's exceptions as a solution to the issue of production for export), at [www.wto.org/english/forums\\_e/ngo\\_e/joint\\_trips.doc](http://www.wto.org/english/forums_e/ngo_e/joint_trips.doc) (last visited July 11, 2002).

259. See *Communication from EU*, *supra* note 197, para. 28 (suggesting as an alternative to a TRIPs Article 31 solution that Members issue a clarifying declaration on TRIPs Article 30's exceptions clause).

To this end WTO Members could adopt a declaration stating that a WTO Member may, in accordance with Article 30 of the TRIPs Agreement, provide that the manufacture, on its territory, of a patented product, without the authorization [sic] of the right holder, is lawful when the tolerated production is meant to supply another country which has granted a compulsory licence [sic] for the import and sale of the product concerned in its territory in order to deal with a serious public health problem.

*Id.*

260. See *supra* note 193 and accompanying text (noting that TRIPs Article 31 authorizes and places conditions on compulsory licenses).

not restrained by TRIPs Article 31's limitations on compulsory licenses.<sup>261</sup>

The benefits of an approach that takes advantage of TRIPs Article 30 exceptions include efficiency and the speed with which Members lacking adequate manufacturing capacities can receive needed pharmaceuticals.<sup>262</sup> Members suffering from public health epidemics would not have to endure a prolonged administrative procedure before being able to receive imports of essential medicines.<sup>263</sup> Additionally, this approach would expand upon already existing language in TRIPs,<sup>264</sup> making it more palatable to many Members.<sup>265</sup>

#### F. SAFEGUARDS AGAINST ABUSE MUST BE IMPLEMENTED

Under either a TRIPs Article 31 or Article 30 based remedy, trade ministers should implement procedures which guarantee that exported pharmaceutical products are used for their authorized purposes.<sup>266</sup> To this end, trade ministers should discuss steps that ensure that the entirety, not just a "predominant" portion, of

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261. See Post-Doha Conditions, *supra* note 255 (suggesting a TRIPs Article 30-based solution is superior to TRIPs Article 31 because it is not subject to the various compulsory licensing conditions imposed by TRIPs Article 31).

262. See Letter from Médecins Sans Frontières et al., *supra* note 258, at 1 (supporting a TRIPs Article 30 solution because it would be administratively simple, would avoid double compensation for the patent holder, and would avoid the need for two separate compulsory licenses); see also Post-Doha Conditions, *supra* note 255 (suggesting that a TRIPs Article 30-based remedy would be more efficient than a TRIPs Article 31(f) solution).

263. See Post-Doha Conditions, *supra* note 255 (suggesting that the reduced administrative barriers under a TRIPs Article 30 approach would result in speedy supply of needed pharmaceuticals and thus, save lives).

264. See *Communication from EU*, *supra* note 197, para. 30 ("The advantage of this [TRIPs Article 30 declaration] approach would be that it could fit within the flexibility offered by the existing TRIPs Agreement, without there being a need to go through a procedure to amend any of its provisions.").

265. See *supra* note 257 and accompanying text (suggesting that a solution based on existing language would generally be more acceptable to a majority of Members than a solution that required an amendment to TRIPs).

266. See *Communication from EU*, *supra* note 197, paras. 23, 31 (advocating strong safeguards, under either a TRIPs Article 31 or Article 30 approach, to ensure that objective of supplying Members in need is achieved and that patent rights are not undermined).



pharmaceuticals manufactured pursuant to a compulsory license for export are sent to the Member in need.<sup>267</sup> In addition, Member representatives should implement restrictions against the re-export of pharmaceuticals from the Member in need.<sup>268</sup> Both the above recommendations are in accordance with the general principle that exceptions to patent rights should be limited in scope.<sup>269</sup> Amendments or declarations to TRIPs that expand exceptions to patent rights in combination with safeguards to ensure limited exceptions will help preserve the balance between patent rights and the public good.

## CONCLUSION

The Declaration on Public Health and TRIPs issued in Doha, Qatar, created, rather than definitively solved, issues related to compulsory licensing. In the coming round of trade talks, WTO Members must come to a clear understanding on the issues of public health and compulsory licensing for export. Developing countries need to accept limits on what constitutes a "public health" concern, while developed countries need to accept a more expansive definition of "third party." The twenty-five million men, women, and children suffering from HIV/AIDS in sub-Saharan Africa are awaiting an answer.

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267. See *id.* para. 31 (suggesting a requirement that the "entirety of the production allowed under the [TRIPs] Article 30-exception must be imported to the Member having granted a licence [sic] for the sole purpose of the compulsory licence [sic]"). See also Vandoren, *supra* note 248 (suggesting a pre-condition on production for export as requiring that the "entire" amount of pharmaceutical produced for export to a Member lacking adequate manufacturing capacity be used "solely" to supply the Member in need).

268. See *Communication from EU*, *supra* note 197, paras. 24, 31 (asserting the need for safeguards against patented pharmaceuticals that are manufactured and exported to a Member in need from being re-exported from either (1) the exporting Member or (2) the importing Member). See also Vandoren, *supra* note 248 (emphasizing that "re-export of any part of the production would be allowed from the benefiting Member's territory").

269. See TRIPs, *supra* note 17, art. 30 (stating that "[m]embers may provide limited exceptions to the exclusive rights conferred by a patent").