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## Patent Wars in the Valley of the Shadow of Death: The Pharmaceutical Industry, Ethics, and Global Trade

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# Patent Wars in the Valley of the Shadow of Death: The Pharmaceutical Industry, Ethics, and Global Trade

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*[T]hat which one man has invented, all the world can imitate. Without the assistance of the laws, the inventor would almost always be driven out of the market by his rivals, who finding himself, without any expense, in possession of a discovery which has cost the inventor much time and expense, would be able to deprive him of all his deserved advantages, by selling at a lower price.*

Jeremy Bentham<sup>1</sup>

*Maintaining monopolies for medicine for poor countries during a worldwide health catastrophe is unethical and immoral.*

Paul Davis, Health GAP Coalition<sup>2</sup>

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\* Associate Professor, University of Arkansas – Fayetteville. 2003-2004 Fellow, Carnegie Council on Ethics and International Affairs. The author would like to thank Jade O. Laye, J.D. 2004, University of Arkansas School of Law, for his help on the research of this article. This article is dedicated to the memory of my brother, Chinedu Uzo Ewelukwa.

1. JEREMY BENTHAM, A MANUAL OF POLITICAL ECONOMY 71 (1839).

2. Press Release, Health GAP Coalition, Brazil Issue's [sic] World's First Compulsory License Citing Health Crisis, Country Will Produce Generic Version of Nelfinavir (Aug. 22, 2001), available at [http://www.healthgap.org/press\\_releases/01/082201\\_HGAP\\_PR\\_BRA\\_CL\\_Nelf.html](http://www.healthgap.org/press_releases/01/082201_HGAP_PR_BRA_CL_Nelf.html). Health GAP is an organization of AIDS and human rights activists who campaign against policies that deny HIV treatment to the millions around the world who need it. See Health

## I. INTRODUCTION

The AIDS epidemic turned the world's attention to the problem of high drug prices in developing countries and the numerous barriers to accessing essential drugs in these countries. The AIDS epidemic also triggered an extensive debate on the relationship between patents,<sup>3</sup> global trade agreements, particularly the Agreement on Trade-Related Aspects of Intellectual Property ("TRIPS Agreement"),<sup>4</sup> and public health, in addition to raising important questions about the role of the World Trade Organization ("WTO")<sup>5</sup> in promoting access to medicine in developing countries. Before November 2001, the core questions were: whether the TRIPS Agreement retarded access to essential medicine in developing countries by raising the cost of patented pharmaceuticals,<sup>6</sup> whether compulsory licensing in developing countries

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GAP, About Health GAP, at <http://www.healthgap.org/hgap/about.html> (last visited Jan. 28, 2005).

3. A patent can be simply defined as:

an exclusive right granted for an invention, which is a product or a process that provides a new way of doing something, or offers a new technical solution to a problem. . . . A patent provides protection for the invention to the owner of the patent. The protection is granted for a limited period, generally 20 years.

World Intellectual Property Organization (WIPO), About Intellectual Property, Inventions (Patents) (emphasis omitted), at <http://www.wipo.int/about-ip/en/patents.html> (last visited Jan. 28, 2005).

4. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1C, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement], available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf). The TRIPS Agreement is arguably one of the most controversial of the Uruguay Round Agreements and has been the subject of numerous articles and commentaries. See generally Amir Attaran, *The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 859 (2002); ROBERT L. OSTERGARD, JR., *THE DEVELOPMENT DILEMMA: THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY RIGHTS IN THE INTERNATIONAL SYSTEM* (2003); Haochen Sun, *A Wider Access to Patented Drugs Under the TRIPS Agreement*, 21 B.U. INT'L L.J. 101 (2003).

5. The WTO is an organization established in 1994 to "provide the common institutional framework for the conduct of trade relations" among Member States. WTO Agreement, *supra* note 4, art. II(2). One of the WTO's basic functions is to "facilitate the implementation, administration and operation, and further the objectives" of the Multilateral Trade Agreements. *Id.* art. III.

6. For articles discussing the early debates surrounding the TRIPS Agreement, see Frederick M. Abbott, *The TRIPS - Legality of Measures Taken to Address Public Health Crises: A Synopsis*, 7 WIDENER L. SYMP. J. 71 (2001); Patrick Marc, Note, *Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?*, 21 N.Y.L. SCH. J. INT'L & COMP. L. 109 (2001); Naomi A. Bass, Note, *Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 GEO. WASH. INT'L L. REV. 191 (2002); Matthew Krammer, Comment, *The Bolar Amendment Abroad: Preserving the Integrity of American Patents Overseas After the South African Medicines Act*, 18 DICK. J. INT'L L. 553 (2000).

was needed to address the problem of access in these countries, and whether the TRIPS Agreement permitted countries to resort to compulsory licensing to address public health problems.<sup>7</sup>

At the 2001 Ministerial Conference<sup>8</sup> in Doha, Qatar, WTO Members adopted the Declaration on the TRIPS Agreement and Public Health ("Doha Declaration").<sup>9</sup> The Doha Declaration was groundbreaking in the sense that it appeared to unequivocally recognize the primacy of public health over commercial interests.<sup>10</sup> The Declaration answered in the affirmative the question of whether WTO Member States can resort to compulsory licensing to address a public health crisis. However, the Declaration left one thorny question unresolved: whether WTO Members with insufficient or no manufacturing capabilities in the pharmaceutical sector, who are thus unable to make use of compulsory licensing, can import generic drugs manufactured under compulsory licenses from other countries (the "Paragraph 6" question).

Between November 2001 and September 2003, fresh debates ensued over the Paragraph 6 question. To allay the fears of developing countries, two decisions were made by the TRIPS Council and the General Council in 2002. On June 27, 2002, the TRIPS Council, acting under paragraph 7 of the Doha Declaration, made a decision to grant the least-developed country members of the WTO an extension on the time in which they had to comply with some of the provisions of the TRIPS Agreement.<sup>11</sup> On July 8, 2002, the General Council adopted a decision

7. When a government grants a compulsory license, the patent holder retains intellectual property rights and is generally entitled to an adequate remuneration. In the pharmaceutical sector, a generic drug is a bioequivalent of a patented drug and is usually intended to be used interchangeably with the original patented drug. A generic drug is not produced under a patent. Under most domestic patent laws, governments can issue compulsory licenses to allow a competitor to produce a patented product or process under license and subject to conditions aimed at safeguarding the legitimate interests of the patent owner.

8. The Ministerial Conference is the highest forum in the structure of the WTO. The Ministerial Conference is composed of representatives of all the WTO Members and meets at least once every two years. Since the establishment of the WTO, the Ministerial Conference has been held five times: Singapore (December 1996), Geneva (May 1998), Seattle (November – December 1999), Doha (November 2001), and Cancun (September 2003).

9. WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001), 41 I.L.M. 755 (2002) [hereinafter Doha Declaration], 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).

10. Sun, *supra* note 4, at 104 (noting that "[t]he Doha Declaration marked a turning point for political and legal relations at the WTO").

11. Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, IP/C/25 (June 27, 2002), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/art66\\_1\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm).

Paragraph 1 of the decision states: "Least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016." *Id.* Paragraph 2 provides that, "[t]his decision is made without prejudice to the right of least-

waiving the obligation of least-developed countries ("LDCs") under Article 70.9 of the TRIPS Agreement with respect to pharmaceutical products.<sup>12</sup> Finally, on August 30, 2003, at a meeting of the WTO General Council,<sup>13</sup> world trade ministers adopted the *Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* ("2003 Decision on Implementation"),<sup>14</sup> which appears to finally lay to rest the lingering questions regarding the relationship between patent rights, the TRIPS Agreement, and access to medicine.

The different battles over the relationship between patents and public health now appear to be over. This article takes a close look at the

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developed country Members to seek other extensions of the period provided for in paragraph 1 of Article 66 of the TRIPS Agreement." *Id.*

On the adoption of the TRIPS Agreement, all WTO Members except developing countries and least-developed countries had one year after the entry into force of the Agreement to comply with the provisions of the Agreement. Except for obligations relating to national treatment and most-favored nation, which became applicable after the expiration of one year, developing countries received an additional transition period of four years. Under paragraph 1 of Article 66 of the TRIPS Agreement, least-developed countries received a ten-year extension on the date stipulated for WTO Members to implement the TRIPS Agreement. *See* TRIPS Agreement, *supra* note 4, art. 66. This meant that they were not expected to implement most provisions of the TRIPS Agreement until 2005. With the June 27, 2002 Decision of the Council for TRIPS, the least-developed countries do not have to implement the TRIPS Agreement until 2016.

12. Least-Developed Country Members — Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, WT/L/478 (July 8, 2002), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/art70\\_9\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art70_9_e.htm).

Paragraph 1 states: "The obligations of least-developed country Members under paragraph 9 of Article 70 of the TRIPS Agreement shall be waived with respect to pharmaceutical products until 1 January 2016." *Id.* Paragraph 2 states: "This waiver shall be reviewed by the Ministerial Conference not later than one year after it is granted, and thereafter annually until the waiver terminates, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement." *Id.*

Article 70(9) of the TRIPS Agreement provides:

Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

TRIPS Agreement, *supra* note 4, art. 70(9).

13. The WTO General Council is composed of representatives of all the Member States. The General Council meets as appropriate and conducts the functions of the Ministerial Conference in the intervals between Ministerial Conference meetings. *See* WTO Agreement, *supra* note 4, art. IV.2.

14. WTO General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, Aug. 30, 2003, WT/L/540 (Sept. 1, 2003) [hereinafter *2003 Decision on Implementation*], available at [http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm).

battlefield more than three years after the war began as an attempt to assess gains and to map progress. In this article, I argue that although the several battles over access may have ended, determining what exactly has been achieved and forecasting the potential impact of the Doha Declaration and the 2003 Decision on Implementation on access to medicine in developing countries may not be easy. It may therefore be a long time before the suffering masses in the Third World derive any tangible benefit from the two texts. There are several reasons for this. First, both the Doha Declaration and the 2003 Decision on Implementation have major loopholes that could still be used to curtail the rights of developing countries in the future. Second, for countries with insufficient or no manufacturing capacity, the 2003 Decision of Implementation contains conditions that are somewhat burdensome and that could discourage the emergence of a robust, generic pharmaceuticals industry. Third, it is doubtful that developing countries will begin to grant compulsory licenses as envisaged in the two texts. To begin with, developed countries could still use covert threats of economic sanctions and other forms of political pressure to compel developing countries to respect the intellectual property rights ("IPRs") of patent holders. In addition, quite apart from the political pressures developed countries may assert, the plain reality is that "[f]ew compulsory licences have ever been granted in developing countries."<sup>15</sup>

The most important but hitherto overlooked problems, however, are the problems of the abuse of patent rights and anti-competitive practices by pharmaceutical companies and the absence of comprehensive rules at the global level to address these problems. In the United States, brand-name pharmaceutical companies, in their attempt to maintain their dominant market share, are increasingly resorting to a host of abusive and anti-competitive practices. Despite the existence of strong antitrust laws in the United States and a multitude of laws and regulations directed at protecting U.S. consumers from false business practices, pharmaceutical companies find ingenious ways to evade the law and to prey on vulnerable consumers. A study of unfolding lawsuits in the United States demonstrates that in the absence of strong antitrust rules at the domestic level and multilateral agreements on competition law at the global level, pharmaceutical companies will find ways to avoid the consequences of the Doha Declaration and the 2003 Decision on Implementation. In other words, absent the development of a strong ethical code of conduct to guide practices in the pharmaceutical industry, the nature of competition in the pharmaceutical industry and the capacity of states and/or the

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15. JAYASHREE WATAL, *INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES* 382 (2001).

WTO to regulate competition in the industry may ultimately determine the overall effect that the Doha Declaration and the 2003 Decision on Implementation will have on access to medicine in poor countries.

In pursuing my argument, I examine and attempt to draw lessons from the present war against abuse of patent rights and anti-competitive practices in the U.S. pharmaceutical industry. The U.S. experience suggests that in the absence of strong public and private oversight, a host of abuses are possible in the pharmaceutical industry. One such abuse is in the form of collusive settlement agreements between brand-name drug manufacturers and generic drug manufacturers that have the effect of delaying the entry of generic drugs into the market. These cases suggest the need, beyond well-intended legal solutions, for public oversight and vigilance by consumer groups and non-governmental organizations.

Undoubtedly, there are strong and compelling reasons why IPRs must be respected and accorded maximum protection; however, there are other values worth protecting besides IPRs. IPRs operate as an incentive for the development of new and useful technology, including pharmaceuticals.<sup>16</sup> IPRs, particularly patents, are important to the pharmaceutical industry for two reasons. First, the industry frequently has to invest a considerable amount of time and resources into researching and developing new drugs.<sup>17</sup> Second, "pharmaceuticals are generally relatively easy to reverse-engineer and thus are open to easy copying in the absence of . . . protection."<sup>18</sup> For developing countries, the protection of IPRs can also encourage the transfer of technology from developed countries.<sup>19</sup> Because IPRs are commercial rights essentially driven towards economic gains,<sup>20</sup> they can and frequently do affect the welfare of the general public. This means that when IPRs are discussed, the emphasis must not be exclusively on the rights of producers of intellectual property ("IP"), particularly patent holders, but rather, the perspective of consumers and the general welfare of nations must also be taken into account.<sup>21</sup>

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16. Shanker A. Singham, *Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry*, 26 BROOK. J. INT'L L. 363, 372 (2000) ("There exists an important relationship between a strong patent regime and Research and Development (R&D).").

17. *Id.* at 373 (observing that research into new drugs is risky, expensive and time consuming).

18. *Economic, Social and Cultural Rights: The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, Report of the High Commissioner, United Nations Comm'n on Human Rights, 52d Sess., Provisional Agenda Item 4, para. 37, U.N. Doc. E/CN.4/Sub.2/2001/13 (2001) [hereinafter U.N. Comm'n on Human Rights].

19. Singham, *supra* note 16, at 364 (arguing that "a strong patent protection regime has a net global social gain, as well as a net social gain to developing countries").

20. See U.N. Comm'n on Human Rights, *supra* note 18, para. 38.

21. OSTERGARD, *supra* note 4, at 12.

Overall, I conclude that the battle over access to medicine was not a waste. It was necessary that the WTO clarify the flexibilities countries enjoy under the TRIPS Agreement to address their domestic problems. Even if developing countries do not fully exercise their right to grant compulsory licenses in the future, the existence of such a right can function as a powerful weapon in bargaining for lower prices from brand-name pharmaceutical companies.<sup>22</sup> Issuing a compulsory license can be a solution to the problem of patent exclusivity; for example, it is frequently used to remedy certain antitrust violations involving IPRs. However, compulsory licenses can also trigger or encourage a range of abusive practices in the pharmaceutical industry as affected companies struggle to maintain their market share and dominant position.

The debate over access to medicine underscored the fact that there are obvious political, social, economic, and policy implications when states decide to adopt strong intellectual property protection.<sup>23</sup> The debate further highlighted the fact that "[a]ll states are not equal in their level of political and economic development,"<sup>24</sup> something that was ignored during the negotiations that produced the TRIPS Agreement.<sup>25</sup> The TRIPS Agreement was the product of aggressive negotiation by developed countries' governments, requiring all signatory states to implement a full "Western-style" IP regime.<sup>26</sup> Unwittingly, largely as a result of intense pressure from developed countries, developing countries signed on to the TRIPS Agreement without addressing the potential social and economic costs of their action.<sup>27</sup>

In the final analysis, the pharmaceutical industry cannot be the enemy for three reasons. First, the battle over access to medicine arose primarily because medicines are essential goods, yet their production does require substantial and very expensive technological input. The

22. As a result of a threat by the Brazilian government to issue a compulsory license, Roche, the Swiss pharmaceutical company, agreed to substantially lower its price for Nelfinavir, a patented AIDS drug. See DUNCAN MATTHEWS, *GLOBALISING INTELLECTUAL PROPERTY RIGHTS: THE TRIPS AGREEMENT* 115 (2002).

23. OSTERGARD, *supra* note 4, at 2 (observing that "states do not adopt strong IPR policies as a matter of rational *economic* policy only, but also as a matter of rational *political* policy").

24. *Id.* at 3.

25. See *id.* at 7 (observing that the US argued there were international benefits in global IPR protection, regardless of where the countries were in their own development stages).

26. *Id.* at 1 (observing that the TRIPS Agreement was a result, in part, of a strong U.S. lobbying effort). Developed countries were the strongest proponents of the TRIPS Agreement because of changes in their industrial base and intense global competition. *Id.* at 7. Essentially, as the comparative advantage of Western nations shifted from agriculture and manufacturing to sectors requiring high technological input, these countries became anxious to see intellectual property rights globalized. *Id.*

27. See OSTERGARD, *supra* note 4, at 7 (noting that the United States pressured "governments of developing countries into accepting stringent IPR regulations").

nature of drugs inevitably means that pharmaceutical companies have a unique type of financial and social responsibility: they provide important public goods.<sup>28</sup> Second, although WTO Members now appear to have the freedom to issue compulsory licenses to address their health problems, the cooperation of patent holders will still be crucial for countries to obtain the technology needed to effectively work the patent. Third, given my predictions that it is unlikely that many developing countries will actually issue compulsory licenses in the future, countries may still have to rely on the goodwill of pharmaceutical companies to meet their pharmaceutical needs through alternative channels.

This article is divided into seven sections. Part II offers a background to the Multilateral Trading System ("MTS"), the TRIPS Agreement, and the compulsory licensing debate as it has unfolded since the explosion of the AIDS epidemic. Part III introduces the reader to the 2003 Decision on Implementation and highlights the main provisions of the Decision. In Part IV, I engage in a critical analysis of the 2003 Decision on Implementation. Part V focuses on pharmaceutical abuses in the United States and the current efforts by the Federal Trade Commission ("FTC") and the private sector to fight these abuses. In Part VI, I examine current efforts to establish a multilateral framework on competition law and policy and the obstacles to these efforts. Paradoxically, although many developing countries do not have any competition law and are likely to benefit from such a framework, developing countries have strongly opposed the idea of a multilateral rule on competition policy. In Part VII, I conclude by noting that although welcomed, and despite the flexibilities afforded by the Doha Declaration and the Decision, few compulsory licenses will be issued.

I advance several reasons for my position. First, very few countries have internal procedures for granting compulsory licenses, and it may be difficult for the countries that do have the procedures in place to exploit these licenses due to lack of capacity.<sup>29</sup> Second, developing countries that are starved of foreign capital and that desire to attract direct foreign investment would most likely refrain from liberally utilizing the flexibilities.<sup>30</sup> Third, developing countries that desire to encourage inventive activity domestically may decide that compulsory licenses are

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28. ANNA THOMAS, VSO GLOBAL EDUC. & ADVOCACY DEP'T, STREET PRICE: A GLOBAL APPROACH TO DRUG PRICING FOR DEVELOPING COUNTRIES 5 (Ken Bluestone et al. eds.) (Position Paper for Voluntary Service Overseas, or "VSO"), available at [http://vso.org.uk/Images/position\\_papers\\_street\\_price\\_tcm8-1605.pdf](http://vso.org.uk/Images/position_papers_street_price_tcm8-1605.pdf); see Singham, *supra* note 16, at 365.

29. MATTHEWS, *supra* note 22, at 114.

30. See *id.* (noting that "foreign companies may be reluctant to invest in developing countries with a propensity to grant compulsory licenses"). In effect, the granting of compulsory licenses has its drawbacks and should not be seen as the preferred option for countries.

counterproductive as they "could work against the interests of new domestic inventors, and have adverse demonstration effects on other potential inventors."<sup>31</sup> Finally, in situations where the cooperation of the IPR holder is needed in order to acquire the technology which would enable a developing country to work with the protected invention, such cooperation may not be forthcoming.<sup>32</sup>

The intersection of patent rights, global trade, public health, and ethics has unearthed many thorny issues. For example, is a balance between intellectual property rights, state sovereignty, and ethics possible? Should ethical concerns and human rights norms trump property (patent) rights? Do the sovereign rights of states allow them the option of "opting out" of onerous and "mischievous" international obligations? Finally, does the TRIPS Agreement prevent Members from taking measures to protect public health?

## II. THE GLOBALIZATION OF INTELLECTUAL PROPERTY LAW: BACKGROUND TO THE TRADE-RELATED ASPECTS OF INTERNATIONAL PROPERTY ("TRIPS") AGREEMENT AND THE COMPULSORY LICENSING DEBATE

The last three hundred years has witnessed tremendous evolution in our notion of property. From its once humble beginnings focused on tangibles, the notion of property has broadened to include intangible products of the human mind such as patents, trademarks, and copyrights. For the most part, this development in the notion of property occurred primarily in Europe and North America.<sup>33</sup> As long as information could be contained within national borders, domestic law was considered sufficient in regulating dealings in intellectual property. However, intangible property is more fluid than tangible property and crosses national boundaries much more readily. Consequently, by the end of the nineteenth century, counterfeiting and piracy in the global marketplace had become a strong concern of many countries creating a growing realization in the industrialized world that multilateral efforts were needed to address these concerns. This triggered a century-long effort directed at expanding and universalizing intellectual property laws (what I refer to as "the globalization project"), culminating in the adoption of the TRIPS

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31. WATAL, *supra* note 15, at 382.

32. *Id.*

33. For literature on the history and development of intellectual property in the West, see generally BRUCE W. BUGBEE, *GENESIS OF AMERICAN PATENT AND COPYRIGHT LAW* (1967); Maximilian Frumkin, *The Origin of Patents*, 27 J. PAT. OFF. SOC'Y 143 (1945); Giulio Mandich, *Venetian Patents (1450-1550)*, 30 J. PAT. OFF. SOC'Y 166 (1948); Frank D. Prager, *A History of Intellectual Property From 1545 to 1787*, 26 J. PAT. OFF. SOC'Y 711 (1944).

Agreement in 1994.<sup>34</sup>

### A. *The TRIPS Agreement*

Initial efforts to globalize and harmonize intellectual property law produced two significant international treaties: the 1883 Paris Convention for the Protection of Industrial Property ("Paris Convention")<sup>35</sup> and the 1886 Berne Convention for the Protection of Literary and Artistic Works ("Berne Convention").<sup>36</sup> However, it was the entry into force on January 1, 1995 of the TRIPS Agreement that marked a major turning point in the globalization project.<sup>37</sup> Negotiated as part of the Uruguay Round of Multilateral Trade Negotiations,<sup>38</sup> the TRIPS Agreement comes as a package deal, meaning that all WTO Members are automatically bound by the agreement.<sup>39</sup>

In terms of coverage, the TRIPS Agreement is the most comprehensive multilateral instrument on intellectual property rights.<sup>40</sup> The TRIPS Agreement is innovative in at least five ways. First, the TRIPS

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34. For an interesting history of the globalization of intellectual property rights and the role of international institutions and global corporate actors in this effort, see generally MATTHEWS, *supra* note 22.

35. See Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, as last revised at Stockholm, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305, available at <http://www.wipo.int/treaties/en/ip/paris/index.html>.

36. See Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, as last revised at Paris, July 24, 1971, 25 U.S.T. 1341, 828 U.N.T.S. 222, available at <http://www.wipo.int/treaties/en/ip/berne/index.html>.

37. For literature on the negotiating history of the TRIPS Agreement, see generally Frank Emmert, *Intellectual Property in the Uruguay Round: Negotiating Strategies of the Western Industrialized Countries*, 11 MICH. J. INT'L L. 1317 (1990); Gail E. Evans, *Intellectual Property as a Trade Issue: The Making of the Agreement on Trade-Related Aspects of Intellectual Property Rights*, 18:1 WORLD COMPETITION, LAW & ECON. REV. 137 (1994); DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* (1998).

38. The TRIPS Agreement was negotiated as part of the Uruguay Round of multilateral trade negotiations. The agreement is annexed to the Final Act embodying the results of the Uruguay Round of multilateral trade negotiations. See Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations, Punta del Este, Uruguay (Sept. 20, 1986), reprinted in RAJ BHALA, *INTERNATIONAL TRADE LAW HANDBOOK* 261 (2d ed. 2001).

39. With the exception of four "plurilateral" agreements, all the WTO agreements apply to all WTO members. With one signature, WTO members each accepted all the Uruguay Round agreements as one single package. See WTO, *Legal Texts: The WTO Agreements* ("The WTO framework ensures a 'single undertaking approach' to the results of the Uruguay Round – thus, membership in the WTO entails accepting all the results of the Round without exception."), available at [http://www.wto.org/english/docs\\_e/legal\\_e/ursum\\_e.htm#Agreement](http://www.wto.org/english/docs_e/legal_e/ursum_e.htm#Agreement) (last visited Jan. 28, 2005).

40. See Trips Agreement, *supra* note 4. Part II of the TRIPS Agreement deals with all types of intellectual property rights. The agreement covers: Copyright and Related Rights (Section 1); Trademarks (Section 2); Geographical Indications (Section 3); Industrial Designs (Section 4); Patents (Section 5); Layout-Designs (Topographies) of Integrated Circuits (Section 6); Protection of Undisclosed Information (Section 7); and Control of Anti-Competitive Practices in Contractual Licences (Section 8). *Id.* arts. 9-40.

Agreement represents the first time in the history of multilateral trade negotiations that intellectual property has been integrated into an international trade agreement. Second, compared to preexisting instruments, the TRIPS Agreement contains a complete provision on enforcement and imposes detailed obligations on states.<sup>41</sup> Third, the TRIPS agreement establishes a strong monitoring and supervisory scheme through the machinery of the TRIPS Council, a marked departure from the norm in previous conventions.<sup>42</sup> Fourth, the TRIPS Agreement addresses compliance and enforcement questions through its automatic linkage with the WTO dispute settlement system; this linkage ensures a permanent, quasi-judicial dispute resolution mechanism to address intellectual property controversies.<sup>43</sup> Finally, WTO Members cannot enter a reservation in respect of any of the provisions of the Agreement without the consent of the other Members.<sup>44</sup> Overall, the TRIPS Agreement offers an institutionalized, multilateral, and comprehensive mechanism for addressing intellectual property-related issues and disputes.<sup>45</sup>

The success of the globalization project is reflected in the minimum substantive and procedural standards of protection for intellectual property protection that the TRIPS Agreement establishes. With respect to patents, the agreement lays down standards relating to patentability, scope of patent protection, limitations on patent rights, and enforcement. Article 27 stipulates that "patents shall be available *for any inventions*, whether products or processes, *in all fields of technology*, provided that they are new, involve an inventive step and are capable of industrial application,"<sup>46</sup> and that "patents shall be available and patent rights enjoyable *without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced*."<sup>47</sup>

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41. *Id.* arts. 41–49.

42. *Id.* art. 68 ("The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights.").

43. The dispute settlement mechanism was established pursuant to a separate agreement. See Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, WTO Agreement, Annex 2, LEGAL INSTRUMENTS- RESULTS OF THE URUGUAY ROUND vol. 31 (1994), 33 I.L.M. 1226 (1994) [hereinafter DSU], available at [http://www.wto.org/english/docs\\_e/legal\\_e/28-dsu\\_e.htm](http://www.wto.org/english/docs_e/legal_e/28-dsu_e.htm).

44. TRIPS Agreement, *supra* note 4, art. 72.

45. Bibek Debroy, *The Compulsory Licensing Anomaly*, in TRIPS AND HEALTHCARE: RETHINKING THE DEBATE 13 (Int'l Pol'y Network July 2001), available at [http://www.policynetwork.net/uploaded/pdf/rethinking\\_the\\_debate\\_0701.pdf](http://www.policynetwork.net/uploaded/pdf/rethinking_the_debate_0701.pdf). (noting that the WTO is "a better forum for establishing global norms in IP, not only because more countries are members of the WTO, but also because the WTO system ensures enforcement and compliance through the dispute resolution and retaliation provisions").

46. TRIPS Agreement, *supra* note 4, art. 27, para. 1 (emphasis added).

47. *Id.* (emphasis added).

## B. Globalization Amidst Growing Discontent

The TRIPS Agreement exposes the North-South asymmetries in global trading arrangements.<sup>48</sup> To developed-country governments, the TRIPS Agreement was conceived primarily as an instrument to combat global counterfeiting and piracy, eliminate distortions in and barriers to global trade, allow the industry to recoup research and development ("R&D") costs, and guarantee a fair return on investment in innovative research.<sup>49</sup> These goals, they argued, must be met within the context of a limited monopoly granted by patents. During the negotiation for the TRIPS Agreement, multinational corporations and developed-country governments also argued that an enhanced global IP regime would facilitate long-term economic development in developing countries by fostering technology and investment flow to the developing countries.<sup>50</sup>

To some non-governmental organizations and some developing-country governments, however, the TRIPS Agreement is but one component of a broader policy of "'technological protectionism' aimed at consolidating an international division of labour whereunder Northern countries generate innovations and Southern countries constitute the market for the resulting products and services."<sup>51</sup> The real motivation for TRIPS, some have argued, was to "freeze the comparative advantages"<sup>52</sup> that had ensured Northern technological supremacy and counter Northern countries' declining competitive position in the global market.<sup>53</sup>

Viewed from the perspective of developing countries, critics also argue that the trend is not really towards a globalization of IPRs (suggesting a convergence of norms and a harmonization of standards), but

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48. Numerous articles have been written on the subject of North-South asymmetries in international trade. Several authors have also explored the implications of the TRIPS Agreement for developing countries. See generally CARLOS M. CORREA, *INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS* (2000); Marco C.E.J. Bronckers, *The Impact of TRIPS: Intellectual Property Protection in Developing Countries*, 31 COMMON MKT. L. REV. 1245 (1994); Esperanza Durán & Constantine Michalopoulos, *Intellectual Property Rights and Developing Countries in the WTO Millenium Round*, 2 J. WORLD INTELL. PROP. 853 (1999).

49. See CORREA, *supra* note 48, at 3-4.

50. See MATTHEWS, *supra* note 22, at 5 ("Given the likely impact of the TRIPS Agreement on developing countries and the possible implications for future renegotiation of the Agreement, global corporate actors have stressed the role of intellectual property protection in facilitating economic development through technology transfer and inward investment.").

51. CORREA, *supra* note 48, at 5 (arguing that the TRIPS Agreement aims at stifling imitative paths to industrialization).

52. *Id.* at 4.

53. See *id.* at 5 (noting the TRIPS Agreement was "an expression of an aggressive action by the US industries to establish international rules that counter their declining competitive position in world markets").

really a universalization of standards of protection that is Northern-grown<sup>54</sup> and suitable for industrialized countries.<sup>55</sup> In other words, given developing countries' dependence upon innovations made in the North<sup>56</sup> and their negligible share of the world market in medium- and high-tech goods,<sup>57</sup> it is believed that industrialized countries have the most to benefit from the TRIPS Agreement.

Finally, there is also the perception in the developing world that the TRIPS Agreement could be used to prevent poor countries from achieving important social and developmental goals. The fear is that by ignoring the profound differences in economic and technological capabilities between the North and the South and by offering a one-size-fits-all approach to intellectual property protection, the TRIPS Agreement will be progressively used to curtail policy options in developing countries and hamper states in their efforts to address serious health emergencies.

### C. *The Pharmaceutical Industry, the AIDS Epidemic, and the Compulsory License Debate*

The pharmaceutical industry is at the center of the debate about the relationship between patent rights, the TRIPS Agreement, and public

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54. *Id.* at 3 (noting that in negotiating the TRIPS Agreement, industrialized countries had the objective of universalizing the standards of intellectual property protection that they had incorporated into their legislation). Correa notes further that the emerging framework of intellectual property protection in the TRIPS Agreement "basically universalizes standards of protection that are suitable for industrialized countries." *Id.* at 5; see also U.N. Comm'n on Human Rights, *supra* note 18, para. 25.

[T]he protection contained in the TRIPS Agreement focuses on forms of protection that have developed in industrialized countries. For example, in the case of patents, the protection in the Agreement is most relevant to the protection of modern forms of technology, such as biotechnology, and most relevant to innovators situated in a selected number of industrialized countries.

*Id.*

55. Some scholars question whether developing countries are really ready to have strong intellectual property rights. They point to the fact that industrialized countries were also able to establish higher standards for intellectual property protection after they had attained a certain level of technological and industrial capacity. See CORREA, *supra* note 48, at 5.

56. See *id.* (citing studies by Nagesh Kumar that estimate that of the patents granted in the United States between 1977 and 1996, developing countries accounted for less than 2%, while 95% of 1,650,800 patents granted were conferred on applicants from ten industrialized countries). See NAGESH KUMAR, TECHNOLOGY GENERATION AND TECHNOLOGY TRANSFERS IN THE WORLD ECONOMY: RECENT TRENDS AND IMPLICATIONS FOR DEVELOPING COUNTRIES 5-9 (The United Nations Univ. Inst. for New Technologies, Discussion Paper Series No. 9702, 1997), available at <http://www.intech.unu.edu/publications/discussion-papers/9702.pdf>.

57. CORREA, *supra* note 48, at 5-6 (citing estimates by Alcorta and Peres to the effect that of the exports of the Group of 7 (G7) to OECD countries, 56.7% consist of medium- and high-tech goods). See LUDOVICO ALCORTA & WILSON PERES, INNOVATION SYSTEMS AND TECHNOLOGICAL SPECIALIZATION IN LATIN AMERICA AND THE CARIBBEAN 8-10 (The United Nations Univ. for New Technologies, Discussion Paper Series No. 9509, 1995), available at <http://www.intech.unu.edu/publications/discussion-papers/9509.pdf>.

health. "Until recently, the patent laws of most poor countries exempted pharmaceutical products from protection."<sup>58</sup> As a result of the TRIPS Agreement, however, many countries amended or are in the process of amending their patent laws to comply with TRIPS. In the wake of the huge AIDS epidemics decimating millions of lives in the developing world, questions have surfaced regarding how to balance the patent rights of pharmaceutical corporations against the sovereign rights of states to determine their internal health policies and to ensure that essential drugs are available and accessible to their citizens. Further, the question of how to balance the patent rights of pharmaceutical corporations against core, internationally-guaranteed rights such as "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,"<sup>59</sup> has also assumed a central place in this debate.<sup>60</sup> Essentially, developing countries' governments, civil society groups, and AIDS sufferers feared that the TRIPS Agreement could be used to disrupt the availability of cheap generic pharmaceutical products, and that developing countries would be forced to obtain brand-name pharmaceutical products from multinational companies at exorbitant prices.

# 1. THE AIDS EPIDEMIC

As of December 2001, the total number of people (adult and children) living with HIV/AIDS ("PLHA") was estimated at forty million,<sup>61</sup> and the total number of living children orphaned by AIDS was estimated at fourteen million.<sup>62</sup> Of the total number of PLHA, most live in the developing world.<sup>63</sup> Five million people became newly infected with

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58. Julian Morris, *Introduction and Summary, in TRIPS AND HEALTHCARE: RETHINKING THE DEBATE 2*, (Int'l Pol'y Network July 2001), available at [http://www.policynetwork.net/uploaded/pdf/rethinking\\_the\\_debate\\_0701.pdf](http://www.policynetwork.net/uploaded/pdf/rethinking_the_debate_0701.pdf); see also MATTHEWS, *supra* note 22, at 114 (observing that "[f]or many developing countries, the underlying rationale for excluding pharmaceutical products from patent protection in the pre-TRIPS era was to enhance access to medicines and healthcare").

59. International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), U.N. GAOR, 21st Sess., Supp. No. 16, art. 12, U.N. Doc. A/6316 (1966).

60. For a human rights analysis of the TRIPS Agreement, see U.N. Comm'n on Human Rights, *supra* note 18, para. 2 (noting that "the TRIPS Agreement could affect the enjoyment of several rights – in particular the right to food, the right to development, the human rights of indigenous peoples").

61. See JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC 8 (2002) [hereinafter REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC], available at <http://www.unaids.org/EN/resources/publications/corporatepublications/report+on+the+global+iv+aids+epidemic+2002+.asp>; see also JOHANNES VAN DAM & SHERRY A. HUTCHINSON, THE POPULATION COUNCIL, ACCESS TO TREATMENT FOR HIV/AIDS: REPORT OF A MEETING OF INTERNATIONAL EXPERTS, 12-13 JUNE 2001, WASHINGTON, DC, USA 1 (2002) [hereinafter ACCESS TO TREATMENT FOR HIV/AIDS], available at <http://www.popcouncil.org/pdfs/horizons/accesstotreatment.pdf>.

62. REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC, *supra* note 61, at 8.

63. ACCESS TO TREATMENT FOR HIV/AIDS, *supra* note 61, at 1.

HIV in 2001, and three million AIDS deaths were recorded in that same year.<sup>64</sup>

The discovery of Highly Active Antiretroviral Therapy ("HAART") as a treatment for AIDS led to a paradigm shift in most of the industrialized world because HAART brought about significant reduction in the prevalence of AIDS-related morbidity and mortality in the West. In the West, it became possible to view AIDS not as a death sentence but as a manageable chronic disease.<sup>65</sup> However, in most of the developing world, the story was different. As a result of the absence of HAART in developing countries, instead of treatment, the focus of national programs and international support was on prevention, the treatment of opportunistic infections, and care and support of affected persons.<sup>66</sup> The principle barrier to treatment frequently cited by national governments and donor agencies was the cost of HAART (estimated at U.S. \$100-\$300 per person per month).<sup>67</sup> Thus, as of 2001, despite breakthroughs in medicine, only 230,000 of the six million people who were sick enough to require HAART were receiving it. Of these, half lived in Brazil.<sup>68</sup> This meant that at least ninety-six percent of people in developing countries who needed treatment were not receiving it.

## 2. DOES TRIPS PROVIDE AN ANSWER?

Against the backdrop of a massive HIV/AIDS epidemic and the reported welfare effects of pharmaceutical product patents in developing countries,<sup>69</sup> some governments in the developing world began to explore

64. REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC, *supra* note 61, at 8.

65. See ACCESS TO TREATMENT FOR HIV/AIDS, *supra* note 61, at 3 ("[I]n the United States, the number of PLHA increased from 174,244 in 1993 to 317,368 in 1999, while mortality associated with AIDS decreased from 45,494 to 16,767 in that same period.").

66. See *id.* at 1.

67. *Id.* at 3. Other reasons cited included the capacity of health care delivery systems and the ability of patients to adhere to lifelong treatment regimens. *Id.* at 1.

68. In Brazil, the government instituted a universal access to AIDS treatment program. This led to a fifty-four percent reduction in AIDS-related mortality between 1995 and 1999. The treatment resulted in overall cost-savings for the government, in terms of avoided hospitalization and reduction in the burden of opportunistic infections, totaling U.S. \$677 million between 1997 and 1999. Some observers attribute the success in Brazil to the government's aggressive involvement in the manufacture of generic versions of several HIV drugs in its own government laboratories. See INT'L COUNCIL OF AIDS SERV. ORGS. (ICASO), THE INTERNATIONAL GUIDELINES ON HIV/AIDS AND HUMAN RIGHTS: HOW ARE THEY BEING USED AND APPLIED? 11 (2002), available at <http://www.icaso.org/docs/JFAP%20-%20Web.pdf>.

69. Poor developing nations appear to be the most affected by global patent protection laws. In many countries, welfare losses that economists attribute to heightened patent protection are beginning to appear. Julio Nogués, a World Bank economist, estimates that welfare loss to developing countries of patent pharmaceutical products would amount to a minimum of U.S. \$3.5 billion and a maximum of U.S. \$10.8 billion, while the income gains by foreign patent owners would be between U.S. \$2.1 billion and U.S. \$14.4 billion. See Julio J. Nogués, *Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries*,

the possibility of using compulsory licenses to lower drug prices. These countries acted on the assumption that the TRIPS Agreement allowed governments to address critical shortages in essential drugs through compulsory licenses. However, countries that attempted to address the domestic health crisis through compulsory licensing came under heavy attack from the pharmaceutical industry<sup>70</sup> and from some governments in the developed world, particularly the U.S. government.<sup>71</sup>

The problem was that even though the TRIPS Agreement addresses conditions for the granting of compulsory licenses and does appear to allow governments some flexibility to enable them to address domestic crises, the entire agreement is riddled with ambiguities and permits multiple interpretations. Upon examination, the TRIPS Agreement affords governments several flexibilities. First, governments can exclude certain inventions from patentability.<sup>72</sup> Second, pursuant to Article 30, governments can place some exceptions on the rights of a patent holder provided that such exceptions do not "unreasonably conflict with the

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31:1 THE DEVELOPING ECONOMIES 24 (1993), available at [http://www.ide.go.jp/English/Publish/De/pdf/93\\_01\\_02.pdf](http://www.ide.go.jp/English/Publish/De/pdf/93_01_02.pdf). Several studies in developing countries support Nogués' conclusions. These studies point to the appearance of about a six-fold increase of drug prices with the introduction of product patents compared to non-patented products; a strong correlation between the introduction of pharmaceutical product patents and significant (as much as forty-five percent) reduction in the consumption of medicine; and wide disparities in prices of drugs between countries where patent protection exists and countries with no protection. See generally Arvind Subramanian, *Putting some numbers on the TRIPS Pharmaceutical Debate*, 10(2) INT'L J. TECH. MGMT. 252-62 (1995); Challú Pablo, *The Consequences of Pharmaceutical Product Patenting*, 15(2) WORLD COMPETITION (1991); National Working Group on Patent Laws, PATENT REGIME IN TRIPS: CRITICAL ANALYSIS (1993).

70. In 2001, a group of multinational drug companies took the South African government to court for attempting to import generic versions of AIDS drugs from India. The multinational companies were forced to withdraw their suit after adverse media attention. See *Drug Companies Drop Lawsuit Against South Africa*, U.S.A. TODAY, June 19, 2001, available at <http://www.usatoday.com/news/world/2001-04-19-drugsuit.htm>.

71. Past attempts by South Africa, Thailand, and Brazil to issue compulsory licenses for the manufacture of critical HIV/AIDS drugs resulted in threats of economic sanctions and of the invocation of the WTO dispute settlement procedure by the U.S. Government. See generally OSTERGARD, *supra* note 4 (discussing attempts by the United States to get the South African government to adjust its patent laws to enhance protection for pharmaceutical patents in Chapter Six, "Life, Death and Intellectual Property: The South Africa-US Patent Dispute").

72. TRIPS Agreement, *supra* note 4, art. 27(2) which states:

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

*Id.* See also *id.* art. 27(3) (permitting WTO Members to exclude from patentability: "diagnostic, therapeutic and surgical methods for the treatment of humans or animals" and "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes").

normal exploitation of the patent.”<sup>73</sup> Third, WTO Members are allowed to control anti-competitive practices and prevent abuse of rights by patent holders.<sup>74</sup> Fourth, parallel importing is very possible under the TRIPS Agreement.<sup>75</sup> Most importantly, the preamble,<sup>76</sup> Article 7 (“Objectives”)<sup>77</sup> and Article 8 (“Principles”)<sup>78</sup> of the TRIPS Agreement provide a broad framework for interpretation that, if followed, would have allowed for a balanced result in the debate.

Although Article 31 of the TRIPS Agreement appeared to accord WTO Members broad rights to grant compulsory licenses,<sup>79</sup> a debate

73. TRIPS Agreement, *supra* note 4, art. 30 (“Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”).

74. TRIPS Agreement, *supra* note 4, 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.”).

75. Parallel importing permits countries to search for the lowest price for patented products worldwide and import from the lowest-priced source. It is based on the principal that once a patent holder sells goods, he has lost his right to control the resale of those goods; in other words, he is said to have “exhausted” his property rights in the product. The TRIPS Agreement is vague on the subject and arguably left the issue of parallel importing unaddressed. *See* TRIPS Agreement, *supra* note 4, art. 6 (“For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”).

76. In the preamble of the TRIPS Agreement, Members recognize “the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives.” TRIPS Agreement, *supra* note 4, pmbl. Members also recognize “the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.” *Id.*

77. TRIPS Agreement, *supra* note 4, art. 7, articulating the objectives as:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the 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.*

78. TRIPS Agreement, *supra* note 4, art. 8(1) (“Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”).

79. Article 31 outlines the conditions a government must meet when issuing a compulsory license. First, there must be a prior effort to negotiate a voluntary license with the patent holder on “reasonable commercial terms” and within a reasonable period. TRIPS Agreement, *supra* note 4, art. 31(b). This requirement is waived in the case of a “national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” *Id.* Second, “the scope and duration of such use shall be limited to the purpose for which it was authorized.” *Id.* art. 31(c). Third, the patent owner is to be paid “adequate remuneration . . . taking into account the economic value of the authorization.” *Id.* art. 31(h).

ensued regarding the precise scope of the flexibility permitted governments and the precise grounds for which compulsory licenses may be issued.<sup>80</sup> The pharmaceutical industry argued that the relationship between TRIPS, patents, and access to medicine was tenuous at best.<sup>81</sup> According to the industry, the causes of lack of access to essential drugs in developing countries were numerous and generally included official corruption, misguided taxation, systemic poverty, exorbitant retail mark-ups, and the general lack of infrastructure.<sup>82</sup> The argument was that patent protection is but “a very small part of a much bigger issue,”<sup>83</sup> and that compulsory licenses should be allowed only in very limited circumstances. Essentially, while welcoming the TRIPS Agreement, the industry called for a tightening of the provisions of the Agreement.<sup>84</sup>

Developing countries, on the other hand, view compulsory licensing as a critical pathway to ensuring low-cost drugs. They argued that by facilitating generic entry and generic competition, it would be possible to ensure that essential drugs are accessible, available, and affordable. While avowing commitment to the TRIPS Agreement, developing countries were of the view that nothing in the TRIPS Agreement reduced the range of options available to governments to promote and protect public health<sup>85</sup> nor placed a restriction on the purposes for which compulsory licenses could be issued.<sup>86</sup> Developing countries also

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80. In the light of efforts by countries such as the United States to “punish” countries that attempted to exercise their rights under Article 31 and in light of a lawsuit filed against the South African Government by a group of pharmaceutical companies, developing countries began to push for a clarification of Article 31. Developing countries wanted a common understanding that confirmed the right of governments to make use of the provisions in the TRIPS Agreement whenever the exercise of intellectual property rights resulted in barriers to the access of essential drugs. At a TRIPS Council meeting of April 2-6, 2001, a decision was made, based on a proposal by the Africa Group, to hold a special session to initiate discussions on the interpretation and application of the relevant provisions of the TRIPS Agreement. See WTO, Council for Trade-Related Aspects of Intell. Prop. Rts., *Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela*, IP/C/W/296 (June 29, 2001) [hereinafter *Submission by the African Group*], available at <http://docsonline.wto.org>.

81. Owen Lippert, *A Sceptic's View of the TRIPS and Essential Medicines Debate*, in TRIPS AND HEALTHCARE: RETHINKING THE DEBATE 30, 33 (Int'l Pol'y Network July 2001), available at [http://www.policynetwork.net/uploaded/pdf/rethinking\\_the\\_debate\\_0701.pdf](http://www.policynetwork.net/uploaded/pdf/rethinking_the_debate_0701.pdf).

82. *Id.*

83. *Id.*

84. For example, see the websites of International Federation of Pharmaceutical Manufacturers Association ([www.ifpma.org](http://www.ifpma.org)) and Pharmaceutical Research and Manufacturers of America ([www.phrma.org](http://www.phrma.org)) for helpful information.

85. *Submission by the African Group*, *supra* note 80, paras. 15-16.

86. Several scholars support the position that the TRIPS Agreement does not limit the grounds upon which compulsory licenses may be issued. See CORREA, *supra* note 48, at 89-90 (arguing that although the TRIPS Agreement refers to five specific grounds for the granting of compulsory licenses, the Agreement “does not limit the Members’ right to establish compulsory licences on other grounds not explicitly mentioned”); see also WATAL, *supra* note 15, at 380

pointed to the fact that some developed countries were “great users of compulsory licences.”<sup>87</sup>

Domestic and international Non-Governmental Organizations (“NGOs”) and AIDS support groups also argued that TRIPS put profit over human lives in the developing world.<sup>88</sup> By preventing the easy and cheap copying of patented drugs, these groups argued, the TRIPS Agreement constrained the ability of developing countries to address immediate losses to the welfare of domestic consumers.<sup>89</sup> The solution, they argued, was compulsory licensing.

### III. THE DOHA DECLARATION AND THE 2003 DECISION ON IMPLEMENTATION: A REVOLUTION IN INTERNATIONAL TRADE LAW?

The Doha Declaration<sup>90</sup> and the 2003 Decision on Implementation<sup>91</sup> now appear to lay to rest the different debates regarding compulsory licensing. The 2003 Decision on Implementation was adopted by the General Council in light of a “Statement of Understanding” read by the Chairperson of the General Council of the WTO.<sup>92</sup> In this section, I will briefly highlight the key provisions of the Doha Declaration, update readers on the Paragraph 6 question (the question left unaddressed in the Doha Declaration), and extensively examine the 2003 Decision on Implementation. In Part A, I examine the main provisions of the Doha Declaration. In Part B, I highlight the main issues that arise from the Paragraph 6 question. In Part C, I highlight and critically examine the main provisions of the 2003 Decision on Implementation. In Part D, I examine the main contours of the Statement of Understanding issued by the Chairperson of the General Council. I will undertake a more detailed evaluation of the merits and demerits of the 2003 Decision on Implementation in Section IV.

#### A. *The Doha Declaration*

The Doha Declaration reiterates the importance of an effective

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(observing that “the final text of Article 31 places no restrictions on the purposes for which such use [of a compulsory license] could be authorized”).

87. *Submission by the African Group*, *supra* note 80, para. 29.

88. *See* Lippert, *supra* note 81, at 32.

89. *Id.*

90. *See* Doha Declaration, *supra* note 9 and accompanying text.

91. *See* 2003 Decision on Implementation, *supra* note 14 and accompanying text.

92. *See* WTO, *The General Council Chairperson's Statement* (Aug. 30, 2003) [hereinafter *Statement of Understanding*], available at [http://www.wto.org/english/news\\_e/news03\\_e/trips\\_stat\\_28aug03\\_e.htm](http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm). The statement was read by Chairperson of the General Council Carlos Pérez del Castillo, Uruguay's ambassador to the WTO. *Id.*

intellectual property regime for the development of new medicines while recognizing concerns regarding the effect of intellectual property on drug prices.<sup>93</sup> The Doha Declaration also stresses the need for the TRIPS Agreement to "be part of the wider national and international action" to address the "public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."<sup>94</sup> Paragraph 4, one of the most ambitious provisions in the declaration, provides:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.<sup>95</sup>

Regarding the flexibilities permitted members under the TRIPS Agreement to promote access to medicine, the Doha Declaration reaffirms "the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."<sup>96</sup> Specifically addressing compulsory licenses, the Doha Declaration states that, "[e]ach Member has *the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted*,"<sup>97</sup> and that in deciding to grant compulsory licenses, "[e]ach 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."<sup>98</sup>

The Doha Declaration was undoubtedly a victory for developing countries. The declaration is most useful to countries with sufficient local technological, productive, and regulatory capacity to support generic industries.<sup>99</sup> Moreover, even if a country has the capacity to support local production, it may be "economically inefficient to require domestic production for every medicine a country may need."<sup>100</sup> For countries with insufficient manufacturing capacity and countries whose

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93. Doha Declaration, *supra* note 9, para. 3.

94. *Id.* paras. 1-2.

95. *Id.* para. 4.

96. *Id.*

97. *Id.* para. 5(b) (emphasis added).

98. *Id.* para. 5(c) (emphasis added).

99. See Sun, *supra* note 4, at 107-08.

100. *Id.* at 109.

generic industries may not operate on an economy of scale for every drug required domestically, the obvious solution is to import generic drugs manufactured under compulsory licenses from other countries. However, the Doha Declaration did not decide the question of whether such importation of generic drugs manufactured under compulsory licenses was permitted. Rather, Paragraph 6 reads:

We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.<sup>101</sup>

The Paragraph 6 issue triggered another year of debates, discussions, and negotiations in the WTO. Although the TRIPS Council considered a draft decision at the end of December 2002, and despite approaching the year-end deadline stipulated in the Doha Declaration, the issue remained unresolved as a result of the inability of WTO Members to reach a consensus.

### B. *The Paragraph 6 Question*

The Paragraph 6 question arises because of a restriction contained in Article 31(f) of the TRIPS Agreement.<sup>102</sup> Article 31(f) appears to prohibit the export of products manufactured under a compulsory license by specifying that compulsory licenses must be authorized predominantly to supply the domestic market of that authorizing Member. The rationale behind Article 31(f) "lies in the territorial nature of patent law and in the need to avoid circumvention of patent rules."<sup>103</sup>

As a result of Article 31(f), uses permitted by a compulsory license are limited to those aimed at predominantly supplying the domestic market of the WTO Member granting such a license. Although Article 31(f) does allow a non-predominant part of the pharmaceutical product manufactured under compulsory license to be exported, difficulties arise

101. Doha Declaration, *supra* note 9, para. 6.

102. Article 31 begins: "Where the law of a Member allows 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, the following provisions shall be respected." TRIPS Agreement, *supra* note 4, art. 31. Among the provisions is Article 31(f), which states that "any such use shall be authorized *predominantly for the supply of the domestic market of the Member authorizing such use.*" *Id.* art. 31(f) (emphasis added).

103. See WTO, Council for Trade-Related Aspects of Intell. Prop. Rts., *Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health: Communication from the European Communities and Their Member States*, IP/C/W/352 para. 3 (June 20, 2002) [hereinafter *EC Communication Relating to Paragraph 6*], available at [http://www.wto.org/english/docs\\_e/docs\\_e.htm](http://www.wto.org/english/docs_e/docs_e.htm).

where a country lacking domestic manufacturing capability is seeking to import massive quantities of generic drugs from the manufacturing country. As stated by the United States in its communication to the WTO:

Difficulties could arise, therefore, when a country with insufficient domestic manufacturing capacity and experiencing grave health problems seeks to import a needed pharmaceutical from a manufacturer in a WTO Member where a patent exists on that pharmaceutical. In this situation, it currently would be inconsistent with Article 31(f) for that WTO Member to grant a compulsory license to its manufacturer to produce the drug solely for export to the country that has insufficient or no manufacturing capacities in the pharmaceutical sector. It is this situation that the TRIPS Council must address.<sup>104</sup>

WTO Members disagreed on the procedural mechanism needed to address the problem as well as the substantive solution that was needed to address the problem. At a March 2002 TRIPS Council meeting, four different solutions were proposed: (1) an authoritative interpretation of Article 30 of the TRIPS Agreement;<sup>105</sup> (2) an amendment to Article 31 in order to overcome the Article 31(f) restriction;<sup>106</sup> (3) a moratorium on dispute settlement with regard to the non-respect of the restriction under Article 31(f);<sup>107</sup> and (4) a temporary waiver with regard to Article

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104. WTO, Council for Trade-Related Aspects of Intell. Prop. Rts., *Paragraph 6 of the Doha Declaration on the TRIPS and Public Health: Second Communication from the United States*, IP/C/W/358 para. 9 (July 9, 2002) [hereinafter *Second Communication from the U.S. on Paragraph 6*], available at [http://www.wto.org/english/docs\\_e/docs\\_e.htm](http://www.wto.org/english/docs_e/docs_e.htm).

105. Article 30 provides that "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." TRIPS Agreement, *supra* note 4, art. 30. An authoritative interpretation of Article 30 would have recognized the right of a WTO member to manufacture a patented drug for export to another country facing a public health crisis without having to resort to compulsory licensing. Numerous NGOs supported this solution. Article XX:2 of the WTO Agreement stipulates the procedure for adopting official interpretation. WTO Agreement, *supra* note 4, art. XX:2.

106. An amendment to Article 31 would have been in the form of a new paragraph which would carve out exceptions to the restrictions imposed by Article 31(f). The European Communities ("EC") supported this solution, arguing that "[t]he insertion of a textual provision into the TRIPS Agreement itself has the advantage of providing for a straightforward, clear, legally secure, effective and permanent solution within an existing legal framework, i.e. Article 31 of the TRIPS Agreement." *EC Communication Relating to Paragraph 6*, *supra* note 103, para. 5; see also WTO, Council for Trade-Related Aspects of Intell. Prop. Rts., *Concept Paper Relating to Paragraph 6 of the Doha Declaration Communication from the European Communities and their Member States*, IP/C/W/339 paras. 16-22 (Mar. 4, 2002), available at [http://www.wto.org/english/docs\\_e/docs\\_e.htm](http://www.wto.org/english/docs_e/docs_e.htm).

107. See *EC Communication Relating to Paragraph 6*, *supra* note 103, para. 6. A moratorium on dispute settlement would have operated as a pledge by WTO Members not to challenge any member that fails to comply with the letter and spirit of Article 31(f). The United States initially proposed and strongly supported this solution.

31(f).<sup>108</sup>

### C. *The 2003 Decision on Implementation*

The 2003 Decision on Implementation takes the form of a provisional waiver to Article 31(f) and allows countries to export generic drugs to third countries with no manufacturing capacity in the pharmaceutical sector.<sup>109</sup> The Decision pertains only to pharmaceutical products.<sup>110</sup> It lays out the obligation of exporting members, eligible importing members, other members of the WTO, and the TRIPS Council. The Decision includes safeguards against abuse and trade diversion and lays down rules to ensure transparency. The Decision also contains provisions on transfer of technology and regional cooperation. The main provisions of the Decision can be delineated through seven different features.

#### 1. QUALIFYING COUNTRIES: WHICH COUNTRIES WILL BENEFIT FROM THE SYSTEM? WHICH COUNTRIES ARE EXCLUDED?

Only "eligible importing Members" can utilize the 2003 Decision on Implementation. Eligible importing members include "any least-developed country Member, and *any other Member that has made a notification to the Council for TRIPS* of its intention to use the system as an importer."<sup>111</sup> The category of importing members is potentially broad. The only requirement is that a country wishing to use the system files a notification of intent with the TRIPS Council. Some countries, mostly industrialized, have voluntarily decided not to use the system as importing Members.<sup>112</sup>

108. *See id.*

109. Paragraph 2 provides that "[t]he obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)." *2003 Decision on Implementation*, *supra* note 14, para. 2.

110. *Id.* at pmb1.

111. *Id.* para. 1(b) (emphasis added).

112. Paragraph 1 notes that "some Members will not use the system set out in this Decision as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency." *Id.* See also footnote 3 to paragraph 1(b) of the Decision, listing the Members that will not use the Decision as importing Members as: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America. *Id.* at n.3; *see also Statement of Understanding*, *supra* note 92:

Until their accession to the European Union, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia agree that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agree that upon their accession to the European Union, they will opt out of using the system as

An "exporting Member" is simply "a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member."<sup>113</sup> It appears to mean that any country with manufacturing capacities, including industrialized countries, can export under this system.

2. QUALIFYING PRODUCTS: WHICH PRODUCTS ARE COVERED BY THIS SYSTEM? WHAT ABOUT VACCINES?

The Decision is strictly limited to pharmaceutical products, which are defined in paragraph 1 as "any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration."<sup>114</sup> Active ingredients necessary for the manufacture of the pharmaceutical products and diagnostic kits needed for their use are also included in this definition. The definition of patented products appears to be broad enough to allow countries to address legitimate public health needs and would extend to vaccines.

3. QUALIFYING DISEASES: WHAT IS THE DISEASE SCOPE OF THE DECISION?

The Decision does not contain a list of qualifying diseases for which the waiver may be used: this is a major victory for developing countries. An effort by the U.S. to limit the disease coverage led to a major deadlock in negotiations and made it impossible for WTO Members to meet the 2002 year-end deadline stipulated in the Doha Declaration. In a January 7, 2003 letter to Ministers of the WTO, the European Union ("EU") Commissioner for Trade, Pascal Lamy, suggested a compromise deal.<sup>115</sup> The EU proposed that the mechanism apply to an initial list of infectious epidemics "which are generally recognised by health experts as those which have the most damaging impact on developing countries," with an added suggestion that Members wishing to import medicines to meet a public health concern not explicitly covered in an initial list be encouraged to seek the advice of the World Health Organization ("WHO").<sup>116</sup> The proposal by the European Communities

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importers . . . . [S]ome other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.

*Id.*

113. 2003 Decision on Implementation, *supra* note 14, para. 1(c).

114. *Id.* para. 1(a).

115. Letter from Pascal Lamy, EU Trade Commissioner, to WTO Ministers, (Jan. 7, 2003), at <http://www.europa.eu.int/comm/trade/issues/global/medecine/docs/plletter.pdf>.

116. *Id.*; see also *EU Seeks to Break the Current Deadlock on WTO Access to Medicines: a*

("EC") was subsequently rejected.

4. CONDITION PRECEDENT TO USING THE SYSTEM: WILL BENEFICIARY COUNTRIES NEED PRIOR AUTHORIZATION FROM THE WTO TO USE THE SYSTEM?

Generally, prior authorization of the TRIPS Council is not required before a member can utilize the mechanisms established by the Decision.<sup>117</sup> However, the Decision does require that both importing and exporting countries file some notification with the Council for TRIPS.<sup>118</sup> Countries other than LDCs that intend to use the system as importers must establish that they have no manufacturing capacity and notify the WTO accordingly.<sup>119</sup>

The Decision also lays down specific requirements that both importing and exporting countries utilizing the system must satisfy.<sup>120</sup> Essentially, all countries have an obligation to ensure that medicines produced under the system are used for their intended purpose and are not diverted to other countries where they could compete with brand-name drugs manufactured by the original patent owner.

*a) Obligation of Importing Countries:* An eligible importing Member must make a prior notification to the Council for TRIPS specifying the "names and expected quantities of the product(s) needed,"<sup>121</sup> confirming that the eligible importing Member in question "has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question,"<sup>122</sup> and confirming that,

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*Multilateral Solution is Needed*, Europa - The European Union On-Line (Jan. 9, 2003), at [http://europa.eu.int/comm/trade/csc/pr090103\\_en.htm](http://europa.eu.int/comm/trade/csc/pr090103_en.htm). The proposal submitted by the EU outlined twenty-three infectious diseases that the EC believed had the most damaging impact on developing countries. In addition to HIV/AIDS, malaria, and tuberculosis, the following additional diseases were suggested: Yellow fever, plague, cholera, meningococcal disease, African trypanosomiasis, dengue, influenza, leishmaniasis, hepatitis, leptospirosis, pertussis, poliomyelitis, schistosomiasis, typhoid fever, typhus, measles, shigellosis, haemorrhagic fevers, and arboviruses. *Id.*

117. 2003 *Decision on Implementation*, *supra* note 14, para. 1(b) n.2 ("It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.").

118. *Id.* para. 2.

119. *Id.* para. 2(a)(ii).

120. *Id.* para. 1.

121. *Id.* para. 2(a)(i).

122. 2003 *Decision on Implementation*, *supra* note 14, para. 2(a)(ii). This requirement is waived for LDCs. The Annex to the Decision sets out two ways that a country can establish that it has insufficient or no manufacturing capacities in the pharmaceutical sector:

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector. For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

“where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision.”<sup>123</sup>

Importing Members have an obligation to prevent re-exportation of the products that have been imported into their territory under the system. To ensure that the products imported under the system are used for the specified public health purposes underlying their importation, eligible importing Members are required to “take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system.”<sup>124</sup>

*b) Obligation of Exporting Countries:* Several obligations are imposed on exporting countries utilizing the system. First, such an exporting country must first issue a compulsory license in accordance with Article 31 of the TRIPS Agreement. Second, the compulsory license issued by the exporting Member must contain certain conditions. It must stipulate that “only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS.”<sup>125</sup> It must also stipulate that “products produced under the licence shall be clearly identified as being produced under the system set out in [the Decision on Implementation] through specific labelling or marking.”<sup>126</sup> The exporting country must also require that suppliers “distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price.”<sup>127</sup> Finally, an exporting country must require that before shipment begins, the licensee shall post on a website “the quantities being supplied to each destination”<sup>128</sup> and “the

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- (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; or
  - (ii) where the Member has some manufacturing capacity in this, it has examined this capacity and found that excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

*Id.* at annex.

123. *Id.* para. 2(a)(iii).

124. *Id.* para. 4.

125. *Id.* para. 2(b)(i).

126. *Id.* para. 2(b)(ii).

127. *Id.*

128. *Id.* para. 2(b)(iii).

distinguishing features of the product(s)."<sup>129</sup>

A third requirement placed on an exporting member pertains to notification. An exporting Member is required to notify the Council for TRIPS of the grant of the license and the conditions attached to it.<sup>130</sup> Finally, an exporting member who has granted a compulsory license under this system has an obligation to pay "adequate remuneration" to the patent holder pursuant to Article 31(h) of the TRIPS Agreement.<sup>131</sup>

*c) Obligations Imposed on Other WTO Members:* All WTO Members are required to take necessary measures to prevent diversion.<sup>132</sup> Members also agree not to challenge actions taken by countries under this Decision. Paragraph 10 stipulates that "Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994."<sup>133</sup>

## 5. SAFEGUARDS AGAINST DIVERSION

Measures against diversion are directed at preventing goods from being diverted from their intended purpose. In the course of negotiations on the Paragraph 6 issue, pharmaceutical companies expressed fear that cheaper drugs produced under compulsory licenses may be diverted to rich country markets where a different pricing system exists. To address this, all WTO Members are obliged to "ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement."<sup>134</sup>

## 6. SURVEILLANCE AND REVIEW MECHANISM

The Council for TRIPS assumes a new monitoring role under the Decision. Paragraph 8 stipulates that the Council for TRIPS "shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council."<sup>135</sup> The notifications required

129. *Id.*

130. *Id.* para. 2(c) ("The information provided shall include the name and address of the licensee, the product[s] for which the licence has been granted, the quantit[ies] for which it has been granted, the countr[ies] to which the product[s] [are] to be supplied and the duration of the licence.").

131. *Id.* para. 3.

132. *Id.* para. 5.

133. *Id.* para. 10.

134. *Id.* para. 5.

135. *Id.* para. 8.

of exporting and importing countries also go to the Council for TRIPS.

## 7. TECHNOLOGY TRANSFERS

The Decision recognizes the desirability of promoting technology transfer and capacity building in the pharmaceutical sector in order to overcome the Paragraph 6 problem. Consequently, the Decision calls on eligible importing Members and exporting Members to use the system in a manner that would promote the objective of technology transfer. Paragraph 7 contains a vague statement in which "Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector."<sup>136</sup>

### D. *The Statement of Understanding*

The original draft of the Decision was unacceptable to the U.S. and to the pharmaceutical industry.<sup>137</sup> To achieve a much needed consensus on the Paragraph 6 question, it became necessary for the Chairperson of the General Council to adopt a statement to accompany the Decision. The Statement of Understanding was issued essentially to placate the United States and the pharmaceutical industry and to ensure that WTO Members arrived at a consensus before the biennial meeting of the WTO Ministerial Conference. The Statement of Understanding has four important clauses: a good faith clause, an anti-diversion clause, a transparency clause, and a peaceful and expeditious settlement of dispute clause.

According to the Statement, WTO Members "recognize that the system that will be established by the Decision should be used in good faith to protect public health and . . . not be an instrument to pursue industrial or commercial policy objectives."<sup>138</sup> The Statement also contains an understanding among Members that the Decision's purpose

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136. *Id.* para. 7.

137. When a draft of the Decision (known as the "Motta text") was circulated in December 2002, the United States was the only country that refused to endorse the text. On top of the Motta text provisions, the U.S. government demanded that any solution to the Paragraph 6 problem be restricted to "humanitarian use" (a vague clause that many feared could disqualify normal generic production), include an "opt-out" clause, which would hinder the economic viability of the solution, impose heavier burdens on suppliers to change the packaging of products made under the system, and incorporate a "review mechanism" to monitor the diversion of generics back into wealthy markets. See Joint Press Release, Médecins Sans Frontières, Oxfam, Health Action Network, Third World Network & Consumer Project on Technology, US Seeks Further Restrictions on Generic Medicines for Developing Countries (Aug. 25, 2003) (discussing how several NGO's involved in the Paragraph 6 question have found additional demands by the U.S. to be a threat to the access of poor countries to needed medicines because they constitute a "redundant layer of bureaucracy that can easily be manipulated to pressure countries out of the system"), available at [http://www.oxfam.org/eng/pr030825\\_TRIPS\\_health.htm](http://www.oxfam.org/eng/pr030825_TRIPS_health.htm).

138. *Statement of Understanding*, *supra* note 92.

would be defeated if products supplied under the Decision are diverted from their intended markets. Consequently, Members agree that "all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision."<sup>139</sup> The Statement, however, specifically states that "[i]t is the understanding of Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals."<sup>140</sup>

The Statement also calls on Members to "seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably."<sup>141</sup> To ensure transparency, the Statement of Understanding requires that notifications made under paragraph 2(a)(ii) of the Decision, pertaining to eligibility of an importing country, include "information on how the Member in question had established . . . that it has insufficient or no manufacturing capacities in the pharmaceutical sector."<sup>142</sup>

The Statement of Understanding also confirms the new monitoring role of the TRIPS Council. Essentially, "[a]ny Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action."<sup>143</sup> Any WTO Member who has concerns that the terms of the Decision have not been fully complied with "may also utilise the good offices of the Director General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution."<sup>144</sup>

### E. Conclusion

After all the battles over access to medicine and the relationship between patent rights, the TRIPS Agreement, and public health, what exactly has been achieved? What can countries that are members of the WTO legitimately do to ensure that essential medicines are available and affordable?

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139. *Id.* The Statement notes that the provisions of paragraph 2(b)(ii), pertaining to the obligations of exporting countries with respect to labeling, "apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients." *Id.*

140. *Id.* Regarding special packaging and labeling, the Statement notes the fact that in the past and for different reasons, companies have developed procedures to prevent diversion of products. *Id.* Attached to the Statement is a "Best practices" guideline that draws upon the experiences of companies.

141. *Id.*

142. *Id.*

143. *Id.*

144. *Id.*

WTO Members have at least four options. First, where patents exist on a desired medicine, developing countries can still attempt to meet their needs by dealing directly with the patent holder through normal commercial arrangements and through aid programs such as donations and discounts.<sup>145</sup> Second, where patents exist on a desired medicine, a WTO Member with manufacturing capacity has the flexibility under the TRIPS Agreement and the Doha Declaration to grant a compulsory license to permit the manufacture of generic versions of the same product.<sup>146</sup> Third, where a WTO Member has insufficient or no manufacturing capability, such a Member can, without a compulsory license, import generic pharmaceutical products manufactured in another country provided there are no patents on the pharmaceutical in question in the importing country and in the prospective exporting country.<sup>147</sup> Fourth, where there are patents in both the importing and exporting country, compulsory licenses would need to be issued in both countries before medicines could be exported.

Although the 2003 Decision on Implementation appears to be a victory for developing countries, its usefulness is yet to be tested. During negotiations, the World Health Organization ("WHO") and civil society groups had recommended a much simpler, workable, and more economically viable solution: allowing generic production for export as a limited exception to a patent right. There are fears that the Decision creates a costly and cumbersome process that could ultimately discourage generic production.

#### IV. ACCESSING GAINS; MAPPING PROGRESS: THE MERITS AND DEMERITS OF THE 2003 DECISION ON IMPLEMENTATION

The objective of both the Doha Declaration and the 2003 Decision on Implementation was to provide those in medicine-deprived countries access to speedy and low-priced supplies of essential medicines, while

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145. See *Second Communication from the U.S. on Paragraph 6*, *supra* note 104, para. 7.

First, difficulty would be expected to arise only in situations where the supply of the pharmaceutical in question has not been provided by the patent holder through normal commercial arrangements or through discount, donation, or other aid programs. A TRIPS-based solution can also only be expected to be effective where Members have, or are provided, the resources necessary to procure pharmaceuticals under the terms of a TRIPS-consistent compulsory licence, which includes the provision of adequate remuneration to the patent holder.

*Id.*

146. See, e.g., *id.* para. 8.

147. In general, developing countries were not required to establish a patent protection regime under the TRIPS Agreement until January 1, 2005. Thus, a developing country with manufacturing capacity and no patent laws can manufacture and export patented drugs without a compulsory license.

maintaining a legal environment that rewards inventors for their investment and encourages research and development into new products. Several questions inevitably arise. Will the adoption of the Decision enable countries in need of affordable medicines to import them quickly and easily from generic manufactures in other countries? Is the solution transparent and economically feasible? Will the Doha Declaration and the Decision ensure that needed drugs are available on a sustained basis? Altogether, is the solution crafted in the Decision expeditious, workable, transparent, sustainable, and legally certain?<sup>148</sup>

These questions are pertinent because although the 2003 Decision of Implementation is seen in some quarters as a balanced solution to the Paragraph 6 question,<sup>149</sup> many NGOs are critical of the Decision.<sup>150</sup> Critics argue that the Decision is intended to:

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148. See, e.g., *Second Communication from the U.S. on Paragraph 6*, *supra* note 104, para. 29 (arguing that “[w]hile each option suggested by Members has some merit, at this stage we believe an expeditious, workable, transparent, sustainable and legally certain solution may more likely be achieved through either a moratorium for dispute settlement or a waiver of the obligation in TRIPS Article 31(f)”).

149. For example, on August 30, 2003, Shannon Herzfeld, Senior Vice President of International Affairs of the Pharmaceutical Research and Manufacturers of America (“PhRMA”), issued a statement that read in part:

With the unanimous adoption of the Menon Statement and the Motta text, we are pleased that these negotiations have come to a conclusion. . . . The two decisions that the General Council reached today – the Motta text and the Chairman’s statement – will ensure that the system will not be abused. The additional clarifications contained in the Chairman’s statement add strong provisions to prevent diversion, and increase the likelihood that the solution will benefit patients in the world’s poorest countries as envisioned in the Doha Declaration. Taken as a whole, this solution reaffirms the critical role of patents in the development of new medicines.

Press Release, The Pharmaceutical Research and Manufacturers of America, Statement from Shannon Herzfeld, PhRMA’s Senior Vice President, International Affairs in reaction to the successful conclusion of the negotiations on TRIPS and Public Health (Aug. 30, 2003), *available at* <http://www.phrma.org/mediaroom/press/releases/30.08.2003.841.cfm>.

150. In a Joint NGO Statement issued on September 10, 2003, fourteen NGOs criticized several aspects of the 2003 Decision on Implementation. According to the Joint NGO statement, the main problems with the rules are:

1. The WTO is requiring the issuance of two compulsory licenses when the new mechanism is used.
2. The WTO has added many constraints on the business practices of the generic companies.
3. The WTO deal introduced an extra layer of uncertainty by stating that the system should not be an instrument to pursue industrial or commercial policy objectives, creating uncertainty over the role that will be played by the businesses that manufacture and sell generic drugs.
4. The decision leaves unclear whether or not economic efficiency is a grounds for determining a lack of manufacturing capacity in the importing country. The lack of clarity on this issue has been defended as a matter of “creative ambiguity”, but already the US is telling the Philippines and other countries that they will oppose “economic efficiency” as grounds for allowing a country to import generics.

- [1] Limit the importance of the Doha Declaration,
- [2] Prejudice more fundamental and sustainable fixes to the 31.f problems,
- [3] Create more and not less uncertainty [sic] regarding what can and cannot be done,
- [4] Give the US and the EU a big public relations bonanza which will be cruelly use [sic] as the basis for more bilateral pressure against the use of compulsory licenses and against better export strategies, as well as a basis to leverage additional concessions from developing countries in other WTO negotiations.<sup>151</sup>

Overall, the belief is that "[t]he new agreement has very modest benefits, and it has very substantial costs, risks and uncertainties."<sup>152</sup>

In this Section, I focus specifically on the 2003 Decision on Implementation in part because the Doha Declaration has already been extensively analyzed in many law review articles. I review the Decision in light of some of the perceived concerns of some of the NGOs. Three main issues will be taken up. First, I examine the viability and sustainability of the waiver mechanism as a solution to the Paragraph 6 question. Second, I examine the nature of obligations imposed on prospective importing and exporting countries to determine whether they are unnecessarily burdensome and onerous, and whether they present an imposition on the sovereignty of a country. Finally, I explore those areas where the Decision is vague and could potentially create problems in the future for countries desiring to utilize the system.

### A. *The Waiver Solution*

Was the waiver solution the best possible solution to the Paragraph 6 question? 'Yes' and 'No.' The 2003 Decision on Implementation, which operates as a temporary waiver, offers a quick solution to a thorny

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5. The deal gives the WTO itself new authority to second guess and interfere in the granting of individual compulsory licenses to generic companies.

6. The United States and other Developed Economies now have greater opportunities to pressure and stop developing countries from issuing compulsory licenses.

Joint NGO Statement on TRIPS and Public Health WTO Deal on Medicines: A "Gift" Bound in Red Tape (Sept. 10, 2003) [hereinafter Joint NGO Statement], available at <http://www.cptech.org/ip/wto/p6/ngos09102003.html>. The statement was signed by the following organizations: ACT Up Paris; Consumer Project on Technology; Consumers International; Essential Action; European AIDS Treatment Group; Health Action International; Health GAP; International People's Health Council; Médecins Sans Frontières; OXFAM International; People's Health Movement; SEATINI; Third World Network; and Women in Development. *Id.*

151. Memorandum from James Love, CPTEch, to WTO TRIPS Negotiators (Dec. 16, 2002) (rejecting the new chairman's December 16, 2002 text for paragraph 6 negotiations) [hereinafter CPTEch Memo], at <http://www.cptech.org/ip/wto/p6/cptech12162002.html>.

152. CPTEch Statement on WTO Deal on Exports of Medicines (Aug. 30, 2003) [hereinafter CPTEch Statement], at <http://www.cptech.org/ip/wto/p6/cptech08302003.html>.

problem but carries with it a lot of legal uncertainty.<sup>153</sup> Compared to a more formal amendment, a temporary waiver retains the advantage of speed<sup>154</sup> and simplicity.<sup>155</sup>

Although the waiver solution has its advantages, an amendment would have offered its own advantages of permanence, sustainability, and legal certainty.<sup>156</sup> However, an amendment would be undeniably more time-consuming and difficult to achieve than a waiver.<sup>157</sup> The United States challenged the idea that an amendment would provide legal certainty and opposed an amendment to Article 31(f) on the grounds that actions of countries acting under an amendment would have been susceptible to legal challenges which would have marred the legal certainty of the solution.<sup>158</sup>

Some NGOs had suggested an authoritative interpretation of Article 30 as a solution. Article 30 of the TRIPS Agreement permits WTO Members to provide limited exceptions to patent rights, "*provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests*

153. See, e.g., *EC Communications Relating to Paragraph 6*, *supra* note 103, para. 6 ("A waiver or a dispute settlement moratorium could be appropriate and effective mechanisms for a solution, but they may fall short of providing the type of sustainable and legally secure solution that the EC are aiming for."); see also Amir Attaran, *Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution*, 17 EMORY INT'L L. REV. 743, 767 (2003) (noting that a waiver is only a temporary solution).

154. In the TRIPS Council, the United States has argued that:

[A]greement can be reached on a . . . waiver much more easily and quickly than on an amendment to the TRIPS Agreement and further delay would be required for Members' formal acceptance. Crafting an amendment on which all Members can agree would delay implementation of the 'expeditious solution' beyond the agreed deadline.

*Second Communication from the U.S. on Paragraph 6*, *supra* note 104, para. 29.

155. *Id.* ("Should an amendment be adopted, it could prove to be either ineffective or seriously harmful in practice. A further amendment of the Agreement would be required to correct this situation.").

156. See, e.g., *EC Communications Relating to Paragraph 6*, *supra* note 103, para. 5 (arguing that an amendment "offer[ed] the best guarantees for a sustainable, balanced and workable solution"); see also WTO Council for Trade-Related Aspects of Intell. Prop. Rts., *Concept Paper Relating to Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Communication from the European Communities and Their Member States*, IP/C/W/339 (Mar. 4, 2002), available at <http://docsonline.wto.org>.

157. See, e.g., *EC Communications Relating to Paragraph 6*, *supra* note 103, para. 7. An amendment to Article 31 would fall under the procedural rules set out by Article X of the Marrakesh Agreement and is, as are all amendments of international agreements, a time-consuming procedure. See *id.*

158. See *Second Communication from the U.S. on Paragraph 6*, *supra* note 104, para. 29 (arguing that "if a country begins production for export relying on either an authoritative interpretation or an amendment, its actions could be challenged as being inconsistent with the interpretation or amendment," and such "a country would only have full legal certainty after the conclusion of a dispute process").

of the patent owner, taking account of the legitimate interests of third parties.”<sup>159</sup> Article 30 is seen to be politically more workable.<sup>160</sup> Article 30 does not require a governmental decision each time a pharmaceutical product is needed and contains no stringent requirements such as the requirement to notify a patent owner of use or to pay reasonable remuneration to the patent holder.

The Article 30 solution was not favored by the United States or the EC.<sup>161</sup> Rejecting this solution, the U.S. argued that Article 30 is “intended to apply to statutory exceptions already provided for in many countries’ laws at the time the TRIPS Agreement was negotiated,”<sup>162</sup> and that interpreting the Article to allow Members “to amend their patent laws to permit compulsory licences to be granted to authorize their manufacturers to produce and export patented pharmaceutical products to other countries would both unreasonably conflict with the normal exploitation of a patent and unreasonably prejudice the legitimate interests of the patent owner.”<sup>163</sup>

The waiver solution is only temporary. Assessment of the wisdom of the solution will depend on how speedily WTO Members can adopt a more permanent amendment to Article 31(f). Although the Decision set a deadline for WTO Members to negotiate and adopt such an amendment,<sup>164</sup> judging by past negotiating practices at the WTO<sup>165</sup> and serious debates that preceded the adoption of the Decision, it could predictably take much more time for Members to negotiate and adopt the necessary amendments. If global corporate actors remain true to their form, they will attempt to influence the negotiating position of developed countries

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159. TRIPS Agreement, *supra* note 4, para. 30 (emphasis added).

160. See Attaran, *supra* note 4, at 870.

161. The EC rejected this idea, arguing that “an authoritative interpretation on Article 30 of the TRIPS Agreement may fail to offer the same level of legal security for all parties involved as a textual addition to Article 31(f) would do.” *EC Communications Relating to Paragraph 6, supra* note 103, para. 6. The EC questioned the legal merit of the Article 30 solution and thought it was doubtful “whether the criteria of Article 30 offer[ed] sufficient scope for such an exception.” *Id.*

162. *Second Communication from the U.S. on Paragraph 6, supra* note 104, para. 31.

163. *Id.*

164. The Decision, including its waivers, “shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member.” *2003 Decision on Implementation, supra* note 14, para. 11. The Decision authorizes the TRIPS Council to:

initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration.

*Id.*

165. See Attaran, *supra* note 153, at 768 (predicting that negotiations could drag on for years).

governments, thus prolonging the amendment process.<sup>166</sup>

### B. *The Conditions Attached*

Does the Decision provide incentive for manufacturers to participate and to produce for export or does it de-incentivize generic production? Does the Decision contain onerous conditions that might discourage countries from utilizing the system? Asia Russell of Health GAP (an AIDS activist organization) has argued that the solution crafted by the Decision “is a failure for people with AIDS, and people everywhere dying of treatable diseases”<sup>167</sup> because “[i]n the time it would take a generic company to comply with all the conditions set out by the U.S., a patent would likely expire anyway.”<sup>168</sup>

Under the Decision, there are at least six steps to acquiring needed medicine through a compulsory license:<sup>169</sup>

- *Step 1:* A prospective importing country must first seek a voluntary license from the patent owner; such a license is supposed to be on commercially reasonable terms and for a commercially reasonable period of time.
- *Step 2:* If attempt to secure a voluntary license fails, an entity must apply for a compulsory license to manufacture the medicine locally.
- *Step 3:* Where the compulsory license is by a country that has no capacity to manufacture the medicine locally and the country is not a least-developing country, such a country must assess its industry’s capacity to produce the medicine locally, notify the TRIPS Council of its determination that it has insufficient capacity or no capacity, and explain and justify its decision regarding capacity.
- *Step 4:* An importing country must identify and notify a willing exporter in a country that has sufficient capacity to manufacture the needed medicine.
- *Step 5:* The prospective exporter must seek a compulsory license from its own government.<sup>170</sup> In granting the license, the prospective exporting country must ensure that the conditions stipulated

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166. MATTHEWS, *supra* note 22, at 6 (suggesting that global corporate actors will continue to play a pivotal role in any future renegotiation of the TRIPS Agreements and that “[t]heir interests are likely to be at the forefront of developed country perspectives on future requirements of international intellectual property protection”).

167. Press Release, Health Global Access Project, Bush Administration, Big Pharma about to secure disastrous “solution” on access to medicines at the WTO, (Aug. 28, 2003), *available at* [http://www.healthgap.org/press\\_releases/03/082803\\_HGAP\\_PS\\_WTO\\_para6\\_aug30text.html](http://www.healthgap.org/press_releases/03/082803_HGAP_PS_WTO_para6_aug30text.html).

168. *Id.*

169. 2003 Decision on Implementation, *supra* note 14.

170. It is possible that the exporter may be required first to seek a voluntary license from the patent holder.

in Article 31 of the TRIPS Agreement are met. One important condition is that the exporting country must pay adequate compensation to the patent holder.

- *Step 6:* If and when a license is granted, the exporter must take adequate measures as stipulated in the Decision to prevent diversion. In particular, the exporter must: (a) produce only the amount necessary to meet the needs of the eligible importing Member; (b) export the entirety of the production to the Member(s) which notified its needs to the Council for TRIPS; (c) clearly identify the products produced under the system through specific labeling or marking, special packaging and/or special colouring/shaping of the products themselves; (d) before shipment begins, post on a website the quantities being supplied to each destination and the distinguishing features of the product(s).

### 1. NOTIFICATION REQUIREMENTS

The Decision creates a somewhat cumbersome procedure for countries with insufficient or no capacity, which does not exist for countries with manufacturing capacity.<sup>171</sup> Although the system is supposed to be automatic, the TRIPS Council can second-guess a country's decision to utilize the system and has enough of a mandate to interfere and scrutinize the granting of a compulsory license.<sup>172</sup> Some NGOs have expressed concern that the notification requirements would be used to increase bilateral pressure on weak importing and exporting countries.<sup>173</sup>

Additionally, some organizations have argued that the Decision authorizes unnecessary intrusion into sovereignty because it authorizes the WTO Secretariat, the TRIPS Council, and the Chair of the TRIPS Council to review the use of compulsory licensing in the most intimate terms. Currently, scrutiny is required on two levels: to evaluate the basis for a country's decision that it lacks manufacturing capacity, and to evaluate whether the obligations imposed on both the importing and exporting countries have been met. Some loss of sovereignty will be

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171. See CPTech Statement, *supra* note 152.

The WTO secretariat, the TRIPS Council and the Chair of the TRIPS council will now begin to routinely review the issuance of individual licenses, and the WTO will now as a matter of expected practice, oversee the use of compulsory licensing in the most intimate terms, looking at the terms of individual licenses, evaluating the basis for deciding manufacturing capacity is insufficient, or reviewing or second guessing any of the new terms and obligations that the new implementation language introduces into the regulation of compulsory licensing of patents on medicines.

*Id.*

172. See Joint NGO Statement, *supra* note 150 (observing that Decision gives "the WTO itself new authority to second guess and interfere in the granting of individual compulsory licenses to generic companies").

173. See CPTech Memo, *supra* note 151, para. 3.

inevitable. The Decision was negotiated on the good faith understanding that it was aimed at addressing the problem of countries with insufficient or no manufacturing capacity. It therefore stands to reason that some kind of review mechanism must be in place to ensure that countries utilizing the system are those for whom it was crafted.

A more troubling concern is the emergence of three classes of states subject to three different rules in a multilateral system made up of sovereign states and guided by the principles of equality and non-discrimination. The first class is comprised of states that choose to issue compulsory licenses under Article 31 of the traditional TRIPS Agreements. These licenses will be subject to very minimal scrutiny but are not immune from legal action via the WTO dispute settlement process. The second class is made up of states that issue compulsory licenses under the Doha Declaration. These licenses will be subject to some measure of scrutiny and are also vulnerable to the possibilities of legal action. The third class represents states with insufficient or no manufacturing capacity utilizing the system established under the 2003 Decision on Implementation. These licenses will be subject to more intense scrutiny because the granting of a compulsory license under the Decision is far more complicated than is the case under the TRIPS Agreement. In return, however, countries utilizing this system receive some measure of immunity from potential lawsuits.

## 2. OTHER CONDITIONS

One problem that arises under the 2003 Decision on Implementation is the need for two separate compulsory licenses to effectuate one import request. Where a pharmaceutical product is patented in both the importing and exporting country, a compulsory license will have to be issued in each country. In other words, compulsory licenses to both exporters and importers would have to be negotiated and issued on a country-by-country and drug-by-drug basis. A manufacturer desiring to produce for export must therefore first obtain a compulsory license from its home country and then ensure that a compulsory license is also issued in the importing country. The granting of two compulsory licenses could create delays due to bureaucratic red tape.

## 3. MEASURES TO PREVENT ABUSES AND TRADE DIVERSION

From the beginning, developed countries expressed concern about abuses and trade diversion<sup>174</sup> and called for stringent preventive measures. The prevention of trade diversion, the EC argued, was "of major

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174. See *EC Communications Relating to Paragraph 6*, *supra* note 103, para. 13 ("It will be in the interest of all . . . that these products would not be diverted from their intended destination and

importance to guarantee the legal security of the right holders concerned and to preserve the basic principles of the TRIPS Agreement.”<sup>175</sup> This explains the stringent conditions imposed on the exporting country and generic drug companies in these countries. Under the system, generic manufacturers must differentiate pill size, shape, and color from brand-name products.

Are the safeguards on re-importation inappropriate? There is a legitimate fear that the safeguards may prove too costly for developing countries and generic manufacturers alike and may discourage the use of compulsory licensing altogether.<sup>176</sup> However, some anti-diversion measures are necessary. Generic drug companies are not paragons of virtue. To prevent unscrupulous generic producers from exploiting the system for their own personal gain, some safeguards are called for.

In conclusion, some of the conditions appear to be burdensome, may impose unnecessary costs on a country wishing to utilize the system, and may delay the delivery of affordable medicine to people who need it most – the sick and the dying. It becomes a procedural nightmare when each condition has to be fulfilled over and over again for each and every drug and for each and every country to which the drug will be exported. The Decision appears to take this into account. For example, it provides that

[i]n the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.<sup>177</sup>

### C. *Dangerous Vagueness*

The fierce negotiation by countries such as the United States, Japan, Switzerland, and the EU at the TRIPS Council to introduce numerous limitations and conditions to an earlier draft of the Decision suggests that the battle over the precise scope of the Decision may be far from over. In the course of the negotiations, the U.S. government pushed for strong limitations, including a fixed list of diseases, restriction of the use of the system to emergency situations, and limits on eligible importing countries.<sup>178</sup> A major concern at the present moment is

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that the system would not be abused for purposes other than to provide pharmaceutical products . . . to those in need.”).

175. *Id.*

176. See CPTech Memo, *supra* note 151, para. 5.

177. 2003 Decision on Implementation, *supra* note 14, para. 4.

178. See MÉDECINS SANS FRONTIÈRES, DOHA DERAILED: A PROGRESS REPORT ON TRIPS AND

that some countries may now attempt to exploit the lacunas in the Doha Declaration and the Decision in furtherance of their narrow interest.<sup>179</sup>

# 1. THE SCOPE OF DISEASES

The Decision is silent on disease scope. It is not clear whether the system can be used to address routine public health problems or whether it is limited to epidemics and other major health emergencies.

The preamble to the Decision makes reference to the Doha Declaration.<sup>180</sup> This could mean that the product scope will be defined by paragraph 1 of the Doha Declaration.<sup>181</sup> The first paragraph of the Doha Declaration reads: "We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."<sup>182</sup>

On the other hand, the Statement of Understanding is very telling. The Statement of Understanding explicitly notes that some countries will only use the system "in situations of national emergency or other circumstances of extreme urgency."<sup>183</sup> It can thus be deduced that the system will normally apply to non-emergencies (including routine public health care). It would be most unwise to restrict the solution to medicines and medical technologies for the treatment of HIV/AIDS, tuberculosis and malaria because "[w]hile there is no doubt that these epidemics are ravaging developing countries, they cannot be considered the sole public health threats in poor regions – either now or in the future."<sup>184</sup>

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ACCESS TO MEDICINES 3 (2003) (observing in their briefing for the 5th WTO Ministerial Conference in Cancún that the proposed list of diseases suggested by the U.S. had no public health rationale) [hereinafter DOHA DERAILED], available at <http://www.accessmed-msf.org/documents/cancunbriefing.pdf>.

179. See CPTech Memo, *supra* note 151, para. 1 ("Lack of clarity has not been useful for developing countries, and whatever is unclear will work against the developing countries.").

180. 2003 Decision on Implementation, *supra* note 14.

Noting the Declaration on the TRIPS Agreement and Public Health (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002.

*Id.* at pmb1. (citations omitted).

181. See EC Communications Relating to Paragraph 6, *supra* note 103, para. 11 (suggesting that the product scope is already defined by the Doha Declaration).

182. Doha Declaration, *supra* note 9, para. 1.

183. Statement of Understanding, *supra* note 92.

184. Handout, CPTech, US Government efforts to limit the scope of diseases in the implementation of the Doha Declaration on TRIPS and Public Health have outraged the public

## 2. ELIGIBLE IMPORTING MEMBERS

It is evident that LDCs qualify to use the system. The more difficult question arises with respect to other developing countries. Where a WTO Member is a large (disease-burdened), middle-income country such as Brazil, the Philippines, or South Africa, problems may arise because it may be difficult for such a country to prove to the satisfaction of the TRIPS Council that it has insufficient or no manufacturing capacity. The Decision also "leaves unclear whether or not economic efficiency is a grounds for determining a lack of manufacturing capacity in the importing country."<sup>185</sup>

## 3. MORATORIUM ON DISPUTE RESOLUTION?

It is not clear whether members who utilize the system are completely immune from lawsuits under the WTO dispute settlement procedure. The Decision appears to create a non-binding moratorium by providing that "Members shall not challenge *any measures taken in conformity with the provisions of the waivers* contained in this Decision."<sup>186</sup> Much will depend on who has the final say on whether measures have been taken in conformity with the Decision and by what standard such determinations are made. Although the reviewing function rests with the Council for TRIPS,<sup>187</sup> it bears remembering that membership in the Council is open to representatives of all WTO Members.<sup>188</sup> The provision on moratorium falls short of an earlier suggestion that a legally binding moratorium is what was needed – a clear determination that actions taken under Article 31(f) would have been non-justiciable.<sup>189</sup>

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health community, and have been presented in a highly dishonest way by the White House and USTR, damaging US reputation abroad (March 5, 2003) (quoting Allan Rosenfield, MD, Dean, Mailman School of Public Health, Columbia University; Michael H. Merson, MD, Dean of Public Health, Yale University; Laurence G. Branch, Ph.D, Dean, College of Public Health, University of Southern Florida; Stephen M. Shortell, Ph.D, Dean, School of Public Health, University of California, Berkeley), at <http://www.cptech.org/ip/wto/p6/cptech03052003.html>.

185. Joint NGO Statement, *supra* note 150.

186. 2003 Decision on Implementation, *supra* note 14, para. 10 (emphasis added).

187. *Id.* para. 8 ("The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council.").

188. WTO Agreement, *supra* note 4, art. IV, § 5.

189. See Attaran, *supra* note 4, at 871 (proposing that the Paragraph 6 mandate was "better satisfied by a rule of non-justiciability, narrowly tailored to deal with the manufacture and export of generic" drugs). According to Attaran, the distinction between moratoriums and non-justiciability is clear:

[W]hereas moratoriums are unilateral and not legally binding, non-justiciability would be multilateral and fully legally binding. This is because where the moratorium is only a promise not to bring a lawsuit[,] . . . non-justiciability is a guarantee that those violations do not result in a lawsuit . . . before the WTO panels in the future.

Clearly, several provisions of the 2003 Decision could pose major problems for countries wishing to utilize the mechanism established under it because of the ambiguities inherent in those provisions. The situation is made worse by the fact that the legal status of the Statement of Understanding accompanying the Decision is not entirely clear. According to the Chairperson of the General Council, the Statement of Understanding "represents several key shared understandings of Members regarding the Decision . . . and the way in which it will be interpreted and implemented."<sup>190</sup>

#### D. Conclusion

On the positive side, the very fact that 146 WTO Members were able to arrive at a measure of consensus in order to address the concerns of countries with insufficient or no capacity is commendable. Also on the positive side is the fact that the scope of diseases for compulsory licensing does not appear to be limited, as the U.S. initially suggested. It is also encouraging that a balance was met between importers and exporters as some of the conditions attached to the Decision are necessary to ensure that cheaper drugs do not flow back from developing countries to developed countries, and to ensure that pharmaceutical companies recoup their investments.

Some of the fears expressed by several NGOs are unfounded and lack merit. For example, some organizations have argued that the Decision "introduced an extra layer of uncertainty by stating that the system should not be an instrument to pursue industrial or commercial policy objectives, creating uncertainty over the role that will be played by the businesses that manufacture and sell generic drugs."<sup>191</sup> They have argued that the 2003 Decision on Implementation "contradicts the basic principles of the WTO and free trade"<sup>192</sup> by prohibiting the export of drugs manufactured under the system to rich countries.<sup>193</sup> The argument is that by reducing the size of countries that might import generic medicine to meet their public health needs, it may not be cost-efficient for any generic manufacturer to participate in the system.<sup>194</sup> These orga-

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Attaran, *supra* note 153, at 770.

190. *Statement of Understanding*, *supra* note 92.

191. Joint NGO Statement, *supra* note 150.

192. *Id.*

193. *Id.* at n.1 (arguing that the Decision "explicitly accepts a protectionist framework, where rich countries can export to poor countries, but 23 rich countries were allowed to bar imports from developing countries").

194. See Discussion Paper, Brook K. Baker, Health GAP, Vows of Poverty, Shrunk Markets, Burdensome Manufacturing and Other Nonsense at the WTO (Sept. 27, 2003) (noting that "23 rich countries, representing 80% of global drug sales opted out of the export/import option, [and that] ten countries seeking admission to the E.U. have also restricted their option to

nizations would want generic producers to be allowed to export drugs produced under the new system to developed countries such as the U.S., Japan, or Australia on the argument that if such large markets are excluded, drug production will not be economically efficient and attractive to generic firms.<sup>195</sup> These lines of argument lack merit and ignore the good-faith understanding on which the Decision was negotiated. Because the Decision was crafted to address the health problems of countries with insufficient or no manufacturing capacity, there is no reason for products manufactured under the system to be shipped to rich countries.

In the future, controversy may arise regarding the effect of the Statement of Understanding. It is currently not clear if and to what extent it eviscerates the Doha Declaration and if and to what extent it detracts from the terms and conditions of the Decision.<sup>196</sup> Three clauses in the Statement of Understanding could pose a problem in the future: the good-faith clause,<sup>197</sup> the anti-diversion clause, and the transparency clause.

#### V. ABUSES IN THE PHARMACEUTICAL INDUSTRY: A REVIEW OF EMERGING CASE LAW (THE U.S. EXAMPLE)

A troubling scenario is unfolding in the pharmaceutical sector in the U.S.: pharmaceutical companies are increasingly resorting to a range of abusive and anti-competitive practices in an effort to preserve monopoly profits and maintain market share. By exploiting loopholes in a law

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import”), available at [http://www.healthgap.org/press\\_releases/03/092703\\_HGAP\\_BP\\_WTO\\_Cancun.html](http://www.healthgap.org/press_releases/03/092703_HGAP_BP_WTO_Cancun.html).

195. See DOHA DERAILED, *supra* note 178, at 3 (suggesting that it is essential to include large markets such as South Africa and Philippines in order to make drug production attractive to generic firms); See also CPTECH Statement, *supra* note 152.

The persons who have negotiated this agreement have given the world a new model for explicitly endorsing protectionism. The United States, Europe, Canada, Australia, Japan and other developed economies will be allowed to bar imports from developing country generic suppliers – under completely irrational protectionist measures that are defended by the WTO Secretariat and its most powerful members as a humanitarian gesture.

*Id.*

196. See Baker, *supra* note 194 (arguing that the Statement of Understanding eviscerates the historic Doha Declaration).

197. The good faith clause reads: “Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.” *Id.* (citing *Statement of Understanding*, *supra* note 92). Baker notes that there is confusion in the international press and NGO community about the text’s good faith requirement. For example, there are speculations on whether it is “designed to limit drug use in the importing country to public, non-commercial use” and whether it “applies to both locally produced generics and imported ones.” Baker, *supra* note 194 (citations omitted).

originally passed to facilitate the speedy entry of generic drugs into U.S. markets, some pharmaceutical companies have been able to either suppress or delay generic competition.

The goal of this part is to highlight the different ways pharmaceutical companies (both brand-name and generic) have attempted to "game" a system originally designed to increase generic competition and improve consumer welfare. By exploiting loopholes in a law passed to increase generic competition, drug manufacturers in the U.S. have become more profitable without providing any corresponding benefit to consumers.<sup>198</sup> The degree of abuse in the U.S. pharmaceutical industry is reflected in the increasing number of private lawsuits against brand-name companies and/or generic companies for abuse of patent rights. Abuse is also reflected in the growing number of antitrust enforcement actions affecting both brand-name and generic drug manufacturers that the Federal Trade Commission ("FTC") is pursuing.<sup>199</sup>

Although the U.S. law at issue is very different from the international agreements under consideration in this article, interesting parallels and useful lessons may be drawn. Many U.S. pharmaceutical companies operate as giant transnational corporations and are likely to be affected by the Doha Declaration and the 2003 Decision on Implementation. Given the tendency of these companies to game a domestic system designed to improve generic competition despite the strong regulatory oversight of the FTC and the rigorous antitrust laws in the U.S., I argue that those pharmaceutical companies affected by the Doha Declaration and the 2003 Decision on Implementation may also attempt to abuse the system established under these instruments absent strong oversight at the global level.

To appreciate the tactics used by pharmaceutical companies to either delay or suppress generic competition in the U.S., an understanding of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("Hatch-Waxman Amendments" or "Hatch-Waxman")<sup>200</sup> is necessary. Enacted in 1984, the Hatch-Waxman Amendments sub-

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198. *Prepared Statement of the Federal Trade Commission Before the U.S. Senate Comm. on the Judiciary*, 108th Cong. (June 17, 2003) (prepared statement presented by Timothy J. Muris, Chairman of the Federal Trade Commission) [hereinafter *Prepared Statement of the FTC 2003*], available at <http://www.ftc.gov/os/2003/06/030617pharmtestimony.htm>.

199. The FTC "enforces federal consumer protection laws that prevent fraud, deception and unfair business practices. . . [and] enforces federal antitrust laws that prohibit anticompetitive. . . practices that restrict competition and harm consumers." FED. TRADE COMM'N, GUIDE TO THE FEDERAL TRADE COMMISSION 1 (April 2004), available at [www.ftc.gov/bcp/conline/pubs/general/guidetoftc.htm](http://www.ftc.gov/bcp/conline/pubs/general/guidetoftc.htm).

200. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (1994)) [hereinafter Hatch-Waxman Amendments].

stantially changed the law governing approval of generic drug products by the Food and Drug Administration ("FDA").<sup>201</sup> One of the goals of Hatch-Waxman was to increase opportunities for market entry by generic drug manufacturers.<sup>202</sup> Although the goal of increasing generic drug entry was achieved,<sup>203</sup> studies now show that the two main Hatch-Waxman provisions governing generic drug approval prior to patent expiration have potential for abuse and are susceptible to strategies that may actually prevent the availability of more generic drugs.<sup>204</sup> In April 2002, the FTC began an industry-wide study that focused on certain aspects of generic drug competition under Hatch-Waxman. The FTC issued its report, *Generic Entry Prior to Patent Expiration: An FTC Study*, in July 2002.<sup>205</sup>

One popular form of abuse is through anti-competitive agreements between brand-name and generic drug companies.<sup>206</sup> Another form of abuse is the improper listing of patents by brand-name companies coupled with frivolous lawsuits against generic companies, which have the effect of delaying FTC approval of a generic drug. Some companies also engage in false and deceptive advertising and marketing practices aimed solely at discouraging use of generic drugs once they are on the market. In this section, Part A provides an overview of Hatch-Waxman. Part B analyzes some of the abuses in the drug industry and the antitrust action the FTC is taking against offending companies. In Part C, I highlight useful lessons that may be drawn from the United States.

### A. *The Hatch-Waxman Amendment: Statutory and Regulatory Background*

The Federal Food, Drug and Cosmetic Act (the "Act") regulates the manufacture and distribution of pharmaceutical drugs in the U.S.<sup>207</sup>

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201. See FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 4-8* (July 2002) [hereinafter *FTC, GENERIC DRUG ENTRY*], <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

202. See *id.* at i.

203. See *id.* ("Generic drugs now comprise more than 47 percent of the prescriptions filled for pharmaceutical products – up from 19 percent in 1984, when Hatch-Waxman was enacted."); see also FAMILIES USA, *THE DRUG INDUSTRY: FACTS AND FIGURES* (2002) (noting that consumers' access to lower-priced generics has increased since the enactment of the Hatch-Waxman Amendment) [hereinafter *FAMILIES USA, THE DRUG INDUSTRY*], available at <http://www.familiesusa.org/site/DocServer/factsheet.pdf?docID=246>.

204. See *FTC, GENERIC DRUG ENTRY*, *supra* note 201, at i.

205. *Id.*

206. The goal of the study was to determine whether some provisions of Hatch-Waxman are susceptible to strategies that delay and deter consumer access to low-cost generic drugs and whether alleged anti-competitive agreements between brand-name and generic drug manufacturers that relied on certain Hatch-Waxman provisions were isolated instances or more typical. *Id.* at 1.

207. 21 U.S.C. §§ 301-399 [hereinafter "the Act"].

Recognizing that the Act's "cumbersome drug approval process delayed entry of relatively inexpensive generic drugs into the marketplace, Congress passed the . . . 'Hatch-Waxman Amendments' to the [Act] in 1984."<sup>208</sup> One of the rationales behind the Hatch-Waxman Amendments was to make generic drugs more readily available.<sup>209</sup> In fact, the Hatch-Waxman Amendments embody Congress' attempt to "balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."<sup>210</sup>

The Hatch-Waxman Amendments established new guidelines that simplify the approval process for generic drugs. Previously, any company wanting to market a new generic drug had to secure approval from the FDA by filing a New Drug Application ("NDA"), a process that is often "time-consuming and costly" because it required companies to submit specific data concerning the drug's safety and effectiveness.<sup>211</sup> Under the new guidelines, a generic drug manufacturer can file an Abbreviated New Drug Application ("ANDA") that incorporates by reference the safety and efficacy data developed and previously submitted by the company that manufactured the original "pioneer" brand-name drug. To obtain FDA approval, the ANDA filer must demonstrate that its product is "bioequivalent" to the pioneer drug.<sup>212</sup> To protect the patent rights of the pioneer drug manufacturer, the ANDA filer must make one of four certifications<sup>213</sup> in its ANDA concerning patents listed with the FDA for the pioneer drug, including that:<sup>214</sup> (1) no patent for the pioneer drug is listed in the Orange Book ("Paragraph I Certification"); (2) the relevant patent listed in the Orange Book has expired ("Paragraph II Certification"); (3) the listed patent will expire on a particular date and the ANDA filer does not seek FDA approval before that date ("Paragraph III Certification"); and (4) the listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the [generic]

208. *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000).

209. See H.R. REP. NO. 98-857 (I), at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N 2647, 2647.

210. *Mylan*, 81 F. Supp. 2d at 32 (citations omitted).

211. See *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 801 (D.C. Cir. 2001) (citations omitted).

212. 21 U.S.C. § 355(j)(2)(A)(iv) (2000).

213. 21 U.S.C. § 355(j)(2)(A)(vii) (2000); see also 21 C.F.R. § 314.94(a)(12)(i)(A) (2004).

214. The Hatch-Waxman Amendments require an NDA to list any patent "which claims the drug . . . or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1) (2000). The FDA maintains and publishes this information in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"). See FTC, *GENERIC DRUG ENTRY*, *supra* note 201, at 5; see also 21 U.S.C. § 355(j)(7)(A) (2000).

drug” (“Paragraph IV Certification”).<sup>215</sup>

From a consumer interest standpoint and the standpoint of competition, an ANDA with a Paragraph IV Certification is dangerous in that it can, and frequently does, set in motion a process that could ultimately delay access to cheaper generics for three years or longer. The regulatory implication of a Paragraph IV Certification is significant in that such an application has the potential to trigger the operation of two provisions of Hatch-Waxman: the “30-month stay” and the “180-day period of exclusivity.”

### 1. THE 30-MONTH STAY

An ANDA containing a Paragraph IV Certification (an “ANDA IV”) has “important legal ramifications [because] [i]t automatically creates a cause of action for patent infringement.”<sup>216</sup> An ANDA applicant making such a certification must notify the owner of the listed patent upon the filing of such certification.<sup>217</sup> Thereafter, the patent holder has forty-five days to initiate a patent infringement suit against the ANDA applicant.<sup>218</sup> If the patent holder does not commence an action within forty-five days, the FDA may approve the ANDA at any time, subject to the fulfillment of the other requirements.<sup>219</sup> If the lawsuit is filed in a timely manner, the FDA cannot approve the ANDA for at least thirty months.<sup>220</sup> Moreover, the court hearing the patent case may extend the 30-month stay if either party fails to “reasonably cooperate in expediting the action.”<sup>221</sup> However, if the court presiding over the infringement action determines before the 30-month period expires that the patent at issue is invalid or not infringed, approval is effective from the date the court decision is made.<sup>222</sup>

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215. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000); *see also* 21 C.F.R. § 314.94(a)(12)(A)(4) (2004).

216. *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000).

217. 21 U.S.C. § 355(j)(2)(B) (2000).

218. 21 U.S.C. § 355(j)(5)(B)(iii) (2000).

219. *Id.*

220. *Id.* There are, however, limited exceptions under which the 30-month period can be altered by the court. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I)-(IV) (2000).

221. 21 U.S.C. § 355(j)(5)(B)(iii) (2000); *see also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740, 744 (E.D.N.Y. 2001) (“Ciprofloxacin I”).

It seems relatively clear . . . that if there is no resolution of the patent litigation and a stay is not granted, and the patent holder has not obtained preliminary injunctive relief, the ANDA filer may begin to market its product. In such an instance, the ANDA filer assumes the risk it might be found liable for infringing the pioneer manufacturer’s patent.

*Id.*

222. 21 U.S.C. § 355(j)(5)(B)(iii)(I) (2000).

## 2. THE 180-DAY EXCLUSIVITY PERIOD

Although a Paragraph IV Certification is potentially dangerous for a generic manufacturer because it places the manufacturer at risk for a patent infringement lawsuit, it does carry some advantages. The Hatch-Waxman Amendments provide that the first company to submit an ANDA IV is awarded a 180-day period of exclusive rights to market the generic formula of the pioneer drug.<sup>223</sup> Prior to the expiration of the exclusivity period, the FDA cannot approve any other ANDA for the same generic drug.<sup>224</sup> The exclusivity period is triggered by either the commercial marketing of the generic drug by the first ANDA filer or the decision of a court finding the pioneer drug's patent to be invalid, unenforceable, or not infringed, whichever is sooner.<sup>225</sup>

### B. *Anti-competitive Practices in the Drug Industry*

Paragraph IV Certification has prompted some in the pharmaceutical industry to employ a number of anti-competitive practices that are currently the subject of private litigation, FTC investigations, and legislative proposals aimed at ensuring fair competition.

One of these abusive practices is the use of collusive agreements between brand-name manufacturers and generic manufacturers, which are aimed at keeping the first generic off the market, thus blocking all subsequent generics from getting to the market. This arises because, as discussed, the first ANDA filer with a Paragraph IV Certification receives 180 days of exclusivity and sometimes controls the timing of the drugs introduced into the market.<sup>226</sup> An agreement between the first ANDA filer and a brand-name drug manufacturer "can effectively prevent generic competition for the brand-name drug for an indefinite

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223. 21 U.S.C. § 355(j)(5)(B)(iv). The 180-days of exclusivity means that "[n]o other generics can go to market until 180 days after the first generic goes to market or wins the patent lawsuit." FAMILIES USA, GETTING ACCESS TO GENERIC DRUGS: A TIMELINE (2002), available at <http://www.familiesusa.org/site/DocServer/genericstimeline.pdf?docID=245>; see also David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 331 (2000) ("[T]he first generic firm to challenge a patent holder is the only generic firm that can enter; until it enters, no other generic firm can enter the market.").

224. See Balto, *supra* note 223, at 331.

225. 21 C.F.R. § 314.107(c) (2004); see also Balto, *supra* note 223, at 331.

226. See 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873 (proposed Aug. 6, 1999) (to be codified at 21 C.F.R. ch. 1, subch. D, pt. 314).

During litigation of the many cases related to 180-day exclusivity, the parties and courts have recognized the potential for the 180-day exclusivity process to substantially delay the entry of competitive generic drug products into the market. This situation can occur when the marketing of any subsequent generic drug product is contingent upon the occurrence of an event that is within the first ANDA applicant's control.

*Id.* at 42,874.

period.”<sup>227</sup> In exchange for agreeing not to enter the market, the first ANDA filer is given a cut of the profits by the brand-name manufacturer, which enjoys a continued monopoly.<sup>228</sup> In one case, a brand-name drug company reportedly paid \$4.5 million a month to a generic manufacturer so that it would not market its generic.<sup>229</sup> In another case, an agreement was made for payments of up to \$10 million per quarter.<sup>230</sup>

Another form of abuse is improper Orange Book listings, which provide the opportunity for frivolous lawsuits by brand-name manufacturers who thereby trigger the 30-month stay. Because the filing of a patent infringement lawsuit within forty-five days of notice of a Paragraph IV Certification results in an automatic delay of the FDA approval of the generic, brand-name manufacturers have an incentive to claim, obtain, and list as many patents as possible in the Orange Book (a practice known as “warehousing” of patents). This puts brand-name companies in a position to bring as many lawsuits as possible against a Paragraph IV filer. This is possible because “[e]ven a completely frivolous patent infringement action will preclude FDA approval for up to 30 months.”<sup>231</sup> Moreover, invalid patents can also form the basis for the 30-month stays.

Overall, by illegally manipulating the patent process and the FDA approval process to delay generic marketing, brand-name companies – sometimes in collusion with generic companies – accumulate millions in additional sales.<sup>232</sup> The ultimate victims in the patent game are consumers who are denied access to cheaper drugs.<sup>233</sup>

## 1. COLLUSIVE AGREEMENTS

Allegations that some brand-name companies have paid or have attempted to pay generic companies not to enter and compete are wide-

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227. FAMILIES USA, PUB. NO. 02-101, COLLUSION AND OTHER ANTICOMPETITIVE PRACTICES: A SURVEY OF CLASS ACTION LAWSUITS AGAINST DRUG MANUFACTURERS 5 (2002) [hereinafter FAMILIES USA, COLLUSION], available at <http://www.familiesusa.org/site/DocServer/classaction%20survey.pdf?docID=247>.

228. *Id.*

229. *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 1340, 1346 (S.D. Fla. 2000).

230. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 701 (E.D. Mich. 2000).

231. FAMILIES USA, COLLUSION, *supra* note 227, at 5.

232. FAMILIES USA, THE DRUG INDUSTRY, *supra* note 203 (observing that for one drug alone, the brand-name manufacturer accumulated at least \$160 million in additional sales by delaying generic market entry from November 2000 to March 2001).

233. *See id.* (“Delaying the introduction of generic competition can protect drug company profits, but it costs consumers millions.”). Studies show that consumers save considerably when they exercise their option by buying cheaper generics. Families USA rightly notes that “[t]he first generic on the market is typically priced 20 to 30 percent below the comparable brand-name drug, but as more generics enter the market, consumers have more choices, and generic prices drop further.” *Id.*

spread. In reaching these agreements, the companies essentially use the generic company's 180-day exclusivity rights to block other generic competitors from entering the market.<sup>234</sup> The FTC has found that frequently a brand-name drug manufacturer and the first generic company to file an ANDA containing a Paragraph IV Certification pertaining to a brand-name drug both have economic incentives to collude to delay generic entry.

By blocking entry, the brand-name manufacturer may preserve monopoly profits. A portion of these profits, in turn, can be used to fund payments to the generic manufacturer to induce it to forgo the profits it could have realized by selling its product. Furthermore, by delaying the first generic's entry - and with it, the triggering of the 180 days of exclusivity - the brand-name and first-filing generic firms can sometimes forestall the entry of other generic products.<sup>235</sup>

Since 2000, the FTC has settled at least three cases against brand-name companies and generic companies by consent orders.<sup>236</sup> In this section, I take a look at on-going private litigation as well as FTC enforcement actions against some companies.

a) Private Litigation: *In re Ciprofloxacin Hydrochloride Antitrust Litigation* ("CIPRO II")<sup>237</sup> (Purchasers vs. Patentee)

In the Cipro litigation, purchasers of the antibiotic ciprofloxacin hydrochloride ("Cipro") aligned with advocacy groups sued Bayer,<sup>238</sup> the brand-name manufacturer of Cipro,<sup>239</sup> and four prospective generic

234. See *Prepared Statement of the FTC 2003*, *supra* note 198, § III.A.

235. *Id.*

236. See *In re Abbott Labs.*, No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000) (decision and order for Abbott Labs.); *In re Abbott Labs.*, No. C-3946, 2000 WL 681849 (F.T.C. May 22, 2000) (decision and order for Geneva Pharms., Inc.); *In re Hoechst Marion Roussel, Inc.*, No. 9293, 2001 WL 502087 (F.T.C. May 8, 2001) (decision and order). The complaint for *In re Hoechst Marion Roussel, Inc.* can be found at <http://www.ftc.gov/os/2000/03/hoechststandrxcomplaint.htm>.

237. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) [hereinafter CIPRO III]. The March 31, 2005, decision of the United States District Court for the Eastern District of New York builds on the court's earlier decisions in CIPRO I and CIPRO II. CIPRO I and II provide some of the statutory and regulatory background to the present case. An understanding of the prior history of this case is therefore important. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003) [hereinafter CIPRO II]; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740 (E.D.N.Y. 2001) [hereinafter CIPRO I]. In CIPRO I, the district court granted plaintiff's motion to remand the case to state court. In CIPRO II, the defendants' motions to dismiss the complaints were granted in part and denied in part and the court also denied plaintiffs' motion for partial summary judgment.

238. "Bayer" corresponds to "Bayer AG, a German company, and its American subsidiary, Bayer Corporation." CIPRO II, 261 F. Supp. 2d at 191.

239. Cipro belongs in the antibiotic group known as quinolones. Cipro is used to treat a wide range of problems including sinusitis, lower respiratory infections, urinary tract infections, and bone, joint, skin infections. As the leading antibiotic used to treat anthrax, Cipro gained

manufacturers: Barr, Rugby, HMR, and Watson ("Generic Defendants").<sup>240</sup> The plaintiffs asserted that Bayer and the Generic Defendants entered into an illegal agreement in which the Generic Defendants agreed to defer entry into the market until the expiration of Bayer's Cipro patent in return for payments from Bayer. Plaintiffs maintained that this arrangement violated federal and state antitrust laws and moved for partial summary judgment on the basis that it was a *per se* illegal market allocation in violation of the Sherman Act's section one prohibition on contracts in restraint of trade.<sup>241</sup> Bayer and the Generic Defendants (collectively "defendants") countered the motion for partial summary judgment with a 12(b)(6) cross-motion to dismiss.<sup>242</sup>

Bayer manufactures and distributes Cipro and, at the time of the litigation, was the assignee of the patent for the active ingredient in Cipro.<sup>243</sup> The Cipro patent (Patent No. 4,670,444 – the "444 Patent") was issued on June 2, 1987.<sup>244</sup> In October 1987, Cipro obtained FDA approval for the United States market.<sup>245</sup> In October 1991, "Barr filed ANDA 74-124 for a generic, bioequivalent version of Cipro."<sup>246</sup> Barr's ANDA "included a Paragraph IV Certification seeking the FDA's permission to market its generic drug before the 444 Patent expire[d] on the grounds that [Bayer's] patent [was] invalid and unenforceable."<sup>247</sup> On December 6, 1991, pursuant to the Hatch-Waxman Amendments, "Barr

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popularity after the September 11th terrorist attacks. According to Consumer Catalyst, Inc., "Cipro is approved for treating seventeen different infections" and "is dispensed in tablet, liquid and intravenous forms." See Consumer Catalyst, Cipro, *available at* [http://www.communitycatalyst.org/index.php?doc\\_id=583](http://www.communitycatalyst.org/index.php?doc_id=583) (last visited Jan. 28, 2005); see also CIPRO II, 261 F. Supp. 2d at 194 (observing that "Cipro has been the best selling antibiotic in the United States for many consecutive years and is described as 'the most prescribed antibiotic in the world'").

240. The full names of the Generic Defendants are as follows: Barr Laboratories, Inc. ("Barr"); The Rugby Group, Inc. ("Rugby"); Hoechst Marion Roussel, Inc. ("HMR"); and Watson Pharmaceuticals, Inc. ("Watson"). CIPRO II, 261 F. Supp. 2d at 191.

241. *Id.* at 191-92. The court found that the injury requirement for a Sherman Act restraint of trade claim was not satisfied by plaintiff's claim that consumers paid inflated prices because Barr would have prevailed in its patent case against Bayer regarding the Cipro patent and thus brought to market (along with other generic manufacturers) a cheaper generic version. *Id.* at 199-202. The court found that this causation, based on the outcome of a specific case, was "too speculative and [was] insufficient to state a claim under the antitrust laws." *Id.* at 201. Plaintiffs' moved, pursuant to Federal Rule of Civil Procedure 56, for partial summary judgment finding that these agreements were *per se* unlawful under section one of the Sherman Act, and various state antitrust and consumer protection laws. *Id.* at 230-32.

242. The cross-motion directly addressed the Sherman Act violation and alleged that the plaintiffs had failed to sufficiently plead the facts. *Id.* at 192.

243. *Id.* at 194.

244. The '444 Patent expired on December 9, 2003. *Id.*

245. FDA approval was granted to Miles, Inc., "the predecessor to Bayer Corporation and the licensee of the 444 Patent." *Id.*

246. *Id.*

247. *Id.*

notified Bayer of its ANDA IV filing and its assertions contained therein regarding Bayer's 444 Patent."<sup>248</sup> "On January 16, 1992, Bayer commenced a timely patent infringement suit against Barr<sup>249</sup> . . . thereby triggering the 30-month statutory waiting period for FDA approval."<sup>250</sup> "Subsequently, in November 1992, Bayer and Barr executed a stipulation," approved by the judge on December 8, 1992, "whereby the parties agreed to extend the 30-month waiting period until final judgment was entered in the patent infringement action."<sup>251</sup> Without the agreement, the stay would have expired on April 22, 1995.<sup>252</sup>

During the pendency of the patent litigation, on January 4, 1995, "the FDA granted tentative approval of Barr's ANDA for generic Cipro."<sup>253</sup> In March 1996, HMR and Rugby got into the action, striking a deal with Barr to help finance the patent litigation in exchange for a share of the rights and profits from the eventual Cipro marketing.<sup>254</sup> Weeks before trial was scheduled to begin, Bayer and Barr settled the patent litigation.<sup>255</sup> "In connection with the settlement, on January 8, 1997, Bayer entered into three separate but interrelated settlement agreements with Barr, HMR and Rugby," and two other companies (the "Settlement Agreements"),<sup>256</sup> as well as a supply agreement with Barr and HMR (the "Supply Agreement").<sup>257</sup> It is the terms of the Settlement Agreements that ultimately gave rise to plaintiff's claims of Sherman Act violations.<sup>258</sup>

Under the Settlement Agreements, Bayer agreed to pay \$49.1 million to Barr, HMR, Rugby, and the two other companies. In return, Barr "agreed to amend its ANDA to change its Paragraph IV Certification to a Paragraph III Certification."<sup>259</sup> A Paragraph III Certification allows Barr "to market generic Cipro only upon expiration of the 444 Patent."<sup>260</sup> Per the agreement, Bayer promptly paid \$49.1 million into a

248. *Id.*

249. *Bayer AG v. Barr Labs., Inc.*, 798 F. Supp. 196 (S.D.N.Y. 1992).

250. *CIPRO II*, 261 F. Supp. 2d at 194.

251. *Id.* at 194-95.

252. *Id.* at 195.

253. *Id.*

254. *Id.*

255. *Id.*

256. The two other companies were Bernard Sherman and Apotex, Inc. *Id.*

257. *Id.* at 195-96.

258. *Id.* at 196 ("The terms of these agreements form the bases of plaintiffs' allegations of a Sherman Act violation.").

259. *Id.*

260. *Id.* Under the Settlement Agreement, Barr preserved the option to re-amend to a Paragraph IV Certification if the '444 Patent was subsequently "declared invalid or unenforceable by a court of competent jurisdiction." *Id.* at 235 n.51 (quoting the Settlement Agreement).

joint escrow account set up by Barr and HMR.<sup>261</sup>

"In the Supply Agreement, Barr and HMR agreed not to manufacture (or to have manufactured) [a generic form of] Cipro in the United States."<sup>262</sup> According to the Agreement, Barr and HMR agreed to distribute in the United States only Bayer-manufactured Cipro or, in the alternative, receive quarterly payments, varying from \$15 million to approximately \$17 million from Bayer until the expiration of the '444 Patent in December 2003.<sup>263</sup> Rather than supply Bayer-manufactured Cipro as stipulated in the Supply Agreement, Bayer opted to make the quarterly payments. Altogether, in addition to the initial payment of \$49.1 million by December 2003, Bayer had made a total payment of approximately \$398 million.<sup>264</sup> Finally, by virtue of a consent judgment between Bayer and Barr the litigation was terminated. Barr affirmed the validity of the '444 Patent and admitted infringement. However, the consent judgment did not mention any payments from Bayer to Barr.<sup>265</sup>

In CIPRO III, decided on March 31, 2005,<sup>266</sup> plaintiffs moved for summary judgment arguing that the Settlement Agreements violated Section 1 of the Sherman Act under a rule of reason analysis.<sup>267</sup> According to the plaintiff, the Settlement Agreements met the "anti-competitive conduct" requirement stipulated in section one of the Sherman Act.<sup>268</sup> Bayer and Generic Defendants also moved for summary

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261. *Id.* at 196.

262. *Id.*

263. *Id.* (observing that the agreement was that Bayer would either "(1) supply Bayer-manufactured Cipro to Barr, HMR and Rugby for distribution in the United States, subject to certain price controls; or (2) make quarterly payments – varying from \$15 million to approximately \$17 million – to the Barr Escrow Account from January 1998 through December 2003") (citations omitted).

264. *Id.*

265. *Id.* ("There was no mention in the Consent Judgment of the payments Bayer agreed to make to the Barr Escrow Account or the agreement by Barr, HMR and Rugby not to manufacture and market a generic form of Cipro.").

266. CIPRO III, 363 F. Supp. 2d 514 (E.D.N.Y. 2005).

267. The district court adopted a rule of reason analysis because, in CIPRO II, it previously found that the Settlement Agreements and Supply Agreement did not warrant *per se* condemnation under section one of the Sherman Act which, according to the court, is "reserved for the most blatant antitrust violations." CIPRO II, 261 F. Supp. 2d at 257. According to the court:

While an unfortunate aspect of the Hatch-Waxman Amendments is that pioneer and generic drug manufacturers have often been entering into mutually beneficial agreements that result in delayed entry of generic drugs into the market place, the cases that have found such agreements *per se* illegal involve findings that the agreements at issue restrained noninfringing products, delayed generic entry and perpetuated litigation. Such is not the case here.

*Id.*

268. Section one of the Sherman Act states:

Every contract, combination in the form of trust or otherwise, or conspiracy, in

judgment arguing that because the Agreements were “within the scope of the ‘444 Patent,” there were “no anti-competitive effects that [were] actionable under the Sherman Act.”<sup>269</sup> The case inevitably required the court to examine the intersection between patent and antitrust laws.<sup>270</sup> The court began by reiterating the three-step approach to the rule of reason analysis:

The rule of reason analysis involves a three-step process. First, the plaintiff must prove that “the challenged action has had an actual adverse effect on competition as a whole in the relevant market.” Next, “the burden shifts to the defendant to establish the ‘pro-competitive redeeming virtues’ of the action.” If the defendant succeeds, the burden shifts back to the plaintiff to “show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition.”<sup>271</sup>

After a long, detailed analysis, the court held that plaintiffs failed to prove the first element, which was to show that the challenged action (the Agreements) had an actual adverse effect on competition as a whole in the relevant market.<sup>272</sup> The court did not go on to look at the second and third steps in the rule of reason analysis.<sup>273</sup> While the court agreed

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*restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding \$100,000,000 if a corporation, or, if any other person, \$1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.*

*See* 15 U.S.C. § 1 (2004).

269. CIPRO III, 363 F. Supp. 2d at 520.

270. *Id.* (“Resolution of this issue requires a close look at the intersection of patent and antitrust laws.”).

271. *Id.* (quoting *K.M.B. Warehouse Distribs., Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 127 (2d Cir. 1995)).

272. *Id.* at 541. In antitrust inquiries, the starting point usually is to define the relevant market. *Id.* at 521. The goal of this important inquiry is to determine whether defendants possess the ability to lessen or destroy competition, that is, whether the defendants possess market power. *Id.* The relevant power analysis may be side-stepped if a plaintiff can “show by direct evidence ‘an actual adverse effect on competition.’” *Id.* (quoting *Geneva v. Barr*, 386 F.3d 485, 509 (2d Cir. 2004)). The court held that:

[g]iven Bayer’s obvious ability to control prices, and its admission that it did not anticipate a commensurate drop in its own production costs for Cipro, it [was] reasonable to accept plaintiffs’ contention and conclude both that the relevant market is for ciprofloxacin and that Bayer had market power within that market.

*Id.* at 523

273. *Id.* at 541.

Because plaintiffs have not shown that the Agreements had anti-competitive effects beyond the scope of the ‘444 Patent, it is not necessary to address the second and third steps of the rule-of-reason analysis — whether defendants can establish the “pro-competitive redeeming virtues” of the Agreements, and whether plaintiffs can

that the Agreements restrained competition, the court did not believe that restraint on competition was beyond the scope allowed by patent law.<sup>274</sup> According to the court:

Here, plaintiffs have failed to demonstrate anti-competitive effects in the market for ciprofloxacin because, although the Agreements undoubtedly restrained competition, they did not do so beyond the scope of the claims of the '444 Patent. The '444 Patent allows a zone of exclusion within the bounds of its claims, and that zone is undiminished by any potential invalidity of the claims. This result is compelled by the presumption of validity Congress accorded patents and the destabilizing effect on patent law that a contrary decision would work. Any readjustment of the competing interests affected by exclusion payments is a matter better addressed by Congress than the courts.<sup>275</sup>

What about the potential harmful effect of patent monopoly on the price of drugs and the ultimate consumers?<sup>276</sup> In the opinion of the court, the ability to charge supracompetitive prices is a legitimate reward of the patent monopoly and is at the core of the patentee's rights.<sup>277</sup> The court was also unmoved by the amount of money (\$398 million) involved in the Settlement Agreements, holding only that "[t]he fact that Bayer paid what in absolute numbers is a handsome sum to Barr to settle its lawsuit does not necessarily reflect a lack of confidence in the '444 Patent, but rather the economic realities of what was at risk."<sup>278</sup> Are parties to a settlement agreement required to preserve the public's inter-

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"show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition."

*Id.* (quoting *K.M.B. Warehouse Distributions*, 61 F.3d at 127).

274. *Id.* at 541. Coming to the question of the effect of the Agreements on competition, the court thought that the ultimate question and "the crux of the matter" was not whether Bayer and Barr "had the power to adversely affect competition for ciprofloxacin as a whole," but "whether any adverse effects on competition stemming from the Agreements were outside the exclusionary zone of the '444 Patent." *Id.* at 523. In other words, the court took as its starting point the fact that patents by their nature had adverse effect on competition. According to the court, "[i]t goes without saying that patents have adverse effects on competition." *Id.*

275. *Id.* at 548.

276. In the instant case, "[p]laintiffs complained that they have been doubly harmed by the Agreements: first by the exclusion of Barr from the market, and second by Bayer's passing on the cost of the settlement payment in the form of increased prices for Cipro." *Id.* at 540.

277. *Id.* ("However, if the Agreements themselves do not exceed the exclusionary power of the '444 Patent, any increased prices resulting from the Agreements are the result of the monopoly inherent in the patent.") (emphasis added). The court cited with approval *United States v. Studiengesellschaft Kohle*, 670 F.2d 1122 (D.C. Cir. 1981), which asserted that "an exclusion of competitors and charging of supracompetitive prices are at the core of the patentee's rights, and are legitimate rewards of the patent monopoly." *Id.* at 1128 (citing *Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964) (dictum)).

278. CIPRO III, 363 F. Supp. 2d at 540-41.

est in lower prices, as the plaintiff tried to argue?<sup>279</sup> The court responded in the negative. According to the court, “[s]uch a rule would only result in parties being less likely to reach settlements, aside from undermining well-settled principles of patent law.”<sup>280</sup> The fact that the ‘444 Patent was the subject of a successful re-examination by the U.S. Patent and Trademark Office undoubtedly weighed strongly in the mind of the court.

The CIPRO III decision raises some disturbing issues. Because the court found that the ‘444 Patent “gave Bayer the right to exclude competition entirely for ciprofloxacin for the term of the patent,” it ultimately concluded that “any conduct within the scope of the patent [was] exempt from antitrust scrutiny.”<sup>281</sup> The lesson learned is that given that patents by their nature have adverse effect on competition,<sup>282</sup> in crafting legislation, lawmakers must be extra careful to avoid leaving loop-holes that may be further explored by patent holders. Another lesson learned is that there are limitations in antitrust laws and that antitrust laws cannot be used to go after every type of anti-competitive practice.<sup>283</sup> The *Cipro* court did not adequately address the injustice that collusive agreements between brand-name companies and generic manufacturers may impose upon consumers, preferring to defer to Congress on the subject. As the leading antibiotic used to treat anthrax, the *Cipro* litigation created implications for national security, which is important, especially in these

279. *Id.* at 541.

280. *Id.* (noting that “to even attempt to quantify the public’s interest in a patent settlement between private parties would require devaluing patents across the board, a result that would contravene the presumption of validity afforded by Congress and impact the very way patent licenses are handled in countless daily transactions”).

281. *Id.* at 524.

282. See *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945) (noting that “a patent is an exception to the general rule against monopolies and to the right to access to a free and open market”); see also *Schering-Plough Corp. v. Fed. Trade Comm’n*, 402 F.3d 1056, 1065-66 (11th Cir. 2005) (“By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present.”).

283. *Id.* at 524 (observing that “any adverse effects within the scope of a patent cannot be redressed by antitrust law”). The court also considered the question of “whether and to what extent the validity of the patent should be a factor in appraising the legality of an exclusion payment, and what sort of inquiry into validity an antitrust court should make.” *Id.* In approaching the question, the court carried out a detailed examination of prior decisions by two federal circuits, two district courts and the Federal Trade Commission (“FTC”) on the subject. Ultimately, the court declined to engage in a post hoc assessment of the validity of the ciprofloxacin patent, concluding, based on cases examined, that courts “have generally agreed that an antitrust court need not make an independent assessment of the underlying patent’s validity.” *Id.* According to the court, “making the legality of a patent settlement agreement . . . contingent on a later court’s assessment of the patent’s validity might chill patent settlements altogether.” *Id.* at 529. The court also thought that such an approach “would undermine the presumption of validity of patents in all cases, as it could not logically be limited to drug patents, and would work a revolution in patent law.” *Id.*

troubling times when threats of international and domestic terrorism abound.<sup>284</sup>

b) FTC Enforcement Action: *Abbott/Geneva*<sup>285</sup>

*Abbott/Geneva*, a leading case settled by consent order, involved an agreement between Abbott Laboratories (“Abbott”)<sup>286</sup> and Geneva Pharmaceutical, Inc. (“Geneva”)<sup>287</sup> (collectively “*Abbott/Geneva*”) relating

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284. The argument put forth by public interest organizations is that assuming terrorists have access to strains of anthrax that are resistant to other readily available antibiotics and have the capacity to deliver anthrax to large numbers of people, public health could be seriously jeopardized if access to generic versions of Cipro is blocked and Bayer is unable to deliver large quantities of the drugs as they are needed by governments and the public. For example, see James Love, *Talking points on Cipro patent dispute*, at <http://www.cptech.org/ip/health/cl/cipro/talkingpoints.html> (Oct. 24, 2001). For interesting discussions on the intersection of patent law and terrorism especially as they relate to Cipro, see James Thuo Gathii, *Balancing Patent Rights and Affordability of Prescription Drugs in Addressing Bio-Terrorism: An Analysis of In re Cirpofloxacin Hydrochloride Antitrust Litigation*, 13 ALB. L.J. SCI. & TECH. 651 (2003); Grace K. Avedissian, Note and Comment, *Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of “Super-Terrorism”*, 18 AM. U. INT’L L. REV. 237 (2002); Daniel Goldberg, *Cornering the Market in a Post-9/11 World: The Future of Horizontal Restraints*, 36 J. MARSHALL L. REV. 557 (2003); Robert Shapiro, *Patent Infringement During a Time of National Emergency: Are Canadian, American and Mexican Governments Permitted to Do so Under Their Domestic Law, NAFTA and TRIPS; If so, at What Cost?* 18 WINDSOR REV. LEGAL & SOC. ISSUES 37 (2004).

285. *In re Abbott Labs.*, No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000) (decision and order for Abbott Labs.); *In re Abbott Labs.*, No. C-3946, 2000 WL 681849 (F.T.C.) (May 22, 2000) (decision and order for Geneva Pharms.). The complaints against Abbott Labs. and Geneva Pharms. are identical, and a copy of the complaint can be found in both decisions/orders. In addition, the orders are materially the same in substance and structure. Thus, further citations, unless otherwise indicated, will be only to the decision/order for Abbott Labs. The complaints may also be found on the Federal Trade Commission’s website: <http://www.ftc.gov/os/2000/05/c3945complaint.htm> (Abbott complaint); <http://www.ftc.gov/os/2000/05/c3946complaint.htm> (Geneva complaint). Each order may also be found on the Federal Trade Commission’s website: <http://www.ftc.gov/os/2000/05/c3945.do.htm> (Abbott order); <http://www.ftc.gov/os/2000/05/c3946.do.htm> (Geneva order).

286. According to its website, Abbott Laboratories was founded by Dr. Wallace C. Abbott over one hundred years ago and is considered today one of the world’s top health care companies; became a public company in 1929, with its financial performance ranking among the best in the world since then; achieved \$19.7 billion in worldwide sales in 1993; and has been named one of “America’s Most Admired Companies” every year since 1984 by FORTUNE Magazine. Abbott Labs., News and Media Center, Company Fact Sheet, at <http://www.abbott.com/news/facts/corp.cfm> (last visited Jan. 28, 2005).

287. As of December 1, 2003, Geneva Pharmaceuticals changed its name to Sandoz. See Media Release, Sandoz, Inc., Geneva Pharmaceuticals, Inc., Renamed Sandoz, Inc. (Dec. 1, 2003), [http://www.us.sandoz.com/site/en/company/news/pool/sandoz\\_name\\_launch.pdf](http://www.us.sandoz.com/site/en/company/news/pool/sandoz_name_launch.pdf). Geneva Pharmaceuticals, one of the leading pharmaceutical companies in the U.S., was a Novartis Company. Sandoz, a pharmaceutical company established in Switzerland in 1886, merged in 1996 with Ciba Geigy, forming Novartis Generics. The Sandoz, Inc. name change took place “to unite its [Novartis’] generics operations.” *Id.*

to Hytrin,<sup>288</sup> Abbott's pioneer brand-name drug.<sup>289</sup> The FTC complaint alleged that Abbott paid Geneva approximately \$4.5 million per month to delay the entry of its generic Hytrin product.<sup>290</sup> According to the FTC complaint, Abbott's initial patent encompassing terazosin HCL expired in 1994 or thereabouts.<sup>291</sup> Between 1993 and 1995, Geneva filed ANDAs for tablet and capsule forms of generic terazosin HCL<sup>292</sup> and was the first company to file an ANDA for each form.<sup>293</sup> Surprisingly, in early 1996, Abbott notified the FDA of a new Hytrin patent ('207 patent), which the FDA listed in the Orange Book.<sup>294</sup> In April 1996, Geneva filed a Paragraph IV Certification with the FDA and duly notified Abbott of the Paragraph IV certification.<sup>295</sup> On June 4, 1996, Abbott promptly sued Geneva, claiming patent infringement by Geneva's terazosin HCL tablet product.<sup>296</sup> By filing the lawsuit within the requisite forty-five day period, Abbott's lawsuit triggered a 30-month stay of final FDA approval of Geneva's tablet ANDA, lasting until December 1998.<sup>297</sup> However, as the first company to submit a Paragraph IV Certification for generic terazosin HCL, Geneva was also entitled to the 180-day period of exclusivity set forth in the Hatch-Waxman Act.<sup>298</sup>

The FTC complaint centered around an April 1, 1998, agreement between Abbott and Geneva. According to this agreement, Geneva agreed not to enter the market with either the generic terazosin HCL capsule or tablet product until the earlier of: "(1) the final resolution of the patent infringement litigation involving Geneva's terazosin HCL tablets product, including review through the Supreme Court; or (2) entry

288. Hytrin contains terazosin HCL, which is used principally to treat benign enlarged prostate and hypertension. See Complaint, *In re Abbott Labs*, No. C-3945, 2000 WL 681848, para. 10-11 (F.T.C. May 22, 2000).

289. See *id.* Hytrin was introduced in 1987 and was the only terazosin HCL product sold in the U.S. until mid-1999, when Geneva finally introduced its generic version. *Id.* para. 11. By 2000, total U.S. sales of terazosin HCL amounted to approximately \$540 million per year. *Id.* para. 10.

290. *Id.* paras. 26-27.

291. *Id.* para. 15.

292. Geneva filed its ANDA for a tablet form of generic terazosin HCL around January 1993 and its ANDA for a capsule form around December 1995. *Id.* para. 16.

293. *Id.*

294. *Id.* para. 17.

295. *Id.* By filing a Paragraph IV certification, Geneva was essentially claiming that its generic terazosin HCL products did not infringe any of Abbott's patents, including Abbott's newly listed '207 patent. *Id.*

296. *Id.* para. 18. It is significant that even though Geneva's capsule and tablet involved the same potential infringement issues, Abbott made no infringement claim against Geneva's capsule product. See *id.*

297. *Id.* para. 19.

298. See *id.* para. 23.

of another generic terazosin HCL product.”<sup>299</sup> At Abbott’s insistence, Geneva also agreed not to transfer, assign, or otherwise relinquish its right to the 180-day period of exclusivity.<sup>300</sup> In return, “Abbott agreed to pay Geneva \$4.5 million per month in non-refundable payments until a district court judgment in the parties’ patent infringement dispute.”<sup>301</sup> Why did Geneva enter such an agreement? To Geneva, the agreement represented the “‘best of all worlds,’ because [the company] obtained a risk-free ‘monetary settlement on an ongoing basis until the litigation was resolved’ and still could market its product exclusively for 180 days after the litigation was over.”<sup>302</sup>

As a result of the agreement, Geneva began receiving monthly payments of \$4.5 million from Abbott and refrained from entering the market with its generic terazosin HCL capsules, which was not under litigation.<sup>303</sup> Geneva also refrained from entering the market with its generic terazosin HCL capsules even after September 1998, when a U.S. district court granted its motion for summary judgment in its patent tablet litigation with Abbott and invalidated Abbott’s patent.<sup>304</sup> However, under the terms of its agreement with Abbott, “Geneva still could not enter the generic terazosin HCL market until after the Supreme Court either denied Abbott’s petition for certiorari or disposed of the patent infringement litigation.”<sup>305</sup> In August 1999, Abbott and Geneva canceled their agreement, perhaps as a result of the FTC investigation, and Geneva finally introduced its generic terazosin HCL capsule product into the marketplace on August 13, 1999.<sup>306</sup>

The FTC complaint alleged that the Abbot/Geneva agreement “acted with the specific intent that Abbott monopolize the relevant market, and engaged in overt acts . . . in furtherance of a conspiracy to monopolize the relevant market, in violation of Section 5 of the Federal Trade Commission Act.”<sup>307</sup> According to the FTC, the acts and practices of Abbott and Geneva “had the purpose or effect, or the tendency or

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299. *Id.* para. 26.

300. *Id.* para. 26.

301. *Id.* para. 27. Abbott and Geneva also agreed that “if the district court declared that Geneva’s tablet product did not or would not infringe any valid and enforceable claim of the ‘207 patent, Abbott would thereafter pay the \$4.5 million monthly payments into an escrow fund until the final resolution of the litigation.” *Id.* The understanding was that the money in the escrow fund would be ceded to the prevailing party. *Id.*

302. *Id.* para. 29.

303. *See id.* para. 30.

304. *Id.* para. 31.

305. *Id.* para. 33. On July 1, 1999, the United States Court of Appeals for the Federal Circuit affirmed the summary judgment in favor of Geneva. The Supreme Court denied certiorari on January 10, 2000. *Id.*

306. *Id.* para. 33.

307. *Id.* para. 41.

capacity, to restrain competition unreasonably and to injure competition by preventing or discouraging the entry of competition in the form of generic versions of Hytrin into the relevant market.”<sup>308</sup>

The case was resolved by consent order.<sup>309</sup> The orders prohibited Abbott and Geneva from entering into NDA/ANDA (brand/generic) Agreements in which: (1) the ANDA First Filer (generic) producer is prohibited from relinquishing its 180-day marketing exclusivity rights, or (2) the ANDA First Filer (generic) producer agrees to refrain from developing any drug product that has potential for FDA approval and that is not the subject of a patent infringement court action.<sup>310</sup> The companies were also required to obtain court approval for any agreements made in the context of an interim settlement of a patent infringement action that provided for payments to the ANDA First Filer (generic) in order to stay off the market, with advance notice to the Commission to allow it time to present its views to the court.<sup>311</sup> Finally, the companies were ordered to give advance notice to the Commission before reaching a similar agreement in non-litigation contexts.<sup>312</sup>

## 2. IMPROPER EXTENSION OF MONOPOLY

Brand-name manufacturers in the U.S. also delay generic competition through the use of improper Orange Book listing, which typically triggers the 30-month exclusivity period under the Hatch-Waxman Act. Improper monopoly extension achieved through the improper Orange Book listing strategy typically “involves abuse of the Hatch-Waxman process itself to restrain trade.”<sup>313</sup> Indeed, the FTC has found that sometimes brand-name drug manufacturers “act strategically to obtain *more than one* 30-month stay of FDA approval of a particular generic drug.”<sup>314</sup>

Improper Orange Book listing could be characterized as a fraud on consumers and the FDA because oftentimes brand-name companies, motivated solely by the desire to delay generic entry, falsely and knowingly list invalid patents. The problem arises because of a loophole in

308. *Id.* para. 34.

309. See *supra* note 285. The consent order in *Abbott Laboratories* is available at <http://www.ftc.gov/os/2000/03/abbott.do.htm>. The consent order in *Geneva Pharmaceuticals* is available at [http://www.ftc.gov/os/2000/03/geneva\\_d&o.htm](http://www.ftc.gov/os/2000/03/geneva_d&o.htm).

310. Order, *In re Abbott Labs*, No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000), § II.

311. *Id.* § III.

312. *Id.* § IV.

313. *Prepared Statement of The Federal Trade Commission on Competition in the Pharmaceutical Industry, Before the U.S. Senate Comm. on Commerce, Science, and Transportation*, 107th Cong. § III.B.1 (Apr. 23, 2002) [hereinafter *Prepared Statement of the FTC 2002*], available at <http://www.ftc.gov/02/2002/04/pharmtestimony.htm>.

314. *Prepared Statement of the FTC 2003*, *supra* note 198, § III.B. (emphasis provided).

the law. Under the Hatch-Waxman Act, not all patents are eligible for listing in the Orange Book and entitled to the special statutory 30-month stay. The Hatch-Waxman Act provides for listing only if two conditions are met. First, listing is called for if the patent "claims the drug . . . or a method of using such drug."<sup>315</sup> Second, listing is also called for if the patent is one "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner [of the patent] engaged in the manufacture, use, or sale of the drug."<sup>316</sup> The difference between listed patents and unlisted patents is that only the former triggers the automatic 30-month stay.<sup>317</sup>

Brand-name companies are increasingly exploiting loopholes in Hatch-Waxman and the FDA approval processes to the detriment of consumers. This arises because, despite the serious legal and competitive implications of Orange Book listings, "it is private parties, rather than the FDA, that in practice determine whether patents are listed."<sup>318</sup> Regarding the Orange Book listing, the role of the FDA is solely ministerial.<sup>319</sup> Not only is the role of the FDA ministerial, generic applicants have no right to bring an action to challenge an NDA holder's Orange Book listing as improper.<sup>320</sup> The overall result is that the FDA's listings do not create any presumption a patent is correct.<sup>321</sup> Nevertheless, as long as a patent remains listed, a brand-name company "can continue to benefit from the availability of an automatic 30-month stay of FDA approval of ANDAs, by initiating a patent suit against generic

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315. 21 U.S.C. § 355(b)(1) (2004); *see also* 21 U.S.C. §§ 355(c)(2), 355(j)(7)(A)(iii) (2004).

316. 21 U.S.C. §§ 355(b)(1); *see also* 21 U.S.C. 355(c)(2), 355(j)(7)(A)(iii) (2004).

317. *See* FED. TRADE COMM'N, IN THE MATTER OF BRISTOL-MYERS SQUIBB COMPANY: ANALYSIS TO AID PUBLIC COMMENT (noting that "[i]n the case of patents not eligible for listing in the Orange Book, a branded firm still can sue a generic company for patent infringement, but under ordinary federal litigation procedures and without the benefit of an automatic 30-month stay") [hereinafter IN THE MATTER OF BRISTOL-MYERS SQUIBB COMPANY], *available at* <http://www.ftc.gov/os/2003/03/bristolmyersanalysis.htm> (last visited Jan. 28, 2005). In the case of unlisted patents, to prevent the sale of the generic product before conclusion of a law suit, "a branded firm must obtain a preliminary injunction, which requires that it demonstrate a likelihood of success on the merits, among other factors." *Id.*

318. *Id.*

319. *Id.*

The FDA has repeatedly stated that its role in patent listings is solely ministerial and that it lacks the resources and expertise to scrutinize patent information in the Orange Book. Even when a generic applicant disputes a patent listing, the FDA merely asks the NDA holder to confirm that the listed patent information is correct. Unless the NDA holder itself withdraws or amends its listed patent information, the FDA will not remove the patent listings from the Orange Book.

*Id.* (citing *Am. Biosci., Inc. v. Thompson*, 269 F.3d 1077, 1080 (D.C. Cir. 2001)).

320. *See Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1329-33 (Fed. Cir. 2001).

321. *See Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 10 F. Supp. 2d 446, 456 (D.N.J. 1998) (stating that "the FDA's listing should not create any presumption that [a] patent was correctly listed").

applicants.”<sup>322</sup>

Because the FDA accepts the Orange Book listing at face value, brand-name companies can defraud the system through improper listing.<sup>323</sup> The net result is that “brand-name companies are increasingly listing in the Orange Book, and suing on, multiple patents, and that these are frequently patents that have been listed after an ANDA has been filed.”<sup>324</sup> In some cases, for example where the patent is obtained and listed after the generic applicant has filed its ANDA, multiple 30-month stays were possible.<sup>325</sup> In these cases, the FTC found that the delay of FDA approval beyond the first thirty months ranged from four to forty months.<sup>326</sup>

a) Private Litigation: *In re Buspirone Patent Litigation*<sup>327</sup>  
(Generic Company vs. Patentee)

In this case, competitors filed antitrust claims against Bristol-Myers Squibb Company (“BMS”)<sup>328</sup> alleging that the company engaged in anti-competitive conduct by improperly extending its monopoly over buspirone hydrochloride (“buspirone”), an anti-anxiety drug sold under the brand-name BuSpar. On February 14, 2002, District Judge John G. Koeltl granted in part and denied in part Bristol-Myers’s motion to dismiss the plaintiffs’ antitrust and related state law claims.

322. IN THE MATTER OF BRISTOL-MYERS SQUIBB COMPANY, *supra* note 317.

323. See, e.g., *Am. Biosci., Inc.*, 269 F.3d at 1080 (observing that the FDA “has refused to become involved in patent listing disputes, accepting at face value the accuracy of NDA holders’ patent declarations and following their listing instructions”).

324. IN THE MATTER OF BRISTOL-MYERS SQUIBB COMPANY, *supra* note 317.

325. See *id.*

326. See *id.*

327. *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002). To fully understand this case, one must also read other related patent dispute cases, all involving disputes over the use and sale of Buspirone. “On August 15, 2001, the Judicial Panel on Multidistrict Litigation consolidated for pre-trial purposes before [the U.S. District Court for the Southern District of New York] four patent actions, which had been consolidated under MDL-1410, and twenty-two antitrust actions, which had been consolidated under MDL-1413.” See *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 340, 342 (S.D.N.Y. 2002) (action by brand-name manufacturer, Bristol-Myers Squibb, against a competitor for the manufacture or sale of generic buspirone for use in accordance with the FDA-approved labeling instructions for BuSpar®).

328. Bristol-Myers Squibb Company is a pharmaceutical company headquartered in New York City. In 2004 it reported \$19.4 billion in global sales. Bristol-Myers Squibb Co., *About Us*, At a Glance, available at <http://www.bms.com/aboutbms/data/> (data as reported in the Bristol-Myers Squibb 2004 Annual Report). In 1980, BMS obtained a patent covering the use of buspirone for the treatment of anxiety (the “763 Patent”). Since 1986, when the FDA approved the drug for human use, BMS has been selling the product. *In re Buspirone Patent Litig.*, 185 F. Supp. 2d at 365.

Involved as the plaintiffs in the consolidated case are generic drug makers, direct purchasers of buspirone products, end-payers, consumer protection organizations or their representatives, and thirty states. *Id.* at 365-66.

The competitors alleged that BMS, by settling a patent infringement suit with Danbury Pharmacal, Inc. ("Danbury") and its affiliate Schein Pharmaceuticals, Inc. ("Schein") in 1994, "attempted to extend and/or extended an unlawful monopoly over [the market of] buspirone products," and that BMS "also entered into a conspiracy to restrain trade in [the buspirone] market" in violation of sections one and two of the Sherman Act.<sup>329</sup> The plaintiffs also alleged that BMS "attempted to extend and/or extended an unlawful monopoly over the market in buspirone tablets in violation of Section 2 of the Sherman Act by abusing a number of provisions of the Hatch-Waxman Amendments."<sup>330</sup> Plaintiffs alleged that through fraudulently filing its '365 Patent with the FDA, BMS caused the agency to list the patent in the Orange Book and, as a result, blocked generic competition with its BuSpar product. Essentially, the plaintiffs argued that the FDA was precluded from approving the generic version of buspirone once BMS listed its '365 Patent in the Orange Book.<sup>331</sup> Specifically, the plaintiffs alleged that BMS made a bad faith attempt to interfere with the generic competitors' entry into the buspirone market by listing the '365 Patent in the Orange Book, on November 21, 2000, less than one day before the '763 Patent expired and by falsely and fraudulently representing to the FDA that the new '365 Patent covered new uses of buspirone and that a reasonable claim of patent infringement could be asserted against generic producers of the drug.

BMS moved to dismiss all the antitrust claims, citing as one of basis for the motion the *Noerr-Pennington* doctrine.<sup>332</sup> The motion to dismiss was granted in part and denied in part. The *Noerr-Pennington* doctrine was articulated by the United States Supreme Court in *Eastern*

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329. *In re Buspirone Patent Litig.*, 185 F. Supp. 2d at 366. In the patent infringement suit by BMS against Danbury and Schein, BMS "argued that Schein would infringe the '763 Patent by manufacturing and selling generic buspirone tablets before the '763 Patent expired." *Id.* The case ultimately settled with BMS paying the defendants \$72.5 million. In the present case, plaintiffs allege that the 1994 settlement by BMS "was a sham used to cover up an unlawful anti-competitive arrangement under which Schein agreed to stay out of the buspirone market and help maintain a public perception that the '763 Patent was valid." *Id.*

330. *Id.* The Hatch-Waxman Amendments are "also known as the Drug Price Competition and Patent Term Restoration Act." *Id.*

331. *See id.* at 366.

332. A detailed analysis of the *Noerr-Pennington* doctrine is beyond the scope of this article. For literature on the subject, see Robert A. Zauzmer, Note, *The Misapplication of the Noerr-Pennington Doctrine in Non-Antitrust Right to Petition Cases*, 36 STAN. L. REV. 1243 (1984); James S. Wrona, *A Clash of Titans: The First Amendment Right To Petition vs. The Antitrust Laws*, 28 NEW ENG. L. REV. 637 (1994); Jeff McGoff, Note, *Exploring the Boundary of the Noerr-Pennington Doctrine in the Adjudicative Process*, 34 U. MEM. L. REV. 429 (2004); Russell Wofford, *Considering the "Pattern Litigation" Exception to the Noerr-Pennington Antitrust Defense*, 49 WAYNE L. REV. 95 (2003).

*Railroad Presidents Conference v. Noerr Motor Freight, Inc.*,<sup>333</sup> and *United Mine Workers v. Pennington*.<sup>334</sup> Essentially, the *Noerr-Pennington* doctrine provides immunity from antitrust liability to individuals who petition the government to take actions even when the petition is motivated by self-interest and the governmental action desired imposes restraints on trade.<sup>335</sup> In *Noerr*, the Supreme Court took as its starting point the rule that “no violation of the [Sherman] Act can be predicated upon mere attempts to influence the passage or enforcement of laws.”<sup>336</sup> The Court went on to hold that “the Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly.”<sup>337</sup>

First Amendment considerations underpin this rule.<sup>338</sup> According to the Supreme Court, to hold that the Sherman Act forbids associations for the purpose of influencing the activity of a branch of the government “would raise important constitutional questions” because “[t]he right of petition is one of the freedoms protected by the Bill of Rights.”<sup>339</sup> The *Noerr-Pennington* doctrine extends to petitioning activity before administrative agencies and courts.<sup>340</sup>

There are exceptions to the *Noerr-Pennington* immunity. “Sham” petitions are not immunized.<sup>341</sup> According to the Supreme Court, where petitioning activity “ostensibly directed toward influencing governmental action, is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competi-

333. *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961).

334. *United Mine Workers v. Pennington*, 381 U.S. 657 (1965).

335. David L. Meyer, Note, *A Standard for Tailoring Noerr-Pennington Immunity More Closely to the First Amendment Mandate*, 95 YALE L.J. 832 (1986) (observing that the *Noerr-Pennington* doctrine “provides antitrust immunity for all genuine efforts to seek governmental action, regardless of whether the petitioning produces incidental injury to competition or the governmental action sought is legitimate and thus immune from antitrust liability”).

336. *Noerr*, 365 U.S. at 135.

337. *Id.* at 136.

338. Rosenfeld, Meyer & Susman, LLP, Newsletters, *U.S. Supreme Court Narrows “Sham Exception” to Noerr-Pennington Doctrine*, Aug. 1993 (observing that “[t]he First Amendment protects the right to petition the government, even when the petition is motivated purely by self-interest”), at <http://www.rmslaw.com/newsletters/art20.htm>.

339. *Noerr*, 365 U.S. at 138.

340. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 509, 510-11 (1972); Rosenfeld, Meyer & Susman LLP, *supra* note 338 (noting that “*Noerr-Pennington* protection extends to the filing of lawsuits for anti-competitive purposes”).

341. See generally Lawrence D. Bradley, *Noerr-Pennington Immunity From Antitrust Liability Under Clipper Express v. Rocky Mountain Motor Tariff Bureau, Inc.: Replacing the Sham Exception with a Constitutional Analysis*, 69 CORNELL L. REV. 1305 (1984); Ann K. Wooster, “Sham” Exception to Application of *Noerr-Pennington Doctrine*, *Exempting from Federal Antitrust Laws Joint Efforts to Influence Governmental Action Based on Petitioning Legislative or Executive Body*, 177 A.L.R. FED. 371 (2002).

tor[,] . . . the application of the Sherman Act would be justified.”<sup>342</sup> A “sham” litigation is one which is “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits”<sup>343</sup> and which “conceals an attempt to interfere directly with the business relationships of a competitor through the use [of] the governmental process — as opposed to the outcome of that process — as an anticompetitive weapon.”<sup>344</sup>

An additional exception to *Noerr-Pennington* immunity exists for conduct in which a party knowingly and willfully makes false representations to the government (the fraud exception).<sup>345</sup> In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.* (*Walker Process*),<sup>346</sup> the Supreme Court held that a party that had monopolized a market through threats of suit, and through a subsequent patent infringement suit based on a patent that the party had obtained by making fraudulent representations to the Patent Office, did not qualify for *Noerr-Pennington* immunity.<sup>347</sup> The *Walker Process* exception can independently strip a patent holder of *Noerr-Pennington* immunity.<sup>348</sup>

In the instant case, BMS argued that its conduct “in listing the ‘365 Patent in the Orange Book and bringing its subsequent patent infringement suits against [competitors] Mylan and Watson [was] immunized from federal antitrust liability under *Noerr-Pennington* standards.”<sup>349</sup> After reiterating the *Noerr-Pennington* rule and its accompanying exceptions, the district court concluded that under current Federal Circuit law, a patent holder who seeks to enforce a patent through litigation can lose *Noerr-Pennington* immunity in two ways:

first, if the asserted patent was obtained through knowing and willful fraud within the meaning of *Walker Process*, and if the plaintiff in the patent infringement suit was aware of the fraud when bringing suit; or second, if the patent infringement suit was a mere sham . . .

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342. *Noerr*, 365 U.S. at 144 (emphasis added); see also *Trucking Unlimited*, 404 U.S. at 515 (“First Amendment rights may not be used as the means or the pretext for achieving ‘substantive evils’ which the legislature has the power to control.”) (citations omitted).

343. *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993).

344. *Id.* at 60-61 (emphasis omitted) (quoting *Noerr*, 365 U.S. at 144 and *Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 380 (1991)).

345. See generally Daniel J. Davis, Comment, *The Fraud Exception to the Noerr-Pennington Doctrine in Judicial and Administrative Proceedings*, 69 U. CHI. L. REV. 325 (2002).

346. *Walker Process Equip., Inc. v. Food Machinery & Chemical Corp.* 382 U.S. 172 (1965).

347. See *id.* at 174-78.

348. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998) (holding in a limited en banc ruling that it is a question of Federal Circuit law whether the fraudulent procurement of a patent and its subsequent use to generate anti-competitive injuries through suits and threats of suit are sufficient to strip a patentee of *Noerr-Pennington* immunity).

349. *In re Busirone Patent Litig.*, 185 F. Supp. 2d 363, 369 (S.D.N.Y. 2002).

namely that it was objectively baseless and subjectively motivated by a desire to impose collateral, anti-competitive injury rather than to obtain a justifiable legal remedy.<sup>350</sup>

Does the *Noerr-Pennington* doctrine apply to Bristol-Myers's conduct in listing the '365 Patent in the Orange Book? According to the district court, the answer depends on whether listing patents in the Orange Book would be considered a petitioning activity for *Noerr-Pennington* purposes.<sup>351</sup> In deciding whether a particular type of conduct is petitioning activity for *Noerr-Pennington* purposes, the court ruled that it was "critical to distinguish between activities in which the government acts or renders a decision only after an independent review of the merits of a petition and activities in which the government acts in a merely ministerial or non-discretionary capacity in direct reliance on the representations made by private parties."<sup>352</sup> According to the court, the *Noerr-Pennington* doctrine:

is not applicable to conduct through which private parties seek to achieve anticompetitive aims by making representations to the government in circumstances where the government does not perform any independent review of the validity of the statements, does not make or issue any intervening judgment and instead acts in direct reliance on the private party's representations.<sup>353</sup>

Ultimately, the district court concluded that BMS's activities in listing the '365 Patent in the Orange Book were not acts of petitioning because the FDA's actions in connection with the listings "[were] non-discretionary and [did] not reflect any decision as to the validity of the representations in an Orange Book listing."<sup>354</sup>

350. *Id.*

351. *Id.* BMS argued that the listing in the Orange Book met the requisite criteria "because it was a request for governmental action, specifically, for the FDA to publish the information submitted to it in the Orange Book." *Id.*

352. *Id.* at 369.

One of the reasons for extending *Noerr-Pennington* immunity to acts through which private parties seek to influence governmental decisions in the first class of cases is that these private parties can often only obtain the anticompetitive effects in question by first convincing the government of the merits of their views and by obtaining a valid and independent governmental decision, which intervenes between the private parties' actions and these anticompetitive results.

*Id.* at 369-70.

353. *Id.* at 370. The court uses *Litton Sys., Inc. v. AT&T Co.*, 700 F.2d 785 (2d Cir. 1983), as an example. In *Litton*, "the Second Circuit held that AT&T's filing of an interface tariff with the Federal Communications Commission . . . was not petitioning activity for *Noerr-Pennington* purposes." *In re Busirone Patent Litig.*, 185 F. Supp. 2d at 370.

354. *Id.* at 371. The court cited as examples supporting its conclusion: *American Biosci., Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001) ("[The FDA] administers the Hatch-Waxman Amendments in a ministerial fashion simply following the intent of the parties that list patents."); *Watson Pharms., Inc. v. Henney*, 194 F. Supp. 2d 442 (D. Md. 2001):

The district court further held that even if the *Noerr-Pennington* doctrine applied to BMS's activities, the antitrust plaintiffs, Mylan and Watson, had "pleaded sufficient facts to warrant an exception to immunity under the reasoning set forth in *Walker Process*."<sup>355</sup> For the district court, the question was "whether the *Walker Process* exception would apply to a fraudulent listing of a patent in the Orange Book along with subsequent lawsuits seeking to exploit the listing for anticompetitive advantage."<sup>356</sup> While noting that neither the Supreme Court nor the Court of Appeals for the Federal Circuit has addressed the question, the court observed that "in creating the *Walker Process* doctrine, the Supreme Court explained that a claim alleging an initial fraud on the Patent Office would avoid *Noerr-Pennington* immunity for a number of reasons that are directly applicable to fraudulent listings in the Orange Book."<sup>357</sup> Paramount in the mind of the court was the fact that "listing submissions, like patent applications, are not adversarial proceedings, subject to the same kind of rigorous adversarial testing as in litigation."<sup>358</sup>

Applying the standard set forth in *Professional Real Estate Investors, Inc.*<sup>359</sup> to the Orange Book listing and the subsequent litigations, the court held that "there was no objective basis for Bristol-Myers to claim that the '365 Patent claimed the use of buspirone, or that the Pat-

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[I]t is paramount to keep in mind that the FDA, in deciding to make an Orange Book listing, is *not* acting as a patent tribunal. It has no expertise — much less any statutory franchise — to determine matters of substantive patent law. . . . In making its decision to list a patent, therefore, it is entirely appropriate and reasonable for the FDA to rely on the patentee's declaration as to the coverage.

*Id.* at 445; Mylan Pharms., Inc. v. Thompson, 139 F. Supp. 2d 1, 10-11 (D.D.C. 2001), *rev'd on other grounds*, 268 F3d 1323 (Fed. Cir. 2001) (noting that the FDA's role in listing patents is purely ministerial).

355. *In re Buspirone Patent Litig.*, 185 F. Supp. 2d at 373. The plaintiffs did not argue that the '365 Patent was fraudulently obtained, but rather that BMS "engaged in fraud on the FDA by . . . claiming that the Patent covered the approved uses of buspirone, when Bristol-Myers knew that these statements were false." *Id.* The plaintiffs also contended that BMS "pursued patent infringement suits against Mylan and Watson and obtained an automatic stay of the FDA's approval of their products, with knowledge that the stay was obtained by making false statements to the FDA." *Id.*

356. *Id.*

357. *Id.*

358. *Id.* at 373-74.

The FDA is required by law to perform even less independent review of the statements made in a listing submission than the Patent Office performs in the patent application review process, thus making the risks of abuse greater. Hence, even if listing were petitioning, the *Walker Process* exception would apply to Bristol-Myers's alleged conduct in this case.

*Id.* at 374.

359. *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993).

ent could have been valid if it did.”<sup>360</sup> “The test for objective baselessness is by definition an objective one.”<sup>361</sup> According to the court:

This is, moreover, not a case in which there are occasional places in which Bristol-Myers has mischaracterized or mistaken the relevant issues or legal standards. It is a case where Bristol-Myers has repeatedly argued for a position that requires establishing a number of claims, each one of which has no basis, and each one of which depends upon reframing or mischaracterizing some critical issue or legal standard for its apparent cogency. This is also not a case in which Bristol-Myers has been arguing for reasonable extensions or developments of the law. Bristol-Myers has taken the straightforward position that it can, in effect, extend a monopoly and reclaim an invention after the expiration of its patent on the invention, when “[i]t is self-evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property.” The public has already paid for its right to these uses by the grant of a limited patent monopoly to Bristol-Myers, which has expired. Bristol-Myers’s argument ignores the law and tries to justify taking property that belongs to the public.<sup>362</sup>

In view of the reasoned analysis above, the district court deemed it “unnecessary to decide whether the *Noerr-Pennington* doctrine applie[d] to some or all of the related state law claims arising out [of] Bristol-Myers’s listing conduct and subsequent patent infringement suits.”<sup>363</sup> The court also did not rule on the qualified immunity argument put forth by BMS,<sup>364</sup> holding only that the plaintiffs’ allegations that BMS’s “conduct in listing the ‘365 Patent in the Orange Book and bringing the subsequent patent infringement suits against Mylan and Watson was performed in bad faith and with knowledge that the ‘365 Patent does not cover uses of buspirone” and that “[t]hese facts, if proven, would be

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360. *In re Buspirone Patent Litig.*, 185 F. Supp. 2d at 376.

The language of the claim, its specification and the prosecution history all demonstrate beyond all reasonable dispute that the ‘365 Patent does not cover the use of buspirone. Moreover, a straightforward application of governing patent law provisions establishes that the ‘365 Patent would have been invalid if it did. Bristol-Myers’s creative legal arguments to the contrary cannot breathe life into claims that have no basis.

*Id.*

361. *Id.* at 375 (“It is not what the parties think of the merits of their position that matters; it is whether there are, in fact, sufficient objective bases for the positions taken.”).

362. *Id.* at 376 (citations omitted) (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989)).

363. *Id.*

364. Bristol-Myers argued that all of the claims arising out of the ‘365 Patent activities should be dismissed because “patent owners enjoy a qualified immunity when they act in good faith to protect their patent rights.” *See id.*

sufficient to strip Bristol-Myers of any qualified patent immunity.”<sup>365</sup> The case is still pending.

#### b) FTC Enforcement Action

i. *Biovail (Tiazac)*<sup>366</sup> The first FTC enforcement action to attempt to remedy the effects of an allegedly anti-competitive Orange Book listing was against Biovail Corporation (“Biovail”).<sup>367</sup> In the complaint, the FTC charged that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent in the Orange Book for the purpose of blocking generic competition to its branded drug Tiazac.<sup>368</sup> As a result of the listing, Biovail was able to bring an infringement lawsuit against Andrx, triggering a 30-month stay of FDA final approval of Andrx’s generic Tiazac product.<sup>369</sup> According to the FTC complaint, Biovail knew that the new patent did not claim the form of Tiazac that it had been marketing, and Biovail did not need this new patent to continue marketing Tiazac without infringement risk.<sup>370</sup> The FTC further alleged that Biovail misleadingly represented to the FDA that the new patent claimed Tiazac existing-and-approved, rather than revised-and-unapproved, to avoid de-listing from the Orange Book and termination of the stay against Andrx.<sup>371</sup> According to the complaint, Biovail’s patent acquisition, wrongful Orange Book listing, and misleading conduct before the FDA were acts in unlawful maintenance of its Tiazac monopoly, in violation of section five of the FTC Act<sup>372</sup> and section seven of the Clayton Act.<sup>373</sup>

On April 23, 2002, the FTC announced that it had accepted for public comment an agreement and proposed consent order with Biovail Corporation.<sup>374</sup> The consent order required Biovail to divest the illegally acquired patent to its original owner, dismiss its infringement case against Andrx (thus allowing entry of generic Tiazac), and refrain from

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365. *Id.* at 376-77.

366. Complaint, *In re Biovail Corp.*, No. C-4060, 2002 WL 727033 (F.T.C. Apr. 23, 2002), available at <http://www.ftc.gov/os/2002/04/biovailcomplaint.htm>.

367. Biovail Corporation describes itself as a “full-service pharmaceutical company, engaged in the formulation, clinical testing, registration, manufacturing, sale and promotion of pharmaceutical products.” Biovail Corp., About Biovail, at <http://www.biovail.com> (last visited Jan. 28, 2005).

368. Complaint, *In re Biovail Corp.*, 2002 WL 727033, para. 1.

369. *Id.* para. 26.

370. *Id.* para. 36.

371. *Id.* paras. 42-44.

372. *Id.* paras. 54-57. Section 5 of the FTC Act is found at 15 U.S.C. § 45 (2000).

373. Complaint, *In re Biovail Corp.*, 2002 WL 727033, paras. 50-53. Section 7 of the Clayton Act is found at 15 U.S.C. § 18 (2000).

374. Order, *In re Biovail Corp.*, No. C-4060, 2002 WL 727033 (F.T.C. Apr. 23, 2002), available at <http://www.ftc.gov/os/2002/10/biovaildo.pdf>.

further action that might trigger another 30-month stay on generic Tiazac entry.<sup>375</sup> The consent order also required Biovail to give the FTC prior notice of patent acquisitions that it intended to list in the Orange Book for Biovail's FDA-approved products.<sup>376</sup>

ii. *In re Bristol-Myers Squibb Company*<sup>377</sup> In an April 18, 2003 complaint,<sup>378</sup> the FTC charged that BMS engaged in a series of unlawful acts to delay competition from generic versions of three of its major drug products.<sup>379</sup> The FTC subsequently announced that it had accepted for public comment an agreement and proposed consent order with BMS, which was intended to settle the charges against the company.<sup>380</sup> In its complaint, the FTC alleged that BMS abused FDA processes in order to block generic competition to the three prescription drugs, and that it misused the regulatory scheme established by Congress to accelerate generic drug approval.<sup>381</sup> At issue was BMS's activities relating to three of its prescription drug products: BuSpar, an anti-anxiety agent, and Taxol and Platinol, two anti-cancer drugs.<sup>382</sup> The action involving BuSpar is discussed here.

BMS began selling BuSpar in 1986, and by 2000, BuSpar sales in the United States were over \$600 million.<sup>383</sup> The FTC complaint alleged that in anticipation of the expiration of its '763 BuSpar Patent in November 2000, BMS filed a new patent application with the Patent and Trademark Office ("PTO") in 1999, involving the use of buspirone to create the metabolite of buspirone.<sup>384</sup> After repeated rejection of its patent application by the PTO,<sup>385</sup> BMS succeeded in obtaining a patent ('365 Patent) only hours before '763 BuSpar Patent was about to expire and proceeded to submit the '365 Patent details to the FDA for listing in the Orange Book.<sup>386</sup> The complaint further alleged that BMS's '365 Patent did not meet either of the statutory requirements for listing a pat-

375. *Id.* § IV.

376. *Id.* § VIII.

377. *In re Bristol-Meyers Squibb Co.*, No. C-4076, (F.T.C. Apr. 18, 2003).

378. Complaint, *In re Bristol-Meyers Squibb Co.*, No. C-4076 (F.T.C. Apr. 14, 2003), available at <http://www.ftc.gov/os/2003/04/bristolmyerssquibbcomp.pdf>.

379. *Id.* para. 1.

380. Order, *In re Bristol-Meyers Squibb Co.*, No. C-4076 (F.T.C. Apr. 14, 2003), available at <http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf>.

381. Complaint, *In re Bristol-Meyers Squibb*, No. C-4076, para. 2.

382. *Id.* paras. 4-6.

383. *See id.* para. 4.

384. *Id.* para. 45. A metabolite is the new molecule created when a pharmaceutical agent breaks down in the body.

385. *See id.* paras. 37-44.

386. *Id.* paras. 45-47. BMS was repeatedly rejected by the PTO because the company had been making and selling BuSpar to treat anxiety in the U.S. for nearly fourteen years. Patent '365 was issued only after BMS requested "a patent that claimed solely the use of the metabolite of

ent in the Orange Book because it "(1) [did] not claim BuSpar or a method of using BuSpar, and (2) it is not one with respect to which a claim of patent infringement could reasonably be asserted against someone selling BuSpar."<sup>387</sup> Furthermore, the complaint alleged that "even though [BMS] knew that the patent covered only a method of using a metabolite, and not a method of using buspirone itself,"<sup>388</sup> it nonetheless declared to the FDA that the '365 Patent claimed a method of using BuSpar in order to list the patent in the Orange Book.<sup>389</sup> Worse, after ANDA filers on BuSpar asserted to the FDA that the '365 Patent did not meet the criteria for listing in the Orange Book, BMS intentionally made an additional false and misleading statement.<sup>390</sup> The FDA, without making any independent determination regarding the scope and coverage of the '365 Patent, accepted at face value BMS's statements and, as of November 21, 2000, deemed the '365 Patent listed in the Orange Book.<sup>391</sup> The FTC complaint charged that BMS "knew that its representations to the FDA - to the effect that the '365 patent claimed a method of using buspirone - were false and misleading, . . . [yet] made these misrepresentations purposely and intentionally, to obtain wrongfully an Orange Book listing of the '365 patent."<sup>392</sup> As a result of its wrongful listing in the Orange Book, BMS "illegitimately acquired the ability to trigger a 30-month stay, thereby delaying entry of generic buspirone, and depriving consumers of lower prices and other benefits of competition."<sup>393</sup> It is pertinent to note that generic competition to BuSpar occurred only after the '365 Patent was removed from the Orange Book in March 2001 following a district court decision ordering BMS to seek de-listing.<sup>394</sup>

The FTC also alleged that the patent infringement suits BMS

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buspirone - not the use of buspirone itself." IN THE MATTER OF BRISTOL-MYERS SQUIBB COMPANY, *supra* note 317, § B.

387. Complaint, *In re Bristol-Meyers Squibb*, No. C-4076, para. 50.

388. *Id.* para. 47.

389. See IN THE MATTER OF BRISTOL-MYERS SQUIBB COMPANY, *supra* note 317, § A.

390. See Complaint, *In re Bristol-Meyers Squibb*, No. C-4076, paras. 52-55.

The FDA asked BMS to provide a declaration that the '365 patent contains a claim for an approved use of buspirone. BMS responded with a declaration expressly affirming that the '365 patent does in fact claim the approved uses of buspirone, a statement that was false and directly contradicted representations BMS made to the PTO to obtain the '365 patent.

IN THE MATTER OF BRISTOL-MYERS SQUIBB COMPANY, *supra* note 317, § A,

391. Complaint, *In re Bristol-Meyers Squibb*, No. C-4076, para. 57.

392. *Id.* para. 58.

393. *Id.*

394. Mylan Pharms., Inc. v. Thompson, 139 F. Supp. 2d 1 (D.D.C. 2001). Later that year in *Mylan Pharms., Inc. v. Thompson*, the Federal Court reversed on jurisdictional grounds, holding that no private right of action existed under the Federal Food, Drug, and Cosmetic Act to seek de-listing. *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1329-33 (Fed. Cir. 2001),

brought against ANDA filers for infringement of the '365 Patent "were objectively baseless" and filed without regard to their merits,"<sup>395</sup> and that the intent and effect of BMS's suits "was to prevent generic buspirone manufacturers from marketing their products for as long as possible, through wrongfully triggering of the 30-month stay."<sup>396</sup> Entry of a lower-priced generic version of BuSpar would have "significantly and immediately decreased BMS's BuSpar sales and market share, and led to a substantial reduction in the average price paid for buspirone products,"<sup>397</sup> hence the motivation to game the system. The FTC thus charged BMS with engaging in acts that willfully maintained its monopolies in buspirone in violation of section five of the FTC Act.<sup>398</sup>

The consent order<sup>399</sup> bars BMS from seeking to list the '365 Patent in the Orange Book in relation to any NDA in which the active ingredient is buspirone.<sup>400</sup> The order also invokes general prohibitions "designed to deter improper listings and to prevent BMS from triggering the Hatch-Waxman automatic 30-month stay in circumstances that could improperly block generic entry."<sup>401</sup> The consent order also contains a general prohibition against making false statements to the FDA.<sup>402</sup> Regarding the allegations that BMS engaged in sham litigation, the consent order bars BMS from asserting "any fraudulent or objectively baseless claim"<sup>403</sup> or from enforcing "any patent that it knows is invalid, unenforceable, or not infringed."<sup>404</sup>

The Orange Book listing scheme established by the Hatch-Waxman Act naively assumed that brand-name companies (as NDA holders) would act in good faith in listing patents.<sup>405</sup> However, there is mounting evidence that listings are made in bad faith (to block generic competition) and are not based on a reasonable, good faith belief that the patents

395. Complaint, *In re Bristol-Meyers Squibb*, No. C-4076, para. 59.

396. *Id.* para. 60.

397. *Id.* para. 65.

398. *Id.* paras. 135-39.

399. Order, *In re Bristol-Meyers Squibb Co.*, No. C-4076 (F.T.C. Apr. 14, 2003), available at <http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf>.

400. *Id.* § II.

401. IN THE MATTER OF BRISTOL-MYERS SQUIBB COMPANY, *supra* note 317. For example, Paragraph VI bars BMS from seeking or maintaining Orange Book listings where the listing of such patent is unlawful. Order, *In re Bristol-Meyers Squibb Co.*, No. C-4076, § VI. Paragraph VII bars BMS from taking any action to obtain or maintain a 30-month Hatch-Waxman stay on FDA approval in certain specified situations. *Id.* § VII.

402. Order, *In re Bristol-Meyers Squibb Co.*, No. C-4076, § VIII. The purpose was "[t]o ensure that BMS does not seek to obstruct generic competition through false statements to the FDA outside the Orange Book listing context, such as through the citizen petition process." IN THE MATTER OF BRISTOL-MYERS SQUIBB COMPANY, *supra* note 317.

403. Order, *In re Bristol-Meyers Squibb Co.*, No. C-4076, § IX.A.

404. *Id.* § IX.B.

405. See IN THE MATTER OF BRISTOL-MYERS SQUIBB COMPANY, *supra* note 317.

listed are listable. As the FTC has noted, "the Orange Book listing scheme is susceptible to opportunistic behavior,"<sup>406</sup> and brand-name companies (as NDA holders) frequently exploit the listing scheme by obtaining patents and listing them in order to block FDA approvals of generic rivals when the NDA holder does not reasonably expect the patents to ultimately hold up in court.<sup>407</sup>

### C. Conclusion

The goal of this section was to highlight how a law enacted in part to stimulate generic competition, and thereby expand consumer access to cheaper alternative life-saving drugs, has been hijacked by brand-name drug manufacturers, sometimes in collusion with generic drug manufacturers. Brand-name drug companies have traditionally been viewed with suspicion. However, as the case studies highlight, generic drug companies are no saints either. Given the proper incentive, some generic drug companies may be willing to delay or disrupt competition and keep drug prices artificially high. Collusion between the generic companies is also possible and is increasingly the focus of FTC enforcement actions.<sup>408</sup>

It is disheartening that drug manufacturers can brazenly engage in fraudulent, anti-competitive practices in a country like the United States, a country with state-of-the-art antitrust laws, a plethora of consumer protection laws, a sound judicial system that provides avenues for those harmed to seek recourse, and a strong public regulatory and enforcement agency able to monitor the activities of the companies concerned, such as the FTC. None of these mechanisms are readily available at the global level. There is at present nothing to stop a pharmaceutical company intent on exploiting loopholes in the Doha Declaration and the 2003 Decision on Implementation from delaying generic competition.

In theory, the combined effect of the TRIPS Agreement, the Doha Declaration, and the 2003 Decision on Implementation will be that developing countries will have more opportunities to obtain essential

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406. *Id.*

407. *See id.*

408. *See Prepared Statement of the FTC 2002*, supra note 313, § III.C. The FTC has identified two potentially competition-reducing categories of agreements that merit the agencies close attention. The first involves exclusive distributorship arrangements, under which a second generic entrant, "rather than bringing a competing product to market, might agree to become the exclusive distributor of the first entrant. Such an arrangement would essentially grant the second entrant an agreed-upon share of the market." *Id.* The goal is to avoid aggressive price competition by dividing up the market. The second category involves division of market segments. *Id.* Under such an arrangement, the first generic agrees to market its product exclusively in one market, while the second entrant agrees to market exclusively in another. *Id.* Again, without having to vigorously compete, the companies can make greater profits in their respective markets. *See id.*

pharmaceutical products at reduced prices.<sup>409</sup> However, an examination of the nature and intensity of competition in the pharmaceutical sector in the U.S. suggests that abuse of patent rights is rife throughout the industry and that in many instances, brand-name pharmaceutical companies will deploy a host of abusive and anti-competitive practices in an effort to protect their market share and maximize their profit.

A study of on-going litigation in U.S. courts and antitrust enforcement actions brought by the FTC, including actions against both branded and generic drug manufacturers, indicates that generic drug companies are not paragons of virtue; given adequate incentive, some generic drug companies will engage in anti-competitive practices that ultimately hurt consumers. In the U.S., although the existence of antitrust and consumer protection laws and the regulatory force of the FTC has helped to keep abuses in the pharmaceutical industry to a bare minimum, companies are still finding ingenious ways to evade the law and the watchful eyes of the FTC. The obvious lesson is that frequently, well-intended laws are not enough to ensure that medicine is available to those who need it most.

Despite the laudable goals of the Doha Declaration and the 2003 Decision on Implementation, with respect to the war over access to medicine in developing countries, there are serious potentials for abuse in the industry. These abuses could ultimately work to deprive the suffering men and women in the Third World of the intended benefit of the two texts. In other words, as attention moves away from the emotive issue of HIV/AIDS and attempts are made to use compulsory licensing to secure the manufacture of drugs needed to treat other diseases, phar-

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409. Countries facing health emergencies can: (i) acquire needed medicine directly from brand-name pharmaceutical companies; (ii) acquire patented drugs through parallel marketing channels; (iii) ensure availability of generics through compulsory licensing that enables local manufacture; (iv) procure generics from another country through the compulsory licensing scheme established under the 2003 Decision on Implementation; and (v) acquire generic products from licensees of brand-name companies in situations where the company has voluntarily licensed its patent.

As explained above, where the prices of pharmaceutical products are lower in a foreign market, parallel importation permits a government to allow the importation of such products into the national market so as to offer drugs at more affordable prices. See *Submission by the African Group*, *supra* note 80, para. 25.

For developing countries, in particular, least-developed countries and smaller economies, "parallel importation" can be a significant way of increasing access to medications, where the prices charged by patent holders for their products are unaffordable. Moreover, in situations where the local manufacture of the product is not feasible, and therefore compulsory licences may be ineffective, parallel importation may be a relevant tool to ensure access to drugs.

*Id.* para. 26.

maceutical companies may be tempted to employ a host of abusive practices in an effort to safeguard their turf.

I envisage at least six possible types of abuses. First, collusive agreements between brand-name companies and generic drug companies may begin to emerge; under these international agreements, generic companies may agree to refrain from requesting compulsory licenses to manufacture generic versions of pharmaceutical products in return for payment or exclusive distribution arrangements. Second, collusive agreements between generic companies, under which the companies agree to inflate prices and engage in other monopolistic practices, may also begin to emerge. Third, abuses in the form of serious attempts by brand-name pharmaceutical companies to influence the decisions of eligible importing and exporting countries regarding whether and when to issue a compulsory license may begin to emerge. Fourth, the world may begin to see abuses in the form of attempts by brand-name companies to delay or block generic competition altogether by challenging the bioequivalence of generic drugs. Fifth, brand-name companies may attempt to undermine the 2003 Decision on Implementation by persistently raising questions about whether exporting countries and manufacturers have satisfied all the requirements stipulated in the Decision, particularly requirements relating to safeguard and anti-diversion.<sup>410</sup> Sixth, although a remote possibility, companies may also engage in false marketing practices aimed at either confusing the general public about the safety of generic drugs or discouraging doctors from prescribing generic drugs.

Abusive practices of multinational companies can adversely affect the trading environment in developing countries and burden consumers with inflated prices for pharmaceutical products. In the United States, the Sherman Act has been particularly useful in addressing monopolistic practices in the pharmaceutical sector. If and when pharmaceutical companies resort to practices which unreasonably restrain trade and adversely impede prompt access to generic drugs, what laws are available to address these practices? Do developing countries and least-developed countries have the requisite legal and institutional capacity to deal with domestic and transborder anti-competitive practices? Are there global trade rules that address potential abuses of patents by right holders? Is there a need for a multilateral agreement on competition? Should such an agreement be developed within the framework of the

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410. See, MÉDECINS SANS FRONTIÈRES, ONE STEP FORWARD, TWO STEPS BACK? ISSUES FOR THE 5TH WTO MINISTERIAL CONFERENCE (2003) 3, available at <http://www.accessmed-msf.org/documents/Pre-CancunBriefing.pdf>. The system may also be abused by governments. Pressure may be brought on developing countries to forgo their privilege under the Decision. Moreover, in the context of bilateral and regional trade negotiations, developed countries may push for tighter patent protection than is envisaged under TRIPS.

WTO? Will the development of such rules be in the overall interest of developing countries?

These questions are pertinent because the Doha Declaration and the 2003 Decision on Implementation cannot in and of themselves prevent the abuse of patent rights by drug companies. These questions will be briefly addressed in Section VI. As will be seen, many developing countries currently lack the necessary legislation and/or enforcement powers to deal with abusive practices of transnational corporations and are thus among the most vulnerable to the effects of anti-competitive activities of international cartels. At first glance, therefore, a multilateral rule on competition would appear to be in the interest of developing countries. A multilateral framework on competition policy could ensure that developing countries have the capacity and tools to deter and remedy anti-competitive practices. Paradoxically, developing countries have resisted efforts to negotiate a global competition rule within the framework of the WTO.

## VI. BETWEEN THE DEVIL AND THE BLUE SEA: IS A GLOBAL COMPETITION RULE THE ANSWER?

In this section, I examine existing global trade rules that address anti-competitive behavior in the pharmaceutical sector, evaluate current efforts towards the development of a global competition rule within the framework of the WTO, and highlight the special concerns of developing countries regarding these initiatives.

### A. *The Treatment of Abusive and Antitrust Practices under the TRIPS Agreement*

Several provisions of the TRIPS Agreement address anti-competitive practices by private actors.<sup>411</sup> Article 8(2) stipulates: "Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."<sup>412</sup> In granting a compulsory license under Article 31 of the TRIPS Agreement to remedy an adjudicated violation of competition, a WTO Member may ignore some of the conditions stipulated in the Agreement

411. See MATTHEWS, *supra* note 22, at 65 (observing that during negotiations for the TRIPS Agreement, developing countries pushed for the inclusion of anti-competitive measures).

412. TRIPS Agreement, *supra* note 4, art. 8(2). See MATTHEWS, *supra* note 22, at 65 (noting that Article 8(2) is broad and is designed to address the abuse of contractual licensing agreements).

that are intended to safeguard the interests of the patent holder.<sup>413</sup> Furthermore, in determining the amount of remuneration to be paid in such cases, "[t]he need to correct anti-competitive practices may be taken into account."<sup>414</sup>

Concerned that patent holders may attempt to impose anti-competitive provisions in contractual licensing agreements, Article 40(2) allows WTO Members to specify in their legislation "licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market."<sup>415</sup> Members may also "adopt, consistently with the other provisions of [the TRIPS] Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member."<sup>416</sup> Article 40 also establishes a "mechanism for

413. TRIPS Agreement, *supra* note 4, art. 31. Article 31(k) of TRIPS exempts Members from applying the conditions in subparagraphs Art. 31(b) and Art. 31(f) "where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive." *Id.* Otherwise, subsections b and f of Article 31 will apply.

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder . . . the following provisions shall be respected:

. . .

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

. . .

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.

*Id.*

414. *Id.* art. 31(k).

415. *Id.* art. 40(2).

416. *Id.* A WTO Member who has cause to believe that an intellectual property right owner that is a national or domiciliary of another WTO Member is undertaking practices in violation of its laws and regulations, and which wishes to secure compliance with such legislation, may request for consultations with the Member whose national is in violation. *Id.* art. 40(3). Article 40(3) stipulates that each Member to whom a request for consultation has been directed, "shall enter, upon request, into consultations" with the State requesting the consultation.

The Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of

extraterritorial investigation and enforcement,” and it creates “conditions for further cooperation through the supply of information.”<sup>417</sup>

The provisions of the TRIPS Agreement give some room for WTO Members to address patent abuses and anti-competitive practices in the pharmaceutical sector. One of the primary mechanisms envisaged in the TRIPS agreement for dealing with anti-competitive practices is compulsory licensing. However, the TRIPS Agreement does not fully deal with problems that could potentially arise after a compulsory license has been issued, i.e., practices that operate to delay or suppress the entry of generic competition even after a compulsory license has been issued. Furthermore, a measure of legal and institutional sophistication is required to effectively utilize the existing provisions of the agreement – something that many developing countries currently lack.

### B. *Is a Global Competition Rule Necessary?*

In the last twenty years there has been a growing call for the development of multilateral rules on anti-competitive practices.<sup>418</sup> The General Agreement on Tariffs and Trade did not provide binding rules on restrictive business practices, with the result that efforts to establish global rules to deal with restrictive business practices have only resulted in non-binding codes of conduct.<sup>419</sup> In 1995, the then WTO Director-General, Renato Ruggiero, observed that there was “an urgent need for a dispassionate analysis at the multilateral level of the overall links between competition policy and trade policy, notably to identify the problems that may require action and the options for such action.”<sup>420</sup> The EU communication of June 1996 “put competition squarely on the international agenda.”<sup>421</sup>

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relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.

*Id.*

417. MATTHEWS, *supra* note 22, at 65 (referring to Articles 40(3) and 40(4)).

418. BERNARD HOEKMAN, COMPETITION POLICY AND THE GLOBAL TRADING SYSTEM: A DEVELOPING-COUNTRY PERSPECTIVE 1 (World Bank, Policy Research Working Paper No. 1735, 1997) (observing that “[s]tarting in the late 1980s, an increasing number of policymakers and academics began calling for the development of multilateral disciplines on anticompetitive practices”), available at <http://www.worldbank.org/research/trade/pdf/wp1735.pdf>.

419. *Id.*

420. Press Release, WTO, Economic globalization increases impact of national competition policies on International Trade—says Renato Ruggiero (Nov. 20, 1995), at [http://www.wto.org/english/news\\_e/pres95\\_e/rome1.htm](http://www.wto.org/english/news_e/pres95_e/rome1.htm).

421. Karel Van Miert, The WTO and Competition Policy: The Need to Consider Negotiations, Address Before Ambassadors to the WTO (Apr. 21, 1998), available at [http://www.europa.eu.int/comm/competition/speeches/text/sp1998\\_038\\_en.html](http://www.europa.eu.int/comm/competition/speeches/text/sp1998_038_en.html).

Until then, the work in the WTO on competition policy had “largely taken the form of responses to specific trade policy issues, rather than a look at the broad picture.”<sup>422</sup> At the first regular biennial meeting of the WTO at the Ministerial level in 1996 in Singapore,<sup>423</sup> Trade Ministers reached an agreement to establish a WTO Working Group on the Interaction between Trade and Competition Policy (“WGTCP”) to look more generally at the relationships between trade and competition policies.<sup>424</sup> Trade ministers also agreed to establish a working group on trade and investment.<sup>425</sup> The task of the WGTCP was merely analytical and exploratory.<sup>426</sup> The WGTCP was authorized only “to study” the interaction between trade and competition policy.<sup>427</sup> The General Council was mandated to keep the work of the WGTCP under review, and to determine after two years how its work should proceed. In 2001, the mandate of the WGTCP was extended.<sup>428</sup>

Since 1996, efforts of the EU and countries like Japan to move the agenda towards negotiating a multilateral framework of competition rules have been largely unsuccessful.<sup>429</sup> While some members call for a

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422. WTO, Competition Policy, at [http://www.wto.org/english/tratop\\_e/comp\\_e/comp\\_e.htm](http://www.wto.org/english/tratop_e/comp_e/comp_e.htm) (last visited Jan. 28, 2005).

423. Trade Ministers met in Singapore from December 9-13, 1996 for a Ministerial Conference as mandated by Article IV of the Agreement Establishing the WTO. See Press Release, WTO, World Trade Organization: Ministerial Conference, Singapore, 9-13 December 1996, Singapore Ministerial Declaration (Dec. 13, 1996) [hereinafter WTO Singapore Ministerial Declaration], at [http://www.wto.org/english/news\\_e/pres96\\_e/wtodec.htm](http://www.wto.org/english/news_e/pres96_e/wtodec.htm).

424. *Id.* para. 20 (“[W]e also agree to . . . establish a working group to study issues raised by Members relating to the interaction between trade and competition policy, including anti-competitive practices, in order to identify any areas that may merit further consideration in the WTO framework.”). Since 1997, the WGTCP has reported annually to the General Council. See WTO, *Report of the Working Group on the Interaction between Trade and Competition Policy to the General Council WT/WGTCP/7* (July 17, 2003) [hereinafter 2003 Report of the WGTCP], available at <http://docsonline.wto.org>. For the Working Group’s previous reports on its activities, see: 1997 (WT/WGTCP/1), 1998 (WT/WGTCP/2), 1999 (WT/WGTCP/3), 2000 (WT/WGTCP/4), 2001 (WT/WGTCP/5) and 2002 (WT/WGTCP/6), available at <http://docsonline.wto.org>.

425. WTO Singapore Ministerial Declaration, *supra* note 423, para. 20.

426. It was agreed that the Working Group will not negotiate new rules or commitments and that “future negotiations, if any, regarding multilateral disciplines in [the areas of trade and competition policy], will take place only after an explicit consensus decision is taken among WTO Members regarding such negotiations.” *Id.*

427. *Id.*

428. The Doha Declaration mandated that negotiations on a global competition rule could start after the 2003 Cancún Ministerial Conference “on the basis of a decision to be taken, by explicit consensus, at that session on modalities of negotiations.” See WTO Ministerial Conference, Ministerial Declaration, WT/MIN(01)/DEC/1 (Nov. 20, 2001), 41 I.L.M. 746 (2002) para. 20 [hereinafter Doha Ministerial Declaration], available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm).

429. In 1999, Japan called for a global agreement on competition. See Ministry of Foreign Affairs of Japan, *Communication From Japan: Preparations for the 1999 Ministerial Conference on Trade and Competition* (1999) (“Members should agree to put the item of competition law and policy on the agenda of the next WTO negotiations with a view to: establishing a competition

multilateral agreement on competition policy, others strongly oppose the idea.<sup>430</sup> Although there appears to be a consensus among WTO Members on the need to address transborder anti-competitive practices, there is a divergence of opinion on how this problem should be addressed. Discussions in the WGTCF have revolved around some core topics that reflect areas where intense study and further discussions are still needed. In the ensuing section, I discuss three related issues: (i) the pros and cons of a multilateral agreement on competition; (ii) the structure of any proposed framework and the need, if any, of such framework to reflect traditional WTO principles, such as the principles of non-discrimination, transparency and procedural fairness; and (iii) the elements of progressivity and flexibility that should be included in any multilateral framework on competition policy to be adopted together with questions relating to technical assistance, capacity building, and special and differential agreement for developing countries.

### 1. THE PROS AND CONS OF A MULTILATERAL RULE

Several arguments are frequently advanced to support the call for a multilateral rule on competition. These include the difficulty of individual countries to effectively address transborder restrictive practices and the need for a more comprehensive, consistent, and coherent approach to anti-competitive practices in the global market place instead of the current case-by-case approach to transborder restrictive practices;<sup>431</sup> the need to ensure that the gains from liberalization are not undermined by anti-competitive behavior of private actors;<sup>432</sup> and the belief that “an international framework of competition rules would contribute to the

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regime for each Member; ensuring effective enforcement in order to properly address anti-competitive practices; and promoting international cooperation in this area.”), available at <http://www.mofa.go.jp/policy/economy/wto/min99/t-compe.html>.

430. WTO, TRADE AND COMPETITION POLICY (noting that “a number of Members have renewed the call for a WTO framework to support the implementation of effective national competition policies by Members and enhance the overall contribution of competition policy to the multilateral trading system while other Members have expressed continuing objections to negotiations on this matter”), at [http://www.wto.org/english/thewto\\_e/minist\\_e/min99\\_e/english/about\\_e/16comp\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min99_e/english/about_e/16comp_e.htm).

431. See Van Miert, *supra* note 421 (“In today’s global economy, there are numerous anti-competitive practices which have an international dimension and which therefore come under the jurisdiction of different competition authorities. This may result in conflicts of law and jurisdiction and might make it difficult for competition agencies to deal with transborder restrictive practices.”).

432. 2003 Report of the WGTCF, *supra* note 424, para. 14 (“Experience had shown that liberalizing trade and encouraging foreign direct investment heightened the dangers posed by anti-competitive practices such as cartels. A multilateral framework would reinforce the application of competition law and policy at the national level and thereby strengthen Members’ ability to address these challenges.”).

development of international trade"<sup>433</sup> by removing barriers to market access.<sup>434</sup> It is also argued that the development of a multilateral agreement on competition policy would "act as an impetus towards building a culture of competition,"<sup>435</sup> "encourage countries without a competition policy to adopt one,"<sup>436</sup> and "ensure that progress made through previous trade and investment liberalization initiatives at multi-lateral, regional and bilateral levels, is not negated by private anti-competitive activities."<sup>437</sup> These arguments are aptly summed up in the 2003 report of the WGTCP:

A multilateral framework on competition policy would establish a coherent set of principles for sound competition policy among all Members, without imposing a harmonized approach, and would promote a more transparent and predictable climate to encourage foreign trade and investment. It would also contribute to the building of institutional capacity in developing countries, and would assist Members lacking a competition law in drafting an appropriate law and establishing an enforcement authority. Cooperation in the context of a multilateral framework offered the prospect of shortening the time frames that developing countries would need to build and embed competition laws and policies that would support their development goals; a key consideration in this regard was the more supportive environment it would provide for better-targeted assistance and capacity building. Finally, an agreement would encourage beneficial cooperation among Members which was important given the increas-

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433. Van Miert, *supra* note 421.

434. *Id.* ("There is also a general consensus that competition policy is a key factor in supporting the competitiveness of industry, in protecting a sound functioning of the economy, and in maximising consumer welfare.").

Renato Ruggiero, Director-General of the World Trade Organization, addressed the topic of competition in a speech delivered at Harvard University in 1996:

But if we have succeeded in getting the rules of competition between countries to work effectively, that very success requires us to go further and consider how the behaviour of companies can serve to distort international competition. We will need to see whether there are any areas where explicit competition rules, or specific understandings, are necessary internationally to complement the statutes that many governments already have on their books. I have no doubt that competition rules are essential to the proper functioning of markets - what we need to clarify, however, is how best to promote such disciplines, both nationally and internationally.

Renato Ruggiero, Director-General, *The Global Challenge: Opportunities and Choices in the Multilateral Trading System*, The Fourteenth Paul-Henri Spaak Lecture, Harvard University, (Oct. 16, 1995), available at [http://www.wto.org/english/news\\_e/sprr\\_e/harvar\\_e.htm](http://www.wto.org/english/news_e/sprr_e/harvar_e.htm).

435. COMPETITION BUREAU, Consultations on the Competition Bureau's Paper "Options for the Internationalization of Competition Policy" – Increased International Cooperation on Competition Policy (1999), available at <http://cb-bc.gc.ca/epic/internet/incb-bc.nsf/vwGeneratedInterE/ct02112e.html>. The Competition Bureau is an agency of the Canadian Government responsible for maintaining and encouraging fair competition in Canada.

436. *Id.*

437. *Id.*

ing prevalence of cross-border anti-competitive activities.<sup>438</sup>

While acknowledging the need for a global rule on competition,<sup>439</sup> developing countries are reticent about the development of such a framework.<sup>440</sup> There are several reasons for this. First, for many poor countries, competition policy is not a high priority.<sup>441</sup> Second, developing countries are afraid that a multilateral framework may not “allow for the preservation of policy space in regard to developmental objectives.”<sup>442</sup> Third, developing countries are very worried about the direct financial cost associated with implementation of such a framework.<sup>443</sup> Fourth, apart from the financial implications of implementing a global competition rule, developing countries are also concerned about additional difficulties that could arise as a result of “disparities between countries and/or their firms in respect of levels of development and competitiveness, experience in the adoption or implementation of competition laws and the capacity to implement such legislation.”<sup>444</sup> Fifth, some countries are concerned about the potential scope of any proposed framework in terms of the types of abusive practices that would be addressed and the place of “existing WTO principles of transparency, non-discrimination and procedural fairness and the proposed multilateral framework on competition policy.”<sup>445</sup> Finally, developing countries also fear that a multilateral agreement on competition would be used as a pretext to open markets for Northern-based corporations rather than to address the anti-competitive behavior of multinational corporations and their impediments to development.<sup>446</sup>

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438. 2003 Report of the WGTCP, *supra* note 424, para. 13.

439. See *id.* para. 18 (“Most developing countries now acknowledged the need to implement a national competition law or policy, out of their own self-interest.”); see also WTO, Working Group on Interaction between Trade and Competition Policy, *Communication from Malaysia, WT/WGTCP/W/239* (July 24, 2003) [hereinafter *Communication from Malaysia*], available at <http://docsonline.wto.org>.

Malaysia acknowledges that a competition policy seeks to ensure efficiency in the market place. There is growing awareness on the need to develop some kind of regulatory control on anti-competitive conduct of firms and multinational companies as the existence of such practices have unnecessarily burdened consumers with not only inflated prices for goods and services but have also adversely affected the trading environment. Concerted efforts need to be undertaken to counter their effects on developing countries.

*Id.*

440. See 2003 Report of the WGTCP, *supra* note 424, para. 17.

441. See *id.*

442. *Id.*

443. See *id.*

444. *Id.*

445. *Id.*

446. See Martin Khor, *WTO competition rules is just Global “welfare” for TNCs* (Apr. 23, 1999), at <http://www.twinside.org.sg/title/welf-cn.htm>.

## 2. STRUCTURE OF A POTENTIAL MULTILATERAL FRAMEWORK

What would be the structure of a potential multilateral framework in terms of the breadth and depth of possible obligations that members will be expected to assume? Will harmonization of national competition laws be an objective of the framework? What core principles would be integrated into the framework? Would there be sufficient flexibility built into the framework taking into account the differences in the situation of WTO Members? These questions are pertinent because paragraph twenty-five of the Doha Declaration – the paragraph that extended the mandate of the WGTCP – specifically calls attention to them.<sup>447</sup>

Discussions in the Working Group indicate that there is a general consensus that hardcore cartels must be addressed in any proposed future rule. Developing countries welcome this focus.<sup>448</sup> Hardcore cartels have been described as “the most unambiguously harmful kind of competition law violation”<sup>449</sup> because they “impose[ ] heavy costs on the economies of countries, particularly developing countries, that lack[ ] effective tools to deal with them.”<sup>450</sup> Although discussions at the WGTCP suggest that there is a growing consensus that hardcore cartels should be addressed, there is currently no generally accepted definition of a hardcore cartel. There is therefore a need for a clearer definition of hardcore cartels and further discussions on what approach should be adopted in dealing with them.

The possible inclusion of WTO principles of non-discrimination, transparency, and procedural fairness into any proposed framework is a major concern for some developing countries and civil society organizations. For example, Malaysia expressed the concern that transparency requirements may be used to impose additional burdens on developing countries.<sup>451</sup> Kenya has questioned the wisdom of universalizing principles developed in the context of trade policy.<sup>452</sup> Martin Khor, Director

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447. In the period until the Fifth Session, further work in the Working Group on the Interaction between Trade and Competition Policy will focus on the clarification of: core principles, including transparency, non-discrimination and procedural fairness, and provisions on hard core cartels; modalities for voluntary cooperation; and support for progressive reinforcement of competition institutions in developing countries through capacity-building.

Doha Ministerial Declaration, *supra* note 428, para. 25.

448. See *Communication from Malaysia*, *supra* note 439, at 2 (“There should be no place for hardcore cartels in any country, irrespective of its level of economic development. Thus, it would be more appropriate for the Working Group to concentrate its efforts on discussing anti-competitive practices particularly those related to hardcore cartels.”).

449. 2003 Report of the WGTCP, *supra* note 424, para. 41.

450. *Id.* (noting also that hardcore cartels raise prices, restrict the supply of essential goods, and can have the effect of impeding the transfer of technology to developing countries).

451. See *Communication from Malaysia*, *supra* note 439, at 1.

452. See WTO, Working Group on Interaction between Trade and Competition Policy,

of Third World Network, argues that increasing advocacy by Northern governments for application of the principles of “non-discrimination,” “national treatment,” and “transparency” reflect a hidden agenda to give foreign corporations (whether as suppliers, local investors, or franchisors) equal, if not better, treatment than what is given to local enterprises.<sup>453</sup>

### 3. FLEXIBILITIES, PROGRESSIVITY, TECHNICAL ASSISTANCE, CAPACITY BUILDING AND SPECIAL AND DIFFERENTIAL TREATMENT

The adoption of a multilateral framework on competition policy would also undoubtedly involve heavy administrative burdens for many developing countries, particularly countries that currently lack competition legislation and institutions.<sup>454</sup> Consequently, “appropriate flexibility and progressivity elements supported by continuing commitments with regard to technical assistance and capacity building” would be necessary.<sup>455</sup> It is also important that any multilateral framework on competition policy “take cognisance of, and accommodate, a substantial degree of pluralism in national competition policies, especially among developing countries, in addition to other, sometimes more interventionist, policies that existed to support development.”<sup>456</sup>

For many countries, the startup process will be plagued by numerous financial and administrative problems, and some countries will need technical assistance in establishing an effective regime.<sup>457</sup> It is therefore important that provisions relating to technical assistance and capacity building be fully fleshed out.<sup>458</sup>

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*Communication from Kenya, WT/WGTCP/W/238 (July 24, 2003) [hereinafter Communication from Kenya], available at <http://docsonline.wto.org>.*

The so-called core principles of transparency, non-discrimination and procedural fairness were developed in the context of trade policy and they were not intended as universal principles applicable to all issues including competition policy. It is not self-evident that it is appropriate or desirable to apply these principles to competition policy.

*Id.*

453. See *Khor*, *supra* note 446.

454. See 2003 Report of the WGTCP, *supra* note 424, para. 18 (noting that implementing a global rule on competition could “pose significant difficulties for countries that lacked a domestic competition law and/or policy”).

455. *Id.* para. 16.

456. *Id.* para. 18.

457. See *Communication from Malaysia*, *supra* note 439, at 2 (“Capacity constraints abound as both the government and private sectors are confronted with the prospect of a new business environment. The international community must continue to focus and prioritise on providing technical assistance to developing countries.”).

458. While there appears to be a general willingness to provide assistance to countries that need it, developing countries may be forgiven for not taking the promises of assistance seriously.

### C. Conclusion

Competition laws and policies are necessary both for the overall well-being of an economy and for the protection of consumers. In general, effective competition law and policy help ensure efficiency in the marketplace and a robust competitive environment. Arguably, a multilateral rule on competition could be in the interest of developing countries.<sup>459</sup> A global competition rule could contribute to the development of institutional capacity in developing countries, assist developing countries currently lacking competition law in drafting appropriate legislation, and encourage beneficial cooperation among WTO Members. Such a multilateral framework could strengthen the ability of developing countries to address dangerous anti-competitive practices in the pharmaceutical sector and in other sectors.

However, given a myriad of socio-economic problems and developmental objectives, negotiations on competition law-related matters may not be a priority for many developing countries. In the context of limited resources and growing obligations under a host of international trade agreements, the resources of many developing countries may be better directed at more important socio-economic policies.<sup>460</sup> In addressing anti-competitive practices in the pharmaceutical sector, developing countries may be content to simply utilize the tools presently available under the TRIPS Agreement.<sup>461</sup>

Fears expressed by developing countries regarding proposed agreements on competition policy have not been overstated, as some proponents of a multilateral agreement claim.<sup>462</sup> Whether a global

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Promises of better-targeted assistance and capacity building in other agreements, including the TRIPS Agreement, have yet to materialize.

459. See WATAL, *supra* note 15, at 374 (noting that international cooperation in breaking-up multinational cartels could be in the interest of developing countries).

460. See *Communication from Malaysia*, *supra* note 439, at 2.

At this point of time, we feel that negotiations on competition law-related matters are not part of the Doha work programme. Domestic competition policy/law may not be a major consideration for developing countries. National priorities and limited capacity may require that scarce resources are allocated for the implementation of more important socio-economic development policies in the country. Alternative domestic approaches to enhance competition in the form of regulatory reform are some of the measures being undertaken.

*Id.*

461. See WATAL, *supra* note 15, at 374 ("[G]iven the freedom presently available under TRIPS on competition policy in general and compulsory license in particular, it may not be prudent to enter the stage of negotiations.").

462. The fears of developing countries, some proponents of a multilateral agreement argue, could be addressed by the inclusion of transitional periods and flexibility in the rules. According to Karel Van Miert:

The developing countries may have most to gain from an international framework of competition rules. On the one hand, they would be able to benefit from the

competition rule will be in the best interests of developing countries will depend on the extent to which the interests of developing countries are fully reflected in any future agreement. It is important that any proposed multilateral framework does not simply become a smokescreen for promoting market access for transnational corporations and imposing anti-trust laws of more developed WTO Members on developing countries. Therefore, one of the purposes of any future multilateral agreement on competition should be to address the challenges currently faced by developing countries by focusing on those anti-competitive practices to which developing countries are most vulnerable. Firm and effective commitments regarding capacity building, technical assistance, and special and differential treatment provisions would also be necessary.

Although important, it is not enough that harmonization not be the goal of any proposed framework.<sup>463</sup> While there are convincing arguments for why a multilateral framework on competition policy may be in the interest of developing countries, there is a strong need to take into account a country's level of development when formulating such an agreement and establishing obligations regarding its implementation. Paragraph 25 of the Doha Declaration buttresses this fact by stating that in discussions on the modalities for a potential multilateral framework, "[f]ull account shall be taken of the needs of developing and least-developed country participants and appropriate flexibility provided to address them."<sup>464</sup>

Overall, should a multilateral framework on competition be negotiated, there would be a need to consider: (i) the different levels of development and economic circumstances of WTO Members; (ii) the different legal, social, and cultural context of Members; (iii) the difference in availability of resources for implementing the terms of any proposed framework; and (iv) the different levels of institutional development and the fact that Members have different administrative systems.<sup>465</sup> Thus, rather than attempting to impose a one-size-fits-all standard, as is the case with the TRIPS Agreement, developing a pro-

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multilateral framework right away - by enabling requests for co-operation to combat anti-competitive business practices and by providing for technical assistance regarding the setting up of domestic competition structures. On the other hand, one could envisage transitional periods in the multilateral framework designed to meet certain specific problems of developing economies.

Van Miert, *supra* note 421.

463. See *id.* ("It is likely that any agreement in the WTO on competition would not match the level of competition policy and instruments achieved by countries, which have decades of experience in antitrust activities. But is this really a problem? We are not talking about replacing national law by international rules.").

464. Doha Ministerial Declaration, *supra* note 428, para. 25.

465. See Khor, *supra* note 446.

posed set of principles that “would embody common values and promote cooperative approaches to competition law enforcement”<sup>466</sup> would be a useful starting point. In the final analysis, it may be important to preserve “the right of a country to choose whether and when to have a competition law and the kind of competition policy to adopt.”<sup>467</sup>

## VII. CONCLUSION

To a great extent, the war over access to medicine in developing countries was unnecessary because the TRIPS Agreement appeared to provide sufficient policy spaces aimed at reducing the potentially adverse effects of a strong intellectual property regime. The war was inevitable, however, given the numerous ambiguities that existed in the TRIPS Agreement, the negotiating history of TRIPS Agreement,<sup>468</sup> and the understandable efforts by the pharmaceutical industry to safeguard their profit margins using every means possible. The TRIPS Agreement was negotiated at a time when the impact of a strong patent protection was not widely understood in the developing world and at a time when the debate on the necessity of a global intellectual property regime was dominated by global corporate actors and countries with intellectual property expertise.<sup>469</sup> Today, not only is the relationship between patent protection and economic growth more understood, new actors “whose views were peripheral in the Uruguay Round negotiations have now entered the debate on global intellectual property protection more wholeheartedly.”<sup>470</sup>

The battles over the precise relationship between patent rights, public health, and state sovereignty reflect the simultaneous convergence of a number of trends that together define the emerging world of the

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466. 2003 Report of the WGTCP, *supra* note 424, para 16.

467. See *Communication from Kenya*, *supra* note 452, at 1 (also observing that “countries should preserve the right to adopt a phased approach in terms of discussion, implementation and enforcement of a competition law” because only then can countries adopt competition regimes that support their industrial policy).

468. See WATAL, *supra* note 15, at 382. During the negotiations there was intense pressure on developing countries to accept stronger obligations relating to the protection of intellectual property rights. Not surprising, “[f]rom the outset, the TRIPS agreement has been controversial.” Pascal Lamy, International Trade in Drugs: Its Role in Equitable Development, Speech to the Association of Pharmaceutical Industry Managers (Mar. 21, 2003) [hereinafter Lamy, International Trade in Drugs], available at [http://www.europa.eu.int/comm/commissioners/lamy/speeches\\_articles/spla162\\_en.htm](http://www.europa.eu.int/comm/commissioners/lamy/speeches_articles/spla162_en.htm).

469. See, e.g., DUNCAN MATTHEWS, TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: WILL THE URUGUAY ROUND CONSENSUS HOLD? 2 (Centre for the Study of Globalisation and Regionalisation, Working Paper No. 99/02, 2002) (noting that debate was dominated by countries “with a negotiating advantage over developing countries in terms of intellectual property expertise”), available at <http://www2.warwick.ac.uk/fac/soc/csgr/research/workingpapers/2002/wp9902.pdf>.

470. *Id.* at 2-3.

twenty-first century. These include the growing convergence of national economic systems, widening disparities of income and development, the rise in the power and influence of transnational corporations, and the explosion of diseases that transcend national boundaries.<sup>471</sup> In the twenty-first century, drugs matter because of their role in equitable and sustainable development and because many developing countries have little or no pharmaceutical manufacturing capacity.<sup>472</sup> In addition, they have few resources to devote to R&D in essential medicine.<sup>473</sup> Also, in the twenty-first century, as a result of globalization, transnational corporations in general and pharmaceutical companies in particular are having to assume new global responsibility that they did not have before.

Compulsory licensing gives developing countries tools to address serious health problems by enabling them to obtain generic drugs at an affordable price.<sup>474</sup> Although an important instrument in efforts to protect public health, compulsory licenses alone "will not address all the problems related to public health."<sup>475</sup> This is because there are many other factors that influence access to medicine in developing countries, such as the level of research and development, quality of diagnoses, capacities of health systems and budgets, quality of drugs, and the adequacy of health care professionals.<sup>476</sup> Given the multiplicity of factors

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471. See Lamy, *International Trade in Drugs*, *supra* note 468 (of the trends in the twenty-first century, Lamy points out: "widening disparities of development, global interdependency of trade movements, acceleration of technological progress which only benefits a minority, the explosion of a deadly disease known as AIDS, the emergence of global civil society, and the inadequacies of national and international governance systems").

472. See *id.* (noting that "little medical and pharmaceutical research is carried out in the developing world, and that these countries have next to no facilities for the manufacture of pharmaceutical products").

473. See *id.*

The gap between North and South is a veritable chasm when it comes to drugs. According to the WHO, developing countries are home to 76% of the world's population, but account for only 20% of world drug consumption. Not only that, but their share has been declining! (In 1976, they represented 24% of world consumption).

*Id.*

474. See *id.*

It is not our aim to encourage the widespread granting of compulsory licences by the developing countries. But it is clear that in negotiations with the major pharmaceutical groups, whose revenues often far exceed those countries' GDP, the fact that the developing countries have the compulsory licence option to fall back on can give them the leverage they need to secure lower prices. In this way, compulsory licensing can operate as an effective form of deterrence.

*Id.*

475. *Submission by the African Group*, *supra* note 80, para. 28.

476. See Lamy, *International Trade in Drugs*, *supra* note 468. Lamy notes a host of factors that account for the gap between the North and South when it comes to drugs. These include:

the near total lack of social security and health insurance systems in the South, inadequate and badly-organised infrastructure, poor hygiene, badly educated and

that influence access to medicine, a combination of policies is needed to ensure that drug prices are lowered on a sustainable basis.<sup>477</sup>

Some battles may be over, but the war against diseases in developing countries continues. For one thing, it is not clear yet whether developing countries will actually maximize the political space now afforded by the Doha Declaration and the 2003 Decision on Implementation. Furthermore, experts rightly note that “[e]ven with newly discounted price for patented anti-retroviral drugs and even with dramatically cheaper equivalents from generic producers, developing countries and their private citizens will find it impossible to buy significant quantities of life-saving AIDS medicines without significant and sustained support from the international community.”<sup>478</sup> Unfortunately, multilateral funding for AIDS treatment has been very poor. Although the Global Fund to Fight AIDS, Tuberculosis, and Malaria (the “Global Fund”) was created in 2001 to finance aggressive intervention against AIDS and other disease killers, the Global Fund suffers from serious under-funding.<sup>479</sup> Most importantly, given the possibilities of abuse in the pharmaceutical industry, the future will depend on the type of rules that exist to address abusive and anti-competitive practices by drug companies, the extent of self-regulation that exists in the industry, the role of ethical codes of conduct in the industry, and the extent to which external pressures can be brought to bear upon the pharmaceutical industry. In this respect, actors such as civil society groups have a pivotal role to play in addressing the growing global influence of the transnational pharmaceutical industry, raising awareness about abuses in the industry, and providing

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trained staff, and the failure to implement certain disease-prevention measures. The underlying problem is thus the same as for other forms of under-development: a crying deficiency of governance and public policy.

*Id.*

477. See Médecins Sans Frontières, Campaign for Access to Essential Medicines, What is the Campaign? (suggesting a host of strategies, including “encouraging generic competition, voluntary discounts on branded drugs, global procurement, and local production”) [hereinafter What is the Campaign?], at <http://www.accessmed-msf.org/campaign/campaign.htm>.

478. BROOK K. BAKER, HEALTH GAP, THE GLOBAL FUND TO TREAT AIDS, TB, AND MALARIA: FULFILING [sic] OR BETRAYING THE PROMISE OF TREATMENT 1, (2002) (noting that during most of the 1990’s, “the actual per person expenditure on all AIDS prevention and treatment programs in Africa dropped to as little as \$3 per person per year”), at <http://www.aidspace.org/gfo/docs/gfo29a.pdf>.

479. See *id.* at 2. (“[O]n April 28, 2001, Kofi Annan, General Secretary of the United Nations, called for the establishment of a Global Funds to Fight AIDS, Tuberculosis, and Malaria. . . . Annan estimated that an initial response to AIDS . . . would cost between \$7 and \$10 billion dollars per year.”). Although, to date, donors have pledged over \$6.1 billion to support programs around the world through 2008, the Global Fund is currently facing a \$0.7 billion shortfall of resources for its 2005 commitments. The Global Fund to Fight AIDS, Malaria, and Tuberculosis, Funding Gap 2005, available at [http://www.theglobalfund.org/en/funds\\_raised/funding\\_gap](http://www.theglobalfund.org/en/funds_raised/funding_gap). See generally The Global Fund, available at <http://www.theglobalfund.org/en/>.

countries with timely information that will be needed to address abuses if and when they arise.

Just as a score of factors influence access to effective medicine, "many actors have a role to play in addressing the access crisis."<sup>480</sup> Both local and national governments clearly "have the responsibility to give priority to public health through strong, pro-health legislation."<sup>481</sup> Attention must now turn to other issues affecting access, such as inadequacies in the health infrastructure of many developing countries.<sup>482</sup> Unless these issues are addressed, many in the developing world will remain without access to essential drugs even if the drugs are offered at extremely low cost or for free.<sup>483</sup>

International organizations such as the World Health Organization, World Bank, and UNAIDS must "adopt and advocate for policies that give the highest level of protection for public health."<sup>484</sup> Along with continuing efforts to reduce the cost of medicine through generic competition, protecting public health also requires concurrent research and advocacy on additional barriers to access,<sup>485</sup> as well as a renewed commitment to supporting the United Nations Global Funds to Fight AIDS, Malaria, and Tuberculosis.

The private sector remains very important. Pharmaceutical companies can contribute to long-term solutions by "cutting their prices for developing countries in a transparent and predictable way."<sup>486</sup> For example, differential pricing remains a viable option.<sup>487</sup> In addition, international donors and foundations remain very important beyond funding disease prevention; they can also fund drug purchase and other treatment programs.<sup>488</sup> Finally, civil society groups have a continuing

480. What is the Campaign?, *supra* note 477.

481. *Id.*

482. See INTERNATIONAL COUNCIL OF AIDS SERVICE ORGANIZATIONS, THE INTERNATIONAL GUIDELINES ON HIV/AIDS AND HUMAN RIGHTS 6 (2002) (observing that "[t]he public profile of the global drug pricing issue has been raised but less attention has been paid to other issues affecting access to treatment") [hereinafter INTERNATIONAL GUIDELINES], available at <http://www.unaids.org/wac/2002/icasoHumanRights.pdf>.

483. See INTERNATIONAL COUNCIL OF AIDS SERVICE ORGANIZATIONS, ADDING INFRASTRUCTURE TO THE ADVOCACY AGENDA EXECUTIVE SUMMARY iii (2003) (observing that there are examples of countries where drugs have been offered at extremely low prices but access to treatment has not increased for people living with HIV) [hereinafter EXECUTIVE SUMMARY], available at <http://www.icaso.org/InfrastructureRep.-ENGrev.pdf>.

484. Médecins Sans Frontières, Campaign for Access to Essential Medicines, Frequently Asked Questions para. 4, at <http://www.accessmed-msf.org/campaign/faq.shtm> (last visited Jan. 28, 2005).

485. See *id.* para. 9.

486. *Id.* para. 4.

487. Differential pricing allows the pharmaceutical industry to provide drugs to the poorest countries at significantly reduced prices.

488. *Id.*

responsibility to monitor and hold accountable all the important players – states, international donors, and pharmaceutical companies – and to expose abuses and other failures when they occur.

It is also important that the integrity of the patent system is preserved through good faith use of the Doha Declaration and the 2003 Decision on Implementation. The patent system is needed to finance new research and development and ensure that drug manufacturers continue to bring newer and better drugs to the market.<sup>489</sup>

The “access to treatment” debate unearthed many hidden factors that impede access to essential drugs for millions in the developing world.<sup>490</sup> In addition to increasing access to essential drugs in developing countries, the debate brought the human right to health back into the spotlight.<sup>491</sup> The “access to treatment” debate has also raised interesting questions about how to balance ethical concerns with economic concerns.<sup>492</sup> Public health is an ethical and human rights issue, but does it necessarily trump substantial economic and other public interests when patent rights are implicated?<sup>493</sup> What constraints should society impose on the rights of a patent holder? Can the pharmaceutical industry be

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489. However, studies in the U.S. and elsewhere show that the industry’s emphasis on R&D is somewhat exaggerated. Data gathered by Families USA shows that, in the U.S. at least, major pharmaceutical companies “spend significantly more on marketing, advertising, and administration than they spend on R&D.” FAMILIES USA, PROFITING FROM PAIN: WHERE PRESCRIPTION DRUG DOLLARS GO 1 (2002), available at <http://www.familiesusa.org/site/DocServer/PPreport.pdf?docID=249>. In its study of nine U.S. pharmaceutical companies that manufacture or market the fifty top-selling drugs for seniors, Families USA found that “[o]n average, the nine companies spent 11 percent of revenue on R&D and 27 percent of revenue on marketing, advertising, and administration.” *Id.* at 5. “No company spent as much as 20 percent of revenue on R&D, whereas every company except Merck spent more than 20 percent of revenue on marketing, advertising, and administration.” *Id.* Finally, the report found that the pharmaceutical industry was very generous to its top executives, with the result that “[t]he 10 highest-paid executives across the nine companies received a total of \$236 million in compensation in 2001, exclusive of unexercised stock options.” *Id.* at 7 (emphasis in original).

490. In the case of HIV/AIDS, barriers to accessing treatment take many forms, including “the cost of drugs, political denial and disinterest, stigma and discrimination, and inadequate health systems.” EXECUTIVE SUMMARY, *supra* note 483, at p. iii. For a discussion on the role of infrastructure and HIV/AIDS treatment, see generally INTERNATIONAL COUNCIL OF AIDS SERVICE ORGANIZATIONS, ADDING INFRASTRUCTURE TO THE ADVOCACY AGENDA (2002), available at <http://www.icaso.org/docs/Adding%20Infrastructure.pdf>.

491. INTERNATIONAL GUIDELINES, *supra* note 482, at 8 (arguing that “[a]ccess to medical treatment of HIV infection is crucial for the respect of the right to health and the right to life”). Essentially some local and global NGOs, drawing on some human rights treaties, argued that access to treatment was a human right issue. The efforts of this organization led to the adoption of the International Guidelines on HIV/AIDS by the Second International Consultation on HIV/AIDS and Human Rights, held in Geneva, Switzerland in September 1996. *See id.* at 1.

492. *See* Lamy, International Trade in Drugs, *supra* note 468 (observing that although public health is an ethical issue, there are other economic interests at stake).

493. *See id.* (“There is nothing to be gained by constructing a false opposition between intellectual property, which is essential if we are to have the innovation we need to produce new drugs, and access to care; instead, we should seek ways to make them work together.”).

trusted to develop sound ethical principles to guide the activities of its members? These are important questions that we must continue to address as the global pharmaceutical industry evolves.