

ARTICLES

TRIPS, PATENTS, AND ACCESS TO LIFE-SAVING DRUGS IN THE DEVELOPING WORLD

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I. INTRODUCTION

Virtually since the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)¹ entered into force as part of the newly created World Trade Organization (WTO) in 1995,² WTO Member States and interested observers have recognized that significant gaps exist in the agreement with respect to patent protection and access to life-saving medicines in developing and least-developed countries (LDCs); but finding and agreeing on improvements to the system has proven to be a much harder proposition.

Many developing countries and non-governmental organizations (NGOs) rapidly grew frustrated waiting for WTO Members to improve the situation of medicinal access in poor countries, losing the battle against such public health epidemics as tuberculosis, malaria, and HIV/AIDS and actively campaigned

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1. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPs] (establishing a multilateral agreement creating minimum protection standards for various forms of intellectual property among Member States).

2. See Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 1, 33 I.L.M. 1125 (1994) (establishing the WTO in the last round of GATT [hereinafter Uruguay Round] and also creating treaties covering various trade topics) [hereinafter WTO Agreement or Agreement Establishing the WTO]. The WTO replaced the GATT as the world trading system and, for the first time, included intellectual property protection. Other topics for negotiation in the expanded international trading system included the following: tariffs, non-tariff measures, tropical products, natural resource-based products, textiles and clothing, agriculture, GATT articles, safeguards, most favored nation agreements and arrangements, subsidies and countervailing measures, dispute settlement, and trade-related investment measures (TRIMs). See General Agreement on Tariffs and Trade: Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations, 25 I.L.M. 1623 (Sept. 20, 1986), 5-8. For more on the creation and mandate of the WTO, see also RAJ BHALA & KEVIN KENNEDY, WORLD TRADE LAW 4(a)-(b) (1st ed. 1998).

for both structural and operational changes within the WTO.³ While those groups succeeded in getting public health issues on the agenda at the Third Ministerial Conference, held in Seattle in 1999, the process of resolving several key health issues did not solidify until the Fourth Ministerial Conference, held in Doha, Qatar in 2001 (Doha Round). During the Doha Round, Members adopted a Declaration on TRIPs and Public Health (Doha Declaration), restating and affirming the right of Member States to take measures to protect public health.⁴ The Declaration also clarified certain controversial textual ambiguities contained in TRIPs and provided assistance to developing countries and LDCs in resolving the public health crises that are devastating many parts of the developing world.

The Doha Round represented the first time international health and development was discussed at every level of WTO governance and is viewed as the first significant victory for developing countries in the short history of TRIPs. The Doha Declaration was also a major success for the highly visible international activist movement that has long campaigned against poor access to pharmaceuticals in developing countries. Correspondingly, both developing countries and NGOs welcomed the Doha Declaration for its recognition that public health issues can take precedence over the rights of private intellectual property holders.⁵

While the Doha Declaration clarified several contentious aspects of TRIPs, it did not completely resolve the debate over patent protection in the developing world. Instead, it left one important and highly contentious issue unresolved: the availability of compulsory licensing exceptions to patent protection for those countries suffering through a public health crisis with insufficient or no manufacturing capabilities. The importance of this issue cannot be understated, as TRIPs Article 31(f) conditions the issuance of compulsory licenses on them being “predominantly for the supply of the domestic market of the Member authorizing such use”; meaning a nation could override valid patent laws only so long as that nation ordered the generic drugs from domestic producers. This requirement precludes a nation

3. For a listing of NGO position papers filed with the WTO before the Doha Round, see WTO, Non-Governmental Organization: Working Papers, *available at* http://www.wto.org/english/forums_e/ngo_e/posp21_e.htm (last visited Feb. 1, 2004).

4. See WTO Ministerial Conference, Declaration on the TRIPs Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration].

5. India called the Declaration “the most important single achievement of the Doha Round” and the Philippines stated the Declaration is “the crowning glory of the WTO’s contribution to global welfare and humanitarian concerns, especially for those who were gravely afflicted by the scourge of epidemics and other public health problems.” WTO Council for TRIPs, Minutes of Meeting Held in the Centre William Rappard on 25-27 and 29 November, and 20 December 2002, IP/C/M/38 (Feb. 5, 2003), ¶¶ 38, 45 [hereinafter Minutes of TRIPs Council Meeting].

with insufficient or no manufacturing capabilities from using the system, and, as most countries needing to make use of the patent exceptions are economically troubled nations with insufficient or no manufacturing capabilities, the exceptions in TRIPs failed to satisfy the needs of those countries that the exceptions were designed to benefit. The Doha Declaration called for the unresolved issues to be resolved through consensus “before the end of 2002”;⁶ unfortunately, even with the concerted efforts of both Members of the WTO and the Chairperson of the TRIPs Council, an agreement could not be reached by the deadline and was only resolved on August 30, 2003, after weeks of heavy negotiation in the days leading to the Fifth Ministerial Conference (Cancún Round).⁷

The Implementation of Paragraph 6 of the Doha Declaration on TRIPs Agreement and Public Health (Implementation Agreement) was only reached following an emotional appeal from numerous African countries when it looked like minor differences would once again scuttle the deal.⁸ Following the plea, the WTO’s 146 Member States realized the importance of successfully concluding the agreement and finally cemented a solution to the Paragraph 6 Mandate by creating an exception to Article 31(f) of the TRIPs Agreement that allows nations with insufficient or no manufacturing capabilities to override intellectual property protection and import generic copies of patented drugs to combat public health crises.⁹

6. Doha Declaration, *supra* note 4, ¶ 6.

7. On November 25, 2002, the Chairperson of the TRIPs Council informed Members that he was holding consultations to the Paragraph 6 Mandate. On November 29, the Chairperson reported that intensive consultations had led to significant progress and that a draft legal instrument was almost finalised. The draft was tabled on December 16, but was not adopted when the U.S. would not agree to the paragraph concerning the scope of diseases covered. *See* Minutes of TRIPs Council Meeting, *supra* note 5, ¶¶ 33-34; Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health, Note from the Chairperson, JOB(02)/217 (Dec. 16, 2002).

8. Council for TRIPs, Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health, WT/L/540 (Aug. 30, 2003) [hereinafter Implementation Agreement]. The African countries “said in a joint statement that . . . 8,480 people had died unnecessarily in Africa from HIV/AIDS and other diseases since the talks stalled” over an accompanying document to the Agreement only two days earlier (Aug. 28, 2003). Canadian Ambassador Sergio Marchi commented at the time: “[T]hey showed that the poorest among us do make a difference in this organization They helped the WTO find its heart and soul.” Naomi Koppel, *WTO Lets Poor Nations Import Cheap Drugs*, ASSOCIATED PRESS, Aug. 30 2003, available at <http://www.aegis.com/news/ap/2003/AP030847.html> (last visited Sept. 1, 2003).

9. The deadlock was broken when Members agreed to attach a statement to the text setting out the conditions under which the measure can be used and stating the rules “should be used in good faith to protect public health [and] not be an instrument to pursue industrial or commercial policy objectives.” *See* Council of TRIPs, The General Council Chairperson’s Statement (Aug. 30, 2003) [hereinafter Chairperson’s Statement], available at http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm (last visited Oct. 1, 2003). U.S. Trade Representative Robert Zoellick called the agreement “the right balance between

While many commentators have addressed and analyzed the various issues associated with plans to supply poorer nations with needed drugs at a reasonable cost,¹⁰ this will be one of the first articles to critically analyze the agreement implementing Paragraph 6 of the Doha Declaration. Part II briefly details the trend of linking intellectual property rights to international trade before summarizing the pertinent provisions of the TRIPs Agreement. Part III introduces the controversy surrounding access to medicines by first detailing the global events that brought the issue to the fore and then by evaluating the accomplishments and unanswered questions of the Doha Declaration. Part IV discusses the agreement implementing the Paragraph 6 Mandate, critically analyzes its provisions, and addresses several lingering questions and problems unaddressed by the agreement. Part V argues that, as a majority of the drugs used to combat public health epidemics such as HIV/AIDS and malaria are off-patent or not patented in many developing countries and LDCs, the agreement will do very little to assist those nations in preventing and treating public health crises and epidemics. The section further argues that issues of extreme poverty, lack of funding for healthcare, and little or no resources available for the storage, transport, and distribution of drugs must be considered and addressed before there can be any hope of alleviating the suffering in the developing world.

II. THE HISTORY AND EFFECT OF THE TRIPs AGREEMENT

A. *Linking Intellectual Property Rights to International Trade*

Prior to the implementation of TRIPs, intellectual property was largely unregulated in the international arena, with the topic not included in GATT and only minimally protected through the agreements administered by World Intellectual Property Organization (WIPO), most notably the Paris and Berne

addressing the needs of the poorest countries while ensuring intellectual property protections that foster the future development of lifesaving drugs.” Australian Minister for Trade, Mark Vaile, stated: “It is a further demonstration that the WTO is able to respond to the public health problems faced by developing countries.” Statement of U.S. Trade Representative Robert B. Zoellick, at <http://www.ustrade-wto.gov/03083101.html> (last visited Apr. 21, 2004). Naomi Koppel, *WTO Finally Gives Poor a Drugs Deal*, SYDNEY MORNING HERALD, Sept. 1, 2003, available at <http://www.smh.com.au/articles/2003/08/31/1062268474373.html> (last visited Sept. 1, 2003).

10. See, e.g., James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers*, 53 FLA. L. REV. 727 (2001); F.M. Scherer, *The Pharmaceutical Industry and World Intellectual Property Standards*, 53 VAND. L. REV. 2245 (2000); Alan O. Sykes, *TRIPs, Pharmaceuticals, Developing Countries, and the Doha “Solution,”* 3 U. CHI. J. INT’L L. 47 (2002); Naomi A. Bass, *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).

Conventions.¹¹ While TRIPS incorporates the Paris and Berne Conventions into its framework, pre-Uruguay Round intellectual property regimes were mostly left to national discretion, with both developed and developing countries differing widely in their approaches to intellectual property protection.¹² For instance, some nations granted patents of relatively long duration, while others granted shorter-term protection;¹³ some nations granted patents for processes and products, and some protected only products;¹⁴ some nations legislated for compulsory licensing of drugs, while others prohibited the measure;¹⁵ some nations required that patent holders produce and sell the drug in the country granting the patent or the holder would lose the protection, and others protected the patent regardless of where production and sales occurred;¹⁶ and some nations did not protect or grant pharmaceutical patent protection, while others fully protected the industry.¹⁷

While the WIPO treaties attempt to harmonize intellectual property protection between signatory countries, the WIPO's many institutional shortcomings, most notably the lengthy negotiation process involved with amending or updating the treaties; the difficulty in reaching consensus on meaningful protection; and the lack of an effective dispute resolution mechanism, render the organization largely ineffective.¹⁸ Due to the inability

11. WIPO, a subdivision of the United Nations, administers the Berne Convention for the Protection of Literary and Artistic Works and the Paris Convention for the Protection of Industrial Property [hereinafter "Paris Convention"]. Both treaties attempt to standardise at least a part of the intellectual property regimes of signatories. For instance, the Paris Convention details basic patent principles, industrial design protection, and trademark protection that must be adhered to in order to qualify for membership. Likewise, the Berne Convention requires signatories to meet certain minimum standards of protection before acceding to the treaty. See generally JOHN H. JACKSON, *THE WORLD TRADING SYSTEM: LAW AND POLICY OF INTERNATIONAL ECONOMIC RELATIONS* 310-13 (2d ed. 1997).

12. Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1072-77 (1996).

13. MICHAEL J. TREBILCOCK & ROBERT HOWSE, *THE REGULATION OF INTERNATIONAL TRADE* 310 (2d ed. 2000).

14. Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT'L L. 507, 519-20 (1996) (reviewing India's patent protection for pharmaceuticals processes but not products).

15. Symposium, *What's Going on in Intellectual Property Law?*, 84 AM. SOC'Y INT'L L. PROC. 256, 258 (1990) (discussing Canada's use of compulsory licensing).

16. R. Carl Moy, *The History of the Patent Harmonization Treaty: Economic Self-Interest as an Influence*, 26 J. MARSHALL L. REV. 457, 475-76 (1993).

17. Bruce Rubenstein, *Latin America Slow to Protect Patents Under NAFTA*, 6 CORP. LEGAL TIMES 14, (1996) (describing Brazil's reluctance to adopt patent protections).

18. Although the WIPO treaties contemplate that signatories can challenge the compliance of another member's regime before the International Court of Justice (ICJ), the treaties contain an opt-out clause allowing Members to declare that they are not subject to the jurisdiction of the ICJ. Thus,

of the WIPO to adequately protect intellectual property rights, many developed countries concluded that the best way to develop and enforce meaningful intellectual property protection would be to link intellectual property rights with international trade and negotiate for their inclusion as part of the larger, more comprehensive Uruguay Round.¹⁹

Meanwhile, as a result of the seemingly rampant cases of piracy in many developing countries and the inability of the WIPO to stem the tide, the United States (U.S.) began to unilaterally enforce its intellectual property rights by virtue of the authority of the United States Trade Representative (USTR) under Section 301.²⁰ In other words, the U.S. initiated litigation in the United States Court of International Trade (USITC) against countries under domestic unfair trade practices laws, even though the respondent countries had violated no international agreement. The U.S. filed numerous cases against developing countries, most notably Brazil, Argentina, India, China, and Taiwan, and extracted concessions from the respondents in a number of cases.²¹ In doing so, the U.S. began the trend of linking intellectual property protection to international trade.²²

the compliance mechanism in the WIPO administered treaties came to be regarded as toothless and unsatisfactory. See Pamela Samuelson, *Challenges for the World Intellectual Property Organization and the Trade-Related Aspects of Intellectual Property Rights Council in Regulating Intellectual Property Rights in the Information Age*, EUR. INTEL. PROP. REV. 578, 581 (1999).

19. During the Uruguay Round, the developed countries, led by the U.S., European Union (EU), Switzerland, and Japan, negotiated hard to establish a high level of intellectual property protection that could be enforced in a binding dispute settlement process.

20. The Trade Act of 1974 allows the President to take "appropriate and feasible action" to encourage a period of "positive adjustment" so that a domestic industry may be better suited to compete against foreign competitors when that foreign competitor has unfairly gained an advantage. See The Trade Act of 1974, 19 U.S.C. § 2251 (2002). When the Uruguay Round was implemented, the U.S. reserved special investigative powers that authorized the President, the Commerce Department, and the U.S. International Trade Commission to retain investigatory power independent of the WTO to determine trade imbalances. Generally known as Section 301, these provisions allow an American industry to request an investigation if the industry perceives that it is sustaining "material injury" attributable to an illegal increase of imports. If it is determined that there is "substantial injury," then the president may take "appropriate and feasible" measures to enforce a "positive adjustment" period to allow the domestic industry to recover from import pressure. See 19 U.S.C. § 2252 (2002) (Section 301 is now part of Public Law 103-465, passed in 1994).

21. See Sykes, *supra* note 10, at 47 n.10.

22. See generally Alan O. Sykes, *Constructive Unilateral Threats in International Commercial Relations: The Limited Case for Section 301*, 23 LAW & POL'Y INT'L BUS. 263, 318-19 (1992) (containing a table of cases decided under section 301). The U.S. continued this process when it negotiated for the inclusion of intellectual property in the North American Free Trade Agreement (NAFTA). The issue of adequate intellectual property protection was of the utmost importance to the U.S. and the agreement would likely not have been successfully concluded if Canada and Mexico had resisted American attempts to include intellectual property into the agreement. See GARY CLYDE HUFBAUER & JEFFREY J. SCHOTT, NORTH AMERICAN FREE TRADE: ISSUES AND RECOMMENDATIONS 173-81 (1992) (noting that the United States should seek to

At the same time, the Uruguay Round negotiations progressed, and the U.S. and other developed countries used the carrot and stick approach to accomplish their goals of providing an adequate system of global intellectual property protection.²³ The stick, of course, was continued unilateral action that would potentially threaten the trade and aid flowing from developed countries to those countries not adequately protecting intellectual property rights. The carrot for negotiating and agreeing to the inclusion of intellectual property in the Uruguay Round came in the form of several sweeteners in other areas of negotiation, particularly in the area of textiles. In addition, developing countries also won several important TRIPs-related concessions, most notably deferred implementation of the substantial portions of the agreement.

B. The TRIPs Agreement

In terms of pharmaceutical protection, TRIPs establishes minimum international standards and attempts to strike a balance between the short-term objective of providing access to life-saving medicines and the long-term objective of encouraging and providing incentives to the pharmaceutical industry for the development of new medicines.²⁴ As is the case with many international agreements negotiated by diplomats, the agreement has both textual and operational flaws, but finally did achieve a system of worldwide uniform intellectual property protection through developed standards backed by the prospects of binding dispute resolution.

Contrary to public opinion, TRIPs does not provide for a global system of intellectual property protection; meaning Members do not automatically recognize other Members' patents. Instead, inventors must apply for

incorporate detailed obligations in the NAFTA that lock in the recent Mexican intellectual property reforms); Christopher Scott Harrison, *Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91*, 26 N.C. J. INT'L L. & COM. REG. 457 (2001) (stating that the U.S. "demanded that U.S. negotiating partners strengthen the protection afforded to intellectual property as a prerequisite to obtaining an agreement") (citing MARCI McDONALD, *YANKEE DOODLE DANDY: BRIAN MULRONEY AND THE AMERICAN AGENDA* 213 (1995) (arguing that as the free trade negotiations with Canada dragged on, "the White House had threatened to throw the whole thing overboard unless Ottawa rammed through the pharmaceutical bill"))).

23. See generally CHAKRAVARTHI RAGHAVAN, *RECOLONIZATION: GATT, THE URUGUAY ROUND & THE THIRD WORLD* 69-80 (1990).

24. While we can now authoritatively state that intellectual property aims to balance the author's incentive to create and the users' right to information, early international agreements saw the aim of intellectual property to be the rights of the author. For an interesting perspective, see Simon Fitzpatrick, *Prospects of Further Copyright Harmonisation*, EUR. INTEL. PROP. REV. 15 (2003).

protection in each Member State in which they wish to be protected.²⁵ Perhaps the most important features of TRIPs are the non-discrimination measures of Articles 3 and 4, which instruct Members to give the same level of protection to other Members' citizens as they do their own citizens and also prohibits Members from discriminating between other Member States in any regard.²⁶

The most pertinent parts of TRIPs in terms of patent protection are Articles 27-34.²⁷ Those Articles require Members to provide a minimal standard of protection for inventions for twenty years from the patent application filing date.²⁸ Importantly, they also require Members to make patent protection available for "inventions, whether products or processes."²⁹ Article 28 grants patent holders certain exclusive rights, including the right to prevent third parties who do not have the consent from the owner from making, using, offering for sale, selling, or importing that product.³⁰ Article 28 also provides the right for patent owners to assign, or transfer by succession, the patent and to conclude licensing contracts.³¹

TRIPs also includes a number of transitional provisions, such as granting LDCs until January 2006 to comply with TRIPs and giving developing countries that have never legislated on intellectual property rights until January 2000 to apply some TRIPs provisions, while giving them until January 2005 to apply other provisions, including several provisions of particular importance to pharmaceuticals.³² Importantly (and controversially),

25. However, fifty-five countries agreed to the Madrid Protocol, which provides signatories the right of a single registration providing protection in several countries, by filing a single international trademark application based on the domestic trademark application for the same mark. For more on the Madrid Protocol, see International Trademark Association, *available at* <http://www.inta.org/madrid/> (last visited Sept. 27, 2003).

26. *See* TRIPs, *supra* note 1, arts. 3 & 4.

27. *Id.* arts. 27-34.

28. *Id.* art. 33.

29. *Id.* art. 27(1). This inclusion was of particular importance to pharmaceutical companies, as the agreement would have been virtually worthless to them without adequate protection given to "processes."

30. *Id.* art. 28(1)(a).

31. *See* TRIPs, *supra* note 1, art. 21(2).

32. *Id.* arts. 65, 66. These transitional periods are of the utmost importance in terms of access to medicines in the developing world, as the delayed implementation of TRIPs allows several countries that possess the ability to cheaply produce copies of patented drugs and sell them for much lower prices than the patent holder. This practice will become more difficult as of January 1, 2005, when the leading generic manufacturing nations (including India) become subject to TRIPs. As a result, compulsory licensing may be less effective in the absence of a generic industry. *See* UK COMMISSION ON INTELLECTUAL PROPERTY RIGHTS REPORT, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY (Sept. 2002), *available at* <http://www.cptech.org/ip/wto/p6/cipr-para6.html> (last visited Sept. 29, 2003) ("[After January 1,

TRIPs also includes a number of exceptions to the exclusive rights of the patent holder. The most important of these exclusions are the general exceptions provided by Article 30, the compulsory licensing provision of Article 31, and the parallel importing clauses contained in Articles 28 and 5.³³

Article 30 grants Members the right to legislate for 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.³⁴

Article 31 permits Members to grant compulsory licenses for patented products and processes under limited circumstances and upon satisfying certain conditions.³⁵ Under a compulsory license, a government is forced to allow the production of a patented product without the necessary permission from the patent holder. In terms of pharmaceutical products, the aim of the practice is to allow countries to produce low-cost generic equivalents of the patented product in certain circumstances and under certain guidelines.

To avoid abuse, Article 31 conditions the granting of a compulsory license on the following pre-conditions:

2005.] without special arrangements, the possibility of compulsory licensing being a vehicle for price reductions will be more limited than at present, even in the few technologically advanced developing countries. For most countries, the only feasible supplier may be the patentee (or his licensee).”). It is worth noting that the quality and safety of generic drugs manufactured in developing countries has been questioned by the World Health Organization (WHO), which stated that such drugs could sometimes be of substandard quality, dangerous, or even lethal. *See WHO Essential Drugs and Medicines Policy, The Rationale of Essential Medicines, at* <http://www.who.int/medicines/rationale.shtml> (last visited Sept. 15, 2003) [hereinafter *WHO Essential Drugs and Medicines Policy*].

33. *See* TRIPs, *supra* note 1, arts. 5, 28, 30 & 31.

34. *See id.* art. 30. Article 30 authorises limited exceptions to patent rights for such things as research, prior user rights, and pre-expiration testing. Often called the “research exception,” the provision is commonly used by countries to advance science and technology by allowing researchers to use a patented invention to gain a better understanding of the technology. In addition, the provision is also used by countries to allow manufacturers of generic drugs to apply for marketing and safety approval without the patent owner’s permission and before the patent protection expires. The generic producers can then market the drug. This practice, often called the “regulatory exception” or “Bolar” provision, has been upheld as conforming with the TRIPs Agreement. *See* Canada—Patent Protection of Pharmaceutical Products—Complaint by the European Communities, WT/DS114/R (Mar. 17, 2000) [hereinafter Canada—Patent Protection of Pharmaceutical Products] (the Panel also held that manufacturing and stockpiling patented drugs prior to the exhaustion of patent protection is not a “limited exception” which can be exempted under Article 30).

35. *See* TRIPs, *supra* note 1, art. 31. Article 31, entitled “Other Use Without Authorization of the Right Holder,” does not expressly refer to the term compulsory licensing. Rather, the permissibility of compulsory licensing is implied when Article 31 is read in conjunction with Article 2(1) of the TRIPs Agreement and Article 5(A)(2) of the Paris Convention. *See id.*; Paris Convention, *supra* note 11, art. 5(A)(2).

- (a) authorization of such use shall be considered on its individual merits;
- (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;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member; [and]
- (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy

a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur[.]³⁶

In relation to patents, one of the most important of these conditions is subsection (b), which permits the granting of a compulsory license only if “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.”³⁷ Importantly, “[t]his requirement may be waived in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.”³⁸ However, “[i]n situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.”³⁹

Subsection (f) also plays an important part in the current controversy surrounding patent protection and access to medicines in the developing world. Subsection (f) restricts the issuance of a compulsory license unless it is used “predominantly for the supply of the domestic market of the Member authorizing such use”;⁴⁰ meaning that a country must have the means to produce the product itself or it cannot get the benefit of the compulsory licensing provision. By requiring foreign compulsory licensees to supply a predominant part of their production to their domestic market, subparagraph (f) limits the licensee’s ability to export medicines to a country with public health needs, and countries that have insufficient or no manufacturing capabilities thus cannot take advantage of the provision. When read with subparagraph (k), which provides that “members are not obliged to apply the conditions set forth in subparagraph[] . . . (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive,”⁴¹ the text appears to expressly limit a government’s use of compulsory licensing to predominantly supply its domestic market, except when necessary to remedy anti-competitive practices.

Subsection (h) is also important to the current debate, and its wording has

36. TRIPs, *supra* note 1, art. 31.

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

38. *Id.*

39. *Id.*

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

41. TRIPs, *supra* note 1, art. 31(f).

proven to be highly controversial. Subsection (h) requires the payment of “adequate remuneration” based on the “economic value of the license,”⁴² but in practice Members can neither agree on the meaning of “adequate remuneration” or that of the “economic value of the license.”

Therefore, while Article 31 grants Members the right to issue a compulsory license, it severely limits the circumstances under which such a license can be issued and requires that adequate remuneration be paid for the license. While it is argued that such limitations and conditions ensure against abuse, the practical effect of the limitations and conditions is that countries with manufacturing capabilities could make only very limited use of the provision, and those countries with insufficient or no manufacturing capabilities could not make use of the provision.

Other notable exceptions in TRIPs include the provisions allowing for the parallel importation of products. No one article governs parallel importation; instead, the activity is governed through Articles 6 and 28.⁴³ In combination, these articles provide that “nothing in [TRIPs] shall be used to address the issue of the exhaustion of intellectual property rights.”⁴⁴ The reason for the ambiguity regarding parallel importation in TRIPs stems from the parties’ failure to reach agreement while negotiating the agreement. In the end, the decision to allow its operation resulted because parties could not agree on how to govern its use or how to otherwise restrict its use. The lack of consensus regarding parallel importing is due to it being something of a double-edged sword: It allows countries to import goods through a third country at a cheaper rate than charged in the importing country; however, it also allows the patent owner to then charge more for the product in wealthy countries or those markets with inelastic product demands.

III. THE DOHA DECLARATION

A. Political Climate Leading to Doha

The issue of access to patented medicines gained worldwide attention in 2000, when several drug companies challenged the legality of the South African Medical and Related Substances Control Act of 1997, which allowed for compulsory licensing of patented pharmaceuticals.⁴⁵ The lawsuit, filed in

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

43. *See id.* arts. 6 & 28.

44. *Id.* art. 6.

45. *See Sarah Boseley, At the Mercy of Drug Giants: Millions Struggle with Disease as Pharmaceutical Firms Go to Court to Protect Profits*, THE GUARDIAN, Feb. 12, 2001 (reporting that approximately forty pharmaceutical companies were challenging Article 15c of South Africa’s 1997

the domestic courts of South Africa, evoked a significant amount of sympathy, strong reactions, and unfavorable publicity for the pharmaceutical companies.⁴⁶ At the same time, the U.S., one of the pharmaceutical companies' biggest supporters in the South African litigation, requested WTO consultations and the establishment of a panel against Brazil over the compulsory licensing provisions in Brazilian industrial property law.⁴⁷

As the negative publicity mounted, the U.S. reversed its position on the South African compulsory licensing laws and negotiated a settlement to its WTO dispute settlement claim against Brazil whereby that country agreed to consult with the U.S. before invoking any domestic compulsory licensing provisions.⁴⁸ In April 2001, the pharmaceutical companies also relented and dropped their challenge to the South African legislation.⁴⁹

Then, in September 2001, the U.S. position regarding compulsory licensing became untenable, as in the wake of the terrorist attacks of September 11 and the subsequent anthrax scares, the U.S. government threatened to issue a compulsory license order against Bayer AG Corporation's antibiotic Cipro (ciprofloxacin) unless the company lowered its selling price so that it could make Cipro available to victims of anthrax attacks.⁵⁰ The U.S. position with regards to its own threat of issuing a compulsory license placed itself in a difficult position, as it was now hard-pressed to remain credible in its requests that developing countries resist overriding patents in favor of making the drug available to the masses.⁵¹

Medicines Act), available at <http://www.guardian.co.uk/Archive/Article/0,4273,4134799,00.html> (last visited Aug. 2, 2003).

46. See, e.g., *id.*

47. Brazil—Measures Affecting Patent Protection—Request for the Establishment of a Panel by the United States, WT/DS199/3 (Jan. 9, 2001).

48. See Press Release, Office of the United States Trade Representative, United States and Brazil Agree to Use Newly Created Consultative Mechanism to Promote Cooperation on HIV/AIDS and Address WTO Patent Dispute, (June 25, 2001) (reporting that the U.S. and Brazil mutually agreed to transfer the dispute to a consultative forum and stating that the U.S. government would continue its policy of not raising objections to compulsory licensing provisions in developing countries' laws if they were aimed at addressing HIV/AIDS), available at <http://www.ustr.gov/releases/2001/06/01-46.htm> (last visited Oct. 15, 2002).

49. See Karen DeYoung, *Makers of AIDS Drugs Drop S. Africa Suit*, WASH. POST, Apr. 19, 2001, at A13 (reporting that the pharmaceutical companies were dropping their suit against the South African government due to the "public relations nightmare"), available at <http://www.washingtonpost.com/ac2/wp-dynA34439-2001Apr18?language=printer> (last visited July 11, 2003).

50. See *U.S. Threat to Cipro Patent Criticized*, INTELL. PROP. STRATEGIST, Nov. 2001. Canada became the first country to make use of the compulsory licensing provisions when it briefly rescinded Bayer's patent. Alan Moran, *Trade Laws and Pharmaceuticals*, 53(4) INST. PUB. AFF. REV. 25 (Dec. 2001).

51. Moran, *supra* note 50.

Many countries immediately noted the inconsistency and apparent double standard of the American position.⁵²

B. What Does the Declaration Do for Patent Protection?

Heading into the Doha Round, the time was ripe for developing countries to push for a shift in stance from developed countries towards access to medicines. Not only did the highly visible plight of many poor and ravaged countries place a significant amount of pressure on developed nations to be sympathetic to the demands of the developing countries and the LDCs, but the U.S. and Canada faced the possibility of looking extremely hypocritical in the wake of its post-September 2001 threats. In such a political climate, the U.S. and other developed countries could not have possibly objected to the needs of the developing world.⁵³

While both developing and developed countries submitted proposals to clarify certain ambiguous terms and phrases in TRIPs, the developing countries secured much of what they sought in the final Declaration.⁵⁴ The final text of the Doha Declaration sought to “clarify” the interpretation of TRIPs and emphasized the “flexibilities” already written into the agreement, including the right of Members to invoke those provisions when needed.⁵⁵ Paragraphs 1 through 5 acknowledge the importance of TRIPs to public health and recognize the flexibilities already existing in the Agreement.⁵⁶ In this regard, these paragraphs contain the Declaration’s most significant conclusions.

Paragraphs 1 through 3 outline the concerns of both developing and

52. See, e.g., Emma Young, *US Accused of Double Standard on Drug Patents*, *NEW SCIENTIST*, Nov. 2, 2001 (reporting French Trade Secretary Francois Huwart as stating that the U.S.’s threats of compulsory licensing with regards to Cipro gave “developing countries the impression that [a] double standard [was] in place”), available at <http://www.newscientist.com/news/news.jsp?id=ns99991512> (last visited May 5, 2002).

53. Prior to the Doha Ministerial Conference, the U.S. recognised the HIV/AIDS epidemic in sub-Saharan Africa and announced it would forgo any WTO challenge to countries that needed to override patents to address HIV/AIDS. See Press Release, Office of the United States Trade Representative, United States and Brazil Agree to Use Newly Created Consultative Mechanism to Promote Cooperation on HIV/AIDS and Address WTO Patent Dispute, *supra* note 48.

54. See generally Draft Ministerial Declaration, Proposal From a Group of Developed Countries, IP/C/W/313 (Oct. 4, 2001) (proposed and submitted to the TRIPs Council by Australia, Canada, Japan, Switzerland, and the U.S.); Draft Ministerial Declaration, Proposal From a Group of Developing Countries, IP/C/W/312, WT/GC/W/450 (Oct. 4, 2001) (proposed and submitted by African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela).

55. See Doha Declaration, *supra* note 4.

56. See *id.* ¶¶ 1-5.

developed countries by providing context to the issue of intellectual property protection for medicines while recognizing the need to balance private property and public welfare interests. These paragraphs form the framework for understanding the rest of the Declaration.⁵⁷ The Declaration begins by “recogniz[ing] 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.”⁵⁸ Paragraphs 2 and 3 reiterate the concern over health epidemics and the high cost of medicines in developing countries.⁵⁹ However, the first sentence of Paragraph 3 underlines the importance of intellectual property protection by reminding Members of the role that strong intellectual property protection plays in the development of new medicines.⁶⁰ Paragraph 2 reiterates that relaxing protections will not completely eliminate the health problems in the developing world.⁶¹

Paragraph 4 strongly affirms the principle that protecting public health and promoting access to medicines is a valid basis for Members to enact exceptions to patent protection in their domestic legislation.⁶² Specifically, Paragraph 4 provides that TRIPs “does not and should not prevent Members from taking measures to protect public health” and “affirm[s] 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.”⁶³ The affirmation in Paragraph 4 reinforces the plain meaning interpretation of TRIPs Article 8, which permits Members to “adopt measures necessary to protect public health.”⁶⁴

Paragraph 5 contains the most controversial provisions of the Doha Declaration, those that provide Members with flexibilities in implementing TRIPs.⁶⁵ Paragraph 5 reaffirms the right of WTO Members to use the provisions in TRIPs for the purposes of Paragraph 4 and sets out the “provisions,” which may be used for this purpose. The “provisions” are as

57. *See id.* ¶¶ 1-3.

58. *Id.* ¶ 1.

59. *See id.* ¶¶ 2-3.

60. *See* Doha Declaration, *supra* note 4, ¶ 3.

61. *Id.* ¶ 2.

62. *See id.* ¶ 4.

63. *Id.* ¶ 4.

64. *See* TRIPs, *supra* note 1, art. 8. While Article 31 of the Vienna Convention, which states the principles of treaty interpretation, may already permit countries to exercise flexibilities to protect public health by virtue of interpreting TRIPs Articles 30 and 31 in light of Article 8; Paragraph 4 of the Doha Declaration ends the debate by conclusively stating that Members have the right to use TRIPs flexibilities in order to protect public health. *See* Vienna Convention on the Law of Treaties, 1155 U.N.T.S. 331 (May 23, 1969), art. 31(1).

65. *See* Doha Declaration, *supra* note 4, ¶ 5.

follows:

- (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPs Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
- (b) Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
- (c) Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- (d) The effect of the provisions in the TRIPs Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the most-favored nation and national treatment provisions of Articles 3 and 4.⁶⁶

Paragraph 6 “recognize[s] that WTO with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement,” but the paragraph leaves the issue unresolved, instead instructing the Council for TRIPs to find an “expeditious solution” to the problem and to report to the General Council before the end of 2002.⁶⁷ It is regretful that this issue could not be resolved during the Doha Round, as extending the timeframe for negotiation simply delayed negotiation on this highly contentious issue.⁶⁸

Paragraph 7 extends the grace period for LDCs, delaying implementation of Sections 5 (patents) and 7 (confidential information) in relation to pharmaceutical products until January 1, 2016, for those countries.⁶⁹

66. *Id.* ¶ 5. As TRIPs did not textually define the term “national emergency,” Members sought to define the term in the Doha Declaration. However, the objective was not reached and the Declaration only provides that Members have the “right to determine what constitutes a national emergency” and expressly indicates that a “public health crises,” such as HIV/AIDS, malaria, and “other epidemics,” will be considered as national emergencies. *See id.*

67. *Id.* ¶ 6.

68. As this article later analyses, a solution was reached on August 30, 2003.

69. *See* Doha Declaration, *supra* note 4, ¶¶ 5 & 7. The U.S. proposed the extension for all LDCs until 2016 with regard to their obligations relating to all pharmaceutical patents. It should also be noted that the extension does not prejudice the right of LDCs to seek other extensions of the transition periods as provided for in TRIPs Article 66.1. *Id.* ¶ 7.

It is also important to note that the Doha Declaration does not restrict Members' rights to use the dispute settlement procedure, with the exception of barring Members from challenging other Members' schemes dealing with the exhaustion of intellectual property rights.⁷⁰ Consequently, developed countries can still use the Dispute Settlement Body (DSB) to enforce their intellectual property rights and while there is no doubt about the meaning of the statements in the Declaration, which clearly allow developing countries to use a number of different means to acquire necessary medicines, the legal effect of the Declaration is unclear. Ministerial Declarations are not binding on Members or the dispute settlement system, and the agreements negotiated by Members (WTO Agreement) would certainly prevail over the Doha Declaration,⁷¹ but the Declaration was careful to recognize this fact and the commitments in TRIPs do not seem to be contradictory to those commitments. Instead, the Declaration could be seen as being interpretive of the imprecise obligations and commitments spelled out in TRIPs; therefore, the Declaration would have persuasive authority in the dispute settlement process.

C. *Doha's Unanswered Questions*

The Doha Declaration provided developing countries with much of what they sought and certainly allows for much broader interpretation of the TRIPs Agreement with respect to a number of issues, including compulsory licensing and parallel importation of patented pharmaceutical products. The Declaration gave developing countries considerable leeway to provide for the health of its citizens by undercutting the profits that patent holders can otherwise earn from medical products, but developing countries did not achieve all their goals at Doha.

The key issue left unresolved by the Doha Round was how to ensure that a country with insufficient or no manufacturing capability in the pharmaceutical sector can receive needed drugs from a third country that has acquired a compulsory license for the purpose of exporting to that troubled nation. As TRIPs Article 31(f) limits compulsory licensing to situations "predominantly for the supply of the domestic market,"⁷² clarification was needed to ensure that countries with insufficient or no manufacturing

70. *Id.* ¶ 5(d).

71. *See* Agreement Establishing the WTO, *supra* note 2. As the WTO is a multi-lateral organisation created and given a mandate by sovereign Member States as a result of a treaty, the Agreements establishing and governing the WTO are the premier source of law in the WTO. Those governing documents can be modified to bind Members only through the appropriate amendment processes of Article X of the Agreement Establishing the WTO. *See id.*

72. TRIPs, *supra* note 1, art. 31(f).

capabilities can take advantage of the provisions designed to assist them.

Although developing countries attempted to add to the Doha Declaration that “[n]othing in the TRIPs Agreement prevents Members from granting compulsory licenses to foreign suppliers to provide medicines in the domestic market” and “nothing in the TRIPs Agreement will prevent Members to grant compulsory licenses to supply foreign markets,” they were unable to persuade developed countries to agree to such language.⁷³ Therefore, the Doha Declaration simply recognized that Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under TRIPs and instructs Members to resolve the issue by the end of 2002.⁷⁴ Unfortunately, despite the best efforts of the Chairperson of the TRIPs Council and all Members, consensus could not be reached as to how best to resolve the problem until August 30, 2003.⁷⁵

The failure of developing countries to resolve the issue during or immediately following the Doha Round was of great importance and highly worrying, as Article 31(f) is predicated on the capacity of a nation to produce. As most LDCs and developing countries, and particularly those countries most needing the drugs, do not have sufficient manufacturing capabilities, the compulsory licensing provision in TRIPs was of no assistance. The issue was even more pressing when one considers that the implementation deadline for many developing countries is growing nearer. Under TRIPs, needy countries can procure medicines from other developing countries or LDCs that produce generic versions of the drugs and do not currently have patent protection for pharmaceutical products. However, this option will be unavailable once suppliers are required to become TRIPs-compliant in the coming years.⁷⁶ Therefore, it was imperative that an agreement be reached; not only to assist countries so deeply enthralled in public health crises, but also so the WTO could look responsive to the needs of its less fortunate Members.

The deadlock was almost broken in December 2002, when every Member of the WTO but the U.S. agreed to support the Chairperson’s Draft of December 16, 2003. Consensus was not reached on the issue until some eight months later, when Members agreed to an implementation scheme in the days leading up to the Cancun Round.

73. See Sykes, *supra* note 10, at 54-55.

74. See Doha Declaration, *supra* note 4.

75. See discussion, *infra* Part IV.

76. See *supra* Part II.B. and note 32.

IV. THE IMPLEMENTATION AGREEMENT

A. *The Agreement's Approach*

The debate over the Paragraph 6 Mandate lasted nearly two years, with both developed and developing countries presenting their positions and compromising in order to reach an agreement. While several WTO Members and NGOs produced draft resolutions throughout the negotiating process attempting to resolve the dilemma, the proposals were firmly divided along a north/south line.⁷⁷ Developing countries suggested creating a new exception under Article 30 of TRIPs (entitled "Exceptions to [Patent] Rights Conferred") authorizing the manufacture and export of generic pharmaceuticals from producer to importing countries in a public health crisis, notwithstanding that the pharmaceutical is patented in the producer country.⁷⁸ Developed countries also advocated amending TRIPs Article 31(f) to create a new exception to the rule that forbids producer countries from exporting more than a small amount of any generic pharmaceutical they make under a compulsory license.⁷⁹

In the end, and perhaps in exchange for developed countries dropping their demands for an exhaustive list of eligible countries, diseases, and pharmaceutical products, all Members agreed to use Article 31 to implement the Paragraph 6 Mandate in the Doha Declaration.⁸⁰ Because Article 31

77. See, e.g., Joint Letter to the TRIPs Council, signed by Medecins Sans Frontieres, Oxfam International, Consumer Project on Technology, Third World Network, Essential Action, and Health Gap (Jan. 28, 2002), available at http://www.oxfam.org/eng/pdfs/pp020128_Trips_council.pdf (last visited Oct. 25, 2003) [hereinafter NGO Proposal]; Draft Communication from the European Communities and Their Member States to the TRIPs Council: Concept Paper for Approaches Relating to Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health (Feb. 1, 2002) [hereinafter EC Proposal] (although referred to as the EC Proposal, the draft was actually submitted by a number of developed countries).

78. See, e.g., Submission by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela (Sept. 18, 2001), available at <http://www.cptech.org/ip/wto/africagroup09182001.html> (last visited Mar. 22, 2004); Submission by Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand, and Venezuela (undated) ¶¶ 8-13, available at <http://www.cptech.org/ip/wto/southsubmission.html> (last visited Mar. 22, 2004). All submissions regarding public health are available at <http://www.iprsonline.org/submissions/publichealth.htm> (last visited Mar. 22, 2004).

79. See Joint Communication from the African Group in the WTO, Proposal on Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health, IP/C/W/351 (June 24, 2002). The African Group also recommended deleting or amending Article 31(f) so as to provide a specific exemption for measures adopted to protect public health and, in particular, to ensure affordable access to pharmaceutical products. See *id.*

80. Similarly, the December 16 Chairperson's Draft also recommended using Article 31(f) to

already establishes agreed terms and conditions for compulsory licensing to ensure a balance in situations in which use is permitted without authorization of the patent owner, most Members believe the solution will be effective in providing for the needs of developing countries and LDCs while also protecting intellectual property rights as best as practically possible.⁸¹

On the other hand, several NGOs criticized the Article 31 solution as being too bureaucratic and slow and viewed the Article 30 solution as more practical due to the political nature of the world trading system.⁸² “Unlike the Article 31(f) amendment, an Article 30 exception [would have] allow[ed] the producer country to manufacture and export without issuing a compulsory license.”⁸³ This seemingly subtle difference is significant because “compulsory licensing is . . . an extraordinary remedy” that has the potential to alienate and offend many developed countries and large multinational companies,⁸⁴ as such, the producer country’s government is unlikely to make that effort just to help a poor country wanting to import pharmaceuticals.⁸⁵ Moreover, governments are often slow to act on their own health needs, so the likelihood that they will come to the aid of a foreign government needing assistance is remote.⁸⁶ Further, and perhaps most importantly, only one country (Canada) has ever issued a compulsory license for pharmaceuticals since TRIPs entered into force. Instead, in every other case where a country

resolve the conflict. *See* Minutes of TRIPs Council Meeting, *supra* note 5.

81. The safeguard provisions of Article 31 are detailed earlier in this article. *See* discussion *supra* Part II.B.

82. Oxfam’s Head of Advocacy in Geneva, Celine Charveriat said: “Developed countries will trumpet this change to WTO patent rules as a big concession, but the proposed deal is largely cosmetic and will not make a significant difference to the millions of sick people who die unnecessarily in the Third World every year.” Oxfam, Press Release, WTO Patent Rules Will Still Deny Medicines to the Poor (Aug. 27, 2003), available at http://www.oxfam.org/eng/pr030827_wto_patents.htm (last visited Sept. 2, 2003). On the other hand, the developing countries themselves feel the deal will ease their situation. Kenya’s envoy to the WTO, Amina Chawahir Mohamed, said: “This is especially good news for the people of Africa who so desperately need access to affordable medicine.” The South African ambassador to the WTO, Faizel Ismail, “said he believed the deal was workable and that his country planned to [immediately] start using it to import desperately needed drugs at lower prices.” Koppel, *supra* note 8.

83. 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, 869 (2002). The limited exceptions to patent rights authorised by Article 30 do not require a government decision in each case. In addition, Article 30 does not require the user to notify the patent owner of its use, nor does it contain a requirement spelling out the particular terms and conditions, including the expiration of the license or setting the remuneration granted to the patent holder. *See* TRIPs, *supra* note 1, art. 30.

84. Attaran, *supra* note 83, at 869.

85. *Id.*

86. *Id.* at 869-70.

has threatened to issue a compulsory license, the interested parties negotiated mutually satisfactory agreements and ended the threat of unilateral action.⁸⁷ Thus, some commentators argue that even with the Article 31(f) solution implemented, compulsory licensing of pharmaceuticals for export to needy developing countries will rarely, if ever, occur.⁸⁸ Instead, those commentators assert that it would have been more feasible to have exporting countries make the one-off amendments to their domestic patent laws to enable the implementation of an Article 30 exception.⁸⁹

Developed countries, however, successfully argued that any approach using Article 30 would “permit otherwise infringing acts, [such as] supply[ing] a patented pharmaceutical for purposes of export[, and] seriously prejudice the rights and obligations of Members under the TRIPS Agreement.”⁹⁰ For example, it is not immediately apparent how an Article 30 exception, consistently invoked with respect to pharmaceuticals, is to be reconciled with the Article 27.1 requirement that “patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology” of the invention.⁹¹ Similarly, it is not apparent how an exception created in the domestic patent law of a producer country, which provides domestic legal force to the Article 30 approach by authorizing the manufacture and export of generic pharmaceuticals for nationals of poor countries, but not for nationals of developed countries, could be reconciled with the Article 4 Most-Favoured-Nation (MFN) requirement.⁹² It is unfortunate that none of the proposals from developing countries or NGOs explained how these conflicts were to be addressed.

Textual uncertainties also plagued the proposed Article 30 approach. For instance, the NGO proposal recommended that the Article 30 exemption

87. Examples of this occurring include Brazil’s threats to issue compulsory licenses to acquire less expensive antiretroviral drugs and the U.S.’s threats to the Bayer Corporation for Cipro in the event of an anthrax attack, both detailed earlier in this article. See discussion, *supra* Part III.A.

88. See, e.g., Attaran, *supra* note 83, at 869.

89. See Daniel Pruzin, *WTO Members Propose Greater Flexibility for Compulsory Licensing of Essential Drugs*, INT’L TRADE REP., June 27, 2002, available at <http://www.bna.com/itr/arch152.htm> (last visited Aug. 5, 2002).

[NGOs] such as Medecins Sans Frontier [(MSF)] and Oxfam International criticised the EU Proposal [and later the Implementation Agreement] for placing too many restrictions on the use of compulsory licensing for export production. “The [EU] Commission is seeking to add a flurry of little steps that makes things needlessly complicated,” argued Ellen ‘t Hoen, coordinator for MSF’s Access to Medicines campaign.

Id.

90. Communication from the United States, Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health, IP/C/N/340 (Mar. 14, 2002).

91. See TRIPs, *supra* note 1, art. 27.1.

92. See *id.* arts. 4 & 30.

include language stating that the exception should be “broader than medicines, and does not raise concerns regarding Article 27.1 restrictions on discrimination by field of technology.”⁹³ However, such language was unlikely to sufficiently meet WTO standards because even such a facially neutral exception may discriminate in violation of Article 27.1 if in practice it is invoked repeatedly in respect of a single technology, such as pharmaceuticals.⁹⁴

Moreover, the Article 30 proposals would have had to contend with the current interpretations of WTO law as promulgated by the DSB, and the only WTO panel to have seriously considered Article 30 interpreted it narrowly, ruling it is illegal to manufacture and stockpile a patented product, even if that product is never sold while the patent remains in force.⁹⁵ If such stockpiling cannot be authorized under Article 30, it seems impossible to authorize the manufacture for export and sale of a product while the patent remains in force. If this ruling is continued to be applied, it would mean that any TRIPs amendment or declaration that would have authorized the Article 30 approach would have had to create an exception for the latter situation, while maintaining the illegality of the former situation, or accept that the exemption would have effectively overturned existing case law, creating legal uncertainty with regards to the previously decided stockpiling issue.

Finally, it was never really understood how Members would put a new “interpretation” of Article 30 into operation, and none of the proposals offered much explanation as to how to operationalize the approach.⁹⁶ Instead, they asserted only that the WTO could operationalize the agreement by putting forward a new “interpretation” of Article 30.⁹⁷ However, the basis for this

93. NGO Proposal, *supra* note 77.

94. *See* United States—Import Prohibition of Certain Shrimp and Shrimp Products, WT/DS58/AB/R (Oct. 12, 1998). In this case the Appellate Body held that it is not just the substance of a rule that is reviewable for discrimination (*de jure* discrimination), but that the manner in which that rule is applied (*de facto* discrimination) is also reviewable. This holding was subsequently applied in a later dispute; therefore, it appears beyond question that it is good law. *See* Canada—Patent Protection of Pharmaceutical Products, *supra* note 34, ¶ 7.94.

95. The Panel held that such conduct is not a “limited exception” that can be exempted under Article 30. *See* Canada—Patent Protection of Pharmaceutical Products, *supra* note 34, ¶ 7.92.

96. *See* NGO Proposal, *supra* note 77. Commentators advocating this approach also failed to adequately explain how to operationalize such an “interpretation.” *See, e.g.,* Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health*, 17 AM. U. INT’L L. REV. 1299, 1344 (advocating that the TRIPs Council adopt a “Formal Interpretative Statement” but failing to detail how this would occur).

97. Such an “authoritative interpretation,” it was said, would have recognised the right of WTO Members to permit third parties to make, sell and export patented public health-related products without the consent of the patent holder in order to address the public health needs in another country.

proposition is highly questionable. The procedure for adopting official interpretations is found in Article IX:2 of the WTO Agreement, which states that an interpretation “shall not be used in a manner that would undermine the amendment provisions” that exist in the formal structural agreements.⁹⁸ In other words, Members cannot side step the formal amendment process by declaring an “interpretation.” It is this side stepping that may have been the undoing of an implementation exemption through “interpretation,” as the Article 30 interpretation also appears to be inconsistent with Article 27.1 (non-discrimination) and Article 4 (MFN). Therefore, it is doubtful that the WTO would have been agreeable to adopting an official “interpretation” of Article 30 that, while not violating Articles 27.1 and 4 on their face, would have in fact violated these Articles once it was relied on and used. This implicit overruling of Articles 27.1 and 4 would have appeared to make the “interpretation” a covert (and prohibited) amendment.⁹⁹

By contrast, Article 31 was the only possible solution that guaranteed legal and economic certainty for all parties. Resolving the problem through Article 31 will, by virtue of a formal guarantee provided by the government in question, supply generic manufacturers a high level of certainty to manufacture under a compulsory license without fear that they will be infringing patent laws. Thus, instead of merely obtaining an open-ended exception that would not even have guaranteed that they would be the only company to manufacture the product, manufacturers under an Article 31 exception will be certain that they are legally manufacturing the patented drug. Further, as the Chairperson’s Draft pointed out, procedures in Article 31 are “minimal and flexible” and have a fast-track provision in situations of extreme urgency or national emergency.¹⁰⁰ While importing countries making use of these provisions must have strong and effective national legislation, the Article 31 approach does not require them to seek WTO approval before implementing the emergency provisions. Instead, for transparency’s sake, importing countries making use of the provisions are simply required to notify the WTO of their use of the system.

98. Agreement Establishing the WTO, *supra* note 2, art. IX, ¶ 2.

99. It has been said that the interpretation power “may not do violence to the text of the [TRIPs] Agreement” by changing “yes” to “no” or “no” to “yes.” See Attaran, *supra* note 83, at 874 n.30 (citing Andrew Creese and Jonathan Quick, *Differential Pricing Arrangements and Feasibility: Context Setting Paper*, World Health Organization, Jan. 21, 2001, Part D, available at Norway Ministry of Foreign Affairs, <http://odin.dep.no/ud/norsk/handelspolitikk/032061-090003/index-hov006-b-f-a.html> (last visited Sept. 17, 2003)).

100. Minutes of TRIPs Council Meeting, *supra* note 5.

B. Lingering Questions of the Implementation Agreement

The Implementation Agreement attempts to resolve the Paragraph 6 Mandate by waiving the Article 31(f) obligations of an exporting Member, effectively providing that a Member State can now issue a compulsory license to produce generic drugs for the express purpose of providing those drugs to another nation in order for that nation to combat a public health problem or epidemic.¹⁰¹

To be TRIPs compliant, the importing Member must notify the TRIPs Council of the “names and expected quantities of the products needed”,¹⁰² confirm that it is either a LDC or that it “has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the products in question”,¹⁰³ and confirm that, if the “product is patented in its territory, [that] it has granted or intends to grant a compulsory licence in accordance with [TRIPs] Article 31.”¹⁰⁴

The Implementation Agreement also outlines the conditions to be followed by the exporting Member when issuing a compulsory license, namely that the Member manufacture “only the amount necessary to meet the needs of the importing Member . . . and that the entirety of the production [actually] be exported to [that other] Member[]”,¹⁰⁵ that “products produced under the licence . . . be clearly [identifiable] as being produced under [a compulsory license], provided that [the] distinction is feasible and does not have significant impact upon price” (such distinguishing characteristics could be made in labeling, marking, special packaging, or by specific coloring or shaping of the product itself);¹⁰⁶ and that “before shipment . . . , the licensee shall post . . . the quantit[y] of the drug being supplied . . . and the distinguishing feature[] of the [drug]” on an identifiable Web site.¹⁰⁷

While the Implementation Agreement and accompanying Chairperson’s Statement¹⁰⁸ help define certain important aspects of the Paragraph 6 Mandate

101. Implementation Agreement, *supra* note 8, ¶ 2(a)(i).

102. *Id.* Paragraph 6 allows regional blocs to be treated as one nation in order to make use of economies of scale.

103. *Id.* ¶ 2(a)(ii).

104. *Id.* ¶ 2(a)(iii).

105. *Id.* ¶ 2(b)(i).

106. Implementation Agreement, *supra* note 8, ¶ 2(b)(ii). This requirement has been criticised by NGOs, which claim that it will be uneconomical for generic manufacturers to export the drugs to countries issuing the compulsory license. *See* MSF Comments on the Draft Chairman’s Statement of 21 August 2003.

107. Implementation Agreement, *supra* note 8, ¶ 2(b)(iii).

108. The agreement was made possible only when the Members agreed to present a Chairperson’s Statement alongside the Implementation Agreement. Among other things, the Statement (i) “recognis[es] that the [compulsory licensing] system . . . should be used in good faith to

and, no doubt, have authoritatively set the guidelines that countries must follow when making use of the patent exceptions available in TRIPs; it is disappointing that the wording of the Agreement could not be refined to avoid, or at least limit, the potential for abuse. Unfortunately, as drafted, several paragraphs of the Implementation Agreement lend themselves to the possibility of abuse or are otherwise unsatisfactory and potentially destabilizing to the entire system of compulsory licensing.

The four main areas the Agreement fails to satisfactorily resolve are the following: (i) the scope of diseases and product coverage; (ii) countries that would be eligible to use the system; (iii) ensuring adequate remuneration; and (iv) safeguarding the system against diversion of drugs into other markets.

1. Scope of Diseases and Product Coverage

As negotiations on the Paragraph 6 Mandate developed, the scope of diseases to be covered by any new exception to patent rights quickly became the major stumbling block towards reaching consensus and resolving the issue. On the one hand, developed countries wanted the scope of diseases to any Doha solution limited to those constituting a true “public health crisis” and also wanted to limit the scope of products covered to those that truly combat the eligible diseases. On the other hand, developing countries argued that Paragraph 1 of the Declaration did not qualify “public health” in Paragraph 4 or limit the scope of diseases that may be addressed when finding a solution to the Paragraph 6 problem. Therefore, developing countries asserted that any agreement could not include a defined list of eligible diseases or exclude any pharmaceutical products used to address public health concerns.

Developed countries countered by revisiting the text and spirit of the Doha Declaration itself. Paragraph 1 states that the Doha Declaration addresses “public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”¹⁰⁹ While the paragraph does not define the list as exhaustive or merely a few of many possible examples of the type of public health problems that would qualify as a “public health problem,” greater clarity can be gleaned by reading Paragraph 1 together with the

protect public health and [not as] an instrument to pursue industrial or commercial policy objectives”; (ii) “recognis[es] that the purpose of the [Implementation Agreement] would be defeated if [drugs were] diverted from the [intended] markets” and calls on Members to take “all reasonable measures” to “prevent such diversion”; and (iii) reiterates the importance of Members to seek expeditious and amicable resolutions to issues arising from the Implementation Agreement. Chairperson’s Statement, *supra* note 9.

109. Doha Declaration, *supra* note 4, ¶ 1.

complementary and mutually supportive Paragraph 6.¹¹⁰ When read together, one realizes that Paragraphs 1 and 6 envisage that the solution to the Paragraph 6 issue should extend only to *diseases causing public health problems* afflicting many developing countries and least developing countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics. Correspondingly, developed countries attempted to limit the scope of the diseases covered to those listed in Paragraph 1 or to those situations that were certifiable health emergencies.¹¹¹ But all attempts to form a defined list were soundly rejected by developing countries as merely attempts to redefine and narrow the scope of health problems reflected in Paragraph 1.¹¹²

Moreover, Swiss attempts to define the pharmaceutical products covered by Paragraph 4 to those “falling within the scope” of those mandated by the Doha Declaration, or, more specifically, to those products “which are required by a WTO Member while dealing with public health problems”¹¹³ were also rejected by developing countries, who insisted that “[p]roduct[s] in the pharmaceutical sector” must be read to include “all medicines and vaccines, including active pharmaceutical substances used in the prevention and treatment of disease and health care, as well as diagnostic products and products used to administer medicines and vaccines.”¹¹⁴

The Implementation Agreement attempts to reach a compromise on the issue by broadly defining the term “pharmaceutical product,” but then limits

110. *See id.* ¶¶ 1 & 6.

111. For instance, Canada recognised the need to balance the interests of developed and developing countries while also stating that any agreement must distinguish between public health crises that “are truly epidemic and those that [are] not.” *See* Minutes of TRIPs Council Minutes, *supra* note 5, ¶ 41.

112. The African, Caribbean, and Pacific Group of States (ACP) reiterated its strong stance against limiting the compulsory licensing provisions to certain diseases when it stated: “[A]ny text that restricts the agreement to a set list of diseases, even involving the WHO in assessing public health concerns, would constitute an unacceptable attempt to restrict ACP’s use of compulsory licensing.” Communication from the ACP, Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health, IP/C/W/401 (May 28, 2003). *See also* Minutes of TRIPs Council Meeting, *supra* note 5, ¶¶ 35, 37 (comments of the African Group and Brazil).

113. *See* Non-Paper from Switzerland, Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health, JOB(02)/109 (Sept. 13, 2002), at 2 [hereinafter Non-Paper from Switzerland].

114. Non-Paper by South Africa, Substantive and Procedural Elements of a Report to the General Council under Paragraph 6 of the Declaration on the TRIPs Agreement and Public Health, JOB(02)/156 (Nov. 5, 2002) [hereinafter Non-Paper by South Africa]. The African Group also stated: “[P]harmaceutical products’ should be construed broadly in order to be meaningful, rather than narrowly in a manner that would restrict it to only limited components of treatment or medicines. ‘Pharmaceutical products’ should be understood to include medicines, related technical processes, and related technical equipment.” Joint Communication from the African Group in the WTO, Proposal on Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health, IP/C/W/351 (June 24, 2002), ¶ 6(b).

its meaning to those products needed to address the public health problems identified in Paragraph 1 of the Declaration.¹¹⁵ The Implementation Agreement defines “pharmaceutical product” 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. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.”¹¹⁶

While the second part of the statement would initially seem to limit “pharmaceutical products” to those public health problems, such as those defined in Paragraph 1 of the Doha Declaration (“HIV/AIDS, tuberculosis, malaria and other epidemics”), a careful reading of Paragraph 1 reveals that the list of products mentioned is not exhaustive.¹¹⁷ Paragraph 1 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.”¹¹⁸

Therefore, Paragraph 1 leaves the list of diseases undefined, and, while it would certainly include HIV/AIDS, tuberculosis, and malaria, it could include any number of other diseases. Further, as the nations wishing to make use of the patent exceptions are the ones that solely decide what constitutes a “public health problem,” the section is lacking direction or limits. Thus, without any hesitation, a country could declare a health emergency and be granted a compulsory license on any drug, including Viagra. Such a perverse result is contrary to the spirit of the Doha Declaration.

Similarly, the issue of product coverage is also ill-defined. While the Implementation Agreement states, “[i]t is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included,” such language does not go far enough as to resolve the issue and could prove troublesome in the future.¹¹⁹ For instance, while the scope of product coverage is intentionally broad, the limits to the definition remain unclear; and while such a definition would probably include most preventative measures, such as vaccines, it is unclear if it also includes all test kits and preventative treatments or what the general limits are to preventative measures.

Resolution of this issue required a concerted effort from all parties

115. Implementation Agreement, *supra* note 8, ¶ 1(a).

116. *Id.*

117. *See id.*; Doha Declaration, *supra* note 4, ¶ 1.

118. Doha Declaration, *supra* note 4, ¶ 1 (emphasis added).

119. *See* Implementation Agreement, *supra* note 8, ¶ 1.

involved, and they should be applauded for reaching agreement. However, the Implementation Agreement leaves the issue of product scope undefined. Careful reading of Paragraph 1 of the Doha Declaration reveals that a public health crisis, while including such diseases as HIV/AIDS, tuberculosis, and malaria, does not exclude countries from calling any disease (including male pattern baldness) a public health crisis and issuing a compulsory license to combat the problem. In addition, Paragraph 1(a) of the Implementation Agreement leaves the scope of products available for compulsory license ill-defined and subject to disagreement.¹²⁰ While it is easier to simply reach agreement and debate the specifics tomorrow, it would be advisable for the parties to agree to defined limits as soon as possible, as opposed to having the dispute settlement process decide the issue in a panel or Appellate Body report.

2. First World Countries Without Manufacturing Capabilities

Another controversial issue that emerged during the Paragraph 6 negotiations was which nations would qualify as “eligible importing Member(s)”; in other words, which countries would be able to make use of the exceptions to patent protection and import generic drugs to combat public health crises.

The reason for the contentiousness of the issue is that, while Paragraph 6 of the Doha Declaration conferred a mandate on WTO Members to resolve the textual difficulty of countries with the concurrent problems of: (1) “insufficient or no manufacturing capacities in the pharmaceutical sector,” and (2) “difficulties in making effective use of compulsory licensing,” it did not include a requirement that a country face a genuine public health problem, nor did it include a requirement that the country lack the resources to purchase needed medicines from the manufacturer.¹²¹ The lack of such requirements could lead to the perverse result of small, wealthy nations, such as Liechtenstein, Luxembourg, or Singapore, qualifying under the exception, as those nations have “insufficient or no manufacturing capacities” for pharmaceuticals. Thus, Paragraph 6 could be read to “solve” the fictitious problems of rich and healthy countries.¹²²

Clearly, it is not appropriate to extend the solution to developed countries or to wealthy developing countries that *choose* not to manufacture certain drugs. And while most parties could agree that the exception to patent protection should assist only poor countries that are truly incapable of

120. *See id.* ¶ 1(a).

121. *See* Doha Declaration, *supra* note 4, ¶ 6.

122. Attaran, *supra* note 83, at 863-64.

manufacturing sufficient quantities of pharmaceuticals, any attempts to limit the use of the proposed exceptions to poor economic countries that lack sufficient manufacturing capabilities met fierce resistance.¹²³ For instance, Hong Kong stated that even though it did not envisage using the exception, it would not agree to its exclusion as an eligible country.¹²⁴ Hong Kong relied on the fact that “the only criterion for eligibility under the [Doha Declaration] was . . . insufficient manufacturing capacities.”¹²⁵ South Africa and other developing nations concurred with the above stance, believing that Members should be allowed to elect not to benefit from the importation of products in the pharmaceutical sector to address public health needs under Paragraph 6, but that Members should not be excluded from the regime.¹²⁶

The position advocated by Hong Kong, South Africa, and others counters the spirit of the Doha Declaration. Paragraph 1 of the Doha Declaration, which states that the WTO Ministerial “recognize[s] 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,” quite clearly implies that Paragraph 6 applies only to developing and LDCs.¹²⁷ Paragraph 1 reflects that the proposals initiated by developing countries as a solution to their problems, and the solution to the Paragraph 6 Mandate should have recognized the history and reasoning behind the Declaration and been predicated on a country’s poor economic *and* poor health status.

In this regard, Paragraph 1(b) of the Implementation Agreement fails to take full account of the purpose of the Doha Declaration and leaves the system open to widespread and potentially debilitating abuse. In order to reach consensus, developed countries abandoned the notion that an “eligible

123. The EC Proposal was quasi-explicit about limiting the Article 30 exception to developing countries, and, while the limitation is missing from Paragraph 28 of that Proposal, it is implied via Paragraph 31, which refers back to preceding paragraphs where the challenges of developing countries are discussed. *See* EC Proposal, *supra* note 77. On the other hand, the NGO Proposals ignored the issue, with many developing countries and NGOs explicitly disagreeing with limiting the Article 30 exception to developing countries. *See, e.g.*, NGO Proposal, *supra* note 77, ¶¶ 28 & 31; Press Release, Trans Atlantic Consumer Dialogue, Consumer Groups Call for the Implementation of WTO Clause Enabling Countries to Import Cheap Medicines (Feb. 2, 2002), *available at* <http://www.tacd.org/cgi-bin/db.cgi?page=view&config=admin/press.cfg&id=18> (last visited Sept. 17, 2003).

124. Minutes of TRIPs Council Meeting, *supra* note 5, ¶ 57-58.

125. *Id.* ¶ 58.

126. In a non-paper to the TRIPs Council, South Africa concludes that “Paragraph 6 addresses Members with insufficient or no manufacturing capacities in the pharmaceutical sector. It does not refer to the categorization of Members based on levels of income or other criteria unrelated to manufacturing capacities.” Non-Paper from South Africa, *supra* note 114.

127. *See* Doha Declaration, *supra* note 4, ¶ 1.

importing Member” must be a poor nation suffering from a public health crisis. Therefore, as drafted and adopted, the Implementation Agreement allows for *any* Member of the WTO to make use of the patent exceptions, so long as that nation is suffering from a public health crisis and has insufficient manufacturing capabilities to meet demand.¹²⁸ While the Implementation Agreement notes that some Members have stated that they will not make use of the system and others have pledged to make use of the system only in situations of national emergency or other extreme circumstances, these statements are unlikely to be binding if, in fact, those nations later decide to make use of the patent exceptions.¹²⁹

3. Adequate Remuneration

Under an existing exception to TRIPs, when and under what circumstances a Member can declare a national emergency is at the sole discretion of the invoking Member.¹³⁰ Moreover, when declaring a national emergency and correspondingly issuing a compulsory license to serve the domestic market, the Member does not have to engage in prior negotiation with the patent holder in an attempt to negotiate “adequate remuneration.”¹³¹ Finally, after invoking the national emergency exception and issuing a compulsory license without prior negotiation, the Member must then pay “adequate remuneration” to the patent holder.¹³²

The position of TRIPs is at odds with the position of developing countries and seemingly that of the Doha Declaration—that Members can make a unilateral determination and offer only minimal payment in return. In addition, the Implementation Agreement confuses the issue even more by first noting in the Preamble that “exceptional circumstances exist justifying waivers from the obligations set out in [TRIPs Article 31(h)]” and then later stating in Paragraph 3 that “[w]here a compulsory licence is granted by an

128. The Annex to the Implementation Agreement deems LDCs “to have insufficient or no manufacturing capacities,” while other nations’ eligibility depends upon their having “no manufacturing capacities in the pharmaceutical sector” or, after examination of its capacity, a finding that its current manufacturing capabilities are “insufficient for the purposes of meeting its needs” (excluding the capacity owned or controlled by the patent holder). Thus, the system shall no longer apply when capacity becomes sufficient to meet its needs. *See* Implementation Agreement, *supra* note 8, Annex.

129. Twenty-three nations (Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, UK, and U.S.) stated that they would only make use of the provisions in national emergency or extreme circumstances. *See* Chairperson’s Statement, *supra* note 9.

130. *See* Doha Declaration, *supra* note 4, ¶ 5(c).

131. *See* Implementation Agreement, *supra* note 8, ¶ 3.

132. *See id.*

exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid.”¹³³

In all likelihood, the Preamble of the Implementation Agreement is simply confirming that the existing right to issue a compulsory license without negotiation with the patent holder in situations of national emergency is preserved in the Agreement, but if that is the case, why does the Preamble use such indirect language? And why does the Preamble use the words “exceptional circumstances” instead of the often-used words “national emergency?”

Unfortunately, the above dilemma is not the only cause for despair in Paragraph 3 of the Implementation Agreement. The meaning of “adequate remuneration” is ill-defined in Paragraph 3, with the provision stating only that adequate remuneration “shall be paid . . . taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member.”¹³⁴

Such drafting ambiguities only invite future dispute and ongoing problems. Developing countries will insist that a temporary license or other such mechanism to aid poor developing countries in providing essential medicines to their citizens will not burden other WTO Member States or pharmaceutical companies, and, therefore, the payment should be very low. On the other hand, it is unsatisfactory to simply assert that a derogation from the rights of the patent owner is harmless simply because it is temporary and issued under controlled circumstances. For that reason, pharmaceutical companies will assert that adequate remuneration means enough compensation to cover the costs of research and development as well as provide a modest profit.¹³⁵

The meaning of “adequate remuneration” should have been more thoroughly addressed and defined during negotiations and must be properly addressed before a dispute arises. While we are justifiably sympathetic to the plight of many developing countries, we cannot let our concern blind us to all

133. *See id.* ¶ 3 & Preamble.

134. *See id.* ¶ 3. Paragraph 3 also states that when the importing Member must issue a compulsory licence (such as when its national system has granted a patent for the drug which is still in force), then the obligation of remunerating the patent holder in the importing Members’ country shall be waived. *See id.* Such a ruling prevents the patent holder from being remunerated in both the exporting and the importing countries.

135. *See, e.g., International Chamber of Commerce, Further Views on Cross Border Compulsory Licensing, Submission to the WTO* (Aug. 8, 2003) [hereinafter *International Chamber of Commerce*], available at http://www.wto.org/english/forums_e/ngo_e/icc_paper_aug03_e.pdf (last visited Sept. 29, 2003).

other realities. We would not permit a nation under a genuine state of emergency as a result of famine, natural disaster, or similar conditions, and with a desperate need for funds, to expropriate businesses and other property from foreign owners without remuneration; so why is medicine any different? Concern and respect should be paid to the property of pharmaceutical companies, just as concern and respect would be paid to the property of any other business.

Developing countries do not necessarily oppose the idea of conditioning a compulsory license, but rather insist that any conditions and “procedures to determine adequate remuneration should not be used to inhibit the expeditious export and import of products under Paragraph 6.”¹³⁶ While developed countries argue that any Member wanting to make use of the Paragraph 6 exception should always negotiate in good faith with the patent holder before invoking compulsory licensing, there is little chance that any developing country will agree to those conditions. However, future negotiations between developed and developing countries could ensure that “adequate remuneration” means reasonable commercial terms or a royalty of value paid even in times of national emergency. While research and development costs for that product, as well as unsuccessful products, are not likely to be taken into account, the solution could be satisfactory to all sides. Developing countries would get access to the drugs for a below-market value cost, and while pharmaceutical companies would be selling the drugs at a drastically reduced price, the exception to their patent rights would be temporary and the payment would cover their expenses.

4. Safeguards Against Diversion

Parallel importing arises when the patent holder sells a product to a buyer who exports the product to a second buyer in another country.¹³⁷ Such practice occurs when the price of the imported product, taking into account transportation and tariffs, is still lower than the price of the same product legally made or imported into the country.¹³⁸ Quite obviously, parallel importation undercuts the ability of a patent holder to engage in price discrimination across national boundaries and can severely reduce profit levels of international companies. Importantly, the Doha Declaration confirmed the existing right available in TRIPs that each WTO Member may establish its own regime of exhaustion of intellectual property rights.¹³⁹ This statement confirms that parallel importing is not in and of itself a violation of any WTO Agreement.¹⁴⁰

136. Non-Paper from South Africa, *supra* note 114, ¶ 11.

137. In intellectual property, parallel importation is the cross-border trade in a patented

International price discrimination, also referred to as tiered pricing, benefits developing countries and other countries with elastic demand for the product.¹⁴¹ International price discrimination also allows companies to charge a high price in countries able and willing to meet the higher price (most often developed nations) in order to recoup the costs of offering a lower price to those markets unable or unwilling to meet the higher price.¹⁴² Pharmaceutical manufacturers often engage in price discrimination between national boundaries, as the elasticity of demand differs widely between markets; thus, when there is a low elasticity of demand in one country (low rate of exit) and a high elasticity of demand in another (high rate of exit), manufacturers will price products accordingly in each country.¹⁴³

However, when supplying pharmaceuticals to the developing world at severely reduced prices, as would be the case under a compulsory license or aid agreement, the existing WTO rules could be used so that the owners' intellectual property rights are exhausted after the first sale. Therefore, nothing would prevent the importing nation that acquired the pharmaceuticals at drastically reduced prices from then exporting the drugs back to the original market or any other market for profit. Of course, because the drugs were exported to the developing country at reduced prices only as a result of the public health problem, such conduct on the part of the developing country would be against the spirit of the Doha Declaration and would prevent the goal of facilitating access to medicines in needy countries from being reached. Therefore, supplying pharmaceuticals to developing countries at reduced prices must be conditioned on the fact that the drugs will be used in that country to ease their health crisis, not simply re-exported out of the country to

product without the permission of the manufacturer or publisher. For more information, see *Health Care and Intellectual Property: Parallel Imports*, available at <http://www.cptech.org/ip/fsd/health-pi.html> (last visited Mar. 20, 2004).

138. *See id.*

139. Doha Declaration, *supra* note 4, ¶ 5(d) (reiterating that these rights are, of course, subject to the most favoured nation and national treatment provisions of TRIPs). *See* TRIPs, *supra* note 1, arts. 3 & 4.

140. *See* Ellen 't Hoen, *TRIPs, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 41 (2002).

141. *See* Sykes, *supra* note 10, at 63-64.

142. *Id.* at 63. Manufacturers and exporters often sell products cheaply in some developing countries in order to expand their market to those who would not otherwise be able to afford the product. *See generally id.* at 63-64.

143. Elasticity of demand depends on a number of different factors, including, but not limited to, the availability of substitutes, government regulations, income levels, and general wealth of the population. *Id.* at 63. For an extensive evaluation of the impact of parallel importing on the pharmaceutical industry, see Claude Barfield & Mark Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185 (1999).

a market willing to pay a higher price for the drugs.¹⁴⁴

While developing countries agreed that re-exporting the reduced-price pharmaceuticals should not be allowed, they had trouble agreeing with their developed country counterparts on the extent of monitoring that should occur and the consequences that should result from re-exportation.¹⁴⁵ Paragraph 4 of the Implementation Agreement attempts to balance the concerns of both developed and developing countries when it instructs importing countries to take measures to prevent re-exportation, but the Agreement leaves unclear the issue of to what extent an importing country must act.¹⁴⁶ Instead, Paragraph 4 merely states that the measures must be “reasonable,” “within their means,” and “proportionate to their administrative capacities and to the risk of trade diversion.”¹⁴⁷ While the Agreement is obviously designed to avoid imposing conditions that developing countries cannot meet while also encouraging them to take responsibility to ensure that medicines reach their intended destinations; the ambiguity of their responsibilities and the lack of repercussions following a breach could potentially unsettle the compulsory licensing system.¹⁴⁸

Moreover, while Paragraph 4 envisions developed countries assisting those developing countries and LDCs that “experience[] difficulty” in preventing diversion, its conditions and guidance are inadequate.¹⁴⁹ Paragraph 4 only allows developed countries to provide technical and financial cooperation to prevent diversion “on request and on mutually agreed terms and conditions” of the importing Member.¹⁵⁰ Therefore, if an importing Member does nothing to prevent (or encourages or even brokers a deal for)

144. Diversion and re-exportation are legitimate concerns of the developed world, because not only are the re-exported drugs diverted away from the people for whom they were intended, but also because the generic drugs manufactured in developing countries are not subject to the scrutiny of the patent holder and may be of inferior quality or even dangerous. See Geoff Dyer, *Netherlands Acts on Re-Sold AIDS Drugs; Genetic Key to Malaria Found*, THE GUARDIAN, Oct. 3, 2002, available at <http://web.worldbank.org/WBSITE/EXTERNAL/NEWS/0,,date:10-03-2002~menuPK:34461~pagePK:34392~piPK:34427~theSitePK:4607,00.html#Story1> (last visited Oct. 1, 2003); *WHO Essential Drugs and Medicines Policy*, *supra* note 32.

145. See, e.g., Non-Paper from Switzerland, *supra* note 113, ¶ B(1) (calling on nations to agree on strict measures to prevent diversion). *Contra* Non-Paper from South Africa, *supra* note 114, ¶ 9 (contending that “[m]easures to prevent . . . diversion should neither place unnecessary or onerous burdens on countries nor render the products in the pharmaceutical sector supplied under paragraph 6 less accessible”).

146. See Implementation Agreement, *supra* note 8, ¶ 4.

147. See *id.*

148. The Implementation Agreement does not provide for judicial redress of the diversion issue, instead viewing the measure’s purpose to ensure medicines reach their destination, not to provide property holders with mechanisms to enforce their rights.

149. See Implementation Agreement, *supra* note 8, ¶ 4.

150. *Id.*

the diversion of medicines away from its citizens and into another market, other Members and/or the patent holder can do nothing to prevent the diversion. The only way in which another Member can become involved is when the importing member requests assistance. Such a system invites abuse and provides no mechanism to stop it. It would seem appropriate for Members to have the ability to become involved in an effort to prevent diversion, particularly if the importing Member is actively participating in such diversion. At the very least, one would expect that the Agreement would include a provision allowing aggrieved Members to complain to and refer the matter to the TRIPs Council.

Interestingly, Paragraph 5 involves the TRIPs Council in respect to preventing products from being imported into other markets in so far as it allows Members to use the means available under their domestic legal systems to prevent such diversion.¹⁵¹ If those domestic legal systems prove ineffective, then “the matter may be reviewed [by] the [TRIPs Council] at the request of that Member.”¹⁵² But this does not completely make up for the Agreement’s exclusion of such referral powers in Paragraph 4, as attempting to prevent the diverted medicines from ending up in one’s country is not the same and not as important as preventing the diversion in the first place.

WTO Members missed an opportunity to allow the TRIPs Council a greater role in the compulsory licensing process. The TRIPs Council could have been involved in the monitoring of transactions and could have better ensured not only that the drugs do not get re-exported but also that only minimal economic, legal, and bureaucratic burdens are placed on the importing country. Such a system, if properly designed, could have been workable and agreeable to all concerned parties.

V. CONCLUDING ANALYSIS AND REMARKS

As much as we would like the Implementation Agreement to be a magic solution that will end the suffering of those inflicted by the health epidemics raging through much of the developing world, such hope is unrealistic. At best, we can only hope that the Implementation Agreement will be the catalyst to encourage structural changes that will ease the suffering in those afflicted countries. While pharmaceutical companies, the TRIPs Agreement, and patent protection more generally, have taken the brunt of the blame for the worsening health situation in the developing world, this assessment of blame is largely unfounded. Unfortunately, the activists and government officials involved have become so tied to their arguments against the pharmaceutical

151. *Id.* ¶ 5.

152. *See id.*

industry that they fail to see the other, more crucial impediments to resolving the crisis.

This view is shared by Bruce Lehman, former U.S. Assistant Secretary of Commerce and Commissioner of Patents and Trademarks in the Clinton Administration and currently president of the International Intellectual Property Institute (IIPI), an organization that works with developing countries to harness their citizens' intellectual property as a source of economic growth. Mr. Lehman contends that patent protection should not be blamed for the health epidemics in Africa and developing countries elsewhere in the world¹⁵³ and further believes that "AIDS activists have done a huge disservice to the problem of providing relief to people in the developing world by directing a disproportionate focus on the patent issue."¹⁵⁴

Even in the best of circumstances, it will not be an easy task to completely end the public health crisis in the developing world. But casually laying the blame at the feet of one party has not helped the situation; on the contrary, it has been divisive and has arguably lengthened the time between the Doha Round and the Implementation Agreement. All interested parties must now realize that many factors other than patent protection play a role in improving the health of the developing world. Only when we actively engage and combat such factors as poor living conditions, the lack of medical facilities, malnutrition, and the lack of means for distributing and administering medicine will we really have a chance at resolving the health crisis.

While the vast majority of tuberculosis and malaria drugs are off-patent and less than twenty percent of the drugs used to combat HIV/AIDS are patented in African countries, the developing world continues to suffer without adequate supply of the needed medicines.¹⁵⁵ The fact of the matter is that the delivery and administration of vaccines and medicines often cost more than the drugs themselves, and it is the cost of transporting, storing, administering, and supervising the drugs that often impedes the delivery of

153. Bruce A. Lehman, *Globalization's Impact on International Trade and Intellectual Property Law: Intellectual Property Rights as a Trade, Health and Economic Development Issue*, 17 ST. JOHN'S J. LEGAL COMMENT 417 (2003).

154. *Id.* at 419-20.

155. Pharmaceutical Research and Manufacturers of America, *Health Care in the Developing World: Intellectual Property and Access to AIDS Drugs* (Jan. 7, 2003) [hereinafter PhRMA], at <http://world.phrma.org/ip.access.aids.drugs.html> (last visited Feb. 20, 2004). Of the fifteen anti-retroviral drugs used for treating AIDS, patent coverage is below twenty percent, with 172 patents out of the 759 that could theoretically apply. Moreover, of fifty-two African nations, only South Africa has patent protection for more than half its AIDS drugs, with fifteen patents out of a possible sixteen. Twenty-five percent of the countries provide no patents and the rest have an average of four patented drugs, with no patents on more than a dozen different triple-therapy cocktails used to combat HIV/AIDS. *Id.*

medicines to the developing world. While some would like us to believe the problem lies simply with the price of the drugs themselves, such statements are illusory and deceitful.

Though several activist organizations have blighted the issue to many around the world, the medical community itself was never convinced that strong patent laws have exacerbated the HIV/AIDS crisis or that patent laws have been an impediment to drug access. For instance, a highly respected 2001 study conducted by Amir Attaran and Lee Gillespie-White and published in the *Journal of the American Medical Association* states:

[It appears that] patents and patent law are not a major barrier to treatment access in and of themselves. We conclude that a variety of de facto barriers are more responsible for impeding access to antiretroviral treatment, including but not limited to the poverty of African countries, the high cost of antiretroviral treatment, national regulatory requirements for medicines, tariffs and sales taxes, and, above all, a lack of sufficient international financial aid to fund antiretroviral treatment.¹⁵⁶

The fact is that the majority of developing countries and LDCs lack the economic foundation to sustain the costs of purchasing, storing, transporting, and administering needed medicines. Many pharmaceutical companies already heavily discount patented drugs for sale in Africa as a matter of good will,¹⁵⁷ but even then, countries such as Tanzania and Nigeria, with health budgets of only around \$8 (USD) per capita a year, cannot afford the storage and administrative costs associated with receiving the drugs.¹⁵⁸ This fact led the Attaran and Gillespie-White study to conclude that “patents generally do not appear to be a substantial barrier to antiretroviral treatment access in Africa today,” and that “the extreme dearth of international aid finance, rather than patents, is most to blame for the lack of antiretroviral treatment in Africa.”¹⁵⁹

156. Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 J. AM. MED. ASS'N 1886 (2001).

157. “Africa comprises only one percent of the world pharmaceuticals market.” Moran, *supra* note 50, at 26.

158. *Id.* For comparison, the average per capita public health expenditure in Western Europe and North America is around \$1,500 (USD), while in Africa the number is frequently under \$20 (USD). International Chamber of Commerce, *supra* note 135, at 8. The price of the cheapest generic triple cocktail to combat HIV/AIDS, on offer by Indian manufacturer Cipla, costs \$350 (USD) per person per year. See PhRMA, *supra* note 155.

159. Attaran & Gillespie-White, *supra* note 156, at 1891. See also WORLD INTELLECTUAL PROPERTY ORGANIZATION, PATENT PROTECTION AND ACCESS TO HIV/AIDS PHARMACEUTICALS IN SUB-SAHARAN AFRICA (discussing a study by the International Intellectual Property Institute which finds the substantial majority of pharmaceuticals to combat HIV/AIDS have never been patented in most African countries), available at <http://www.wipo.int/about->

Clearly, developed countries have a duty to the countries suffering through the HIV/AIDS crisis or otherwise inflicted with public health problems, and several factors must be addressed, including funding, medical infrastructure, education, and intellectual property regulations. It is also clear, however, that blaming pharmaceutical companies and intellectual property rights for the HIV/AIDS crisis is excessively simplistic. It is important to realize that the issue of global access to medicine requires measures and policies much broader than simply amending global intellectual property protection. There can be no doubt that the situation is dire in many countries. But if those countries cannot even afford to buy and distribute pharmaceutical products that are off-patent, then we must ask if the issuance of compulsory licenses, or otherwise allowing access to patented pharmaceutical products, will even do any good.

In order to ease the suffering in the developing world, we must expand our thinking and search for ways to finance the purchase and distribution of the drugs. One innovative way to finance creative solutions would be to encourage the creation of both private and public partnerships and philanthropic organizations to help alleviate the suffering. The burden of resolving the public health crisis in the developing world should not fall solely on the pharmaceutical industry. Instead, the financial cost of improving the public health of the developing world should be the responsibility of the entire international community.

As noted, many pharmaceutical companies sell pharmaceuticals at heavily reduced prices to developing countries, but asking them to incur losses *ad infinitum* is unrealistic. Such action is a de facto, discriminatory tax on the industry and reduces its ability to compete for capital and other resources with other industries. In order for pharmaceutical companies to continue researching and developing new drugs to combat health problems associated with the developing world, they must be given incentives not only to sell their products for reduced prices in the developing world but also to continue researching to find cures for diseases affecting the developing world. If we continue to rely on pharmaceutical companies to discount prices for developing countries without providing the incentives to do so, we will, in all likelihood, cause the companies to exit the market and thus reduce the number of new drugs to service the developing world. Just as expropriating a foreign-owned manufacturing plant or a foreign-owned bank account would result in less foreign investment in a country, so too does expropriating a company's intellectual property result in less research and development into medicines to prevent and treat diseases afflicting the expropriating country.

The pharmaceutical companies can only ever hope to generate modest profits in the developing world, but it may be that modest profit is vital to ensure that research and development continues for certain diseases. Unlike most other industries, research and development costs are a large part in the production of pharmaceuticals.¹⁶⁰ Not only do pharmaceutical companies spend millions of dollars developing and trialing new drugs, but they must also endure the rigorous process of gaining regulatory approval to market and sell the product. This process can take years and add millions to the cost of getting the drug to market. Subsequent manufacturers free-ride on the work and effort of the original manufacturer, incurring a fraction of the costs to sell the drug. Therefore, the manufacturer requires a period of restricted competition to recoup its research and development and regulatory costs, as well as to make a small profit in order to encourage future creation.¹⁶¹

The importance of a period of limited competition for pharmaceutical products is underscored by the current rate of return in the industry. Again, unlike other industries, the vast majority of research and development in the pharmaceutical industry fails to produce new products. Therefore, companies rely on the products that do get approved for sale and placed on the market to not only recover its own research and development costs, but also to fund research and development for other products.¹⁶² In this regard, adequate patent protection is essential to the health of the entire industry.

Another reason why patent protection cannot be the sole cause of the public health crisis in the developing world is the fact that, as a result of the lengthy implementation deadlines for TRIPs, many developing countries (and particularly sub-Saharan countries) have not become subject to TRIPs and, consequently, currently have little or no intellectual property protection. In this regard, since there is no patent protection in those countries, patents cannot possibly be preventing access to affordable medicines. In addition, since no country other than Canada has ever issued a compulsory license for the generic production of a patented drug, and, due to the transitional implementation provisions of the TRIPs and the Doha Declaration, the

160. Sykes, *supra* note 10, at 60 (citation omitted). It has been estimated that the actual manufacturing and administrative costs for pharmaceuticals are less than ten percent of the total price, with research and development and trials accounting for thirty percent of the total. Sales, taxes, and royalties account for twenty-four percent and distribution accounts for fifteen percent of the total. Moran, *supra* note 50, at 25.

161. Sykes, *supra* note 10, at 57. Surveys of “executives in a range of industries were asked what percentage of inventions . . . in the early-1980s would not have been developed without [adequate] patent protection.” The survey revealed fourteen percent of all products would not have been invented, but sixty percent of pharmaceutical products would not have been developed without patent protection. *Id.* at 61 (citations omitted).

162. *Id.* at 61.

likelihood that countries would even need to use such a provision is minimal. When these two factors are taken into the equation, one begins to see the issue of compulsory licensing as being somewhat of a red herring.

Numerous diseases, such as HIV/AIDS, malaria, and tuberculosis, are at an epidemic level in many developing countries, even though those same diseases are either largely under control or eliminated in developed countries. In order for companies to invest research and development dollars into those diseases, there needs to be some promise of return. It simply does not make good economic sense for any industry to pour money into a product that does not have at least a promise of return. The incentives to research into the area of diseases afflicting the developing world are weak, even in countries that provide intellectual property protection; but if the possibility of return is removed, the problems will inevitably compound and ensure that no research takes place into those diseases. Yes, a developing country in a state of crisis could invoke compulsory license in such a situation, but it could be that no drug would be on the market to alleviate the problem due to lack of research and development in the area.

Patent protection under TRIPs must take into account the interests of the developing world, but it also must ensure that the pharmaceutical industry's incentive to create remains strong. If properly administered, a system of intellectual property rights, combined with a compulsory licensing regime that ensures "adequate remuneration" and fair parallel importing schemes, could strike the appropriate balance. On the other hand, a system of intellectual property that guarantees no return on investment and allows for the expropriation of intellectual property rights without proper compensation or enforceable limits will reduce the incentive to research and invest into the area and lead to a situation where the funding of cures for "third world diseases" ceases to exist. Such a situation must be avoided.