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The Power of a Patent: The Impact of Intellectual Property Protections in the Free Trade Area of the Americas Agreement on the Plight of Prescription Drug Availability and Affordability in Central and South America

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THE POWER OF A PATENT: THE IMPACT OF INTELLECTUAL PROPERTY PROTECTIONS IN THE FREE TRADE AREA OF THE AMERICAS AGREEMENT ON THE PLIGHT OF PRESCRIPTION DRUG AVAILABILITY AND AFFORDABILITY IN CENTRAL AND SOUTH AMERICA

Angelina Yearick Heimel

I. INTRODUCTION

Worldwide, future access to essential prescription medicines remains undetermined as pharmaceutical companies and governments try to balance affordability and availability while preserving intellectual property (IP) standards.[1] This dilemma is exacerbated in many countries of Central and South America, where the infectious disease burden is great.[2] These diseases, including HIV/AIDS, malaria, and tuberculosis, have been eradicated or afflict a much smaller percentage of the population in more developed countries.[3] In Central and South America, however, only 5 of the 34 countries in the region even have the capabilities to manufacture pharmaceutical products without importing ingredients.[4] Considering the public health implications of restricting medication accessibility and the lack of pharmaceutical resources, developing countries (DCs) and least developed countries (LDCs) have been historically reluctant to legislate IP criteria.[5]

The affirmation of IP, such as the issuance of patents including those governing pharmaceutical products, are traditionally part of Western culture.[6] Patents are granted to give an inventor the right to own his invention and to reward him for his contribution to better some aspect of society.[7] Most developed countries adopted these ideals and supported the development of the World Trade Organization (WTO), which incorporated the Agreement on Trade-Related Aspects of Intel-

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[1] *See* World Trade Organization, *Cancún: The Real Losers are the Poor* (Sept. 18, 2003), *at* http://www.wto.org/english/news_e/news03_e/news_sp_18sep03_e.htm.

[2] *See* Mary Moran & Nathan Ford, *The G8 and Access to Medicines: No More Broken Promises,* 361 LANCET 1578 (2003), *at* http://www.lancet.com (last visited Nov. 23, 2004).

[3] *See id.*

[4] *See* Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, WORLD HEALTH ORG. ESSENTIAL POLICIES & MED. 13 (June 2002), *at* http://www.who.int/medicines/library/par/who-edm-par-2002-3/doha-implications.doc (last visited Nov. 23, 2004) [hereinafter Correa, Implications of Doha].

[5] *See* John A. Harrelson, *TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion*, 7 WIDENER L. SYMP. J. 175, 187 (2001).

[6] *See id.*

[7] *See id.*

lectual Property (TRIPS) in 1994.[8] The overall goals of this agreement were to promote advances in technology, distribution, and conveyance of new technological advances, and to play a role in "the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare."[9]

Simultaneous to the WTO discussions on IP, trade, and the development of TRIPS, talks emerged around the creation of a free trade zone encompassing the Americas. The Free Trade Area of the Americas (FTAA) is a proposed agreement modeled after the North American Free Trade Act (NAFTA), to be made among 34 democratic countries of the Americas, excluding Cuba.[10] Formal negotiations started in 1998 and are set to culminate in December 2005.[11] The success of the larger FTAA agreement is founded on the smaller, usually bilateral, Free Trade Agreements (FTAs) made between the United States and a targeted country.[12] Concurrently, Canada is pursuing bilateral and smaller multilateral FTAs with Central and South American countries.[13]

This article will focus on the recent developments of the FTAA in light of the post-TRIPS negotiations. Some of the latest legislative decisions made by Central and South American countries favor provisions that actually involve stricter IP standards than the original TRIPS agreement set forth.[14] The discussion will review the effects of these additional provisions in the negotiations of trade agreements with the United States in

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[8] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round 31, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

[9] M. Kent Ranson et al., *The Public Health Implications of Multilateral Trade Agreements*, *in* HEALTH POLICY IN A GLOBALISING WORLD 18 (Kelley Lee et al. eds., 2002).

[10] Tanja Sturm, *MSF Activists Urge Latin American Countries to Fight 'TRIPS-Plus' Provisions in FTAA Negotiations*, WORLD MARKETS ANALYSIS, Aug. 29, 2003.

[11] *See id.*

[12] *See Free Trade Deals: What You Don't See May Be What You Get*, GLOBAL ECONOMIC JUSTICE REPORT, v. 2(1), p. 1-12, February 2003 [hereinafter Free Trade Deals].

[13] *See id.*

[14] *See* Rebecca Palser, *"TRIPS-Plus" Provisions Set for Inclusion in US-Chile FTA*, WORLD MARKETS ANALYSIS, Nov. 28, 2002.

the Central and South American region. This article will also present new developments that focus on preserving public health initiatives for access to essential medications.

Part II provides the historical background of the modifications and clarifications made to the TRIPS document regarding pharmaceutical access over the past five years and the main events leading up to these changes. In addition, Part II will present a review of the proposed solutions for developing countries that, if implemented, would potentially appease TRIPS proponents, yet continue to provide needy populations with essential medicines. In addition, Part II will continue with a discussion of the current status of applying TRIPS to public health initiatives in DCs and LDCs.

Part III will discuss the formation of the FTAA, including the purpose of the agreement, the countries targeted, and the benefits of these agreements. The approaches to IP protections and pharmaceutical access of three Central and South American countries, Brazil, Chile, and Guatemala, in preparation for the FTAA, will be highlighted.

Part IV will examine the implementation of TRIPS through the FTAA and smaller FTA agreements, specifically focusing on the access to prescription medications and generic equivalents. This section will also review the current status of the FTAA negotiations and the future outlook on pharmaceutical access for Central and South Americans.

II. TRIPS DEVELOPMENT, REFINEMENT AT DOHA, AND FUTURE OUTLOOK

One of the driving forces of developing the TRIPS agreement was to create universal standards for patents on pharmaceutical products.[15] The Intellectual Property Committee (IPC), a collaboration of 12 transnational corporations based in America, along with the International Intellectual Property Alliance and the Pharmaceutical Research and Manufacturers of America, heavily influenced the conception of the TRIPS agree-

[15] *See TRIPS, Intellectual Property Rights and Access to Medicines*, HIV/AIDS ANTIRETROVIRAL NEWSLETTER (WHO, Regional Office for the Western Pacific), Dec. 2002, at 1 [hereinafter HIV Newsletter].

ment.[16] The TRIPS agreement encapsulated many of the patent protections these corporations enjoyed in the United States to worldwide applicability.[17] Patents rights were broadened to limit exceptions to these rights and to strengthen the restrictions on compulsory licensing of pharmaceutical products.[18] While TRIPS set out minimum standards for IP protection, the agreement also included enforcement and dispute resolution procedures with a compliance date of January 2005 for all WTO Members.[19]

The incorporation of TRIPS into the global pharmaceutical industry by the 2005 deadline soon revealed that this agreement was going to have very broad applications to public health initiatives around the world.[20] Thus, the application of the TRIPS agreement has been a source of controversy for pharmaceutical companies, governments, non-governmental organizations (NGOs), and human rights organizations worldwide.[21] Essentially, "the introduction of . . . TRIPS standards . . . delay the marketing of generic version of new drugs, and, thus the competition they entail. Hence it is anticipated that the prices of new drugs will remain high for a longer period of time, which will result in reduced access for many people, notably in developing countries."[22] However, right after the initial TRIPS agreement was issued, NGOs and activists publicized the public health implications of the agreement and the WTO has slowly responded.[23]

The main social deliberation has been whether patents on pharmaceutical products are rights or privileges.[24] Pharmaceutical companies purport to have the ability to limit the distribu-

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16 *See* Susan K. Sell, *TRIPS and the Access to Medicines Campaign*, 20 WIS. INT'L L.J. 481, 481, 485-89 (2002) [hereinafter Sell, Access Campaign].

17 See Carlos M. Correa, *TRIPS Disputes: Implications for the Pharmaceutical Sector*, QUNO.COM (June 2001), *at* http://www.geneva.quno.info/pdf/OP5.pdf (last visited Nov. 23, 2004).

18 *See id.*

19 *See* Sell, Access Campaign, *supra* note 16, at 489. *See also* TRIPS Agreement, *supra* note 8, art. 65, para. 4.

20 *See id.* at 497.

21 *See generally* Susan K. Sell, *Post-TRIPS Developments: The Tension Between Commercial and Social Agendas in the Context of Intellectual Property*, 14 FLA. J. INT'L L. 193 (2002) [hereinafter Sell, Post-TRIPS].

22 *See* HIV NEWSLETTER, *supra* note 15.

23 *See generally* Sell, Post-TRIPS, *supra* note 21.

24 *See* Sell, Access Campaign, *supra* note 16, at 497.

tion of drugs by claiming IP rights.[25] Many public health advocates see the enforcement of patents as a privilege, where the privilege can be revoked when there are higher reaching goals such as public health emergencies.[26]

The TRIPS agreement was not developed around an access to essential medications or a public health initiative. Therefore, the world's population has not had an opportunity to realize the potential complications of the agreement made by trade and business elitists, especially if IP is deemed a "right."[27] In the ensuing years since the enactment of the TRIPS agreement, many activists, NGOs, and the World Health Organization (WHO), have petitioned the WTO and its members to reconsider the agreement in light of the public health implications on decreased access to pharmaceuticals.[28]

A. *WTO Ministerial Conventions Respond to Pharmaceutical Access Concerns*

The first ministerial convention to address the limitations that the TRIPS agreement created on pharmaceutical access was held in 1999 in Seattle, Washington.[29] At that time, there was an enormous debate on the availability and pricing of antiretroviral (ARV) drugs for the HIV/AIDS epidemic in Africa.[30] In assumed compliance with TRIPS, the South African government, for example, had enacted the South African Medicines and Related Substances Control Act Amendments.[31] The purpose of these amendments was to make ARV drugs affordable to its infected populace.[32] After their enactment, many lawsuits

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[25] *See id.*

[26] *See id.*

[27] *See* John Braithwaite & Peter Drahos, GLOBAL BUSINESS REGULATION 576 (2000).

[28] *See* Zita Lazzarini, *Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil*, 6 YALE HUM. RTS. & DEV. L.J. 103, 117 (2003).

[29] *See* Ellen 't Hoen, *Public Health and International Law: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha*, 3 CHI. J. INT'L L. 27, 34 (2002).

[30] *See id.* at 30.

[31] *See* Rosalyn S. Park, *The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients*, 11 MINN. J. GLOBAL TRADE 125, 136 (2002).

[32] *See* Debora Halbert, *Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs*, 1 SEATTLE J. SOC. JUST. 257, 269 (2002).

ensued from pharmaceutical companies around the world.[33] Under much pressure from humanitarians and the media, President Clinton and other world leaders vowed to help South Africa and other nations in their plight against HIV/AIDS.[34] Regardless, the Seattle convention did little to change the expectations of implementing TRIPS in all WTO-participating countries by the 2005 deadline.[35]

In 2001, the WTO convened again in Doha, Qatar, shifting their focus to the public health initiatives of DCs and LDCs with the 2005 implementation deadline looming.[36] Some significant public health commitments were solidified at Doha in the "Doha Declaration."[37] As stated in the declaration, "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health."[38] One of the most significant benefits for DCs and LDCs was the extension of the deadline for enacting TRIPS IP protections into law until 2016.[39]

B. *Proposed Solutions in the Doha Declaration on Public Health*

The Doha Declaration was created to address the ways that DCs and LDCs could circumvent IP issues and gain access to prescription medications, utilizing options under the TRIPS agreement.[40] Specific articles in the TRIPS agreement allowed for exceptions, including article 30 patent exceptions and article 31 compulsory licensing mechanisms.[41] Other alternative ways to skirt restrictive IP laws, which may be feasible for DCs and LDCs in the future, are parallel importing, patent exhaustion, and subsidies.[42]

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[33] *See id.* at 261.

[34] *See id.* at 272.

[35] *See* 't Hoen, *supra* note 29, at 35.

[36] *See id.* at 38.

[37] *See* Correa, Implications of Doha, *supra* note 4, at 1.

[38] World Trade Organization, *Doha Declaration on the TRIPS Agreements and Public Health*, para. 5(c), WT/MIN(01)/DEC/2, *at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited Nov. 23, 2004) [hereinafter Doha Declaration].

[39] *See* 't Hoen, *supra* note 29, at 41.

[40] *See id.* at 40.

[41] *See generally* Correa, Implications of Doha, *supra* note 4.

[42] *See* Harrelson, *supra* note 5, at 197.

C. *Article 31 Exceptions*

One of the major debates after the TRIPS agreement was how DCs and LDCs could benefit from the compulsory licensing mechanism described in Article 31.[43] A compulsory license is defined as "[a] statutorily created license that allows certain parties to use copyrighted material without the explicit permission of the copyright owner in exchange for a specified royalty."[44] Historically, DCs and LDCs have not used compulsory licensing to access essential medicines during public health crises.[45] However, under the Doha Declaration, much liberty has been given to these countries to use compulsory licenses as a tool for meeting their pharmaceutical needs.[46]

There are a few other ways countries might utilize compulsory licensing and still be compliant with TRIPS.[47] One mechanism is parallel compulsory licensing where the importing country's compulsory license is duly recognized by the exporting country.[48] While the mechanism appears simple, this solution is procedurally difficult to implement.[49] For example, the ex-

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[43] *See* 't Hoen, *supra* note 29, at 40. TRIPS Agreement, Article 31(b) states, in part, "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." TRIPS Agreement, *supra* note 8, art. 31.

[44] *See* BLACK'S LAW DICTIONARY 931 (7th ed. 1999).

[45] *See* Frederick M. Abbott, *WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries*, IPRCOMMISSON.ORG (Feb. 14, 2002). Abbott provides several reasons why DCS have not used compulsory licensing, including:

> (1) The TRIPS Agreement has only recently begun to increase the incidence of patent protection; (2) use has been opposed by developed country WTO Members and interested industry groups within them, and a strong political commitment to act in the face of this opposition is required; (3) some developing countries have expressed concern regarding a potential backlash from foreign direct investors; (4) developing country enterprises may find it easier to reach accommodation with foreign patent holders than to challenge them through the compulsory licensing process for various economic and administrative reasons; and . . . (5) effectively implementing compulsory licensing requires that certain preconditions related to administrative, financial and technical capacity be met, and these conditions are often not met in developing countries.

Id.

[46] *See id.*

[47] *Id.*

[48] *Id.*

[49] *Id.*

porting country is still required to retain the principal portion of its product in the domestic market, and the exporting country must have legislation in place to be able to accept the importing country's license.[50] Other alternatives, such as regional patents or creating pharmaceutical production export zones, are also available to countries in need of importing essential medicines, but have yet to be utilized widely.[51]

D. *Other Flexibilities Under TRIPS*

Article 30 of TRIPS also provides some narrow exceptions to pharmaceutical and other issued patents.[52] The exporting country is in charge of determining whether to authorize patent exceptions under this regulation, following the criteria set out in the Article.[53] Article 30 provides a different flexibility from Article 31, as stated in footnote 7 of Article 31.[54] The text clearly supports that Article 31 compulsory licensing procedures are distinguishable from Article 30 patent exceptions.[55]

Some commentators have also recommended the practice of parallel importation for LDCs to get pharmaceuticals.[56] Parallel importation is defined as "[g]oods bearing valid trademarks that are manufactured abroad and imported into [a country] to compete with domestically manufactured goods."[57] Typically, a drug manufacturer offers its pharmaceutical products at different prices around the globe.[58] The benefit of parallel importing

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[50] *See* Abbott, *supra* note 45.

[51] *See id.* A regional patent system involves several countries coming together to issue a common compulsory license. The requirement of supplying the domestic market could be met by classifying the group market as the domestic market. *Id.*

[52] *See* TRIPS Agreement, *supra* note 8, art. 30.

[53] *See* Abbott, *supra* note 45. *See also* TRIPS Agreement, *supra* note 8, art. 30, which states, "members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." *Id.*

[54] *See* TRIPS Agreement, *supra* note 8, art. 31. Footnote 7 to Article 31 states, "'Other use' refers to use other than that allowed under Article 30." *Id.*

[55] *See id.*

[56] *Id.*

[57] *See* BLACK'S LAW DICTIONARY, *supra* note 44, at 1136.

[58] *See* Thomas F. Mullin, *Comment, AIDS, Anthrax, and Compulsory Licensing: Has the United States Learned Anything? A Comment on Recent Decisions on*

is that the countries can shop around the world for optimum pricing.[59] The downside is that pharmaceutical companies realize a smaller profit margin with parallel importing, and in turn, their interests in funding research and development for the infectious diseases that burden DCs and LDCs may be reduced.[60]

The Doha Declaration also elucidated the use of patent exhaustion as a potential means for increasing pharmaceutical access.[61] Patent exhaustion has been defined as, "once the patent holder has sold a patented invention, the patent holder has no further right to exclude others from subsequent use, including offering to sell or distribute the patented invention . . . "[62] There are currently many limitations to patent exhaustion under national laws. DCs and LDCs would have to adopt national exhaustion policies, which to date, they have been hesitant to implement.[63]

Subsidies are a consideration for assisting countries in obtaining much-needed drugs, especially for combating HIV/AIDS epidemics.[64] The International Intellectual Property Institute (IIPI) put forth a plan that takes the focus off of the patent debate and shifts it towards pricing issues.[65] The proposal includes separating countries by ability to afford pharmaceuticals, structuring prices based on this affordability scale, and forming a worldwide "system of subsidies" for countries at the bottom of the affordability scale.[66] This plan, however, requires many stages to implement effectively, including national exhaustion of patent rights, tiered pricing of pharmaceuticals, bulk purchasing options, and a World Bank to coordinate fundraising efforts.[67] Similarly, another potential

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the International Intellectual Property Rights of Pharmaceutical Patents, 9 ILSA J. INT'L & COMP. L. 185, 192 (2002).

[59] *See id.*

[60] *See* Nabila Ansari, *International Patent Rights in a Post-Doha World*, 11 CURRENTS: INT'L TRADE L.J. 57, 65 (2002).

[61] *See* Doha Declaration, *supra* note 38, para. 5(d).

[62] James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291, 308 (2002).

[63] *See id.* at 309.

[64] Harrelson, *supra* note 5, at 197.

[65] *See id.*

[66] *See id.* at 197-98.

[67] *See id.* at 198-99.

solution is to have the significant debt owed by DCs and LDCs forgiven so as to enable them to redirect resources toward reducing disease burdens.[68]

As trade and public health advocates discuss possible solutions for DCs and LDCs to comply with TRIPS, global support for infectious disease treatment and prevention activities are diminishing.[69] This past July, for example, at the European donors conference to fight AIDS, tuberculosis, and malaria, the donations fell short of the expected amounts.[70] Unfortunately, as scientific technology has advanced with effective treatments for these diseases, the world community has not responded in getting aid to areas of greatest need.[71]

E. *The Post-Doha Era: Lingering Issues*

During the meeting at Doha, drafters of the declaration readily recognized that the issue of compulsory licensing under TRIPS was not globally inclusive.[72] Paragraph 6 stated that, "We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement."[73] Many supporters of the need for access to pharmaceuticals express that DCs and LDCs should be allowed to use compulsory licensing if they have insufficient pharmaceutical manufacturing capabilities.[74] However, some of the general interpretations of TRIPS would not allow for an exception for countries to utilize compulsory licensing for public health initiatives.[75]

Article 31 of the TRIPS agreement allows compulsory licensing to be used domestically but not for exportation, which

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[68] *See id.* at 200.

[69] *See* Julio Godoy, *Health: AIDS Fund Falls Short of Expectations*, INTER PRESS SERV., Jul. 17, 2003.

[70] *See id.*

[71] *See id.*

[72] *See* Correa, Implications of Doha, *supra* note 4, at 17.

[73] Doha Declaration, *supra* note 38, para. 6.

[74] *See* Sell, Access Campaign, *supra* note 16, at 517.

[75] *See* Thomas A. Haag, *Comment, TRIPS since Doha: How Far Will the WTO Go Toward Modifying the Terms for Compulsory Licensing?*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 945, 953 (2002).

creates a host of problems for DCs and LDCs.[76] Despite strict conditions set for utilizing compulsory licensing, there are no limits on the grounds for issuing these licenses.[77] Under TRIPS, Article 31(b) states in part that, "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."[78] The Doha Declaration clarified that countries can determine the circumstances of a national emergency, which can include public health epidemics.[79] The declaration also provided that the term "emergency" does not necessarily constitute only short-term crises.[80]

The main obstacle DCs and LDCs face for utilizing compulsory licensing is found in Article 31(f) of the TRIPS agreement.[81] There are two intertwined issues within this section of the TRIPS agreement. First, if a country cannot manufacture the pharmaceutical product, it will not be able to import generic drugs if the country exporting the drugs is under a compulsory license.[82] Second, when a country takes advantage of a compulsory license, the principal part of the manufacturing of the pharmaceutical product must be to supply the country's domestic market, which limits the quantity of medications that can be exported.[83]

In addition, theoretical and logistic issues exist in suggesting the use of compulsory licensing for DCs and LDCs to fulfill their prescription drug needs.[84] Although somewhat debatable, pharmaceutical companies claim that strong patent regulations are needed to counterbalance the research and development costs of pharmaceuticals.[85] Also, countries must be

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[76] *See* TRIPS Agreement, *supra* note 8, art. 31. *See also* Sell, Access Campaign, *supra* note 16, at 500.

[77] *See* Correa, Implications of Doha, *supra* note 4, at 13.

[78] TRIPS Agreement, *supra* note 8, art. 31.

[79] *See* Doha Declaration, *supra* note 38, para. 5(b)-(c).

[80] *See* Correa, Implications of Doha, *supra* note 4, at 14.

[81] *See* Abbott, *supra* note 45. *See also* TRIPS Agreement, *supra* note 8, art. 31(f). Article 31(f) follows that: "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use . . . . " *Id.*

[82] *See id.*

[83] *Id.*

[84] *See* 't Hoen, *supra* note 29, at 44.

[85] *See* Ansari, *supra* note 60.

able to manufacture the pharmaceutical product without the support of the patent owner.[86] In addition, a country must be able to afford the royalties owed to the patent holder(s) to use compulsory licenses.[87]

For countries that do manufacture generically equivalent pharmaceuticals, there are prohibitions on large exportations of lesser-priced drugs under compulsory licenses.[88] Very few DCs and LDCs have the capabilities to wholly produce the pharmaceuticals they need,[89] and import many of the products to subsidize their pharmaceutical manufacturing industries.[90] Until TRIPS participation becomes mandatory in 2005, DCs and LDCs that do not have the means of manufacturing pharmaceuticals can take advantage of the exportation of generic medications by developed countries.[91] Importation of generic medications into DCs and LDCs, however, will become increasingly difficult after full TRIPS implementation, even though these DCs and LDCS have until 2016 to comply with TRIPS.[92] Additionally, supplying countries may no longer be able to export the pharmaceutical ingredients on which DCs and LDCs have been relying (under Article 31(f)) after January 2005.[93]

The Doha Declaration did not fully outline all of the flexibilities available under the TRIPS agreement.[94] A remaining option includes exceptions to the protection of test data under Article 39.3 so that generic equivalents can be ready for market upon the expiration of the patent.[95] The exceptions to patent rights under Article 30 are also vague and ambiguous, and subject to further interpretation.[96] Additionally, some DCs and LDCs do not currently patent pharmaceuticals and therefore cannot utilize standard compulsory licenses as a means of ac-

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86 *See id.*

87 *See id.*

88 *See id.*

89 *See* Correa, Implications of Doha, *supra* note 4, at 18.

90 *See id.*

91 *See* Ansari, *supra* note 60.

92 *See* Abbott, *supra* note 45.

93 *See* Correa, Implications of Doha, *supra* note 4, at 18.

94 *See id.* at 43.

95 *See id.*

96 *Id.*

quiring medications.[97] Other options may need to be created to accommodate these countries, especially if they face public health emergencies.

At the end of article 6 of the Doha Declaration, the Council for TRIPS agreed to expedite the means of finding a resolution to the "Paragraph 6" problem.[98] The deadline was set for the December 2002 to report back to the WTO General Council.[99] The TRIPS Council proposed the "December 16" or "Motta text," which had many provisions that would significantly complicate the production of generic pharmaceutical products.[100] The "Motta Text" lacked the votes to be adopted; voters were swayed by the viewpoints of many NGOs who found the text to be ineffectual.[101]

F. *Failure of Cancún WTO Ministerial to Settle Doha Issues*

In August of 2003, the TRIPS Council again convened to review the issues of exportation of pharmaceutical products using compulsory licensing.[102] The decision of the Council was to apply a temporary TRIPS waiver where eligible DCs and LDCs can import generic equivalents of patented drugs from manufacturing countries under compulsory licensing regulations.[103] This waiver will be in effect until TRIPS is amended.[104] Many countries opted out of the importation provisions, but some DCs retained the rights to utilize the waiver under times of national emergency.[105]

The interim waiver contains a 12-step process that eligible countries must follow to evade TRIPS pharmaceutical access

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[97] *See* 't Hoen, *supra* note 29, at 44.

[98] *See* Doha Declaration, *supra* note 38, para. 6.

[99] *See id.*

[100] Campaign for Access to Essential Medicines–Mèdecines Sans Frontières, *Doha Derailed: A Progress Report on TRIPS and Access to Medicines*, ACCESSMED-MSF.ORG 2, *at* http://www.accessmed-msf.org/documents/cancunbriefing.pdf (Aug. 27, 2003) [hereinafter Doha Derailed].

[101] *See id.*

[102] World Trade Organization, *Decision Removes Final Patent Obstacle to Cheap Drug Imports available at* http://www.wto.org/english/news_e/pres03_e/pr350_e.htm (Aug. 30, 2003) [hereinafter WTO Patent Obstacle].

[103] *See id.*

[104] *Id.*

[105] *See* World Trade Organization, *The General Council Chairperson's Statement at* http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm (Aug. 30, 2003) [hereinafter Chairperson's Statement].

barriers.[106] The steps include issuing voluntary and compulsory licenses, working with the exporting country, the private manufacturer if involved, and the importing country.[107] The process is difficult to implement and must be repeated by the exporting country each time there is a request for importing pharmaceutical products by an eligible country.[108] The Council also explicitly restricted the use of compulsory licenses to those covered by paragraph 6 of the Doha Declaration in the waiver.[109]

Some commentators thought that the waiver would be the bridge to bringing trade negotiators and public health advocates closer to reaching a workable solution to the pharmaceutical access barriers created by TRIPS.[110] However, two new challenges have been created for DCs and LDCs by the interim waiver. First, DCs and LDCs do not have a clear interpretation of their limitations and autonomy to gain access to affordable medications.[111] Second, DCs and LDCs will need to propose a workable and lasting solution to amend the TRIPS agreement.[112] Without the amendment, NGOs and public health supporters warn that these new compulsory licensing terms do not secure generic drug production for the future.[113] Even the most recent WTO Ministerial Conference left remaining crucial determinations about this issue unsettled.[114]

III. PREPARING FOR THE FREE TRADE AREA OF THE AMERICAS (FTAA)

A. *Purpose and Benefits of FTAA*

There has been an increasing trend for WTO-participating nations to negotiate regional trade agreements, a trend coined

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106 *See* Carlos Correa, *Access to Drugs Under TRIPS: A Not So Expeditious Solution*, ICTSD.ORG 21, *at* http://www.ictsd.org/monthly/bridges/BRIDGES8-1.pdf (Jan. 2004).

107 *See id.*

108 *See id.* at 22.

109 *See* Chairperson's Statement, *supra* note 105.

110 *See* WTO Patent Obstacle, *supra* note 102.

111 *See* Correa, *supra* note 106, at 22.

112 *See id.*

113 *See Flawed WTO drugs deal will do little to secure future access to medicines in developing countries*, DOCTORSWITHOUTBORDERS.ORG, *at* http://www.doctorswithoutborders.org/pr/2003/08-30-2003_pf.html (Aug. 30, 2003).

114 *See* Doha Derailed, *supra* note 100, at 1.

"regionalism."[115] There are several major initiatives happening simultaneously. These include nations choosing regional trade agreements (RTAs) over larger multilateral agreements, countries seeking to negotiate with new and distant partners, and large "mega-blocs" of countries making one trade agreement, such as the FTAA.[116]

The purpose of the FTAA is to increase the ease of trade and investments in the Americas.[117] Along with the potential for increased prosperity, the goals of the agreements include supporting democracy, alleviating poverty and inequities, and working with DCs and LDCs towards ongoing growth and development in many sectors.[118] The pending agreements are very comprehensive, including agriculture, IP, tariffs, and other trade-related items.[119]

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[115] *See* C.P. Chandrasekhar & Jayati Ghosh, *Regional Trade and Investment Agreements*, BUS. LINE, Jan. 20, 2004.

[116] *See id.*

[117] *See generally Antecedents of the FTAA Process, The Preparatory Process*, FTAA-ALCA.ORG (last visited Nov. 30, 2004).

[118] *See Free Trade Area of the Americas – FTAA: First Summit of the Americas: Miami – December 19-11, 1994: Plan of Action*, FTAA-ALCA.ORG (last visited Feb. 19, 2004) [hereinafter FTAA Plan of Action]. The FTAA Plan of Action lists twenty-two goals in creating this agreement, including:

> I. Preserving and Strengthening the Community of Democracies of the Americas: 1. Strengthening Democracy, 2. Promoting and Protecting Human Rights, 3. Invigorating Society/Community Participation, 4. Promoting Cultural Values, 5. Combating Corruption, 6. Combating the Problem of Illegal Drugs and Related Crimes, 7. Eliminating the Threat of National and International Terrorism, 8. Building Mutual Confidence; II. Promoting Prosperity Through Economic Integration and Free Trade: 9. Free Trade in the Americas, 10. Capital Markets Development and Liberalization, 11. Hemispheric Infrastructure, 12. Energy Cooperation, 13. Telecommunications and Information Infrastructure, 14. Cooperation in Science and Technology, 15. Tourism; III. Eradicating Poverty and Discrimination in Our Hemisphere: 16. Universal Access to Education, 17. Equitable Access to Basic Health Services, 18. Strengthening the Role of Women in Society, 19. Encouraging Microenterprises and Small Businesses, 20. White Helmets—Emergency and Development Corps; IV. Guaranteeing Sustainable Development and Conserving Our Natural Environment for Future Generations: 21. Partnership for Sustainable Energy Use, 22. Partnership for Biodiversity, 23. Partnership for Pollution Prevention.

Id.

[119] *See* Maria Julia Oliva, *Intellectual Property in the FTAA: Little Opportunity and Much Risk*, 19 AM. U. INT'L L. REV. 45, 57 (2003).

The United States is the primary negotiator in the FTAA agreement and the smaller FTA with individual countries and groups of countries. Creating this trade zone is a crucial and strategic expansion for the United States because as of two years ago, the US was only participating in 1 of the 30 FTAs in existence in the Western Hemisphere.[120] Some commentators also report that by formulating these regional agreements, the larger developed countries have more influence over DCs and LDCs during multilateral WTO agreement negotiations.[121]

The US faces direct trade competition from the European Union.[122] By utilizing politically motivated trade negotiations to create FTA with particular countries, and remaining at the forefront of the multilateral FTAA, the US can effectively counter the trade competition with the European Union.[123] As one commentator notes, "[m]aking agreements selectively permits the United States to choose the terms on which it will allow certain countries access to its market."[124]

B. *Countries Prepare for FTAA Integration*

In Central America, more than 1.8 million people live with HIV/AIDS, and the disease is the second leading cause of death in the region.[125] Generic drug availability has been the only facilitator of driving down prices for ARV drugs needed to treat this population.[126] The pending FTAA agreement is impacting the access to prescription medications in the countries of Central and South in different ways, depending on how the country chooses to negotiate with the United States in the smaller

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120 Laura Altieri, Comment, *Between Empire and Community: The United States and Multilaterilism 2001-2003: A Mid-Term Assessment*, 21 BERKELEY J. INT'L L. 847, 867 (2003).

121 *See* Chandrasekhar, *supra* note 115.

122 *See id.* at 866.

123 *See id.*

124 *See id.* at 877.

125 *See Make Trade Fair for the Americas: Agriculture, Investment And Intellectual Property: Three Reasons To Say No To The FTAA* (Jan. 26, 2003), *at* http://www.oxfam.org/eng/pdfs/pp030126_FTAA.pdf [hereinafter Make Trade Fair].

126 *See* Press Release, Medicines Sans Frontieres, Congressional Decree in Guatemala Hinders Access to Medicines (Jul. 14, 2003) *available at* http://217.29.194.251/msfinternational/invoke.cfm?objectid=236090A9-D94B-4720-8E0CC66E7884E4F6&component=toolkit.article&method=full_html&CFID=41273&CFTOKEN=27519176 [hereinafter Guatemala Hinders Access].

FTAs. Below are three examples of how countries are preparing for the FTAA by integrating IP laws into their own legal systems or participating in FTAs with the United States.

1. *Guatemala*

Approximately 67,000 people are living with HIV/AIDS in Guatemala.[127] According to Mèdecines Sans Frontièrs, only 1,500 of those afflicted are receiving ARV therapy due to the cost of the treatment.[128] For those receiving treatment, the approximate cost per month ranges from $320 (USD) to $800 (USD), while the average monthly income in Guatemala is $160 (USD).[129] At the present time, the medications in the ARV course of therapy are not under patent in Guatemala, so the generic drug market is accessible for NGOs and other groups to assist the Guatemalan people in obtaining treatment for HIV/AIDS.[130]

The Guatemalan Congress enacted the first IP restriction on prescription medications in April of 2003.[131] They enhanced the Guatemalan Industrial Property Law to give five years of market exclusivity to pharmaceutical manufacturers from the date of registration of the drug patent in Guatemala.[132] The impact of this decree is that the release of new, comparable generic drugs will be delayed because the drug regulatory agency cannot use the inventor's data to approve generically equivalent products during the exclusivity period.[133] Unfortunately, this law also extends to the production of pharmaceuticals even where there is no patent on a particular drug.[134] The restrictions on marketing authorization of test data create an access barrier that cannot be remedied, as compared to patents, which

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127 Campaign for Access to Essential Medicines–Mèdecines Sans Frontières, *Trading Away Health: Intellectual Property and Access to Medicines in the Free Trade Area of the Americas (FTAA) Agreement*, ACCESSMED-MSF.ORG, *at* http://www.accessmed-msf.org/documents/FTAAdoc.pdf (Aug. 2003) [hereinafter Trading Away Health].

128 *See id.*

129 *Id.*

130 *Id.*

131 *See* Guatemala Hinders Access, *supra* note 126.

132 *See id.*

133 *Id.*

134 *Id.*

can be overridden by compulsory licensing procedures.[135] Currently, in Central America, Guatemala is the only country with test data exclusivity laws.[136]

2. *Chile*

Effective January 1, 2004, the FTA between Chile and the United States was enacted.[137] The United States-Chilean FTA includes several provisions that go beyond the TRIPS minimum standards including compulsory licensing restrictions, limits on test data use, and extended patent stipulations.[138] One of the main negotiations was the use of a five-year protection on test data,[139] which means that during this five-year period, the patent holder has exclusivity on its development data and generic manufacturers cannot use the data to create less expensive versions of the pharmaceuticals while the drug is still under patent.[140] In the long-term, test data exclusivity increases medication prices, because generic competition will not be available when the medication comes off patent.[141]

In Chile, there are more than 20,000 people living with HIV/AIDS.[142] The FTA provisions, first and foremost protecting IP, are slated to have an enormous and deleterious effect on the accessibility and affordability of ARV-therapy drugs and others.[143] The United States-Chilean FTA sets a precedent in Central and South America for future bilateral FTA.[144] The United States has now solidified its bargaining power to include higher IP standards in other FTA negotiations, similar to those included in this agreement.[145]

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135 *See Provisions in CAFTA Restrict Access to Medicines: Latin American and Caribbean Countries Urged Not to Include Such Provisions in FTAA*, ACCESSMED-MSF.ORG, *at* http://www.accessmed-msf.org/publications.asp?scntid=42200410494&contenttype=PARA& (Feb. 3, 2004) [hereinafter Provisions in CAFTA].

136 *See* Trading Away Health, *supra* note 127.

137 *See* Tanja Sturm, *US-Chile FTA Negotiations Likely to Include "TRIPS-Plus" Provisions,* WORLD MARKETS ANALYSIS, Nov. 28, 2002.

138 *See id.*

139 *Id.*

140 *Id.*

141 *Id.*

142 *See* South America: Chile *at* http://www.nationmaster.com/country/ci/Crime (last visited Nov. 30, 2004).

143 *See* Palser, *supra* note 14.

144 *See id.*

145 *See generally* Palser, *supra* note 14.

3. *Brazil*

Brazil has been a model for the Latin American region on providing access to affordable medications,[146] especially to the 500,000 Brazilian people suffering from HIV/AIDS.[147] The government developed a national AIDS program to offer ARV therapy to all citizens with HIV/AIDS using generic medications.[148] Brazil was able to provide medications by negotiating discounts on pharmaceuticals and domestically manufacturing generic medications.[149] Through this program, the Brazilian government has reported a $2 billion (USD) savings over a 6-year period and has saved at least another half-million people from being infected.[150] The Minister of Health attributes the success "of free universal HIV care: [to] . . . (1) committed leadership at the top; (2) involvement of community and civil society groups . . . and (3) affordable medicines."[151]

Brazil is in a unique position among the South American countries. It is considered an upper-middle-income country and the largest economy in the region, and has full manufacturing capabilities for pharmaceutical products.[152] However, the disparity between the rich and poor is alarming, and this disparity is an indicator of the inequalities of health status among the Brazilian people, especially the poor.[153]

The government of Brazil has, so far, remained committed to the health initiatives they have commenced despite pressures from the US and other WTO members to force Brazil to comply with proposed FTAA IP regulations.[154] Some analysts believe that the US is pursuing bilateral and multilateral FTAs to potentially isolate Brazil and other opponents to the US trade stipulations.[155] One commentator noted that in looking at the FTAA from Brazil's perspective, "the FTAA is not a genuine

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146 *See* Trading Away Health, *supra* note 127.

147 *See* South America: Brazil *at* http://www.nationmaster.com/country/br/Health (last visited Nov. 30, 2004).

148 *See id.*

149 *See* Lazzarini, *supra* note 28, at 128.

150 *See id.* at 129. *See also* Trading Away Health, *supra* note 127.

151 *Id.*

152 *See* Lazzarini, *supra* note 28, at 130. *See also* Correa, Implications of Doha, *supra* note 4.

153 *Id.*

154 *See* Trading Away Health, *supra* note 127.

155 *See* Free Trade Deals, *supra* note 12.

free-trade area at all but a preferential trading system that benefits the United States at the expense of its Latin American trading partners."[156]

IV. CLOSING THE DOOR ON PHARMACEUTICAL ACCESS IN THE FTAA?

A. *The Use of 'TRIPS-plus' Provisions in IP Legislation*

The harsh IP rules that developed countries are trying to push DCs and LDCs to legislate and incorporate into FTA and the FTAA agreement go beyond the requirements of the TRIPS agreement.[157] These stipulations are typically referred to as 'TRIPS-Plus' provisions.[158] The requirements include, "efforts to extend patent life beyond the . . . TRIPS minimum, to tighten patent protection, to limit compulsory licensing. . .or to limit exceptions which facilitate prompt introduction of generics."[159]

These provisions directly affect pharmaceutical patents. One limitation is that the patent exclusivity would be extended beyond the 20-year international standard, which was the minimum standard set in the TRIPS agreement.[160] This is especially troublesome for generic drug development if a patent is delayed at issuance.[161] In addition, the proposed FTAA gives pharmaceutical companies the authority to have increased test data protection for 5 years.[162] This provision would also delay the introduction of generic pharmaceutical products because companies have to wait 5 years before even starting equivalent drug development.[163] The TRIPS agreement does not require a test data minimum standard in IP legislation, but the United States has added it to the 'TRIPS-Plus' provision negotiations.[164]

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156 *See id.* (quoting Alex Gourevitch, *Lula's Rules: Brazil Could Undo Bush's Trade Scheme*, AM. PROSPECT, Nov. 8, 2002).

157 *See* Trading Away Health, *supra* note 127.

158 *See id.* (stating that, "'TRIPS-Plus' is a non-technical term, which refers to any IP provision that is more stringent than the TRIPS Agreement requires.").

159 *See* 't Hoen, *supra* note 29, at 30.

160 *See id.*

161 *See* Sturm, *supra* note 137. *See also* Oliva, *supra* note 119, at 64.

162 *See* Make Trade Fair, *supra* note 125.

163 *See id.*

164 *See US Pressure Threatening Access to Medicines in Central America: CAFTA Negotiations Roll Back US Promises to Put Public Health Before Profits*,

While the proposed FTAA encompasses minimum IP standards similar to TRIPS, these rules have been cited as the most stringent IP standards written to date.[165] There is much suspicion that the United States has two agendas in these trade agreements, one with the WTO in supporting DCs and LDCs public health initiatives and the other in light of favorable trade agreements that incorporate stricter IP provisions.[166] According to the FTAA Plan of Action, the United States should be supporting the "equitable access to basic health services" and "promoting and protecting human rights," both of which may be found to include access to essential medicines.[167]

This double standard in trade negotiations was most recently evident in the Cambodian accession to the WTO in August 2003.[168] Cambodia agreed to add 'TRIPS-Plus' provisions to their IP legislation after much pressure from the United States, despite their national patent law passed in 2003 that excluded pharmaceutical patents until 2016 as per the Doha Declaration.[169] The United States also has many tactics to employ when enforcing IP rules, utilizing provisions in the smaller FTAs, the FTAA negotiations, the TRIPS agreement, and trade sanctions against violating countries.[170]

Recently, several countries, concurrent with their bilateral FTA negotiations with the US, have enacted tougher IP laws than the TRIPS agreement required.[171] The laws were effective immediately instead of in 2005, the developed countries' TRIPS

DOCTORSWITHOUTBORDERS.ORG, *at* http://www.doctorswithoutborders.org/pr/2003/12-13-2003_pf.html (Dec. 13, 2003).

[165] *See* David Vivas Eugui, *Intellectual Property in the FTAA: New Imbalances and Small Achievements. In* BRIDGES: ICTSD ANALYSIS 18-22 (2002), *at* http://www.iprsonline/ictsd/docs/VivasBridgesYear6N8NovDec2002.pdf (last visited Nov. 30, 2004).

[166] *See US Seeks Further Restrictions on Generic Medicines for Developing Countries*, DOCTORSWITHOUTBORDERS.ORG, *at* http://www.doctorswithoutborders.org/pr/2003/08-25-2003_pf.html (Aug. 25, 2003).

[167] *See* FTAA Plan of Action, *supra* note 118.

[168] *See Access to Medicines at the WTO: Countries Must Save Lives Before Celebrating Success*, ACCESSMED-MSF.ORG, *at* http://www.accessmed-msf.org/publications.asp?scntid=12920039472&contenttype=PARA& (Sep. 11, 2003).

[169] *See id.*

[170] *See* Make Trade Fair, *supra* note 125.

[171] *See* Nick Ashwell, *Bilateral Trade Deal with US Takes Precedence Over FTAA, Says Colombian Official*, WORLD MARKETS ANALYSIS, Sept. 5, 2003. *See also* Guatemala Hinders Access, *supra* note 126.

compliance date.[172] In addition, the FTAA is a binding agreement for all of the participating countries, so the IP requirements in this agreement would supersede the Doha Declaration. The extended TRIPS compliance deadline of 2016 for DCs and LDCs would be rolled back to the signing date of the FTAA.[173]

Draft proposals of FTAs between the United States and some Central and South American countries are limiting these countries' abilities to utilize compulsory licensing.[174] Under the FTAA and other agreements, participating countries would lose much of the flexibility afforded in the Doha Declaration.[175] Countries would only be allowed the usage of compulsory licensing "for public, non-commercial purposes, and during declared national emergencies or other situations of extreme urgency."[176] This is especially troublesome for the DCs and LDCs countries of Central and South America who do not have independent pharmaceutical manufacturing capabilities[177] because the ability to import ingredients or pharmaceutical products will not be possible under the current draft of the FTAA.[178]

Some commentators warn that initiating patent programs into DCs and LDCs may result in increased administration, medication, and technology costs.[179] This seems likely if DCs and LDCs enact 'TRIPS-Plus' IP legislation, and are forced to resort to more cumbersome patent exemptions to gain access to medications. For these reasons, long-term benefits seem uncertain, particularly for the poorest countries. Bernard Pécoul, director of the Campaign for Access to Essential Medicines, sponsored by Médecines Sans Frontiéres, stated, "Generic competition is just starting to bring life-saving medicines into people's reach, but if FTAA imposes stricter rules, drug prices will

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172 *See id.*

173 *See* Trading Away Health, *supra* note 127.

174 *See* Oliva, *supra* note 119, at 65.

175 *See id.*

176 *Id.* at 66.

177 *See* Correa, Implications of Doha, *supra* note 4, at 13.

178 *See* Oliva, *supra* note 119, at 66.

179 *See* Ansari, *supra* note 60, at 66.

inevitably shoot up. Developing countries must resist pressure to negotiate their people's health."[180]

B. *Current Status of FTAA Negotiations*

In mid-September 2003, the United States entered into negotiations to create a multilateral agreement with Central America.[181] These talks were held in Managua, Nicaragua, and many of the provisions on IP included 'TRIPS-Plus' provisions.[182] Near the end of December of 2003, several countries entered into the US-Central America Free Trade Agreement (CAFTA).[183] The participating countries included El Salvador, Honduras, Nicaragua, and Guatemala.[184] These countries are some of the poorer countries worldwide, and the affordability of pharmaceuticals is already severely distorted.[185]

The text of the agreement was made publicly available in late January 2004 confirming the inclusion of 'TRIPS-Plus' provisions.[186] Assisting this negotiation were the recent IP provisions included in the US-Chile FTA, new Colombian IP legislation, and the current draft of the FTAA.[187] Colombia is also set to start its own bilateral FTA negotiations with the United States in early 2004, concluding in July 2005.[188] It is speculated that the Andean Community Pact, including Bolivia, Ecuador, and Peru, will most likely sign agreements similar to CAFTA and the US-Colombian FTA.[189]

IP standards have been a sticking point in the larger FTAA negotiations.[190] With the US signing the smaller FTAs containing 'TRIPS-Plus' provisions for IP protection (which apply to

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[180] *FTAA agreement threatens access to affordable medicines in the Americas*, DOCTORSWITHOUTBORDERS.ORG, *at* http://www.doctorswithoutborders.org/pr/2003/08-28-2003_pf.html (Aug. 28, 2003).

[181] *See* Henry Dummett, *Central America to Discuss Generic Drugs with US at Free Trade Meeting*, WORLD MARKETS ANALYSIS, Sept. 11, 2003.

[182] *See id.*

[183] *See* Tanja Sturm, *US-Central American FTA Set to Tighten IP Protection*, WORLD MARKETS ANALYSIS, Dec. 18, 2003.

[184] *See id.*

[185] *See id.*

[186] *See* Provisions in CAFTA, *supra* note 135.

[187] *See* Sturm, *supra* note 184.

[188] *See* Ashwell, *supra* note 171.

[189] *See id.*

[190] *See* Matthew Haggman, Peter Zalewski, *A Plan for Access*, BROWARD DAILY BUS. REV., Nov. 19, 2003.

many areas of IP, not just pharmaceuticals), the platform for inclusion of these terms into the larger agreement has been established.[191] Commentators have implied that the smaller FTAs serve as the "insurance policy against the potential failure of the FTAA."[192] Conversely, some countries are pushing for the WTO to decide the issue.[193] There is agreement that TRIPS standards should serve as the foundation for IP standards in the FTAA, but countries such as Brazil do not want to increase the IP protection beyond minimum TRIPS compliance.[194]

NGOs and other humanitarian groups continue to raise the issue of the impact of infectious disease burdens in DCs and LDCs that are not in the forefront of these negotiations.[195] While HIV/AIDS is getting most of the press in the access to pharmaceuticals campaign, there remain other diseases affecting millions of people, yet the research and development for effective pharmaceuticals is not being conducted.[196] For example, in Central and South America, 18 million people are afflicted with Chagas disease and over 100 million are at risk of contracting it.[197] At present, only one pharmaceutical company is pursuing any research on Chagas disease.[198] As the patent protections increase through the FTAA, research on Chagas disease and other infectious diseases that mainly affect the poor will most likely decline because the pharmaceutical market is not profitable.[199]

Even as FTAA negotiations continue and more bilateral and multilateral FTAs are signed with 'TRIPS-Plus' provisions, there is another avenue of hope for better access to prescription medications in DCs and LDCs. In October 2002, two Thai citizens with HIV prevailed in a suit against Bristol-Myers Squibb

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191 *See id.*

192 *See* Free Trade Deals, *supra* note 12.

193 *See* Haggman, *supra* note 191.

194 *See id.*

195 *See* Gustavo Gonzalez, *FTAA Talks a Matter of Life and Death, MDs say,* INTER PRESS SERV., Nov. 19, 2003.

196 *See* Trading Away Health, *supra* note 127. Chagas disease, which is caused by a parasite, afflicts mainly poor people as the parasite-transmitting insects live in the walls of mud and straw homes.

197 *See id.*

198 *See* Gonzalez, *supra* note 196.

199 *See id.*

and the Thai Department of Intellectual Property.[200] The litigation concerned the amendment of the patent on the ARV drug didanosine by the defendants to include a dose restriction, thereby extending its patent protection beyond the original grant.[201] Commentators reported that Thailand had been under substantial trade pressure from the United States to implement strict IP legislation at the expense of public health initiatives.[202]

In finding for the plaintiffs, the court found that, "injured parties . . . are not limited to manufacturers or sellers of medicines protected by patent. Those in need of medicine are also interested parties to the granting of the patent."[203] This is the first time where the Doha Declaration has been utilized in a court ruling, supporting public health concerns over IP protections.[204] In addition, supporters of the access to essential medicines campaign cite this decision as "set[ting] an important precedent that essential drugs are not just another consumer product but a human right, and that patients are injured by patents."[205] This case could have many potential ramifications towards better access to medicines in the Americas despite the current and proposed trade agreements.

V. CONCLUSION

The question still remains whether the price of drugs is really the focal issue. The WHO states that, "[a]ccess to medicines depends on many factors, notably rational selection and use of drugs, adequate and sustainable financing, affordable prices, and reliable supply systems."[206] Most drugs in DCs and LDCs are obtained through self-funding due to a lack of

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[200] *See* Nathan Ford et al., *The Role of Civil Society in Protecting Public Health Over Commercial Interests: Lessons from Thailand*, 363 LANCET 560, 561 (Nov. 14, 2004), *at* http://www.thelancet.com.

[201] *See id.*

[202] *See id.* at 562.

[203] *See id.* at 561 (quoting *Aids Access Foundation v. Bristol-Myers Squibb Company & Department of Intellectual Property*. The Central Intellectual Property and International Trade Court, BC Tor Por 34/2544, RC Tor Por 93/2545 (2002)(Thail.).

[204] *See id.*

[205] *See id.* at 562.

[206] HIV Newsletter, *supra* note 15.

health insurance.[207] Countries do not have the infrastructure to support public health initiatives such as disease screenings, counseling, surveillance activities, and partner notification programs, which are especially needed for HIV/AIDS prevention and treatment.[208] DCs and LDCs have a shortage of public health staff, including nurses, doctors, and other health workers, in addition to few facilities which have the experience to provide treatment and monitor patients' drug regimens.[209] These countries also do not or are not able to provide community resources including health education, drug treatment, or mental health care, which are equally important social services offered in most developed countries.[210]

Further complicating the situation are the structural issues countries face, including, "low levels of economic development, frequent population migrations, political instability, gender inequality, drug policies that promote risky behavior or further marginalize drug users, and laws and policies that maintain any of these conditions."[211] Due to their limited resources, the importance of public health initiatives diminishes as a political priority in these countries.[212] A different view of health factors manifested by social epidemiologists encompasses, "fundamental determinants of health [such as] . . . income, socio-economic status, social capital, social cohesion, and race/racism."[213]

With either view, the world must help DCS and LDCS determine:

> how to guarantee government commitment and resources to provide access to pharmaceuticals, especially during difficult economic times . . . although the current intellectual property system may be interpreted or modified, if necessary, to permit access to drugs at affordable prices, the international community must still fulfill the long-term need for sustainable domestic development and public health capacity.[214]

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207 *See id.*

208 Lazzarini, *supra* note 28, at 128.

209 *Id.*

210 *Id.*

211 *Id.* at 115.

212 *Id.*

213 *Id.* at 116.

214 Lazzarini, *supra* note 28, at 136.

As an example, ARV therapy treatment for HIV/AIDS is not only expensive, but also requires a strict and complex schedule for taking the medications.[215] The rigidity of the treatment schedule is to be followed to secure optimum drug performance, and also helps to prevent the development of ARV therapy-resistant strains of HIV.[216]

Potentially, the impact of issuing compulsory licenses, for example, for these and other drugs could produce a lesser impact than projected;[217] however, the risk of not utilizing the options under TRIPS could lead to the revocation of the newest waiver. Some commentators encourage cautious optimism, stating that, "even in view of enormous human suffering due to the HIV-AIDS epidemic, [an impact] may not automatically be assumed, without further investigation, to be a 'measure necessary to protect public health' as it may be required by TRIPS Article 8."[218] If countries can get the pharmaceutical products at an affordable price, however, the incentive to develop and refine the infrastructure to dispense medications is much more likely.

There are a number of possible ways that trade agreements and public health initiatives can coexist and benefit all parties involved.[219] The prescription drug needs of DCs and LDCs may precipitate a new IP agreement or amendments to TRIPS provisions affecting essential medication production and/or importation. Any changes to the agreement however would require a three-fourths majority vote of WTO members.[220] A further approach could be that each country's pharmaceutical needs would be evaluated on a case-by-case basis to determine the appropriate level of IP protection to be afforded.[221] Another possibility includes adopting a "patently unreasonable" standard to allow a country to procure evidence about its internal IP policy standards, which might be in conflict with the TRIPS agree-

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[215] *See* Markus Nolff, *Compulsory Patent Licensing in View of the WTO Ministerial Conference Declaration on the TRIPS Agreement and Public Health*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 133 (2002).

[216] *See id.*

[217] *See id.*

[218] *Id.*

[219] *See* Ranson, *supra* note 9, at 37.

[220] *See id.*

[221] *See id.*

ment.[222] As the TRIPS provisions are mandatorily implemented, the public health concerns of DCs and LDCs will most likely be brought to the forefront. Hopefully, this will encourage these countries and developed countries to be better global citizens about the world's health.

The FTAA is an important commitment to DCs and LDCs from developed countries with existing effective public health initiatives.[223] Unfortunately, these needs are being overlooked during the FTAA negotiations and smaller FTAs due to the influence on negotiators to protect IP rights. As public awareness of these issue grows, additional support for the public health agendas of NGOs will most likely surface. Only then can the pharmaceutical needs of the DCs and LDCs remain a top worldwide priority.

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[222] *See id.* at 38.

[223] *See* Gonzalez, *supra* note 196.