

2010

The TRIPS Agreement: Helping or Hurting Least Developed Countries' Access to Essential Pharmaceuticals?

Marla L. Mellino
Fordham Alumnus

Follow this and additional works at: <https://ir.lawnet.fordham.edu/iplj>



Part of the [Entertainment, Arts, and Sports Law Commons](#), and the [Intellectual Property Law Commons](#)

Recommended Citation

Marla L. Mellino, *The TRIPS Agreement: Helping or Hurting Least Developed Countries' Access to Essential Pharmaceuticals?*, 20 *Fordham Intell. Prop. Media & Ent. L.J.* 1349 (2010).
Available at: <https://ir.lawnet.fordham.edu/iplj/vol20/iss4/6>

This Note is brought to you for free and open access by FLASH: The Fordham Law Archive of Scholarship and History. It has been accepted for inclusion in *Fordham Intellectual Property, Media and Entertainment Law Journal* by an authorized editor of FLASH: The Fordham Law Archive of Scholarship and History. For more information, please contact tmelnick@law.fordham.edu.

The TRIPS Agreement: Helping or Hurting Least Developed Countries' Access to Essential Pharmaceuticals?

Marla L. Mellino*

INTRODUCTION	1350
I. BACKGROUND	1355
A. <i>TRIPS Agreement</i>	1355
B. <i>The Doha Declaration</i>	1359
C. <i>August 30, 2003, TRIPS Council Decision</i>	1361
II. APPLICATION OF TRIPS, DOHA, AND THE DECISIONS	1365
A. <i>World Organizations</i>	1366
B. <i>Member Country Reactions</i>	1368
C. <i>Utilization of Compulsory Licenses</i>	1370
D. <i>Utilization of the Paragraph 6 System</i>	1372
III. ISSUES AFFECTING THE IMPLEMENTATION OF TRIPS	
PROVISIONS	1374
A. <i>Complexity of Legislation</i>	1374
B. <i>Hesitancy Brought on by Fear of Retaliation</i>	1376
C. <i>Interference with Intellectual Property Rights and Their Benefits</i>	1377
D. <i>Technology Not Suited for LDCs</i>	1379
E. <i>Purpose of TRIPS Is Not for Promotion of Public Health</i>	1380

A PDF version of this Note is available online at <http://iplj.net/blog/archives/volumexx/book4>. Visit <http://iplj.net/blog/archives> for access to the IPLJ archive.

* J.D., Fordham University School of Law, 2010; M.B.A., John Carroll University, 2006; B.S., John Carroll University, 2003. Special thanks to my husband for his love, support, and home-cooked meals; my mom, dad, and sister for their love and encouragement; and the editors and staff of IPLJ for making this Note possible.

1350	<i>FORDHAM INTELL. PROP. MEDIA & ENT. L.J.</i> [Vol. 20:1349]	
	<i>F. Lack of Sustainability</i>	1381
IV.	ANALYSIS OF OPTIONS	1381
	<i>A. TRIPS Options—Short Term</i>	1381
	1. Compulsory Licenses.....	1382
	2. Paragraph 6 System.....	1382
	3. Parallel Importation	1383
	<i>B. Long Term Options</i>	1383
	1. Collaborative Groups.....	1383
	2. Private-Public Partnerships.....	1385
	CONCLUSION.....	1387

INTRODUCTION

How many people complain about the cost of medication in the United States? How much of a strain does payment for the treatment of a deadly disease put on the average American? Most people dealing with this situation in America would answer that ensuring funds are available to continue treatment puts a huge amount of stress on an individual or a family—so much stress that, at times, an individual or a family may be forced to file for bankruptcy. Now imagine this person or family lived in Sub-Saharan Africa. How much of a strain does this payment cost them? Unfortunately, most Africans in Sub-Saharan countries affected with a disease never even get to that point. The strain they deal with is the strain of wondering daily if they will ever have access to treatment. High prices, clinics or hospitals located out of reach, insufficient government infrastructure, and lack of properly trained medical practitioners are just some of the reasons why affected individuals in countries like those in Sub-Saharan Africa have access problems, with high prices being blamed as one of the main reasons for lack of access.¹

¹ See Graham Dutfield, *Delivering Drugs to the Poor: Will the TRIPS Amendment Help?*, 34 AM. J.L. & MED. 107, 107–08 (2008); see also COMM’N ON INTELLECTUAL PROP. RIGHTS, INNOVATION & PUB. HEALTH, WORLD HEALTH ORG., PUBLIC HEALTH: INNOVATION AND INTELLECTUAL PROPERTY RIGHTS 202 (2006), available at <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>.

But there are two sides to every story. To understand why high prices are sought, you must put yourself in the shoes of an American pharmaceutical company competing with other drug companies for a profit and having to expend millions of dollars on testing to gain approval from the Food and Drug Administration (the “FDA”) before being able to market a drug.² As a drug company, you also know that your main profits are derived from sales of drugs that are still covered by a patent.³ Once a drug goes off patent, generic companies enter the market and erode your profit margin.⁴

The United States affords a high level of protection to intellectual property holders, including pharmaceutical companies owning patent rights.⁵ By giving the patent owners this protection, pharmaceutical companies are able to obtain the profits necessary to cover their research initiatives and foster innovation.⁶ If these companies were not afforded this high level of protection, there would be no incentive to expend the millions of dollars it costs to push a drug through the stages of testing necessary to gain FDA marketing approval.⁷ The United States is also active in pursuing infringers to ensure that the benefits of the statutorily-granted protection are not eroded.⁸

Other countries do not offer such generous protection to begin with or do not offer intellectual property holders the means to effectively police infringing activity, even if the right is

² See Dutfield, *supra* note 1, at 117.

³ See Marcia Angell, *The Truth About the Drug Companies*, N.Y. REV. BOOKS (July 15, 2004), <http://www.nybooks.com/articles/17244>.

⁴ See *id.*; Dutfield, *supra* note 1, at 117.

⁵ See Christopher Lea Lockwood, *Biotechnology Industry Organization v. District of Columbia: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals*, 19 ALB. L.J. SCI. & TECH. 143, 148–49 (2009).

⁶ See *id.*

⁷ See Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 283, 285 (2008); see also Lockwood, *supra* note 5, at 148 (discussing the patent protection necessary in light of the four principle stages of research required to enter a drug on the market: “1) discovery of new compounds, 2) preclinical testing in laboratories . . . , 3) clinical trials, and 4) FDA review”).

⁸ See Stefan Kirchanski, *Protection of U.S. Patent Rights in Developing Countries: U.S. Efforts to Enforce Pharmaceutical Patents in Thailand*, 16 LOY. L.A. INT’L & COMP. L. REV. 569, 569–70, 582 (1994).

recognized.⁹ This can be a problem for intellectual property holders in countries like the United States. The incentive for an American company to enter its goods into a market affording little intellectual property protection is very low. Incentive to enter or keep a product in a market is also low where intellectual property protection, if granted, is not adequately enforced. In markets where intellectual property rights are not adequately enforced, patent owners experience profit erosion due to the presence of infringing products on the market.¹⁰

In an effort to solve the problem of varying levels of intellectual property protection across country borders, members of the World Trade Organization (the “WTO”)¹¹ adopted the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS” or the “TRIPS Agreement”).¹² The purpose of the TRIPS Agreement is to enable “the protection and enforcement of intellectual property rights” across country borders so as to promote “technological innovation and . . . the transfer and dissemination of technology.”¹³

However, TRIPS presented a problem to the least developed countries (“LDC”s), such as those in Sub-Saharan Africa, because these countries do not have the infrastructure in place to provide adequate patent protection, nor do they have capabilities to properly enforce patent rights, if and when they are granted within

⁹ See Baris Karapinar & Michelangelo Temmerman, *Benefiting from Biotechnology: Pro-Poor Intellectual Property Rights and Public-Private Partnerships*, 27 BIOTECH. L. REP. 189, 198 (2008).

¹⁰ See Kirchanski, *supra* note 8, at 571–72.

¹¹ WORLD TRADE ORG., <http://www.wto.org> (last visited Apr. 12, 2010). The WTO “is the only global international organization dealing with the rules of trade between nations.” *What Is the WTO?*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm (last visited Apr. 12, 2010). The WTO consists of a group of 153 countries, wherein the countries are referred to as “member” countries. *Id.* Some of its functions include: “administering WTO trade agreements, [serving as a] forum for trade negotiations, handling national trade disputes, monitoring national trade policies, [providing] technical assistance and training for developing countries, and cooperati[ng] with other international organizations.” *Id.*

¹² Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 108 Stat. 4809, 869 U.N.T.S. 299 [hereinafter TRIPS].

¹³ *Id.* at art. 7.

their countries.¹⁴ Perhaps a bigger problem and one that is heard frequently among critics and protesting countries is that the higher level of protection that member countries must provide to patent holders under TRIPS has the potential to maintain drug prices at high levels. As a result, citizens of Sub-Saharan countries suffer because they do not have the income to pay for the price demanded for patented protection. Thus, there is inevitable tension between the need for a company to obtain profits from its patented invention and a current need to alleviate the public health problems in LDCs by providing drugs at low or no cost.¹⁵ In the area of pharmaceuticals, this is especially problematic when looking at the treatments available for HIV/AIDS and other epidemics. For instance, as of the end of 2008, 67% of the world's HIV population resided in Sub-Saharan Africa.¹⁶

However, despite TRIPS' intended proliferation of stronger intellectual property protection across all member countries, which allows patent owners to reap greater economic benefits from their patents, it does not preclude access to life-saving treatment for poor LDCs unable to obtain patented life-saving treatments at the typical commercial rates.¹⁷ It left open the possibility of compulsory licenses and parallel importation for use by developing and least developed countries to obtain needed pharmaceuticals.¹⁸

But criticism of the TRIPS Agreement led to the adoption of the Doha Declaration ("Doha").¹⁹ Doha's purpose was two-fold: to stress that TRIPS accounts for the developing and least developed countries' public health problems, and to further clarify the provisions that countries can use to foster transfer of

¹⁴ See *infra* Part II.A.

¹⁵ Bird & Cahoy, *supra* note 7, at 283.

¹⁶ *Worldwide AIDS & HIV Statistics*, AVERT, <http://www.avert.org/worldstats.htm> (last visited Apr. 12, 2010).

¹⁷ *Fact Sheet: TRIPS and Pharmaceutical Patents Obligations and Exceptions*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#importing (last visited Apr. 12, 2010) [hereinafter *WTO Obligations*].

¹⁸ *Id.*

¹⁹ World Trade Organization, Ministerial Declaration of 14 November 2001 on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter *Doha Declaration*]; see also Hoachen Sun, *The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health*, 15 EUR. J. INT'L L. 123, 125 (2004).

intellectual property and essential pharmaceutical products necessary to treat those afflicted with epidemic diseases such as HIV/AIDS.²⁰

Unfortunately, despite the language of TRIPS/Doha and recognition of the public health problem by member countries,²¹ access to much needed pharmaceuticals is still difficult for poorer nations to obtain and little has been done by the member countries through TRIPS to increase access. For example, since a 2003 decision by the TRIPS Council allowing non-producing LDCs to import pharmaceuticals, only one country has seen its benefits—Canada has used the system to provide drugs to Rwanda.²²

The current state of affairs cannot be maintained if we are to further public health initiatives related to the LDCs. This Note analyzes the options currently available through TRIPS for transfer of pharmaceutical technology to LDCs, how effective these options are, and what should be done in the long term to help ease the public health problems worldwide. Part I will provide background on the TRIPS Agreement and its relevant declaration and decisions relating to public health. Parts II and III will analyze the conflict that exists between the uniform intellectual property rights that TRIPS promotes and the LDCs' lack of access to life-saving treatments, despite the public health provisions. Part IV will argue first that current TRIPS public health measures are not sufficient to solve the problem of access to essential pharmaceuticals in the long term because the conflict mentioned above will always remain. Second, it will argue that mechanisms like public-private entities should be utilized to solve the problem instead.

²⁰ See *id.* ¶¶ 1–5.

²¹ The TRIPS Agreement applies to all WTO members. *Overview: The TRIPS Agreement*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Apr. 5, 2010) [hereinafter *WTO Overview*].

²² Pascal Lamy, Dir.-Gen., World Health Org., Address at the 11th Annual International Generic Pharmaceutical Alliance Conference in Geneva (Dec. 9, 2008), available at http://www.wto.org/english/news_e/sppl_e/sppl111_e.htm.

I. BACKGROUND

A. *TRIPS Agreement*

Annex 1C of the Marrakesh Agreement Establishing the World Trade Agreement, otherwise known as the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS, was signed in Marrakesh, Morocco, on April 15, 1994.²³ The TRIPS Agreement came about in order to foster the free movement of technology and innovation between member countries by attempting to circumscribe a uniform set of intellectual property rights that are protected and enforced across member countries.²⁴ While this was beneficial for protection of intellectual property rights, especially in developed countries, it was problematic for LDCs because recognition of intellectual property rights allows the rights holder to assert its patent and obtain monopoly pricing.²⁵

Within this broad agreement, provisions exist to specifically address the effect of intellectual property rights on public health.²⁶ Under Article 8 of the TRIPS Agreement, members are able to “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of th[e] Agreement.”²⁷ In other words, it recognizes that public health problems, among others, may exist and allows members to adopt special measures to deal with these problems, as long as the measures are limited to those allowed by the TRIPS Agreement.²⁸ Examples of these measures, to be discussed in further detail below, include an explicit allowance for compulsory licenses and

²³ TRIPS, *supra* note 12.

²⁴ *Id.* at art. 7.

²⁵ See, e.g., Damien Geradin, Anne Layne-Farrar & A. Jorge Padilla, *The Complements Problem Within Standard Setting: Assessing the Evidence on Royalty Stacking*, 14 B.U. J. SCI. & TECH. L. 144, 150–51 (2008) (discussing the issue of monopoly pricing for over-protective patents); Barton E. Showalter & Jeffery D. Baxter, *Strategic Use of Software Patents*, 547 PLI/Pat 1057, 1074–75 (1999) (discussing monopoly pricing as an after-effect of software patents).

²⁶ TRIPS, *supra* note 12, at art. 8.

²⁷ *Id.*

²⁸ See *id.*

an implicit allowance of parallel importation through a failure to proscribe the activity, as established in the Doha Declaration.²⁹

In reference to patents, such as those on pharmaceutical products and processes, TRIPS entitles a patent owner to have its exclusive rights of production, use, sale, and importation protected when dealing with another member country.³⁰ Members can provide exceptions to these exclusive rights if they “do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.”³¹ These exceptions can take the form of special measures that are aimed at dealing with public health problems such as the lack of access to pharmaceuticals.³²

The first measure is a compulsory license.³³ The traditional definition of a compulsory license is a government’s granting of a license without the permission of the rights holder.³⁴ Generally, before a compulsory license can be granted under the TRIPS Agreement, the requesting party must first attempt to obtain a voluntary license from the patent owner on reasonable commercial terms.³⁵ However, the term “reasonable commercial terms” is not defined by the TRIPS Agreement. If a voluntary license cannot be obtained, then a compulsory license can then be issued.³⁶ But, in “the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use,” a compulsory license can be issued without first negotiating for a voluntary license on reasonable commercial terms.³⁷ The purpose

²⁹ See Doha Declaration, *supra* note 20, ¶¶ 5–6.

³⁰ TRIPS, *supra* note 12, at art. 28.

³¹ *Id.* at art. 30.

³² See Doha Declaration, *supra* note 19, ¶ 5.

³³ *Id.*

³⁴ Makan Delrahim, Deputy Assistant Att’y Gen., U.S. Dep’t of Justice, Address at the British Institute of International and Comparative Law, Forcing Firms to Share the Sandbox: Compulsory Licensing of Intellectual Property Rights and Antitrust (May 10, 2004), available at http://www.justice.gov/atr/public/speeches/203627.htm#N_29_.

³⁵ TRIPS, *supra* note 12, at art. 31(b); see also *TRIPS and Public Health: Frequently Asked Questions*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Apr. 14, 2010) [hereinafter *TRIPS FAQ*].

³⁶ TRIPS, *supra* note 12, at art. 31.

³⁷ *Id.* at art. 31(b).

of the exception to the negotiation requirement is to save time,³⁸ although the TRIPS Agreement does not specify what would qualify as a national emergency or other circumstance of extreme urgency.

Due to lack of resources, LDCs such as those in Africa would be unable to offer commercially reasonable terms to a patent owner of pharmaceutical products or processes. To bypass the requirement to negotiate for a voluntary license on these terms, the government of an LDC would have to assert a national emergency or other circumstance of extreme urgency when requesting a compulsory license.³⁹ The license would then enable the LDC to utilize the patented formula or technology. But, even if the exception is invoked, TRIPS still requires that “the right[s] holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.”⁴⁰ TRIPS does not clarify what would constitute “adequate remuneration.”⁴¹ This will be considered in more detail later in Part I.C.

The TRIPS Agreement also leaves the notion of parallel importation on the table.⁴² It does not explicitly allow for parallel importation, yet it does not explicitly prohibit it either.⁴³ Under parallel importation, goods are sold into the parallel market at a much cheaper price than they could have been sold through the patent owner.⁴⁴ While this is beneficial for the party that seeks to

³⁸ *TRIPS FAQ*, *supra* note 35.

³⁹ TRIPS, *supra* note 12, at art. 31(b).

⁴⁰ *Id.* at art. 31(h).

⁴¹ JAMES LOVE, WORLD HEALTH ORG., REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES 5 (2005), http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf.

⁴² Parallel importation occurs when goods are produced by the patent owner or with the patent owner’s permission, through a license, and then subsequently imported into another country without permission of the patent owner. *International Exhaustion and Parallel Importation*, WORLD INTELL. PROP. ORG., http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm (last visited Apr. 14, 2010) [hereinafter *WIPO Parallel Importation*].

⁴³ See *The TRIPS Agreement and Pharmaceuticals: Parallel Import*, WORLD HEALTH ORG., <http://apps.who.int/medicinedocs/en/d/Jh1459e/6.4.html> (last visited Apr. 14, 2010).

⁴⁴ See, e.g., *Yamaha Corp. of Am. v. United States*, 961 F.2d 245, 248–49 (D.C. Cir. 1992).

purchase goods on the parallel market, it is disconcerting to the patent owner because the patent owner would lose profits that it could have earned had it been the seller. But this type of importation is based on the doctrine of patent exhaustion, wherein the rights afforded by a patent on a batch of products are exhausted once a party has initially sold that batch.⁴⁵ Thus, under the doctrine of patent exhaustion, the patent owner has no rights in a product once the product has been sold to the first party, regardless of whether or not the first party resells the good.⁴⁶ An LDC cannot afford to pay retail, so parallel importation is one method by which it can gain access to life-saving treatments at much lower prices.

Despite the two available options aimed at improving public health access for LDCs—compulsory licenses and parallel importation—there was little movement on the part of the developing countries to use them.⁴⁷ Complaints arose that developed countries were acting contrary to the furtherance of public health by setting forth intellectual property requirements, such as the recognition and enforcement of patent protection for epidemic-treating pharmaceuticals, that could not be met by LDCs.⁴⁸

Another problem with TRIPS that became apparent was that a compulsory license would only be beneficial if the licensee country had the infrastructure and capability to make use of the formula or technology because a license only gives authority to use the formula in the patent.⁴⁹ Thus, a country that lacks the facilities to manufacture the formula or technology will be unable to make use of the compulsory license. Certain developing countries such as Brazil do have manufacturing capabilities, but many LDCs such as those in Sub-Saharan Africa do not. Therefore, a compulsory license, as allowed under article 31 of the TRIPS Agreement, would be of little or no use to those countries. The Doha

⁴⁵ *WIPO Parallel Importation*, *supra* note 42; *see* *Quanta Computer, Inc. v. LG Elecs., Inc.*, 128 S. Ct. 2109, 2115–17 (2008).

⁴⁶ *See id.*

⁴⁷ *See* Jerome H. Reichman, Comment, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 247, 248 (2009).

⁴⁸ *See id.*

⁴⁹ *Id.*

Declaration was adopted, in part, to deal with this issue and to highlight the importance of the implementation and interpretation of the TRIPS Agreement provisions aimed at public health.⁵⁰

B. The Doha Declaration

The fourth Ministerial Declaration⁵¹ was adopted at the Fourth Session of the World Trade Organization's Ministerial Conference in Doha, Qatar in November of 2001, and it includes the public health-specific Declaration on the TRIPS Agreement and Public Health (the "Doha Declaration").⁵² This declaration was meant to stress the importance of using TRIPS to further public health by "promoting both access to existing medicines and research and development into new medicines."⁵³ It sought to accomplish this by clarifying the options available to member countries.⁵⁴

The Public Health Declaration states that "each member has the right to grant compulsory licen[s]es and the freedom to determine the grounds upon which such licen[s]es are granted."⁵⁵ It allows for each member to determine, for the purposes of issuing a compulsory license, "what constitutes a national emergency or other circumstances of extreme urgency."⁵⁶ It specifically referred to emergencies relating to HIV/AIDS and other epidemic diseases.⁵⁷

But under the language of the TRIPS Agreement, a compulsory license could only be granted for use in the domestic market of the requestor.⁵⁸ This has two important implications: one, a country lacking sufficient manufacturing capacity cannot make use of it, and two, a country that was issued a compulsory license could only

⁵⁰ Doha Declaration, *supra* note 19, ¶ 6.

⁵¹ World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Ministerial Declaration].

⁵² Doha Declaration, *supra* note 19.

⁵³ Ministerial Declaration, *supra* note 51, ¶ 17.

⁵⁴ See Doha Declaration, *supra* note 19, ¶ 5.

⁵⁵ *Id.* ¶ 5(b).

⁵⁶ *Id.* ¶ 5(c).

⁵⁷ "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." *Id.*

⁵⁸ TRIPS, *supra* note 12, at art. 31(f).

produce the licensed technology for its domestic use and could not export the product to other countries that lacked manufacturing capabilities.⁵⁹ Doha “recognize[d] 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.”⁶⁰ Although the Public Health Declaration did not resolve the issue, it called on the Council for TRIPS to address the problem and find a solution by the end of 2002.⁶¹

The Public Health Declaration also touches upon parallel importation by interpreting the TRIPS Agreement to allow for each member to establish how it would proscribe the activity.⁶² Again, parallel importation allows for an LDC to buy the good for a lower price than if it obtained the good straight from the patent owner.⁶³ An example would be Brazil obtaining a license from an American company to manufacture and sell an HIV/AIDS drug domestically, and then selling the product to Africa without permission from the American company.

Taking into account the difficulties of establishing a system by which 1) intellectual property rights will be protected, and 2) violations of those rights will be enforced in an LDC, the Public Health Declaration also stresses that TRIPS give LDC members until January 1, 2016 to comply with certain sections of the TRIPS Agreement.⁶⁴ This deadline is an exception to the one-year deadline for developed countries and the 2005 deadline for developing member countries.⁶⁵ The Public Health Declaration also recognizes the “right of least developed country members to

⁵⁹ See *id.* at art. 31(e).

⁶⁰ Doha Declaration, *supra* note 19, ¶ 6.

⁶¹ *Id.*

⁶² See *id.* ¶ 5(d).

⁶³ See *supra* note 42 and accompanying text.

⁶⁴ Doha Declaration, *supra* note 19, ¶ 7 (“We also agree that the least developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement.”).

⁶⁵ TRIPS, *supra* note 12, at art. 65.

seek other extensions of the transition periods.”⁶⁶ The Declaration specifically states that this exception applies “with respect to pharmaceutical products.”⁶⁷ Since the intellectual property regimes of LDCs are not as developed, it is likely that they will seek additional extensions in order to implement the TRIPS Agreement’s requirements. But extending the deadline for compliance without further specifying how to comply or assisting with compliance will not help member countries become compliant, especially if they can keep seeking extensions of the transition periods.⁶⁸

C. August 30, 2003, TRIPS Council Decision

In addition to the further clarification and direction provided by Doha, issues that arise from the administration of the TRIPS Agreement are addressed through decisions delivered by the Council for TRIPS.⁶⁹ The most important decision related to public health is the August 30, 2003 Decision (the “2003 Decision”).⁷⁰ This decision purported to solve the issue of compulsory licensing in the case of member countries lacking production capabilities.⁷¹

The 2003 Decision specifically took into account the instruction of the Doha Declaration to find a solution to the problem of the difficulties that “WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licenses.”⁷² A compulsory license, with nothing more, does not provide much help to a country that does not have the manufacturing ability to make use of the license. As such, the 2003 Decision sets forth the

⁶⁶ Doha Declaration, *supra* note 19, ¶ 7.

⁶⁷ *Id.*

⁶⁸ *See* TRIPS, *supra* note 12, at art. 66(1).

⁶⁹ *TRIPS Council*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/intel6_e.htm (last visited Apr. 3, 2010). The Council for TRIPS is the body responsible for administering TRIPS. *Id.*

⁷⁰ Decision of the General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Aug. 30, 2003) [hereinafter 2003 Decision].

⁷¹ *Id.*

⁷² Doha Declaration, *supra* note 19, ¶ 6.

framework for a system (otherwise known as the Paragraph 6 System) in which the affected LDC can obtain needed pharmaceutical products through a compulsory license that allows for importation from another member country with sufficient manufacturing capabilities.⁷³ “Within that framework, each WTO member decides for itself how it will implement the decision domestically” through its legislation.⁷⁴

LDCs are identified as “eligible importing [m]ember[s]” under the decision,⁷⁵ and other member countries can be eligible to become importing members as long as they meet certain guidelines.⁷⁶ An eligible importing member may use the system “in the case of a national emergency or other circumstances of extreme urgency or . . . [for] public non-commercial use.”⁷⁷ This is consistent with the compulsory license language in both TRIPS and the Doha Declaration.⁷⁸

The 2003 Decision also sets out requirements that must be met in order for countries to participate in the Paragraph 6 System.⁷⁹ Requirements for importing countries, such as LDCs, to import pharmaceutical products include, but are not limited to, specification of “the names and expected quantities of the product needed” to the Council for TRIPS, and granting a compulsory license if that pharmaceutical product is patented in the LDC’s territory.⁸⁰

⁷³ See 2003 Decision, *supra* note 70, ¶ 6.

⁷⁴ *Features of the Regime*, CAN.’S ACCESS TO MEDS. REGIME, http://www.camr-cam.gc.ca/intro/regime_e.html (last visited Apr. 16, 2010).

⁷⁵ 2003 Decision, *supra* note 70, ¶ 1(b).

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ See *supra* notes 33–37, 55–57 and accompanying text.

⁷⁹ See 2003 Decision, *supra* note 70, ¶ 2(a).

⁸⁰ *Id.* (according to paragraph 2(a) of the 2003 Decision, importing countries must: “(i) specif[y] the names and expected quantities of the product(s) needed; (ii) confirm[] that the eligible importing [m]ember in question, other than a least developed country [m]ember, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and (iii) confirm[] that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision”).

The exporting member countries also must meet certain requirements.⁸¹ They can only manufacture the amount necessary to meet the needs of the importing member, whose needs were already specified to the Council for TRIPS,⁸² and the entire amount of that production must then be exported to the requesting importing member.⁸³ The products must be specifically identified as being produced under the system laid out in the 2003 Decision.⁸⁴ Finally, prior to shipping, any exporting member must post on a website the quantities being supplied to the destination and the distinguishing features of the product.⁸⁵

In addition, the exporting member countries must provide adequate remuneration, “taking into account the economic value to the importing [m]ember,” whereas this requirement is waived for importing countries.⁸⁶ As stated earlier, “adequate remuneration” is not detailed in TRIPS, the Doha Declaration, or the 2003 Decision.⁸⁷ In fact adequate remuneration varies widely from country to country.⁸⁸ In *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*, James Love points out that countries should focus on two issues when setting forth their own guidelines for remuneration, one of which is to ensure that the royalty is not so high that it presents “a barrier for

⁸¹ *Id.* ¶ 2(b) (“[T]he compulsory licen[s]e issued by the exporting [m]ember under this Decision shall contain the following conditions: (i) only the amount necessary to meet the needs of the eligible importing [m]ember(s) may be manufactured under the licen[s]e and the entirety of this production shall be exported to the [m]ember(s) which has notified its needs to the Council for TRIPS; (ii) products produced under the licen[s]e shall be clearly identified as being produced under the system set out in this Decision through specific label[ing] or marking. Suppliers should distinguish such products through special packaging and/or special colo[r]ing/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and (iii) before shipment begins, the licensee shall post on a website [certain] information.”).

⁸² *Id.* ¶ 2(b)(i).

⁸³ *Id.*

⁸⁴ *Id.* ¶ 2(b)(ii).

⁸⁵ *Id.* ¶ 2(b)(iii).

⁸⁶ *Id.* ¶ 3.

⁸⁷ See generally TRIPS, *supra* note 12; Ministerial Declaration, *supra* note 51; Doha Declaration, *supra* note 19; 2003 Decision, *supra* note 70.

⁸⁸ LOVE, *supra* note 41, at 5.

access to medicines.”⁸⁹ This is especially true when a compulsory license is issued for the very purpose of improved access to medicines at lower prices.⁹⁰ Typically, in a situation where a compulsory license is issued for public health reasons in low-income countries, the remuneration has been between 0 and 6% of the generic price.⁹¹

Though compulsory license remuneration in public health situations is typically low, the TRIPS provision nonetheless allows for substantial discretion.⁹² It is likely that TRIPS left this provision somewhat arbitrary in order to pacify all member countries, especially developed member countries in which patent protection is significantly more important in helping patent holders obtain profits. In fact, patent holders that do not agree with the level of remuneration that the country offers can bring a complaint before the TRIPS Council.⁹³ So, although guidelines have been published, it is unlikely that a consensus will be reached on the prevailing standard for adequate remuneration any time soon.

The 2003 Decision also opened another avenue to bring much needed pharmaceutical products to developing or least developed countries—an importing member that has produced or imported a pharmaceutical product may export the product to another developed or developing country that is a party to the same regional trade agreement and shares the same health problem.⁹⁴ It states that “[i]t is understood that this will not prejudice the territorial nature of the patent rights in question.”⁹⁵ In effect, the 2003 Decision is condoning parallel importation to the extent that similarly suffering developing or least developed countries can

⁸⁹ *Id.* (noting two paramount issues: 1) “the system of setting royalties should not be overly complex or difficult to administer, given the capacity of the government managing the system,” and 2) “the amount of the royalty should not present a barrier for access to medicines”).

⁹⁰ *Id.*

⁹¹ *See id.* at 7–9.

⁹² *Id.* at 5.

⁹³ *See* Gustav Ando, *World’s First Compulsory License Issued in Malaysia for Generic HIV/AIDS Drug*, WORLD MARKET ANALYSIS, Feb. 24, 2004.

⁹⁴ 2003 Decision, *supra* note 70, ¶ 6(i).

⁹⁵ *Id.* ¶ 6(i).

export pharmaceutical products to each other if they are in need of treatment for the same health problems.

After the 2003 Decision, many countries announced that they would not use the Paragraph 6 System to import, even if they meet the specific requirements and guidelines.⁹⁶ These member countries consist mainly of the United States, Canada, European countries, Australia, and New Zealand.⁹⁷ Another group of member countries specified that it would only use the system to import in national emergencies or other circumstances of extreme urgency.⁹⁸ This group includes member countries such as China, Israel, Mexico, Turkey, and United Arab Emirates.⁹⁹

The provisions of the 2003 Decision were formally accepted as an amendment to the TRIPS Agreement on December 6, 2005, and will be formally built into TRIPS when two-thirds of the WTO's members have ratified the change.¹⁰⁰ But, despite the fact that this option is now on the table, it has seen very little use. Even as recently as December of 2008, the Director-General of the WTO, Pascal Lamy, admitted that criticism of the cumbersome and complex nature of the system has possibly stymied any or most positive effects.¹⁰¹ A more detailed analysis will be provided in Parts III and IV.

II. APPLICATION OF TRIPS, DOHA, AND THE DECISIONS

While much focus has been placed on ensuring that a framework exists for the furtherance of public health, as mentioned above, member countries have been slow to implement the procedures laid out in TRIPS, the Doha Declaration, and the decisions that followed.¹⁰² Various reasons, such as the

⁹⁶ *WTO Obligations*, *supra* note 17.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ Decision of General Council, *Amendment of the TRIPS Agreement*, WT/L/641 (Dec. 6, 2005); *see also* Press Release, World Trade Org., Members OK Amendment to Make Health Flexibility Permanent (Dec. 6, 2005), *available at* http://www.wto.org/english/news_e/pres05_e/pr426_e.htm.

¹⁰¹ Lamy, *supra* note 22.

¹⁰² *See infra* Part III.

complexity of a country's legislation relating to the provisions, fear of trade retaliation, interference with basic intellectual property rights, and lack of technology suited for LDCs, continue to stymie the progress on providing access to essential pharmaceuticals.¹⁰³

While placing measures to further public health in written agreements is certainly one step towards that goal, countries must move beyond mere verbal and written support and actually begin to implement these principles. Additionally, many of the most visible global organizations are also dedicated to finding solutions for these public health problems,¹⁰⁴ but again, they have produced very little more than verbal and written support. The following are examples of how the provisions in the TRIPS Agreement are being treated or applied throughout the world.

A. World Organizations

The United Nations (the "U.N.") is a prominent global organization "committed to maintaining international peace and security, developing friendly relations among nations and promoting social progress, better living standards and human rights."¹⁰⁵ In fact, the U.N. established UNAIDS¹⁰⁶—a program specifically dedicated to the "global commitment to scale up access to HIV treatment, prevention, care and support."¹⁰⁷ In a 2006 declaration, twelve years after TRIPS was signed and five years after Doha, the U.N. went so far as to "[r]eaffirm that the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights does not and should not prevent members from taking measures now and in the future to protect public health."¹⁰⁸ Members also "[r]esolve[d] to assist developing

¹⁰³ See *infra* Part III.

¹⁰⁴ See, e.g., *Health, The International Response*, UNICEF, http://www.unicef.org/health/index_response.html (last visited Apr. 5, 2010); see also *infra* Part II.A.

¹⁰⁵ *UN at a Glance*, UN, <http://www.un.org/en/aboutun/index.shtml> (last visited Apr. 5, 2010).

¹⁰⁶ UNAIDS, <http://unaids.org> (last visited Apr. 5, 2010).

¹⁰⁷ *Universal Access to HIV Treatment, Prevention, Care and Support*, UNAIDS, <http://www.unaids.org/en/CountryResponses/UniversalAccess/default.asp> (last visited Apr. 5, 2010).

¹⁰⁸ G.A. Res 60/262, ¶ 43, U.N. Doc. A/RES/60/262 (June 15, 2006) [hereinafter G.A. Res 60/262].

countries”¹⁰⁹ and “[e]ncourage pharmaceutical companies, donors, multilateral organizations and other partners to develop public-private partnerships in support of research and development and technology transfer.”¹¹⁰

These statements are encouraging and show that the organization supports the public health initiatives of TRIPS. But merely setting forth reaffirmations and resolutions in a declaration will not ensure implementation of the public health initiatives by participating countries. These countries actually have to act on the points in these declarations through modification of certain legislation and regional and bilateral treaty agreements. Mention was also made to private-public partnerships,¹¹¹ the viability of which will be developed further in Part IV.

The World Health Organization (the “WHO”) is another prominent global organization addressing public health problems.¹¹² Its responsibilities include “providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.”¹¹³ It has also called for measures to increase the access to life-saving pharmaceuticals, such as removing intellectual property barriers to research and development for public health.¹¹⁴ WHO member countries participated in drafting a resolution outlining steps needed to improve public health, though barely referring to the provisions in TRIPS.¹¹⁵ But again, these steps are essentially broad measures only touching upon the surface. To give life to these resolutions, countries will have to ensure that the legislation and treaty agreements allow for such measures.

¹⁰⁹ *Id.* ¶ 44.

¹¹⁰ *Id.* ¶ 46.

¹¹¹ *See infra* Part IV.B.2.

¹¹² *See* WORLD HEALTH ORG., <http://www.who.int/en> (last visited Mar. 3, 2010).

¹¹³ *About WHO*, WORLD HEALTH ORG., <http://www.who.int/about/en> (last visited Apr. 5, 2010).

¹¹⁴ *See* World Health Assembly Resolution on Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WHA. Res. 61.21, ¶ 2, 61st World Health Assembly, 8th plen. mtg. WHO Doc. WHA61/2008/Rec.21 (May 24, 2008).

¹¹⁵ *See generally id.* at annex.

The real problem in implementing TRIPS-like provisions is that the TRIPS Agreement's main purpose is to afford a system of uniform protection measures for intellectual property rights of all member countries.¹¹⁶ By signing TRIPS, developed countries looked to secure in other member countries the same or a similar level of rights that they afford their domestic intellectual property owners.¹¹⁷ Promoting public health measures was only a side issue, and therefore exceptions were carved out of TRIPS to facilitate this secondary purpose.¹¹⁸ In fact, the system set forth in the 2003 Decision is contrary to the main purpose of facilitating protection of intellectual property rights cross-border.¹¹⁹ This issue will be analyzed further in Part III.

B. Member Country Reactions

A prime example of the juxtaposition between developed countries' push for greater intellectual property protection across borders, and the detrimental effect that increased protection has on the LDCs' ability to obtain pharmaceuticals at affordable prices, is the lawsuit brought by thirty-nine pharmaceutical companies, including the United States and European companies, to block legislation passed by the South African government in 1997.¹²⁰ The legislation aimed to allow for the parallel importation of drugs, generic replacement of brand-named drugs, and price controls.¹²¹ The pharmaceutical companies argued that the legislation was counter to South Africa's commitment to TRIPS, specifically, to promote recognition and protection of the companies' patents. South Africa, on the other hand, argued that its actions were in line with TRIPS.¹²²

¹¹⁶ See TRIPS, *supra* note 12, at pmb1.

¹¹⁷ See WTO Overview, *supra* note 21.

¹¹⁸ See *id.*

¹¹⁹ See *infra* Part III.

¹²⁰ *Int'l Activity Report, South Africa: Big Pharma Backs Down*, DOCTORS WITHOUT BORDERS (2001), <http://doctorswithoutborders.org/publications/ar/report.cfm?id=1204> [hereinafter *Big Pharma Backs Down*]; see also Anthony Stoppard, *Health—South Africa: Drug Companies Drop Lawsuit Against Government*, INTER PRESS SERVICE (Apr. 19, 2001), <http://www.aegis.com/news/ips/2001/IP010413.html>.

¹²¹ *Big Pharma Backs Down*, *supra* note 120.

¹²² *Id.*

During this time, the United States also placed South Africa on its Special 301 Report.¹²³ As will be discussed in Part III, the Office of the United States Trade Representative (the “USTR”) created the Special 301 Report to list and give notice to countries that it believes to have committed trade violations.¹²⁴ Once they have been put on notice by the Special 301 Report, countries are subject to trade sanctions if actually found to be in violation of trade agreements.¹²⁵

But shortly after initiating the lawsuit, the pharmaceutical companies were met with much resistance from, amongst others, non-governmental organizations like Medecins Sans Frontiers.¹²⁶ Finally, in 2001, around the time when the Doha Declaration was highlighting the importance of facilitating access to pharmaceutical drugs for LDCs, the pharmaceutical companies dropped the lawsuit.¹²⁷

Despite the aforementioned treatment of South Africa, countries such as the United States are currently expressing their support of public health initiatives taken by LDCs. But it is still questionable whether or not the support will move beyond mere express support to actionable support. In the April 2009 Special 301 Report, the USTR acknowledged its support of public health measures, although using a supportive rather than a proactive tone.¹²⁸ For instance, the United States “respects a country’s right to protect public health, in particular, to promote access to medicines for all and supports the vital role of the patent system in promoting the development and creation of new and innovative lifesaving drugs.”¹²⁹ The United States also “respects” rights to grant compulsory licenses and notes the country’s acceptance of the 2005 Amendment, adopted by the TRIPS General Council,

¹²³ Scott Lucyk, *Patents, Politics and Public Health: Access to Essential Medicines Under the TRIPS Agreement*, 38 OTTAWA L. REV. 191, 213 (2006).

¹²⁴ See OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2009 SPECIAL 301 REPORT 1 (2009) [hereinafter 2009 SPECIAL 301 REPORT], available at <http://www.ustr.gov/sites/default/files/Full%20Version%20of%20the%202009%20SPECIAL%20301%20REPORT.pdf>.

¹²⁵ See *id.* at 39.

¹²⁶ See *Big Pharma Backs Down*, *supra* note 120.

¹²⁷ Stoppard, *supra* note 120.

¹²⁸ See 2009 SPECIAL 301 REPORT, *supra* note 124, at 6.

¹²⁹ *Id.*

promoting public health.¹³⁰ Additionally, the USTR stated in its Special Report that “[t]he United States will work to ensure that the provision of our bilateral and regional trade agreements are consistent with these views, and do not impede the taking of measures necessary to protect public health.”¹³¹

In order to give credence to the TRIPS provisions on public health and its statement above, the United States needs to be proactive and set forth provisions in its trade agreements and legislation that foster “access to medicine” for all. Mere verbal and written support in a report is not enough. In fact, critics are quick to point out that the United States has no problem issuing compulsory licenses for its own gain,¹³² yet discourages others from using them, especially in public health circumstances (as seen in the case of South Africa).¹³³ Other countries that signed on to TRIPS must also move past mere support and become active in implementing health measures. To date, only one country has taken the initiative to export pharmaceutical products through the Paragraph 6 System—Canada.¹³⁴

C. Utilization of Compulsory Licenses

Prior to 2005, developing countries and LDCs could more easily obtain generic HIV/AIDS drugs from India through compulsory licenses that did not fall under the reach of TRIPS because India did not recognize patents on medicines and had expansive manufacturing capabilities.¹³⁵ But in 2005, India implemented intellectual property protection for patents on medicines to comply with TRIPS; thus the use of such compulsory licenses dropped considerably.¹³⁶ Because countries could no

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² The United States issued a compulsory license for the antibiotic Ciprofloxacin, from Bayer, during the Anthrax scare in 2001. *See* LOVE, *supra* note 41, at 28.

¹³³ Dutfield, *supra* note 1, at 112.

¹³⁴ Kanaga Raja, *Members Discussed Implementation of TRIPS “Para 6” Solution*, THIRD WORLD NETWORK (Feb. 22, 2010), <http://www.twinside.org.sg/title2/wto.info/2010/twninfo100212.htm>.

¹³⁵ *See* Sangeeta Shashikant, *More Countries Use Compulsory License, But New Problems Emerge*, THIRD WORLD NETWORK (May 19, 2005), <http://www.twinside.org.sg/title2/health.info/twninfohealth004.htm>.

¹³⁶ *See id.*

longer use compulsory licenses to obtain generic versions of patented pharmaceuticals from India, they were forced to follow the provisions for obtaining a compulsory license highlighted in the Doha Declaration.

Initially, countries were slow to implement any of these provisions, but developing countries with manufacturing capabilities started to take advantage of them around 2006.¹³⁷ In 2006, Thailand issued a compulsory license for Efavirenz, an HIV drug manufactured by Merck & Co.,¹³⁸ and in January of 2007, Thailand also issued a compulsory license on the antiretroviral HIV/AIDS drug, Kaletra, made by Abbott Laboratories.¹³⁹ Then, in May of 2007, Brazil followed suit by issuing a compulsory license for Efavirenz after price negotiations broke down between the country and Merck.¹⁴⁰ On a similar note, the Philippines introduced legislation that made it easier to issue compulsory licenses and allow for parallel importation.¹⁴¹ Again, compulsory licenses allow countries to provide needed treatment at a much lower cost than if they would have had to purchase directly from the patent owner.¹⁴² Although these countries are not as financially destitute as an LDC, they still do not possess the resources of a developed nation.

While this relatively recent uptick in compulsory license activity is positive for countries with manufacturing capabilities, there are negatives, as discussed later in Part III. The licenses are also useless for a country with no manufacturing capacities because a compulsory license, on its own, only requires that the patent owner allow the requesting party to make use of the formula or technology encompassed in the patent.¹⁴³ Most LDCs would

¹³⁷ Gail E. Evans, *Strategic Patent Licensing for Public Research Organizations: Deploying Restriction and Reservation Clauses to Promote Medical R&D in Developing Countries*, 34 AM. J.L. & MED. 175, 181–83 (2008).

¹³⁸ *Examples of Health-Related Compulsory Licenses*, CONSUMER PROJECT ON TECH., <http://www.cptech.org/ip/health/cl/recent-examples.html> (last visited Apr. 13, 2010).

¹³⁹ Evans, *supra* note 137, at 184 (noting that U.S.-based Abbott Laboratories owned the patent on the antiretroviral drug licensed by Thailand).

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² See Dutfield, *supra* note 1, at 120.

¹⁴³ Doha Declaration, *supra* note 19, ¶ 6.

need to utilize the Paragraph 6 system to obtain the needed medicines because they do not have manufacturing capabilities within their own countries. But, to date, Rwanda is the only country without sufficient manufacturing capabilities to make sufficient use of a compulsory license and take advantage of the Paragraph 6 system.¹⁴⁴

D. Utilization of the Paragraph 6 System

In 2004, Canada implemented a version of the Paragraph 6 System by modifying its drug patent legislation with An Act to Amend the Patent Act and the Food and Drugs Act—The Jean Chrétien Pledge to Africa (the “Jean Chrétien Act”).¹⁴⁵ The Jean Chrétien Act set up the legal framework for what is known as Canada’s Access to Medicines Regime (“CAMR”).¹⁴⁶ CAMR lays out the requirements that must be met for a country, such as an LDC, to import disease-treating drugs.¹⁴⁷ It also lays out the requirements for companies willing to take part in the manufacture and export of the drugs to requesting countries.¹⁴⁸ The goal of the CAMR is “to facilitate timely access to generic versions of patented drugs and medical devices, especially those needed by least developed or developing countries to fight HIV/AIDS, malaria, tuberculosis and other diseases.”¹⁴⁹ In September of 2007,

¹⁴⁴ See Tove Iren S. Gerhardsen, *Rwanda Pioneers Use of WTO Patent Flexibility for HIV/AIDS Medicine*, INTELL. PROP. WATCH (July 20, 2007), <http://www.ip-watch.org/weblog/2007/07/20/rwanda-pioneers-use-of-wto-patent-flexibility-for-hiv-aids-medicine> (noting that Rwanda was the first and only country to import patented medicine produced without authorization from patent holders because it was a country “with insufficient or no manufacturing capacities in the pharmaceutical sector” (internal quotation marks omitted)).

¹⁴⁵ *Background*, CAN.’S ACCESS TO MEDS. REGIME, http://www.camrrcam.gc.ca/intro/context_e.html (last visited Apr. 13, 2010) [hereinafter *Background*, CAMR].

¹⁴⁶ *Id.*

¹⁴⁷ *Requirements for Importing Countries*, CAN.’S ACCESS TO MEDS. REGIME, http://www.camr-rcam.gc.ca/countr-pays/import/index_e.html (last visited Apr. 13, 2010) [hereinafter *Requirements for Importing Countries*, CAMR].

¹⁴⁸ *Requirements for Companies*, CAN.’S ACCESS TO MEDS. REGIME, http://www.camr-rcam.gc.ca/compan-entrepris/req-exig/index_e.html (last visited Apr. 13, 2010) [hereinafter *Requirements for Companies*, CAMR].

¹⁴⁹ *Background*, CAMR, *supra* note 145.

Canada utilized its version of the system to ship generic HIV/AIDS medicines to Rwanda.¹⁵⁰

The requirements of an importing country under CAMR are to identify a drug from the list of eligible products, notify the WTO of its need, and then find a suitable pharmaceutical company from which it can import the drug.¹⁵¹ The exporting party, the pharmaceutical company, is first required to enter into a sales agreement with the importing country for a specified quantity of a specific drug.¹⁵² The company is also required to submit an application to Canada's Commissioner of Patents to obtain an authorization for export.¹⁵³ Additional terms and conditions after authorization must be met, including certain anti-diversionary measures.¹⁵⁴ The products to be exported must meet the same safety, efficacy, and quality requirements that drugs for national use are required to meet.¹⁵⁵ In addition, the product manufactured for export must have special markings, coloring, and labeling that will distinguish it from the patented version that is sold on the national level.¹⁵⁶

In 2008, upon the authorization of GlaxoSmithKline and the Canadian subsidiaries of Shire and Boehringer Ingelheim, general drug maker Apotex manufactured a "fixed dose triple combination antiretroviral medicine" for export to Rwanda.¹⁵⁷ Apotex has since sent out two total shipments of the AIDS drug to Rwanda.¹⁵⁸ Despite these successful shipments, no other developing country has tried to import drugs from Canada.¹⁵⁹ Even Rwanda would

¹⁵⁰ Nikki Bozinoff, *A Pharm Reduction Approach*, DOMINION (Apr. 9, 2010), <http://www.dominionpaper.ca/articles/3288>.

¹⁵¹ *Requirements for Importing Countries*, CAMR, *supra* note 147.

¹⁵² *Requirements for Companies*, CAMR, *supra* note 148.

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Anti-Diversionary Measures—Companies*, CAN.'S ACCESS TO MEDS. REGIME, http://www.camr-rcam.gc.ca/compan-entrepris/req-exig/anti_e.html (last visited Apr. 13, 2010).

¹⁵⁷ *Big Pharmaceutical Firms Agree to Generic Drugs for Rwanda*, AFRICA GOOD NEWS (Oct. 21, 2009), <http://www.africagoodnews.com/health/big-pharmaceutical-firms-agree-to-generic-drugs-for-rwanda.html> [hereinafter *Generic Drugs for Rwanda*].

¹⁵⁸ *Id.* One shipment of the generic drug amounts to a one-year supply. *Id.*

¹⁵⁹ *See* Raja, *supra* note 134.

have to restart the CAMR process if it wanted to reorder the same drug because of the provision in CAMR that limits the quantity of the license to the amount originally requested by the country.¹⁶⁰

III. ISSUES AFFECTING THE IMPLEMENTATION OF TRIPS PROVISIONS

A. *Complexity of Legislation*

As alluded to in the section above, the Paragraph 6 System has been implemented only once with little or no indication of when it will be implemented again.¹⁶¹ The generic manufacturer Apotex and other critics have pointed out several issues with CAMR that may account for the failure of additional implementation.

Apotex indicated that CAMR is too complicated a process and that other countries wishing to import drugs have not yet made any effort to “jump through the hoops imposed by CAMR.”¹⁶² In its criticism, it cites to such problems as the difficulty that LDCs have in identifying the proper process to obtain import permission.¹⁶³ Other critics have also found the legislation to be “overly complex and unusable.”¹⁶⁴ They cite to the lack of input in the legislative process from the governments of the developing countries as one of the root problems.¹⁶⁵ For instance, there are over nineteen sections and one hundred sub-clauses in the legislation to read

¹⁶⁰ Jillian C. Cohen-Kohler, Laura C. Esmail & Andrea Perez Cosio, *Canada's Implementation of the Paragraph 6 Decision: Is It Sustainable Public Policy?*, GLOBALIZATION & HEALTH (Dec. 6, 2007), available at <http://www.globalizationandhealth.com/content/pdf/1744-8603-3-12.pdf>; see also *Requirements for Importing Countries*, CAMR, *supra* note 147.

¹⁶¹ See Raja, *supra* note 134.

¹⁶² Press Release, Apotex Inc., Second Shipment of Life-Saving Aids Drug Leaving for Africa (Sept. 18, 2009), available at <http://www.apotex.com/global/about/press/20090918.asp>.

¹⁶³ Letter from John Hems, Dir., Can.'s Access to Meds. Regime, to Douglas Clark & Brigitte Zirger, Dirs., Apotex Inc. (Jan. 23, 2007) [hereinafter CAMR Letter], available at http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_apotex_18-eng.pdf.

¹⁶⁴ Cohen-Kohler, Esmail & Cosio, *supra* note 160.

¹⁶⁵ *Id.*

through and interpret.¹⁶⁶ This requires some level of legal training or support to analyze and implement.¹⁶⁷ As such, significant resources must be spent on this analysis, but unfortunately, resources are limited in LDCs.¹⁶⁸ The legislation also restricts the list of medicines available—if a drug is not on the list, it cannot be manufactured for export.¹⁶⁹ This is a problem because LDCs are in need of many drugs that are not on the list.¹⁷⁰ These examples of the complicated nature of the importation system are by no means exhaustive, as other criticisms have been launched.

Other problems cited by Apotex affect the manufacturer.¹⁷¹ Requirements such as trying to obtain a voluntary license prior to a compulsory license, or having to renew a compulsory license, are unnecessary, time consuming, and add to the cost of the process.¹⁷² Unlike TRIPS, CAMR still requires a negotiation period with the patent owner before a country may apply for a compulsory license.¹⁷³ The costs of the negotiations alone act as a deterrent to generic manufactures.¹⁷⁴ In fact, Apotex itself threatened to abandon the project, citing that the process was too “costly and complicated.”¹⁷⁵ On a positive note, the three drug companies initially authorizing Apotex to manufacture the “triple combination” medicine have just recently pledged their continued

¹⁶⁶ MARILYN MCHARG, MEDECINS SANS FRONTIERES CAN., REVIEW OF THE CANADIAN ACCESS TO MEDICINES REGIME: SUBMISSION TO THE GOVERNMENT OF CANADA (2007), available at http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_msf_11-eng.pdf.

¹⁶⁷ See *id.*; see also Cohen-Kohler, Esmail & Cosio, *supra* note 160 (“Administratively, the CAMR assumes that developing country governments have the requisite knowledge and human resource capacity to make use of the regime.”).

¹⁶⁸ MCHARG, *supra* note 166.

¹⁶⁹ *Id.*

¹⁷⁰ See *id.*

¹⁷¹ See CAMR Letter, *supra* note 163.

¹⁷² *Id.*

¹⁷³ *Preparing to Submit an Application*, CAN.’S ACCESS TO MEDS. REGIME, http://www.camr-rcam.gc.ca/compan-entrepris/applic-demande/prepar_e.html (last visited Apr. 16, 2010) (“At least 30 days before submitting the application, the company must try to obtain from the patent holder a voluntary licen[s]e to make and export the patented product.”).

¹⁷⁴ Paige E. Goodwin, Note, *Right Idea, Wrong Result—Canada’s Access to Medicines Regime*, 34 AM. J.L. & MED. 567, 578 (2008).

¹⁷⁵ *Generic Drugs for Rwanda*, *supra* note 157.

support of the distribution of the less expensive version of their medicine.¹⁷⁶

The Apotex example highlights the complexities in the process for exporting drugs to developing countries and LDCs. Even in a country that has the legislation in place to facilitate the export/import process, the generic manufacturer threatened to back out and no additional countries have requested aid. Therefore, CAMR should be used as a case study for countries thinking of implementing TRIPS provisions within their legislation. The Council for TRIPS should also study this drug product exchange and examine whether changes can and should be made to the Paragraph 6 system. This issue will be analyzed further in Part IV.

B. Fear of Retaliation

On top of the legislative aspects preventing widespread implementation of the Paragraph 6 system, LDCs may be hesitant to seek products from an exporting country for fear of trade retaliation.¹⁷⁷ The same fear is present when a developing or least developed country issues a compulsory license or partakes in parallel importation. Trade retaliation occurs when a first country such as the United States places sanctions on a second country for partaking in a trade-related activity that negatively affects a certain market in the first country.¹⁷⁸

For instance, when Thailand issued its compulsory license in 2007, the United States responded by placing Thailand on the Special 301 Report.¹⁷⁹ As briefly discussed in Part II, the United States' Special 301 Report was born out of section 301 of the U.S. Trade Act of 1974.¹⁸⁰ Relating to intellectual property, section 301 allows the United States to take action in the form of trade sanctions against those countries that do not provide adequate

¹⁷⁶ *Id.*

¹⁷⁷ Dutfield, *supra* note 1, at 123.

¹⁷⁸ Feroz Ali. K, *Intellectual Property Rights—US, Trade Sanctions and IPRs*, HINDU BUS. LINE (June 15, 2004), <http://www.thehindubusinessline.com/2004/06/15/stories/2004061500111100.htm>.

¹⁷⁹ See Evans, *supra* note 137, at 184.

¹⁸⁰ See Lucyk, *supra* note 123, at 212; Ali. K, *supra* note 178.

intellectual property protection.¹⁸¹ The United States places these countries on a watch list, otherwise known as the Special 301 Report.¹⁸²

In yet another example of retaliation, as previously discussed in Part II, the Clinton administration put South Africa on the section 301 watch list after it attempted to pass similar legislation.¹⁸³ As such, the legislation was never implemented in South Africa, even though the lawsuit brought by the pharmaceutical companies was dropped.¹⁸⁴ Because placement on such lists can lead to trade sanctions, these countries are always mindful of the effects that certain actions can have on foreign direct investments.¹⁸⁵ Thus, unless TRIPS is amended to include a deterrent mechanism to prevent countries from partaking in trade retaliation after a compulsory license is issued, this hesitancy may remain.

C. Interference with Intellectual Property Rights of Patent Holders

While compulsory licenses, parallel importation, and the Paragraph 6 System are allowed by TRIPS and do provide for a way in which LDCs can obtain products at substantially less than retail price,¹⁸⁶ they are not methods which should be sustained in the long run due to their interference with intellectual property rights.

In the case of a compulsory license without export capabilities, the patent owner is forced to license its formula or technology for little remuneration at best, especially when dealing with LDCs.¹⁸⁷ When a patent owner is forced to license his formula or technology for little pecuniary gain, he is giving up one of the benefits of

¹⁸¹ See Trade Act of 1974, § 301, 19 U.S.C. § 2411 (2006); see also Ali. K, *supra* note 178.

¹⁸² See Ali. K, *supra* note 178.

¹⁸³ Lucyk, *supra* note 123, at 213.

¹⁸⁴ *Id.*

¹⁸⁵ Evans, *supra* note 137, at 184.

¹⁸⁶ See Dutfield, *supra* note 1, at 121–22.

¹⁸⁷ See Lucyk, *supra* note 123, at 209–10 (describing that royalties under a compulsory license tend to be lower than the profits lost by the licensor, particularly where the compulsory license is specifically implemented to lower prices).

obtaining a patent.¹⁸⁸ As stated previously, one of the purposes of implementing the patent system is to encourage innovation by giving the inventor a monopoly over that specific technology so that he can recoup the costs he incurred in developing the invention.¹⁸⁹

On the other side of the argument, under TRIPS, this license is only given in very limited circumstances—such as a country’s dire need for treatment of epidemic diseases.¹⁹⁰ Thus, in the markets where companies make most of their profits, the patent monopoly will still be recognized. Additionally, the patent owner will not have to devote any of its production or capital to the manufacture of drugs because it is only licensing the technology in the patent. Regardless, this method of promoting public health still goes against the purpose of the TRIPS Agreement and erodes the benefits of a patent owner’s temporary monopoly.¹⁹¹

Parallel importation also encroaches on the benefits that a patent owner hopes to receive from its patent. When a country obtains a patented product through a channel other than the patent owner, it is eroding the monopoly to which the patent owner may be entitled. This can happen when a country with a valid license from the patent owner has an intellectual property regime in place that allows for parallel importation.¹⁹² Although countries differ in their treatment of parallel importation, the main purpose of TRIPS is to promote increased protection of intellectual property rights.¹⁹³ Thus, allowing a country to buy patented products from a party other than the patent owner contravenes this purpose.

¹⁸⁸ See Bird & Cahoy, *supra* note 7, at 284.

¹⁸⁹ See *id.* at 283–84.

¹⁹⁰ See Lucyk, *supra* note 123, at 193.

¹⁹¹ See Bird & Cahoy, *supra* note 7, at 283.

¹⁹² See KEITH E. MASKUS, WORLD INTELLECTUAL PROP. ORG., PARALLEL IMPORTS IN PHARMACEUTICALS: IMPLICATIONS FOR COMPETITION AND PRICES IN DEVELOPING COUNTRIES 1, 2 (2001); see also Goodwin, *supra* note 174, at 572 (noting that such a risk is evident in implementation of these provisions, such that the 2003 Decision requires the importing country to “take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system” (internal quotation marks omitted)).

¹⁹³ See Goodwin, *supra* note 174, at 570.

With the Paragraph 6 system, the patent owner also loses possible revenue and experiences erosion of its monopoly.¹⁹⁴ In addition, generic companies must devote production capacities and capital. The profits of a generic company are eroded because resources are used to manufacture drugs for export through the Paragraph 6 System that could be used to generate a profit. But one beneficial effect would be the positive press that the companies receive from these public health efforts.

D. Technology Not Suited for LDCs

Another categorical reason why the public health provisions in TRIPS are not currently suited to provide a long-term solution to the problem of lack of access to essential pharmaceuticals is that the technology and treatments available through these provisions are not necessarily directed towards the needs of those in developing and least developed countries.¹⁹⁵ A patent provides innovation incentive to pharmaceutical companies to produce drugs that will give them a healthy return on their investment.¹⁹⁶ Unfortunately, treatment of tropical diseases or forms of diseases occurring mostly in LDCs provide little or no innovation for a pharmaceutical company to spend resources due to the low return on investment they would receive.¹⁹⁷ This is because these diseases are prevalent in poor countries, yet virtually non-existent in the developed countries where citizens can afford to pay the retail prices that pharmaceutical companies charge to recoup their investment.

¹⁹⁴ See Lucyk, *supra* note 123, at 200.

¹⁹⁵ See *A Guide to the Post-2005 World: TRIPS, R&D and Access to Medicines*, MEDECINS SANS FRONTIERES (Feb. 25, 2005), http://www.msf.org/msfinter-national/invoke.cfm?objectid=88694E5B-0FED-434A-A21EDA1006002653&component=toolkit.article&method=full_html&CFID=14506321&CFTOKEN=57431063; see also Aaron S. Kesselheim, *Think Globally, Prescribe Locally: How Rational Pharmaceutical Policy in the U.S. Can Improve Global Access to Essential Medicines*, 34 AM. J.L. & MED. 125, 125 (2008).

¹⁹⁶ See *A Guide to the Post-2005 World*, *supra* note 195.

¹⁹⁷ LDCs are not a profitable market due to low buying power that their people and governments possess. See *id.* Drug companies cannot turn a profit by marketing and selling a drug solely in LDCs. See *id.*; see also Dutfield, *supra* note 1, at 112–13 (pointing out that the poor are disproportionately affected by diseases and receive little resources compared to people affected by diseases prevalent in a developed country).

Thus, while TRIPS may be able to help in situations of national emergency or public health crises where a patent for the disease actually exists, its public health provisions are not the optimal solution for the future. Long-term feasibility is questionable, at best, because TRIPS fails to alleviate the “constant tension between patent holder and consumer” and attempts to “mediate [it] through a complex body of rules.”¹⁹⁸

E. Purpose of TRIPS Is Not for Promotion of Public Health

The main purpose of TRIPS is not to help curb the HIV/AIDS epidemic in LDCs. Rather, its purpose is to ensure that holders of intellectual property rights in one member country receive reciprocal protection in another member country. This is accomplished by setting up a framework in which countries can implement legislation and negotiate bilateral and multilateral treaties.¹⁹⁹ It has been asserted that TRIPS owes its existence to the United States and developed European countries as a means of securing an “advantage in knowledge-based industries.”²⁰⁰ These countries knew that they were no longer the manufacturing powerhouses that they once were and that their advantage would now have to depend on the knowledge that they produced.²⁰¹ Thus, they wanted a means by which their intellectual property could be protected outside of their own countries and TRIPS was their vehicle of choice.

Public health was not on their agendas and it did not really come into focus until after TRIPS had been established—when prices for life-saving treatments remained high.²⁰² Because developed countries want greater intellectual property protection outside of their borders for their inventions and because LDCs become subject to higher prices and subsequent lack of access if they recognize these higher levels of protection, there is a constant conflict between developed countries and LDCs.²⁰³

¹⁹⁸ Evans, *supra* note 137, at 186.

¹⁹⁹ See TRIPS, *supra* note 12, at pmb1.

²⁰⁰ Lucyk, *supra* note 123, at 212.

²⁰¹ *Id.*

²⁰² See *id.*

²⁰³ See *id.* at 213.

F. Lack of Sustainability

One of the problems with the Paragraph 6 System and parallel importation is the lack of sustainability that results for LDCs such as those in Sub-Saharan Africa. The public health measures enumerated in the TRIPS Agreement allow countries to import pharmaceutical products.²⁰⁴ But by continuously allowing for the importation of these life-saving treatments, an LDC may never learn how to sustain itself without relying on developed countries.²⁰⁵ Additionally, while TRIPS calls for the observance of intellectual property rights across all of its member countries,²⁰⁶ it does not give guidance on how to develop a fully functional intellectual property regime. LDCs will never be able to fully take advantage of the agreement if they are not able to implement the proper framework to recognize intellectual property rights. The ultimate goal should be for these countries to have full manufacturing and distribution capabilities as well as an intellectual property regime capable of protection and enforcement of such rights.

IV. ANALYSIS OF OPTIONS

A. TRIPS Options—Short Term

All three of the aforementioned public health measures in TRIPS—compulsory licenses, the Paragraph 6 System, and parallel importation²⁰⁷—can promote public health by offering avenues in which developing and least developed countries could obtain otherwise unaffordable treatment for epidemic diseases such as HIV/AIDS. But, due to the limitations outlined in the previous sections, TRIPS lacks viability as a long-term public health solution and continues to stymie those efforts. Accordingly, these measures should be seen as short-term solutions to the lack of access problem that developing countries and LDCs are

²⁰⁴ See Dutfield, *supra* note 1, at 122.

²⁰⁵ See Evans, *supra* note 137, at 178.

²⁰⁶ *Id.* at 179–80.

²⁰⁷ See *supra* Part I.A; see also Dutfield, *supra* note 1, at 121–22.

experiencing. As will be discussed later in Part IV.B, there are other options that are more feasible as long-term solutions.

1. Compulsory Licenses

Compulsory licenses alone or within the Paragraph 6 System can deliver much needed assistance by providing LDCs with the essential medicines that they need to treat epidemic diseases such as HIV/AIDS in the short term. If an LDC has manufacturing capabilities, access to a compulsory license alone would enable it to manufacture drugs for those in need at a much lower cost.²⁰⁸ Also, the mere option of being able to assert a compulsory license can strengthen the bargaining power of a country with manufacturing capabilities to obtain a lower price from patent holders of pharmaceuticals such as anti-AIDS drugs.²⁰⁹ But in addition to the limitations stated in section A, compulsory licenses outside the Paragraph 6 System cannot be used by countries lacking manufacturing capability.

2. Paragraph 6 System

In order to provide essential medicines for those member countries without manufacturing capabilities, member countries with production capabilities can produce the drugs and export them to the requesting importing member country.²¹⁰ Again, even though this Paragraph 6 system has barely been utilized up to this point, there is now a model, CAMR,²¹¹ which other countries can use as an example when revising their own legislation.

By analyzing Canada's drug patent legislation and the CAMR Rules, member countries to the TRIPS Agreement can find provisions in the legislation that are necessary as well as provisions that can be changed to ensure more use of the system. If changes can be made to allow for a less complex system in which producing parties can go about manufacturing and exporting in a less costly and cumbersome way and importing parties are not hampered by burdensome procedures for importing drugs, the

²⁰⁸ Lucyk, *supra* note 123, at 193.

²⁰⁹ Dutfield, *supra* note 1, at 120.

²¹⁰ See Reichman, *supra* note 47, at 247-49.

²¹¹ See Goodwin, *supra* note 174, at 569.

system may find more use. Some suggestions include removing the negotiation requirement prior to applying for a compulsory license, removing unnecessary clauses to make it easier for LDCs to analyze the legislation, and expanding the number of drugs available for export.²¹² The negotiation requirement is not present in TRIPS and would only hinder a generic company's ability or desire to manufacture drugs for export. However, while this system, if implemented properly, can provide the LDCs lacking manufacturing capacity with the drugs necessary to treat epidemic diseases in the short-term, it should not be a long-term solution.

3. Parallel Importation

Member countries can also make use of parallel importation to bring in needed drugs that are produced in other countries. Even though this system of parallel importation undermines the intellectual property rights of the country that owns the rights to the drug,²¹³ it is one method by which a country can obtain pharmaceutical products at a price cheaper than purchasing them from the patent owner at their retail price.²¹⁴

B. Long Term Options

1. Collaborative Groups

One model of providing public health assistance to LDCs that has had early success is a group known as the International Drug Purchase Facility, or UNITAID.²¹⁵ UNITAID was founded in 2006 as a funding institution by a group of countries that "aim to provide further drug access at affordable prices to developing countries on a sustainable and predictable basis."²¹⁶ These countries utilize long-term funding commitments, such as the collection of taxes on airline flights, to purchase drugs or other

²¹² See MCHARG, *supra* note 166.

²¹³ See MASKUS, *supra* note 192, at 2.

²¹⁴ See *id.* at 121.

²¹⁵ *Mission*, UNITAID, <http://www.unitaid.eu/en/UNITAID-Mission.html> (last visited Apr. 12, 2010).

²¹⁶ G.A. Res 60/262, *supra* note 108, ¶ 48.

diagnostic tools at a high volume, which allows for a steep reduction in cost.²¹⁷

With TRIPS, the LDC requesting the drug treatment is not fiscally equipped to purchase the drugs and does not receive financial help from other parties, except the patent owner and/or member country that is providing the technology or drugs. This places a huge burden on the providing party because their only form of compensation, if any, is “adequate remuneration.” Unlike the provisions in TRIPS, UNITAID actually purchases the drugs, albeit at a reduced cost from the original retail price, using funds pooled from numerous countries.²¹⁸ Thus, the patent owner actually receives compensation. UNITAID, in a sense, has managed to alleviate most of the tension between allowing a patentee to obtain profits from its patented invention and providing affordable access to low-income countries, whereas this tension still remains in a compulsory license situation through TRIPS.

For example, UNITAID will often work in conjunction with other organizations like UNICEF and the WHO.²¹⁹ UNITAID will provide the funding (through mechanisms such as the collection of airline taxes) and its partner organizations are responsible for procuring drugs at reduced prices.²²⁰ Just recently, UNITAID obtained a 60% reduction in price for pediatric HIV/AIDS medicines, which allowed for three times as many infected children to be treated as would be treated at 100% of the price.²²¹ So while 40% of retail price is a deep reduction in price, it is better than a compensation percentage of less than 6%, which is typical for remuneration in a compulsory license situation.²²²

The success of this group is just one indication that countries are willing to take action to help alleviate the world’s public health

²¹⁷ *How Innovative Financing Works*, UNITAID, <http://www.unitaid.eu/en/How-innovative-financing-works.html> (last visited Apr. 12, 2010).

²¹⁸ *See Questions and Answers*, UNITAID, http://www.unitaid.eu/images/NewWeb/documents/en_qa_finalrevised_mar10.pdf (last visited Apr. 12, 2010).

²¹⁹ *Id.*

²²⁰ *See id.*

²²¹ *See Statement on World AIDS Day*, UNITAID, <http://www.unitaid.eu/en/20081201165/News/UNITAID-statement-on-world-AIDS-day.html> (last visited Apr. 12, 2010).

²²² *See LOVE, supra* note 41, at 7–9.

problems despite the lack of implementation of TRIPS provisions. In just a few years of existence, UNITAID has grown to twenty-nine countries and has already been able to commit \$730 million towards its goal, and it is currently providing for those in need.²²³ In fact, over twenty countries in Sub-Saharan Africa are receiving funds.²²⁴ Compare this with the one instance where the Paragraph 6 system was used—and only two countries were involved.

UNITAID is a means for countries to participate in alleviating the world's public health problems in which the constant tension that remains with a compulsory license/export scenario—the patentee's right to obtain profits from its invention versus affordable access for low-income countries—is greatly reduced. As mentioned above, because the main purpose of TRIPS is to foster shared intellectual property rights across country borders, and not to provide access to life-saving treatments,²²⁵ this tension will always exist when the provisions of TRIPS are used.

2. Private-Public Partnerships

Like TRIPS, however, UNITAID fails to provide a framework through which the country to which it is providing aid can eventually sustain itself. A 2006 U.N. Political Declaration alludes to another option that may provide for sustainability and furtherance of intellectual property rights in addition to access to essential and affordable medicines on a long-term basis.²²⁶ In this Declaration, the U.N. “[e]ncourage[s] pharmaceutical companies, donors, multilateral organizations and other partners to develop public-private partnerships in support of research and development and technology transfer, and in the comprehensive response to HIV/AIDS.”²²⁷

²²³ *Achievements*, UNITAID, <http://www.unitaid.eu/en/Achievements.html> (last visited Apr. 12, 2010).

²²⁴ *Countries Benefiting from HIV/AIDS Funding*, UNITAID, <http://www.unitaid.eu/en/Countries-benefiting-from-HIV/AIDS-funding.html> (last visited Apr. 12, 2010).

²²⁵ See Keith E. Maskus, *Intellectual Property Challenges for Developing Countries: An Economic Perspective*, 2001 U. ILL. L. REV. 457, 457.

²²⁶ G.A. Res 60/262, *supra* note 108, ¶ 45.

²²⁷ *Id.* ¶ 46.

A public-private partnership can help achieve the ultimate goal of full manufacturing and distribution capabilities as well as a fully functional intellectual property regime for LDCs. In this type of partnership, private enterprises join forces with public sector organizations or international organizations.²²⁸ The private party or even the international organizations are the parties that shoulder most of the financial and technological risk.²²⁹ For LDCs, this is important because their governments and citizens cannot afford to shoulder the burden on their own. The private enterprise will also impart its expertise in areas like product development and dissemination.²³⁰ An example of this partnership is the Kenya Medical Research Institute (“KEMRI”).²³¹ KEMRI is a state owned corporation that partners with both local and outside organizations such as the Wellcome Trust and the Centers for Disease Control (the “CDC”), wherein these organizations impart their expertise to KEMRI.²³² KEMRI is now instrumental in providing pharmaceutical research, development, and local innovation in Kenya.²³³ It is also connected to the hospital systems where it assists in the delivery of healthcare.²³⁴

While solutions such as public-private partnerships should be preferred over the Paragraph 6 System and parallel importation, compulsory licenses may be necessary for quite some time. This necessity is due to the fact that manufacturing capacity and technological know-how does not give a country the actual technology that might be needed to provide sustained treatment. More often than not, this technology will be patent-protected, and without the funds to either purchase the drugs outright from the patent owner or pay a reasonable fee for a license, a compulsory license will be needed.²³⁵ But, over time, the hope is that with the

²²⁸ Evans, *supra* note 137, at 187.

²²⁹ *See id.* at 186–88.

²³⁰ *See id.*

²³¹ *Id.* at 187.

²³² *See id.* at 187–88.

²³³ *See id.*

²³⁴ *Id.* at 188.

²³⁵ Theodore C. Bailey, *Innovation and Access: The Role of Compulsory Licensing in the Development and Distribution of HIV/AIDS Drugs*, 2001 U. ILL. J.L. TECH. & POL’Y 193, 194.

help of partnerships and other methods, these countries will generate innovative technology on their own.

CONCLUSION

The public health provisions in TRIPS (compulsory licenses, the Paragraph 6 System, and parallel importation) have not been very successful in alleviating the world's public health problems. Although some countries were able to provide low cost medicines to their citizens through compulsory licenses,²³⁶ the few countries making use of them have been subject to retaliation and resistance.²³⁷ The Paragraph 6 System, although it provided treatment for those in need in Rwanda,²³⁸ has only been used once and has received much criticism. In addition, no other country has taken advantage of it. Although countries and organizations appear to support the provisions, the support has been limited to passive written and verbal support.

While these provisions may be able to provide short-term and emergency options, they are ineffective for long-term solutions to public health problems. Tension will always remain between member countries seeking profits through better intellectual property protection and countries needing access to patented medicines. Because of this tension, developing and least developed countries will remain cautious for fear of retaliation and loss of foreign direct investment.²³⁹ In addition, requirements for implementation of these provisions are somewhat cumbersome and complex, making them difficult to implement.

Although it is beyond the scope of this Note to solve the world's public health problems, ventures such as private-public partnerships can avoid the tension resulting from TRIPS and provide long-term sustainability by imparting funds, and technological, manufacturing, and distribution know-how. Private-public partnerships can also help implement an intellectual property regime.

²³⁶ See Reichman, *supra* note 47, at 249–50.

²³⁷ See *id.* at 249.

²³⁸ See Cohen-Kohler, Esmail & Cosio, *supra* note 160.

²³⁹ Dutfield, *supra* note 1, at 123.

In essence, because of its focus on equal and rigorous protection of intellectual property rights, TRIPS hurts LDCs' access to essential pharmaceuticals despite the various public health provisions built into the agreement. Thus, the TRIPS Agreement should not be used as a long-term solution to the public health problem of access to essential pharmaceuticals.