Use of Paragraph 6 Systems for Access to Medicine

Laura Chung

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Use of Paragraph 6 Systems for Access to Medicine

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Use of Paragraph 6 System for Access to Medicine

Laura Chung†

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I. Introduction

The intellectual property protection regime under the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS Agreement") of the World Trade Organization ("WTO") raises certain public health concerns regarding access to medicine.¹ However, the TRIPS Agreement includes various flexibilities that may be utilized by its member nations to ameliorate its negative impact on access to medicine.² One such flexibility is the Paragraph 6 System, which is a mechanism that permits a nation with insufficient or no manufacturing capacities to utilize compulsory licensing effectively by importing generic drugs from another country.³

This paper will highlight some of the difficulties involved in using the Paragraph 6 System as determined by its first and only use in the trade of Apo-TriAvir from Canada to Rwanda. This paper will propose potential revisions that may be made to the Paragraph 6 System or other future legislation implementing the Paragraph 6 System at a national level in order to render future usage of the System more effective. Finally, this paper will attempt to provide a realistic view of the impact of intellectual property protection on access to medicine.


² See id. at art. 27. Article 27 of the TRIPS agreement gives participating countries discretion in the protection of patented processes or products when there is a concern for the "ordre public or morality, including to protect human, animal, or plant life or health...." Id. Furthermore, under Article 27 the TRIPS agreement allows members to "exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals ...." Id.

II. What is the Paragraph 6 System?

To fully understand the Paragraph 6 System, it is important first to understand the limitations that the TRIPS Agreement places on exercising compulsory licensing.

The Paragraph 6 System is a special type of compulsory licensing scheme. A compulsory license refers to a governmental authorization to exploit a patented invention without the consent of the patent holder.

According to the Doha Declaration, adopted by the TRIPS Council in 2001, each member nation has the “freedom to determine the grounds upon which [compulsory] licenses are granted.” However, Article 31 of the TRIPS Agreement lays out certain procedural restrictions on using compulsory licensing, including: (1) “authorization on individual merits”; (2) “prior negotiations”; (3) “adequate remuneration”; and (4) “judicial review of the decisions,” which are explained in further detail below.

The requirement for “authorization on individual merits” refers to the obligation of the member nations to consider whether to grant compulsory licensing on a medicine-by-medicine basis. A blanket compulsory licensing for all pharmaceutical products is not permissible. The “prior negotiations” requirement obliges the member nations not to grant a compulsory license unless the patent owner has been given an opportunity to license the drug voluntarily based on “reasonable commercial terms and conditions.” For example, in the event that a government would like to issue a compulsory license in order to produce a patented medicine domestically, the government is first required to contact

4 Id. at pmbl.
5 TRIPS Agreement, supra note 1, at art. 31. Article 31 outlines the guidelines that regulate a member country whose laws permit the use of a product or process without the authorization of the patent holder. Id.
6 See Ministerial Declaration, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration].
7 Id. ¶ 5.
9 TRIPS Agreement, supra note 1, at art. 31(a).
10 Id. art. 31(b).
the patent holder for a voluntary license. Additionally, the "adequate remuneration" requirement and the "judicial review of the decisions" requirement ensure that the patent holder is paid for the use of the patented product under the compulsory license, and that the patent holder is provided with a judicial forum within which the legitimacy of the compulsory license can be challenged.\(^{11}\)

It is important to note that, in the event of "national emergencies or other circumstances of extreme urgency," the requirement of prior negotiation with the patent holder is waived.\(^{12}\) In such a case, the patent holder can be notified after the use, "as soon as reasonably practicable."\(^{13}\) In the event of "public non-commercial use," the patent holder should be informed promptly if the government or government contractor "knows or has demonstrable grounds" to know that a valid patent exists on the invention.\(^{14}\)

In addition, Article 31(f) of the TRIPS Agreement sets forth that the use of compulsory licensing should be "predominantly for the supply of the domestic market."\(^{15}\) The obligation of Article 31(f) imposes hardships upon countries with insufficient or no manufacturing capacities in making effective use of the compulsory licensing scheme.\(^{16}\) One implication of Article 31(f), for example, is that a country without manufacturing capacity, even if it were to issue compulsory licensing, would not be able to obtain the necessary medicine from another country with compulsory licensing where it is manufactured to serve its domestic market.\(^{17}\) Thus, even if a compulsory license is granted, a country without manufacturing capacity might not have any practical way of obtaining the necessary medicine at a competitive price.

\(^{11}\) See id. art. 31(h), 31(i).

\(^{12}\) Id. art. 31(b).

\(^{13}\) Id.

\(^{14}\) TRIPS Agreement, supra note 1, art. 31(b).

\(^{15}\) Id. art. 31 (f).

\(^{16}\) See Decision of 30 Aug. 2003, supra note 3, at pmbl.

\(^{17}\) See TRIPS Agreement, supra note 1, art. 31(f).
The Paragraph 6 System attempts to solve this issue by allowing the use of compulsory licensing for exportation purposes by "waiving" two major restrictions placed on the use of compulsory licensing under the TRIPS Agreement.¹⁸

First, with respect to an exporting country, the Paragraph 6 System waives the "predominantly for the domestic market" requirement of Article 31(f).¹⁹ This allows a country with manufacturing capacities in which a medicine may be protected by a valid patent to produce the medicine legally at a price below the price set by the patent holder for the purpose of exportation to an eligible importing country.

Secondly, the Paragraph 6 System waives the "adequate remuneration" requirement of Article 31(h) with respect to an eligible importing country.²⁰ Adequate remuneration pursuant to Article 31(h) is to be paid by a generic drug supplier in the exporting county, "taking into account the economic value to the [eligible] importing Member."²¹ Thus, the generic drug supplier or the exporting nation is in charge of determining the royalty rate paid to the patent holder.

The Paragraph 6 System does not waive the prior negotiation requirement of Article 31(b), mentioned above. Accordingly, an entity in the importing country must seek a voluntary license from the patent holder prior to obtaining a compulsory license from the government of an exporting country.²²

Moreover, in determining the eligibility of a country as an importing member, any least-developed country is "deemed to have insufficient or no manufacturing capacity in the pharmaceutical sector."²³ However, other countries can become

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¹⁹ Id.
²⁰ Id. ¶ 3.
²¹ Id.
eligible by notifying the TRIPS Council of its lack of or insufficient manufacturing capacity.\textsuperscript{24}

The Annex of the Decision of 30 August 2003 regarding Implementation of Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health by the TRIPS Council states the following:

For other eligible importing Members[,] insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; OR 
(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member’s needs, the system shall no longer apply.\textsuperscript{25}

The above-mentioned notification does not need to be approved by a WTO body.\textsuperscript{26} Thus, it may be characterized as a naked self-declaration. However, twenty-three developed countries gave assurances to the TRIPS Council that they would refrain from using the system as an importing country.\textsuperscript{27} In addition, ten nations within the European Union, Hong Kong, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Taiwan, Turkey, and the United Arab Emirates declared that they would not use the system, except in the case of “national emergency or other circumstances of extreme urgency.”\textsuperscript{28} This list suggests that the intended recipients of the system are largely least-developed countries.

\textsuperscript{24} CORREA, supra note 22, at 17.
\textsuperscript{25} Decision of 30 Aug. 2003, supra note 3, at annex.
\textsuperscript{26} Id. ¶ 1(b) n. 2.
\textsuperscript{27} Id. ¶ 1(b) n. 3. The nations that agreed not to use the system as importing countries were Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom, and the United States. Id.
\textsuperscript{28} CORREA, supra note 22, at 12.
The Paragraph 6 System also sets forth additional procedural requirements, including providing a notice to the TRIPS Council, clearly identifying the exported medicine with specific labeling or marking, and taking "reasonable measures within [the importing country’s] means" to prevent the diversion of the imported pharmaceutical products to other countries.

While the Decision of 30 August 2003 originally established the Paragraph 6 System as an interim waiver, it is currently being offered in the form of a 2005 Protocol to amend the TRIPS Agreement permanently, which would require ratification by two thirds of the 153 WTO members. As of February 2010, only 26 member countries, counting the European Communities as one member, have acted to accept the 2005 Protocol formally.

III. Events Leading to Implementation of the Paragraph 6 System

To understand the necessity of the Paragraph 6 System properly, it is important to examine the historical events that have led to its implementation.

A. Transition from Paris Convention to the TRIPS Agreement

Prior to adoption of the TRIPS Agreement, the Paris Convention for the Protection of Industrial Property ("Paris Convention") of 1883, within the World Intellectual Property Organization ("WIPO"), provided the framework for international

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29 See Decision of 30 Aug. 2003, supra note 3, ¶ 2(a) n. 5.
30 Id. ¶ 2(b)(ii).
31 Id. ¶ 4; see also CORREA, supra note 22, at 16 (outlining the purpose and expectations of "anti-diversion measures" to be taken by the importing countries).
32 See CORREA, supra note 22, at 5.
34 TRIPS Council Minutes, supra note 33, ¶ 102.
intellectual property protection. The Paris Convention provided a greater flexibility to its member countries than the TRIPS Agreement with regard to the patent protection of pharmaceuticals. Under the Paris Convention, member nations were not required to provide patent protection for “all fields of technology,” and many countries chose to exclude pharmaceutical products from patent protection altogether. Further, the patent term varied from state to state, and the failure to work a patent locally within a country—for example, to manufacture the patented product inside the country—was considered a valid ground for granting a compulsory license.

To highlight some of the flexibilities afforded under the Paris Convention, the patent law of India can be examined in detail. Pursuant to its Patents Act of 1970, which purposely weakened intellectual property protection for pharmaceuticals, India did not grant product patents for pharmaceuticals, food products or agrochemicals from the early 1970s until mid-2000s. Only process patents were available for these subject matters. In addition, the patent term for pharmaceutical process patents was purposefully shortened to five years from the initial grant of seven years from the filing, whichever came first, and licensing was granted automatically for pharmaceutical patents at an

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35 K. Balasubramaniam, Patent Policies and Pharmaceutical Prices, Lecture delivered to Post Graduate Diploma in Health Development, Faculty of Medicine, University of Colombo (Oct. 16, 2004), in TRIPS AND PHARMACEUTICAL INDUSTRY: IMPACT ON DEVELOPING COUNTRIES, 15, 16-17 (Manish Ashiya ed., 2007).

36 Id.


38 See generally, RESOURCE BOOK ON TRIPS AND DEVELOPMENT, supra note 37, at 482-83 (referencing the relationship of the TRIPS Agreement with Articles 5.A.2 and 5.A.4 of the Paris Convention).


41 Id. at app. II.
exceptionally low royalty rate of 4%. In fact, many countries were offering patent terms that ranged from fifteen to seventeen years for product patents, and seven to ten years for process patents, under the Paris Convention.

The Indian Patents Act of 1970 allowed the Indian domestic pharmaceutical sector to grow rapidly, transforming the nearly foreign-dominated India pharmaceutical market of the 1970s to a primarily domestic market. By the mid-1990s, 70% of domestically consumed drug in bulk was produced by domestic companies. Indian generic drug manufacturers flourished in this environment by producing, often by reverse engineering, pharmaceutical products protected in most developed countries at that time, thus quickly emerging as an important international source of generic drugs. The Indian Patent Act suggests that different levels of intellectual property protection may actually favor a given country, depending on its unique economic developmental phase.

The flexibilities permitted under the Paris Convention were eliminated in 1995, when the WTO adopted the TRIPS Agreement. The TRIPS Agreement established a high global minimum standard of intellectual property protection in "all fields of technology" except for "diagnostic, therapeutic and surgical methods for the treatment of humans or animals." WTO member

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42 Id.
43 See Balasubramaniam, supra note 35, at 18.
44 See Lanjouw, supra note 40, at 4.
45 Id.
46 See Pervez N. Ghauri, Intellectual Property, Pharmaceutical MNEs and the Developing World, 44 JOURNAL OF WORLD BUSINESS 206, 208 (2009) (explaining that six developed countries account for 90% of patents, with the U.S. accounting for half of the total); Nicoli Natra, The (Political) Economics of Antiretroviral Treatment in Developing Countries, 16 TRENDS IN MICROBIOLOGY 574, 574 (2008) (noting that reverse-engineering is one of several modes by which many generic drugs are produced in Brazil and India); Richard Smith, Trade, TRIPS, and Pharmaceuticals, 373 THE LANCET 684, 685 (2009). Brazil, Thailand and India have substantial capacity to produce generics; India became an important generic drug supplier for the developing world by not providing patents on medicines until 2005. Id.
48 TRIPS Agreement, supra note 1, art. 27.1, 27.3(a).
nations were obligated to grant patents for pharmaceutical products.\textsuperscript{49} Also, in line with the contemporaneous U.S. Patent Act and the European Patent Convention of 1973, the patent term was extended to twenty years, not fifteen to seventeen years, as it had been in many developing countries at the time.\textsuperscript{50} The TRIPS Agreement also required that product patents be granted for pharmaceuticals, in addition to process patents, eliminating the option of using reverse engineering to produce a patent-protected compound with a process not covered by the process patent.\textsuperscript{51} This requirement would eventually have a major impact on the availability of generic drugs, as explained below.

Further, the TRIPS Agreement required that the “patent rights [be] enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”\textsuperscript{52} In effect, the Agreement eliminated the local working requirement as valid grounds for granting compulsory licenses.\textsuperscript{53} Brazil and other mid-income countries have advocated local production as part of its efforts to increase technology transfer.\textsuperscript{54}

Because the national law of each member differed significantly at the time of its adoption, as well as the economic status and specific needs of each nation, the TRIPS Agreement sets forth a schedule of transition periods for compliance, dependent upon the economic status of each member nation, as designated by the United Nations.\textsuperscript{55} For example, some of the mid-income developing countries, including India, were allowed to defer compliance until 2005, while the least-developed countries, such as Rwanda, were allowed a longer transition period.\textsuperscript{56}

\textsuperscript{49} See World Health Org., supra note 47, at 238.
\textsuperscript{50} Balasubramaniam, supra note 35, at 18.
\textsuperscript{51} Id.
\textsuperscript{52} TRIPS Agreement, supra note 1, art. 27.1.
\textsuperscript{54} Id.
\textsuperscript{55} See HESTERMeyer, supra note 8, at 70.
\textsuperscript{56} Id. at 70-72 (discussing the details of TRIPS compliance schedules); TRIPS
B. Impact of AIDS Epidemic in Refining the TRIPS Agreement

The discussion regarding the events leading to the implementation of the Paragraph 6 System would not be complete without considering the role that the Acquired Immune Deficiency Syndrome ("AIDS") epidemic and the development of antiretroviral drugs had played in shaping the TRIPS Agreement.57

The AIDS epidemic was first recognized in the United States in the early 1980s with isolated incidences of a mysterious and deadly new disease, predominantly occurring among the homosexual population.58 This disease was referred to as AIDS for the very first time in 1982.59

In 1983, the Human Immunodeficiency Virus ("HIV") was identified as the cause of AIDS.60 In the United States, the research effort for finding a cure started immediately.61 In particular, Burroughs-Wellcome PLC, now GlaxoSmithKline ("GSK"),62 and the U.S. National Cancer Institute ("NCI"), a part of the U.S. Department of Health and Human Services, played a major role in developing the very first antiretroviral drug indicated for treating AIDS.63 GSK’s research, which began in 1983, resulted in Food and Drug Administration ("FDA") approval of the first antiretroviral medicine for treating HIV, Retrovir®,64 in 1987.65 FDA approval was followed by the patent grant for its Agreement, supra note 1, art. 65.4.

57 HESTERMeyer, supra note 8, at 255-56 (explaining that limited access to AIDS medication put pressure on the WTO before the Doha Agreement).

58 See Alvin Silverstein, Virginia Silverstein & Laura Silverstein Nunn, The AIDS Update 19-22 (1st ed., 2008) (discussing the first instances that doctors encountered before AIDS was identified).

59 Id. at 23.

60 Id. at 25.


63 Cochrane, supra note 61, at 1611-12 (discussing the collaboration between the two institutions).

64 RETROVIR, Registration No. 1418913.
active ingredient, zidovudine, in February 1988.\textsuperscript{66} This patent expired in 2005.\textsuperscript{67} However, it took until 1996 for “highly active anti-retroviral therapy” (“HAART”) to emerge.\textsuperscript{68} In its current form, HAART is now considered a powerful treatment that combines two nucleoside reverse transcriptase inhibitors with a protease inhibitor, or non-nucleoside reverse transcriptase inhibitor.\textsuperscript{69}

Between 1985 and 1996, GSK and various other researchers in the U.S. and Europe developed several more compounds belonging to the same category of medicine as zidovudine.\textsuperscript{70} These compounds were referred to as nucleoside reverse transcriptase inhibitors for their effect of suppressing HIV, a retrovirus, from replicating itself by inhibiting the reverse transcription of its genome through the process of nucleoside analog substitution.\textsuperscript{71} GSK obtained FDA approval for its second nucleoside reverse transcriptase inhibitor for AIDS, lamivudine, in 1995.\textsuperscript{72}

In 1995, the first approved protease inhibitor, saquinavir, was developed by Hoffmann-La Roche,\textsuperscript{73} a Swiss pharmaceutical company.\textsuperscript{74} Protease inhibitors suppress replication of a virus by inhibiting the activity of a viral protease, “an enzyme that cuts

\textsuperscript{65} See Broder, supra note 62, at 3 tbl.1 (detailing the approval date and length of research).
\textsuperscript{66} Cochrane, supra note 61, at 1612.
\textsuperscript{67} HESTERMeyer, supra note 8, at 6.
\textsuperscript{68} K. Porter et al., Determinants of Survival Following HIV-1 Seroconversion After the Introduction of HAART, 362 THE LANCET 1267, 1267 (2003).
\textsuperscript{69} Thomas Cihlar & Adrian S. Ray, Nucleoside and Nucleotide HIV Reverse Transcriptase Inhibitors: 25 Years After Zidovudine, 85 ANTIVIRAL RES. 39, 43 (2010).
\textsuperscript{70} See Broder, supra note 62, at 3 tbl. 2 (showing a list of approved antiviral medications).
\textsuperscript{71} See Cihlar, supra note 69, at 40 (describing the development of zidovudine).
\textsuperscript{72} See Kanikaram Satyanarayana & Sadhana Srivastava, Patent Pooling for Promoting Access to Antiretroviral Drugs (ARVs) – A Strategic Option for India, 4 THE OPEN AIDS J. 41, 42 tbl. 1 (2010) (showing a list of all approved antiviral drugs).
\textsuperscript{73} Broder, supra note 62, at 3 tbl.1.
\textsuperscript{74} Hoffmann-La Roche, Company Portrait, ROCHE, http://www.roche.com/about_roche/at_a_glance/company_portrait.htm (last visited Oct. 28, 2010).
long protein strands into functional viral proteins." Reverse transcriptase inhibitors and protease inhibitors are much less effective when administered separately.

In 1996, by combining a protease inhibitor discovered by Hoffmann-La Roche with two nucleoside reverse transcriptase inhibitors in a clinical study with 862 individuals, the modern form of antiretroviral treatment, HAART, was introduced for the first time. HAART proved to be a powerful treatment for AIDS, reducing the mortality rate by 84% within four years of its introduction in developed countries.

C. Doha Declaration and Call for the Paragraph 6 System

By 2000, the AIDS epidemic had spread worldwide. Further, it had quickly become clear that the HAART treatment, which had significantly reduced the mortality rate of AIDS in developed countries, remained prohibitively expensive for many living in the least-developed countries.

Under the "Accelerating Access" initiative, a program funded by the Joint United Nations Programme on HIV/AIDS ("UNAIDS"), some pharmaceutical companies volunteered to provide antiretroviral treatments at a reduced price to African countries, where approximately "25 million people [were] infected with HIV." However, by February 2001, only three countries—Senegal, Uganda, and Rwanda—had reached a drug distribution agreement with the pharmaceutical companies. In Senegal, the

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75 Silverstein et al., supra note 58, at 119.
76 See Hestermeier, supra note 8, at 8 (explaining the effectiveness of the combined treatment compared to the downsides of using only one of the drugs).
77 See Porter et al., supra note 68, at 1267.
80 See AVERT, supra note 78 (describing the cost of AIDS treatment in Sub-Saharan Africa).
82 Id.
agreement lowered the price of annual treatment per person to approximately $1000 - $1800, approximately 10% of the U.S. price for the same medicine. Even with the 90% reduction in price, the treatment was still too expensive for many Africans to afford, and the limited supply did not go far in the face of the shortage confronting the developing countries.

South Africa was particularly devastated, where approximately 20% of its adult population carried HIV, and 600 people were dying from AIDS each day. In what was called the “defiance campaign,” the Treatment Action Campaign (“TAC”), a non-governmental organization based in South Africa, imported generic fluconazole, a meningitis medicine crucial in treating many AIDS patients, from Thailand to South Africa in open violation of South African patent law in 2000. At that time, the South African government was negotiating for price concession of fluconazole with Pfizer. TAC openly blamed the South African government for 600 people dying from AIDS each day, and urged the government to take a humanitarian exemption and to import generic drugs under its Medicines Amendment Act of 1997.

In the meantime, Cipla Limited, an Indian generic drug manufacturer, had been targeting the African market and offering African countries antiretroviral treatments at a price far below the reduced rates offered by the brand-name pharmaceutical

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83 Id.
84 See HESTERMeyer, supra note 8, at 9 (discussing a 2005 study that showed that 80% of those who needed the drugs in developing countries has no access to them).
87 James, supra note 86.
companies. While the South African government was considering the option of obtaining the necessary medicines under compulsory licenses, Cipla approached the South African government, asked for a unilateral license in the case that a compulsory license was granted, and offer to provide the supply at a five percent royalty rate.

In response to Cipla's offer, in April 2001, thirty-nine pharmaceutical companies jointly brought a lawsuit against the South African government, claiming that South Africa's Medicines Amendment Act of 1997 violated the TRIPS Agreement. Due to public outcry, this lawsuit was eventually dropped. However, the debate among the international community regarding the TRIPS Agreement had reached its pinnacle.

In November 2001, the heated debate led to the Doha Declaration, which clarified the terms of the TRIPS Agreement with respect to parallel importation and compulsory licensing. Particularly important for understanding the Paragraph 6 System is paragraph 5 of the Doha Declaration, which specifies that "[e]ach member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted." Further, Doha paragraph 6 states 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. We

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90 *Id.* at 88-89.

91 *Id.* at 91.

92 *Id.* at 90.

93 *HESTERMeyer*, *supra* note 8, at 9-15.

94 Abbott, *supra* note 33, at 7-9; Archana Jaktar, Compulsory Licensing and the Anti-Competitive Effects of Patents for Pharmaceutical Products: From a Developing Countries' Perspective, Remarks at GARNET Annual Conference (Nov. 11, 2009) at 12-13 (stating that South African law suit led to Doha Declaration of 2001, which reaffirmed the flexibilities available under TRIPS Agreement) (full text of remarks on file with author).

95 Doha Declaration, *supra* note 6, ¶ 5(c) (emphasis added).
instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.96

In other words, paragraph 6 of the Doha Declaration promoted the TRIPS Council members to come up with a solution for WTO member countries that have insufficient or no manufacturing capacities.97 This solution came about in 2003, with the adoption of the Decision of 30 August 2003 regarding Implementation of Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health.98 Because this system implements a solution for the problem identified in paragraph 6 of the Doha Declaration, the system is now referred to as the “Paragraph 6 System.”99

IV. First and Only Case of Utilizing the Paragraph 6 System and Lessons Learned

The Paragraph 6 System has been used only once, by the trade of Apo-TriAvir from Canada to Rwanda.100 Because the Paragraph 6 System has been used only once, the Canada-Rwanda deal provides valuable lessons regarding the strengths and weaknesses of the Paragraph 6 System as specified under the Decision of 30 August 2003.

The Canada-Rwanda deal would not have been possible without the initiative taken by the Canadian government to change its legislation. Additionally, Apotex, a Canadian generic drug producer, took an active role in the transaction by agreeing to supply Apo-TriAvir to Rwanda.101

96 Id. ¶ 6 (emphasis added).
97 Abbott, supra note 33, at 8-9.
98 Id. at vii.
99 Id. at 2.
100 Frederick M. Abbott, Introductory Note to World Trade Organization Canada First Notice to Manufacture Generic Drug for Export, 46 ILM 1127, 1127 (2007) [hereinafter Canada Notice].
101 See generally id. at 1127 (discussing the process by which Apotex came to manufacture medication for Rwanda).
A. Apo-TriAvir and Impact of Patent Protection on Price

To understand the need for the Paragraph 6 System, it is helpful to have some familiarity with the medicine involved, and the reason that the brand-name versions of antiretroviral drugs are so expensive.

Apo-TriAvir is a convenient, fixed-dose combination of three different antiretroviral drugs: zidovudine, lamivudine, and nevirapine. Zidovudine (Retrovir®) was the first FDA-approved antiretroviral for AIDS, while lamivudine was another antiretroviral developed by GSK. Nevirapine is an active ingredient of Viramune®, marketed by Boehringer Ingelheim.

Once an AIDS/HIV patient has been placed on a cocktail treatment of Apo-TriAvir, also referred to as the first-line treatment, it is critical that the patient adhere to a consistent medicine regimen for many years. Skipping multiple doses or discontinuing the medicine can result in drug-resistant variations of the virus, complicating further treatment. The introduction of fixed-dose combinations made the application of the cocktail treatment much easier for patients to manage.

Apo-TriAvir is similar to GSK’s Trizivir in that it is a fixed-dose combination approved by the FDA that combines three medications into one AIDS cocktail treatment. Both

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103 Satyanarayana, supra note 72, at 42 tbl.1.
104 VIRAMUNE, Registration No. 1905263.
105 Satyanarayana, supra note 72, at 42 tbl.1.
107 In the United States and developing countries, simplified HIV regimens in the form of co-packaged drugs (such as blister packs) may facilitate distribution and improve patient adherence. See Food and Drug Administration, Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV: Guidance for Industry—Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV 2, available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125278.htm.
108 TRIZIVIR, Registration No. 2966217.
combinations include zidovudine and lamivudine.\textsuperscript{110} However, Trizivir\textsuperscript{®} costs approximately $14,600 per year, per patient in the United States.\textsuperscript{111} Considering that a 3-year supply can cost approximately $43,800, antiretroviral treatment is very expensive, even for those living in the United States.\textsuperscript{112} Because antiretroviral treatment can be essential to maintaining health or life for many HIV/AIDS patients, the patent holder may exercise severely disproportionate bargaining power when setting the price of treatment.\textsuperscript{113}

While debates continue as to whether patent protection actually improves or worsens the overall quality of healthcare, it is clear that patents impact price. With respect to the Canada-Rwanda deal, Apotex offered to produce Apo-TriAvir at approximately $0.405 per tablet ($295 per annual supply), as opposed to $20 per tablet for Trizivir\textsuperscript{®} in the United States ($14,600 per annual supply).

The effect of patents on the price of patented goods, including antiretroviral treatments, can be examined using a typical demand and supply curve.

\textsuperscript{110} About ApoTriavir, supra note 102; Prescribing Information: Trizivir, supra note 109.

\textsuperscript{111} Canada Issues Compulsory License for HIV/AIDS Drug Export to Rwanda. In First Test of WTO Procedure, BRIDGES WEEKLY TRACE NEWS DIGEST, Sept. 26, 2007, at 5, available at http://ictsrd.net/downloads/bridgesweekly/bridgesweekly11-32.pdf (The cost for brand version of Apo-TriAvir costs $20 per pill vs. $0.405 from Apotex. Two pills of this fixed dose combination are taken per day. Accordingly, $20 x 2 x 365 days = $14,600 per person per year).


\textsuperscript{113} Ghauri, supra note 46, at 209 (arguing that the drugs are a basic need, and patents can impose hardship in developing countries, to do inability to afford); see also Siripen Supakankunti et al., Impact of the World Trade Organization TRIPS Agreement on the Pharmaceutical Industry in Thailand, 79 BULL. OF THE WHO 461 (2001).
Because U.S. law allows patent holders to exclude others from making, using or selling the patented product in a given market, the patent holder has the ability to determine the market price of the product. In other words, the patent holder has a monopoly. The above economic model presumes that, as an economic actor, the patent holder sets prices to maximize profit, rather than to promote public health.

The price of the medicine is set at $P_m$, the monopoly price when patent protection exists, as compared to $P_c$, the competitive price, when no protection exists. In practice, pharmaceutical companies might not set prices solely to maximize their profit. Nevertheless, in the case of antiretroviral medicines, the brand-name combinations typically cost approximately $9,000-16,000 per patient per year in the United States, while the generic drug combinations are available at $88-261 per patient per year.

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115 See Dinyar Godrej, The Great Health Grab: The World's Giant Drug Companies Pursues Profit Above All Else, NEW INTERNATIONALIST, Nov. 2003, at 9 (discussing the ways in which pharmaceutical companies control drug prices); Jaktar, supra note 94, at 1 (discussing the use of monopoly to set prices for patented products).

116 Avert, supra note 78; WHO, UNAIDS, AND UNICEF, TOWARDS UNIVERSAL ACCESS: SCALING UP PRIORITY HIV/AIDS INTERVENTIONS IN THE HEALTH SECTOR 74 fig. 4.13 (2009) [hereinafter UNIVERSAL ACCESS] ("The median price paid for first-line treatment (prequalified by WHO or approved or tentatively approved by the United States Food and Drug Administration) in low-income countries in 2008 ranged from $88 per person per year for the fixed-dose combination of 3TC + NVP + d4T (the most widely used combination) to $261 for the fixed-dose combination EFV + [3TC + AZT]"); see generally Médecins Sans Frontières, A matter of life and death: The role of patents in access to essential medicines (2001), available at...
Accordingly, price bears a strong correlation to the existence of patent protection.

Monopoly pricing is very expensive for society in general, particularly when applied to important products like medication. In the absence of patent protection, the quantity of medicine supplied to society would be \( Q_e \). However, due to patent protection, only the quantity corresponding to \( Q_m \) is supplied to the society. This difference in quantity, \( Q_e - Q_m \), correlates directly to the number of people who cannot afford the necessary treatment because of monopoly pricing. This lack of treatment corresponds to a loss of health and life for many HIV/AIDS patients.

Additionally, the monopolist obtains revenue equivalent to the sum of boxes A and B as profit above the cost of production. In particular boxes B and F correspond to consumer surplus, which the consumer loses because of the monopoly, while box B represents consumer surplus that has been converted into revenue for the pharmaceutical companies. The boxes E and F represent a deadweight loss to the society, which neither the consumer nor any producer can capture because of the monopoly.

http://www.doctorswithoutborders.org/publications/reports/2001/doha_11-2001.pdf; Edward Gardner et al., The Association of Adherence to Antiretroviral Therapy with Healthcare Utilization and Costs for Medical Care, 6 APPL HEALTH ECON HEALTH POLICY 145 (2008) (noting that in the high adherence quartile, antiretroviral costs were approximately $17,513 for patients who started initial treatment between 1997 and 2003 and that the wholesale price is very high; however, certain patients in the United States may qualify for prescription discount programs, such as the US Public Health Service Section 340B); Sherry Boschert, Starting Antiretrovirals for Chronic HIV in Adults, INTERNAL MEDICINE NEWS (Dec. 1, 2005), http://findarticles.com/p/articles/mi_hb4393/is_12_36/ai_n29240264/?tag=content;coll (showing that recommended regimes of cocktail antiretroviral therapy wholesale price ranged from $40.06 to 64.89 per day as of 2005); Bruce Schackman et al., The Lifetime Cost of Current Human Immunodeficiency Virus Care in the United States, 44 MEDICAL CARE 990 (2006) (estimating the monthly cost of first-line antiretroviral to be approximately $1140 – $13680 per year – in 2004; further in calculating life-time cost, cost reduction by use of generic was not applied as the “newer patent-protected drugs were assumed to be continue to be preferred based on efficacy and convenience”); World Health Organization, GPRM - Global Price Reporting Mechanism: Transaction prices for Antiretroviral Medicines and HIV Diagnostics from 2008 to March 2010 (May 2010), www.who.int/hiv/pub/amds/GPRMsummary_report_may2010.pdf (showing that many pharmaceutical companies apply different price schemes to the least developed countries, developing countries, and developed countries).
When the patented and monopolized product is life-saving medication, as it is in the case of antiretroviral treatments, the loss of consumer surplus B corresponds to other necessities of life that a patient may forgo to obtain treatment. For example, patients and their families may consume a substantial portion of their life savings in order to obtain the necessary treatments for their sickness. In fact, in developed countries where access to medicine exists regardless of the person's economic status, the total quantity supplied may be close to the total quantity necessary, regardless of the price of the medicine. In such a case, the national government may end up paying for a substantial portion of the monopoly rent A and B to the pharmaceutical company.

The public health impact can be far more severe in countries where access to medicine is not guaranteed. A large portion of the population could be excluded from access altogether, as has happened in many African countries in the early 2000s.

B. Cost of Developing New Medicine

Nevertheless, most developed countries have supported the patent protection of pharmaceuticals. The rent A and B to the brand-name pharmaceutical producers, according to the developed countries, is the source of funds necessary for the research and development (R&D) of new drugs. Development can be extremely costly and risky for those who undertake it.

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117 See generally Decision of 30 Aug. 2003, supra note 3 (describing agreement of twenty-three developed countries in support of pharmaceutical patent protection).
Developed countries, in particular the U.S., bear a large portion of the world’s R&D costs for new drugs. It is estimated that, while 80% of world population lives in the developing countries, people in developing countries represent only 10% of world pharmaceutical sales revenue. The size of the pharmaceutical market in several developed countries can be glanced at a graph from Jane Parry’s article “Intellectual Property and the Challenges of China,” reproduced below.

![Graph of A Booming Pharmaceutical Market](image)

In 2005, the U.S. alone spent $262 billion on over-the-counter (“OTC”) drugs. Furthermore, the U.S. market is larger than the next nine markets combined: Japan, Germany, France, China, England, Brazil, Italy, Canada and Spain. In other

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118 Ghauri, supra note 46, at 209 (noting that Argentina, Brazil, India, and Mexico have developed a thriving generic industry in the absence of patent protection).

119 Godrej, supra note 115, at 10; Smith, supra note 46, at 685 (providing recent global pharmaceutical sales data; North America, Europe, Japan, and Latin America account for 85% of the global pharmaceutical market, which leaves only 15% for the rest of the world).


121 Id.

122 See id.
words, a substantial portion of the market is concentrated in the United States, Europe, and a handful of other developed countries. For the brand-name pharmaceutical companies, the countries outside the top ten markets, including most mid-income and least-developed countries, comprise only a small fraction of their overall revenue. Sub-Saharan Africa, where two-thirds of the world’s HIV/AIDS patients live, accounted for only about 1% of the global pharmaceutical market in 2001.

The cost of R&D and the necessity of patent protection for new drugs can be better understood by studying the resources that GSK—and the U.S. government—used in developing the first antiretroviral, zidovudine (Retrovir®).

The financial statement provided by GSK to its stockholders reveals that GSK spent approximately $50 million to develop zidovudine. Furthermore, GSK actually spent about $726 million to research about a dozen other drugs before Retrovir® resulted in a commercial success. Thus, in making Retrovir®, GSK recouped financial losses from other unsuccessful ventures.

Additionally, the production costs remained high for GSK during the initial years of Retrovir® production: by receiving FDA approval, the company committed itself to spending tens of millions of dollars on materials and equipment. Cheaper alternatives did not exist because, as the first producer of new pharmaceutical compounds, GSK could not obtain a large quantity of cheap intermediates, which are available to generic producers. Moreover, the initial market for antiretroviral treatment remained small, while the fixed costs associated with producing each unit of the medicine remained high. These factors, in addition to

123 Godrej, supra note 115, at 10.
126 O’Reilly, supra note 125, at 124.
128 O’Reilly, supra note 125, at 124.
129 Id.
clinical studies that must be conducted, contribute to the price
difference between a brand-name drug and its generic versions.

GSK’s financial statement demonstrates that new drug
development is very expensive and highly risky.\textsuperscript{130} If a company
invests several million dollars in an ultimately unsuccessful
compound, that company can quickly lose its economic holding.
The revenue secured by the patent protection guarantees that some
pharmaceutical companies can recoup the cost of R&D. These
companies can even make a profit above and beyond the costs, by
attracting the best prospects for new drug development.

Developing a new drug now costs approximately $115-802
million for the pharmaceutical industry.\textsuperscript{131} Additionally,
substantial spending on basic science research and time-
consuming trial and error cannot be avoided.\textsuperscript{132} The United States,
for example, spent about $170 billion on R&D in 1995, and about
35% of the funding came from the federal government.\textsuperscript{133} Without
the structured support for R&D that exists in developed countries
like the U.S., the discovery of powerful new medications, such as
zidovudine and Apo-TriAvir, most likely would not have
occurred.\textsuperscript{134} Advocates of the patent system argue that the
streamline of continuous development and discovery of better
medication over time enriches the public domain with new and
better drugs that were not available only a few decades ago.\textsuperscript{135}

\textsuperscript{130} See David Cavalla, \textit{Does R&D pay?}, \textit{Drug Discovery Today}, March 2010, at
230.

\textsuperscript{131} HESTERMEYER, \textit{supra} note 8, at xxxiii.

\textsuperscript{132} See \textit{generally} Broder, \textit{supra} note 62, at 2-6 (outlining the various difficulties
inherent to HIV treatment research).

\textsuperscript{133} See Adam B. Jaffe, \textit{Trends and Patterns in Research and Development
(1996).

\textsuperscript{134} See \textit{generally} Broder, \textit{supra} note 62 (discussing the success of the R&D
model—including the FDA’s involvement—used in developing antiretroviral
medications).

\textsuperscript{135} Broder, \textit{supra} note 62, at 1-5 (characterizing the development of the first
antiretroviral treatment as “treating the untreatable,” and noting that scientific advance
saves lives; these life saving discoveries occur through continual researches and
development, and allocating resources for that purpose is crucial for developing new and
better treatments for AIDS.); HESTERMEYER, \textit{supra} note 8, at 29-33 (noting that patents
have been traditionally used as a mechanism of rewarding inventors for their useful
innovations for a limited time, on the basis that it spurs innovation). Henry Grabowski,
C. Rwanda and Other Eligible Importing Countries

The economic condition of Rwanda, which was the importing country in the landmark Canada-Rwanda deal, sheds some light regarding on the condition of many least-developed countries that are battling the AIDS epidemic.

While the GDP per capita of Rwanda is approximately $1000 per year, the majority of Rwandans live below the poverty line, earning approximately 250 Rwandan francs per day, which amounts to approximately $157 per year or $ 0.43 per day. The prevalence of AIDS in the adult Rwandan population (age fifteen to forty-nine) is 2.8%, with approximately 150,000 people living with HIV in Rwanda as of 2007. The prevalence rate is high among many African countries, with sub-Saharan Africa home to...
approximately 22 million people infected with HIV.\textsuperscript{139} This number amounts to about two-thirds of people infected with HIV in the world.\textsuperscript{140}

Given that generic antiretroviral treatments cost about $88-261 per year, the treatments are not affordable even at their competitive price to a large majority of people living in Rwanda. The cost of brand-name antiretroviral treatment ($10,000 per year) is even higher. By the end of 2008 the WHO estimated that about 58% of people who need treatment in sub-Saharan Africa are not receiving it.\textsuperscript{141}

Income disparity tends to exaggerate the problem of prohibitively expensive treatment in many countries with the greatest need for antiretroviral medicine. It has been estimated that the top 20% of earners in South Africa earn twenty-two times as much as the bottom 20% of earners.\textsuperscript{142} In Brazil, the top 10% of earners makes about 48% of total income, as compared to about 41% in Mexico, about 30% in United States, and about 24% in Canada.\textsuperscript{143}

\textsuperscript{139} Id. at 39.

\textsuperscript{140} Id.

\textsuperscript{141} UNIVERSAL ACCESS, supra note 116. This report includes estimated numbers of people (all ages) and children younger than 15 years receiving and needing antiretroviral therapy and antiretrovirals for preventing mother–to–child transmission and coverage. Id.


\textsuperscript{143} Id.
The effect of income disparity can be studied graphically in the following hypothetical model:

Income disparity results in an L-shaped demand curve, making the price impact of a monopoly more pronounced, as illustrated in Economy B in the above demand curves. Significantly fewer people are able to afford antiretroviral medicine in countries with high income disparity, as a large portion of the population remains in poverty.

Further, the above graph presumes that the pricing of \( P_m \) in Economy A, set by a brand-name pharmaceutical company to maximize its profit in a hypothetical developed country (Economy A), supplies to a hypothetical least-developed country with significant income disparity (Economy B). This presumption is realistic in view of international protection of patent rights. This protection allows the pharmaceutical companies to set prices in both developed and under-developed economies. Such price-setting behavior may be detrimental to those living in the least-developed countries by making treatment cost prohibitive.

\[144\] *Id.* at 50-52.
Provided that the least-developed country forms a completely closed economy in which price is determined by its own demand and supply, as shown in the above demand curve for a hypothetical Economy B', the monopoly price of the medicine, \( P_m' \), would be set lower than \( P_m \), the monopoly price established to maximize profit in a developed Economy A. Accordingly, allowing the pharmaceutical manufacturers to set prices in both the developed and least-developed country may lower the number of people who can access treatment in the least-developed country.

In the Rwanda-Canada deal, the problem of price carryover from hypothetical Economy A to hypothetical Economy B manifests itself in the form of the buying power of international currency. As stated above, the majority of people in Rwanda make about 250 Rwandan francs per day, which converts to about $0.43 per day.

The 250 Rwandan francs, though small, is a sufficient amount of income for Rwandan residents to obtain necessities for one day; for example, a kilogram of Irish potatoes costs about 230 Rwandan francs.\(^{145}\) When converted to U.S. dollars, 250 Rwandan francs are not sufficient to buy a bottle of orange juice in the U.S.\(^{146}\) Because the cheapest generic antiretroviral treatments from India cost $0.24-1.00 per day, a majority of Rwanda


\(^{146}\) See The Associated Press, Tropicana Orange Juice Raising Prices, N.Y. TIMES, Mar. 11, 2010, at B6 (noting that the price of a 59-ounce bottle of orange juice is $3.59, which is much more than the $0.43 that corresponds to 250 Rwandan francs).
residents cannot afford these treatments without some type of governmental or humanitarian aid.

In an international context, local currency conversion involves a vicious cycle of trade deficit and weakening national economies: no easy solution exists. Because pharmaceutical companies can set prices for least-developed nations based on their profits in developed nations, the “local working requirement” as a ground for granting compulsory licensing has been a major loss for the developing countries. Domestic productions of drugs might provide a greater chance of the drugs becoming affordable within the country. Additionally, domestic production in least-developed nations can help those countries obtain a technology transfer that would foster the growth of their domestic pharmaceutical sectors.

The irony of the situation lies in the fact that supplying generic drugs or even free humanitarian aid to least-developed countries is not likely to affect pharmaceutical companies’ brand-name profits greatly, provided the medication is not rerouted to another market. As illustrated by the graphs above, a large

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147 Smith, supra note 46, at 684-85 (noting that the global pharmaceutical market is substantial in size (valued at $650 billion in 2006) and that because developing countries often do not produce the brand-name drugs and are forced to pay high prices to pharmaceutical producers in developed countries, many developing countries exhibit a trade deficit in modern medicine); see also HESTERMeyer, supra note 8, at 146-147. Pharmaceutical patents can be a source of significant rent transfer from developing countries to developed countries as those who are ill seek to obtain available treatment at high costs. Id.

148 HESTERMeyer, supra note 8, at 242 (noting that the Paris Convention recognized failure to work as a valid ground for granting compulsory license (Article 5A(2))); Article 27 of TRIPS has been considered by some as eliminating the local working requirement by stating that no discrimination should be applied as to whether the products are imported or locally produced); see also Cicero Gontijo, supra note 53, at 23.

149 HESTERMeyer, supra note 8, at 242-244.

150 Ghauri, supra note 46, at 209 (noting that the health expenditure markets in developing countries are small in comparison to that of developed countries; in many countries, a vast majority of the population cannot afford the drug, and it follows that forfeiting the market will not make big monetary difference to big pharmaceutical companies’ revenues); John H. Barton, supra note 124 (arguing that the pharmaceutical “market in poor countries is so small that it provides only a minimal incentive [to supply medicines in those countries]—the total market of the poorest countries (for example, sub-Saharan Africa or the United Nations’ Least Developed Countries) is on the order of
percentage of people living in the least-developed countries currently belong to the \( Q_c-Q_t \) zone in the demand curve: people who cannot afford the medicine at monopoly prices. The fact that their market makes up only a very small faction of the total revenue for brand-name pharmaceutical producers supports the view that the least-developed countries should be allowed to use the Paragraph 6 System, and other flexibilities embedded within the TRIPS Agreement, to increase access to medicine.

D. **Canada’s Legislation and Apotex’s Role in Exporting Apo-TriAvir**

The Canada-Rwanda deal could not have occurred without Canada. In fact, without more countries actively changing their own legislation to allow the use of compulsory licenses as an exporting country, the Paragraph 6 System cannot be utilized effectively. In this way the Canadian effort is especially praiseworthy, apart from the merits of its legislation. Additionally, for countries contemplating the adoption of a national legislation for utilizing the Paragraph 6 System, the Canada’s Access to Medicine Regime ("CAMR") is an example from which many lessons can be learned.

As of November 2009, only a handful of countries—Switzerland, the European Communities, and Pakistan—had amended their national law so that the Paragraph 6 System could be used.\(^1\)

The effort to change Canadian patent law to allow the use of the Paragraph 6 System started soon after the adoption of the Decision of 30 August 2003, which implemented the Paragraph 6 System for the first time.\(^2\) In September of 2003, Canada became the first country to announce its intent to implement the Paragraph 6 System.\(^3\)

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1 percent of the global pharmaceutical market;" because the market size is very small, supplying medicine to these countries at cost of production would not greatly impact the originator pharmaceutical companies’ profit).

\(^1\) TRIPS Council Minutes, *supra* note 33, at 23-25.

\(^2\) Canada Notice, *supra* note 100, at 1127.

\(^3\) *Id.*
In May 2004, the legal framework for CAMR, as set out by Prime Minister Jean Chrétien’s Pledge to Africa, along with a supporting set of regulations, was passed into law by amending the Canadian Patent Act, and the Regime came into force on May 14, 2005.\textsuperscript{154}

Several features of CAMR are worth noting to understand fully the tasks involved in adopting national legislation that supports the use of the Paragraph 6 System.

First, CAMR is characterized by its provision of a list of pharmaceutical products that may be produced for exportation.\textsuperscript{155} Any medicine not included on the list can be added by a petition.\textsuperscript{156} In fact, Apo-Triavir was not on the pre-approval list, and Apotex had to petition to add the combination.\textsuperscript{157} This feature is not entirely necessary and may create additional burdens for the generic drug producer.\textsuperscript{158} Thus, other nations considering the adoption of a national legislation implementing the Paragraph 6 System should consider avoiding this approach.

In addition, as required by the Decision of 30 August 2003, CAMR requires the applicant for a compulsory license to attempt a negotiation for a voluntary license with the patent holder.\textsuperscript{159} In accordance with the requirements of the CAMR, Apotex contacted the patent holders—GSK, Shire Biochem and Boehringer Engelheim—in September 2007.\textsuperscript{160} All of the patent holders

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\textsuperscript{154} Id.; THE AIDS IN AFR. WORKING GROUP AND THE ACCESS TO DRUGS INITIATIVE, INTERNATIONAL HUMAN RIGHTS PROGRAM, \textit{Making Canada’s Access to Medicines Regime Work for Countries in Need: A Case Study on Ghana}, (Univ. of Toronto, Jan. 2007), 3 [hereinafter Toronto].

\textsuperscript{155} See Toronto, \textit{supra} note 154, at 8.

\textsuperscript{156} See Patent Act, R.S.C., ch. P-4, §21.02 and §21.03(1)(1)(Can.) [hereinafter CAMR]. Schedule 1 lists those drugs pre-approved for exportation. Id.

\textsuperscript{157} See \textit{generally id.}, at Schedule 1 (Schedule 1 reveals that Apo-TriAvir was not on the original pre-approved list of drugs for exportation); Canada Notice, \textit{supra} note 100, at 1127.

\textsuperscript{158} See \textit{generally} Toronto, \textit{supra} note 154, at 8.

\textsuperscript{159} Canada Notice, \textit{supra} note 100, at 1127.

\textsuperscript{160} See Kaitlin Mara, \textit{Efficacy of TRIPS Public Health Amendment In Question At WTO}, INTELLIGENT PROPERTY WATCH (Mar. 1, 2010, 4:51 PM), http://www.ip-watch.org/weblog/2010/03/01/efficacy-of-trips-public-health-amendment-in-question-at-wto/. The TRIPS Agreements requires that in order to receive a compulsory license, the patent holders must be contacted to see if they will grant a voluntary license. When Apotex sought a compulsory license in Sept. 2007, Apotex had to have contacted the
refused voluntary licensing, allowing Apotex to apply for a compulsory license in September 2007.\textsuperscript{161} Apotex obtained the compulsory license by October 2008.\textsuperscript{162} While this requirement is burdensome, it cannot be eliminated from national legislation unless the Paragraph 6 System itself is modified. However, it is recommended that a time period be provided under which the patent holder can challenge the compulsory licensing so that the generic producer can conclude the trade under an assurance that its conduct is lawful.\textsuperscript{163}

CAMR also provides a mechanism for determining the royalties based on the level of economic development of the importing country.\textsuperscript{164} This approach has been praised for its high level of transparency.\textsuperscript{165} In the case of the Canada-Rwanda deal, following Rwanda’s petition, both GSK and Shire waived their right to the low royalty fee determined in accordance with Rwanda’s place on the UN Human Development Index.\textsuperscript{166} This royalty-determining approach reduces transactional costs by providing the potential supplier of the generic drug with a method of predicting royalty. Other nations may also prefer to adopt this approach in their national legislation.

Further, as required by the Decision of 30 August 2003, CAMR provides for a notice to be made to the TRIPS Council regarding: (1) the product to be exported, (2) the quantity of the drug, and (3) the importing country.\textsuperscript{167} To provide this notice, CAMR sets out a “drug-by-drug, country-by-country application process,” to comply with the notice requirement of the TRIPS Council.\textsuperscript{168}

\begin{footnotesize}
\begin{enumerate}
\item The compulsory license was granted in May 2008, and shipment was to be made by September 2008.
\item CAMR § 21.08.
\item Abbott, \textit{supra} note 33, at 38.
\item Mara, \textit{supra} note 160.
\item CAMR § 21.04(2)(f); Toronto, \textit{supra} note 154, at 6.
\item Mara, \textit{supra} note 160.
\end{enumerate}
\end{footnotesize}
According to Apotex, under CAMR, “the process of obtaining a license to produce a product [for exportation] has to restart every time a new country makes a request [for importation].”\(^{169}\) This creates a great deal of uncertainty that many generic drug producers might not be willing to undertake; thus, an approach that reduces the burden for the generic drug producer should be determined.\(^{170}\) For example, a system that allows generic drug producers to apply initially without providing the name of the importing country could better streamline the application process.\(^{171}\)

**E. Difficulties in Using the System and Suggested Approaches for Improvement**

Several difficulties involved in using the Paragraph 6 System have been identified by the example of the Canada-Rwanda deal. In particular, during the TRIPS Council meetings held on October 27-28, 2009; November 6, 2009; and March 2, 2010, the Council members examined the progress of Paragraph 6 System.\(^{172}\)

Contrary to the urgency of the issue raised by several developing and least-developed countries in the 2003 meeting that implemented the Paragraph 6 System, the TRIPS Council determined that only twenty-six members (counting the European Communities as one member) have formally accepted the Protocol of 2005, which proposes to amend the TRIPS Agreement permanently to include the provisions of the Paragraph 6 System.\(^{173}\) Considering that a ratification by two thirds of the 153 WTO members is necessary to amend the TRIPS Agreement, and that most of the least-developed countries, the intended

\(^{169}\) *Id.*

\(^{170}\) *See generally,* *id.* (stating that the generic drug producers cannot rely upon such an uncertain system).

\(^{171}\) *See generally,* Toronto, *supra* note 154, at 6 (arguing that the information that is required adds time and makes the process more complicated than a system which would not possess this requirement).


\(^{173}\) TRIPS Council Minutes, *supra* note 33, at 22.
beneficiaries of the Paragraph 6 System, have not accepted the Protocol, many members of WTO, including India, Brazil, China, Ecuador, Cuba, Egypt, and Indonesia, raised concerns that the Paragraph 6 System was not working effectively.\footnote{See id. at 25; Mara, supra note 160.}

Some of the issues raised in the TRIPS council meeting include: the complexity of utilizing Canada’s system and the length of time it takes to use such a system; the uncertainty and high burden placed on the generic drug producer by the Paragraph 6 System; and criticisms that the use of the System is not demand driven, or otherwise economically sound.\footnote{Mara, supra note 160.} However, several members, including the U.S., Canada, European Communities Argentina, and Switzerland, argued that its rare use might not necessarily indicate its inefficacy.\footnote{Id.} Rather, they argued that the access issue has substantially improved since 2003, and that many other options are now available to the least-developed countries to obtain the necessary medicine.\footnote{Id.}

With respect to the complexity of the system, Brazil and several other developing countries noted that, in the case of the Canada-Rwanda deal, it took approximately three years for the first shipment of Apo-TriAvir to be delivered to Rwanda from the time Apotex first applied to use the system in Canada.\footnote{TRIPS Council Minutes, supra note 33, at 24-25; News, supra note 172.} The timeline provided by Canada during TRIPS Council meeting is provided below:

- May 2005 – CAMR regulation took effect
- December 2005 – Apotex applied to use the System
- June 2006 – Apotex was approved as a compulsory licensing exporter
- July 2007 – Apotex identified Rwanda as a customer
- September 2007 – after requesting voluntary licensing from the patent holder, Apotex applied for a compulsory licensing to produce Apo-TriAvir.
- October 2007 – Compulsory licensing was granted
to Apotex

- May 2008 – Apo-TriAvir was produced by Apotex
- September 2008 – the first shipment of Apo-TriAvir was shipped to Rwanda

The timeline indicates that while Apotex applied to use the System in December 2005, it took until July 2007 for Apotex to identify Rwanda as a customer. Thus, at least for the Canada-Rwanda deal, it appears that locating an importing country for the deal proved to be a significant burden for Apotex.

In fact, commentators have noted that while CAMR requires the applicant to identify a prospective purchaser, who is to be a developing country, before filing the application, such a practice is contrary to the industry’s customary procurement practices in purchasing generic pharmaceuticals. The customary practice in generic purchase involves public bidding. In other words, the purchaser or the correct producer cannot be identified until it is clear that the generic drug maker can produce a certain amount at a certain price; thus, the CAMR procedure, which requires the identification of each purchaser before filing the application, is incompatible with the customary practice.

By the time Rwanda obtained the necessary shipment of Apo-TriAvir from Apotex, Indian generic makers were producing similar products at even lower prices. This fact demonstrates that the length of time necessary for the negotiation to materialize must be shortened for an effective use of the Paragraph 6 System, and that generic drug producers should not be required to provide

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179 News, supra note 172.
180 Mara, supra note 160.
181 See generally id. The fact that it took Apotex three years to ship its first shipment to Rwanda shows that this was a burden for the company. Id.
182 See Toronto, supra note 154, at 6-7; Canada Notice, supra note 100, at 1128.
183 Canada Notice, supra note 100, at 1128.
184 See id. Until the public bidding process takes place to identify who is able to produce the needed amount of the drug and who is willing to purchase the drug, the application process cannot begin. Once a producer and a purchaser have agreed to a bid, the producer can file the application, as the producer is unable to name the purchaser until this point.
185 Id.
the identity of importing counties when the applications are initially filed.

Another hindrance to the application process is that the patent holder can attempt to delay the process by seeking court actions or challenging the compulsory license. Many generic drug producers would not be willing to take on the expensive venture of implementing the manufacture of a drug and obtaining necessary regulatory approvals in the face of such uncertainty. Currently, several different venues by which generic drugs may be purchased exist for most countries; some of these venues remain viable options that provide a greater certainty for obtaining necessary medicine at a desired price and quantity.

In addition, the Paragraph 6 System’s requirement to specially mark the exported drugs, as implemented by CAMR, essentially limits the profit that a generic drug producer may obtain by participating in the System by limiting the producer to exporting only the quantity needed. Also cumbersome is the time and effort involved. The generic drug producer has to maintain the necessary manufacturing facilities and pass all regulatory requirements in order to produce the generic drug. Thus, at this time, use of the system is not very attractive to generic drug producers. A method by which the generic drug produced for an exporting country can be supplied to additional markets, including other eligible countries, may be necessary for the generic drug producer to operate with a profit.

The United States, Switzerland, Canada, and European Communities have argued that the rare use of the Paragraph 6 System is not an indication of its ineffectiveness or its lack of

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186 Tsai, supra note 163, at 1078-79.
187 See Mara, supra note 160 (stating that the mandate that the generic drug producer must contact the patent holder creates a burden that the generic drug producer may not view as outweighing any benefit that comes of it).
188 See CORREA, supra note 22, at 5.
189 See Mara, supra note 160; see generally, Toronto, supra note 154, at 10-11 (explaining that under CAMR the producer is restricted from exporting more than what is needed by the importing country, and the limited quantity implies that the profits are limited).
190 See generally Mara, supra note 160 (noting that in order to benefit, a producer must have the facilities and the capacity to manufacture the drug).
workability. Rather, they argue that the Canada-Rwanda deal indicates that the system can be effectively used, and the deal paves the way for wider use of the system. Further, many other flexibilities exist as possible options for member countries to obtain the necessary medicine at this time.

Some commentators have noted that the requirement that a country notify the TRIPS Council of its need to use the Paragraph 6 System may be working as a deterrent for some developing countries to using the system. Many countries have faced severe political pressures when they have attempted to use compulsory licensing, including economic and political pressures from developed countries.

For example, in 2007, when Thailand issued a compulsory license for Abbott’s Kaletra®, U.S. Trade Representatives put Thailand on a “priority watch list.” In addition, Abbot retaliated by withholding its application for regulatory approval for its new heat-resistant form of Kaletra®, which would have been very beneficial in Thailand’s hot climate. This type of hostile treatment from developed countries would necessarily cause hesitation on the part of developing and least-developed countries in taking the necessary political or legislative initiative to use the Paragraph 6 System.

However, the Canada-Rwanda deal also illustrates that open communication regarding access to medicine at TRIPS

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191 See generally TRIPS Council Minutes, supra note 33, at 23-25.
192 Canada also argues that the Canada-Rwanda deal is indicative of a system that can be effectively used. See id. at 23; see also Mara, supra note 160.
193 See CORREA, supra note 22, at 5.
194 See Mara, supra note 160.
196 KALETRA, Registration No. 2451327.
197 Alcorn, supra note 195; U.S. Trade Representative, supra note 195.
198 Alcorn, supra note 195.
Council meetings since the Doha Declaration of 2001 has substantially increased international consensus to allow the least-developed countries to utilize the flexibilities embedded in the TRIPS Agreement. Unquestionably, more least-developed countries may consider utilizing the Paragraph 6 System as a result of the Canada-Rwanda deal.

V. Importance of the Paragraph 6 System and Actions Required to Ensure Effective Use of the System

Even with the various difficulties involved in using the Paragraph 6 System, it is predicted that it and other compulsory licensing schemes will become more and more important to developing and least-developed countries in the coming decades as the current international source of generic medicine depletes over time.

A. Expiration of Transition Periods and Elevated Importance of the Paragraph 6 System

In order to comply with the TRIPS transition period schedule, numerous mid-income developing countries—including India, China, and Brazil—became fully compliant with the TRIPS Agreement by 2005 by granting both process and product patents for pharmaceutical products. For the least-developed country members, the Doha Declaration of 2001 extended the transition period for full compliance with the TRIPS Agreement with respect to pharmaceutical patents to January 1, 2016.

Many of the mid-income countries that became fully compliant with the TRIPS Agreement in 2005 served as sources of

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199 HESTERMeyer, supra note 8, at 258-60, 261-64. Hestermeyer and other authors agree that Doha Declaration reafﬁrmed the Member countries’ right to use the flexibilities of TRIPS to the full extent. The Paragraph 6 System stems from one of these flexibilities through series of international negotiations and council meetings. Id. See also TRIPS Council Minutes, supra note 33. An overview of the meeting minutes indicates that there is now a consensus among the Members that the use of the flexibilities available under the TRIPS Agreement is acceptable; this is in sharp contrast to prior assertions made between the developed and developing countries regarding that types of measures are permissible. Id.

200 HESTERMeyer, supra note 8, at 260.

201 Doha Declaration, supra note 6, ¶ 7.
generic drugs before the transition. In particular, a large portion of the world’s generic AIDS medicine originates from India. For example, Médecins Sans Frontières (“MSF”), also known as Doctors Without Borders, obtains approximately 84% of its generic AIDS medicine in India. The 2005 changes to Indian patent law, however, will gradually result in a depletion of this source of cheap generic drugs. The change is not significantly noticeable at this time because many of the drugs that are now available in generic form in India will remain unprotected by patents, unless the patent application for the active ingredients was deposited with the Indian Patent Office under the mailbox provision of the TRIPS Agreement. However, new drugs developed after 2005 are likely to be protected by both product and process patents in India and by other mid-income countries that produce generic drugs.

While it may not be economically attractive for many generic drug producers to serve as a Paragraph 6 System exporter in the current market, as the sources of the generic drug are substantially depleted over time, the only method by which a country with insufficient or no manufacturing capacities may obtain certain medicines at competitive pricing may be to utilize the Paragraph 6 System.

In addition, the Paragraph 6 System may prove to be increasingly important as those now using the first-line treatment for HIV/AIDS shift into using second-line treatments. Patients on the antiretroviral treatment are expected to use the treatment for several years or decades because no permanent cure for AIDS exists. A large number of these patients develop drug resistance

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204 Shashikant, supra note 202.

205 Universal Access, supra note 116, at 68.
or side effects within this time period, causing them to switch over to a second-line combination.206

Based on one study, almost 22% of people on treatment need to switch over to a second-line treatment within a five-year time period.207 The second-line combinations for AIDS currently remain substantially more expensive than the first-line combinations.208 Médecins Sans Frontières predicts that second-line combinations are not likely to drop 99% in price like the first-line combinations.209 Indeed, second-line combinations can cost up to four to eleven times as much as the first-line treatments.210 An increased percentage of current patients under the first-line treatment will switch over to the second-line treatment in the future.211 For these treatments and other widely patent protected treatments, the Paragraph 6 System may prove to be an important mechanism for obtaining a bulk of the medicine at competitive prices.

B. Initiatives National Governments Must Take To Use the System

Governmental action is necessary at various levels to use the Paragraph 6 System or the general compulsory licensing scheme.

First, a country must implement national legislation to support use of the Paragraph 6 System.212 As noted above, only a handful of nations have taken the steps to actively change their national patent law to provide a legal framework for generic drug producers such as Apotex to act as a supplier under the Paragraph 6 System.213 In addition, the response from the least-developed

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206 See generally id., at 76 (noting that the rate of individuals needing second-line treatments is increasing as more individuals are becoming resistant to first-line treatments).
207 Satyanarayana, supra note 72, at 43 (“Data from Africa show that over a five year period 22% people needed such a switch-over.”).
208 Shashikant, supra note 202.
209 Satyanarayana, supra note 72.
210 Id.
211 See Shashikant, supra note 202.
212 See Correa, supra note 22, at 5-8.
213 See id. at 7-8.
countries, the primary intended beneficiaries of the Paragraph 6 System, has been tepid at best.\textsuperscript{214} Member nations should consider amending their national patent laws in an effective manner to facilitate compulsory license requests and the Paragraph 6 System, as stated above.\textsuperscript{215}

Secondly, the Paragraph 6 System is a way in which a government can obtain a bulk of generic drugs by negotiating for their importation at a national level. In other words, the national governments of the least-developed nations must take on the role of invoking the use of the Paragraph 6 System for the benefit of its population.\textsuperscript{216}

As noted above, while some developing countries have historically faced severe opposition from brand-name pharmaceutical companies and developed nations when attempting to grant compulsory license, awareness of the access to medicine issue has substantially improved through open dialogue within the international community. While the developed countries should remain true to their commitment in supporting access to medicine by living up to the promise of the Doha Declaration, the least-developed countries should find ways to take initiatives in using the flexibilities currently available under the TRIPS Agreement.\textsuperscript{217}

In addition, the antiretroviral medicines cannot be distributed without a health service system. Unfortunately, many people in the least-developed countries have only limited access to health service professionals, as illustrated in the figures below which are from a WHO report.\textsuperscript{218} Without first establishing an effective distribution system, access to medicine will remain a great challenge even if the necessary medications are obtained via the Paragraph 6 System or other TRIPS flexibilities.

\begin{itemize}
\item \textsuperscript{214} TRIPS Council Minutes, \textit{supra} note 33, at 24.
\item \textsuperscript{215} \textit{See} CORREA, \textit{supra} note 22, at 5-8.
\item \textsuperscript{216} \textit{See} Shashikant, \textit{supra} note 202.
\item \textsuperscript{217} \textit{Id.}
\end{itemize}
Some developing and least-developed countries have successfully set up a government-based AIDS program or national health insurance program to increase access to health services.

For example, Brazil’s AIDS program has been very successful in increasing access to antiretroviral treatment. A glimpse of Brazil’s commitment to provide access to medicine can be obtained from its Constitution of 1988, which declares access to medicine to be a constitutional right. Even with the high income disparity in the country—the top 20% of earners making approximately twenty-four times the income of the bottom 20% of

219 HESTERMeyer, supra note 8, at 10-11.

220 Article 196 of Brazilian Constitution of 1988 states that, “Health is the right of all persons and the duty of the State and is guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at universal and equal access to all actions and services for the promotion, protection and recovery of health.” CONSTITUIÇÃO FEDERAL [C.F.] art. 196.
earners—Brazil’s AIDS program successfully reduced its AIDS mortality rate by providing free access to antiretroviral medicines for all residents determined to be in need of treatment.\footnote{A.S. Nunn et al., *Evolution of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to AIDS treatment*, 4 PLoS MEDICINE 1804, 1805 (2007).} According to one study, due to the improvement in the health condition of Brazilians under treatment, the AIDS program may have actually saved approximately $200 million in health costs.\footnote{Paulo R. Teixeira, Marco Antônio Vitória, & Jhoney Barcarlo, *Antiretroviral Treatment in Resource-Poor Settings: the Brazilian Experience*, 18 AIDS 55, S6-S7 (Supplement 3 2004).}

Moreover, having a national program has allowed Brazil to negotiate for price concession for antiretroviral medicine more effectively. Brazil has at times utilized compulsory licensing. For example, Brazil issued compulsory licensing for Roche’s nelfinavir in 2001, and for Merck’s Efavirenz in 2007.\footnote{Brazil’s Success in AIDS Fight Depends on Cheap Drugs, AFP (Jul. 30, 2008), http://afp.google.com/article/ALeqM5ieTOIHsJgOHEPjVBfKCZg751OCRQ; Nicoli J. Nattrass, *The (Political) Economics of Antiretroviral Treatment in Developing Countries*, 16 TRENDS IN MICROBIOLOGY 574, 575 (2008); International Centre for Trade and Sustainable Development, *Brazil Grants Compulsory License*, News and Analysis, BRIDGES WEEKLY TRADE NEWS DIGEST, May 9, 2007, available at http://ictsd.org/i/news/bridges/11643/.} In addition, through active government involvement in procuring necessary medicine, and by employing the threat of compulsory licensing, Brazil has successfully reduced the cost of antiretroviral treatment by over 50%.\footnote{Nunn, supra note 221, at S5.} One study indicates that Brazil has saved approximately $1.2 billion between 2001 and 2005 by price concession over antiretroviral treatments.\footnote{Id. ("We estimate that in the absence of price declines for patented drugs, Brazil would have spent a cumulative total of $2 billion on drugs for HAART between 2001 and 2005, implying a savings of $1.2 billion from price declines").}

Establishing an effective distribution system is the first step in increasing access to medicine. As demonstrated by the example of Brazil, national governments can save billions of dollars in healthcare costs by improving their national health care systems and negotiating for price concessions by obtaining medicines in bulk.\footnote{Wendell Roelf, *S. Africa to Buy Cheaper AIDS Drugs Despite Opposition*, REUTERS (Apr. 13, 2010), http://www.reuters.com/article/idUSTRE63C3Q520100413;}
VI. Impediments & Potential Threats to the Paragraph 6 System

Apart from the various issues regarding efficiency of the system and the lack of governmental initiatives to implement the system at the national legislation level mentioned above, there remain several potential impediments to effectively using the Paragraph 6 System and other flexibilities available under the TRIPS Agreement. Some of the major impediments are: (1) TRIPS-plus agreements; (2) seizure in transit; and (3) the patent pooling system proposed by UNITAID.

A. TRIPS-plus Agreements

Bilateral or multilateral agreements made outside the context of the TRIPS Agreement can reduce the flexibilities embedded in the TRIPS Agreements by imposing obligations beyond those imposed by the TRIPS Agreement, thereby creating agreements that are now referred to as “TRIPS-plus” agreements.

TRIPS-plus agreements can substantially reduce or possibly eliminate the benefit that can be derived from the Paragraph 6 System. For example, the U.S. Free Trade Agreements ("FTAs") with Australia, various Central American countries, Chile, Jordan, and Morocco, each require data exclusivity for at least five years after the date of a pharmaceutical product’s first regulatory approval in the respective country.

Generic drug makers usually rely on the clinical data generated by brand-name companies to obtain regulatory approval in different countries. With the data exclusivity requirement,

Nattrass, supra note 223, at 574-75 (noting that the governments in Thailand and Brazil substantially lowered the cost of HAART for the nation as a whole by involving themselves in negotiation, and were able to provide a larger amount of coverage than expected for their respective populations considering their economic, demographic and institutional characteristics); see also Amy S. Nunn, supra note 221, at 1804.

227 Part V.B.

228 See Shashikant, supra note 202.

229 CORREA, supra note 22, at 7-8.

230 Smith, supra note 46, at 687 (explaining that generic drug producers often rely on the data produced by the originator companies to obtain approval of the generic versions of the drug); Chutima Akaleephan, Extension of Market Exclusivity and Its Impact on the Accessibility to Essential Medicines, and Drug Expense in Thailand: Analysis of the Effect of TRIPS-Plus Proposal, HEALTH POLICY 91, 175, 179 (2009).
even if a generic drug maker intends to produce the medicine, it would not be able to sell the medicine until it has generated sufficient clinical data of its own for the drug's regulatory approval in the respective countries. This data generation may be costly and could take up to several years to produce, in addition to being a tremendous waste of resources in terms of duplication of data. Most often, generic drug producers would be deterred from supplying the medicine during those first five years, creating a de facto extension of the patent term.\textsuperscript{231}

Some FTAs require patent term extension of new drugs based on the time lost in administrative delay while granting the patent.\textsuperscript{232} These requirements are in line with similar legislation under U.S. patent law, known as the Hatch-Waxman legislation.\textsuperscript{233} This type of patent term extension can be very costly to national healthcare consumers or to the national government if the government provides the treatment.

According to one study conducted to assess the cost increase associated with the potential implementation of a U.S.-Thailand FTA Agreement, it is estimated that the typical five-year market exclusivity extension may increase the annual costs of all innovative drugs used in Thailand from approximately $146.3 million to $696.4 million, representing 9.4-44.7% of the total medicine expenditure in Thailand as of 2002.\textsuperscript{234} As such, the long-

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Requirements such as test data exclusivity and patent term compensation are typical to TRIPS-plus agreement with US, and the author notes that these types of requirements lead to an extension of monopoly and can add up to a substantial health cost to the nation over five year period. \textit{Id.}


\textsuperscript{232} Akaleephun, supra note 230, at 175 (noting that one of the common requirements of TRIPS-plus agreement includes patent term compensation for granting delay).

\textsuperscript{233} Shashikant, supra note 202; 35 U.S.C. § 156.

\end{footnotesize}
term effect of adopting a TRIPS-plus agreement can be substantial in terms of health cost. Developing countries need to consider the cost associated with implementing FTAs carefully before engaging in international agreements that may compromise the flexibilities provided under the TRIPS Agreement.

Economic development plays a big part in improving public health, and the prestige offered in having an FTA with the U.S. and other developed countries still continues to lure many developing and least-developed countries to form such FTAs. Currently, the United States is in the process of negotiating FTAs with Columbia, Panama, and South Korea, to name a few. These FTAs include provisions regarding data exclusivity and patent term extension for time lost due to the administrative delay caused in the patent granting process. Countries entering into an FTA, well as other bilateral or regional agreements, should carefully examine the potential negative public health implications and possible economic impact of adopting a TRIPS-plus agreement.

B. Seizure in Transit

Recently, European authorities have seized a number of consignments of generic drugs in transit from India to other countries under EC Regulation 1383/2003, a new regulation purportedly implemented as a measure against counterfeit medicine. As international trade often requires shipment of the products through a number of ports while en route to the destination country, such seizure in transit poses a big threat to utilizing the Paragraph 6 System and other flexibilities embedded in the TRIPS Agreement.

During the TRIPS council meeting held on October 27-28, and November 6, 2009, the Indian representative deemed the seizure in transit as one of many “serious impediments to access to medicines.” As pointed out by the India representative during

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235 Id. at 174.
236 Id. at 175.
237 TRIPS Council Minutes, supra note 33, at 48.
238 Id.
239 Id. at 47.
the meeting, the seizure in transit incident was inconsistent with the Paragraph 6 System, as such seizure could prevent the hypothetical shipment of a generic drug from an exporting country to a least-developed country in a timely manner.\textsuperscript{240}

In previous TRIPS council meetings, the European Communities have stated that these incidents are caused by procedural difficulties and have given assurance that necessary measures will be taken to avoid seizure of generic medicines.\textsuperscript{241} It is extremely important for the international community that the European Communities take prompt measures to ensure this type of interference with other countries’ legitimate rights in trade do not occur in the future.

\textbf{C. Patent Pooling}

Under its 5 February 2010 resolution, UNITAID, an international organization that supplies HIV/AIDS, malaria, and tuberculosis drugs, is currently working on the implementation of a voluntary patent pooling system in which brand-name pharmaceutical companies can contribute their patents in exchange for royalties from licensees.\textsuperscript{242} The details of this voluntary patent pooling system are scheduled to be agreed upon by June 2010.\textsuperscript{243} Surprisingly, the patent pooling system, which has been proposed as a solution for easier access to obtaining licenses, has been identified as a threat to the current compulsory licensing scheme.\textsuperscript{244}

\textsuperscript{240} \textit{Id.} at 48-49.

\textsuperscript{241} \textit{Id.} at 47-48.


\textsuperscript{243} \textit{Id.} at 11.

\textsuperscript{244} See Letter from NWGPL, Centad, Locost, Drug Action Forum, AIDAN, and IHES, to the UNITAID Board Chair (Dec. 11, 2009) (on file with author). In a joint letter submitted by NWGPL, Centad, Locost, Drug Action Forum, AIDAN, IHES, several civil society organizations noted the potential danger of a badly drafted patent pooling system as potentially undermining of compulsory licensing scheme, reducing supports for patent oppositions in India, from where many of generic drugs now originate, suppressing of local production of HIV medicines, etc. \textit{Id.}
Commentators agree that there may be many potential benefits within a well-implemented patent pooling system. For example, because antiretroviral treatments often cover several patented products, patent pooling may facilitate the development of fixed-dose combinations by using known ingredients from different pharmaceutical companies. Additionally, according to the preliminary plan proposed during the 2009 meeting at UNITAID, the royalty rate paid to the patent holder will be determined based on the economic condition of the user country. Setting the royalty rate based on the economic condition of the user country may create a system of licensing akin to multi-level price discrimination. Such a system would allow the brand-name pharmaceutical companies to retain some portion of their economic rent in the developed countries in order to recoup R&D costs while also significantly reducing the transaction costs for obtaining licenses.

However, several potential problems have been identified with regard to the patent pooling system. These include the possibility that the patent pooling system will actually prevent the least-developed countries from using compulsory licensing to obtain antiretroviral drugs at an even cheaper price. The brand-name pharmaceutical companies may argue that voluntary licensing at a reasonable royalty rate has already been provided.

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245 Satyanarayana, supra note 72, at 50-52 (indicating that the various potential benefits include lowering price for developing countries, and easier and faster development of combinations); Equal Treatment, supra note 85, at 23; Daniele Dionisio, Unbiased HIV Patent Pool: A Free-Market, Middle-Income Countries Open Model (April 1, 2010), INTELLECTUAL PROPERTY WATCH, http://www.ip-watch.org/weblog/2010/04/01/unbiased-hiv-patent-pool-a-free-market-middle-income-countries-open-model (noting that a well-implemented system may provide increased access while allowing the brand name pharmaceutical complies to maintain high R&D standards and some marketing power); Mohga Kamal Yanni, Historic Decision on Access to Medicines: UNITAID Patent Pool Approved to Lower Prices for HIV Treatment, Oxfam International, OXFAM INT’L BLOGS, HEALTH AND EDUCATION FOR ALL (Dec. 18, 2009, 3:09 PM), http://blogs.oxfam.org/en/blog/09-12-18-historic-decision-HIV-medicines-unitaid-patent-pool-approved.

246 See Satyanarayana, supra note 72, Table 1.

247 UNITAID, supra note 242.

248 Letter from the UNITAID Executive Board, submitted to the UNITAID Board Chair (Dec. 11, 2009) (on file with author).
when the patent holder is a part of the patent pooling system.\textsuperscript{249} In such a case, the “prior negotiation” requirement of Article 31(b) for granting compulsory patent license would be impossible to satisfy, and the compulsory license scheme may become unusable.\textsuperscript{250}

There are also concerns that this system will substantially erode the economic benefits for the innovators of the new drugs, and reallocate them to the middle-income countries such as India, China, Brazil, South Africa, and Thailand, which have the manufacturing facilities to produce generic drugs in bulk for exportation.\textsuperscript{251} As participation in the patent pool system would be voluntary, the brand-name pharmaceutical companies may have an unfairly high amount of leverage in shaping the system or may even fail to participate altogether.\textsuperscript{252}

The international community has much at stake in the careful examination of the details of implementing this patent pooling system.

VII. Conclusion

Even with its complex procedural requirements, the Paragraph 6 System is expected to become increasingly important to countries with insufficient or no manufacturing capacities, especially as India and other important international sources of generic drugs become fully compliant with the TRIPS Agreement.

Several recommendations have been made with respect to measures that individual countries should take to facilitate the use of the Paragraph 6 System, including providing an effective distribution system and actively negotiating for price concession, as Brazil has done so successfully.

Countries that may benefit from the Paragraph 6 System need to take action to make the necessary legislative changes in facilitating the use of the System. Further, those countries that

\textsuperscript{249} Id.

\textsuperscript{250} Id.


\textsuperscript{252} Id.
may be eligible to act as importing nations should provide an effective mechanism through which those in need—the medical community and patients who need their medication—can bring their need to the attention of the national government in order to act on their behalf.

As illustrated by the Apo-TriAvir trade between Canada and Rwanda, to implement national legislation as a potential exporting country, the procedure for requesting compulsory licensing under the Paragraph 6 System should be simplified as much as possible. In particular, while CAMR required generic drug producers to provide the identity of the importing country on their initial applications, this approach should be avoided as it may not conform to the customary practice in purchasing generic drugs.

In addition, the international community has a high stake in UNITAID’s careful framing of the patent pooling scheme. Also, the European Communities should ensure that legitimate international trade of generic drugs is not hindered by any incidence of seizure in transit.

Lastly, countries should refrain from taking on TRIPS-plus obligations through FTAs or other bilateral or regional treaties, as the flexibilities embedded in the TRIPS Agreement may be compromised by these treaties. Having at their disposal all flexibilities available under the TRIPS Agreement and maintaining a zone of autonomy may prove to be of paramount importance to future legislators, because without such flexibilities, each country cannot choose the legislation or regime that best serves the unique needs of its population. In interest of good governance, restrictive FTAs, seizure in transit, and other mechanisms by which one country tries to decide the legislation of another country should be curtailed, leaving each country to determine for itself the best way to protect its public health.