
THE IMPLICATIONS OF RWANDA'S PARAGRAPH 6 AGREEMENT WITH CANADA FOR OTHER DEVELOPING COUNTRIES

Christina Cotter[†]

I. Introduction

On July 17, 2007, Rwanda became the first country to notify the World Trade Organization ("WTO") that it planned to import HIV drugs under Paragraph 6 of the Doha Declaration¹ on the Trade-Related Aspects of Intellectual Property Rights Agreement ("TRIPS Agreement").² On October 4, 2007, Canada notified the WTO that it had authorized the production of a generic version of patented anti-viral drugs for export to Rwanda.³ Specifically, Canada gave Apotex, Inc., its largest pharmaceutical company, the authority to produce an anti-viral medication called Apo-TriAvir, a generic combination of three patented HIV drugs, without permission from the patent holders ("Paragraph 6 Agreement").⁴ This groundbreaking agreement between Rwanda and Canada is the first of its kind and its ultimate success or failure will influence other developing nations that consider following suit.

This article will examine the legal ramifications surrounding Rwanda and Canada's Paragraph 6 Agreement, and most importantly, the implications the agreement has for other developing countries in need of life-saving drugs. Currently, Rwanda and Canada's agreement is not progressing as smoothly as was originally expected. Although the policy behind the agreement—the circumvention of patent rights in furtherance of human welfare—is an admirable one, the process has proven difficult to implement for three reasons.

First, some of the difficulty stems from the complexity of Canada's generic-drug legislation.⁵ Legislation that is replete with red tape prevents developing countries and generic manufacturers from successful and timely completion of Paragraph 6 Agreements.⁶ Potential beneficiary-nations of Canada's legislation,

[†] Juris Doctor candidate, May 2009, Loyola University Chicago School of Law. The author would like to thank Timothy and Maureen Cotter for all of their assistance with law school.

¹ World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, Nov. 14, 2001, available at http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [hereinafter Doha Declaration].

² World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, Notification under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, IP/N/9/RWA/1, Jul. 19 2007, available at http://docsonline.wto.org/GEN_viewerwindow.asp?http://docsonline.wto.org:80/DDF/Documents/t/IP/N/9RWA1.doc.

³ *Id.*

⁴ Jillian C. Cohen-Kohler, *Canada's Implementation of the Paragraph 6 Decision: is it Sustainable Public Policy?* GLOBALIZATION AND HEALTH 2007, Dec. 6, 2007, available at <http://www.globalizationandhealth.com/content/3/1/12>.

⁵ Cohen-Kohler, *supra* note 4.

⁶ *Id.*

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as well as generic manufacturers, have voiced criticisms surrounding the Canadian process.⁷ Therefore, wealthy countries that wish to use their manufacturing capacities to provide generic drugs in the future should enact simple, straightforward legislation.

Second, on a global level, developing countries are discouraged from using the TRIPS Agreement to procure generic drugs from wealthy donor states such as the United States, because the donor states threaten to pull funding in order to protect pharmaceutical companies from generic competition.⁸ Because of this pressure from wealthy states, Paragraph 6 of the Doha Declaration on TRIPS will likely go unused until the WTO creates a policy that truly supports human lives over big business. Therefore, the WTO should clarify and strengthen its policy toward human welfare in the context of TRIPS.

Finally, developing nations lack the infrastructure and distribution capabilities necessary to provide the infected with anti-viral medications. Currently, there is uncertainty as to how Rwanda will distribute the generic drugs it plans to import, leading to the possibility that upon receipt the drugs will sit in storage, or be diverted elsewhere illegally.⁹ Without a distribution plan, no amount of generic drugs will be able to save infected citizens. Therefore, in the future, the WTO should demand that developing nations present plans for distribution of generic drugs before they are allowed to move forward under Paragraph 6.

The next section of this article briefly discusses Rwanda's AIDS epidemic.¹⁰ Sections three and four discuss the TRIPS Agreement and the initial level of patent protection it provided pharmaceutical manufacturers.¹¹ Section five discusses the Doha Declaration and its implications for patent circumvention.¹² Section six discusses the issue of Paragraph 6 and how it enabled Rwanda to form an agreement with Canada.¹³ Section seven discusses the logistics of Canada's plan for exporting generic drugs to Rwanda, as well as the criticisms those involved have of it.¹⁴ Finally, Section eight discusses the implications of the plan between Canada and Rwanda for other countries, as well as suggestions for future success of similar agreements.¹⁵

⁷ *Id.*

⁸ Brook K. Baker, *Arthritic Flexibilities: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, BEPRESS LEGAL SERIES (Dec. 16, 2003), available at <http://law.bepress.com/expresso/eps/108>.

⁹ Do Hyung Kim, *Research Guide on TRIPS and Compulsory Licensing: Access to Innovative Pharmaceuticals for Least Developed Countries*, GLOBALEX, Feb. 2004, available at http://www.nyulawglobal.org/globalex/TRIPS_Compulsory_Licensing.htm.

¹⁰ *See infra* §II.

¹¹ *See infra* §III, IV.

¹² *See infra* §V.

¹³ *See infra* §VI.

¹⁴ *See infra* §VII.

¹⁵ *See infra* §VIII.

II. Brief History of Rwanda's AIDS Epidemic

Out of Rwanda's population of approximately 9.3 million people, an estimated 200,000 are infected with HIV or AIDS.¹⁶ As of late 2007, only 44,395 of those infected were receiving anti-viral treatment.¹⁷ Without anti-viral drugs, HIV progresses to AIDS much more rapidly.¹⁸ The onset of AIDS often prevents the infected from working, exacerbating Rwanda's cycle of poverty.¹⁹ In addition to the many Rwandans suffering from HIV and AIDS infection, there are estimated to be over 200,000 children who have been orphaned due to the AIDS epidemic.²⁰ Therefore, war-torn Rwanda is in need of access to inexpensive anti-viral drugs in order to prolong and enhance the lives of the sick and of their families.

A. Causes of Transmission

Most HIV infections in Rwanda occur through sexual intercourse, but unsafe blood transfusions or unsanitary drug injection practices also account for a small fraction of transmissions.²¹ The cultural opinion common to some developing countries that men can have multiple wives creates an opportunity to spread the disease within families.²² Additionally, the well-documented civil war and massacre of the Tutsi people in Rwanda significantly contributed to the AIDS epidemic, as many women were brutally raped by rebels and became infected.²³ Some of these infected women then transmitted the disease to their children or spouses.

B. Inadequate Medical Facilities

Rwanda's AIDS crisis is compounded due to the nation's inadequate medical resources. There is only one physician for every 60,000 people in Rwanda, and

¹⁶ HIV InSite, <http://hivinsite.ucsf.edu/global?page=CR09-rw-00> (last visited May 15, 2008).

¹⁷ United Nations General Assembly Special Section on HIV/AIDS: Rwanda, (Jan. 2006- Dec. 2007), UNAIDS, available at http://data.unaids.org/pub/Report/2008/rwanda_2008_country_progress_report_en.pdf.

¹⁸ U.S. Dept. of Health and Human Services, *How HIV Causes AIDS, NIAID Fact Sheet*, (Nov. 2004), <http://www.niaid.nih.gov/factsheets/howhiv.htm> (last visited May 15, 2008).

¹⁹ Ruth Kornfield et al., *Living with AIDS in Rwanda: A Study in Three Provinces*, John Hopkins University Center for Communication Programs, Feb. 2002, available at <http://www.jhuccp.org/pubs/sp/22/22.pdf>.

²⁰ HIV/AIDS, Tuberculosis, and Malaria Research and Programs in Sub-Saharan Africa, http://researchafrica.rti.org/index.cfm?fuseaction=home.country_view&country_id=15#country-profile (last visited May 15, 2008).

²¹ UNAIDS, *supra* note 17.

²² James C. McKinley, Jr., *Ravaged by War and Massacre, Rwanda Faces Scourge of AIDS*, N.Y. TIMES, May 28, 1998, available at <http://query.nytimes.com/gst/fullpage.html?res=9E0DEFDE1338F93BA15756C0A96E958260>.

²³ Lindsey Hilsum, *Don't Abandon Rwandan Women Again*, N.Y. TIMES, April 10, 2004, available at <http://query.nytimes.com/gst/fullpage.html?res=9A05E0DD1338F933A25757C0A9629C8B63>.

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only thirty hospitals in the entire country.²⁴ In contrast, the United States has one doctor for every 400 people.²⁵ The lack of doctors and hospitals makes distribution and patient follow-up very difficult. Therefore, Rwanda needs an advanced infrastructure in place in order for the Paragraph 6 Agreement with Canada to be effective.

III. History of the TRIPS Agreement

The emergence of the technology and pharmaceutical sectors in the 1980's led to a shift in international trade policy and put the focus on intellectual property.²⁶ In 1994, at the behest of the pharmaceutical and technology sectors, intellectual property became a leading topic at the Uruguay Round of General Agreement of Trades and Tariffs ("GATT"), where the WTO was formed.²⁷ The WTO was created in Uruguay to enforce trade agreements among member states.²⁸ Additionally, the WTO adopted the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") to, "reduce distortions and impediments to international trade. . . promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."²⁹ Although the TRIPS Agreement covers many types of intellectual property, this article is limited to the Agreement's effect on international patent law in regard to pharmaceuticals.

IV. The TRIPS Agreement's Objectives

The TRIPS Agreement attempts to strike a balance between two competing objectives—economic welfare and social welfare. Pharmaceutical companies and the developed countries where they are based would like patents to be strictly enforced in order for drug inventors to be the sole benefactors of their creations.³⁰ This argument is based on the fact that it is much more expensive to be the developer of a drug than it is to later acquire the knowledge and create a generic drug.³¹ If generics are allowed without limitation, the incentive for pharmaceutical companies to create new drugs will diminish.³² In contrast, developing countries and researchers would like to gain knowledge of patented drugs and

²⁴ HIV/AIDS, Tuberculosis, and Malaria Research and Programs in Sub-Saharan Africa, *supra* note 20.

²⁵ Sandya Nair, *Doctor Shortage Facing U.S.*, THE JOHN HOPKINS NEWSLETTER, Feb. 27, 2004.

²⁶ See generally, Phillip McCalman, *The Doha Agenda and Intellectual Property Rights* (Oct. 2002) (unpublished manuscript, available at www.adb.org/Economics/pdf/doha/McCalman.pdf) (discussing changes in intellectual property rights and trade).

²⁷ *Id.* at 1.

²⁸ Cohen-Kohler, *supra* note 4.

²⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights, preamble, 1994, 33 I.L.M. 81 [hereinafter TRIPS].

³⁰ McCalman, *supra* note 26, at 1.

³¹ *Id.*

³² *Id.*

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create less expensive versions of them, which could then be distributed to the infected for less money and allow developing countries to deal with health crises more affordably.³³

Both sets of interests have positive and negative consequences for public health. If inventors are financially rewarded for their initiatives, they will spend more money on researching and creating new products that can save lives.³⁴ However, if pharmaceuticals are too expensive, many developing countries will not be able to afford them.³⁵ This is why allowing researchers to develop less expensive models is so important for the survival of populations in developing countries. In order to strike a balance, the TRIPS Agreement aims to “contribute to the promotion of technological innovation” as well as aid “the transfer and dissemination of technology.”³⁶ However, it has proven difficult to satisfy both the pharmaceutical companies and the developing countries in desperate need of affordable drugs.

A. Patent Protection Under TRIPS

Articles 7 and 8 of Part One of the TRIPS agreement are of particular importance to intellectual property rights, and thus patented medications.³⁷ Article 7 provides that intellectual property should be protected “in a manner conducive to social and economic welfare. . .”³⁸ and Article 8 provides that abuse of intellectual property rights should be avoided when it results in restraining the international transfer of information.³⁹ Some international scholars have noted that these articles, at least as interpreted before the Doha Declaration, favor the promotion of innovation and the interests of pharmaceutical companies instead of promoting access to drugs for developing countries.⁴⁰

In regard to patents, the TRIPS Agreement provides that member states must give protection to “any inventions. . . in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”⁴¹ Additionally, member states must allow an inventor a patent for at least twenty years.⁴² A patent prevents third parties from “making, using, offering for sale, selling or importing” the product in the territory of the patent’s grant.⁴³

³³ See TRIPS and Public Health: *Canada is First to Notify Compulsory License to Export Generic Drug*, World Trade Organization, Oct. 4, 2007, available at http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm.

³⁴ *Id.*

³⁵ *Id.*

³⁶ TRIPS, *supra* note 29, art. 7.

³⁷ *Id.* arts. 7, 8.

³⁸ *Id.* art. 7.

³⁹ *Id.* art. 8.

⁴⁰ See Kim, *supra* note 9.

⁴¹ TRIPS, *supra* note 29, art. 27.1.

⁴² *Id.* art. 33.

⁴³ *Id.* art. 65.4.

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Therefore, WTO members are obligated to provide patent protection to pharmaceutical inventors under TRIPS Agreement Article 27.⁴⁴

There are exceptions to this mandate of patent protection under the TRIPS Agreement. Although member states are specifically prohibited from discriminating against a certain field of technology when awarding patents,⁴⁵ there is an exception that allows researchers to use inventions protected by patents for the advancement of science and technology. Specifically, Article 8(2) states that, “[a]ppropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”⁴⁶ This general provision opened the door to circumvention of patent rights.

B. Compulsory Licensing under the TRIPS Agreement

Article 31 of the TRIPS Agreement takes the general policy behind Article 8(2) and specifically applies it to situations where patent circumvention is needed to combat a national emergency. Under Article 31, member-state governments have permission to grant licenses to generic manufacturers for the reproduction of patented products without the right holder's permission under limited conditions.⁴⁷ This process is called “compulsory licensing.” One of the conditions where patent circumvention is allowed is a national emergency, such as an epidemic.⁴⁸ Although generally the WTO aims to protect the interests of the patent holder, in national emergencies there is no need for a member nation to attempt to retain a voluntary license before the compulsory one can be granted.⁴⁹ Therefore, with the permission of the WTO, Article 31 allows developing nations to grant compulsory licenses to generic manufacturers without the permission of the patent owners.

Despite Article 31's underlying policy of social welfare, developing countries that wished to move under the original meaning of Article 31 faced many hurdles. For example, developing nations still needed permission from the WTO before they could declare an emergency situation that warrants compulsory licensing.⁵⁰ Additionally, a compulsory license could only be used to serve the producer's domestic market.⁵¹ This limitation was a barrier to poor countries like Rwanda because most nations experiencing health epidemics do not have the

⁴⁴ *Id.* art. 27.1.

⁴⁵ *Id.*

⁴⁶ TRIPS, *supra* note 29, art. 8.

⁴⁷ *Id.* art. 31(b).

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.* 31(a).

⁵¹ *Id.* 31(f).

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capabilities to manufacture generic drugs domestically.⁵² The WTO first addressed Article 31's shortcomings in Paragraph 6 of the Doha Declaration.⁵³

V. The DOHA Declaration

In 2001, the Doha Declaration on TRIPS and Public Health further clarified nations' rights regarding the circumvention of pharmaceutical patents. Specifically, the WTO emphasized at Doha that TRIPS should be interpreted in a way that supports world public health.⁵⁴ In order to support world health, the WTO named access to pharmaceuticals in developing countries a priority.⁵⁵

The WTO recognized that patents generally allow inventors to monopolize markets and charge higher prices because consumers lack access to competitive alternatives for the duration of the patent.⁵⁶ Although financial incentives to pharmaceutical inventors are important because they encourage research and development, high prices lead to limited access for developing countries that cannot afford to pay.⁵⁷ In response to this situation, the Doha Declaration extended exemptions on pharmaceutical patents until 2016 for developing countries.⁵⁸ This means that developing countries can manufacture and distribute generic versions of drugs without the permission of the patent holder for the next eight years.⁵⁹ The declaration also gives member states the power to decide what constitutes a national emergency without the WTO's input, by stating, "each member has the right to determine what constitutes a national emergency. . . it being understood that public health crises, including those relating to HIV/AIDS. . . can represent a national emergency. . ." ⁶⁰ This provision paved the way for Rwanda to declare its own national emergency in 2007.⁶¹

VI. The Paragraph 6 Issue

Although Doha was a large step in the right direction in assisting developing countries in the fight against HIV/AIDS and other epidemics, the issue of domestic production – the so-called "Paragraph 6" issue – was still unresolved after Doha.⁶² Paragraph 6 of the declaration states:

We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in mak-

⁵² McCalman, *supra* note 26, at 6.

⁵³ *Id.* at 8.

⁵⁴ Doha Declaration, *supra* note 1.

⁵⁵ *Id.* at §17.

⁵⁶ Cohen-Kohler, *supra* note 4.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ Doha Declaration, *supra* note 1, at § 5.

⁶⁰ *Id.* at § 5(b).

⁶¹ Cohen-Kohler, *supra* note 4.

⁶² TRIPS and Public Health, *supra* note 33.

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ing effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and report to the General Council before the end of 2002.⁶³

Because Article 31(f) of TRIPS declares that compulsory licensed products should be made "predominantly for the supply of the domestic market,"⁶⁴ countries like Rwanda that cannot produce generic drugs domestically were unable to obtain them from other countries without violating the TRIPS Agreement. African-state WTO members were particularly interested in resolving this issue, and on August 20, 2003, a solution was created.⁶⁵ Specifically, the WTO decided to simplify the process of importing generic drugs made under compulsory licensing for countries that cannot produce those drugs domestically by creating three waivers.⁶⁶

A. Waivers to Article 31

First, and most importantly, exporting countries' duties under Article 31(f) were waived, meaning developing countries can now import generic products made in wealthier countries, which have the appropriate manufacturing capacity.⁶⁷ This was important for Canada because it did not wish to be in violation of its WTO obligations should it export generic drugs to a country in need.

Second, exporting countries only, and not the developing importing countries, are responsible for remuneration to the patent holder.⁶⁸ This removes an additional burden for countries like Rwanda when receiving assistance. Third, exporting constraints were removed for developing countries, making it possible for them to work jointly with others.⁶⁹ This means groups of developing countries with smaller populations can jointly declare an emergency.⁷⁰ By working together, developing countries can each address their domestic health emergencies through the grant of one compulsory license to one generic producer, instead of many.⁷¹

B. Concerns with Paragraph 6's Policy

Although the August 2003 decision is a positive step for developing countries that cannot produce generic drugs domestically, developed countries and pharmaceutical companies still have many concerns. For example, many fear that the

⁶³ Doha Declaration, *supra* note 1, at § 6.

⁶⁴ TRIPS, *supra* note 29, art. 31(f).

⁶⁵ TRIPS and Public Health, *supra* note 33.

⁶⁶ *Id.*

⁶⁷ Holger P. Hestermeyer, *Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines*, ASIL Insight International Economic Law Edition, Dec. 10, 2007, available at <http://www.asil.org/insights/2007/12/insights071210.html>.

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ McCalman, *supra* note 26, at 8.

⁷¹ *Id.*

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generic drugs could be diverted to other markets instead of reaching the intended recipients.⁷² Additionally, pharmaceutical companies have expressed concern over perceived patent violations.⁷³ Specifically, these criticisms have come to light surrounding Canada's plan for the exportation of Apo-TriAvir.⁷⁴

VII. Canadian Export Plan

In 2004, after the implementation of Paragraph 6 of the Doha Declaration on TRIPS, Canada amended its patent law with the hope of being the first country to manufacture generic drugs for export to a developing nation.⁷⁵ The amendment process resulted in a law called Canada's Access to Medicines Regime ("CAMR"), which allows the production and export of generic drugs to developing countries without the permission of the patent holder in connection with the TRIPS Agreement.⁷⁶ In July 2007, Rwanda was the first country to notify the WTO that it intended to move under Paragraph 6 and import drugs from Canada.⁷⁷ In September 2007, Canada's patent commissioner gave Apotex, Inc. a compulsory license to produce and export a triple fixed-dose, anti-viral AIDS drug to Rwanda.⁷⁸

With the compulsory license in place, Rwanda stands to receive a huge discount on generic anti-viral drugs. Specifically, Apotex plans to export 260,000 packages of single-dose Apo-TriAvir,⁷⁹ each costing around \$.40 per pill, as opposed to the \$20 per pill that consumers in developed countries must pay for the name-brand version.⁸⁰ Despite the many prerequisites, if successful, the manufacture and export of Apo-TriAvir will result in 21,000 HIV patients in Rwanda being treated for one year.⁸¹ This is 50% more than the current group of 44,000 people receiving anti-viral drugs.

A. Obtaining a Compulsory License under CAMR

CAMR has its own application process that is more demanding than the WTO process outlined in Article 31 of the TRIPS Agreement. This has led to much criticism from developing countries and generic manufacturers alike. Due to CAMR's complicated nature, it took nearly four years for Rwanda to implement

⁷² TRIPS and Public Health, *supra* note 33.

⁷³ Cohen-Kohler, *supra* note 4.

⁷⁴ Hestermeyer, *supra* note 67.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Canada Issues Compulsory License for HIV/AIDS Drug Export to Rwanda*, in *First Test of WTO Procedure*, 11 BRIDGES WEEKLY TRACE NEWS DIGEST 32, (Sept. 26, 2007), available at <http://www.ictsd.org/weekly/07-09-26/story2.htm>.

⁸⁰ *Id.*

⁸¹ *Id.*

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the regime.⁸² Additionally, despite Apotex's philanthropic intentions, it faced many legal challenges from the patent holders,⁸³ which further inhibited the process.

Unlike the process under TRIPS alone, CAMR requires the generic producer to attempt to get a *voluntary* license from the patent holder before Canada can issue a compulsory license.⁸⁴ The three pharmaceutical companies that hold patents for the anti-viral drug that Apotex wished to produce—GlaxoSmithKline, Shire, and Boehringer Ingelheim—were unwilling to give Apotex a voluntary license.⁸⁵ In accordance with CAMR, Apotex attempted to negotiate with these pharmaceutical companies for over a year without success.⁸⁶ Only when Rwanda notified the WTO of its intention to declare a national emergency in July 2007 did Canada finally grant a compulsory license to Apotex despite the resistance of the patent owners.⁸⁷

Additionally, before the life-extending drugs could be shipped, CAMR required Apotex to create a website providing information about the generic drug - specifically surrounding its packaging - in order to prevent illegal diversion to other markets besides Rwanda.⁸⁸ This website was completed in early 2008, and therefore Apotex has fulfilled its duties under CAMR.

B. Schedule for Exportation

At the time of this article's completion, the schedule for delivery of Apo-TriAvir remains unknown. Recently, Rwanda failed to provide tender to Apotex as was previously planned.⁸⁹ According to Apotex's Director of Public and Governmental Affairs, Elie Betito, Apo-TriAvir cannot be shipped until Rwanda completes the tender process.⁹⁰ Experts speculate that Rwanda's failure to complete this process is the result of pressure not to follow through.⁹¹ Therefore, the timing of exportation is uncertain, and Rwandans continue to suffer in the absence of generic drugs.

C. Criticism of CAMR

Many criticisms have arisen surrounding CAMR since its creation over three years ago. These criticisms include the concern that the law's requirements are

⁸² *Id.*

⁸³ Hestermeyer, *supra* note 67.

⁸⁴ *Id.*

⁸⁵ *Canada Issues Compulsory License for HIV/AIDS Drug Export to Rwanda*, *supra* note 79.

⁸⁶ *Id.*

⁸⁷ Cohen-Kohler, *supra* note 4.

⁸⁸ *Id.*

⁸⁹ Hestermeyer, *supra* note 67.

⁹⁰ Email from Elie Betito, Director of Public and Governmental Affairs, Apotex, Inc., to Christina Cotter (Feb. 25, 2008) (on file with author).

⁹¹ Baker, *supra* note 8.

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too complex and prevent successful implementation.⁹² The length of time between CAMR's creation and its actual application lends credence to this opinion.

1. *Criticism from Developing Countries*

Developing WTO member-states have found CAMR to be overly complex, as well as unresponsive to the needs of its beneficiaries. One developing country representative has said of the legislation, "the needs of developing countries must be taken into consideration any time international programs have been set up . . . if you are trying to increase access to medicines and then you set up a new criteria and processes, that in themselves becomes the barriers, and then we have not done much."⁹³ In fact, it took three years for Rwanda to implement Canada's plan, and it has been the only developing country to do so.⁹⁴ Richard Elliott, the Executive Director of the Canadian HIV/AIDS Legal Network, has noted that the lack of importers is a wake-up call to Canada to simplify the process of obtaining generic drugs.⁹⁵

Additionally, many developing countries are unable to begin the process of obtaining drugs through CAMR because they fear that wealthier states will stop donating money should they seek to circumvent pharmaceutical patents. As one health activist noted, "[a] country that wants to do this has to stick its neck out and make an order and say to the world . . . we intend to use the WTO system, specifically Canada's. . . and there will be an immediate backlash . . ."⁹⁶ Backlash comes from developed states that use their strong influence over poorer states to further the agendas of pharmaceutical companies. For example, the United States may offer millions of dollars to a developing country for medicine, on the condition that it buys patented products only.⁹⁷ Another health activist has said, "[i]f I'm sitting here, and I'm in Malawi, and I've got \$200 million annually from the US for drugs as long as I buy patent drugs, do you think I'm going to thumb my nose at that? It's part of the bigger architecture."⁹⁸ Therefore, developing countries appear to be unwilling to take action under Paragraph 6 for fear that it will lead to decreased donations.

2. *Criticism from the Generic Drug Industry*

The generic drug industry desires additional incentives for participating in CAMR. For example, currently CAMR's "Good Faith Clause" requires that the average price of the generic drug be less than twenty five percent of the cost of

⁹² Hestermeyer, *supra* note 67.

⁹³ Cohen-Kohler, *supra* note 4.

⁹⁴ *Id.*

⁹⁵ *Rwanda First to Use Canada's Access to Medicines Regime to Buy Affordable AIDS Drug*, LEGAL NETWORK NEWS, Issue 28, Oct. 2007, at 1, available at <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=1234>.

⁹⁶ Cohen-Kohler, *supra* note 4.

⁹⁷ *Id.*

⁹⁸ *Id.*

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the patented version.⁹⁹ Companies believe that this rule subjects them to substantial liability while providing little financial benefit.¹⁰⁰ One industry insider has said, “[i]nternational companies who operate in Canada . . . say why should I go to Canada and lose money because the Canadian government has an objective?”¹⁰¹ The general consensus from generic manufacturers is that Canada's procedures do not facilitate the producers who are trying to save lives.¹⁰²

VIII. Implications for Other Nations

It is uncertain whether Rwanda will complete the process of generic drug importation at this time. Unfortunately, if the Rwanda plan ultimately fails, it will set a poor precedent for other nations contemplating action under Paragraph 6. However, other countries can learn from the challenges faced under Rwanda and Canada's agreement.

First, developed countries that wish to export generic drugs should enact simple legislation that facilitates the production of those drugs. CAMR's complexity posed many problems for Apotex and for Rwanda, and therefore should serve as a cautionary example for future exporters. Specifically, future legislation should be similar to Article 31 of TRIPS, which does not require the generic producer to attempt to receive a voluntary license prior to a compulsory license being granted. Had Canada's process been more similar to Article 31, Apotex would not have spent over a year's time attempting to receive a voluntary license in vain.

Additionally, the WTO should take steps to prevent pharmaceutical companies and the developed states where they are based from inhibiting the success of Paragraph 6 agreements. The Doha Declaration's policy of world health will never become reality if developing countries are pressured against following through with their plans to import generic drugs. Unfortunately, Rwanda seems to be experiencing just this type of pressure. Although Apo-TriAvir is ready for shipment, Rwanda has not taken the final step to complete the deal, and experts speculate that this is because of pressure from developed nations against the export of generic drugs.¹⁰³ Therefore, the WTO should develop policies that prohibit this type of pressure since thousands of lives are at risk every day. Specifically, the WTO should clarify its position on human welfare under Paragraph 6.

Finally, developing countries acting under Paragraph 6 in the future should consider distribution methods from the onset and have an infrastructure in place upon the generic drugs' arrival. It is still unclear how Rwanda will efficiently distribute generic medication when and if it is received. As already indicated, the medical facilities in Rwanda and other developing countries are lacking and the

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ Baker, *supra* note 8.

Implications of Rwanda's Paragraph 6 Agreement

TRIPS Agreement does not provide guidance for the distribution of generic drugs. Despite distribution uncertainty, the fight against malaria and other epidemics is instructive. Currently, Rwanda's National Malaria Control Program, an initiative funded by multiple nongovernmental organizations ("NGOs"), provides Malaria drugs at \$.10 a dose and is monitored by the government.¹⁰⁴ More importantly, NGOs and their local partners oversee the distribution of these malaria drugs at the local level.¹⁰⁵ If Rwanda could get similar help on the local level for the distribution of Apo-TriAvir, the program could be successful. In the future, the WTO should provide that production of generic drugs is allowed only in conjunction with the developing state's efforts to create distribution methods. Therefore, when future developing countries decide to move forward under Paragraph 6, they should already be working with donors or NGOs to create these distribution chains.

IV. Conclusion

Although the future of the agreement between Rwanda and Canada is uncertain, it should serve as a case study for other countries wishing to receive or manufacture generic drugs under Paragraph 6. If lessons can be learned from the slow and arduous process of the Rwanda/Canada agreement, perhaps the next Paragraph 6 agreement will be a success.

¹⁰⁴ Julia Ross, *Treating Child Malaria in Rwandan Communities*, EJOURNAL USA: ECONOMIC PERSPECTIVES, Aug. 2005, at 25, available at <http://usinfo.state.gov/journals/ites/0805/ijee/ijee0805.pdf>

¹⁰⁵ *Id.*
