Could the Paragraph 6 Compulsory License System be Revised to Increase Participation by the Generics Industry? Lessons Learned from an Unheralded and Unsuccessful Attempt to Use Canada's Access to Medicines Regime

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The long-awaited amendment to the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement codifying the so-called Paragraph 6 System finally came to pass in 2017. The Paragraph 6 System facilitates the export of generic copies of patented drugs to developing countries in the name of public health, even in the absence of authorization from the patent holder. However, the Paragraph 6 System has proven disappointing in practice; in over a decade of existence under a temporary waiver, there has only been one single completed use of the system anywhere in the world. In that instance, Canada ex-

L'amendement tant attendu de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC) de l'Organisation mondiale du commerce (OMC) a finalement été adopté en 2017. Le système du paragraphe 6 facilite l'exportation de copies génériques de médicaments brevetés aux pays en développement au nom de la santé publique, même en l'absence d'autorisation du titulaire du brevet. Cependant, le système du paragraphe 6 s'est révélé décevant dans la pratique. Depuis plus d'une décennie d'existence en vertu d'une dispense temporaire, il n'y a eu qu'une seule utilisation complète du système partout dans le

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Citation: Adam R Houston & Reed F Beall, "Could the Paragraph 6 Compulsory License System be Revised to Increase Participation by the Generics Industry? Lessons Learned from an Unheralded and Unsuccessful Attempt to Use Canada's Access to Medicines Regime" (2019) 12:2 McGill JL & Health 227.

Référence : Adam R Houston et Reed F Beall, « Could the Paragraph 6 Compulsory License System be Revised to Increase Participation by the Generics Industry? Lessons Learned from an Unheralded and Unsuccessful Attempt to Use Canada's Access to Medicines Regime » (2019) 12 : 2 RD & santé McGill 227.

ported HIV/AIDS medication to Rwanda in 2007 under Canada's Access to Medicines Regime (CAMR). There have, however, been unsuccessful attempts to use the system. In this article, we document a recent and largely unknown attempt by a Canadian generics company that almost became the world's second use of the Paragraph 6 System. What transpired illuminates what motivated one generics company (Teva Canada) to use CAMR in order to produce drugs containing tenofovir disoproxil, commonly used to treat and prevent HIV. Given that Teva turned to CAMR only after losing a patent case in court, we argue that the ensuing events suggest Teva's strategy may have been to use CAMR as a way to better position itself to enter the Canadian market once the patents had expired on the brand name product. We discuss whether policymakers could more powerfully leverage generics companies' drive to enter domestic markets in a way that would more effectively motivate them to make use of CAMR and other Paragraph 6 mechanisms, and in doing so make a meaningful contribution to global health.

monde. Dans ce cas, le Canada a exporté des médicaments contre le VIH au Rwanda en 2007 en vertu du Régime canadien d'accès aux médicaments (RCAM). Cependant, il y a eu des tentatives infructueuses pour utiliser le système. Dans cet article, nous documentons une tentative récente et largement inconnue d'une société canadienne de génériques qui est presque devenue la deuxième utilisation au monde du système du paragraphe 6. Ce qui s'est passé illumine ce qui a motivé une compagnie générique (Teva Canada) à utiliser le RCAM afin de produire des médicaments contenant du ténofovir disoproxil, couramment utilisés pour la prévention et le traitement du VIH. Teva s'est tourné vers le RCAM seulement après avoir perdu une affaire de brevet en cour. Nous soutenons que les événements qui ont suivi suggèrent que la stratégie de Teva aurait pu être d'utiliser le RCAM pour mieux se positionner sur le marché canadien une fois que les brevets auraient expiré sur le produit de marque. Nous discutons de la possibilité pour les décideurs de mieux tirer parti des efforts des sociétés génériques pour pénétrer les marchés nationaux de façon à les motiver plus efficacement à recourir au RCAM et aux autres mécanismes prévus au paragraphe 6, contribuant ainsi de façon significative à la santé mondiale.

Introduction

The idea that sick people should have access to vital medicines is uncontroversial. Considerably more controversial is the issue of how best to ensure access at an affordable price. In January 2017, the World Trade Organization (WTO) announced that the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement had been amended "to ease poor countries' access to affordable medicine."[1] This amendment marks the first time any of the WTO accords have been revised since the organization came into existence in 1995. Unfortunately, this ostensibly landmark amendment merely codifies a longstanding mechanism for improving access to medicines that has almost never been utilized and, in its current form, shows little promise of meeting its goal.

The mechanism in question is the Paragraph 6 System – so named for the section of the 2001 Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) in which it was first contemplated.[2] Recognizing that compulsory licensing provisions were only of use to countries capable of producing their own drugs, the subsequent 2003 Implementation of Paragraph 6 Decision adopted an approach that allowed states to engage in compulsory licensing for the purpose of exporting cheaper generic equivalents to low-income countries which lacked domestic production capacity.[3] Following this Decision, the Paragraph 6 System has been in effect as a temporary waiver from the requirements under TRIPS article 31(f) that a compulsory license be "predominantly for the supply of the domestic market of the Member authorizing such use."[4] Nevertheless, even though over 30 countries have passed laws to facilitate such compulsory licenses for export over the past 15 years, there has only been one single instance of its use, anywhere in the world, during that

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1 WTO, News Item, "WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines" (23 January 2017), online: <www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm>.

2 WTO, *Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (2001), 4th Sess [WTO, *Doha Declaration*].

3 WTO, General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 (2 September 2003) [WTO, *Implementation of Paragraph 6*].

4 WTO, *Agreement on Trade-Related Aspects of Intellectual Property Rights,* 1869 UNTS 299, 15 April 1994 (entered into force 1 January 1995), art 31(f); see *ibid*, art 2.

time.[5] This occurred in 2007, when the Canadian generics manufacturer Apotex exported an HIV treatment to Rwanda under Canada's Access to Medicines Regime (CAMR).[6]

The recent report of the United Nations Secretary-General's High-Level Panel on Access to Medicines acknowledges the nearly non-existent use of this mechanism since its inception. Nonetheless, the report does not reject the underlying approach as a failure, concluding instead that "WTO Members should revise the paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license."[7] What the report fails to do, however, beyond some broad references to increased political commitment and simplified domestic legislation, is to provide specific guidance on what might be done to increase use of the Paragraph 6 System.

As such, the topic of improving the implementation of Paragraph 6 remains ripe for discussion. While a considerable body of literature exists discussing the weaknesses of the Paragraph 6 System and its domestic implementation, most of these discussions are either largely speculative in nature, given that the mechanism has so rarely been used, or focus on the lone instance of successful utilization of the System.[8] Largely absent from the literature is analysis of failed attempts to use the Paragraph 6 System. Analyzing such failures could reveal not only barriers to success, but also the circumstances and incentives that led generics companies to attempt

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5 See Amir Attaran, "Why Canada's Access to Medicines Regime Can Never Succeed" (2010) 60 UNBLJ 150 at 152.

6 See WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *Notification under Paragraph 2(c) of the Decision of 20 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc IP/N/10/CAN/1 (8 October 2007).

7 High-Level Panel on Access to Health Technologies, *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines*, (September 2016) at 9, online: <http://www.unsgaccessmeds.org/final-report> [*UN High-Level Panel Report*].

8 See e.g. Muhammad Z Abbas & Shamreeza Riaz, "WTO 'Paragraph 6' System for Affordable Access to Medicines: Relief or Regulatory Ritualism?" (2018) 21:1-2 J World Intellectual Property 32; Laura Chung, "Use of Paragraph 6 Systems for Access to Medicine" (2010) 36 NCJ Intl L & Com Reg 137; Matthew Rimmer, "Race Against Time: The Export of Essential Medicines to Rwanda" (2008) 1:2 Public Health Ethics 89.

using the Paragraph 6 System in the first place. To address this gap, this article draws upon previously unreleased documents obtained through access to information requests to examine the actions actually taken by a generics company attempting what could have become the world's second use of the Paragraph 6 System. Similar to the first, and only, successful use, this attempt again involved the export of HIV medications from Canada under CAMR.

The article begins with a brief introduction to the Paragraph 6 System and its implementation in Canada via CAMR. It then examines Teva Canada's partially successful but ultimately abandoned attempt to use CAMR to export products containing tenofovir disoproxil. This drug has recently taken on increased importance both domestically and internationally as a core component of pre-exposure prophylaxis (PrEP), a daily medication used as a preventative measure against HIV infection. The article then helps to fill the gaps in the UN High-Level Panel's Report by identifying the business-driven, rather than purely philanthropic, motivations generics companies have for engaging with Paragraph 6. The article concludes by suggesting potential reforms to CAMR and similar Paragraph 6 mechanisms in order to account for the interests of generics companies and thereby encourage their participation in helping provide access to affordable medicines in the future.

I. Background

A. Compulsory licensing and the Paragraph 6 System

Compulsory licensing is a mechanism by which a country authorizes the production of a generic version of a patented medicine without authorization of the patent holder (although the patent holder will nonetheless receive some compensation for this loss of exclusive rights). Compulsory licensing is a permissible feature of domestic patent law under the 1995 TRIPS Agreement, which sought to harmonize the patent laws of WTO member states so that even the lowest income members would eventually offer the same level of patent protection as wealthy ones. Before TRIPS, the protections extended to pharmaceuticals differed greatly from country to country. A primary concern motivating the inclusion of compulsory licensing in TRIPS was that patent protection allows companies to charge prices that are out of reach for some patients, particularly those in low- and middle-income countries. This concern came to the forefront with the development of effective antiretroviral drugs for HIV, which at the time they were introduced cost far more than was affordable for low-income countries hardest hit by

the epidemic. This issue ultimately prompted the Doha Declaration, which explicitly clarified the permissibility of compulsory licensing under TRIPS.[9]

However, because patents are granted on a country-by-country basis, compulsory licenses are generally issued for domestic use (although TRIPS article 31(f) allows exports so long as the predominant use is for the domestic market). Consequently, compulsory licensing is primarily useful only in countries with sufficient domestic pharmaceutical production capabilities. Many countries lacking drug production capacity thus wanted an alternative mechanism for procuring generic medicines from abroad when circumstances made this necessary, such as when patent-holding companies refused to offer medicines at reasonable prices or to negotiate voluntary licenses with generic suppliers.

In response to concerns first raised in Paragraph 6 of the Doha Declaration, the Paragraph 6 System was launched in 2003.[10] The Paragraph 6 System facilitates coordinated compulsory licensing between WTO members; an exporter from one WTO member can supply patented medicines to another member, even though doing so might otherwise violate patent rights in both countries. The WTO has requirements for each of the three parties involved: the exporting government, the licensee that said government has authorized to manufacture the medicine, and the importing government. The exporting government must notify the WTO of the compulsory license with its specifics (such as the name and address of the licensee, the product(s) involved, the quantity or quantities to be produced for export, the designated importing country or countries, and the duration of the compulsory license). In turn, importing countries (unless they are a least-developed country) are required to make a one-time notification to the WTO of their intent to use the Paragraph 6 System. Then, each time that country arranges for an import, they are required to notify the WTO of details about the products and the quantities needed, that they do not have sufficient domestic manufacturing capacity for the product needed, and that they have issued a compulsory license (or intend to issue a compulsory license). The WTO makes these government notifications to the WTO available on its dedicated webpage.[11]

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9 WTO, *Doha Declaration*, supra note 2 at para 5b.

10 WTO, *Implementation of Paragraph 6*, supra note 3.

11 See WTO, "Notifications by Exporting WTO Members", online: <www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm>.

B. Canada's Access to Medicines Regime

Canada was quick to seize upon the idea of compulsory licensing for export, becoming the first country to announce its intention to change its laws to accommodate the Paragraph 6 System at the national level.[12] The *Jean Chrétien Pledge to Africa Act* was passed in 2004 and came into force the following year.[13] The *Act* established CAMR as a humanitarian legacy project for the outgoing Prime Minister. Not only was CAMR well received internationally, burnishing Canada's reputation as a promoter of human rights, it was also popular domestically among Canadians eager to help alleviate the scourge of HIV around the world. Furthermore, it found general support among many of the multinational generic drug manufacturers based in Canada.[14]

CAMR served as the latest chapter in Canada's interesting history with compulsory licensing for pharmaceuticals. The country's permissive compulsory licensing regime from the late 1960s until the late 1980s helped Canada develop a thriving generics industry, including major companies like Novopharm and Apotex. Between 1987 and 1993, however, successive reforms to the *Patent Act*, particularly in relation to trade agreements such as the North American Free Trade Agreement (NAFTA), greatly curtailed compulsory licensing in Canada.[15] Consequently, compulsory licensing for export via CAMR offered manufacturers the possibility of regaining some of the market that had been lost when domestic compulsory licensing was

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12 See Emily Ng & Jillian Clare Kohler, "Finding Flaws: The Limitations of Compulsory Licensing for Improving Access to Medicines: An International Comparison" (2008) 16 Health LJ 143 at 143, n 4.

13 *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, SC 2004, c 23. See also Health Canada, "Canada's Access to Medicines Regime: Background" (1 October 2004), Government of Canada, online: <www.canada.ca/en/health-canada/services/canada-access-medicines-regime/introduction/background.html>.

14 See Jim Keon, "Editorial: Canada First to Pass Legislation on Delivering Generic Medicines to Developing Countries" (2004) 1:4 J Generic Medicines 292 at 292.

15 See Canada, Library of Parliament, "Patent Protection for Pharmaceutical Products in Canada: Chronology of Significant Events", by Kristen Douglas & Célia Jutras, PRB 99-46E (Ottawa: Library of Parliament, revised 6 October 2008), online: <http://publications.gc.ca/collections/collection_2009/bdp-lop/prb/prb9946-1e.pdf>.

essentially abolished. As such, it was no mystery why companies like Apotex – which advertises itself as "proudly Canadian"[16] – were eager to see CAMR launched: the noble goal of increasing access to medicines in low-income countries was complemented by potential benefits for generic suppliers based in Canada.

Unfortunately, despite ample publicity and goodwill, CAMR did not fulfill the expectations of either access to medicines advocates or Canada's generics companies. Few developing countries expressed much interest in using the mechanism. After concluding the famed 2007 deal for antiretrovirals, Apotex publicly declared it would not use CAMR again unless the mechanism were simplified.[17] At the same time, there is speculation that the real reason Apotex was reluctant to repeat the experience is that in order to win the tender for the drug it supplied under CAMR, the company sold the drug at an unprofitably low price.[18] Whatever the case, Apotex's sale of an HIV triple-therapy drug to Rwanda in 2007 remains the only time CAMR, and the Paragraph 6 System, has been used anywhere in the world.

C. Revisiting the usefulness of CAMR and the Paragraph 6 System today

Much of the published literature on CAMR and the Paragraph 6 System more broadly maintains that such mechanisms remain a potentially valuable tool for increasing access to medicines, and focuses on simplifying the laborious bureaucratic process that is blamed for its underuse. Such concerns are highlighted in the UN High-Level Panel's Report.[19] Unsurprisingly, CAMR has been a particular focus of analysis, given that its one-off

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16 Apotex, "About Us", online: <http://www1.apotex.com/ca/en/about-us/about-apotex>.

17 See Apotex Inc, "CAMR Federal Law Needs to be Fixed if Life-Saving Drugs for Children are to be Developed", Newswire (14 May 2009). See also Tanya Talaga, "Hope for Cheap HIV Drugs Dims" *The Star* (19 September 2009), online: <https://www.thestar.com/life/health_wellness/2009/09/19/hope_for_cheap_hiv_drugs_dims.html>.

18 See e.g. Attaran, *supra* note 5 at 153–54; Reed F Beall, Randall Kuhn & Amir Attaran, "Compulsory Licensing Often Did Not Produce Lower Prices For Antiretrovirals Compared To International Procurement" (2015) 34:3 Health Affairs 493.

19 *Supra* note 7 at 23.

use made it the world's most successful implementation of the Paragraph 6 System. The need to expand the scope of CAMR to include a broader range of drugs and to simplify the process of making long-term deals with importing countries are but two examples of reforms that have been discussed extensively by a variety of stakeholders, including the generics industry.[20] It is worth recognizing, however, that Canadian generics companies have frequently proven willing (as seen in the case study below) to go to the time and expense of patent challenges.[21] This suggests that the amount of resources and effort they are willing to expend on complex legal processes correlates directly with the expected commercial payoff. It should also be noted that previous efforts to revise CAMR have been bogged down by partisan political debates on the merits of specific reforms.[22]

In the interim, however, global access to medicines has changed substantially. Over the course of the first decade after the Doha Declaration – even as the Paragraph 6 System lay dormant – the number of people with access to antiretroviral medicines in sub-Saharan Africa increased more

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[20] See e.g. Canadian Generic Pharmaceutical Association, "Canada's Access to Medicines Regime Consultation Paper" (24 January 2007), online: <www.camr-rcam.gc.ca/review-reviser/camr_rcam_cgpa_01_e.pdf>; Richard Elliot, Canadian HIV/AIDS Legal Network, "Getting the Regime Right: Compulsory Licensing of Pharmaceuticals for Export" (Brief to the House of Commons Standing Committee on Industry, Science and Technology regarding Canada's Access to Medicines Regime delivered in Ottawa, 18 April 2007), online: <www.aidslaw.ca/site/getting-the-regime-right-brief-to-the-house-of-commons-standing-committee-on-industry-science-and-technology-regarding-canadas-access-to-medicines-regime/?lang=en>; Paige E Goodwin, "Right Idea, Wrong Result: Canada's Access to Medicines Regime" (2008) 34 American JL & Medicine 567; Marilyn McHarg & Médecins Sans Frontières Canada, "Review of the Canadian Access to Medicines Regime: Submission to the Government of Canada" (2007), online: <www.camr-rcam.gc.ca/review-reviser/camr_rcam_msf_11-eng.pdf>; Ashley Weber & Lisa Mills, "A One-Time-Only Combination: Emergency Medicine Exports and the TRIPS Agreement under Canada's Access to Medicines Regime" (2010) 12:1 Health & Hum Rights 109.

[21] See Paul Grootendorst, Ron Bouchard & Aidan Hollis, "Canada's Laws on Pharmaceutical Intellectual Property: The Case for Fundamental Reform" (2012) 184:5 CMAJ 543.

[22] See e.g. "Bill C-398 An Act to amend the Patent Act (drugs for international humanitarian purposes)", *House of Commons Debates*, 41st Parl, 1st Sess, (28 November 2012).

than 100-fold.[23] Numerous factors have contributed to the increase in access to antiretrovirals, including patent expirations, compulsory licenses for domestic markets, and negotiated discounts (sometimes in the shadow of compulsory licenses), as well as the emergence of large-scale philanthropic procurement by programs such as the US President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria. Even before the Paragraph 6 System came into existence, the Indian manufacturer Cipla had begun to offer triple-combination antiretroviral therapy for sale to all countries for less than a dollar per day; since then, India has been dubbed the "pharmacy of the developing world," producing inexpensive drugs for export without making use of the Paragraph 6 System.[24] It is of course possible that the existence of Paragraph 6 has provided leverage for countries to negotiate other means of affordable access; however, such indirect influence was not its primary intent.[25]

As a result, while access to medicines remains a very serious challenge in many lower income countries, it is not clear that compulsory licensing for export mechanisms like CAMR will ever play a major role in expanding access to widely needed drugs like antiretrovirals. Nevertheless, despite falling prices and increasing access, there will always be medicines that are priced beyond the reach of many who need them, and countries that lack the manufacturing capacity to produce a given drug and therefore cannot directly benefit from issuing a domestic compulsory license. For example, as more complex drugs are developed for smaller groups of patients, there may well be a place for countries like Canada, operating through mechanisms like CAMR, in emerging and niche areas not already being served by Indian or Chinese manufacturers. For CAMR and similar mechanisms to be utilized in this regard, however, generics companies must be willing to engage in the process.

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23 UNAIDS, Press Release, "HIV Treatment Now Reaching More than 6 Million People in Sub-Saharan Africa" (6 July 2012), online: <www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2012/july/20120706pafricatreatment>.

24 Ellen 't Hoen et al, "Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All" (2011) 14:1 J Intl AIDS Soc 1 at 4.

25 See Reed Beall & Randall Kuhn, "Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis" (2012) 9:1 PLoS Medicine e1001154 at 2–3.

To this end, a key question that must be addressed is what motivates generics companies to participate in such processes. Sometimes glossed over in the oversimplified patients versus patents debate is the fact that generics companies are themselves profit-seeking businesses, not charities. Indeed, the lack of sufficient commercial incentives in CAMR has been specifically identified as an issue by members of the Canadian generics industry.[26] Given the competitive disadvantage Canadian generics manufacturers face in production costs and pricing compared with rivals in India and elsewhere, there need to be other considerations, like commercial incentives, in order to attract them at prices that low-income customers are willing to pay.

There has been little exploration of how commercial incentives have motivated engagement with the Paragraph 6 System in practice. Although the single successful exercise of Paragraph 6 using CAMR is well documented, unsuccessful attempts to use CAMR or its equivalent in other countries have left few public records and attracted even less attention. At the same time, such cases are important because they can shed light on what attracted generics companies to the mechanism in the first place, as well as the barriers that ultimately stood in the way. The following part of this article seeks to fill this gap by documenting what nearly became Canada's second use of CAMR, and in turn the world's second use of the Paragraph 6 System, while highlighting the lessons that can be learned from it.

II. THE SECOND ATTEMPT TO USE CAMR

A. Teva's little-known attempt to use CAMR for tenofovir disoproxil

Tenofovir disoproxil is an antiretroviral medication used to treat HIV and the Hepatitis B virus. It appears on the World Health Organization's Model List of Essential Medicines, both alone and in combination with other antiretroviral drugs. As of the 20th edition of the list, released in 2017, its essential indications now include pre-exposure prophylaxis (PrEP).[27] At the time this story begins, Gilead held unexpired Canadian formulation pat-

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[26] See Jillian C Cohen-Kohler, Laura C Esmail & Andre Perez Cosio, "Canada's Implementation of the Paragraph 6 Decision: Is It Sustainable Public Policy?" (2007) 3:12 Global Health at 3–4.

[27] World Health Organization, *WHO Model List of Essential Medicines*, 20th ed (2017) at 19, online: <https://www.who.int/medicines/publications/essentialmedicines/en/>.

ents for tenofovir disoproxil and its salt form, tenofovir disoproxil fumarate (TDF).[28] The generic pharmaceutical manufacturer Teva Canada Limited (the successor to Canadian generics giant Novopharm) challenged these patents to market its own products containing tenofovir disoproxil in Canada. Generics companies undertake these types of patent challenges in order to enter the market sooner, rather than waiting for the patent to expire. Teva's main argument in its challenge was that these patented forms of tenofovir disoproxil were obvious, and therefore invalid.[29] Unfortunately for Teva, Canada's Federal Court ruled against them in December 2013, "prohibiting the Minister from issuing a Notice of Compliance to Teva in respect of its proposed tenofovir disoproxil fumarate product until the expiry of Canadian Letters Patent 2,261,619."[30]

Following its courtroom loss, Teva turned to CAMR, seeking an alternative outlet for the sale of its generic product. Drugs eligible for CAMR are listed in Schedule 1 of the Canadian *Patent Act*.[31] In February 2014, Teva wrote a letter to Health Canada and Industry Canada, asking that tenofovir disoproxil and certain combination drugs containing it be added to Schedule 1. In support of its application, Teva stated that:

> [i]n addition to supporting Canada's commitment to international humanitarian aid, Canadian manufacturing will also benefit…. Exportation of these medicines for international humanitarian aid will create sustainable work for Canadians and will go a long way to help the many patients in other parts of the world who are unable to access these life-saving medicines.[32]

As a result, a proposed amendment adding the requested products to Schedule 1 was circulated in the Canada Gazette.[33] Two letters were re-

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28 See *Gilead Science Inc v Canada (Minister of Health)*, 2013 FC 1270 at paras 3–4.

29 See *ibid* at para 7.

30 *Ibid* at para 85.

31 RSC 1985, c P-4, Schedule 1.

32 Letter from Teva to Rona Ambrose, Minister of Health (27 February 2014).

33 Order Amending Schedule 1 to the Patent Act (2014-1), (2014) C Gaz I, 3049, online: <http://gazette.gc.ca/rp-pr/p1/2014/2014-12-20/html/reg1-eng.php> [Gazette].

ceived in response. The first was from the Canadian Generic Pharmaceutical Association, supporting the amendment.[34] The second was from Gilead, which did not explicitly object to generic versions of its drugs being licensed under CAMR, but instead raised a question frequently asked by CAMR's critics: whether a Canadian compulsory-licensed generic could successfully enter the highly competitive global market.[35] In the case of tenofovir, Indian generics companies were already supplying developing countries at some of the lowest prices in the world, pursuant to a voluntary license agreement with Gilead.[36]

In July 2015, the amendment came into force, adding the following drugs to the CAMR list under Schedule 1 of the *Patent Act*:

- efavirenz + emtricitabine + tenofovir disoproxil (tablet, 600 mg + 200 mg + 300 mg);
- emtricitabine + tenofovir disoproxil (tablet, 200 mg + 300 mg);
- tenofovir disoproxil (tablet, 300 mg).[37]

Teva was thus successful in taking the initial step towards making use of CAMR.

B. Why did Teva want tenofovir disoproxil added to Schedule 1?

Based on the sequence of events described above, one probable motivation behind Teva's attempt to use CAMR was a business interest in gaining an early foothold in Canada by manufacturing tenofovir disoproxil within its borders, thereby laying the foundation for future expansion in the Canadian domestic market. Although Canada has relatively low HIV

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34 Letter from Jim Keon, President, Canadian Generic Pharmaceutical Association to Paul Halucha, Senior Director General, Marketplace Framework Policy Branch, Industry Canada (19 January 2015).

35 Letter from Brandon Boss, Associate General Counsel, Gilead Sciences Inc to Paul Halucha, Senior Director General (Marketplace Framework Policy Branch), Industry Canada (19 January 2015).

36 See Medicines Patent Pool, "License Overview," online: <www.medicinespatentpool.org/current-licences/>.

37 See Gazette, *supra* note 33 at 3052.

prevalence, making it a smaller market for antiretroviral drugs, the use of TDF in pre-exposure prophylaxis (PrEP) opens up a larger market for preventative therapy. Gilead's Truvada, a combination pill containing TDF, was approved in Canada as the first drug for daily use as PrEP in 2016.[38] The commercial appeal of this product is reflected not only in the time and expense of Teva's initial patent challenge, but also in the subsequent market entry of numerous companies in the immediate aftermath of the expiry of the TDF patent, and the ongoing expansion of both public and private insurance coverage for PrEP.[39]

Having operative manufacturing facilities in Canada would allow Teva to hit the ground running in the Canadian market once Gilead's patents expired. In the immediate aftermath of the abolition of compulsory licensing, Canadian patent law had been amended to incorporate another provision favourable to the generics industry: a "stockpile exception" that permitted generics companies to begin manufacturing drugs six months before a patent expired in anticipation of post-expiry sales. However, Canada's Patent Act was amended in 2001 to remove this exception in the wake of a successful WTO challenge by the European Union.[40] Thus, without a compulsory license for export through CAMR, similar production would be in violation of Gilead's patents.

Indeed, in a subsequent dispute over tenofovir following the patent challenge discussed earlier, Gilead attempted to amend a patent infringement claim to argue that, given Teva's stated intention to enter the Canadian market as soon as it received a Notice of Compliance from the Minister of Health, it must have "necessarily stockpiled sufficient quantities of finished

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38 See "Health Canada Issues Notice of Compliance for Gilead's Truvada® for Reducing the Risk of Sexually Acquired HIV Infection", *Cision* (29 February 2016), online: <www.newswire.ca/news-releases/health-canada-issues-notice-of-compliance-for-gileads-truvada-for-reducing-the-risk-of-sexually-acquired-hiv-infection-570475811.html>.

39 See Vik Adhopia, "Ontario to Cover HIV Prevention Pill Under Public Health Plan", *CBC News* (17 September 2017), online: <www.cbc.ca/news/health/hiv-prep-coverage-1.4302184>.

40 See Mélanie Bourassa Forcier & Jean-Frédéric Morin, "Canadian Pharmaceutical Patent Policy: International Constraints and Domestic Priorities" in Ysolde Gendreau, ed, *An Emerging Intellectual Property Paradigm: Perspectives from Canada* (Northhampton: Edward Elgar Publishing, 2008) 81 at 97–98.

product."[41] The judge did not permit the amendment, stating that this assertion amounted "to no more than bald speculation."[42] However, it is worth considering that if Teva had indeed created a stockpile in anticipation of winning their patent challenge, CAMR might well have seemed a logical avenue for disposing of it. Even before accounting for the potential benefits to Teva, such as recouping at least some of the manufacturing costs, saving money on storage or disposal, and potentially yielding a positive public relations story about providing drugs to a low-income country, an outcome that involves getting drugs to patients seems far preferable to destroying them.

Ultimately, this situation suggests that companies might pursue Paragraph 6 compulsory licenses more often if the mechanism allowed them to begin production in anticipation of entering the domestic market sooner and more efficiently than would have otherwise been possible, thereby obtaining a first-mover advantage in the potentially lucrative generic market.

III. LESSONS FOR CAMR AND THE PARAGRAPH 6 SYSTEM

A. The commercial advantages of CAMR

Can this motivation for using CAMR be reconciled with the goals of CAMR itself? Absolutely. While the primary goal of CAMR is to promote access to medicines in low-income countries, promoting Canadian business is already a consideration. Indeed, the CAMR website advertises itself as a place to "[f]ind out more about Canada's Access to Medicines Regime and how your country or company can benefit from it."[43] If CAMR could be successfully used as a means to begin production in anticipation of Canadian market entry, it might serve as an incentive for more companies to take advantage of it. A first-mover advantage may be an attractive proposition to generics companies with an eye toward future domestic profitability, even if domestic compulsory licenses are not permitted, and even if profit margins

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41 *Gilead Sciences Inc v Teva Canada Ltd*, 2016 FC 31 at para 23.

42 *Ibid*.

43 Health Canada, "Canada's Access to Medicines Regime", online: <www.canada.ca/en/health-canada/services/canada-access-medicines-regime.html>.

on lower-priced exported generics are small or non-existent as a result of competition from countries like India.

First-mover advantages could be further incentivized in countries like Canada by drawing inspiration from the United States, where the first generics company that successfully challenges a patent is allowed to enter the domestic market six months earlier than all other competitors.[44] The new incentive would be premised on producing the drug for export to low-income (and less profitable) countries rather than on challenging the patent. Such a system would have given Teva a clear first-mover advantage in the Canadian market for generic PrEP. If desired, the goal of increasing access in other countries could be further incentivized by tying the length of the eventual domestic exclusivity period to the period of less profitable export prior to domestic entry. In turn, to ensure the underlying goal of improving access to medicines was met, extending these benefits under CAMR (or similar mechanisms elsewhere) would come with the crucial proviso that entry into the domestic market would be contingent on continuing to export the drug at an affordable price to existing customers abroad, at least for a reasonable period in order to prevent disruption of treatment while an alternative source was identified (i.e., the company utilizing CAMR could not abruptly and unilaterally redirect its production entirely to the Canadian market).

These incentives would not only be available without the expense of a patent challenge, they would also promote access to drugs with unassailable patents that would easily withstand such a challenge, not just those drugs with weaker patents. And as a further bonus for the participating generics company, the promotion of affordable access in lower income countries is valuable public relations material, particularly at a time when negative public perceptions of the pharmaceutical industry are affecting generics companies as well. Initiating reforms to provide domestic incentives of this kind has the potential to increase participation of the generics industry by buttressing the primarily humanitarian goal of CAMR with a business one. With provisions in place to promote a first-mover advantage, the end result of more medicines reaching more patients who need them is a positive one for all involved.

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44 See *Drug Price Competition and Patent Term Restoration Act of 1984*, 21 USC § 355(j)(5)(B)(iv).

B. Why did Teva not ultimately make use of CAMR?

Although the reforms proposed above are informed by Teva's engagement with CAMR, that story, much like Teva's attempt to use CAMR, remains incomplete. Despite successfully advocating for Schedule 1 of the *Patent Act* to be amended to cover drugs they desired to produce, Teva never took the next step of formally applying to sell those drugs under CAMR. It is unclear why this was the case. It is worth noting, however, that in contrast to vocal public comments by Apotex regarding CAMR, Teva has been silent about both its experiences and its motivations. Indeed, they declined the authors' request for comment on this matter.

In the absence of concrete evidence, what actually occurred is a matter of speculation. One possibility is that Teva could not find any developing country that wished to make a deal under CAMR, though there does not appear to be any public evidence of an effort to court prospective buyers. Similarly, it may be the case – though once again no public evidence is readily at hand – that Teva's efforts to take advantage of CAMR were thwarted by one of the multiple bureaucratic hurdles in the process identified elsewhere. It is also possible, perhaps in tandem with the factors above, that by the time Schedule 1 was amended, Teva simply decided to wait out the clock until July 2017, when the Canadian patent in question expired. Still another possibility is that Teva struck a deal with Gilead, agreeing to stay out of the market in any capacity until the relevant patents expired. Arrangements like these, which delay the entry of generics to the potential detriment of consumers, are a recognized concern in the United States.[45] This is precisely what occurred in the US, where Teva reached a settlement in a similar patent dispute with Gilead, stating it would not market TDF products until the patents expired.[46] Teva's first product containing TDF was approved in the US in June 2017, following the expiry of the patent.[47] However, it seems a generic version is unlikely to reach the American market until 2021 as a result of the deal between the companies; this has led access to medicines advocates to raise antitrust concerns with the Attorney General in New York

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45 See Aaron S Kesselheim, Jerry Avorn & Ameet Sarpatwari, "The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform" (2016) 316:8 JAMA 858 at 861.

46 Gilead Sciences Inc, Press Release, "Gilead and Teva Reach Settlement Agreement in Viread® Patent Litigation" (19 February 2013).

47 US Patent No 090894 (6 August 2017).

State.[48] Fortunately, if there was any such arrangement between the companies in Canada, its terms have not delayed Teva's market entry since the expiry of the patent.

Indeed, a search of Health Canada's Drug Product Database shows that by the end of July 2017, Teva had three products containing tenofovir approved for sale, the same three that had been added to the CAMR list under Schedule 1.[49] The market will be a crowded one; similar products from Apotex, Mylan Pharmaceuticals, and Pharmascience Inc. were also approved that same month. Initial pricing for both the Gilead product and the first of the generic PrEP products (from Apotex) to hit the shelves serve as a reminder of the potential value to generics companies of CAMR reforms that would bolster the first-mover advantage of entering the market before the competition.[50] The question that now remains is whether Teva will attempt to sell its Canadian-made products in low-income markets as well. Even as competition increases and prices decrease in Canada, it seems unlikely that Teva will focus its attention on exporting inexpensive TDF to lower income countries, particularly in the absence of incentives to do so.

CONCLUSION

Despite the immense amount of political capital invested in its creation, and its slightly ironic fame as world's only Paragraph 6 mechanism ever successfully put to use, CAMR remains largely irrelevant both to global health and to generic drug manufacturers based in Canada. This is not merely because of flaws in the existing CAMR mechanism that make it less user friendly than it could be, which many scholars have identified, but also from its underlying failure to reconcile humanitarian goals with the business motivations necessary to make the mechanism functional. Similar conclusions

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48 Letter from James Krellenstein et al to Eric T Schneiderman, New York State Attorney General (4 August 2017) re: Antitrust Concerns Regarding Generic Truvada Paragraph IV Litigation, online: <http://freepdfhosting.com/32291a93f6.pdf>.

49 Health Canada, "Drug Product Database," online: <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp> (using search terms "Teva" and "tenofovir").

50 See Taylor Simmons, "How More Ontarians Could Gain Access to a '99.9%' Effective HIV-prevention Drug", *CBC News* (3 August 2017), online: <www.cbc.ca/news/canada/toronto/generic-prep-toronto-1.4232689>.

can be drawn about the Paragraph 6 System more broadly. It is important to acknowledge the fact that generic drugmakers are, at their core, businesses trying to make money, not philanthropic organizations in service of the access to medicines movement. Consequently, rather than viewing the permanent amendment of TRIPS to codify the Paragraph 6 System as a conclusive victory for global health, it is better seen as an occasion for countries like Canada to revisit their attempts to implement it and the assumptions underlying those attempts. After all, TRIPS itself is a trade agreement with only occasional reference to health, not the reverse. The goal of improving access to medicines is a noble one, but means little without a pragmatic approach to ensuring the mechanism is actually used in practice. As noted earlier in this article, the United Nations Secretary-General's High-Level Panel on Access to Medicines has highlighted the need to "find a solution" to bridge the gap between the aspirations of the Paragraph 6 System and its practical impact.[51] Undertaking reforms to incentivize industry participation as outlined above, particularly if coupled with other proposed reforms to CAMR and similar mechanisms, could help create the solution.

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[51] *UN High-Level Panel Report*, *supra* note 7 at 9.