

2010

The Best of Intentions: Why the Proposed Changes to the Canadian Access to Medicines Regime Should Not Be Implemented

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NOTE: THE BEST OF INTENTIONS: WHY THE PROPOSED
CHANGES TO THE CANADIAN ACCESS TO MEDICINES
REGIME SHOULD NOT BE IMPLEMENTED

CARLY L. HUTH[†]

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I. INTRODUCTION

The number of HIV patients needing medication will continue to rise beyond the year 2015.¹ The cost of HIV medication will also increase.² The increase in both the number of patients and the cost of treatment will challenge the ability of nations to provide adequate access to medicines.³ Providing for better access, compulsory licensing⁴ allows for the production of patented pharmaceuticals at a lower cost to the consumer.⁵ Although countries issue compulsory licenses for domestic production,⁶ there is only one successful example of exportation of medication under a compulsory license: the license issued by the Canadian government for pharmaceuticals exported to Rwanda.⁷ Allowing for the exportation of medication under a compulsory license is vital because not all countries have the ability to manufacture pharmaceuticals.⁸

¹ See ALL-PARTY PARLIAMENTARY GROUP ON AIDS, THE TREATMENT TIMEBOMB 6–8 (2009), <http://www.aidsportal.org/repos/APPGTimebomb091.pdf> (noting that the rise in patients needing treatment will be due to a variety of factors, including people starting treatment earlier, staying on medication longer, and meeting current unmet needs).

² *Id.* at 10–12 (noting that the increase in cost of medications will be due to better medications with less side effects, as well as the need for second and third line medications).

³ *Id.* at 5:

We can predict many of the changing treatment needs of people living with HIV in the coming decade and they are not compatible with treatments and prices available today. Maintaining HIV treatment to keep people alive will cripple developing economies, or place unbearable strains on richer countries trying to support them.

⁴ A compulsory license, as defined by the World Trade Organization (“WTO”), is when the authorities license companies or individuals other than the patent owner to use the rights of the patent—to make, use, sell or import a product under patent (i.e. a patented product or a product made by a patented process)—without the permission of the patent owner. Allowed under the WTO’s TRIPS (intellectual property) Agreement provided certain procedures and conditions are fulfilled.

WORLD TRADE ORGANIZATION, JULY 2008 PACKAGE: BRIEFING NOTES, JARGON BUSTER (2008), http://www.wto.org/english/tratop_e/dda_e/meet08_brief07_e.htm.

⁵ See Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: The Collective Bargaining Approach*, 45 AM. BUS. L.J. 283, 283–84 (2008) (“Developing nations have attempted to resolve this tension through the issuance of patent compulsory licenses—authorizations for government-approved generic copies—so that those in need of the most important new treatments can obtain them at an affordable price.”).

⁶ See Jamie Feldman, Note, *Compulsory Licenses: The Dangers Behind the Current Practice*, 8 J. INT’L BUS. & L. 137, 149 (2009) (“High, middle, and low-income nations have all issued health related compulsory licenses.”).

⁷ See Mark D. Penner & Peter G. Armstrong, *Removing Barriers? An Overview of the Canadian Access to Medicines Regime*, 21 I.P.J. 357, 360 (2009).

⁸ See Jessica L. Greenbaum, Comment, *TRIPs and Public Health: Solutions for Ensuring Global Access to Essential AIDS Medication in the Wake of the Paragraph 6 Waiver*, 25 J.

Despite this example, the Canadian Access to Medicines Regime (“CAMR”),⁹ Canada’s compulsory licensing scheme, is underutilized.¹⁰ Recently, Bill C-393,¹¹ in the Canadian House of Commons and its complementary bill in the Senate, Bill S-232,¹² were brought before the Canadian Parliament. These bills propose to streamline the implementation of CAMR.¹³

This paper highlights the significant changes to CAMR proposed by this recent legislation. These changes reflect an attempt to remedy the problems of the current regime, but in doing so they create broader rights that are not compliant with the Agreement on Trade-Related Aspects of Intellectual Property Rights¹⁴ (TRIPs Agreement).¹⁵ Section II of this paper discusses the international

CONTEMP. HEALTH L. & POL’Y 142, 151 (2008) (“Although ninety percent of those infected with the HIV/AIDS virus live in developing countries, almost eighty percent of these countries do not have the means necessary to produce anti-retroviral drugs.”).

⁹ The CAMR is part of the Canadian Patent Act and also references the Canadian Food and Drugs Act. Canadian Patent Act, R.S.C., ch. P-4, §§ 21.01-21.2 (1985), available at http://laws.justice.gc.ca/eng/P-4/page-6.html#anchorbo-ga:s_21_01; Canadian Food and Drugs Act, C.R.C., ch. 870, §§ C.01.001-C.09.035 (2009), available at http://laws.justice.gc.ca/eng/F-27/page-2.html#anchorbo-ga:l_II-gb:s_37.

¹⁰ See George Tsai, Note, *Canada’s Access to Medicines Regime: Lessons For Compulsory Licensing Schemes Under the WTO Doha Declaration*, 49 VA. J. INT’L L. 1063, 1080–96 (2009) (discussing shortcomings of the regime). It is possible that such shortcomings have resulted in a lack of use of the regime.

¹¹ Bill C-393, *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 2d Sess., 40th Parl., 2009, (1st reading 25 May 2009), <http://www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=4329904&Language=e&Mode=1>.

¹² Bill S-232, *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 2d Sess., 40th Parl., 2009, http://www.parl.gc.ca/content/Senate/Bills/402/public/S-232/S-232_1/S-232_text-e.htm.

¹³ See *House of Commons Debates* (12 June 2009) (Ms. Judy Wasylycia-Leis) (Can.), <http://www.parl.gc.ca/HousePublications/Publication.aspx?Pub=journals&Mode=1&Parl=40&Ses=2&Language=E&DocId=3987263&File=0#Int-2833462> [hereinafter *Debates*, Wasylycia-Leis].

¹⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of Uruguay Round, 1869 U.N.T.S. 299, 33 I.L.M. 1125, 1197–1225, [hereinafter TRIPs Agreement].

¹⁵ See *House of Commons Debates* (12 June 2009) (Mr. Marc Garneau) (Can.), <http://www2.parl.gc.ca/HousePublications/Publication.aspx?Pub=journals&Mode=1&Parl=40&Ses=2&Language=E&DocId=3987263&File=0#Int-2833462> [hereinafter *Debates*, Garneau] (suggesting that the proposed legislation may not be compliant with the TRIPs Agreement). While Mr. Garneau discusses TRIPs Agreement compliance issues, he only briefly outlines several areas of concern. This paper takes a closer look at the proposed legislation’s compliance with the TRIPs Agreement, in the context of complaints brought against the current CAMR regime, in order to illustrate why these changes were proposed. In addition, this paper discusses several positive steps taken by the proposed legislation, in contrast to Mr. Garneau’s contentions.

development of compulsory licenses for exportation, including the TRIPs Agreement. Section III provides an overview of Canada's current legislation as well as Canada's experiences under such legislation. As a contrast, India's current compulsory licensing regime is also set out in Section III. Next, Section IV(A) presents the problems encountered under the current Canadian legislation. This Section goes on to show how the proposed legislation's answers to these problems are not compliant with the TRIPs Agreement. However, to dismiss the bill in its entirety would be detrimental to creating a working regime, as several of the amendments reflect positive changes. To illustrate these positive changes, Section IV(B) compares amendments to other nations' legislation. The paper concludes by discussing that while the proposed legislation should not pass as it stands, the positive changes should guide Canada and other nations in creating better medicine regimes.

II. INTERNATIONAL AGREEMENTS AND COMPULSORY LICENSING

Canada's current medicines regime is based on international agreements and declarations, in particular Article 31 of the TRIPs Agreement and the Doha Declaration.¹⁶ Canada must continue to comply with these agreements in any future legislation.¹⁷

Article 31 of the TRIPs Agreement sets out basic provisions addressing compulsory licensing.¹⁸ Provisions include limiting the time and scope of the license,¹⁹ and allowing for adequate remuneration to the rights holder.²⁰ Article 31 also requires the party seeking a compulsory license to negotiate with the patent holder on reasonable commercial terms.²¹ This negotiation requirement

¹⁶ TRIPs Agreement, *supra* note 14, art. 31, at 1209–10; World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration]; *see* Tsai, *supra* note 10, at 1064 (“CAMR is based on and enabled by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights . . . which took effect January 1, 1995, requiring all WTO member nations to meet minimum standards in their laws and practices regarding intellectual property protection.”).

¹⁷ The current CAMR actually goes beyond what is required under the TRIPs Agreement. *See* Greenbaum, *supra* note 8, at 158 (“This voluntary license requirement makes the law even more rigorous than the standards for compulsory licensing.”).

¹⁸ TRIPs Agreement, *supra* note 14, art. 31, at 1209–10.

¹⁹ *Id.* art. 31(c), at 1209.

²⁰ *Id.* art. 31(h), at 1210.

²¹ *Id.* art. 31(b), at 1209:

[S]uch use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of

may be waived in two circumstances: (1) a national emergency or (2) public non-commercial use.²² Article 31 also contains several restrictions on production.²³ These restrictions are the result of tensions between developed and developing nations that were present during the negotiations.²⁴ The tension is notably present in Article 31, subdivision (f), which restricts production predominantly to supply the domestic market.²⁵ This restriction presented a barrier for developing nations that lack adequate manufacturing capabilities.²⁶

World Trade Organization (“WTO”) member countries recognized Article 31(f) as a burden on developing countries when preparing the Doha Declaration.²⁷ The Doha Declaration states that the TRIPs Agreement “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”²⁸ Since Article 31(f) presented a barrier to accessing medicines, the Doha Declaration provided that the TRIPs Council should come up with a solution to the Article 31(f) problem.²⁹

public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.

²² *Id.*

²³ *Id.* art. 31(c), (f), at 1209–10 (stating, for example, that the use shall be noncommercial and limited in scope and duration).

²⁴ Tsai, *supra* note 10, at 1067 (discussing the developed nations stance of greater intellectual property protection, while developing nations “have argued that the strict limitations of the TRIPS Agreement have overly restricted users’ interests in pharmaceutical technology, especially in the context of health crises . . .”).

²⁵ See TRIPs Agreement, *supra* note 14, art. 31(f), at 1210.

²⁶ See Tsai, *supra* note 10, at 1068 (discussing how Article 31(f) presented significant barriers to developing countries because those with manufacturing capacity cannot recoup production costs through exportation and those countries without manufacturing capacity cannot import drugs from manufacturing countries).

²⁷ Doha Declaration, *supra* note 16, ¶ 1.

²⁸ *Id.* ¶ 4.

²⁹ *Id.* ¶ 6:

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 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.

In response, the TRIPs Council rendered a decision in 2003 (2003 Council Decision).³⁰ The Decision stated that certain countries are eligible to import pharmaceuticals under a compulsory license.³¹ Eligible countries include least developed nations, and nations under certain emergency or other limited circumstances.³² The Decision also emphasized the narrow scope of the license³³ and implemented certain procedural requirements. For example, the TRIPs Council must be notified when the importing and exporting countries decide to use a compulsory license.³⁴ Other requirements regulate special packaging³⁵ and state that remuneration to the patent holder only needs to be paid by one of the countries.³⁶

³⁰ Council for Trade-Related Aspects of Intellectual Property Rights, *Decision of the General Council: Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health*, WT/L/540 (Aug. 30, 2003) (on file with author), http://www.wto.org/english/tratop_e/trips_e/implement_para6_e.htm [hereinafter 2003 Council Decision].

³¹ *Id.* ¶ 1(b).

³² *See id.*

³³ *See id.* ¶ 2(b)(i) (noting that the compulsory license should be for “only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the license and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPs . . .”).

³⁴ *See id.* ¶ 2(a) (providing that the importing member must notify the TRIPs Council); *Id.* ¶ 2(c) (providing that the exporting member must notify the TRIPs Council).

³⁵ *Id.* ¶ 2(b)(ii):

Products produced under the license shall be clearly identified as being produced under the system set out in this Decision through specific labeling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price.

Id. ¶ 2(b)(iii) (“[B]efore shipment begins, the licensee shall post on a website . . . the following information: the quantities being supplied to each destination as referred to in indent (i) above; and the distinguishing features of the product(s) referred to in indent (ii) above . . .”).

³⁶ *Id.* ¶ 3:

Where a compulsory license is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPs Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory license is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

In addition to the Doha Declaration and the 2003 Council Decision, WTO member nations have debated implementing Article 31bis.³⁷ Article 31bis is an amendment to the TRIPs Agreement that would replace the 2003 Council Decision.³⁸ Article 31bis would provide a specific regime for the exportation of pharmaceuticals under a compulsory license.³⁹ As of the date of this paper the amendment is pending, needing the approval of two thirds of the WTO's membership.⁴⁰ WTO members have until December 31, 2011 to approve the amendment.⁴¹ The United States was the first to accept Article 31bis on December 17, 2005.⁴² Other countries later followed suit including India and Canada.⁴³ Despite the fact that it has not been sufficiently approved, Article 31bis is the subject of much criticism and political discussion. Pharmaceutical companies lobby against it because of concerns of re-importation.⁴⁴ Even proponents of compulsory legislation criticize Article 31 bis for being too complex.⁴⁵

Many countries have implemented a compulsory licensing exportation regime based on Article 31 of the TRIPs Agreement, the Article 31bis amendment and the Doha Declaration, including China,⁴⁶ India⁴⁷ and Canada,⁴⁸ with the notable

³⁷ Press Release, World Trade Organization, Members OK Amendment to Make Health Flexibility Permanent (Dec. 6, 2005), http://www.wto.org/english/news_e/pres05_e/pr426_e.htm.

³⁸ Decision of the General Council, *Amendment of the TRIPs Agreement*, WT/L/641 (Dec. 6, 2005), available at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm. The specific text of Article 31bis can be found in the Annex to the Protocol Amending the TRIPs Agreement section of the amendment.

³⁹ *See id.*

⁴⁰ World Trade Organization, Members Accepting Amendment of the TRIPs Agreement, http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last updated Feb. 8, 2010).

⁴¹ *Id.*

⁴² *Id.*

⁴³ *See id.*

⁴⁴ *See* Posting of Shamnad Basheer to Spicy IP, <http://spicyipindia.blogspot.com/2008/01/doha-style-compulsory-licenses-for.html> (Jan. 31, 2008, 18:40 IST) (stating that pharmaceutical companies are concerned that the compulsory licensing regime will harm their full-price sales, through political pressure and re-sales from the original countries of importations).

⁴⁵ *See id.* (noting that proponents of compulsory licensing have criticized the WTO licensing regime as time consuming and expensive).

⁴⁶ She Ji Gong Gong Jian Kang Wen Ti de Zhuan li Shi Shi Qiang Zhi Xu Ke Zheng Ban Fa (Di 37 Hao) [Relating to Public Health Issues, the Implementation of Compulsory Licensing of Patented Method (Order No. 37)] (promulgated by the State Intellectual Prop. Office, Nov. 29, 2005, effective Jan. 1, 2006).

⁴⁷ The Patents (Amendment) Act, No. 15 of 2005; INDIA CODE (2005), available at <http://indiacode.nic.in/>.

⁴⁸ Canadian Patent Act, R.S.C., ch. P-4, §§ 21.01-21.2 (1985), available at http://laws.justice.gc.ca/eng/P-4/page-6.html#anchorbo-ga:s_21_01.

exception of the United States.⁴⁹ Canada and India are the only countries in which compulsory licensing for exportation has been attempted.⁵⁰

III. CURRENT IMPLEMENTATION AND USAGE OF THE COMPULSORY LICENSING EXPORTATION REGIME

In this section, Canada's and India's compulsory licensing regimes, and their experiences under each regime, are compared. On a spectrum of compulsory licensing provisions, Canada—at one extreme—is too complex, while India—at the other extreme—is too vague.⁵¹

A. Complexities in the Current Canadian Access to Medicines Regime

The Canadian government developed CAMR in 2005, amending both the Canadian Patent Act⁵² and the Canadian Food & Drugs Act.⁵³ The amendment to the Patent Act identifies who can apply for a compulsory license, the application process, royalty requirements and grounds for termination of the license.⁵⁴ The application process is complex.⁵⁵ For example, the applicant must negotiate with the patent holder for at least thirty days before applying.⁵⁶ In addition, the application itself has numerous requirements.⁵⁷ CAMR also allows the patent

⁴⁹ In 2006, Senator Patrick Leahy (D-VT) introduced Senate Bill No. 3175: Life-Saving Medicines Export Act of 2006 to Congress. S. 3175, 109th Cong. (2006). The bill would have amended Title 35 of the U.S. Code to grant the exportation of patented pharmaceuticals under a compulsory license. The bill was referred to the Senate Judiciary Committee, but never became law. Govtrack.us, S. 3175: Life-Saving Medicines Export Act of 2006, <http://www.govtrack.us/congress/bill.xpd?bill=s109-3175> (last visited Mar. 28, 2010) (emphasizing the bill was not passed after two readings to Congress and was then referred to the Senate Committee on the Judiciary).

⁵⁰ See Emily Ng & Jillian C. Kohler, *Finding Flaws: the Limitations of Compulsory Licensing for Improving Access to Medicines—an International Comparison*, 16 HEALTH L.J. 143, 163–69 (2008).

⁵¹ See *id.*

⁵² Canadian Patent Act, R.S.C., ch. P-4, §§ 21.01-21.2.

⁵³ Canadian Food and Drugs Act, C.R.C., ch. 870, §§ C.01.001-C.09.035 (2009), http://laws.justice.gc.ca/eng/F-27/page-2.html#anchorbo-ga:l_II-gb:s_37.

⁵⁴ See Canadian Patent Act, R.S.C., ch. P-4, §§ 21.01-21.2. Schedules 2, 3 and 4 lay out which countries are eligible importers and Section 21.03(1) permits Schedule amendments subject to certain criteria. The application process is discussed in Section 21.04. The royalty requirements are set out in Section 21.08. The termination of the license is set out in Sections 21.13 and 21.14.

⁵⁵ See Paige E. Goodwin, *Right Idea, Wrong Result—Canada's Access to Medicines Regime*, 34 AM. J.L. & MED. 567, 573 (2008).

⁵⁶ See Canadian Patent Act, R.S.C., ch. P-4, § 21.04(3)(c); relevant language, *infra* APPENDIX, at 151.

⁵⁷ See Canadian Patent Act, R.S.C., ch. P-4, § 21.04(2); relevant language, *infra* APPENDIX, at 150–51.

holder to litigate the amount of royalty payments.⁵⁸ Allowing for litigation surrounding royalty payments creates uncertainty with respect to the application process.⁵⁹

Some of the requirements in the current CAMR go beyond what the TRIPs Agreement requires. For example, CAMR sets a two-year time limit to the license⁶⁰ whereas the TRIPs Agreement requires only that the license be limited in duration.⁶¹ Also, CAMR provides a schedule of which pharmaceuticals can be licensed.⁶² In contrast, the TRIPs Agreement does not require defining specific pharmaceuticals that can be produced under a license,⁶³ but instead the TRIPs Council defined pharmaceutical products broadly in their 2003 Council Decision.⁶⁴

A Canadian government commissioned review of CAMR was published in May 2007.⁶⁵ The review included information from various stakeholders from pharmaceutical manufacturers to non-governmental organizations (“NGOs”).⁶⁶ Manufacturers of predominantly patented brand name pharmaceuticals, referred to as the “innovative pharmaceutical industry” throughout the report, believed that many of the CAMR provisions were necessary to adequately protect their rights.⁶⁷ In contrast, NGOs and manufacturers of predominantly generic pharmaceuticals (“generic companies”) had many suggestions for changing CAMR. For instance, NGOs called for a broadening of the—definition of pharmaceuticals,⁶⁸ and both NGOs and many generic companies suggested an overhaul of the application

⁵⁸ See Canadian Patent Act, R.S.C., ch. P-4, § 21.08(4); relevant language, *infra* APPENDIX, at 152.

⁵⁹ See Penner & Armstrong, *supra* note 7, at 373.

⁶⁰ See Canadian Patent Act, R.S.C., ch. P-4, § 21.09; relevant language, *infra* APPENDIX, at 152. The two-year time limit may be renewed for another two years pursuant to Section 21.12.

⁶¹ See TRIPs Agreement, *supra* note 14, art. 31(c), at 1209 (“[T]he scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive”); Goodwin, *supra* note 55, at 582 (noting that CAMR goes beyond the TRIPs Agreement with the two-year time limit).

⁶² Canadian Patent Act, R.S.C., ch. P-4, Schedule 1.

⁶³ See TRIPs Agreement, *supra* note 14, art. 31, at 1209-10; Goodwin, *supra* note 55, at 579.

⁶⁴ See 2003 Council Decision, *supra* note 30, ¶ 1(a).

⁶⁵ GOVERNMENT OF CANADA, REPORT ON THE STATUTORY REVIEW OF SECTIONS 21.01 TO 21.19 OF THE PATENT ACT (2007), http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_report_rapport-eng.pdf [hereinafter GOVERNMENT OF CANADA, 2007 REPORT].

⁶⁶ *Id.* at 6.

⁶⁷ See generally *id.* (analyzing the concerns of “innovative pharmaceutical” companies throughout).

⁶⁸ *Id.* at 10 (stating that the list of pre-approved pharmaceutical products eligible for export should be eliminated or broadened in order to better meet the needs of developing countries).

process.⁶⁹ Although all stakeholders unanimously supported the current royalty formula, NGOs and generic companies noted that allowing the patent holder to litigate for additional royalties discouraged uptake of CAMR.⁷⁰ In the end, the report concluded that an overhaul of the current regime was unnecessary.⁷¹

B. Complexities in CAMR as Illustrated by the Canadian/Rwandan Experience

Under CAMR, Canada exported medication to Rwanda using a compulsory license.⁷² Apotex Inc., a Canadian generic pharmaceutical manufacturer, attempted to negotiate a voluntary license with three pharmaceutical companies holding patents to the HIV/AIDS cocktail Apo TriAvir in May 2007.⁷³ After negotiations failed, Apotex applied for and was granted a compulsory license in August 2007.⁷⁴ Both Canada and Rwanda notified the WTO of their intent to use a compulsory license for the drug cocktail, as required by the 2003 Council Decision and the CAMR application.⁷⁵ More than a year after this notification, Rwanda received its first shipment of generic HIV/AIDS drugs.⁷⁶

This example illustrates some of the current problems with CAMR.⁷⁷ First, the cocktail that Apotex wanted to use was not included on CAMR's schedule of drugs.⁷⁸ Thus, Canada first had to amend the schedule.⁷⁹ Second, Apotex faced problems during the CAMR required negotiations, because CAMR did not clearly state what the applicant needed to show.⁸⁰ More than a year elapsed between notification to the WTO and delivery of the drugs, revealing the time consuming nature of CAMR, which stems from its complexities, as discussed above.⁸¹

⁶⁹ See *id.* at 13 (proposing several alternatives to the application process).

⁷⁰ *Id.* at 17.

⁷¹ See GOVERNMENT OF CANADA, 2007 REPORT, *supra* note 65, at 40; Penner & Armstrong, *supra* note 7, at 376 (noting that the Report's conclusion of how "the Government should focus on non-legislative measures" was mainly due to the fact that Rwanda had applied for a compulsory license).

⁷² See Tsai, *supra* note 10, at 1076–80.

⁷³ *Id.* at 1078.

⁷⁴ *Id.* at 1079.

⁷⁵ *Id.*

⁷⁶ See Shipment Record, Apotex, Rwanda: Apo-Triavir, http://www.apotex.com/apotriavir/product/rwanda_shipments.pdf (last visited Apr. 27, 2010); Press Release, Apotex, Second Shipment of Life-Saving Aids Drug Leaving for Africa (Sept. 18, 2009), <http://www.apotex.com/global/about/press/20090918.asp> (stating that a second shipment was sent to Rwanda).

⁷⁷ See Tsai, *supra* note 10.

⁷⁸ See *id.* at 1077.

⁷⁹ *Id.*

⁸⁰ *Id.* at 1078.

⁸¹ See *id.* at 1079.

C. Vagueness in India's Current Compulsory Licensing Regime

India amended its patent law to add a compulsory licensing for exportation regime in 2005 through the addition of Section 92A.⁸² The regime is a relatively short provision in comparison to CAMR.⁸³ Section 92A allows for a compulsory license to be given to any country having “insufficient or no manufacturing capacity” under terms set forth by the Indian Controller General of Patents.⁸⁴ Unlike CAMR, the Indian provision does not set out a specific schedule of pharmaceuticals that can be manufactured, but instead gives a broad definition.⁸⁵ In addition, the provision for India does not include certain TRIPs Agreement requirements, such as indicating the amount of pharmaceutical product to be produced.⁸⁶ This stands in contrast to CAMR, which provides for such requirements in the application process.⁸⁷ In fact CAMR, as noted above, goes beyond the TRIPs Agreement requirements in certain circumstances.⁸⁸ In contrast to CAMR, the Indian regime is vague because of its broad scope and silence on certain international requirements.⁸⁹

⁸² The Patents (Amendment) Act, 2005, No. 15 of 2005, INDIA CODE (2005), available at <http://indiacode.nic.in/>.

⁸³ *See id.*

⁸⁴ *Id.* §§ 92(A)(1), 92 (A)(2).

⁸⁵ *See id.* (stating that pharmaceutical product is defined as “[A]ny patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use”).

⁸⁶ *See* Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 604 (2007):

[I]n contrast with the TRIPs framework, India's Section 92A is completely silent on any obligation of the Indian government or the compulsory licensee to specify the amount of pharmaceutical products that will be exported, to specially label or mark those products, or make public any information about the export by posting to a website or other means of publication.

⁸⁷ *See* Canadian Patent Act, R.S.C., ch. P-4, §§ 21.01-21.2 (1985), available at http://laws.justice.gc.ca/eng/P-4/page-6.html#anchorbo-ga:s_21_01.

⁸⁸ *See* Greenbaum, *supra* note 8, at 158.

⁸⁹ *See* Ng & Kohler, *supra* note 50, at 166 (discussing ambiguity in the Indian legislation); Mueller, *supra* note 86, at 604 (discussing the Indian provision's silence in respect to certain TRIPs Agreement requirements).

D. Vagueness in Section 92A as Illustrated by the Indian/Nepal Experience

Natco Pharma Ltd., an Indian generic pharmaceutical manufacturer, applied to the Indian government for a compulsory license in September 2007.⁹⁰ The license was requested to produce anti-cancer drugs which would be exported to Nepal.⁹¹ Pfizer, one of the patent holders, challenged the application in the Indian court system, and the court granted Pfizer a hearing.⁹² In September 2008, Natco reportedly withdrew the application.⁹³ Litigation stemming from ambiguities in the Indian regime delayed and possibly resulted in blocking the compulsory license.⁹⁴

Indian and Canadian compulsory licensing schemes are viewed as two extremes in a spectrum of licensing provisions.⁹⁵ The Indian provision can be viewed as too vague, and the fact that Natco withdrew the application is an indication of this.⁹⁶ On the other hand, the Canadian regime has been criticized as too complex.⁹⁷ Clearly, reform in this area of patent law is necessary for both legal and policy reasons.

⁹⁰ See Ng & Kohler, *supra* note 50, at 166; see generally Latha Jishnu, *Cancer Drug Puts License, Patent Rules to Test*, BUS. STANDARD, Jan. 16, 2008, <http://www.business-standard.com/india/storypage.php?autono=310813>.

⁹¹ See Posting of Shamnad Basheer to SpicyIP, <http://spicyipindia.blogspot.com/2008/01/roche-vs-natco-indias-first-doha-style.html> (Jan. 16, 2008, 16:44 IST) (noting that the application specified the amount to be produced, which is not a specified requirement under the Indian compulsory licensing provision, Section 92A, but is required under the TRIPs Agreement). This may suggest that while the regime is vague, the implementation of the regime may add clarification, at least in certain areas.

⁹² See Posting of Shamnad Basheer to SpicyIP, <http://spicyipindia.blogspot.com/2008/09/breaking-news-natco-withdraws-doha.html> (Sept. 28, 2008, 23:11 IST).

⁹³ *Id.*

⁹⁴ See *id.* (suggesting that Natco may have withdrawn the application out of fear it would lose on the merits); Ng & Kohler, *supra* note 50, at 168 (noting that it is unclear whether a hearing should be granted to the patent holders, as the Indian provision, Section 92A, does not specify that this is a right granted under the regime).

⁹⁵ See, e.g., Ng & Kohler, *supra* note 50, at 163–69.

⁹⁶ See generally *id.* (discussing the vagueness of the Indian regime).

⁹⁷ News Release, Jack Kay, President and COO, Apotex, The Apotex Experience with Canada's Access to Medicines Regime (Apr. 23, 2007), http://www.canadiangenerics.ca/en/news/apr_23_07_kay.asp [hereinafter Kay]. This was a presentation by Jack Kay to the Canadian House of Commons Standing Committee on Industry, Science and Technology.

IV. PROPOSED CHANGES TO CAMR

A. *Lack of TRIPS Compliance in the Proposed Changes to CAMR*

This section sets out major changes to CAMR, which propose to streamline the compulsory licensing process.⁹⁸ These changes are in response to criticisms levied against the current CAMR.⁹⁹ The criticisms can be separated into three main categories: complexity, balancing of interests, and lack of incentives. While the proposed amendments address these criticisms, they create a regime that is not compliant with TRIPs Agreement requirements.

1. *Complexity in the Current CAMR Regime*

Apotex Inc., the Canadian generic pharmaceutical manufacturer, discussed problems it had experienced with CAMR before the Canadian House of Commons Standing Committee on Industry, Science and Technology.¹⁰⁰ Apotex President and COO, Jack Kay, noted the complexity of CAMR, stating that the requirements were, “impossible to navigate.”¹⁰¹ The complexity of the current CAMR regime is also echoed by importing countries.¹⁰² Specifically, much of the complexity of the current CAMR regime is based on the application process.¹⁰³ Proposed legislation would repeal several CAMR application requirements.¹⁰⁴ Important changes include deleting the requirement to state the maximum quantity of pharmaceuticals that will be produced,¹⁰⁵ and repealing the need to note information about the version of the pharmaceutical product and information regarding the importing country.¹⁰⁶ Instead, the amended statute would merely require the name of the pharmaceutical product and “any other information that may be prescribed.”¹⁰⁷ In this way, the proposed amendment contains vague language, which may create uncertainty as to what information is necessary in order to apply.

⁹⁸ See *Debates*, Wasylycia-Leis, *supra* note 13, at 1335–40.

⁹⁹ See *id.*

¹⁰⁰ See Kay, *supra* note 97.

¹⁰¹ *Id.*

¹⁰² See Christina Cotter, *The Implications of Rwanda’s Paragraph 6 Agreement with Canada for Other Developing Countries*, 5 LOY. U. CHI. INT’L. L. REV. 177, 187 (2008).

¹⁰³ See Goodwin, *supra* note 55, at 582–83.

¹⁰⁴ See Bill C-393, *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 2d Sess., 40th Parl., 2009, <http://www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=4329904&Language=e&Mod e=1>. Paragraph 4(2) would revise Section 21.04(2) of the Canadian Patent Act. See relevant language, *infra* APPENDIX, at 150–51.

¹⁰⁵ See *id.*

¹⁰⁶ See *id.*

¹⁰⁷ *Id.*

Thus, the proposed amendment would move CAMR's application closer toward the Indian side of the spectrum. As with the Indian provision, vague language in the CAMR provision may raise speculation on whether it is compliant with international agreements.¹⁰⁸ In particular, the amendments to CAMR would delete the requirement to state the maximum quantity of pharmaceuticals that would be produced under the license.¹⁰⁹ The 2003 Council Decision states that the importing country should notify the TRIPs Council of the expected quantity of the product.¹¹⁰ The TRIPs Council stated that a compulsory license shall be issued for "only the amount necessary to meet the needs of the eligible importing Member(s)"¹¹¹ Therefore, by deleting the need to state the maximum quantity of pharmaceuticals to be produced, the proposed amendment is not compliant with the TRIPs Agreement.¹¹² Still, the implementation of the proposed changes may clarify compliance. For example, application materials, including forms, are currently available on the CAMR website.¹¹³ If the Canadian government decides to continue this practice after the passage of the amendments, such materials may provide some clarity. However, as the proposed amendment is written, compliance with the TRIPs Agreement requirements is not guaranteed.

The proposed amendments to CAMR would also change the conditions for granting a compulsory license. Currently, the negotiating provision in CAMR requires a thirty day mandatory negotiation period with the patent holder.¹¹⁴ The proposed amendment would replace this requirement, stating that a compulsory license will be granted, "if the applicant has complied with the prescribed requirements."¹¹⁵ Again, the amendment appears to move CAMR towards the

¹⁰⁸ See Mueller, *supra* note 86, at 605 (noting India's Section 92A's silence on certain parts of the TRIPs Agreement compulsory licensing framework may raise questions as to its compliance). In addition to raising speculation about compliance, the creation of a vague provision may also lead to uncertainty in the application process, as illustrated by the Nepal/India example. See Ng & Kohler, *supra* note 50, at 166–69.

¹⁰⁹ See Bill C-393, 40th Parl. Paragraph 4(2) would revise Section 21.04(2) of the Canadian Patent Act. See relevant language, *infra* APPENDIX, at 150–51.

¹¹⁰ See 2003 Council Decision, *supra* note 30, ¶¶ 2(a)(i), 2(b)(i).

¹¹¹ *Id.* ¶ 2(b)(i).

¹¹² See *Debates*, Garneau, *supra* note 15, at 1350.

¹¹³ Government of Canada, Canadian Access to Medicines Regime, Forms, http://www.camr-rcam.gc.ca/doc/form/index_e.html (last visited Mar. 28, 2010).

¹¹⁴ See Canadian Patent Act, R.S.C., ch. P-4, § 21.04(3)(c) (1985), available at http://laws.justice.gc.ca/eng/P-4/page-6.html#anchorbo-ga:s_21_01; relevant language, *infra* APPENDIX, at 151–52.

¹¹⁵ See Bill C-393, *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 2d Sess., 40th Parl., 2009, ¶ 4(3), (1st reading 25 May 2009), <http://www2.parl.gc.ca/HousePublications/Publication.aspx?>

Indian side of the spectrum.¹¹⁶ The vague language in the provision again raises questions about the adequacy of CAMR meeting international agreements.¹¹⁷ TRIPs Article 31 allows for a waiver of the negotiation requirement, “in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.”¹¹⁸

A general repeal of the negotiation requirement, along with repeal of a specific schedule of pharmaceuticals, leads to a waiver greater in scope than allowed by the TRIPs Agreement.¹¹⁹ In this respect, the proposed amendment could be seen as the opposite of current CAMR legislation. The current CAMR goes beyond what is required in the TRIPs Agreement, by requiring a negotiation period of thirty days, with no option for a waiver.¹²⁰ The proposed amendment would not only repeal the mandatory negotiation period, but would not require any negotiation whatsoever.¹²¹ Therefore, while the proposed repealing of the negotiation provision may be an effort to lessen the complexity of the current CAMR regime, it may go too far, leading to questions of compliance.¹²²

2. *Balancing of Interests*

Apotex Inc. also criticized¹²³ CAMR for attempting to balance the interests of large, brand name pharmaceutical companies to the detriment of the regime.¹²⁴ For example, the current CAMR allows for the patent holder to litigate for an

DocId=4329904&Language=e&Mode=1. Paragraph 4(3) would revise Section 21.04(3) of the Canadian Patent Act. See relevant language, *infra* APPENDIX, at 151–52.

¹¹⁶ Compare Bill C-393, 40th Parl. (proposing changes to CAMR), with The Patents (Amendment) Act, 2005, No. 15 of 2005; INDIA CODE (2005), available at <http://indiacode.nic.in/> (where Section 92A mirrors the language of the proposed changes in Bill C-393).

¹¹⁷ See Mueller, *supra* note 86, at 603 (noting how India’s Section 92A’s silence regarding certain parts of the TRIPs Agreement compulsory licensing framework may raise questions as to its compliance). The proposed amendment would leave CAMR silent on certain TRIPs Agreement requirements, leading to similar questions. In fact, questions have been raised during the reading of the bill in the Canadian House of Commons. See *Debates*, Garneau, *supra* note 15, 1350.

¹¹⁸ TRIPs Agreement, *supra* note 14, art. 31(b), at 1209.

¹¹⁹ See *Debates*, Garneau, *supra* note 15, 1350.

¹²⁰ See Canadian Patent Act, R.S.C., ch. P-4, § 21.04(3)(c) (1985), available at http://laws.justice.gc.ca/eng/P-4/page-6.html#anchorbo-ga:s_21_01; relevant language, *infra* APPENDIX, at 152.

¹²¹ See Bill C-393, 40th Parl. Paragraph 4(3) would revise Section 21.04(3) of the Canadian Patent Act. See relevant language, *infra* APPENDIX, at 151.

¹²² See *Debates*, Garneau, *supra* note 15, at 1350.

¹²³ See GOVERNMENT OF CANADA, 2007 REPORT, *supra* note 65, at 18–19 (stating similar criticisms by NGOs and generic companies at the time of CAMR’s 2007 review).

¹²⁴ Kay, *supra* note 97.

increase in royalties.¹²⁵ The proposed bills would repeal the section of CAMR which allows for the Canadian Federal Court to determine a larger royalty.¹²⁶ This proposed legislation may indicate a change in balancing these interests. Repealing the patent holders' right to litigate for increased royalties would decrease uncertainty in the application process brought by the possibility of litigation.¹²⁷

However, repealing these requirements may render the amended CAMR non-compliant with TRIPs Agreement requirements.¹²⁸ Article 31 of the TRIPs Agreement requires that the patent holder receive adequate remuneration and that decisions regarding remuneration be reviewable by the courts or higher authority.¹²⁹ Removing the right of the patent holder to litigate the issue of remuneration removes the review process as required by the TRIPs Agreement.¹³⁰ Therefore, the act of removing the royalty litigation provision, without providing for any other form of review, is not compliant with the TRIPs Agreement.¹³¹

In addition, the pharmaceutical industry would likely argue that removal of this subsection substantially decreases their rights as patent holders. Pressure placed on the importing countries from pharmaceutical companies is one of the major reasons cited for the lack of success of the exportation of pharmaceuticals under compulsory licenses.¹³² Importing countries often depend on donations by developed countries to buy patented medicines from these nations' pharmaceutical companies.¹³³ Decreasing remedies available to the patent holders will likely not do anything to improve their opinion of the compulsory

¹²⁵ See Canadian Patent Act, ch. P-4, § 21.08(4); relevant language, *infra* APPENDIX, at 152.

¹²⁶ Bill C-393, 40th Parl. Paragraph 8(2) would revise Section 21.08(4) of the Canadian Patent Act. See relevant language, *infra* APPENDIX, at 152.

¹²⁷ See Penner & Armstrong, *supra* note 7, at 370 (noting that NGOs and generic companies criticized CAMR for the uncertainty brought to the regime by the royalty and validity provision). By repealing these provisions, the revised CAMR would appear to place emphasis on the applicants rather than on the rights holder.

¹²⁸ *Debates*, Garneau, *supra* note 15.

¹²⁹ See TRIPs Agreement, *supra* note 14, arts. 31(h), at 1210 (“[T]he right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization); 31(j), at 1210 (“[A]ny decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member....”).

¹³⁰ See *Debates*, Garneau, *supra* note 15.

¹³¹ *Id.*

¹³² Cotter, *supra* note 102, at 187.

¹³³ See *id.* (quoting a health activist discussing the pressure from pharmaceutical companies, “[i]f I’m sitting here, and I’m in Malawi, and I’ve got \$200 million annually from the U.S. for drugs as long as I buy patented drugs, do you think I’m going to thumb my nose at that? It’s part of the bigger architecture”).

licensing scheme, and applicants may feel additional pressure not to use the regimes.

3. *Lack of Incentives*

Another criticism of CAMR is the lack of incentives it provides for generic companies.¹³⁴ The proposed legislation deals with one aspect of incentives: it allows generic companies to practice economies of scale.¹³⁵ Under the proposed amendment to the application process, the application no longer has to state the maximum amount of product that will be produced.¹³⁶ In addition, the time period requirement, which is currently a two-year term of production, which can be extended for another two years, would also be repealed.¹³⁷ Therefore, generic manufacturers would potentially be able to produce a larger amount of medication at a lower cost to themselves and the respective importing country.¹³⁸

However, repealing the requirement to specify the maximum amount of pharmaceuticals to be produced and the time limit may lead to questions about the scope of the license. Article 31, subdivision (c) of the TRIPs Agreement provides that a compulsory license should be limited in both scope and duration.¹³⁹ By not providing for a time limit,¹⁴⁰ or for an amount of pharmaceuticals that can be

¹³⁴ See *id.* at 187–88.

¹³⁵ See Brook K. Baker, *Arthritic Flexibilities: Analysis of WTO Action Regarding Paragraph 6 of Doha Declaration on the TRIPs Agreement and Public Health*, 14 *IND. INT'L & COMP. L. REV.* 613, 703 (2004) (describing economies of scale as important to the generics industry):

Economies of scale can be viewed from the perspective of either the producer or the purchaser. From a producer perspective, increased production distributes fixed costs over a greater number of units, thereby reducing overall costs per unit. Thus, the more that is produced and sold to consumers, the lower the average cost of producing that unit. This acts as an incentive for producers to manufacture more units. The purchaser benefits from economies of scale along the same premise, as purchasing more units decreases the per-unit cost. Think of it as buying in bulk.

See also Mike Gumbel, *Is Article 31bis Enough? The Need to Promote Economies of Scale in the International Compulsory Licensing System*, 22 *TEMP. INT'L & COMP. L.J.* 161, 172 (2008).

¹³⁶ Bill C-393, *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 2d Sess., 40th Parl., 2009, (1st reading 25 May 2009), available at <http://www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=4329904&Language=e&Mode=1>. Paragraph 4(2) would revise Section 21.04(2) of the Canadian Patent Act. See relevant language, *infra* APPENDIX, at 150–51.

¹³⁷ Bill C-393, 40th Parl. Paragraph 9 would revise Section 21.09 of the Canadian Patent Act. See relevant language, *infra* APPENDIX, at 152.

¹³⁸ See Gumbel, *supra* note 135, at 172.

¹³⁹ TRIPs Agreement, *supra* note 14, art. 31(c), at 1209; *Debates*, Garneau, *supra* note 15.

¹⁴⁰ The Indian legislation similarly does not provide for a time limit; however Section 92A(2) provides that the Controller will grant a license, “under such terms and conditions as may be

produced, the proposed amendment would, in my opinion, significantly broaden the scope of the license. Such a broad scope would not comport with the TRIPs Agreement.¹⁴¹

Although the proposed changes to CAMR attempt to remedy complaints levied at the current regime by NGOs and generic companies, the proposed changes remove much of the language from the current provisions, leading to a license that is broader in scope. In fact, the scope of the amended provisions would be so broad as to render them noncompliant with the TRIPs Agreement.¹⁴²

B. Positive Proposed Changes to CAMR

While many changes to CAMR broaden the scope of the compulsory license to a point that is not compliant with the TRIPs Agreement, several proposed amendments reflect positive changes. This section compares these changes to other nations' compulsory licensing legislation and suggests that other countries should consider their implementation.

For example, the proposed amendment takes a positive step in broadening the definition of pharmaceuticals.¹⁴³ The proposed legislation would change the definition of pharmaceutical products eligible for the license from those listed in Schedule 1.¹⁴⁴ The proposed legislation would define pharmaceuticals as, "any drug, as defined in section 2 of the Food and Drugs Act, and includes monitoring products and products used in conjunction with a pharmaceutical product."¹⁴⁵ In addition, the proposed amendment would allow for the manufacture of active ingredients.¹⁴⁶ The 2003 Council Decision stated that active ingredients should be included in a definition of pharmaceutical products; however it also included diagnostic kits.¹⁴⁷ While it is unclear whether or not the proposed amendment

specified and published by him." The Patents (Amendment) Act, No. 15 of 2005, § 92A(2); INDIA CODE (2005), available at <http://indiacode.nic.in/>.

¹⁴¹ See *Debates*, Garneau, *supra* note 15.

¹⁴² *Id.*

¹⁴³ *But see Debates*, Garneau, *supra* note 15 (criticizing the repealing of Schedule 1 of CAMR—the list of eligible pharmaceuticals to be produced—as rendering Canada in “default of its international trade treaty obligations under the TRIPs agreement.”).

¹⁴⁴ Canadian Patent Act, R.S.C., ch. P-4, Schedule 1 (1985), available at <http://laws.justice.gc.ca/eng/P-4/page-20.html#anchors:1>.

¹⁴⁵ Bill C-393, *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 2d Sess., 40th Parl., 2009, ¶ 2 (1st reading 25 May 2009), available at <http://www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=4329904&Language=e&Mode=1>. Paragraph 2 would revise Section 21.02 of the Canadian Patent Act. See relevant language, *infra* APPENDIX, at 148.

¹⁴⁶ See Bill C-393, 40th Parl. Paragraph 4(1) would revise Section 21.04(1.1) of the Canadian Patent Act. See relevant language, *infra* APPENDIX, at 148.

¹⁴⁷ See 2003 Council Decision, *supra* note 30, ¶ 1(a):

would include diagnostic kits,¹⁴⁸ broadening the definition of pharmaceuticals can be seen as a positive step, embodying the spirit of the 2003 Council Decision.

The European Union (EU) and the Republic of Korea, have already implemented flexible definitions that include active ingredients and diagnostic kits.¹⁴⁹ A broad, flexible definition of pharmaceutical products is critical in providing for better access to medicines, as illustrated by Apotex's experiences under the current CAMR. Apotex had difficulty with obtaining a compulsory license under the current CAMR because the desired pharmaceuticals were not included on Schedule 1, the list of approved pharmaceuticals of CAMR.¹⁵⁰ Because providing better access to medicines is a vital purpose of the Doha Declaration,¹⁵¹ countries should provide for a broad definition of pharmaceutical products to allow for such access.¹⁵² The proposed legislation clearly broadens the definition of pharmaceuticals, and is thus a positive step.

Furthermore, another positive change that the proposed legislation presents is redefining which countries are eligible to apply for a compulsory license under CAMR. Under the proposed legislation, eligible parties would be countries recognized by the United Nations as least developed countries, or named by the Organisation for Economic Co-operation and Development ("OECD") as eligible for official development assistance.¹⁵³ The current CAMR, in discussing eligible

'pharmaceutical product' means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included

¹⁴⁸ While diagnostic kits are not specifically mentioned in the proposed definition, the amended definition would include, "products used in conjunction with a pharmaceutical product." Bill C-393, ¶ 2. This could possibly be construed as a diagnostic kit. Paragraph 4(1) would revise Section 21.04(1.1) of the Canadian Patent Act.

¹⁴⁹ Council Regulation 816/2006, art. 2(1), 2006 O.J. (L 157) 1 (EC), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:157:0001:0007:EN:PDF>; Republic of Korea Patent Act (amended 2005), No. 950, art. 107(8), available at <http://lists.essential.org/pipermail/ip-health/2005-November/008728.html>.

¹⁵⁰ See Tsai, *supra* note 10, at 1077.

¹⁵¹ Doha Declaration, *supra* note 16, ¶ 3, at 746.

¹⁵² See Ng & Kohler, *supra* note 50, at 155 (suggesting that the best definition of pharmaceutical products is "Norway's Regulations, section 108, which define 'pharmaceutical products' as those 'covered by paragraph 1 (a) of the General Council Decision.'").

¹⁵³ Bill C-393, *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 2d Sess., 40th Parl., 2009, 3(1) (1st reading 25 May 2009), available at <http://www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=4329904&Language=e&Mode=1>. Paragraph 3(1) would revise Section 21.03(1) of the Canadian Patent Act. See relevant language, *infra* APPENDIX, at 148.

participants in the regime, distinguishes between countries that are members of the WTO and those that are not.¹⁵⁴ The proposed amendment would remove this distinction.¹⁵⁵ This change would put CAMR more in line with India's legislation.¹⁵⁶ India has been praised for not making this distinction.¹⁵⁷ In contrast, the Republic of Korea's law requires a showing of "insufficient or no manufacturing capacity" of non-WTO members who are not least developed nations, essentially requiring more of non-WTO member countries.¹⁵⁸

While the 2003 Council Decision discusses importing countries as "eligible importing Member,"¹⁵⁹ India and the EU have not limited their compulsory licensing provisions to WTO member nations.¹⁶⁰ In addition, civil society advocates argue that the 2003 Council Decision does not limit nations in choosing to provide for exportation to non-WTO member nations.¹⁶¹ Because access to medicines is considered part of the fundamental right to human health by the General Assembly of the United Nations, distinctions should not be created with respect to a nation's WTO membership status.¹⁶² Thus, the proposed legislation's deletion of consideration of a prospective importing nation's WTO status can be seen as a positive step that other countries should consider.

¹⁵⁴ See Canadian Patent Act, R.S.C., ch. P-4, § 21.03(1)(b) (1985), available at http://laws.justice.gc.ca/eng/P-4/page-6.html#anchorbo-ga:s_21_01; relevant language, *infra* APPENDIX, at 148–49.

¹⁵⁵ See Bill C-393, 40th Parl., ¶ 3(1). Paragraph 3(1) would revise Section 21.03(1) of the Canadian Patent Act. See relevant language, *infra* APPENDIX, at 148–49.

¹⁵⁶ The Indian legislation would remain broader, only requiring that a country have insufficient manufacturing capacity. The Patents (Amendment) Act, No. 15 of 2005, § 92A; INDIA CODE (2005), available at <http://indiacode.nic.in/>. In addition, the EU also includes countries named on the OECD Development Assistance Committee's list. Council Regulation 816/2006, art. 4(c), 2006 O.J. (L 157) 1 (EC), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:157:0001:0007:EN:PDF>.

¹⁵⁷ See Ng & Kohler, *supra* note 50, at 153 (noting that access to medicines is a fundamental right that should not be based on WTO membership).

¹⁵⁸ Republic of Korea Patent Act (amended 2005), No. 950, art. 107(7)(ii), available at: <http://lists.essential.org/pipermail/ip-health/2005-November/008728.html>. See Ng & Kohler, *supra* note 50, at 153 (discussing the Korean provision, which requires that non-WTO members must show sufficient evidence of lack of manufacturing capacity and what constitutes sufficient evidence is not clear).

¹⁵⁹ See 2003 Council Decision, *supra* note 30, ¶ 1(b).

¹⁶⁰ See *supra* text accompanying note 155.

¹⁶¹ See Richard Elliot, *Pledges and Pitfalls: Canada's Legislation on Compulsory Licensing of Pharmaceuticals for Export*, 1 INT'L J. INTELL. PROP. MGMT. 94, 104 (2006).

¹⁶² See Ng & Kohler, *supra* note 50, at 151–53.

Another positive proposal broadens the ability of an importing country to re-export the drugs produced under the compulsory license.¹⁶³ This proposed amendment is an implementation of Paragraph 6(i) of the 2003 Council Decision.¹⁶⁴ The implementation of the proposed amendment can be seen as both compliant with the TRIPs Agreement and helpful to incentivize generic companies to use the CAMR regime.¹⁶⁵ A similar provision can also be found in EU legislation.¹⁶⁶ The Dutch and Indian provisions are silent on the issue of re-importation, which may lead to uncertainty among importing nations.¹⁶⁷ Therefore, nations should implement a provision allowing for regional trade of the licensed pharmaceuticals, as suggested by the 2003 Council Decision.

¹⁶³ See Bill C-393, *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 2d Sess., 40th Parl., 2009, ¶ 12(4), (1st reading 25 May 2009), available at <http://www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=4329904&Language=e&Mode=1> (“Paragraph (1)(g) does not apply if a product is exported to a party to a relevant regional trade agreement that is not listed in the Schedule for re-export to parties to the agreement that are listed in the Schedule.”). Paragraph 12(4) would add language to Section 21.14 of the Canadian Patent Act.

¹⁶⁴ 2003 Council Decision, *supra* note 30, ¶ 6(i):

With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: (i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favorable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question

¹⁶⁵ Allowing for re-exportation to regional trading partners allows generic manufactures to practice economies of scale. *See id.*

¹⁶⁶ See Council Regulation 816/2006, art. 10(4), 2006 O.J. (L 157) 1 (EC), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:157:0001:0007:EN:PDF>.

¹⁶⁷ Rijksoctrooiwet 1995 [Patent Act 1995], art. 57(1), Stb. 1995, 51 (Neth.), available at <http://www.cptech.org/ip/health/cl/netherlands-export-rules.html>; The Patents (Amendment) Act, No. 15 of 2005, § 92A; INDIA CODE (2005), available at <http://indiacode.nic.in/>.

V. CONCLUSIONS

In conclusion, Canadian bills C-393 and S-232 attempt to address many of the criticisms of the current CAMR.¹⁶⁸ However, in addressing these concerns, the proposed legislation creates a process that may not be compliant with the TRIPs Agreement.¹⁶⁹ Specifically, the proposed legislation removes certain language in the current CAMR, creating a vague regime that can be compared to the Indian scheme under Section 92A of the Indian Patents Act.¹⁷⁰ The proposed legislation is likely to be contentious with patent holders, as it removes the negotiation requirement and the ability for the patent holder to litigate for increased royalties.

Despite these apparent issues, the proposed legislation puts forward several positive changes that would create a better regime. A broader definition of pharmaceuticals is a positive change that would codify the spirit of the Doha Declaration,¹⁷¹ and incorporate elements of the 2003 Council Decision.¹⁷² Removing the distinction between WTO member nations and non-WTO member nations would increase access to medicines and, therefore, would be in line with the Doha Declaration.¹⁷³ Lastly, allowing an importing country to re-export the licensed pharmaceuticals as part of a regional trade agreement would also be a positive step by directly implementing a provision of the 2003 Council Decision.¹⁷⁴

Taking the above into account, the proposed legislation should not pass as it is currently drafted. However, the Canadian government could try to increase use of CAMR by other means. The 2007 government sponsored review of CAMR discussed efforts of the Canadian government to tackle the issue of access to medicines, including publicizing CAMR.¹⁷⁵ However, Apotex, in discussing their experiences with CAMR, noted that currently CAMR relied on the initiative of generic manufacturers, but that the government should take the lead.¹⁷⁶ The Canadian government may want to rethink their allocation of resources with respect to CAMR. For example, while the Canadian government has raised

¹⁶⁸ See *Debates*, Wasylycia-Leis, *supra* note 13.

¹⁶⁹ See *Debates*, Garneau, *supra* note 15.

¹⁷⁰ The Patents (Amendment) Act, No. 15 of 2005, § 92A; INDIA CODE (2005), available at <http://indiacode.nic.in/>. In creating a vague regime, the proposed legislation may also create problems similar to those experienced by India, that is, litigation surrounding the compulsory licensing applications. See Ng & Kohler, *supra* note 50, at 166.

¹⁷¹ Doha Declaration, *supra* note 16, ¶ 3, at 746.

¹⁷² 2003 Council Decision, *supra* note 30, ¶ 1(a).

¹⁷³ See Doha Declaration, *supra* note 16, ¶ 17, at 748–49.

¹⁷⁴ 2003 Council Decision, *supra* note 30, ¶ 6(i).

¹⁷⁵ See GOVERNMENT OF CANADA, 2007 REPORT, *supra* note 65.

¹⁷⁶ See Kay, *supra* note 97.

awareness of the existence of CAMR, the government could direct more resources towards navigating the complexities of the regime.

While developing nations may be wary of losing donations from pharmaceutical companies, potential importing nations may also want to look at the example of Brazil, which has used the threat of compulsory licensing as leverage to get pharmaceutical companies to lower their prices.¹⁷⁷ Therefore, a developing nation may not even need to complete the CAMR process to obtain better access to pharmaceuticals.

¹⁷⁷ See Greenbaum, *supra* note 8, at 154.

APPENDIX

CURRENT CANADIAN ACCESS TO
MEDICINES REGIME AND PROPOSED AMENDMENTS

Current CAMR ¹⁷⁸	Proposed Amendments: Bill C-393 ¹⁷⁹ and Bill S-232 ¹⁸⁰
<p>21.02 The definitions in this section apply in this section and in sections 21.03 to 21.19.</p> <p>“pharmaceutical product” means any patented product listed in Schedule 1 in, if applicable, the dosage form, the strength and the route of administration specified in that Schedule in relation to the product.</p>	<p>2. Section 21.02 of the Act is replaced by the following:</p> <p>210.02 The definitions in this section apply in sections <u>21.01</u> to <u>21.16</u>. “authorization” means an authorization granted under subsection 21.04(1). <u>“pharmaceutical product” means any drug, as defined in section 2 of the Food and Drugs Act, and includes monitoring products and products used in conjunction with a pharmaceutical product.</u></p>
<p>21.03 (1) The Governor in Council may, by order,</p> <p>[Section (a) not included]</p> <p>(b) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 2 by adding the name of any country recognized by the United</p>	<p>3. (1) Subsections 21.03(1) and (2) of the Act are replaced by the following:</p> <p>21.03 (1) The Governor in Council may, by order, on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend <u>the Schedule to add the name of a country if the country is</u> <u>(a)</u> recognized by the United Nations as being a</p>

¹⁷⁸ Canadian Patent Act, R.S.C., ch. P-4, §§ 21.01-21.2 (1985), available at http://laws.justice.gc.ca/eng/P-4/page-6.html#anchorbo-ga:s_21_01. The current CAMR regime provisions have been edited for brevity, but include all Sections relevant to this paper. The original emphasis remains.

¹⁷⁹ Bill C-393, *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 2d Sess., 40th Parl., 2009, (1st reading 25 May 2009), available at <http://www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=4329904&Language=e&Mode=1>.

¹⁸⁰ Bill S-232, *An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act*, 2d Sess., 40th Parl., 2009, available at http://www.parl.gc.ca/content/Senate/Bills/402/public/S-232/S-232_1/S-232_text-e.htm. The proposed amendments have been edited for brevity but include all passages relevant to this paper. The original emphasis has been left in. Language that is underlined indicates new language to be inserted.

Current CAMR ¹⁷⁸	Proposed Amendments: Bill C-393 ¹⁷⁹ and Bill S-232 ¹⁸⁰
<p>Nations as being a least-developed country that has,</p> <p>(i) if it is a WTO Member, provided the TRIPS Council with a notice in writing stating that the country intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, and</p> <p>(ii) if it is not a WTO Member, provided the Government of Canada with a notice in writing through diplomatic channels stating that the country intends to import pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision, that it agrees that those products will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of that decision;</p> <p>(c) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 3 by adding the name of any WTO Member not listed in Schedule 2 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision; and</p> <p>(d) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 4 by adding the name of</p> <p>(i) any WTO Member not listed in Schedule 2 or 3 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with</p>	<p>least-developed country; <u>or</u> (<i>b</i>) named on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance</p>

Current CAMR ¹⁷⁸	Proposed Amendments: Bill C-393 ¹⁷⁹ and Bill S-232 ¹⁸⁰
<p>the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, or</p> <p>(ii) any country that is not a WTO Member and that is named on the Organization for Economic Co-operation and Development’s list of countries that are eligible for official development assistance and that has provided the Government of Canada with a notice in writing through diplomatic channels</p> <p>(A) stating that it is faced with a national emergency or other circumstances of extreme urgency,</p> <p>(B) specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the country to deal with the emergency or other urgency,</p> <p>(C) stating that it has no, or insufficient, pharmaceutical capacity to manufacture that product, and</p> <p>(D) stating that it agrees that that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision.</p> <p>[Subsection (2) not included]</p>	
<p>This language represents a new Subsection that has no counterpart in the current CAMR.</p>	<p>4. (1) Subsection 21.04(1) of the Act is replaced by the following:</p> <p><u>(1.1) In addition to what is authorized under subsection (1), an authorization under that subsection authorizes the person to</u></p> <p><u>(a) manufacture any active ingredient used in the manufacture of a finished product; and</u></p> <p><u>(b) make, construct and use any patented invention solely for the purpose of manufacturing any active pharmaceutical ingredient used in the manufacture of a finished</u></p>

Current CAMR ¹⁷⁸	Proposed Amendments: Bill C-393 ¹⁷⁹ and Bill S-232 ¹⁸⁰
	<u>product.</u>
<p>21.04(2) The application must be in the prescribed form and set out</p> <p>(a) the name of the pharmaceutical product to be manufactured and sold for export under the authorization;</p> <p>(b) prescribed information in respect of the version of the pharmaceutical product to be manufactured and sold for export under the authorization;</p> <p>(c) the maximum quantity of the pharmaceutical product to be manufactured and sold for export under the authorization;</p> <p>(d) for each patented invention to which the application relates, the name of the patentee of the invention and the number, as recorded in the Patent Office, of the patent issued in respect of that invention;</p> <p>(e) the name of the country or WTO Member to which the pharmaceutical product is to be exported;</p> <p>(f) the name of the governmental person or entity, or the person or entity permitted by the government of the importing country, to which the product is to be sold, and prescribed information, if any, concerning that person or entity; and</p> <p>(g) any other information that may be prescribed.</p>	<p>4.(2) Subsection 21.04(2) of the Act is amended by adding “and” at the end of paragraph (a) and by repealing paragraphs (b) to (f).</p>
<p>21.04 Conditions for granting of authorization</p> <p>(3) The Commissioner shall authorize the use of the patented invention only if</p>	<p>4.(3) Subsection 21.04(3) of the Act is replaced by the following:</p> <p>(3) The Commissioner shall <u>grant an authorization only</u> if the applicant has complied with the prescribed requirements.</p>

Current CAMR ¹⁷⁸	Proposed Amendments: Bill C-393 ¹⁷⁹ and Bill S-232 ¹⁸⁰
<p>(a) the applicant has complied with the prescribed requirements, if any;</p> <p>(b) the Minister of Health has notified the Commissioner that the version of the pharmaceutical product that is named in the application meets the requirements of the Food and Drugs Act and its regulations, including the requirements under those regulations relating to the marking, embossing, labeling [sic] and packaging that identify that version of the product as having been manufactured [subsections (i) and (ii) not included]</p> <p>(c) the applicant provides the Commissioner with a solemn or statutory declaration in the prescribed form stating that the applicant had, at least thirty days before filing the application,</p> <p>(i) sought from the patentee or, if there is more than one, from each of the patentees, by certified or registered mail, a licence to manufacture and sell the pharmaceutical product for export to the country or WTO Member named in the application on reasonable terms and conditions and that such efforts have not been successful, and</p> <p>(ii) provided the patentee, or each of the patentees, as the case may be, by certified or registered mail, in the written request for a licence, with the information that is in all material respects identical to the information referred to in paragraphs (2)(a) to (g); and</p> <p>[Section (d) not included]</p>	
<p>21.08 Federal Court may determine royalty</p> <p>(4) The Federal Court may, in relation to any authorization, make an order providing for the payment of a royalty that is greater than the</p>	<p>8.(2) Subsections 21.08(4) to (7) of the Act are repealed.</p>

Current CAMR ¹⁷⁸	Proposed Amendments: Bill C-393 ¹⁷⁹ and Bill S-232 ¹⁸⁰
royalty that would otherwise be required to be paid under subsection (1).	
21.09 An authorization granted under subsection 21.04(1) is valid for a period of two years beginning on the day on which the authorization is granted.	9. Section 21.09 of the Act is repealed.