

**Canada’s Access to Medicines Regime:  
Lessons for Compulsory Licensing Schemes  
under the WTO Doha Declaration**

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## INTRODUCTION

Canada's Access to Medicines Regime (CAMR) was among the first domestic statutes implementing the World Trade Organization (WTO) 30 August Decision regarding paragraph 6 of the Doha Declaration.<sup>1</sup> CAMR provides a system for pharmaceutical manufacturers to export generic drugs to least developed countries (LDC) and developing nations through compulsory licensing, which is an "authorization granted by a government to a party other than the holder of a patent on an invention to use that invention without the consent of the patent holder."<sup>2</sup> While CAMR aims to balance the commercial interests of current pharmaceutical patent holders with broader humanitarian objectives, the legislation, in its current form, is difficult to use and thus fairly ineffective. The shortcomings of CAMR are evident in the ongoing transaction involving the export of Apo TriAvir, an antiviral cocktail medication used for the treatment of HIV/AIDS, by Apotex—a Canadian generic pharmaceutical manufacturer—to Rwanda.<sup>3</sup>

CAMR is based on and enabled by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which took effect January 1, 1995, requiring all WTO member nations to meet minimum standards in their laws and practices regarding intellectual property protection.<sup>4</sup> The TRIPS Agreement allows for the grant of compulsory licenses to combat national health emergencies or other circumstances of extreme urgency. The scope of this compulsory licensing power was more clearly defined in both the Doha Declaration in 2001 and the Decision of the WTO General Council of 30 August 2003

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1. Holger P. Hestermeyer, *Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines*, 11 ASIL INSIGHT, Dec. 2007, at <http://www.asil.org/insights071210.cfm>.

2. UN CONF. ON TRADE & DEV. & INT'L CENTRE FOR TRADE & SUSTAINABLE DEV., RESOURCE BOOK ON TRIPS AND DEVELOPMENT 461 (2005) [hereinafter TRIPS RESOURCE BOOK].

3. 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, 185–88 (2008).

4. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS].

implementing paragraph 6 of the Doha Declaration.<sup>5</sup> The 30 August Decision allows for the granting of compulsory licenses to generic manufacturers in developed nations, such that the manufacturer may export a generic licensed drug to a specified importing nation. The Decision, however, contains numerous provisions limiting the grant of a compulsory license and receipt of a licensed drug.

This Note discusses the international law backdrop for the enactment of CAMR and focuses specifically on the terms of the 30 August Decision in the context of the limits it places on the CAMR legislation. The CAMR legislation will be treated as a case study illustrating the potential pitfalls of compulsory licensing legislation passed pursuant to the 30 August Decision. By examining CAMR, this Note attempts to illuminate problems that future legislation implementing the Decision should avoid. This Note focuses on the practical problems that the CAMR legislation presents to generic manufacturers seeking to obtain a generic license under its terms and proposes possible solutions to address these difficulties. In general, I argue that in order for CAMR to have a practical impact, there must be greater commercial incentives for generic manufacturers to take advantage of CAMR's compulsory licensing provisions.

This Note also addresses various policy concerns with the scope of both the CAMR legislation and the 30 August Decision. I argue that in order for the 30 August Decision to enable effective compulsory licensing that meets the humanitarian aims of the TRIPS Agreement, the restrictions on qualifying as an eligible importing nation under the Decision's compulsory licensing regime must be relaxed. With regard to the scope of pharmaceutical products covered under the CAMR legislation, I argue that the exhaustive list of eligible pharmaceutical products in CAMR should be expanded to match the broad definition of eligible pharmaceutical products in the 30 August Decision.

Part I discusses the international legal foundations for the CAMR legislation provided by the antecedent TRIPS Agreement. This Part not only illustrates the legal basis for compulsory licensing legislation such as CAMR, but also emphasizes the humanitarian objectives that underlie the purported rationale for CAMR's enactment. Part II discusses Canada's export of Apo TriAvir to Rwanda using a compulsory license

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5. Decision of the General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, ¶ 6, WT/L/540 (Aug. 30, 2003) [hereinafter 30 August Decision]; World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

granted under CAMR. The Rwandan transaction is a paradigmatic case of the inefficiencies of the CAMR legislation. Part III discusses the shortcomings of the current CAMR legislation and proposes possible solutions to improve its effectiveness, in particular the practical business disincentives for generic manufacturers created by the CAMR legislation and the specific policy issues concerning the drafting and terms of the legislation.

I. LEAD UP TO CAMR: ARTICLE 31 OF THE TRIPS AGREEMENT, 2001 DOHA DECLARATION, AND 30 AUGUST 2003 DECISION

The TRIPS Agreement, in conjunction with the Doha Declaration and the 30 August Decision, provides a basic framework in which WTO member nations are allowed to enact compulsory licensing legislation. Under Article 8 of the TRIPS Agreement, “members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health . . . provided that such measures are consistent with the provisions of this Agreement.”<sup>6</sup> Permission to legislate to protect public health was affirmed by the WTO in the Doha Declaration in more explicit terms: “[W]e affirm that the 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*.”<sup>7</sup>

While the 30 August Decision implementing paragraph 6 of the Doha Declaration certainly allows for compulsory licensing legislation, it also serves as a limit on the breadth of such legislation. Therefore, to understand the limitations of a compulsory licensing provision such as Canada’s, it is important to examine the history and negotiations that shaped the 30 August Decision. While, for the most part, the Canadian legislation contains greater limitations on use than the 30 August Decision,<sup>8</sup> the 30 August provisions are by no means lax. The following Section will explore the political process that yielded paragraph 6 of the Doha Declaration, and, ultimately, the compulsory licensing framework created by the 30 August Decision.

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6. TRIPS, *supra* note 4, art. 8.1.

7. Doha Declaration, *supra* note 5, ¶ 4 (emphasis added).

8. Richard Elliot, *Pledges and Pitfalls: Canada’s Legislation on Compulsory Licensing of Pharmaceuticals for Export*, 1 INT’L J. INTELL. PROP. MGMT. 94, 109 (2006) (“The chief defects of Canada’s law on compulsory licensing of pharmaceuticals for export are two-fold: (i) it falls short of fully reflecting the ‘flexibilities’ allowed under WTO law; and (ii) it contains some TRIPS-plus features that undermine its functionality.”).

A. *Negotiation, Politics, and Compromise Behind the WTO  
Compulsory Licensing Provisions*

The United States, the European Union (EU), and Japan pushed for the passage of the TRIPS Agreement, predominately as a means of protecting intellectual property at a time when their knowledge-based industries were becoming increasingly important to the global economy.<sup>9</sup> Disparity of interests and resources between developed nations (those seeking stronger intellectual property (IP) protection) and developing and least developed nations (those seeking freer access to agricultural markets and participation in the WTO trade system) led to the “power politics” that helped establish IP protections in the form of the TRIPS Agreement.<sup>10</sup> It has been hypothesized that the United States employed Section 301 of the U.S. Trade Act of 1974 in conjunction with its bilateral negotiations with developing nations in order to apply trade pressures and sanctions to induce general conformity with U.S. standards of IP protection and acceptance of the TRIPS Agreement.<sup>11</sup>

This difference in bargaining positions and priorities is evident in the context of the shortage of essential medicines in much of the poorer world. Developed countries, in general, have maintained that high levels of IP protection are the best means of increasing access to medicines by promoting investment in research and development, whereas lesser developed countries 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.<sup>12</sup> This divergence

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9. See James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291, 294 (2002); Scott Lucyk, *Patents, Politics and Public Health: Access to Essential Medicines Under the TRIPS Agreement*, 38 OTTAWA L. REV. 191, 212 (2007).

10. Lucyk, *supra* note 9, at 212.

11. PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM 88–90 (2002); Lucyk, *supra* note 9, at 212. Using Section 301, the U.S. Trade Representative could put target countries with “subpar” IP protections on one of three “watch lists” of escalating priority. Countries on the “priority watch list” and the “priority foreign country” watch list are subject to the possibility of trade retaliation and sanctions by the United States. DRAHOS & BRAITHWAITE, *supra*, at 90. Between 1985 and 1992, over ninety Section 301 investigations were initiated. Lucyk, *supra* note 9, at 212. Peter Drahos and John Braithwaite criticize the practice of utilizing the 301 sanctions as a “mechanism of economic coercion.” DRAHOS & BRAITHWAITE, *supra*, at 93.

12. Gathii, *supra* note 9, at 294. Frederick Abbott and Jerome Reichman characterize this divergence between developed and less developed countries with regard to IP priorities as a “push to ever higher levels of protection favoring the owners of existing innovation, with little regard for the needs of future innovators or the general public in access to knowledge and free competition.” Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921, 926 (2007).

of priorities between developed countries on the one hand and developing countries and LDCs on the other hand was evident in the WTO negotiations over compulsory licensing provisions.

This tension reaches back to the drafting of the original compulsory licensing provision in Article 31 of the TRIPS Agreement. Under the Anell Draft, one of several drafts preceding the final TRIPS Agreement in 1995, the clause on compulsory licensing stated: "PARTIES shall minimise the grant of compulsory licences in order not to impede adequate protection of patent rights."<sup>13</sup> The draft also contained numerous restrictions similar to those contained in the final TRIPS Agreement. For example, a compulsory license is, among several other restrictions, restricted to a "[declared] national emergency" or "critical peril to life of the general public."<sup>14</sup> Furthermore, under the Anell Draft, a compulsory license permitted "manufacture for the local market only," similar to the domestic use requirement contained in Article 31(f) of the TRIPS Agreement.<sup>15</sup> Records of the TRIPS Negotiating Group showed considerable resistance by developing countries to the strict requirements imposed by developed countries for the granting of compulsory licenses.<sup>16</sup> Nonetheless, the TRIPS Agreement was successfully negotiated with these restrictions in place, the most notable of which—Article 31(f)'s domestic use requirement—effectively prevented generic drugs, manufactured under compulsory license, from being exported to those poorer nations that do not have adequate pharmaceutical manufacturing capabilities.<sup>17</sup>

The TRIPS Agreement, which entered into force in 1995, contained, along with other constraints, a practically ineffectual compulsory licensing provision. The restrictive nature of the original agreement became especially apparent in the access to medicines dilemma aggravating the HIV/AIDS epidemic.<sup>18</sup> This growing concern on the part of developing countries and LDCs regarding the restrictions of the TRIPS Agreement was brought to light by a lawsuit filed in March 2001 by forty-one global pharmaceutical companies against South Africa. In the suit, the

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13. GATT Secretariat, *Chairman's Report to the GNG: Status of Work in the Negotiating Group*, pt. IV, § 5A.1, MTN.GNG/NG11/W/76 (July 23, 1990).

14. *Id.* pt. IV, § 5A.2(a)–(b).

15. *Id.* pt. IV, § 5A.3.5.

16. TRIPS RESOURCE BOOK, *supra* note 2, at 465.

17. See *infra* Part I.B for further discussion on the restrictions of Article 31(f) of the TRIPS Agreement and the inability of many poorer nations to develop any pharmaceutical manufacturing capability.

18. See Lucyk, *supra* note 9, at 213.

pharmaceutical companies objected to provisions of the South African Medicines Act giving the South African Health Minister permission to issue compulsory licenses in addition to his preexisting authority to allow parallel imports of pharmaceutical products when public health was at stake.<sup>19</sup> While the lawsuit was eventually dropped, the case generated significant public focus on the issue of compulsory licensing and access to essential medicines.<sup>20</sup> This public interest was evidenced in the media campaigns of domestic nongovernmental organizations, such as ACT UP and Health GAP, as well as the activity of international organizations, such as Médecins Sans Frontières, the World Health Organization, and the UN Development Programme, in promoting access to essential medicines.<sup>21</sup> During the same period, the issue of compulsory licensing in the TRIPS Agreement also surfaced as WTO dispute settlement proceedings initiated by the United States against Brazil concerning Article 68 of the Brazilian Industrial Property Law, which permitted compulsory licensing where there is a lack of local manufacturing of the patented product.<sup>22</sup> The complaint was eventually withdrawn by the United States, but it, like the South African lawsuit, addressed the emerging issue of compulsory licensing of essential pharmaceuticals.

These events led to a special session of the TRIPS General Council in June 2001 to discuss interpretation of the TRIPS Agreement.<sup>23</sup> A joint developing country paper, endorsed by the Africa Group, the Association of Southeast Asian Nations, and Brazil, argued for an interpretation of the TRIPS Agreement provisions in light of the humanitarian objectives of Articles 7 and 8 of the TRIPS Agreement, and a coalition of developing countries, led by the Africa Group, proposed six elements to be included in a declaration at the approaching Doha conference. These elements include the recognition of compulsory licenses issued to a foreign manufacturer, the right to “parallel import”<sup>24</sup> drugs originally pro-

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19. Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?*, 7 J. INT'L ECON. L. 73, 78–79 (2004) (arguing that the South African legislation lacked the nonexclusivity, nonassignability, and remunerative requirements of Article 31 of the TRIPS Agreement).

20. *Id.*

21. Lucyk, *supra* note 9, at 214.

22. Matthews, *supra* note 19, at 80.

23. See Gathii, *supra* note 9, at 296.

24. Parallel importation “occurs when products made and marketed by the patent owner in one country are imported into another country without the approval of the patent owner, normally in order to take advantage of differential pricing between the two countries, whereby different

duced for sale in different markets, and a moratorium on all dispute actions aimed at preventing or limiting access to medicines or protection of public health.<sup>25</sup> These goals were opposed by the United States and Switzerland, which declared that they would not endorse such a proposal at the Doha conference.<sup>26</sup> Even in light of this disagreement, however, the Doha Declaration reaffirmed the right of every WTO member to protect public health, provide access to medicines for all, and to grant compulsory licenses and determine the grounds on which these licenses are granted.<sup>27</sup> Most importantly, paragraph 6 of the Declaration recognized the fact 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,” and mandated that the TRIPS General Council find a solution to this problem before the end of 2002.<sup>28</sup> The accomplishments of the Doha Declaration were described as a “concrete success” for developing countries.<sup>29</sup>

In the subsequent negotiations over the implementation of the mandate in paragraph 6 of the Doha Declaration, the United States and other developed nations tried to limit compulsory licensing to only the most severe public health problems and only the most needy nations.<sup>30</sup> In its second communication to the TRIPS General Council regarding paragraph 6 of the Doha Declaration, the United States opined that paragraph 1 of the Doha Declaration “makes it clear that the public health problems addressed by the Declaration are those gravely afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics.”<sup>31</sup> Furthermore, the United States endorsed an export mechanism that would permit only “*developing* country Member[s] having sufficient manufacturing capacity in the pharmaceutical sector” to export generic drugs to a receiving member.<sup>32</sup> The proffered justification for this restriction was to develop the “potential” of the “pharmaceutical production capacity”

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prices are available for the same product in different markets.” Matthews, *supra* note 19, at 99.

25. Gathii, *supra* note 9, at 296–97.

26. *Id.*

27. See Doha Declaration, *supra* note 5.

28. *Id.* ¶ 6.

29. Matthews, *supra* note 19, at 81 (citing Peter Drahos, *Developing Countries and International Intellectual Property Standard-Setting*, 5 J. WORLD INTELL. PROP. 765, 781 (2002)).

30. Abbott & Reichman, *supra* note 12, at 936.

31. Second Communication from the United States, *United States—Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, ¶ 10, IP/C/W/358 (July 9, 2002).

32. *Id.* ¶ 16 (emphasis added).

of developing countries and LDCs by disallowing exports by producers in the developed world.<sup>33</sup> That proposal was based on unrealistic assumptions about the production capacity of developing countries and LDCs; it was especially impracticable given the reality that developing countries and LDCs are precisely those countries with insufficient or no manufacturing capacity in the pharmaceutical sector.<sup>34</sup>

Ultimately, the position of the developing countries regarding these two issues prevailed in the 30 August Decision.<sup>35</sup> The scope of the Decision is broad with respect to which pharmaceutical products qualify for a compulsory license, and there is no limitation of eligible exporting country status to developing countries or LDCs.<sup>36</sup> On the other hand, the Decision still contains rather restrictive limits on how a developing country can qualify as an eligible *importing* nation.

*B. Relevant Compulsory Licensing Provisions of the TRIPS Agreement, Doha Declaration, and 30 August Decision*

The TRIPS Agreement requires all WTO member nations to ensure that their laws and practices regarding intellectual property rights meet specified minimum standards.<sup>37</sup> Part of the stated rationale behind the agreement was to promote and protect intellectual property rights “to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare.”<sup>38</sup> While this language is undoubtedly open ended, the humanitarian motivation of the drafters is clear: the benefits from technological innovation cannot accrue only to the makers of that technology, and consequently, the agreement must protect both manufacturer rights and user rights in a manner conducive to social welfare.

Those humanitarian policy objectives are reflected in Article 31 of the TRIPS Agreement, which allows for use of a patent without the authorization of the patent holder.<sup>39</sup> In other words, Article 31 allows for

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33. *Id.* ¶ 15 (“If the solution were available to producers in the developed world, there might be little opportunity for producers in developing and least-developed Members to supply pharmaceuticals under this mechanism.”).

34. Only about a dozen developing countries (including China, India, Brazil, Argentina, and South Africa) have the pharmaceutical manufacturing capacity to produce significant quantities of generic drugs for export. Matthews, *supra* note 19, at 78.

35. Abbott & Reichman, *supra* note 12, at 937.

36. The following Section addresses individual provisions of the 30 August Decision in detail.

37. See TRIPS, *supra* note 4.

38. *Id.* art. 7.

39. See *id.* art. 31.

circumvention—by governments and third parties authorized by the government—of the patent holder’s exclusive right to prevent others from using its patented technology.<sup>40</sup> Such use, which typically takes place pursuant to the issue of a “compulsory license” on the patented technology, is subject to a number of requirements and restrictions. Most notably, otherwise unauthorized use under Article 31 is allowed only where the proposed user has failed in its attempt to obtain a voluntary license from the patent holder, or in a situation of “national emergency or other circumstances of extreme urgency.”<sup>41</sup> The use must be a noncommercial use or must remedy an anticompetitive practice; the use must also be nonexclusive and nonassignable, and remuneration must be paid to the patent holder.<sup>42</sup> Article 31 was a step in the right direction towards acknowledging the compulsory licensing rights advocated by developing countries and LDCs.<sup>43</sup>

Article 31(f) states, however, that compulsory use can only be authorized “predominantly for the supply of the domestic market of the Member authorizing such use,” thus preventing Article 31 from being realistically employed as an effective tool.<sup>44</sup> The “domestic use” requirement of Article 31(f) dramatically reduces the ability of poorer and lesser developed nations—precisely those nations facing “circumstances of extreme urgency”—to take advantage of the generic pharmaceuticals that could otherwise be produced under an Article 31 compulsory license. The barrier comes from the fact that these nations simply do not have, and often are not capable of obtaining, the technological means to engineer and produce generic drugs.<sup>45</sup> On the other hand, Article 31(f) prevents more developed nations—those nations *with* the means to pro-

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40. *Id.* art. 31(b).

41. *Id.* art. 31(c), (d), (h).

42. *Id.*

43. See Elliot, *supra* note 8, at 95.

44. TRIPS, *supra* note 4, art. 31(f).

45. Brook K. Baker, *Arthritic Flexibilities: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 IND. INT’L & COMP. L. REV. 613, 705 (2004) (identifying as impediments to LDC generics manufacturing the lack of technologies, lack of skilled labor, a weak financial sector, limited foreign investment, lack of an efficient distribution network, lack of domestic drug legislation and enforcement mechanisms, and the lower likelihood that an investment in a domestic generics producer will turn a profit in a low cost market without significant exports to other low cost markets). Professor Baker also references a draft report by Warren Kaplan and others estimating that a “critical mass” of a gross domestic product greater than about \$100 billion and population of greater than about 100 million must be reached before any “indigenous” pharmaceutical industry can realistically survive. *Id.* at 705.

duce generics—from exporting the drug to these lesser developed nations.

Professor Brook Baker, Co-Chair of the Health Global Access Project, has reviewed the barriers to domestic manufacture of generics in LDCs.<sup>46</sup> Besides the obvious lack of necessary technologies in many of these nations, the local production of pharmaceuticals, as a business investment, often simply does not make economic sense, as the decision to sink a large investment into a generic-producing venture will only be justified if that cost can be recouped. The low retail price of generics means that expenses can often be recouped only by mass export to a great number of consumers. Startup generic firms in LDCs are poorly positioned to make that move, especially if they have to compete with larger, more established global firms. Further obstacles to local production include a lack of skilled labor, a weak financial sector, the diminished flow of foreign investment, the questionable quality of product, the lack of an efficient system for storing and transporting drugs, and the lack of an enforceable regime of drug legislation.<sup>47</sup>

This practical difficulty was acknowledged in paragraph 6 of the Doha Declaration: “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.”<sup>48</sup> A more definite solution finally arrived in the form of the 30 August Decision to implement paragraph 6 of the Doha Declaration, which expressly set out the requirements for the export of pharmaceuticals manufactured under Article 31 to LDCs and developing nations. Most importantly, paragraph 2 of the 30 August Decision removed the constraints of Article 31(f) on exporting nations.<sup>49</sup> But, the Decision, along with the accompanying General Council Chairperson’s Statement (GCC Statement), set forth numerous limiting conditions and requirements for eligible exports under Article 31. On December 6, 2005, the TRIPS General Council issued a decision to amend permanently the TRIPS Agreement to incorporate the system of compulsory licensing proposed in the 30 August Decision.<sup>50</sup> The amendment will come into force after two-thirds of all WTO member nations accept it;

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46. *See id.*

47. *See id.* at 703–06 (discussing the economic costs of local generic manufacture in developing countries and the importance of economies of scale for the generic pharmaceutical industry).

48. Doha Declaration, *supra* note 5, ¶ 6 (emphasis added).

49. 30 August Decision, *supra* note 5, ¶ 2.

50. Decision of the General Council, *Amendment of the TRIPS Agreement*, WT/L/641 (Dec. 6, 2005).

the deadline for acceptance is December 31, 2009.<sup>51</sup> While this two-thirds majority—103 of 153 member nations—has yet to be reached, once it is, the 30 August Decision will apply to all members, even those that have not yet accepted the amendment.<sup>52</sup>

Some of the key provisions of the 30 August Decision, which are helpful for understanding the corresponding CAMR provisions, are as follows:

(1) Eligible pharmaceutical products: Paragraph 1 defines a pharmaceutical product eligible for compulsory license as “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 [Doha] Declaration.”<sup>53</sup> This is a very broad definition that is not limited to specific disease conditions. The “public health problems” recognized in paragraph 1 of the Doha Declaration include *but are not limited to* “those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”<sup>54</sup>

(2) Eligible importing nations: Least developed WTO members are automatically included as eligible importing nations.<sup>55</sup> Certain developed nations have voluntarily opted out of eligibility as importers.<sup>56</sup> Certain European nations, not yet members of the EU, have agreed that until their accession to the EU, they can only qualify as eligible import-

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51. Decision of the General Council, *Amendment of the TRIPS Agreement—Extension of the Period for the Acceptance By Members of the Protocol Amending the TRIPS Agreement*, WT/L/711 (Dec. 18, 2007).

52. 30 August Decision, *supra* note 5, ¶ 10. For members that have accepted the amendment, the amendment will take effect in those member countries and replace the 30 August Decision. *Id.* ¶ 11. As of January 28, 2009, the following WTO member nations, listed in order of ratification, have accepted the amendment: the United States, Switzerland, El Salvador, South Korea, Norway, India, the Philippines, Israel, Japan, Australia, Singapore, Hong Kong, China, the European Communities, Mauritius, Egypt, Mexico, Jordan, Brazil, and Albania. World Trade Organization, *Members Accepting Amendment of the TRIPS Agreement* (Aug. 6, 2008), at [http://www.wto.org/english/tratop\\_e/TRIPS\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/TRIPS_e/amendment_e.htm).

53. 30 August Decision, *supra* note 5, ¶ 1.

54. Doha Declaration, *supra* note 5, ¶ 1; *see also* TRIPS RESOURCE BOOK, *supra* note 2, at 484.

55. 30 August Decision, *supra* note 5, ¶ 1(b). The WTO recognizes as LDCs those countries recognized as such by the United Nations. There are currently forty-nine LDCs, including Rwanda, on the UN list. World Trade Organization, *Understanding the WTO: The Organization, Least-developed Countries*, at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm) (last visited Feb. 13, 2009).

56. World Trade Organization General Council, *Chairperson's Statement*, WT/GC/M/82 (Nov. 13, 2003) [hereinafter GCC Statement] (Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom, and the United States).

ing nations in situations of “national emergency or other circumstances of extreme urgency.”<sup>57</sup> Certain member nations, similarly, have agreed that they can only qualify as eligible importing nations in situations of “national emergency or other circumstances of extreme urgency.”<sup>58</sup>

(3) Insufficient or no manufacturing capacity: All eligible importing nations—other than LDCs, which are presumed to have insufficient manufacturing capacity<sup>59</sup>—must establish via notification to the TRIPS General Council that they have insufficient or no manufacturing capacity in the pharmaceutical sector. This notification must “include information on how the Member in question had established” insufficient manufacturing capacity.<sup>60</sup>

(4) Compulsory license conditions: The compulsory license issued by the exporting member must (i) limit the amount of the pharmaceutical to be manufactured to only the amount necessary to meet the needs of the eligible importing member (as determined by the exporting member); (ii) clearly identify the exported product as such, distinguishing it from the patented pharmaceutical; and (iii) notify the TRIPS General Council of the grant of the license.<sup>61</sup>

(5) Remuneration & noncommercial use: Whenever a compulsory license is granted, “adequate remuneration” must be paid to the patent holder, taking into account the “economic value of the authorization.”<sup>62</sup> It is not specified who pays the adequate remuneration, although some possible candidates are the importing country, the exporting country, and the generic manufacturer. Furthermore, the GCC Statement declared that the system established under the 30 August Decision should be “used in good faith” to protect public health, and should not “be an instrument to pursue industrial or commercial policy objectives.”<sup>63</sup>

## II. ENACTMENT OF CAMR AND THE EXPORT OF APO TRIAVIR FROM CANADA TO RWANDA

Shortly after the implementation of the 30 August Decision, the Canadian government responded to pressures by Canadian civil organiza-

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57. *Id.* (Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia).

58. *Id.* (China, Hong Kong, Israel, Korea, Kuwait, Macao, Mexico, Qatar, Singapore, Taiwan, Turkey, and United Arab Emirates).

59. 30 August Decision, *supra* note 5, ¶ 7, annex.

60. GCC Statement, *supra* note 56.

61. 30 August Decision, *supra* note 5, ¶¶ 2(b)–(c).

62. TRIPS, *supra* note 4, art. 31(h).

63. GCC Statement, *supra* note 56.

tions and the UN Special Envoy on HIV/AIDS in Africa by committing, in September 2003, to enact Canadian legislation, enabling compulsory licensing for export to developing countries and LDCs.<sup>64</sup> In May 2004, Canada amended its patent laws to reflect the WTO decision, becoming one of the first member nations to do so.<sup>65</sup> These amendments were codified in CAMR.<sup>66</sup> CAMR provisions are contained in Section 21 of the Consolidated Statutes of Canada as part of the Patent Act.<sup>67</sup> The CAMR legislation, which sets forth the process for obtaining a compulsory license for export, also references Part C of the Canadian Food and Drug Regulations.<sup>68</sup> Compliance with CAMR is governed by the therapeutic products directorate of Health Canada, the agency to which a manufacturer applies for export authorization under CAMR.<sup>69</sup>

The application process for a compulsory license for export under CAMR is more demanding than the process set forth by the 30 August Decision. The specific provisions and requirements of CAMR are addressed in greater detail in the remainder of this Note, and the export of Apo TriAvir to Rwanda under CAMR illustrates the general features of the procedure for obtaining a compulsory license under the legislation.

On July 17, 2007, Rwanda became the first country to notify the WTO that it intended to take advantage of the compulsory licensing provisions of the 30 August Decision, paragraph 6 of the Doha Declaration, and Article 31 of the TRIPS Agreement by importing the generic HIV/AIDS cocktail drug Apo TriAvir from Canada.<sup>70</sup> The production and export of this drug was the first—and currently the only—use of the CAMR legislation since its adoption in 2004.<sup>71</sup> While this inceptive use of CAMR is certainly positive progress towards the humanitarian objec-

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64. Elliot, *supra* note 8, at 96.

65. Canada and Norway were the first nations to pass compulsory licensing legislation implementing the 30 August Decision. See TRIPS RESOURCE BOOK, *supra* note 2, at 483–84. Since then, India, China, and South Korea have enacted their own forms of compulsory licensing legislation. TRIPS, *Intellectual Property Rights and Access to Medicines*, HIV/AIDS ANTIRETROVIRAL NEWSL. (World Health Org., Manila, Phil.), Dec. 2002, at 5, available at <http://www.who.int/3by5/en/Dec2002.pdf>.

66. See Hestermeyer, *supra* note 1.

67. Canada's Access to Medicines Regime, R.S.C., ch. P-4, § 21 (1985) (Can.).

68. *Id.* § 21.04(3)(b); see Food and Drug Regulations, C.R.C., ch. 870, §§ C.01.001–C.09.035 (2009) (Can.).

69. BUREAU OF POLICY, SCI., & INT'L PROGRAMS, THERAPEUTIC PRODS. DIRECTORATE, MINISTRY OF HEALTH, CANADA'S ACCESS TO MEDICINES REGIME: APPLICATION PROCESS FOR DRUGS FOR EXPORT TO DEVELOPING AND LEAST DEVELOPED COUNTRIES § 2.1 (2006), available at [http://www.camr-rcam.gc.ca/doc/guidance/camr\\_appl\\_rcam\\_dema-eng.php](http://www.camr-rcam.gc.ca/doc/guidance/camr_appl_rcam_dema-eng.php) [hereinafter HEALTH CANADA GUIDANCE DOCUMENT].

70. Hestermeyer, *supra* note 1.

71. Cotter, *supra* note 3, at 185.

tives of the TRIPS Agreement, the actual unfolding of the Canada-Rwanda transaction has left much to be desired. As of the March 2009, only one shipment of Apo TriAvir tablets has reached Rwanda.<sup>72</sup> This shipment was sent in September 2008.<sup>73</sup>

Rwanda has been and is currently experiencing an HIV/AIDS epidemic. Of the country's total population of approximately 9.3 million people, an estimated 200,000 are infected with HIV or AIDS.<sup>74</sup> As of 2007, only around 44,000 patients were receiving antiviral treatment.<sup>75</sup> The high infection rate, combined with the country's lack of doctors and hospitals,<sup>76</sup> cycle of poverty, and history of civil war, makes the need for help to fight the HIV/AIDS epidemic urgent.

In December 2004, Canadian generic pharmaceutical manufacturer Apotex committed to and began development of a "fixed-dose" combination of three HIV/AIDS antiviral drugs: zidovudine, lamivudine, and nevirapine.<sup>77</sup> These three original drugs were still under Canadian patent protection; the patents were held by pharmaceutical groups Glaxo-SmithKline (GSK), Shire, and Boehringer Ingelheim.<sup>78</sup> Apotex's new "cocktail" drug—Apo TriAvir—cost about forty cents per pill, compared to roughly twenty dollars for the patented version.<sup>79</sup> Apotex planned to export 260,000 packages of Apo TriAvir, which is enough to treat 21,000 HIV/AIDS patients for one year.<sup>80</sup>

Apotex faced numerous hurdles in its pursuit of a compulsory license for Apo TriAvir under CAMR. Initially, at the time that Apotex proposed Apo TriAvir in 2004, neither it nor any other "combination" or "cocktail" drug was included in Schedule 1 of the Patent Act, the exhaustive list of all of the pharmaceutical products that qualified for generic manufacture under CAMR.<sup>81</sup> The schedule was thereby amended pursuant to Section 21.03(1)(a) of CAMR to include the combination of zidovudine, lamivudine, and nevirapine in 2005, and Apo TriAvir sub-

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72. See Apotex, Rwanda: Apo-Triavir, at [http://www.apotex.com/apotriavir/product/rwanda\\_shipments.pdf](http://www.apotex.com/apotriavir/product/rwanda_shipments.pdf) (last visited Mar. 21, 2009) (detailing export authorization information for Apo TriAvir).

73. *Id.*

74. Cotter, *supra* note 3, at 179.

75. *Id.*

76. In Rwanda, there is only one physician for every sixty thousand people and there are only thirty hospitals in the entire country. *Id.* at 179–80.

77. Hestermeyer, *supra* note 1.

78. Cotter, *supra* note 3, at 186.

79. *Id.* at 185.

80. *Id.*

81. See Canada's Access to Medicine Regime, R.S.C., ch. P-4, § 21.03(1) (1985) (Can.).

sequently received manufacturing approval from Health Canada in August 2006 to begin manufacturing the drug.<sup>82</sup>

The second substantial challenge that Apotex faced, following Health Canada's approval of Apo TriAvir, was negotiating for voluntary licenses from GSK, Shire, and Boehringer Ingelheim for use of their patented drugs. Section 21.04(3)(c) of CAMR requires an applicant to demonstrate that it "sought from the patentee . . . a license 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."<sup>83</sup> Exact criteria for what sort of negotiations will satisfy the CAMR requirement are not stated. Negotiations between Apotex and the three manufacturers stalled, and Apotex ultimately failed to obtain a voluntary license from any of the manufacturers.<sup>84</sup>

The final major obstacle that Apotex faced came from the Rwandan end of the transaction. Even after clearing all of the domestic hurdles imposed by CAMR, Apotex still had to win a Rwandan government tender for the purchase of Apo TriAvir (required by Rwandan law for import of generics). Apotex had to beat out other potential generics manufacturers vying for the contract.<sup>85</sup>

The following synopsis clarifies the unfolding of events leading up to the export of Apo TriAvir to Rwanda under CAMR. Nine months after the 30 August Decision, in May 2004, Canada enacted CAMR. Seven months later, in December 2004, Apotex agreed to produce a fixed-dose combination generic drug for HIV/AIDS; such a drug did not exist at the time in Canada.<sup>86</sup> After another nine months, in September 2005, the Canadian Parliament amended Schedule 1 of the Canadian Patent Act to include the fixed-dose combination of zidovudine, lamivudine, and nevirapine. Health Canada finally approved Apo TriAvir almost a year later in August 2006. Apotex then sought to fulfill CAMR's voluntary license negotiation requirements; Boehringer and GSK received formal requests for a voluntary license on May 11, 2007.<sup>87</sup> Apotex claimed that

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82. *Id.* § 21.04(3)(b).

83. *Id.* § 21.04(3)(c).

84. Press Release, Apotex, Life Saving AIDS Drug for Africa Gets Final Clearance (Sept. 20, 2007), at <http://www.apotex.com/PressReleases/20070920-01.asp>. Apotex had asked to sell and export 15.6 million tablets at a cost of \$0.405 per tablet and requested a royalty-free license. Hestermeyer, *supra* note 1.

85. *Canadian WTO Notification Clears Path for Rwanda to Import Generic HIV/AIDS Drug*, BRIDGES WKLY. TRADE NEWS DIGEST, Oct. 10, 2007, at 7.

86. Hestermeyer, *supra* note 1.

87. Ann Silversides, *Not a Single Pill*, OTTAWA CITIZEN (Can.), Aug. 13, 2006, at C1,

the patent holders were intentionally stalling the negotiations, although the patent holders denied as much.<sup>88</sup> Meanwhile, in July 2007, Rwanda notified the WTO that it planned to import Apo TriAvir under CAMR.

In August 2007, a year after Health Canada approved Apo TriAvir, each of the three patent holders claimed to have granted Apotex a voluntary license.<sup>89</sup> In its press release of September 20, 2007, however, Apotex claimed: "In the end, GSK and Shire did not oppose the application, but chose not to grant a voluntary license, requiring Apotex to navigate the complexities of the CAMR. Boehringer Ingelheim was also not prepared to freely grant a license."<sup>90</sup> Apotex likely persuaded the Canadian government of its side of the story, because it was granted a compulsory license on September 20, 2007.<sup>91</sup> In October 2007, Canada notified the WTO of the grant of the compulsory license and of its intention to export Apo TriAvir to Rwanda. Apotex did not actually receive Rwanda's final tender approval—winning the bid to supply Rwanda with the generic drug—until May 2008, and the first and only package of Apo TriAvir to reach Rwanda to date was shipped on September 23, 2008, more than five years after the WTO's implementing decision.

It took more than a year for a shipment to be delivered after Rwanda first notified the WTO of its intention to import Apo TriAvir. Apotex's uphill battle shows only part of the difficulties that CAMR poses for similar prospective generic manufacturers seeking to manufacture for export. Unless these procedural complexities are eliminated, CAMR, in its present form, will not be able to deliver on the humanitarian objectives of the TRIPS Agreement. With the Apo TriAvir case in mind, this Note further explores the logistical and policy problems present in the CAMR legislation.

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available at <http://www.canada.com/ottawacitizen/features/aids/story.html?id=33dd04aa-52b6-437e-b4d1-d4c8d59010a4&k=72027>.

88. *Id.*

89. Press Release, Boehringer Ingelheim (Canada) Ltd., Boehringer Ingelheim Offers a Licence to Apotex to Export BI's Patented Product Nevirapine to Developing Countries with Terms Better than that Required by Canadian Legislation (Aug. 22, 2007), at [http://www.boehringer-ingelheim.ca/news\\_releases/2007/2007-08-27.asp](http://www.boehringer-ingelheim.ca/news_releases/2007/2007-08-27.asp); Press Release, GlaxoSmithKline, GSK Gives Consent Under Canada's Access to Medicines Regime for Generic Version of HIV/AIDS Medicine for Use in Rwanda (Aug. 8, 2007), at [http://www.gsk.com/media/pressreleases/2007/2007\\_08\\_08\\_GSK1105.htm](http://www.gsk.com/media/pressreleases/2007/2007_08_08_GSK1105.htm); Press Release, Shire BioChem, Inc., Shire Supports Canada's Access to Medicines Regimes (Aug. 15, 2007), at [http://www.shire.com/shire/uploads/press/shire/CAMR\\_15Aug07.pdf](http://www.shire.com/shire/uploads/press/shire/CAMR_15Aug07.pdf).

90. Press Release, Apotex, *supra* note 84.

91. *Id.*

### III. PROBLEMS AND DIFFICULTIES WITH CAMR

As the Apotex endeavor demonstrates, there are a number of requirements in CAMR that make it difficult, if not practicably unworkable, for a generic manufacturer to develop and export a pharmaceutical generic. In addition to the practical difficulties that CAMR poses for applicants, there are a number of restrictions written into the legislation that, some argue, overly limit its scope of application and thus its effectiveness as public policy.<sup>92</sup> Professor Jillian Cohen-Kohler sums it up well in her characterization of the CAMR legislation in light of the TRIPS Agreement provisions from which it originated: “[T]he Canadian legislation took a complicated regime and . . . made it even more complex.”<sup>93</sup> While there are many difficulties with CAMR, two particular problems merit further discussion: the commercial disincentives it creates for generic manufacturers applying for a compulsory license and its narrow scope of coverage.

#### A. *Business Disincentives for Generics Manufacturers*

A generics manufacturer who elects to manufacture a pharmaceutical for export under the CAMR legislation exposes itself to considerable commercial liability for little economic benefit. It is no surprise that no Canadian generics manufacturer other than Apotex has since tried to export a drug under the CAMR legislation; it is an illogical business decision. Considerable investment and transactional costs must be sunk into development of a generic drug and into navigating the procedural and legal quagmire of CAMR, investment which yields little to no profit beyond recoupment of costs. In addition to the low price for a generic drug required by the CAMR legislation—manufacturers cannot charge more than twenty-five percent of the average price of an equivalent product in Canada—Canadian manufacturers need to compete against generic manufacturers from other countries with much lower costs of production and more amenable patent laws. Without rational business incentives to engage in production under CAMR, Canadian generic manufacturers will probably opt not to compete against these foreign manufacturers in what is almost sure to be a money-losing venture.

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92. See, e.g., Elliot, *supra* note 8, at 98–109 (discussing the numerous “TRIPS-plus” provisions contained in the CAMR legislation that prevent it from fully implementing the objective of the 30 August Decision to promote more affordable medicines for all).

93. Jillian C. Cohen-Kohler et al., *Canada’s Implementation of the Paragraph 6 Decision: Is It Sustainable Public Policy?*, 3 GLOBALIZATION & HEALTH (2007), at <http://www.globalizationandhealth.com/content/pdf/1744-8603-3-12.pdf>.

Three primary business disincentives for generic manufacturers under CAMR—high costs, low return on investment, and competition from abroad—are addressed below.

1. *High Costs*

There are four substantial costs incurred by a generic manufacturer under CAMR: production costs, transaction costs, royalty fees, and costs associated with obtaining regulatory approval for a drug manufactured under CAMR.

Production costs are the research and development (R&D) costs of “reverse engineering” an existing patented pharmaceutical product, as well as the costs of physical production—including creating or maintaining a physical plant for production, paying production personnel, and distribution and transportation costs. The production costs of creating a generic pharmaceutical product under CAMR would be theoretically similar to creating any other pharmaceutical generic, although perhaps greater in the case of “cocktail” medicines in which more than one drug would need to be reverse engineered. While the high production costs may be comparable between CAMR drugs and other generic drugs, the costs may become prohibitive when, in the instance of a CAMR product, the opportunity for the manufacturer to earn a reasonable profit on sales of the drug is limited.<sup>94</sup>

Transaction costs include fees (presumably legal fees) and time expended by the generic manufacturer to meet the requirements imposed in CAMR for obtaining a compulsory license. Some of the steps required by CAMR include providing a certified copy of notice in writing to the WTO of compliance with various requirements, including quantity, type of pharmaceutical, and lack of sufficient manufacturing capacity in the receiving country;<sup>95</sup> disclosing information about the generic product on a dedicated website;<sup>96</sup> and issuing an export notice to every known party that will be handling the generic product.<sup>97</sup>

Perhaps the most significant transactional cost, however, is the cost associated with the process of negotiating for a voluntary license from the patent holder. Any applicant for a compulsory license is required to

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94. See *infra* Part III.A.2 for a discussion of the ways CAMR restricts revenue from sales of generics manufactured under it.

95. Canada's Access to Medicines Regime, R.S.C., ch. P-4, § 21.04(3)(d)(iii) (1985) (Can.).

96. *Id.* § 21.06.

97. *Id.* § 21.07.

engage in these negotiations by Section 21.04(3)(c) of CAMR, which requires

a solemn or statutory declaration . . . that the applicant had, at least thirty days before filing the application [for a compulsory license], sought from the patentee or, if there is more than one, from each of the patentees . . . a [license] 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.<sup>98</sup>

Because there are no time limits prescribed for how long a generic manufacturer must negotiate, nor any guidance as to what constitutes “reasonable terms and conditions” or reasonable negotiation efforts, the voluntary license negotiation requirement may entail quite a bit of time and expense. Representatives from the generic drug industry have described the process of attempting to obtain a voluntary license as “lengthy, complex and expensive.”<sup>99</sup> As is the case with the R&D and production costs mentioned above, it is unlikely generic manufacturers can earn enough of a profit selling a generic drug under CAMR to justify such a significant expenditure on transaction costs simply to meet the CAMR application requirements.

CAMR also requires the holder of a compulsory license to pay a royalty fee to the patentee or patentees of the original drug.<sup>100</sup> The statutory language of the royalty provision in CAMR leaves room for judicial or administrative discretion in determining the amount of the royalty. The Governor in Council considers the “humanitarian and non-commercial reasons” underlying the transaction in determining the royalty,<sup>101</sup> and the Federal Court is given discretion to increase the amount set by the Governor in Council.<sup>102</sup>

Finally, the generics manufacturer must consider the costs of obtaining regulatory approval for the generic pharmaceutical product from Health Canada. Section 21.04(3)(b) of CAMR states: “The Commissioner shall authorize the use of the patented invention only if . . . the version of the pharmaceutical product . . . meets the requirements of the *Food and Drugs Act* and its regulations.”<sup>103</sup> The relevant guidance

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98. *Id.* § 21.04(3)(c).

99. Cohen-Kohler et al., *supra* note 93.

100. Canada’s Access to Medicines Regime, R.S.C., ch. P-4, § 21.08.

101. *Id.* § 21.08(2).

102. *Id.* § 21.08(4), (6).

103. *Id.* § 21.04(3)(b).

document from Health Canada uses the same standard: “Drugs exported to least-developed and developing countries under Canada’s Access to Medicines Regime will meet the same rigorous standards for safety, efficacy and quality as those available to Canadians.”<sup>104</sup> While other pharmaceutical generics manufactured for domestic sale in Canada must satisfy the same regulatory requirements, aside from CAMR, Canadian law does not require regulatory approval for any other exported pharmaceuticals.<sup>105</sup> Therefore, Canadian generics manufacturers must meet a higher regulatory standard for exports under CAMR than for ordinary exports.

Meeting the regulatory requirements is not difficult for a “direct copy” generic (i.e., a product exactly identical to an existing drug), because the applicant can file an “abbreviated new drug submission” (ANDS) under Food and Drug Regulation (FDR) C.08.002.1. This means that the applicant need only show that the new drug is equivalent to an existing drug that has already cleared approval.<sup>106</sup> On the other hand, combination or “cocktail” drugs are classified as “new drugs” under FDR C.08.001,<sup>107</sup> so an applicant has to meet the new drug regulatory approval requirements, which are more rigorous than filing an ANDS. Satisfying the regulatory process may be costly and can be viewed as an unnecessary expense, considering the lack of a regulatory requirement for ordinary non-CAMR exports.<sup>108</sup>

It is clear that the costs required of a generic manufacturer under CAMR are not insubstantial, especially considering the limited allowable recovery of these costs under CAMR.

## 2. *Limited Return on Investment*

The high costs incurred by a generics manufacturer under CAMR can be recouped by payments from the importing purchaser nation for the generic drug, but any profit past the break-even point is minimal or nonexistent. The CAMR legislation sets a price limit on how much a

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104. HEALTH CANADA GUIDANCE DOCUMENT, *supra* note 69, § 1.2.

105. See Elliot, *supra* note 8, at 102.

106. Food and Drug Regulations, C.R.C., ch. 870, § C.08.002.1 (2009) (Can.).

107. *Id.* § C.08.001.

108. It is worth noting that the Therapeutic Products Directorate of Health Canada—the regulatory body for new drug evaluation—has relaxed its standards somewhat for the evaluation of cocktail drugs produced under CAMR. It has stated that its review will be “sufficiently flexible so as not to require the full range of clinical trial and other data that would normally be the standard for reviewing a new drug.” Elliot, *supra* note 8, at 103. There is also a separate “CAMR workload queue” to expedite processing of regulatory submissions of CAMR products. See HEALTH CANADA GUIDANCE DOCUMENT, *supra* note 69, § 2.5.4.

manufacturer can charge for a generic drug manufactured under its authorization. This low price limit, in combination with a short window for production of the generic before the authorization expires, makes it all but impossible for a generic manufacturer to hope to turn any sort of reasonable profit on its investment.

Section 21.17 of CAMR states that if the price of a generic pharmaceutical product manufactured under a compulsory license exceeds twenty-five percent of the average price of an equivalent product in Canada, the patentee can apply to the Federal Court for an order stating that the essence of the agreement with the generics manufacturer is commercial in nature.<sup>109</sup> If this is found to be the case, the Federal Court has the power either to terminate the compulsory license or to require the generic manufacturer to pay, in addition to the existing royalty, an “amount that the Federal Court considers adequate to compensate the patentee for the commercial use of the patent.”<sup>110</sup> By charging only twenty-five percent of what is typically charged for a comparable drug, it is uncertain whether a drug manufacturer will even be able to recover its costs—much less earn any sort of realistic profit.

CAMR also sets short limits on how long a compulsory license is valid. A compulsory license is valid for a maximum of four years—two years’ initial duration and one additional two-year renewal.<sup>111</sup> This limited term of production “severely limits the likelihood of being able to negotiate a contract that allows for economies of scale and that generates a revenue stream worth the start-up expense of manufacturing a generic version.”<sup>112</sup>

In comparison with other drugs these generic manufacturers could be producing—those with less initial investment cost and no low ceilings on pricing or time limit on production—producing drugs under CAMR is simply a money-losing proposition. As such, it is a business decision that generic manufacturers are simply unwilling to make. As a spokesperson for a Canadian generics firm put it, “Well, we might end up with a couple of orders, but at the end of the day we won’t make any money out of it . . . I’m not going to be able to develop it, because I’m in business to make money and I can only do so many products.”<sup>113</sup> While changes to some of the burdensome CAMR requirements may reduce existing transactional and regulatory costs involved in obtaining a com-

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109. Canada’s Access to Medicines Regime, R.S.C., ch. P-4, § 21.17(1) (1985) (Can.).

110. *Id.* § 21.17(3).

111. *Id.* §§ 21.09, 21.12.

112. Elliot, *supra* note 8, at 107.

113. Cohen-Kohler et al., *supra* note 93.

pulsory license, the legislation must allow for greater profits to be earned on the sale of these generics in light of the high cost of manufacturing any pharmaceutical product. Until generic manufacturers can earn a reasonable profit from a CAMR drug, producing generics under CAMR will remain an unjustifiable business decision.

### 3. *Competition from Abroad*

Even if a company decides to produce a generic drug under CAMR, the product will have to compete with drugs manufactured in other countries with much lower costs of production and laxer or even non-existent pharmaceutical patent restrictions. Drugs can be manufactured in these countries for a fraction of the price of manufacturing a comparable drug in a developed nation like Canada.

A paradigm example of a competing nation that can produce generics for far less cost is India. India can lawfully produce generic versions of pharmaceutical products because its patent law currently protects process only, and not actual pharmaceutical compounds.<sup>114</sup> Therefore, it is able to export reverse-engineered generics to nations where there is no domestic pharmaceutical patent bar without having to clear any sort of compulsory licensing or regulatory framework such as the one that CAMR requires. Besides lower transactional and regulatory costs, manufacturing and production costs are also lower in India. For example, the average production cost per employee in the manufacture of a pharmaceutical is about fifteen dollars per hour in Canada, compared to about one dollar per hour in India.<sup>115</sup> Furthermore, the estimated cost for a facility capable of producing twenty million dosages is about \$1 billion in Canada, compared to about \$130 million for a comparable Indian facility.<sup>116</sup> These drastic savings in costs associated with production of pharmaceuticals is reflected in the prices of Indian generics; Rwanda could have purchased an Indian drug similar to Apo TriAvir for fourteen cents per tablet—compared with the actual forty cents per tablet price of Apo TriAvir.<sup>117</sup>

International generics manufacturers choosing where to manufacture generics for export are fully cognizant of this disparity in production costs. As a representative from a generic drug company stated: “You have international companies, who operate in Canada and say, why

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114. See Baker, *supra* note 45, at 658.

115. Cohen-Kohler et al., *supra* note 93.

116. See *id.*

117. Hestermeyer, *supra* note 1.

should I go to Canada and lose money because the Canadian government has an objective”?<sup>118</sup> Given the disparity of regulatory, production, and manufacturing costs between Canada and some developing nations, Canadian firms that produce generic drugs under CAMR will face tough price competition from generic firms abroad.

#### 4. *Creating Realistic Business Incentives: Suggestions for Incentivizing Generic Manufacturers under CAMR*

In order for CAMR to achieve its humanitarian goals, the legislation must include “commercial incentives to galvanize the generic drug industry to make use of this legislation.”<sup>119</sup> The first step towards making a CAMR transaction an attractive business proposition is to reduce the costs involved in navigating and satisfying the requirements of the legislation. The major transactional cost of obtaining a compulsory license under CAMR—the absolute requirement that a generic manufacturer negotiate for a voluntary license from the patent holder—is one that is not universally required by the TRIPS Agreement. Article 31 explicitly states: “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 public non-commercial use.”<sup>120</sup> Therefore, CAMR and analogous regimes in other countries are not obligated to require that a generic manufacturer attempt to obtain a voluntary license as a condition for granting a compulsory license. Eliminating the requirement will significantly reduce costs incurred by a generic manufacturer obtaining a compulsory license.<sup>121</sup>

Price and manufacturing time limits must also be relaxed to allow for greater recovery of cost and for some moderate profit to incentivize the decision to take advantage of a CAMR compulsory license. Allowing a generic manufacturer to produce a drug for a longer period by extending the length of a compulsory license and charging a higher amount for sale of that drug is fully compatible with the requirements set out in Article 31 of the TRIPS Agreement and the 30 August Decision; neither expressly prescribes a limit on price or license period.<sup>122</sup>

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118. Cohen-Kohler et al., *supra* note 93.

119. *Id.*

120. TRIPS, *supra* note 4, art. 31(b).

121. See *supra* Part III.A.1 for a discussion of the costs involved with attempting to obtain a voluntary license.

122. While the 30 August Decision does not contain an express limit on how long a compulsory license is valid, it does limit production of a generic drug to “only the amount necessary to meet the needs of the eligible importing Member[.]” 30 August Decision, *supra* note 5, ¶ 2(b)(i).

While adjusting the existing legislation to include more “business-friendly” provisions is certainly a necessity to incentivize generic manufacturers to make use of CAMR, a more favorable statute, by itself, is only half the battle. Even if better business incentives induce generic manufacturers like Apotex to produce generics under CAMR, eligible importing nations, by definition, have limited resources to contribute to those incentives. Thus, it is worth asking whether there is any compulsory licensing-for-export regime that will be able to create commercial incentives for generic manufacturers while simultaneously keeping the drugs affordable for developing countries and LDCs. It seems difficult, even if all transactional costs are eliminated, to allow generic manufacturers in developed countries like Canada to earn even moderate profits—enough to act as an incentive to participate in the CAMR-type legislation—while maintaining a low purchase price for the least affluent nations. While the twenty-five percent price cap mentioned earlier may be an overly restrictive limit on manufacturers’ profits, it serves the purpose of ensuring that the generics remain affordable for LDCs. There is thus a disparity between the bottom line of generic manufacturers and the purchasing power of importing nations—a gap that may require external intervention to bridge.

One possible method of balancing these interests is through a subsidy—paid by the exporting nation—of the amount paid by the importing nation. In other words, the generic manufacturer would be allowed to charge a higher price for the exported drug, and the importing nation and the exporting nation would divide the cost of the drug. The importing country would pay some portion of the price, up to a price cap analogous to, although perhaps higher than, the twenty-five percent cap now in place.

A similar end could be reached through other forms of governmental assistance by the exporting country. For example, the government could provide tax benefits as an incentive to use the CAMR legislation. The legislation could keep a low price ceiling on generic drugs, but allow tax breaks for the generic manufacturer to incentivize production—for example, a statutory exemption on gross revenue derived from sale of the drug. Alternatively, the government could pledge research grants to subsidize the costly R&D and production associated with producing a generic under CAMR. One can think of a variety of ways that govern-

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This guideline suggests, however, that it would not violate the Decision if a generic drug had to be produced for longer than four years if the needs of the importing nation required extended production.

mental intervention could further the policy goals of compulsory licensing legislation like CAMR.

These proposed changes to the CAMR legislation reflect an idealized balance between the interests of the generic manufacturers, the exporting nations, and the importing nations, but leave out the interests of a very important group: the pharmaceutical patent holders. The government financial incentives proposed above could also be targeted at patent holders to encourage them to participate as true partners in CAMR. At root, though, CAMR's terms and requirements are not arbitrarily complex. The relative difficulty of obtaining a compulsory license stems from, in part, the political influences of the pharmaceutical lobby.<sup>123</sup> Thus, it would be very difficult, as a practical matter, to implement these changes to incentivize generic manufacturers to utilize CAMR. Such changes would unquestionably be opposed by "big pharma" patent holders. In the spirit of the 30 August Decision, however, the CAMR legislation was meant to serve the humanitarian end of providing realistically priced access to desperately needed life-saving drugs in LDCs. Perhaps legislation like CAMR can successfully serve this goal through generic manufacture for export. If it truly is to become an effective regime, the same humanitarian interests that produced the 30 August Decision could override any of the pharmaceutical industry's objections.<sup>124</sup>

While CAMR's restrictions may limit the direct revenue that a generic manufacturer is able to earn from the sale of a drug, it is possible that a generic manufacturer may still be motivated to produce a drug under the legislation in order to get a "head start" over other generic manufacturers in distributing a generic drug once the patent on the original drug has expired. In other words, by being able to reverse engineer, obtain regulatory approval for, and ultimately begin manufacturing a drug *before* the patent for that drug expires, a generic manufacturer could theoretically enjoy a temporary *de facto* monopoly following expiration of the drug's patent, during which time it would be the only generic manufacturer distributing the generic. In such a way, CAMR could, practically speaking, serve a function similar to the now repealed

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123. See Elliot, *supra* note 8, at 100–02 (discussing pressure from pharmaceutical manufacturers regarding the list of drugs included under CAMR).

124. A full discussion of the balancing of the interests of patent holders and the need for global access to medicines is beyond the scope of this Note. This Note is concerned with how to improve CAMR to make it a piece of practicably workable legislation such that it can achieve its humanitarian goal. Whether or not this goal reflects a prudent policy choice is a wholly different concern.

“stockpiling” provision of Canada’s Patent Act<sup>125</sup> by allowing generic manufacturers preemptively to violate a patent in order to have on hand an inventory of drugs upon expiration of the patent. If the benefit of this immediate domestic release outweighs the short term loss the generic manufacturer suffers by exporting under CAMR, then it would still make good business sense for companies to utilize the legislation, albeit not for its intended purposes.

Yet, despite this possible use of CAMR as a “stockpiling” provision, the legislation has not been widely exploited in this way by generic manufacturers. A possible explanation is that the drugs eligible for compulsory licensing under CAMR may simply not be domestically profitable. As the purpose of CAMR is to facilitate access to pharmaceutical products that address public health epidemics in LDCs, “especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics,” many of the drugs on Schedule 1 (the exhaustive list of CAMR-eligible drugs) treat infectious diseases that mainly afflict developing countries and LDCs.<sup>126</sup> The global research effort of pharmaceutical companies, in terms of R&D funding allocated to developing drugs to combat these diseases, is low in the case of HIV/AIDS and tuberculosis, and very low in the case of malaria and other infectious and parasitic diseases.<sup>127</sup> Assuming that R&D investment correlates with commercial viability, there simply is not a tenable domestic market for the pharmaceutical products included in Schedule 1.<sup>128</sup>

Furthermore, Section 55.2(1) of the Patent Act contains a similar provision that allows generic manufacturers preemptively to reverse en-

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125. The “stockpiling” provision states: “It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires.” Patent Act, R.S.C., ch. P-4, § 55.2(2) (1985, repealed 2001) (Can.).

126. Canada’s Access to Medicines Regime, R.S.C., ch. P-4, § 21.01 (1985) (Can.).

127. See Andrés de Francisco, *Progress in measuring the 10/90 gap*, in GLOBAL FORUM FOR HEALTH RESEARCH, 10/90 REPORT ON HEALTH RESEARCH 2003–2004, at 105, 123 (Sheila Davey ed., 2004), available at [http://www.globalforumhealth.org/site/002\\_What%20we%20do/005\\_Publications/001\\_10%2090%20reports.php](http://www.globalforumhealth.org/site/002_What%20we%20do/005_Publications/001_10%2090%20reports.php) (select “Chapter 5” hyperlink).

128. It is theoretically possible for a generic manufacturer petition to amend Schedule 1 to include a domestically lucrative drug (e.g., one that treats a chronic disease). Such a petition would likely fail, however, as the amendment procedure requires that the pharmaceutical product, to fall under the purview of CAMR, be “used to address public health problems . . . especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.” Canada’s Access to Medicines Regime, R.S.C., ch. P-4, § 21.03(a)(i). Furthermore, the amendment must be approved by the Minister of Industry, Minister of Health, and the Governor in Council. See *id.* § 21.03(a). Therefore, it is unlikely that a generic manufacturer would be able to readily manipulate the system to take advantage of CAMR’s stockpiling potential.

gineer and manufacture a drug still under patent for use in clearing the regulatory and marketing review process.<sup>129</sup> In being able to do so, the generic manufacturer is able to begin selling a generic product immediately after the expiration of the drug's patent, assuming regulatory approval is obtained. Thus, Section 55.2(1) gives generic manufacturers the same "head start" in production that they would get under CAMR, without confining them to the limited list of eligible pharmaceuticals in Schedule 1 or causing them to incur a short term loss from exporting the pharmaceutical.

While CAMR holds the potential to function as a "stockpiling" provision, allowing generic manufacturers to release a drug manufactured under its terms without delay upon expiration of the patent, the benefits to be reaped from this "head start" are not significant enough to outweigh the short term loss that the manufacturer would have to suffer. As a result, generic manufacturers have not been utilizing the legislation to exploit this function. To be effective, CAMR cannot rely on its limited benefit as a "stockpiling" provision; the legislation must be amended to offer tangible business incentives to encourage participation by generic manufacturers.

#### *B. Problems with CAMR as Public Policy: Coverage Issues*

In addition to the commercial disincentives that CAMR poses for generic manufacturers, the legislation also contains some problematic provisions regarding the scope of its application. Most significantly, the legislation limits: (1) the scope of which countries fall under "eligible importing members" and (2) which pharmaceutical products are eligible for compulsory license. These limits, while certainly necessary as measures that define the breadth of the statute's application, are overly restrictive and limit the amount of humanitarian aid that CAMR can realistically provide.

##### *1. "Eligible Importing Member"*

CAMR's limitation on which countries are eligible to import licensed drugs is tied to the requirements of the 30 August Decision.<sup>130</sup> Section

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129. Patent Act, R.S.C., ch. P-4, § 55.2(1) (1985) (Can.) ("It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.").

130. The determination of which pharmaceutical products are included in Schedule 1 is left

21.03 of CAMR expressly refers to the standards set forth in paragraph 1 of the 30 August Decision in its amendment process for adding nations to Schedules 3 and 4—schedules of developing nations that are allowed to import under CAMR in certain circumstances.<sup>131</sup> In other words, the CAMR legislation, in determining which developing countries *other than* LDCs are eligible for export under CAMR, adopts the prerequisite conditions set forth by the WTO in the 30 August Decision. Thus, in order to broaden the scope of those countries eligible for export under CAMR, the parallel limitations in the 30 August Decision must be relaxed as well.

CAMR contains three schedules of countries that are eligible to import under the regime. Each schedule is subject to different requirements that must be met before the countries included in it are considered eligible to import. Schedule 2 nations, the LDCs that can import under the regime—Rwanda, for example—are only required to specify the name of the pharmaceutical product to be imported.<sup>132</sup> Schedule 3 nations, which are comprised of WTO developing member nations, in addition to specifying the name of the pharmaceutical product, are also required to provide notification that they have “insufficient or no pharmaceutical manufacturing capacity” pursuant to the conditions set forth in the 30 August Decision.<sup>133</sup> Finally, Schedule 4 nations, comprised of WTO member and non-WTO member developing nations, must provide both the name of the pharmaceutical product for import and notification of “insufficient or no pharmaceutical manufacturing capacity,” as well as notice that it is “faced with a national emergency or other circumstance of extreme urgency” pursuant to the conditions set forth in the 30 August Decision.<sup>134</sup> In sum, while LDCs are automatically eligible importing members, developing nations must provide additional proof of either insufficient pharmaceutical manufacturing ca-

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solely to the discretion of the Minister of Industry, Minister of Health, and Governor in Council. See Canada's Access to Medicines Regime, R.S.C., ch. P-4, § 21.03(a). Even if the CAMR provisions were “tied to” the 30 August Decision, the latter's definition of “pharmaceutical product” is very broad. TRIPS RESOURCE BOOK, *supra* note 2, at 484; see also 30 August Decision, *supra* note 5, ¶ 1.

131. Canada's Access to Medicines Regime, R.S.C., ch. P-4, § 21.03(1)(c), (d)(i) (requiring that, in order to amend Schedule 3 and 4, the Canadian Minister for International Trade and Minister for International Cooperation, respectively, notify the WTO Council of which nations are to be added “in accordance with the [30 August Decision]”).

132. *Id.* § 21.04(3)(d)(i), sched. 2.

133. *Id.* § 21.04(3)(d)(iii), sched. 3; see also 30 August Decision, *supra* note 5, ¶ 2(a)(ii); GCC Statement, *supra* note 56.

134. Canada's Access to Medicines Regime, R.S.C., ch. P-4, § 21.04(3)(d)(iv), sched. 4; see also 30 August Decision, *supra* note 5, ¶ 1(b); GCC Statement, *supra* note 56.

capacity or both insufficient capacity and national emergency or extreme urgency.<sup>135</sup>

The guidelines for determining what qualifies as “insufficient pharmaceutical manufacturing capacity” are contained in the GCC Statement: “To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established . . . that it has insufficient or no manufacturing capacity in the pharmaceutical sector.”<sup>136</sup> The guidelines are vague at best. Professor Baker describes them as “terribly uncertain.”<sup>137</sup> Furthermore, there are no additional guidelines in either the 30 August Decision or the GCC Statement as to what constitutes a “national emergency” or “circumstance of extreme urgency.” The vagueness of these additional qualifying criteria for developing nations gives developed countries—who are the most critical of allowing compulsory licensing—a tool to limit use of the legislation.<sup>138</sup> By setting the bar for insufficient pharmaceutical manufacturing capacity very high—for instance, counting any rudimentary physical plants as sufficient manufacturing capacity—the TRIPS General Council could easily deem any of the nations on Schedules 3 or 4 as ineligible for import.<sup>139</sup> For

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135. This preference towards LDCs over developing nations is mirrored in the 30 August Decision, which qualifies “any least-developed country Member” as an eligible importing member, but requires of other non-LDC nations “notification to the Council for TRIPS of its intention to use the system as an importer . . . in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” 30 August Decision, *supra* note 5, ¶ 1(b) (emphasis added).

136. GCC Statement, *supra* note 56.

137. Baker, *supra* note 45, at 639.

138. See *supra* Part I.A for a discussion of the resistance by the United States and other developed nations against proposals for more liberal compulsory licensing provisions under the TRIPS Agreement.

139. The fear of the General Council abusing its discretion in limiting the number of eligible importing nations is justified, of course, only if the Council is predominantly controlled by developed nations opposed to expanded compulsory licensing rights. While discussion of the complex political factors affecting influence and control of the Council is beyond the scope of this Note, it is fairly evident from threats of Section 301 sanctions, other trade incentives (e.g., agricultural benefits), and many bilateral agreements—discussed *supra* Part I.A—that the United States can exert significant economic pressure on other WTO member nations to enforce their IP standards. See DRAHOS & BRAITHWAITE, *supra* note 11, at 93. Drahos and Braithwaite have written that “the TRIPS [General] Council process currently operates as a floor, a platform upon which the US and the [European Commission] are building a new bilateralism to further ratchet up intellectual property standards . . . . Now Europe is working through the Council for TRIPS to push this ‘highest possible level’ globally.” *Id.* at 207. While the possibility that developed nations exercising predominant influence on the TRIPS General Council may be counterbalanced by the existence of a “veto coalition” of developing nations and LDCs, it is worth discussing further the type of discretion accorded to the TRIPS General Council should it enforce the anticompetitive licensing agenda of developed nations, in light of the influence that can be exerted on these poorer na-

example, the United States has treated insufficient capacity as a “technical term addressing *theoretical* physical plant capacity no matter how inefficient or impracticable local production would be.”<sup>140</sup> This is simply an “ad hoc notification-and-review process” in which it is up to the discretion of the Council whether or not to recognize insufficient capacity, thus conferring eligibility under CAMR.<sup>141</sup> Furthermore, in its first paragraph 6 submission to the TRIPS General Council, the United States interpreted insufficient manufacturing capacity as not applying to “countries that choose not to manufacture certain drugs based on policy, economic, or other reasons.”<sup>142</sup>

Such uncertainty as to whether developing countries will be eligible to benefit from a compulsory license limits the effectiveness of the legislation. While developing countries do not demonstrate the same level of need as LDCs, many of the countries in Schedules 3 and 4 *do* demonstrate need for the affordable import of generic pharmaceuticals. For example, in 2003, Brazil sought to import generic versions of antiretroviral drugs from India, whose patent laws effectively allowed the legal manufacture of generics.<sup>143</sup> While Brazil had a “highly competent generic industry,” it was “seeking to fill a temporary gap in its ability to source these drugs locally.”<sup>144</sup> Like Brazil, many developing nations may have pharmaceutical production capabilities significant enough that they would not qualify under the 30 August Decision or GCC Statement standards, yet they are incapable of completely handling the country’s demand for a particular pharmaceutical. In this instance, the option to import comparably cheap generics to fill a production gap would prove immensely useful. Developing countries are also better positioned than LDCs to pay a higher price for generic drugs. This would prove beneficial to a generic manufacturer’s ability to recoup its investment in a generic drug.

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tions via bilateral agreements and the independent economic pressures discussed above. *See id.* at 207–09.

140. Baker, *supra* note 45, at 639–40 (emphasis added).

141. *Id.*

142. Communication from the United States, *United States—Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/340 (Mar. 14, 2002). Certain economic and political factors can make it realistically impossible for a country to develop pharmaceutical manufacturer capabilities of scale. *See supra* note 45 and accompanying text.

143. Indian patent law only recognizes patents protecting the process for manufacturing a drug, not the drug itself. Therefore, generic firms could copy a drug as long as they used a different process. *See Baker, supra* note 45, at 659.

144. *Id.*

Putting all of the developing nations and LDCs in the same schedule and eliminating the vague and potentially prejudicial “insufficient pharmaceutical manufacturing capacity” and “national emergency or other circumstance of extreme urgency” requirements of the 30 August Decision would allow the benefit of compulsory licensing to accrue more effectively to developing nations. In other words, developing nations, like LDCs, should be expressly included in paragraph 1(b) of the 30 August Decision—without any prerequisite of insufficient manufacturing capacity or national emergency—as automatically eligible beneficiaries of compulsory licensing exports. Helping these developing nations is fully consistent with the humanitarian aims of CAMR and the TRIPS Agreement. While their need for affordable generics may not be as dire as that of LDCs, developing countries could combat their own health epidemics and drug shortage problems by importing supplementary generics under compulsory license.

## 2. *Eligible Pharmaceutical Products*

Schedule 1 of CAMR provides an exhaustive list of the pharmaceutical products on which compulsory licenses can be granted under CAMR.<sup>145</sup> This list can be amended upon the recommendation of the Minister of Health to include additional pharmaceuticals “that may be used to address public health problems afflicting many developing and least-developed countries.”<sup>146</sup> The Apo TriAvir deal, discussed above, has already demonstrated the problems encountered by a generic manufacturer attempting to gain regulatory approval on a new combination drug that was initially not included in Schedule 1. Limitations on which drugs can be reproduced as generics—indeed, the existence of an exhaustive list altogether—is indicative of the influence of “political lobbying by [patent]-holding brand-name pharmaceutical companies” in the drafting of CAMR.<sup>147</sup> Richard Elliot, Executive Director of the Canadian HIV/AIDS Legal Network, claims that the existence of *any* limiting list whatsoever is “negative precedent,” because of the “international consensus” achieved through the 30 August Decision, which rejected specific efforts by developed countries to limit its scope to specific diseases or pharmaceuticals as “unethical and unsound health policy.”<sup>148</sup> Indeed, if the purpose of the legislation is indeed to “address

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145. Canada’s Access to Medicines Regime, R.S.C., ch. P-4, sched. 1 (1985) (Can.).

146. *Id.* § 21.03(1)(a)(i).

147. Elliot, *supra* note 8, at 101.

148. *Id.*

public health problems . . . especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics,”<sup>149</sup> then *any* drug effective in combating such a health epidemic should fall under its purview. Furthermore, expanding the scope of Schedule 1 is entirely consistent with the broad terms of the 30 August Decision regarding eligible pharmaceutical products. Paragraph 1 of the Decision states that “*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 [Doha] Declaration” is eligible for inclusion under the Decision.<sup>150</sup> Restrictions on the eligibility of pharmaceuticals for generic manufacture—like the restrictions on “eligible importing members” discussed above—limit the effectiveness of the CAMR legislation and increase the transactional burden for a generic manufacturer seeking a license for either a cocktail medication or a drug not currently on the list.<sup>151</sup>

Schedule 1 of CAMR, while containing many first-line antiretroviral drugs that are crucial in fighting numerous health epidemics, fails to contain affordable second- and third-line antiretroviral therapy and antimalarial agents, which are increasingly in demand in developing countries.<sup>152</sup> Moreover, many of the first-line antiretroviral drugs listed in Schedule 1 are already available off-patent elsewhere.<sup>153</sup> As the Apotex case demonstrates, however, there are not many combination “cocktail” drugs that are currently produced and included in Schedule 1; such drugs are now in much greater demand due to the ease of their administration—the user may take one Apo TriAvir pill rather than three separate pills, for example. Furthermore, the evolving health needs of a developing country may involve a greater demand for treatment of noninfectious diseases. As a population’s life expectancy increases, chronic degenerative diseases will increase, bringing with them different treatment needs. For example, there is likely to be an increased demand for drugs to treat cancer, diabetes, and other degenerative dis-

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149. Canada’s Access to Medicines Regime, R.S.C., ch. P-4, § 21.03(1)(a)(i).

150. 30 August Decision, *supra* note 5, ¶ 1 (emphasis added); *see also* Doha Declaration, *supra* note 5, ¶ 1; TRIPS RESOURCE BOOK, *supra* note 2, at 484.

151. As discussed *supra* Part III.A.1, a generic manufacturer is required to obtain regulatory approval from Health Canada for each generic drug to be licensed for export. Cocktail drugs are classified as “new drugs” under the Food and Drug Regulations, and thus a generic manufacturer must meet new heightened drug regulatory approval requirements. Food and Drug Regulations, C.R.C., ch. 870, § C.08.001 (2009) (Can.).

152. *See* Cohen-Kohler et al., *supra* note 93.

153. *Id.*

eases.<sup>154</sup> CAMR must be flexible to accommodate this need for cocktail drugs, as well as the evolving health needs of LDCs and developing countries.

### CONCLUSION

Canada's attempt to implement the compulsory licensing provisions set forth in the TRIPS Agreement and the 30 August Decision is worthy of study given the potentially great impact compulsory licensing could have on fighting global health epidemics. CAMR is a paradigm example of legislation that gives developed countries—precisely those with the means of production—a tool to alleviate the global health crises plaguing much of the least developed world. By learning from the mistakes of CAMR, other developed nations may pass legislation that utilizes the compulsory licensing provisions of the TRIPS Agreement in a more effective manner.<sup>155</sup>

The sale of Apo TriAvir under CAMR has shown that to be effective compulsory licensing legislation must eliminate the commercial disincentives it creates for potential generic manufacturers through high transaction costs and strict restrictions on drug pricing. In addition to creating commercial incentives for generic manufacturers to take advantage of its terms, CAMR and similar legislation must broaden coverage to allow for export not only to LDCs, but also to developing countries, and it must allow for a greater range of pharmaceutical products to be eligible for compulsory licensing. This will only be possible, however, if the definition of an eligible importing member produced by provisions in the 30 August Decision is relaxed.

While broadening the scope of CAMR and creating greater incentives for generic manufacturers to take advantage of it may be detrimental to the interests of pharmaceutical patent holders, this impact must be weighed against the humanitarian benefits that the legislation can provide. While such a policy debate—to what extent patent holders' rights can be sacrificed in order to provide drugs to those in need—is beyond the scope of this Note, the proposed rationale for enactment of the CAMR legislation was to provide access to drugs needed to combat severe global health epidemics. If the terms of the legislation are not

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154. *See id.*

155. In the United States, Senator Patrick Leahy of Vermont attempted to introduce compulsory licensing legislation in the 109th Congress, but the bill was never voted upon. Life-Saving Medicines Export Act of 2006, S. 3175, 109th Cong. (2006).

changed, it will remain practically ineffectual, as demonstrated by the export of Apo TriAvir to Rwanda. Thus, in order to achieve effectively its humanitarian objective, compulsory licensing legislation under the TRIPS Agreement must be attuned to both the commercial objectives of generic manufacturers it relies on, as well as the practical needs of the importing countries it purports to help.