

# PRESCRIPTION UNFILLED: THE “JEAN CHRETIEN PLEDGE FOR AFRICA ACT” AND ACCESS TO ESSENTIAL DRUGS

A L V I N B A J W A \*

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The *Jean Chretien Pledge to Africa (JCPA)*<sup>1</sup> arose from a decision by the World Trade Organization (WTO) General Council in August 2003 to allow states to grant compulsory licenses for drugs otherwise protected by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Before TRIPS, generic drug companies capitalized on lenient or non-existent patent laws in developing countries to reproduce drugs that were patent-protected in the West. India serves as a prominent example; after the abolishment of patents in the 1970s, India’s generic manufacturing industry grew exponentially, producing drugs for domestic consumption and international export, mainly to other developing countries with similarly unregulated markets.<sup>2</sup> TRIPS, in effect, aimed to reinforce patent protection in the developing world. During the Doha Round of WTO negotiations, developing countries had expressed concerns that TRIPS limited their ability

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<sup>1</sup> An Act to Amend the Patent Act and Food and Drugs Act, SC 2005, c 23.

<sup>2</sup> Amy Kapczynski, “Harmonization and its Discontents: a Case Study of TRIPS Implementation in India’s Pharmaceutical Sector” (2009) 97(6) *California Law Review*, 1571 at 1581.

to provide life-saving medicines to their most impoverished residents.<sup>3</sup> These worries had existed during the previous Uruguay Round when TRIPS was negotiated but the developing world was largely presented with a “take-it-or-leave-it offer” to either accept TRIPS or be excluded from the GATT.<sup>4</sup> This meant that India and other countries in which generic manufacturers operated were given until 2005 to become TRIPS compliant.<sup>5</sup>

After the WTO General Council’s decision, several countries expressed interest in enacting national laws supporting compulsory licenses. Canada was the first country to pass such a statute. However, the *JCPA* went above and beyond what is required by the WTO General Council decision in terms of patent protection. Although the reasons for these differences were left unexplained in the legislation, this could be due to the lobbying of pharmaceutical companies<sup>6</sup> and the overly bureaucratic nature of the policy process in Canada.<sup>7</sup> Ultimately, this produced an ineffective legislative scheme which has only been used once (and there is no sign it will be used in the immediate future). In 2012, a private member’s bill (Bill C-398) to remove administrative obstacles from the *JCPA* failed upon second reading.<sup>8</sup> The government’s official response was that it feared the bill would not adhere to Canada’s TRIPS obligations, although legal experts argued it was still in line with the General Council’s decision.<sup>9</sup>

This paper will explain how a stronger role by the Canadian government could better facilitate the *JCPA* and improve access to essential drugs in poor countries. This issue is important because it engages Canada’s moral duty as a developed country to assist poor countries in accessing

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<sup>3</sup> Faina Weitsman, *The Trade-Related Aspects of intellectual Property Rights (TRIPS) Agreement and Access to Patented Medicines in Developing Countries – Canada’s Bill C-9* (LL.M. Thesis, University of Manitoba Faculty of Graduate Studies, 2006) [unpublished] at 139.

<sup>4</sup> *Ibid* at 33.

<sup>5</sup> *Ibid* at 137.

<sup>6</sup> Canadian Generic Pharmaceutical Association, News Release, “The CGPA supports Canada’s initiative to make generic medicines available to developing countries” (2014) online: CGPA <<http://www.canadiangenerics.ca/en/news/billc9.asp>>

<sup>7</sup> Edward Hore, “Bill C-9: An Act To Amend The Patent Act and The Food And Drugs Act – A Model For The World But Is It Workable?” (Paper delivered at “Pharma Patents” at the Canadian Institute Toronto, 9-10 November 2004) at 16. The author implied that although Jean Chretien’s intent to utilize the General Council’s decision was sincere, perhaps the legislative process went astray when lower-level officials tried to accommodate lobbying demands in to the *JCPA*.

<sup>8</sup> Canada, C-398 *An Act to amend the Patent Act* (Drugs for International Humanitarian Purposes) 1st Sess, 41st Parl, 2012, (Bill defeated at Second Reading on 28 November 2012)<<http://www.parl.gc.ca/LegisInfo/BillDetails.aspx?billId=5349039&Language=E&Mode=>>

<sup>9</sup> Canadian HIV/AIDS Legal Network, Media Release, “Fixing Canada’s Access to Medicines Regime: What you need to know about Bill C-398” (October 2012) at 3.

essential drugs, especially when doing so produces no harm for Canada's domestic industry. It could be a positive-sum solution. However, ineffectual legislation in this area allows for the continual suffering of sick people in developing countries. When people are "dying from diseases which are treatable with medicines, delays are inexcusable."<sup>10</sup>

Further, this paper will examine the impact of the JCPA and critique its flaws to determine how the Act could be reworked to better fulfill its objectives. It will begin by analyzing the single case where the JCPA was used. Afterward, it will broadly assess the Act's most central flaw: the obstacles it places on generic manufacturers and developing states. Following that, legal, as well as alternative solutions, for increasing access to essential medicines in poor countries will be examined. Although the initial ambition behind the JCPA can be admired, a stronger role for government is necessary in order to increase access to drugs for disadvantaged people in poor countries.

### Why generic drugs are needed

Essential drugs<sup>11</sup> are the foundation of almost every public health program aimed at reducing disease and death in developing countries.<sup>12</sup> They provide treatment for existing illnesses and contribute to prevention strategies. Indeed, a public health program cannot be effective without reliable access to adequate quantities of essential drugs.<sup>13</sup> A long chain of steps is involved in bringing medicine to patients: research and development of the active ingredient, production, quality control, wholesale distribution, reliable information for health care providers, drug dispensing facilities, and observance of safe use.<sup>14</sup> Any disharmony between these factors could limit

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<sup>10</sup> Emily Ng & Jillian Clare Kohler, "Finding Flaws: the Limitations of Compulsory Licensing for Improving Access to Medicines—an International Comparison" (2008) 16 Health LJ 143 at 172.

<sup>11</sup> World Health Organization, "WHO Model List of Essential Medicines," 17<sup>th</sup> List (March 2011) online: <[http://whqlibdoc.who.int/hq/2011/a95053\\_eng.pdf](http://whqlibdoc.who.int/hq/2011/a95053_eng.pdf)>. The WHO defines essential medicines as "those that satisfy the priority health needs of a population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available in functioning health systems at all times in adequate amounts." The WHO Model List is intended to serve as a guide for countries and institutions when developing drug distribution and access strategies.

<sup>12</sup> Bernard Pecoul et al, "Access to Essential Drugs in Poor Countries: a Lost Battle" (1999) 281:4 Journal of the American Medical Association 361 at 3.

<sup>13</sup> World Health Organization Regional Office for Africa, Afro Essential Medicines Price Indicator, (September 2007) online: <<http://apps.who.int/medicinedocs/documents/s17746en/s17746en.pdf>>, at 8.

<sup>14</sup> Pecoul, *supra* note 12.

access to medicine, particularly for poor people. Access to drugs does not guarantee effective treatment. However, it is essential to establish a distribution and administration network in developing countries.<sup>15</sup> Yet, since brand name drugs are prohibitively priced for many, generic versions are necessary to improve access to drugs. The discount between brand and generic versions varies between drugs. For HIV anti-retroviral treatment (ARV), the brand cost per patient per year is roughly \$10,000 while a generic substitute would only cost a few hundred dollars.<sup>16</sup> On average, a generic drug with recently expired patents will cost as little as 1/30<sup>th</sup> of the price of their brand name counterparts.<sup>17</sup>

Although a number of economic factors can affect the price of brand name drugs in any given state, the strength of the national health-care system (which frequently subsidizes medicines) and domestic generic pharmaceutical industry are particularly important factors. For example, research shows a wide discrepancy across the world in base prices for the brand and generic version of the common antibiotic ciprofloxacin:<sup>18</sup> in countries with strong national health-care infrastructure, medicine tends to have greater affordability.<sup>19</sup> In lieu of government support, the most impoverished residents of poor countries must rely on NGOs and charities. Greater access to generic alternatives can reduce costs for these organizations and help bridge the access to medicines gap in states that cannot rely on a robust health-care system or pharmaceutical industry.

Developing countries struggle to expend necessary resources to serve their populations. In Kenya, there is a 15% HIV prevalence rate among adults.<sup>20</sup> Out of 200,000 persons in desperate need of anti-retroviral drugs (ARV), only 20,000 are receiving treatment.<sup>21</sup> These recipients are typically paying for treatment out of pocket via a cost-sharing system.<sup>22</sup> Further, at least 40% of health services are provided by church-aligned health facilities which

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<sup>15</sup> World Health Organization, Mission for Essential Drugs and Supplies, Kenya: Case Study (Switzerland: World Health Organization, 2004) at 4.

<sup>16</sup> Paige E. Goodwin, "Right Idea, Wrong Result—Canada's Access to Medicines Regime" (2008) 34 Am JL & Med 567 at 567.

<sup>17</sup> *Ibid.*

<sup>18</sup> Health Action International, News Release "Global pill price 'snapshot' reveals large differences in the price of ciprofloxacin" (11 January 2010) online: HAI Global <<http://www.haiweb.org/medicineprices/05012010/PressRelease.pdf>>.

<sup>19</sup> The Economist, "The Price of Pills," (18 January 2010) online: The Economist <<http://www.economist.com/node/15320793>>.

<sup>20</sup> *Supra* note 15 at 1.

<sup>21</sup> *Ibid.*

<sup>22</sup> *Ibid.*

receive no subsidies from government.<sup>23</sup> This is emblematic of the lack of state funding for essential drugs in the developing world.

In addition to HIV ARV treatment, many other pervasive illnesses in the developing world also have drugs and vaccines that are currently patent-protected. For example, Recombivax HB, a vaccine for Hepatitis B (a disease that is widespread in Sub-Saharan Africa and Southeast Asia) costs approximately ten times more than other vaccines in the World Health Organization's (WHO) Extended Programme on Immunization (a WHO and UNICEF program aimed at providing vaccines to children in developing countries).<sup>24</sup> A new drug for bacterial meningitis was determined to have a higher efficacy rate than a common treatment, but costing ten times more. Bacterial meningitis is the main cause of pneumococcal disease, a severe acute respiratory tract infection which is the primary cause of death of children in Africa. Since patents lead to prohibitive pricing, generic versions of these drugs are needed to help NGOs (non-governmental organizations) in containing diseases and improving health care in regions like Africa.

### Flaws of the Jean Chretien Pledge to Africa Act

Under the JCPA, Canada allows domestic generic manufacturers to produce and export patent protected medication to developing countries. Despite its lofty goals, the Act is seriously flawed and has had little impact. It has only been used once (with Rwanda) for a single shipment of HIV ARV drugs manufactured by Apotex.<sup>25</sup> Details of that case illustrate the Act's deficiencies and why it has not been employed more often.

Firstly, despite the Act having been constructed with the express intent of enticing generic manufacturers to fill the access to drugs gap, Médecins Sans Frontières (MSF) initiated and guided the Rwanda/Apotex deal to fruition.<sup>26</sup> Apotex's involvement was procured by MSF and the NGOs international contacts facilitated the eventual deal with Rwanda.<sup>27</sup>

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<sup>23</sup> *Ibid.*

<sup>24</sup> Pecoul, *supra* note 12 at 364.

<sup>25</sup> Holger P. Hestermeyer, "Canadian Made Drugs for Rwanda: the First Application of the WTO Waiver on Patents and Medicines" (2007) 11:28 ASIL Insights online: American Society for International Law <<http://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and>>.

<sup>26</sup> Richard Elliot, "Delivery Past Due: Global Precedent Set Under Canada's Access to Medicines Regime" (2008) 13:1 HIV/AIDS Policy & Law Review 4 at 5-6, online: <<http://www.aidslaw.ca/site/delivery-past-due-global-precedent-set-under-canadas-access-to-medicines-regime-hiv-aids-policy-law-review-131/>>.

<sup>27</sup> *Ibid.*

Secondly, since the drugs were not included in the schedule of exempted drugs listed in the amended *Patent Act*<sup>28</sup> the drugs were a 3-in-1 combination of drugs that did not previously exist, the Act had to be amended before manufacturing could take place. This process took nine months. It then took an additional year for Health Canada to approve the generic drug. However, MSF had not yet found a developing country willing to accept the importation and take the request to the TRIPS Council and Government of Canada, as required by the Act.<sup>29</sup>

There are many reasons for this, but there is a belief that developing countries did not want to draw the ire of powerful supporters of international patent protection like the United States.<sup>30</sup> The embers of the well-known US-South Africa dispute of 1998 were still warm. In this dispute, pharmaceutical companies filed suit against the South African government to repeal a law which allowed the state to issue compulsory licenses for any domestic health emergencies.<sup>31</sup> The United States government openly supported the suit by withholding trade benefits and threatening trade sanctions unless the law was amended.<sup>32</sup> It did not relent from this position until the negative publicity and protests became loud enough to be politically embarrassing (for example, Al Gore was publically heckled at campaign events in 1999 by activists for “killing babies in Africa”).<sup>33</sup>

Nonetheless, the United States initiated a WTO trade dispute with Brazil in 2001 over a Brazilian law which created loopholes enabling generic manufacturers to circumvent TRIPS and receive compulsory licenses for patent-protected critical illness drugs.<sup>34</sup> In that case, the two countries eventually reached an agreement outside of the dispute resolution board. Since demonstrating openness to use compulsory licenses can bring criticism from the world’s most influential economies, it is easy to understand why MSF had difficulty persuading governments of developing nations to enter into business with Apotex.

In July 2007, Rwanda, after notable intervention by the Clinton Foundation, eventually agreed to partner with Apotex and entered into a

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<sup>28</sup> *Patent Act*, RSC 1985, c P.4, s. 21.02.

<sup>29</sup> Elliot, *supra* note 26 at 5.

<sup>30</sup> Hestermeyer, *supra* note 25.

<sup>31</sup> Ellen F.M. 't Hoen, “TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha, and Beyond.” (2002) 3 *Chi J of Int'l L* 41 at 43.

<sup>32</sup> *Ibid* at 44.

<sup>33</sup> *Ibid*.

<sup>34</sup> *Ibid* at 45

contract to receive the drugs.<sup>35</sup> Rwanda would receive 15.6 million tablets for US\$0.40 per tablet.<sup>36</sup> However, before the compulsory license could be issued, Apotex had to notify the patentees of its intent to export and attempt to negotiate a voluntary license.<sup>37</sup> In September of that year, the company received a two-year compulsory license from the federal government and exported the drugs in 2008 and 2009.<sup>38</sup> At the end of its license, Apotex stated it would not be seeking renewal as the process was overly bureaucratic and did not make economic sense for the company.<sup>39</sup>

### *Obstacles for Generic Manufacturers*

Since the Act places most of the responsibility for carrying out its objectives on private actors, generic manufacturers must take on heavy burdens. As a result, the financial costs of developing drugs for poor countries are not worthwhile for generic manufacturers. Overall, there is a large amount of uncertainty and little financial reward. Amendment of the *JCPA* or introduction of a new access to medicines regime to place greater responsibility on government actors could make it more effective.

Manufacturers must invest a large amount of capital at the initial outset, since the medications most required by poor countries are often newer drugs that are still patent-protected in Canada.<sup>40</sup> Therefore, the generic manufacturer has to perform significantly more research, testing, and development than if it were a product the company already manufactured. There are no additional incentives (like potential sales domestically) to make a generic version of a recent drug. Furthermore, although poor countries tend to have high demand for treatments of tropical diseases, research and development has been steadily declining in this area during the past few decades.<sup>41</sup> To fill this void, the government of Canada could award grants to generic manufacturers for the development of newer drugs or drugs aimed at

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<sup>35</sup> Elliot, *supra* note 25 at 5.

<sup>36</sup> Bernard Hoekman & Michel Kostecki, *The Political Economy of the World Trading System: WTO and Beyond*, 3<sup>rd</sup> ed (New York, Oxford University Press 2001) at 365.

<sup>37</sup> Elliot, *supra* note 26 at 5-7.

<sup>38</sup> *Ibid* at 6.

<sup>39</sup> Apotex Corp, News Release, "CAMR Federal Law Needs to be Fixed if Life-Saving Drugs for Children are to be Developed" (14 May 2009) online: Apotex <<http://www.apotex.com/global/about/press/20090514.asp>>.

<sup>40</sup> Canadian Generic Pharmaceutical Association, News Release, *Bill C-9, An Act to Amend the Patent Act and The Food and Drugs Act: Submission to House of Commons Standing Committee on Industry, Science and Technology*, online: <<http://www.canadiangenerics.ca/en/news/bille9.asp>>.

<sup>41</sup> Ng, *supra* note 10 at 364.

tropical diseases, which will also reduce risk for the manufacturers. Otherwise, their only incentive is making end profits from NGOs and charities. As mentioned above, that profit margin is not very lucrative.<sup>42</sup>

Since a poor country is unlikely to commit to purchasing drugs before a generic company invests in development, the risk for manufacturers is high. Governmental and NGO partners require the manufacturer to have a history of creating safe, effective versions of a particular drug before purchase. Although this is normal practice in business, it is inefficient if the goals are humanitarian. A lack of a guarantee makes the potential for loss substantial. One way to reduce this risk is for a governmental agency to guarantee the purchase of a set amount of drugs, perhaps through the Canadian International Development Agency (CIDA) or a similar organization. This would be in line with CIDA's general mandate to manage Canada's resources effectively and accountably to achieve meaningful, sustainable results in the international effort to help people living in poverty.<sup>43</sup> It is worth mentioning that CIDA's direct, on-the-ground involvement in African health care mainly consists of infrastructure support like providing vocational training to nurses or improving access to clean water.<sup>44</sup> Although the agency finances United Nations and WHO-based programs like the Global Fund which purchase and distribute vaccines and medicines,<sup>45</sup> it has never undertaken a role as expansive as purchasing drugs from generic manufacturers and directly distributing them among the NGO network in a poor country. This intermediary role would still be consistent with the organization's historical directive of contributing to development in poor countries.

One of the greatest deterrents for generic manufacturers is the large role the patent-holder plays in the process, especially in regards to the ability to commence litigation. The Act requires patent-holders to receive a royalty when a compulsory license is granted for their product. This is reasonable. If a generic company is going to profit from a patent-holder's invention, they should receive remuneration. The Act has a reasonable royalty rate formula<sup>46</sup> (ranging on a sliding scale from 0.02% to 3.5% depending on the importing country's ranking in the UN Human Development Index<sup>47</sup>). The final royalty

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<sup>42</sup> Elliot, *supra* note 26 at 42.

<sup>43</sup> Canadian International Development Agency, "Mission and Mandate" (Ottawa: 19 June 2013) online: Foreign Affairs, Trade and Development Canada <<http://www.acdi-cida.gc.ca/acdi-cida/acdi-cida.nsf/eng/NIC-5493749-HZK>>.

<sup>44</sup> Canadian International Development Agency "Lists by Sector" (Ottawa: 14 August 2014).

<sup>45</sup> Canadian International Development Agency "Project Profile" (Ottawa: 14 August 2014).

<sup>46</sup> *Supra* note 1, s 21.08.

<sup>47</sup> Ng, *supra* note 10 at 160.

is set by CAMR (Canada's Access to Medicines Regime), but the Act allows parties the right to appeal a royalty amount to the Federal Court.<sup>48</sup> Under the *EU Regulation*, "remuneration paid to the patent holder is limited by a ceiling of 4% where the product is used in situations of extreme urgency".<sup>49</sup> In court, the ceilings can be lifted if a judge deems it appropriate. This is so because Canada believes a "one-size-fits-all" royalty approach does not duly honour the spirit of TRIPS reconciliation from which the Act was born.<sup>50</sup>

This provision is extending deference to the patent-holders by acting as a safeguard against situations where generic profits may be higher than originally envisioned.<sup>51</sup> If this occurs, the Act does not consider it appropriate to restrict brand companies from that extra profit. Specifically, it stipulates that if the exported drug is sold at a price 25% or more of "the average price in Canada," then the deal is "commercial in nature" and the patent-holder has a right to recourse.<sup>52</sup> To establish a deal with a poor country as non-commercial, the court can authorize a supervised audit of the generic company's business plan, thereby creating a further obstacle. It is incongruous for the government to rely on the capitalist spirit of generic manufacturers to fill the access to medicine gap while stipulating the dealings retain a humanitarian nature, as if to compel the companies to act as non-profit agencies.<sup>53</sup> Restricting that spirit further limits the efficacy of the Act. Generic manufacturers believe that if brand companies contest royalties and other issues in court, the litigation costs will harm their already low profit margins.<sup>54</sup> Balancing generic manufacturers and brand patent-holders interests is a difficult task, but the obstacles are major disincentives to participation by the former. If the government seriously wants to fulfill the Act's humanitarian objectives, it will have to limit the rights of brand companies.

Another obstacle for generic manufacturers is the two-year limit on compulsory licenses, with only one right of renewal, thereby ensuring

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<sup>48</sup> *Supra* note 1, s. 21.08(4).

<sup>49</sup> Ng, *supra* note 10 at 161.

<sup>50</sup> *Ibid* at 161.

<sup>51</sup> *Ibid* at 159-160.

<sup>52</sup> *Supra* note 1 at s 21.17 (1). These terms are ambiguous and undefined in the Act, thereby making it difficult for generic manufacturers to plan around them.

<sup>53</sup> Ng, *supra* note 10 at 171.

<sup>54</sup> Government of Canada, Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act (Ottawa: Multimedia Services Section Communications and Marketing Branch, 2007) at 19, online: Canada's Access to Medicines Regime <[http://www.camr-rcam.gc.ca/review-reviser/camr\\_rcam\\_report\\_rapport-eng.pdf](http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_report_rapport-eng.pdf)> [Government of Canada Statutory Review].

compulsory licenses are valid for a maximum of four years.<sup>55</sup> Nothing in TRIPS<sup>56</sup> or the WTO General Council's decision calls for limits on compulsory licenses.<sup>57</sup> There is little reason to include this limitation, except as a commitment to patent protection and discouragement to generic manufacturers.<sup>58</sup> The government felt the two-year period was reasonable because it aligned with the typical shelf life of a drug.<sup>59</sup> However, the cap limits generic manufacturers from engaging in long-term planning and increases risk. In effect, it only gives a company four years to recoup their investment, which prevents them from "achieving the necessary economies of scale and provides a reduced market incentive for generics to even negotiate such contracts."<sup>60</sup> Naturally, a longer license allows more decision-making flexibility and certainty for companies. After obtaining a license to manufacture a certain drug for a specific country, if the company wants to sell that same drug to a different country, CAMR should allow for a way to streamline the application process. As whole regions like sub-Saharan Africa or Southeast Asia suffer from epidemics, it is ineffective to restrict trade to state boundaries. It would be more effective if manufacturers could contract with an NGO to administer drugs in two or more countries, since many NGOs have wide networks.

All of the aforementioned obstacles effectively discourage generic manufacturers to get involved. If the Act wants to better utilize market forces to fill the gap in access to medicines, it should remove these barriers. Otherwise, a vague and ineffectual limbo will remain between humanitarian outreach and trade-based aid policy.

### *Obstacles for Developing States*

Another reason for which the Act has only been employed once is that it provides challenging obstacles for developing countries. This is due to a number of factors which demonstrate that the Canadian government will have to take a strong and active role in order to realistically increase access to essential medication.

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<sup>55</sup> Elliot, *supra* note 26 at 15.

<sup>56</sup> Ng, *supra* note 10 at 15.

<sup>57</sup> Hestermeyer, *supra* note 25.

<sup>58</sup> Hore, *supra* note 7 at 16.

<sup>59</sup> Weitsman, *supra* note 3 at 108

<sup>60</sup> Ng, *supra* note 10 at 171.

One major obstacle is the lack of political will in developing countries to pursue compulsory licenses. For example, in Guatemala, a generic company would be unlikely to receive the government's support as the AIDS issue is not on the government's political agenda, despite MSF wishing to import ARV drugs.<sup>61</sup> Since the Act stipulates that only governments or agents of government can enter into negotiations with generic manufacturers,<sup>62</sup> NGOs like MSF in Guatemala are unable to take action on their own without political support. While it is theoretically sensible for NGOs to obtain support from a state before importing drugs, it can be a practical obstacle for organizations seeking to help populations in need. Also, it is an unnecessary component of the Act, on top of what is required by the WTO General Council decision.<sup>63</sup> Further, requiring NGOs to seek permission from an importing country may subject the NGO to manipulation by that state's government.<sup>64</sup> Since developing countries typically lack strong rule of law and are plagued by petty corruption, this can make the work of NGOs more difficult. By not allowing NGOs to directly contract with generic manufacturers, Canada is in effect enforcing the drug and customs laws of Guatemala when their role should be focused toward the facilitation of generic drugs to poor countries.

As previously mentioned, another obstacle is the political pressure and threat of trade penalties from developed states like the United States and European Union towards developing countries that pursue compulsory licenses. Intellectual property protection is very important for developed states. In fact, TRIPS' inclusion in the WTO would likely not have succeeded without the US's insistent advocacy.<sup>65</sup> The United States engaged in notable disputes against South Africa and Brazil in the late 1990s and early 2000s that served to show it was willing to reinforce international IP protection with the muscle of trade threats.<sup>66</sup> In the dispute against Brazil, the United States argued that Brazil's domestic patent laws violated TRIPS.<sup>67</sup> The impugned law was a provision of Brazil's intellectual property statutory regime which required holders of patents in Brazil to manufacture their products in the

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<sup>61</sup> Weitsman, *supra* note 3 at 114.

<sup>62</sup> *Supra* note 1 at s 21.04(2)(f).

<sup>63</sup> Ng, *supra* note 10 at 153-154.

<sup>64</sup> *Ibid* at 154.

<sup>65</sup> Weitsman, *supra* note 3 at 16.

<sup>66</sup> 't Hoen, *supra* note 31 at 44.

<sup>67</sup> *Ibid* at 45.

country.<sup>68</sup> If the patent-holder did not fulfill this requirement, the product became subject to compulsory licensing after three years.<sup>69</sup>

This law was used to manufacture generic versions of the ARV drugs used in Brazil's AIDS program.<sup>70</sup> It was credited for significantly reducing the cost and increasing the scope of the program.<sup>71</sup> The United States argued it discriminated against American owners of Brazilian patents, while Brazil countered that the law was in line with TRIPS' article 2.1 which allows for compulsory licenses if there is a failure to work and develop a patent<sup>72</sup> (this is in line with the belief that an owner should not be able to just sit on a patent for the entire term; if the owner is not developing the patent, others should be free to develop it). The United States ultimately settled with Brazil and dropped the dispute.<sup>73</sup> However, the effects were clear: the United States would employ its considerable economic resources to deter compulsory licenses and protect patent-holders rights. Although Brazil is not a state for which the JCPA is intended, this case effectively illustrated how the risk of trade penalties is real enough to deter states from pursuing compulsory licenses. In fact, since Brazil is considered one of the more powerful developing economies, poor countries may have even more reason to stay away from such initiatives.

To combat this lack of political will in importing countries, the government of Canada should take a more active role in persuading developing states' governments to contract with Canadian generic manufacturers. This can be done as part of trade deals. Similar duties are already part of the mandate of the Canadian Trade Commissioner Service (CTCS). This service assists Canadian businesses in establishing business relations abroad by providing market knowledge and foreign contacts. The CTCS already possesses the infrastructure to help Canadian businesses support aid and development initiatives in the developing world.<sup>74</sup> The service specifically assists Canadian businesses in bidding and landing untied aid contracts from bilateral or multinational agencies.<sup>75</sup> Using this knowledge,

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<sup>68</sup> *Ibid.*

<sup>69</sup> *Ibid.*

<sup>70</sup> *Ibid.*

<sup>71</sup> *Ibid.*

<sup>72</sup> *Ibid.*

<sup>73</sup> *Ibid.* at 46.

<sup>74</sup> Canadian Trade Commissioner Service, "Development Markets," (Ottawa: 16 July 2014) online: Government of Canada <<http://www.tradecommissioner.gc.ca/eng/development-humanitarian-aid-markets/dev-markets.jsp>>

<sup>75</sup> *Ibid.*

the CTCS could assist Canadian generic manufacturers in procuring contracts from the UN and international organizations that administer the funds. At the very least, the CTCS could help Canadian generic drug companies partner with NGOs like MSF and other on-the-ground organizations that bid on these projects.

The projects typically encompass a multiple-pronged approach (socio-economic development, education, and health care) to combat a targeted ill. For example, there is currently a \$20 million contract available from the Organization for Economic Co-operation and Development (OECD) to combat and reduce HIV/AIDS transmission for the “most at risk populations” in a region of Cameroon.<sup>76</sup> The winning tender must contain a strategy that involves the multiple prongs mentioned above. If the Act’s legislative scheme was more efficient and facilitating, Canadian generic manufacturers could be involved in such bids with NGOs and international organizations. Instead, the Act needlessly limits manufacturers by requiring them to contract with agents of government despite aid programs in the developing world being typically run by donor organizations, not national governments.

## Legal Solutions

Although this paper advocates for a broader policy overhaul involving greater government involvement, some minor changes to the legal mechanisms of the Act and CAMR can increase its efficiency without increasing government’s role and invoking all of the political discussion which that type of change normally involves. Removing schedule 1, eliminating vagueness, and applying the Act to non-member states of the WTO would be a step in the right direction.

Schedule 1 should be removed and the Act instead should follow the wide parameters outlined in the WTO’s Paragraph 6 decision regarding which drugs qualify for compulsory licenses. The WTO simply states “all pharmaceuticals” and “allows the importing country to notify the WTO of whichever products they need.”<sup>77</sup> The Act goes beyond the WTO’s requirements by containing a schedule of drugs that generic manufacturers may manufacture. Under the Act, all drugs to be exported must be listed on

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<sup>76</sup> Organization for Economic Co-operation and Development, “Untied Official Development Assistance” (25 November 2013) online: OECD: <<http://webnet.oecd.org/UNTIEDAIDWEB/NotificationList.aspx?Lng=en&Mnu=true&GroupBy=when>

<sup>77</sup> Goodwin, *supra* note 16 at 578.

Schedule 1.<sup>78</sup> This is required for not only new drugs but new combinations and dosages of approved drugs.<sup>79</sup> Due to the fluid and dynamic nature of HIV/AIDS treatment, requiring generic manufacturers to obtain formal amendment of the Schedule to add new drugs is an unnecessary delay.<sup>80</sup> It took nine months for the Schedule 1 amendment to pass in the Rwanda/Apotex case. It is confounding that the Act goes beyond the WTO's decision to impose its own stifling measures.

Eliminating certain vague terms and provisions of the Act can decrease the amount of business uncertainty generic manufacturers face. For example, the Act requires a generic company to negotiate for a volunteered license from the brand patent holder before applying for a compulsory one. The Act stipulates that negotiations involve "reasonable terms and conditions."<sup>81</sup> CAMR has not provided any guidance on what "reasonable" constitutes and is silent on what it expects from negotiation efforts.<sup>82</sup> For purely commercial dealings, state input on negotiation processes is abnormal and unwarranted. But for transactions involving humanitarian affairs, a high level of government involvement could expedite the process. Otherwise, patent holders can stifle the process via negotiation techniques such as "by making the mere offer to negotiate."<sup>83</sup> Such a threat of delay is an obstacle for generic manufacturers.

Removing the negotiation requirement altogether and allowing manufacturers to apply directly for a compulsory license could overcome the vagueness surrounding negotiation. Generic companies have expressed that this would be far more attractive for them.<sup>84</sup> Although this may limit the rights of the patent holder, such rights are inevitably relegated in any discussion of compulsory licenses to relieve humanitarian crises.

Also, the Act does not apply to non-WTO member states. In order to be added to Canada's list of eligible importing states, a non-WTO member must declare "an emergency or other circumstances of extreme urgency."<sup>85</sup> Although many poor states that would theoretically benefit from the JCPA are WTO members, this provision is nonetheless a needless hurdle for the few

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<sup>78</sup> *Ibid* at 574.

<sup>79</sup> *Ibid* at 579.

<sup>80</sup> *Ibid*.

<sup>81</sup> *Supra* note 1 at s 21.04(3)(c)(i).

<sup>82</sup> Stacey B. Lee "Can Incentives to Generic Manufacturers Save the Doha Declaration's Paragraph 6?" (Summer 2013) 44 *Geo J Int'l L* 1387 at 1401.

<sup>83</sup> *Ibid*.

<sup>84</sup> Goodwin, *supra* note 16 at 578.

<sup>85</sup> Elliot, *supra* note 26 at 7.

poor markets that possess non-member or observer status. Further, it is a demonstration of “bad faith” that goes against the Act’s humanitarian principles.<sup>86</sup> Such a provision is representative of a conflict at the core of the Act: is its primary purpose to facilitate the aid of sick residents of poor countries or to demonstrate that the current framework of the WTO and international patent law can fill the access to medicines gap? Since the Act was schematically constructed with greater attention to the latter, its ineptitude in achieving the former is not surprising. Removing this discriminatory policy would signal to manufacturers and NGOs that Canada’s main aim is providing medicine to those in need. This, along with changes discussed below in the “Alternative Solutions” section of the paper, can help reignite interest among generic manufacturers.

### **Alternative Solutions**

Since breakthrough discoveries and innovations that have high social value “will be ignored by private drug companies if they have low commercial appeal,”<sup>87</sup> it is necessary for government to fill this gap by creating conditions that reward pharmaceutical companies for fully developing and actualizing such discoveries.<sup>88</sup> This section examines the ways that this could be done by implementing economic prizes for not only the creation of such drugs but also for increasing their availability in the developing world. Economic prizes do not entail direct subsidies. Instead, they involve creating conditions that increase competition, reward commercialization of applied research, and provide benefits for increasing access to drugs in the developing world.

#### *Advanced Purchases*

A legislative scheme committing government to an advanced purchase of essential drugs can lead to pharmaceutical companies (brand and generic) investing more heavily in lifesaving drugs.<sup>89</sup> This would provide pharmaceutical companies with a guaranteed purchaser and with an incentive to develop innovative drugs through commercialization.<sup>90</sup> This type of “pull

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<sup>86</sup> *Ibid* at 8.

<sup>87</sup> Marhi Kim & Bryan Schwartz, “Economic Prizes: a New Model for Pharmaceutical Innovations” (2006) 6 *Asper Rev Int’l Bus & Trade L* 1 at 43.

<sup>88</sup> *Ibid*.

<sup>89</sup> Michael Kremer, “Pharmaceuticals and the Developing World” (2002) 16 *Journal of Econ. Perspectives* 67 at 75.

<sup>90</sup> *Ibid*.

program” can be more beneficial than a push program of direct subsidies because it prevents a company from diverting those funds to other projects.<sup>91</sup> It also retains a spirit of competitiveness, as companies will seek to be the first to obtain the defined award.<sup>92</sup>

In relation to the JCPA, it would be more enticing to generic manufacturers if they could use their compulsory licenses to sell directly to the Canadian government, rather than forging a market. This will reduce costs, as they do not need to expend efforts in obtaining contracts from foreign governments. It will also provide a guaranteed minimum income, which allows for more long-term planning. The investment of research, testing, and obtaining a compulsory licensing will become worthwhile, even if selling at reduced rates for the developing world market. Overall, an advanced purchasing commitment addresses two fundamental flaws with the current Act: it provides economic certainty for generic manufacturers and increases the role of government.

Canada has already performed advanced purchase schemes to improve access to drugs in the developing world. In 2007, Canada was one of five countries along with the Bill & Melinda Gates foundation to launch an advanced market commitment pledge of \$1.5 billion to the developer of marketable vaccines for pneumococcal disease.<sup>93</sup> The pledge program was later adopted by the GAVI Alliance, which receives funding from 46 different countries.<sup>94</sup> By creating a market, it invigorated pharmaceutical companies’ efforts and the vaccine is currently being implemented around the developing world.<sup>95</sup>

Also, such an initiative allows government, not market forces, to dictate which diseases or illness should receive priority. This needs-based allocation of resources ensures that the deadliest and most widespread illnesses are combated.<sup>96</sup> It also allows government to push for vaccines that ensure long-term immunization, rather than short durations. For example, it is less meaningful for poor countries if pharmaceutical companies develop a malaria vaccine geared towards travelers or individuals intending to spend a

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<sup>91</sup> *Ibid* at 83-84.

<sup>92</sup> *Ibid* at 83.

<sup>93</sup> GAVI Alliance, News Release, “Advance Market Commitments ‘promising solutions’ to global health challenges” (7 March 2013) online: <<http://www.gavialliance.org/library/news/press-releases/2013/advance-market-commitments-promising-solutions-to-global-health-challenges/>>.

<sup>94</sup> *Ibid*.

<sup>95</sup> *Ibid*.

<sup>96</sup> Kim, *supra* note 87 at 35.

short time in a country.<sup>97</sup> Yet, under the current Act, a company can obtain a compulsory license to sell a short-term malaria vaccine to MSF that has little benefit for the residents of a poor country.

### *Encouraging Donations*

A problem with compulsory licensing and the differential pricing paradigm (the concept of not charging developing states the full price that is charged in the developed world) it creates, is that it devalues international IP protection and discourages pharmaceutical companies from R&D investment. If a company is not going to be able to realize the full economic benefits of its discovery, it has less reason to pursue similar discoveries. There can be negative political repercussions of lowering prices of drugs in the developed world<sup>98</sup> which may undermine the value of property rights in the north. Although American Aids activists may laud pricing \$10,000 ARV drugs for under \$500 in Africa, they may also demand reduced prices in the United States. This is part of the reason why pharmaceutical companies so aggressively push for international IP protection and consistent pricing.<sup>99</sup>

However, simply donating drugs and providing enhanced tax deductions to pharmaceutical companies can be effective, as this would protect the integrity of patent law while also allowing for price differentiation.<sup>100</sup> Deductions can be measured by a drug's social value in the developing country rather than its manufacturing cost in Canada, since the former would likely be higher. Donating drugs can employ the same procedural safeguards mentioned in the JCPA (such as ensuring that the donations reach intended patients and punishing re-export of the drugs). This can provide more economic certainty for generic manufacturers than the Act in its current form, as it is naturally easier to acquire importing partners if one is giving away a product for free, as opposed to charging a price that is likely to be undercut by a more competitive generic manufacturer in India.

There are also significant marketing benefits to be had from the goodwill associated with donating medication and creating products for the public good.<sup>101</sup> Official state acknowledgement and promotion can be worked in as part of the deal. Pharmaceutical companies already spend such high

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<sup>97</sup> Kremer, *supra* note 97 at 83.

<sup>98</sup> *Ibid* at 78.

<sup>99</sup> *Ibid*.

<sup>100</sup> *Ibid*.

<sup>101</sup> Kim, *supra* note 87 at 34.

amounts on marketing that donations can be considered part of that budget. In 2000, brand companies devoted 35% of their budget to marketing (which is greater than the portion spent on R&D), demonstrating the importance of promotion and positive publicity to the industry.<sup>102</sup> Positive publicity can:

- 1) connote positive images to help combat the popular negative image associated with big pharmaceutical companies;
- 2) provide cross-promotional benefits to a company's other drugs; and
- 3) expand a company's reach in a developing market (territory is a fundamental part of sales).<sup>103</sup>

As a whole, the marketing benefits can be an important factor in encouraging pharmaceutical companies to enter donation/tax deduction deals.

## Conclusion

A discussion of international patent protection (IPP) and access to medicines would be remiss without mention of globalization and the larger forces at play. Jagdish Bhagwati espoused that effective lobbying by pharmaceutical companies has effectively turned the WTO from a basic goods and services facilitator in to a “royalty-collection agency.”<sup>104</sup> Bhagwati acknowledges international patent law naturally creates a problem of incongruity for free trade, especially in the field of pharmaceuticals.<sup>105</sup> On the one side, masses of the poor suffer from illnesses which human scientific ingenuity has the capacity to alleviate. On the other side, classical liberalism (the ideological foundation of free trade) dictates that a person has full right to the fruits of their labour. However, the WTO inflamed this divide by allowing TRIPS to include a twenty-year patent term, “a period so long that few economists can be found who would call it [an] efficient” balancing of the two forces.<sup>106</sup> Hence, compulsory license measures like the JCPA have so far been ineffectual in bridging the access to medicines gap. Such attempted solutions are far too concerned with the perspective of IPP stakeholders than correcting public health crises in poor countries.

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<sup>102</sup> *Ibid.*

<sup>103</sup> *Ibid.*

<sup>104</sup> Jagdish Bhagwati, *In Defense of Globalization* (New York: Oxford University Press, 2004) at 182.

<sup>105</sup> *Ibid.* at 184.

<sup>106</sup> *Ibid.*

Ultimately, if IPP is going to be so strongly entrenched in free trade, the solution will not arise from traditional free market ideology. It must involve a greater role for national governments. Compulsory licenses can be an effective tool if they remove obstacles for generic manufacturers and place more onus on government to facilitate transactions. The *JCPA* was written with laudable intentions but it is too feeble in its present form to be effective, as demonstrated by having only been utilized once in nine years. Alternative solutions like advanced purchase agreements and incentivizing donations should be explored. With the *JCPA*, Canada sought to take a leadership role on an important global issue by being the first country to integrate the WTO General Council decision in to its national law.<sup>107</sup> Now the opportunity for leadership lies in pursuing bold alternative solutions that place greater responsibility on government.

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<sup>107</sup> Weitsman, *supra* note 3 at 64.

