

# Delivering on the Pledge: Global Access to Medicines, WTO Rules, and Reforming Canada's Law on Compulsory Licensing for Export

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*The global AIDS crisis has highlighted the importance of expanded and sustainable access to lower-cost, generic medicines in realising the development aspirations of many low- and middle-income countries. In 2003, WTO members decided to relax a restriction in the TRIPS Agreement, ostensibly to permit countries with insufficient pharmaceutical manufacturing capacity to make effective use of compulsory licensing by importing generics. Canada and a handful of other jurisdictions have implemented that WTO decision, but none of these regimes have yet been used to supply any developing country with any medicine. While Canada's law suffers from a number of features that hinder its usefulness, more*

*fundamentally the flaw lies in the underlying WTO decision. This article outlines the relevance of WTO rules on intellectual property to the global inequity in access to medicines and reviews key developments at the WTO underlying such legislation. It then discusses the key features, positive and negative, of Canada's law, and the two initiatives to date to use it. Finally, it presents reforms that would streamline the legislation, making it more likely to meet the needs of both developing country purchasers and potential generic exporters; the alternative regime presented here would bypass the flawed 2003 WTO decision but remain TRIPS-compliant.*

*La crise mondiale du SIDA a soulevé l'importance d'accroître l'accès durable à des médicaments génériques plus abordables afin de promouvoir les projets de développement des pays à faible et à moyen revenu. En 2003, les membres de l'OMC ont choisi d'assouplir l'une des restrictions de l'ADPIC, sous prétexte de permettre aux pays ayant une capacité de fabrication pharmaceutique insuffisante de faire bon usage de la concession de licences obligatoires par l'importation de médicaments génériques. Tant le Canada qu'un nombre important de juridictions ont mis en application la décision de l'OMC, sans toutefois qu'un seul de ces régimes n'ait été utilisé jusqu'à maintenant pour fournir de la médication aux pays en développement. Quoique la législation canadienne fasse état de certaines déficiences qui nuisent à son utilité, la lacune provient plus fondamenta-*

*ment de la décision de l'OMC. L'article dresse la pertinence des règles de l'OMC sur la propriété intellectuelle quant à l'iniquité mondiale prévalant sur la situation de l'accès aux médicaments, et commente les développements clés au sein de l'OMC qui sous-tendent cette législation. Puis, l'auteur traite des éléments importants, tant positifs que négatifs, de la législation canadienne, ainsi que des deux initiatives actuelles cherchant à l'appliquer. Finalement, il propose des réformes dans le but de rationaliser la législation, ralliant de façon plus réaliste les besoins des acheteurs, soit les pays en développement, et des exportateurs potentiels de médicaments génériques. Le régime alternatif proposé ici permettrait de remédier à la décision problématique de l'OMC de 2003 tout en demeurant conforme à l'ADPIC.*

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Worldwide access to affordable medicines is a human rights imperative, a critical component of an effective response to the global public health crisis of HIV/AIDS, and fundamental to realizing the development aspirations of many low- and middle-income countries suffering tremendous human and economic losses as a result of this and other treatable diseases. The use of lower-cost, generic pharmaceuticals is central to scaling-up treatment and ensuring sustainable supply at prices that developing countries can afford. On August 30, 2003, members of the World Trade Organization (WTO) adopted unanimously a decision that relaxed a restriction in the *Agreement on Trade-Related Aspects of Intellectual Property Rights*<sup>1</sup> (TRIPS or TRIPS Agreement), in order to allow the compulsory licensing of patented pharmaceutical products in a WTO Member for the purpose of producing and exporting generics to eligible countries lacking sufficient manufacturing capacity.<sup>2</sup> In May 2004, Canada enacted the first detailed legislation implementing the WTO decision; a handful of other jurisdictions have also adopted similar laws or other instruments. However, it was not until September 2007, after years of concerted effort by NGOs and a generic manufacturer, that the first steps were taken to use the WTO decision for the first time, via Canada's law, to supply an eligible importing country with any generic medicine. In that month, Canada's Commissioner of Patents issued the first compulsory licence to a Canadian

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<sup>1</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, Annex 1C of the *Marrakesh Agreement Establishing The World Trade Organization*, Legal Instruments – Results of the Uruguay Round Vol. 31, 33 I.L.M. 1197 (1994) [*TRIPS Agreement*].

<sup>2</sup> WTO General Council, "Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", WTO Doc. IP/C/W/40 (30 August 2003), online: WTO <[http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm)> [*August 30th Decision*].

generic manufacturer, authorizing Apotex, Inc. to export a fixed-dose combination antiretroviral (ARV) AIDS drug to Rwanda.

As is the case with each of the regimes that have been adopted to date to implement the WTO's decision, the Canadian legislation suffers from a number of flaws that hinder its usefulness. More fundamentally, however, the primary flaw is the cumbersome process set out in the underlying WTO mechanism. This article first presents the backdrop of global inequity in access to medicines, and the relevance of WTO rules on intellectual property to this public health, human rights, and development failing. It then provides a brief overview of debates and developments at the WTO regarding intellectual property and access to medicines, and the WTO 2003 decision that is the basis of Canada's current legislation on compulsory licensing of pharmaceuticals for export. This is followed by a more detailed discussion of key features, positive and negative, of Canada's law, and a brief look at the two initiatives to date to use it to secure lower-cost medicines for patients in developing countries. Finally, the article concludes by proposing reforms that would create a more streamlined process better able to meet the needs of both developing country purchasers and potential generic exporters, so that the initial effort to export generic medicines to Rwanda does not remain an isolated instance of the Canadian regime's use. The alternative regime presented here would bypass the flawed WTO 2003 decision but remain within the bounds of Canada's obligations under TRIPS.

## 2. GLOBALIZING THE HEALTH GAP: INEQUITY AND INTELLECTUAL PROPERTY

In 2000, the World Health Organization (WHO) estimated that currently one-third of the world's population then lacked access to "essential drugs",<sup>3</sup> with this figure rising to over 50 percent in the poorest parts of Africa and Asia.<sup>4</sup> Several years later, this situation remained largely unchanged: as of 2004, the total number of people with access to essential medicines remained an estimated 30 percent of the world population (somewhere between 1.3 and 2.1 billion people), with the lack of access particularly concentrated in Africa and India.<sup>5</sup> The HIV/AIDS crisis has highlighted the urgent need for "scaling up" the global response to the health needs of the developing world, including drastically expanding access to health care goods and technologies whose benefit has been reserved largely to the fortunate minority living in wealthier countries. The Joint United Nations Programme on HIV/AIDS (UNAIDS) has estimated that approximately 2.1 million adults and children died of AIDS in 2007,<sup>6</sup> and has previously estimated the cumulative death toll since the beginning of the recorded pandemic as approximately 25 million.<sup>7</sup> In the same year, an estimated 2.5 million people were newly infected with HIV, bringing to roughly 33 million the number of people currently living with

<sup>3</sup> WHO, *WHO Medicines Strategy: Framework for Action in Essential Drugs and Medicines Policy 2000-2003*, WHO/EDM/2000,1, (Geneva: WHO, 2000) at 2, online: WHO <<http://www.who.int/medicinedocs/>> [*WHO Medicines Strategy*]. The most current version of the list of essential medicines is: WHO, WHO Model List of Essential Medicines, 15th ed (March 2007), online: <[www.who.int/medicines/publications/essentialmedicines/](http://www.who.int/medicines/publications/essentialmedicines/)>.

<sup>4</sup> *WHO Medicines Strategy, ibid.*

<sup>5</sup> WHO, *The World Medicines Situation* (Geneva: WHO, 2004) at 61, 63 [*The World Medicines Situation*].

<sup>6</sup> UNAIDS & WHO, *AIDS Epidemic Update: December 2007* (Geneva: UNAIDS & WHO, 2007) at 1, online: <[http://data.unaids.org/pub/EPISlides/2007/2007\\_epiupdate\\_en.pdf](http://data.unaids.org/pub/EPISlides/2007/2007_epiupdate_en.pdf)>.

<sup>7</sup> UNAIDS, *2006 Report on the Global AIDS Epidemic* (May 2006) UNAIDS/06.13E at 4, online: <[http://www.unaids.org/en/HIV\\_data/2006GlobalReport/default.asp](http://www.unaids.org/en/HIV_data/2006GlobalReport/default.asp)>.

the virus around the world, almost 90 percent of whom live in sub-Saharan Africa, Asia, Latin America or the Caribbean.<sup>8</sup>

Expanding access to antiretroviral treatment (ART) for those living with HIV/AIDS is economically sound,<sup>9</sup> has been demonstrated to be feasible even in some of the most resource-poor settings,<sup>10</sup> and “is not just a moral necessity, but a necessary component of economic stabilization and an ultimate return to economic development in high prevalence parts of the world.”<sup>11</sup> In September 2003, the WHO and UNAIDS declared “the lack of access to antiretroviral drugs to be a global health emergency”,<sup>12</sup> an assessment recognized soon thereafter by the UN General Assembly, which has also recognized that access to HIV/AIDS medication is part of the human right to health under international law.<sup>13</sup> Describing HIV/AIDS as “the greatest

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<sup>8</sup> *Supra* note 6.

<sup>9</sup> For a recent review of debates and studies as to the economic dimensions of various interventions in the HIV/AIDS epidemic, particularly in the developing world, see: Jean-Paul Moatti *et al.*, “Antiretroviral Treatment for HIV-Infected Adults and Children in Developing Countries: Some Evidence in Favor of Expanded Diffusion” in Steven Forsythe, ed., *State of the Art: AIDS and Economics* (POLICY Project and International AIDS-Economics Network, July 2002) 96, online: <<http://www.policyproject.com/pubs/other/SOTAecon.pdf>>. See also the numerous published studies and reports cited therein, as well as the numerous articles in Jean-Paul Moatti *et al.*, eds., *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries* (Paris: Agence nationale de recherches sur le sida, 2003).

<sup>10</sup> See e.g. Antiretroviral Therapy in Lower Income Countries (ART-LINC) Study Group, “Cohort Profile: Antiretroviral Therapy in Lower Income Countries (ART-LINC): International Collaboration of Treatment Cohorts” (2005) 34 *International Journal of Epidemiology* 979.

<sup>11</sup> Commission on Macroeconomics and Health, *Macroeconomics and Health: Investing in Health for Economic Development* (Geneva: WHO, 2001) at 51 [*Macroeconomics and Health*]. Mark Heywood, one of the world’s leading AIDS activists, has pointed out that “[i]f we use terminology like ‘developing countries’, we give the impression that the whole world is moving in the same direction, albeit at varying rates. The whole world is not moving in the same direction. Many so-called ‘developing countries’ are more accurately described as undeveloping countries. They are going backwards. Confirmation of this can be found in the Human Development Reports produced annually by the UNDP. On a whole range of vital indicators, development is now being reversed”: Mark Heywood, “Drug Access, Patents and Global Health: ‘Chaffed and Waxed Sufficient’”, (2002) 23 *Third World Q.* 217 at 218 [Heywood, “Drug Access, Patents and Global Health”].

<sup>12</sup> WHO & UNAIDS, *Treating 3 Million by 2005: Making it Happen – The WHO Strategy* (Geneva: WHO, 2003) at 5-6, online: <<http://www.who.int/3by5/publications/documents/en/3by5StrategyMakingItHappen.pdf>> [*Treating 3 Million by 2005*].

<sup>13</sup> *Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria*, GA Res. 58/179, UN GAOR, 58th Sess., Supp. No. 49, UN Doc. A/RES/58/179 (22 December 2003), online: <[www.un.org/Depts/dhl/resguide/r58.htm](http://www.un.org/Depts/dhl/resguide/r58.htm)>. The resolution was adopted with 181 votes in favour, 1 vote against (United States) and no abstentions. This General Assembly resolution supplements repeated resolutions by States within the UN Commission on Human Rights, over five years, that access to medication constitutes a fundamental part of the human right to health: *Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria*, CHR Res. 2001/33, UN Doc. E/CN.4/RES/2001/33; *Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria*, CHR Res. 2002/32, UN Doc. E/CN.4/RES/2002/32; *Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria*, CHR Res. 2003/29, UN Doc. E/CN.4/RES/2003/29; *Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria*, CHR Res. 2004/26, UN Doc. E/CN.4/RES/2004/26; *Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria*, CHR Res. 2005/23, UN Doc. E/CN.4/RES/2005/23, all online via <[www.ohchr.org](http://www.ohchr.org)>. At the same session, the General Assembly overwhelmingly reaffirmed the human

health crisis the world faces today”, on 1 December 2003 (World AIDS Day), the WHO and UNAIDS launched their plan for putting 3 million people in developing countries on ART by the end of 2005.<sup>14</sup> That target was not reached, although the total number of people on treatment tripled during that time: as of December 2005, an estimated 1.3 million people in low- and middle-income countries were receiving ART, of the estimated 6.5 million people in need.<sup>15</sup> Treatment scale-up has gained momentum and commitments are being made, at least rhetorically, to strive for “universal access to treatment for all those who need it by 2010.”<sup>16</sup>

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right to the highest attainable standard of health: “The right of everyone to the enjoyment of the highest attainable standard of physical and mental health”, GA Res. 58/173, UN GAOR, 58th Sess., Supp. No. 49, UN Doc. A/RES/58/173 (22 December 2003), online: <[www.un.org/Depts/dhl/resguide/r58.htm](http://www.un.org/Depts/dhl/resguide/r58.htm)>. That resolution was adopted with 174 votes in favour, two votes against (United States, Marshall Islands) and 4 abstentions (Australia, Czech Republic, Sweden, United Kingdom). In 2006, the General Assembly unanimously reaffirmed that access to medication in the context of pandemics such as HIV/AIDS is one of the fundamental elements of the right to health: *Political Declaration on HIV/AIDS*, GA Res. 60/262, UN GAOR, 60th Sess., Supp. No. 49, UN Doc. A/RES/60/262 (2006) at para. 12, online: <[www.un.org/ga/aidsmeeting2006](http://www.un.org/ga/aidsmeeting2006)>, <[www.un.org/Depts/dhl/resguide/r60.htm](http://www.un.org/Depts/dhl/resguide/r60.htm)> [*Political Declaration on HIV/AIDS*].

<sup>14</sup> *Treating 3 Million by 2005*, *supra* note 12 at 3. *Treating 3 Million by 2005* also addresses numerous other elements of the action necessary to “scale up” access to ARVs within the context of comprehensive, effective, safe and sustainable delivery of health care to people living with HIV/AIDS in developing countries (with attendant spin-off benefits for responding to health conditions more generally). For an accessible overview describing the practical challenges in securing ARV therapy for people in developing countries, see MSF, WHO & UNAIDS, *Surmounting Challenges: Procurement of Antiretroviral Medicines in Low- and Middle-Income Countries – The Experience of Médecins Sans Frontières* (2003), online: <[www.accessmed-msf.org/documents/procurementreport.pdf](http://www.accessmed-msf.org/documents/procurementreport.pdf)>. The need for a multi-faceted approach to ensuring access to HIV/AIDS care, treatment and support – including attention to medicine prices and related intellectual property issues – is also recognized by UNAIDS and the Office of the UN High Commissioner for Human Rights in the guidance they provide to states on ensuring their responses to HIV/AIDS reflect human rights norms: “Guideline 6: Access to HIV/AIDS prevention, treatment, care and support (revised)”, *International Guidelines on HIV/AIDS and Human Rights*, 2006 Consolidated Version (Geneva: OHCHR & UNAIDS, 2006), at paras. 23-53, online: <[http://www.ohchr.org/english/issues/hiv/docs/consolidated\\_guidelines.pdf](http://www.ohchr.org/english/issues/hiv/docs/consolidated_guidelines.pdf)>.

<sup>15</sup> WHO & UNAIDS, *Progress on Global Access to HIV Antiretroviral Therapy: A Report on “3 by 5” and Beyond* (Geneva: WHO, 2006), online: <[www.who.int/hiv/fullreport\\_en\\_highres.pdf](http://www.who.int/hiv/fullreport_en_highres.pdf)> [*Progress on Global Access*].

<sup>16</sup> See e.g., *2005 World Summit Outcome*, GA Res. 60/1, UN GAOR, 60th Sess., Supp. No. 49, UN Doc. A/RES/60/1 (2005) at para. 57(d); Group of Eight, *Gleneagles Communiqué on Africa, Climate Change, Energy and Sustainable Development*, 8 July 2005, online: <[http://www.fco.gov.uk/Files/kfile/PostG8\\_Gleneagles\\_Communique,0.pdf](http://www.fco.gov.uk/Files/kfile/PostG8_Gleneagles_Communique,0.pdf)>, via <[www.g8.gov.uk](http://www.g8.gov.uk)>. See also the stated commitment to scaling up towards the goal of “universal access to comprehensive prevention programs, treatment, care and support by 2010”: *Political Declaration on HIV/AIDS*, *supra* note 13 at para. 49; Group of Eight, “Fight Against Infectious Disease”, St. Petersburg, 16 July 2006, at para. 15, online: <<http://en.g8russia.ru/docs/10.html>>. While the HIV/AIDS pandemic and other major diseases such as malaria and tuberculosis have necessarily received considerable attention, it should be remembered that non-communicable diseases in poor countries and poor populations represent a growing global burden, and that globalization of patent rules on pharmaceuticals directly and indirectly affects the development of epidemics of non-communicable diseases as well: Robert Beaglehole & Derek Yach, “Globalisation and the Prevention and Control of Non-communicable Disease: the Neglected Chronic Diseases of Adults” (2003) 362 *Lancet* 903-908.

One crucial element in scaling up treatment is the expanded use of generic antiretroviral drugs. Not surprisingly, the global evidence demonstrates that intellectual property protection rules affect the price of medicines, which in turn is an important determinant of access. The developing world bears a disproportionate share of the global disease burden, without the public resources for spending on health care to match. The WHO has reported that in developing and transitional countries 50-90 percent of pharmaceuticals are paid for by patients themselves and medicines are the major out-of-pocket health expense for poor households in most developing countries.<sup>17</sup> Yet poor people cannot afford patent-protected prices for medicines.<sup>18</sup> The WTO Secretariat has recognized that “for low-income countries and poor people in particular, bringing down the cost of medicines is key to gaining access to drugs. In developing countries, 25 to 65 percent of total health expenditures are spent on pharmaceuticals, but government health budgets are too low to purchase enough medicines and poor people often cannot afford to buy them on their own.”<sup>19</sup> Therefore, it is not surprising that the entire continent of Africa accounts for approximately only 1.3 percent of global pharmaceutical sales.<sup>20</sup>

Roughly 14 percent of those in the developing world fortunate enough to receive ART live in one country, Brazil, even though it has just over 3 percent of the global total number of people in need of HIV/AIDS treatment.<sup>21</sup> Brazil was one of the first developing countries to

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<sup>17</sup> Jonathan D. Quick *et al.*, “Twenty-five Years of Essential Medicines” (2002) 80 Bull. WHO 913 at 914, online: <[http://www.who.int/bulletin/archives/80\(11\)913.pdf](http://www.who.int/bulletin/archives/80(11)913.pdf)>.

<sup>18</sup> *Macroeconomics and Health*, *supra* note 11 at 87.

<sup>19</sup> WHO & WTO, *WTO Agreements & Public Health: A Joint Study by the WHO and the WTO Secretariat* (WHO/WTO, 2002) at para. 165, online: <<http://www.who.int/mediacentre/news/releases/who64/en/>>.

<sup>20</sup> UN Development Programme, *Human Development Report 2001: Making New Technologies Work for Human Development* (New York & Oxford: Oxford University Press, 2001) at 108, online: Human Development Reports <<http://hdr.undp.org/reports/global/2001/en/>>. For more detailed data, see *The World Medicines Situation*, *supra* note 5 at 31-51, and Kumariah Balasubramaniam, “Access to Medicines: Patents, Prices and Public Policy – Consumer Perspectives” in Peter Drahos & Ruth Mayne, eds., *Global Intellectual Property Rights: Knowledge, Access and Development* (Houndmills, Hampshire: Palgrave MacMillan, 2002) 90. This means not only that millions are going without needed medicines because of poverty, but also that there is little substance to the claim that patent protection in such countries is needed to, or will, stimulate investment by the private pharmaceutical sector in researching and developing medicines needed for people in those markets. Indeed, many developing countries have implemented patent protection in their domestic legislation, including for pharmaceuticals, even before required to under TRIPS. There is ample evidence that such rules, and in particular their implementation in developing countries with significant capacity to produce generic medicines or the active pharmaceutical ingredients therefore, have constrained access to medicines in the developing world generally. But the promised increase in research and development into medicines for the public health needs of the world’s poor people and nations has not materialized. See Patrice Trouiller *et al.*, “Drug Development for Neglected Diseases: a Deficient Market and a Public Health Policy Failure” (2002) 359 *Lancet* 2188-94; [UK] Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (London: Commission on Intellectual Property Rights, 2002) at 33, online: <[www.iprcommission.org](http://www.iprcommission.org)> [Commission on Intellectual Property Rights].

<sup>21</sup> *Progress on Global Access*, *supra* note 15 at Annex 1.

have implemented a large-scale programme of universal, free distribution of antiretrovirals.<sup>22</sup> Brazil's success in responding to the HIV/AIDS epidemic has been made possible, in part, by the local production of generic formulations of roughly half of the 15 antiretroviral drugs distributed through its programme, and by negotiating, upon threat of compulsory licensing, for substantial price reductions by the manufacturers of several other imported patented medicines. Commentators note that "experience suggests, however, that the efficacy of this strategy rests upon the possibility of credibly using the mechanism of compulsory licensing. Thus, domestic production capacity is a crucial element that strengthens the bargaining power of government agencies."<sup>23</sup> Indeed, recent research on determinants of source prices for ARVs in Brazil and 13 African countries between 1998 and 2002 found that, among other factors, the existence of patent protection on a drug at country level was associated with increases in prices. While the data showed that lower prices were found in countries with organised public programmes for ARV delivery and which had participated in the Accelerated Access Initiative launched in 2001 by the UN and six major brand-name pharmaceutical companies, it also showed that after adjusting for these factors, "the introduction of generic competition remained an essential factor for price decreases."<sup>24</sup> Data compiled by the international humanitarian organization Médecins Sans Frontières (MSF) has also demonstrated that competition by generic producers, where feasible, has had the most significant and sustained effect

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<sup>22</sup> The human, social and economic benefits of this pro-active health measure are tremendous. Between 1996 and 2002 Brazil has seen total net savings estimated at US\$200 million over six years, as well as preventing more than 60,000 cases of AIDS, 90,000 deaths and 358,000 hospital admissions: Paolo R. Teixeira, Marco Antônio Vitória & Jhoney Barcarolo, "The Brazilian Experience in Providing Universal Access to Antiretroviral Therapy" in *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries*, *supra* note 9 at 69-88 [Teixeira, "The Brazilian Experience"]. In addition, "a study presented at the XIVth International AIDS conference [in 2002] has shown that the survival rate has increased substantially with ARV therapy in Brazil. In this study, the average survival time before availability of combined therapy was less than 6 months and now is close to 5 years": *ibid.* at 78 [reference omitted]. Teixeira et al. note that Brazil's policy of free and universal access to medicines dates back to 1991, although clearly the field of available anti-retroviral therapies was more limited at that time: *ibid.* at 76. However, the advent of protease inhibitors in improved combination therapy in 1996 coincided with legislation passed the same year (Law No. 9313 of 13 November 1996), under which every patient with HIV/AIDS is guaranteed, free of direct cost, all medications required for treatment, including anti-retroviral drugs, according to treatment criteria and guidelines established by the national Ministry of Health. Between 1996 and 2001, Brazilian prices for ARVs produced domestically by public laboratories witnessed an average reduction of 82 percent. Over the same period, in the case of those drugs produced by patent-holding multinational companies, Brazil negotiated price reductions averaging 70 percent. Between 1997 and 2001, the average annual cost per patient on ART has decreased by 48 percent, in spite of the proportional increase in the number of patients using more complex and more expensive therapeutic regimes: Ministry of Health of Brazil, *AIDS: the Brazilian experience / SIDA: la experiencia Brasileña* (Brasília: Ministry of Health, 2001); Ministry of Health of Brazil, *National AIDS Drug Policy* (Brasília: Ministry of Health, 2001).

<sup>23</sup> Teixeira, "The Brazilian Experience", *ibid.* at 83. See also Fabienne Orsi *et al.*, "Intellectual Property Rights, Anti-AIDS Policy and Generic Drugs. Lessons from the Brazilian Public Health Program" in Jean-Paul Moatti *et al.*, *supra* note 9, 109.

<sup>24</sup> Stéphane Lucchini *et al.*, "Decrease in Prices of Antiretroviral Drugs for Developing Countries; from Political 'Philanthropy' to Regulated Markets?" in Jean-Paul Moatti *et al.*, *supra* note 9, 169 at 196, 200-201, 203.



in lowering prices for ARVs for developing countries, an effect which has been seen at both national and international levels.<sup>25</sup>

Consequently, the exploding HIV/AIDS pandemic has drawn particular attention to the impact of intellectual property rules,<sup>26</sup> such as those being globalized through TRIPS,<sup>27</sup> in impeding access to urgently needed medicines. The UN High Commissioner for Human Rights has raised concerns about the impact of TRIPS restricting access to medicines for the poor, given the far lower cost of equivalent generics than patent-protected brand-name medicines.<sup>28</sup> Many activists and other experts have pointed out that, in addition to barriers posed by patent regimes already in existence at the advent of TRIPS, or implemented in the decade thereafter,

the likelihood that essential medicines will be covered by patents will increase after 2005, when all member countries of the World Trade Organization are required to put into force a harmonized patent system that includes pharmaceutical products. Moreover, in the event of a substantial increase in donor funding for low-income countries, firms that might previously have decided against taking out a patent for their products may decide to do so on new drugs as a negotiating tactic vis-à-vis the donors.<sup>29</sup>

Treatment activists have long recognized that multiple barriers exist to securing access to medicines, and that intellectual property rules are but part of the problem. Some commentators

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<sup>25</sup> See the data summarized in Médecins Sans Frontières, *Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries*, 10th ed. (Campaign for Access to Essential Medicines - Médecins Sans Frontières, July 2007) at 5ff, online: <<http://www.accessmed-msf.org/documents/Untangling10.pdf>> [*Untangling the Web of Price Reductions*].

<sup>26</sup> Some writers have argued that the term “intellectual monopoly privileges” (IMPs) is preferable to the phrase “intellectual property rights” (IPRs). See e.g. Peter Drahos, *A Philosophy of Intellectual Property* (Aldershot, UK: Dartmouth, 1996). See also: Food Ethics Council, *TRIPS with everything? Intellectual Property and the Farming World* (Food Ethics Council, 2002) at 9.5, online: <<http://www.foodethic-scouncil.org/files/trips.pdf>> which refers to “intellectually-based monopoly privileges (IMPs)”.

<sup>27</sup> UNCTAD and ICTSD, *UNCTAD-ICTSD Resource Book on TRIPS and Development* (1 June 2005), online: IPRsonline.org <<http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm>>; Robert Weissman, “A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries” (1996) 17 U. Pa. J. Int’l Econ. L. 1069.

<sup>28</sup> *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights: Report of the High Commissioner*, UN ESCOR, 53rd Sess (27 June 2001), UN Doc. E/CN.4/Sub.2/2001/13 at paras. 42-44, online: <[http://ap.ohchr.org/documents/dpage\\_e.aspx?s=115](http://ap.ohchr.org/documents/dpage_e.aspx?s=115)>.

<sup>29</sup> *Macroeconomics and Health*, *supra* note 11 at 87. For more detailed discussion, see Karin Timmermans, “Ensuring Access to Medicines in 2005 and Beyond” in Pedro Roffe, Geoff Tansey & David Vivas Eugui, eds., *Negotiating Health: Intellectual Property and Access to Medicines* (London: Earthscan, 2006) 41. Particular concern exists in relation to the impact of TRIPS-compliance by countries with significant generic drug manufacturing capacity, such as India and China, which have been key sources of raw materials and/or finished products. For an excellent and extended discussion of the Indian situation, see Sudip Chaudhuri, *The WTO and India’s Pharmaceutical Industry: Patent Protection, TRIPS, and Developing Countries* (Oxford: Oxford University Press, 2005). Note that, in the case of “least-developed countries” (LDCs) belonging to the WTO, the original deadline for granting patents on pharmaceutical products has been delayed until 2016: WTO Council for TRIPS, “Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations

have dismissed patents as a relatively insignificant barrier to HIV/AIDS treatment in developing countries,<sup>30</sup> but such claims have been criticized as overly simplistic and exaggerated, and the data cited in those studies in fact demonstrates that patents tend to be found where the population and HIV prevalence are higher and where pharmaceutical markets are the largest.<sup>31</sup> Economic analysis by Borrell and Watal (the latter currently counsel in the WTO's Intellectual Property Division) has estimated the impact of intellectual property protection on access to AIDS drugs:

This paper offers for the first time an estimate of exclusion from unsubsidized access to ARV therapy [for AIDS] in poor countries. Only the equivalent of 1.21% of the patients in need of HAART therapy were able to afford the high local prices of even a single-drug ARV therapy through unsubsidized channels in 1999. The vast majority of patients suffered from not having the new drugs locally available. Only in a very selected group of poor countries were ARVs locally available soon after they were launched in a high-income market.

The main finding of the paper is that patents do constrain access to unsubsidized ARV therapy in developing countries. We found that the net impact of having patent regimes on expected access to ARV in the developing countries of our sample is significant.<sup>32</sup>

The basic conclusion that stronger intellectual property protection is not necessarily in developing countries' interests has been affirmed over and over. The WHO has recognized that TRIPS rules can adversely affect public health and has supported full use of the crucial safe-

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with Respect to Pharmaceutical Products", WTO Doc. IP/C/25 (27 June 2002), online: <[http://www.wto.org/english/tratop\\_e/trips\\_e/art66\\_1\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm)>. This provides some relief, but does not address the difficulties created by the existence of pharmaceutical patents in countries that are potential suppliers of generic products, who are not principally LDCs.

<sup>30</sup> See for example Amir Attaran & Lee Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" (2001) 286 J.A.M.A. 1886; Amir Attaran, "How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?" (2004) 23:3 Health Affairs 155.

<sup>31</sup> In particular, and not coincidentally, they are likely to have been patented in those developing countries with a large number of people living with HIV/AIDS and/or higher concentrations of resources. Among other ways in which patents may operate as barriers to treatment access, this patenting strategy, by constraining the possible global market for generic ARVs, impedes the possible economies of scale that could incentivize generic manufacturers and help make feasible the sustainable, massive scale-up of ARV treatment that is urgently needed as part of an effective response to the AIDS pandemic. As Heywood points out, commenting on this phenomenon as it relates to patent coverage on ARVs on the African continent: "The carpet bombing of South Africa and certain combinations of medicines with patents blocks generic suppliers from whom 'entry into the South African market is necessary...to reach the economics of scale (volume) needed for the most efficient production': Heywood, "Drug Access, Patents and Global Health", *supra* note 11 at 227; see also Consumer Project on Technology *et al.*, "Comment on the Attaran/Gillespie-White and PhRMA Surveys of Patents on Antiretroviral Drugs in Africa" (16 October 2001), online: Consumer Protection on Technology <[www.cptech.org/ip/health/africa/dopatentmatrinafrica.html](http://www.cptech.org/ip/health/africa/dopatentmatrinafrica.html)>.

<sup>32</sup> Joan-Ramon Borrell & Jayashree Watal, "Impact of Patents on Access to HIV/AIDS Drugs in Developing Countries", CID Working Paper No. 92 (Working Papers: Centre for International Development at Harvard University, May 2002) at 22, online: <[www2.cid.harvard.edu/cidwp/092.pdf](http://www2.cid.harvard.edu/cidwp/092.pdf)>.

guards to mitigate this impact.<sup>33</sup> After extensive research, the UK Commission on Intellectual Property Rights produced a lengthy report in 2002 with recommendations aimed at aligning intellectual property rules with development objectives in developing countries. It pointed out that the current intellectual property system hardly plays any role in stimulating research on diseases particularly prevalent in developing countries, unless there happens to also be a substantial market in the industrialized world; it does, however, increase the cost of access to many products and technologies needed by less affluent developing countries.<sup>34</sup> The Commission endorsed the regular use of compulsory licensing, among other policy tools, by developing countries in order to secure access to more affordable medicines. The UN Development Programme has also affirmed that:

...drug prices are a critical determinant of access to health care. Patented drugs are substantially more expensive than generic versions. ... Several studies for developing countries have estimated the impact of patents on drug prices.... Their estimated increases range from 12 per cent to 68 per cent once TRIPS is implemented. In the case of anti-retroviral drugs for HIV/AIDS, patented drugs that cost US\$10,000-\$12,000 per patient per year are available for US\$200-300 in their generic form...<sup>35</sup>

More recently, the WHO Commission on Intellectual Property Rights, Innovation and Public Health, established in 2003 by a resolution of Member States at the World Health Assembly, issued its detailed report looking specifically at the health implications of intellectual property regimes. After an exhaustive review of the evidence and examining many different proposals for stimulating both R&D into medicines for poor people and their access to medicines, the Commission recommended *inter alia* that countries take measures to make use of compulsory licensing to facilitate access to cheaper medicines.<sup>36</sup> And as Scherer and Watal have observed:

How the TRIPS agreement is interpreted and implemented could have life or death consequences for the citizens of less well-developed nations. Some nations – especially those that in the past have actively encouraged generic substitution for drugs protected elsewhere by patents – will experience a substantial economic shock, com-

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<sup>33</sup> WHO, “Globalization, TRIPS and Access to Pharmaceuticals” (March 2001) No. 3 WHO Policy Perspectives on Medicines at 5-6, online: <[http://whqlibdoc.who.int/hq/2001/WHO\\_EDM\\_2001.2.pdf](http://whqlibdoc.who.int/hq/2001/WHO_EDM_2001.2.pdf)>.

<sup>34</sup> Commission on Intellectual Property Rights, *supra* note 20 at 33.

<sup>35</sup> UN Development Programme, *Making Global Trade Work for People* (London: Earthscan Publications, 2003) at 209 [references omitted]. The cost of one year’s regime for ARVs has been reduced further since this publication, with some courses of combination treatment now available from generic producers for as low as US\$148 for the most widely used first-line combination (stavudine + lamivudine + nevirapine), although second-line treatment remain significantly more expensive (e.g., with prices more than 10 times higher): *Untangling the Web of Price Reductions*, *supra* note 25.

<sup>36</sup> *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (Geneva: WHO, 2006) at 139-140, online: WHO <[www.who.int/intellectualproperty](http://www.who.int/intellectualproperty)>.

pensated to an unknown degree by an increase in pharmaceutical innovation. But consequences will redound throughout the world health system.<sup>37</sup>

### 3. ACCESS TO MEDICINES AND THE WTO: DOHA, CANCÚN AND BEYOND

The TRIPS Agreement requires all WTO countries to adopt certain minimum standards for protecting private intellectual property rights, including with respect to pharmaceutical inventions. Those rules create temporary monopolies over patented pharmaceuticals, meaning the company holding the patent can charge high(er) prices. On November 14, 2001, at the WTO's Fourth Ministerial Conference in Doha, Qatar, Members unanimously adopted a ministerial Declaration on the TRIPS Agreement and Public Health (Doha Declaration).<sup>38</sup> The Doha Declaration, as it came to be known, was made in response to criticisms from numerous developing countries and from civil society organizations to the effect that WTO rules on intellectual property – specifically the rules on pharmaceutical patents – were impeding access to more affordable medicines.<sup>39</sup>

In the seven-paragraph Doha Declaration, WTO Members “recognize the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”<sup>40</sup> In one of the most important passages in the Doha Declaration, WTO Members also stated that:

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<sup>37</sup> Frederic M. Scherer & Jayashree Watal, “Post-TRIPS Options for Access to Patented Medicines in Developing Nations” (2002) 5:4 J. Int'l Econ. L. 913 at 938. However, whatever flexibilities may remain in TRIPS are being undermined by the proliferation of international rules on intellectual property as countries such as the US pursue “TRIPS-plus” provisions in bilateral and regional agreements: Frederick M. Abbott, “Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines”, in Keith Maskus & Jerome Reichman, eds., *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* (Cambridge: Cambridge University Press, 2005).

<sup>38</sup> WTO, *Declaration on the TRIPS Agreement and Public Health*, 14 November 2001, Ministerial Conference, WTO Doc. WT/MIN(01)/DEC/2, 4th Sess., online: WTO <[http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm)> [*Doha Declaration*]. For a summary and commentary on the Declaration, see Richard Elliott, “WTO Ministerial Conference adopts Declaration on TRIPS and Public Health” (2002) 6:3 Can. HIV/AIDS Pol'y & L. Rev. 50 [Elliott].

<sup>39</sup> For commentary on the global advocacy efforts leading up to the Doha Declaration, see: Ellen 't Hoen, “TRIPS, Pharmaceutical Patents and Access to Essential Medicines: A Long Way from Seattle to Doha” (2002) 3 Chi. J. Int'l L. 27; Frederick M. Abbott, “The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO” (2002) 5:2 J. Int'l Econ. L. 469-505; Haochen Sun, “The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health” (2004) 15:1 E.J.I.L. 123-150; Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (Geneva: World Health Organization, June 2002). online: WHO <[http://www.who.int/medicines/areas/policy/WHO\\_EDM\\_PAR\\_2002.3.pdf](http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf)>; and additional commentary by Elliott, *supra* note 38. For an extensive compilation of documentation on this and related developments dealing with intellectual property and access to medicines, see the excellent website of the Consumer Project on Technology (now Knowledge Ecology International) online: <[www.cptech.org/ip/health](http://www.cptech.org/ip/health)>.

<sup>40</sup> *Doha Declaration*, *supra* note 38 at para. 1. Contrary to suggestions by some countries (e.g., the U.S.) and multinational brand-name pharmaceutical companies after the Doha conference, the Declaration is not limited to covering only the three named diseases and other epidemics; these are simply identified as particularly serious illustrations of “public health problems” of concern to WTO Members. This point proved to be particularly contentious in subsequent WTO negotiations, and in the drafting of the Canadian legislation on compulsory licensing for export.

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that 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.*

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.<sup>41</sup>

WTO members further recognized that this flexibility includes the right of each country “to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.”<sup>42</sup> A compulsory licence is an authorization granted to someone other than the patent owner, without the patent owner’s consent, to use, make, sell, or import a patented product. Without this licence, a generic pharmaceutical company making its version of a patented product could be sued for patent infringement. In exchange, the recipient of the compulsory license must pay “adequate remuneration” to the patent holder (to be defined under a WTO Member’s own laws).<sup>43</sup> By introducing competition from generic manufacturers into the market, compulsory licensing is one policy tool that can make needed medicines more affordable.

However, WTO members also recognized in the Doha Declaration (paragraph 6) that countries “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>44</sup>

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<sup>41</sup> *Ibid.* at para. 4 [emphasis added]. Under the rules of treaty interpretation in international law, both customary and as codified in the 1969 *Vienna Convention on the Law of Treaties* (VCLT), the *Doha Declaration* is correctly understood as a text carrying legal effect in the interpretation of TRIPS. The VCLT (Article 31) provides that a treaty’s terms shall be interpreted “in their context”, which includes “any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions”, as well as “any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation.” The *Doha Declaration* clearly qualifies as “context” for the interpretation of TRIPS, as a unanimous, explicit directive from all WTO Members on this point: Abbott, *supra* note 37; Frederick M. Abbott, “Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health”, Occasional Paper 9 (Geneva: Quaker United Nations Office, February 2002) 40-41, online: Quaker UN Office <<http://www.quano.org/geneva/pdf/economic/Occasional/Compulsory-Licensing.pdf>>, [Abbott, “Compulsory Licensing for Public Health Needs”]; Paul Vandoren, “*Médicaments sans Frontières?*: Clarification of the Relationship between TRIPS and Public Health Resulting from the WTO Doha Ministerial Declaration” (2002) 5:1 J.W.I.P. 5 at 8; Sandra Bartelt, “Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health” (2003) 6:2 J.W.I.P. 283 at 302; James Thuo Gathii, “The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties” (2002) 15:2 Harv. J. L. & Tech. 291-317; Steve Charnovitz, “The Legal Status of the Doha Declarations” (2002) 5:1 J. Int’l Econ. L. 207-211. Another author has taken the position, although without much explanation, that aside from whether the Doha Declaration is a legally binding agreement between WTO Members, it constitutes a supplementary means of TRIPS interpretation under VCLT Article 32: Carmen Otero García-Castrillón, “An Approach to the WTO Ministerial Declaration on the TRIPS Agreement and Public Health” (2002) 5:1 J. Int’l Econ. L. 211-219.

<sup>42</sup> *Doha Declaration*, *supra* note 38 at para. 5(b).

<sup>43</sup> *TRIPS Agreement*, *supra* note 1 at art. 31(h).

<sup>44</sup> *Doha Declaration*, *supra* note 38 at para. 6.

Article 31(f) of the TRIPS Agreement says that ordinarily compulsory licensing may only be used “predominantly” for the purpose of supplying the domestic market of the country where the licence is issued.<sup>45</sup> This limits the use of compulsory licensing to produce generic pharmaceuticals for export. For countries lacking sufficient capacity to make their own generic medicines and, therefore, needing to import such medicines, Article 31(f) makes it difficult for them to use compulsory licensing to address their population’s health needs. As *The Economist* succinctly editorialized at the time:

As they stand, the WTO’s rules leave the vast majority of poor, disease-ridden countries in a pickle. They cannot afford to buy the patented versions of essential drugs; they do not have the resources to make cheaper generic versions; and they cannot import generics, because the countries that make them are not allowed to export them.<sup>46</sup>

Having recognized this difficulty — which became known as the “Doha paragraph 6 problem” — WTO members committed to finding “an expeditious solution” by the end of 2002 (a deadline they ultimately failed to meet). In the course of the negotiations that followed the Doha Declaration, several countries — including Canada, the European Community (EC) states, Japan, Australia, and Switzerland — joined with the US in trying to narrow the scope of any “solution” to the restriction in TRIPS Article 31 on using compulsory licensing primarily for the purpose of exporting generic pharmaceuticals to other countries. They sought to impose various conditions and restrictions that were at odds with the text and spirit of the Declaration, such as limiting which countries would be able to use it, and for which diseases, as well as imposing onerous obligations on any attempts to invoke it.<sup>47</sup> Those efforts were resisted by health activists and by developing countries, many of whom argued that another provision of TRIPS provided a preferable approach — namely, Article 30, which allows for “limited exceptions” to the exclusive patent rights required by the treaty. This approach also attracted the support of the World Health Organization,<sup>48</sup> but was summarily dismissed by the US and a number of other developed countries, and WTO Members eventually concentrated their efforts on devising a solution based on tinkering with Article 31 of the TRIPS Agreement

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<sup>45</sup> *TRIPS Agreement*, *supra* note 1 at art. 31(f). Note that this restriction does not apply where a compulsory licence is issued to remedy a practice that a court or administrative process has found to be “anti-competitive”: *TRIPS Agreement*, *supra* note 1 at art. 31(k).

<sup>46</sup> “A WTO deal on drugs”, *The Economist*, 1 September 2003, online: <[http://www.economist.com/agenda/displaystory.cfm?story\\_id=E1\\_NDNDQGP](http://www.economist.com/agenda/displaystory.cfm?story_id=E1_NDNDQGP)> .

<sup>47</sup> Frederick M. Abbott, “The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health” (2005) 99 *Am. J. Int’l L.* 317-358. See also: MSF, “Reneging on Doha: an MSF analysis of recent attempts to restrict developing countries’ use of compulsory licensing to a set list of diseases” (May 2003), online: MSF Access Website <<http://www.accessmed-msf.org/documents/reneingondoha.pdf>>; MSF, “Doha Derailed: A Progress Report on TRIPS and Access to Medicines: MSF Briefing for the 5th WTO Ministerial Conference” (2003), online: MSF Access Website <<http://www.accessmed-msf.org/prod/publications.asp?scntid=27820031110385&contenttype=PARA&>>.

<sup>48</sup> “Statement by the Representative of the World Health Organization”, WTO Council for TRIPS (17 September 2002) online: WHO <<http://www.who.int/mediacentre/trips/en/>> [WHO Statement]; see also WHO, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, Health Economics and Drugs, Essential Drugs and Medicines Series No. 12, WHO/EDM/PAR/2002.3 (June 2002), online: WHO <[http://www.who.int/entity/medicines/areas/policy/WHO\\_EDM\\_PAR\\_2002.3.pdf](http://www.who.int/entity/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf)>.

so as to relieve against the restriction in Article 31(f) on using compulsory licensing primarily for export.<sup>49</sup>

By December 2002, all WTO members except one had agreed on a draft text of a solution. The US was unwilling to approve the text without the addition of a limited list of diseases for which compulsory licences could be used by developing countries to secure cheaper medicines. As one critic put it: “The U.S. wants to have a global debate over the issue of the scope of disease. [U.S. President] George Bush and [U.S. Trade Representative] Robert Zoellick want to argue that the diseases their own children receive treatment for are off limits to poor children in poor countries. They cannot win this argument.”<sup>50</sup> Indeed, in the end they did not — at least not so overtly.

Because of the U.S. position, the WTO negotiations collapsed on 20 December 2002, with no solution reached by the deadline WTO Members had set for themselves. With no resolution in sight, attention began to turn to the upcoming Fifth WTO Ministerial Conference, in September 2003 in Cancún, Mexico. It was becoming increasingly obvious that this unwillingness of wealthy countries to solve this outstanding grievance of the developing world, after 20 months of negotiations, was threatening to derail progress at the conference on the “Doha Development Agenda” launched in Doha. Finally, less than two weeks before the conference was to begin in Cancún, the U.S. agreed to join the consensus previously reached by all other WTO members in December 2002. On 30 August 2003, the General Council of the WTO unanimously adopted a decision on “Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,”<sup>51</sup> which purported to be the “solution” to the difficulties faced by WTO members lacking sufficient pharmaceutical manufacturing capacity “in making effective use of compulsory licensing under the TRIPS Agreement”. The decision took the form of an “interim waiver” of TRIPS Article 31(f), the provision that restricts the use

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<sup>49</sup> For discussion, see Abbott, “Compulsory Licensing for Public Health Needs”, *supra* note 41; Haochen Sun, “A Wider Access to Patented Drugs Under the TRIPS Agreement” (2003) 21 B.U. Int’l L.J. 101- 136.

<sup>50</sup> James Love, “CPTech statement on collapse of Doha paragraph 6 negotiations” (20 December 2002), online: Consumer Project on Technology <<http://lists.essential.org/pipermail/ip-health/2002-December/003951.html>>.

<sup>51</sup> *August 30th Decision*, *supra* note 2. At the end of 2005, WTO Members decided to convert the 2003 “interim” waiver into a permanent amendment to TRIPS, the first time a major WTO treaty has been so amended. On 6 December 2005, in a carefully choreographed procedure that also included re-reading the original Chairperson’s Statement from 30 August 2003, the General Council, acting on behalf of the Ministerial Conference, adopted a protocol for amending TRIPS permanently: WTO General Council, “Amendment of the TRIPS Agreement, Decision of 6 December 2005”, WTO Doc. WT/L/641 (8 December 2005), online: World Health Organization <[http://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm)> [*Amendment of the TRIPS Agreement, Decision of 6 December 2005*]; WTO General Council, Chairperson’s Statement (6 December 2005), online: <[www.wto.org/english/news\\_e/news05\\_e/trips\\_319\\_e.doc](http://www.wto.org/english/news_e/news05_e/trips_319_e.doc)>. For a discussion, see South Centre & Centre for International Environmental Law, “The 6 December 2005 TRIPS Amendment and Public Health at the WTO” online: (Fourth Quarter 2005) Intellectual Property Quarterly Update <[http://www.ciel.org/Publications/IP\\_Update\\_4Q05.pdf](http://www.ciel.org/Publications/IP_Update_4Q05.pdf)>. The amendment is to take effect once two-thirds of WTO Members have ratified it, which Members stated is to occur by 1 December 2007; until that time, the interim waiver in the August 30th Decision remains in force. As of October 2006, three countries (the U.S., Switzerland and El Salvador) had ratified the permanent amendment.

of compulsory licensing to produce generic pharmaceuticals for export.<sup>52</sup> The decision states that measures taken by a WTO Member in conformity with the system it outlines “shall not” be challenged at the WTO.<sup>53</sup>

However, in the eight months following the breakdown of negotiations in December 2002, the U.S. had succeeded in some of its efforts to narrow the scope of this solution that was ultimately agreed on in August 2003. With the Cancún meeting approaching, the U.S. turned its effort to negotiating the text of a statement to be issued from the Chairperson of the General Council setting out WTO members’ “shared understandings” of the Council’s decision, in an effort to limit the application of the actual General Council’s Decision. A “Chairperson’s statement” was eventually adopted in conjunction with the text of the actual Council decision.<sup>54</sup> The precise legal significance of such a statement for TRIPS interpretation remains unclear, but as discussed below, the Canadian experience with domestic implementation of the Decision has shown that this tactic has borne some fruit, at least with an implementing government eager or willing to accommodate the desires of “Big Pharma”.

For example, the U.S. pushed for a statement that the decision would not be used for “commercial gain” — an obvious attempt to limit the system to only government or public production of pharmaceuticals on charitable grounds, and to exclude any possibility of compulsory licences being granted to private generic companies. This proposal was rejected on the grounds that it would severely hamper the system’s real effect, given that no private company, including a generic manufacturer, would produce without the prospect of some commercial gain. However, in the end, the Chairperson’s statement says that the system set out in the General Council’s Decision will “not be an instrument to pursue industrial or commercial policy objectives” (of WTO Members, presumably). It remains to be seen whether this “understanding” will be used to undermine efforts at increasing the capacity of private, for-profit generic companies to manufacture products for export to importing countries using the new

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<sup>52</sup> For more detailed discussion of the *August 30th Decision* and the politics and process of its negotiation, see Carlos Correa, “Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health”, *Essential Drugs and Medicines Policy*, WHO/EDM/PAR/2004.4 (Geneva: World Health Organization, 2004), online: <[http://www.who.int/medicines/areas/policy/WTO\\_DOHA\\_DecisionPara6final.pdf](http://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf)>; Paul Vandoren & Jean Charles Van Eeckhaute, “The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making it Work” (2003) 6 J.W.I.P. 779-793, online: <<http://www.blackwell-synergy.com/toc/jwip/6/6>>; Frederick M. Abbott, “The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health” (2005) 99 A.J.I.L. 317-358 [Abbott, “The WTO Medicines Decision”]; 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?” (2004) 7 J.I.E.L. 73-107; Duncan Matthews, “Is History Repeating Itself? The Outcome of Negotiations on Access to Medicines, the HIV/AIDS Pandemic and Intellectual Property Rights in the World Trade Organization” (2004) 1 L. Soc. Jus. & Global Dev. J., online: <[http://www2.warwick.ac.uk/fac/soc/law/elj/lgd/2004\\_1/matthews/](http://www2.warwick.ac.uk/fac/soc/law/elj/lgd/2004_1/matthews/)>; Pedro Roffe, Christoph Spennemann & Johanna von Braun, “From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health”, in Pedro Roffe, Geoff Tansey & David Vivas-Eugui, eds., *Negotiating Health: Intellectual Property and Access to Medicines* (London: Earthscan, 2006) 9-26.

<sup>53</sup> *August 30th Decision*, *supra* note 2 at para. 10.

<sup>54</sup> General Council, “General Council Chairperson’s Statement”, (30 August 2003) WTO Doc. WT/GC/M/82 at 6 (para. 29) online: WTO <[http://www.wto.org/english/tratop\\_e/trips\\_e/gc\\_stat\\_30aug03\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/gc_stat_30aug03_e.htm)> [*Chairperson’s Statement*].



WTO system. As noted below, this aspect of the Chairperson's statement certainly had an unfortunate impact on Canada's law implementing the August 30th Decision.

In addition, the U.S. (and the EC) sought to establish lists of which countries would be eligible to use the system to import generic pharmaceuticals, based on data about the extent of their manufacturing capacity or level of income. These efforts were also rejected: the decision is clear that WTO members determine for themselves whether to use the system to import pharmaceuticals. In the case of "least-developed" countries, as recognized by the United Nations, the decision deems them automatically to have insufficient pharmaceutical manufacturing capacity and therefore to be eligible to use the scheme in the August 30th Decision to import generic pharmaceuticals. In the case of any other country belonging to the WTO, it must establish that its capacity is either non-existent or currently insufficient to meet its needs. The Chairperson's statement requires that the country notify the TRIPS Council in writing of how it reached this determination. It also says that any country can raise an issue regarding the interpretation or implementation of the decision for review at the TRIPS Council "with a view to taking appropriate action."<sup>55</sup> This should *not* be mistaken as a requirement that the WTO approve the country's decision. However, this provision could be used by countries such as the U.S. to pressure developing countries not to use the system to import generic pharmaceuticals.

Although it failed to establish a closed list of eligible and ineligible importing countries, the U.S. was successful in getting specific WTO members to commit, on the record, not to use the system as importers. According to the Chairperson's statement, 11 countries agreed to use compulsory licences to import pharmaceuticals only in situations of "national emergency or other circumstances of extreme urgency."<sup>56</sup> In addition, 10 Eastern European countries also committed to use compulsory licensing to import in emergency situations only, and to opt out of importing entirely upon acceding to the European Union.<sup>57</sup> Finally, 23 high-income countries committed to opt out of the system entirely, even if confronted with a national emergency for which their own domestic capacity to produce generic medicines is insufficient.<sup>58</sup> The governments of these countries have effectively agreed to further restrictions on their sovereign rights to use compulsory licensing – recognized in the TRIPS Agreement and reaffirmed in the Doha Declaration – in order to placate the patent-protected pharmaceutical industry and the U.S. government.

The General Council's August 30th Decision and accompanying Chairperson's statement received a mixed reaction. The World Health Organization said it was "encouraged" by the decision, but its enthusiasm was clearly qualified by concern about its future application. Given the history of the negotiations, WHO felt it necessary to stress that:

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<sup>55</sup> *Ibid.*

<sup>56</sup> Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates.

<sup>57</sup> Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic, and Slovenia.

<sup>58</sup> Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

The agreement covers all medicines. Among the diseases that could be more effectively tackled as a result of this decision are AIDS, tuberculosis and malaria. WHO will work with the countries which could make use of the new arrangements to assist them to achieve the full public health benefit from the lower prices. Given the urgency of the health needs in the poorest countries, the work to implement this agreement must proceed as quickly as possible. The full impact of the agreement will depend on how effectively it can be implemented in countries. For the agreement to have the intended impact on public health, countries will need to review the full range of medicines required from multiple suppliers, including generic producers, when making purchasing decisions. WHO continues to urge Member States to consider using to the full the TRIPS flexibilities with regard to the protection of public health.<sup>59</sup>

A coalition of NGOs, including those most directly engaged in the WTO negotiations, issued a statement saying that although the deal was being described as a gift to the poor, it was “a gift bound in red tape.”<sup>60</sup> They were critical of the unnecessary complexity of the system set out in the decision – such as requiring compulsory licences in both importing and exporting countries, and giving the WTO itself new authority to second-guess the decisions of sovereign countries to grant individual compulsory licences – and of other opportunities for the U.S. and other wealthy countries to pressure developing countries into not issuing licences. However, like the WHO, they also urged every country to begin to use the August 30th Decision and other TRIPS Agreement flexibilities to increase access to affordable medicines.

#### **4. CANADA'S IMPLEMENTATION OF THE WTO AUGUST 30<sup>TH</sup> DECISION: THE JEAN CHRÉTIEN PLEDGE TO AFRICA**

Even before the adoption of the Doha Declaration in November 2001, members of the Global Treatment Access Group (GTAG),<sup>61</sup> a coalition of Canadian civil society organizations and other activists, had been urging the Canadian government through various means (letters, public presentations, meetings with government officials) to make the necessary legislative changes to allow Canadian generic pharmaceutical manufacturers to supply developing countries. Like the NGOs seeking to influence negotiations at the WTO on the “Doha paragraph 6 problem” posed by restrictions on compulsory licensing under TRIPS Article 31(f), they had argued that Canada should take advantage of the flexibility offered in TRIPS Article 30 to carve out “limited exceptions” to patent rights to allow the more liberal use of compulsory licensing for exporting lower-cost generics to countries in need. There was little

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<sup>59</sup> “Statement of the World Health Organization on WTO access to medicines decision” (1 September 2003), online: WHO <<http://www.who.int/mediacentre/news/statements/2003/statement10/en/>>.

<sup>60</sup> Joint NGO Statement on TRIPS and Public Health, “WTO Deal on Medicines: A ‘Gift’ Bound in Red Tape” (10 September 2003) online: Consumer Project on Technology <<http://www.cptech.org/ip/wto/p6/ngos09102003.html>>.

<sup>61</sup> The Global Treatment Access Group is an affiliation of Canadian civil society organizations undertaking joint advocacy in support of global realization of the human right to the highest attainable standard of health, with a particular focus on access to comprehensive care, treatment and support for people with HIV/AIDS and other health needs in developing countries. GTAG membership is wide-ranging, including human rights advocates, AIDS organizations, development NGOs, humanitarian organizations, faith-based groups, labour unions and student groups. For additional information or documentation, see online: <[www.aidslaw.ca/gtag](http://www.aidslaw.ca/gtag)>.

response from the government, but it was clear that action was unlikely until there was an outcome to the multilateral negotiations at the WTO on the issue. As noted above, the use of TRIPS Article 30 as the basis for a solution was not pursued in the WTO negotiations, where discussion focused instead on waiving and/or amending TRIPS Article 31(f). It was clear that the Canadian government had no appetite, at that time, for unilaterally adopting an approach that could test the parameters of TRIPS Article 30 and set a positive global precedent in this fashion. Subsequent developments, however, indicate the need to revisit this approach; this point is discussed in further detail below.

In September 2003, shortly after adoption by WTO Members of the August 30<sup>th</sup> Decision, Canadian NGOs and Stephen Lewis, the UN Special Envoy on HIV/AIDS in Africa, called on the Government of Canada to implement the decision in domestic law, so as to clear a legal path for Canada's generic pharmaceutical industry to contribute to scaling up access to medicines in developing countries. What followed was an intense eight-month campaign of advocacy by civil society groups which secured important amendments to the legislation before it was enacted, including successfully resisting efforts by both the patented pharmaceutical industry and the Canadian government to incorporate measures that would have sabotaged or seriously undermined the legislation.<sup>62</sup> The legislation, with the unusual short title of the *Jean Chrétien Pledge to Africa* (JCPA) after the former Liberal Prime Minister during whose tenure the bill was first introduced in November 2003, was finally passed in Parliament in May 2004, with unanimous support in both the House of Commons and the Senate.<sup>63</sup> It received royal assent on 14 May 2004 and thereby passed into law, making Canada the first country to enact such legislation.<sup>64</sup> Regrettably, it was another year to the day before the government proclaimed the bill into force, and only after further pressure from GTAG member groups.<sup>65</sup> The

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<sup>62</sup> For some further detail of the course of the civil society advocacy campaign, see: Richard Elliott, "Medicines for All?: Commitment and Compromise in the Fight for Canada's Law on Compulsory Licensing for Export", in Jillian Clare-Cohen, Patricia Illingworth & Udo Schüklenk, eds., *The Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing and Pricing* (London: Pluto Press, 2006) 227-238, online via: <[www.aidslaw.ca/gtag](http://www.aidslaw.ca/gtag)> Publications.

<sup>63</sup> *An Act to amend the Patent Act and the Food and Drugs Act (Jean Chrétien Pledge to Africa)*, S.C. 2004, c. 23, online: <<http://www.canlii.org/ca/as/2004/c23/>>.

<sup>64</sup> On the same day, Norway promulgated changes to regulations under its Patent Act to implement the WTO Decision, although with significantly less detail. Those regulations were scheduled to come into force on 1 June 2004. The text is available online at: <<http://lists.essential.org/pipermail/ip-health/2004-July/006812.html>>. On 16 July 2004, the U.S. and Canada adopted a Memorandum of Understanding agreeing that the intellectual property provisions of the North American Free Trade Agreement (NAFTA) would not be applied so as to block the implementation of Canada's legislation: Letter from R Zoellick, U.S. Trade Representative to Hon. J Peterson, Canadian Minister for International Trade (16 July 2004), online via: <<http://www.cptech.org/ip/health/c/canada/c9.html>>.

<sup>65</sup> See Letter to Prime Minister Paul Martin re: Priorities for Canada & Other G8 Leaders in Addressing HIV/AIDS & Development, Joint letter from civil society organizations to Prime Minister Paul Martin (26 April 2005), online via: <[www.icad-cisd.com](http://www.icad-cisd.com)>; Sarah MacGregor, "Not Law Yet – Chrétien's Pledge to Africa Unfulfilled", Embassy Magazine, 27 April 2005; Civil society organizations' "Open Letter" to all parties in House of Commons, 4 May 2005, on file with author; Canadian HIV/AIDS Legal Network, "Media release: Generic drugs bill still not in force one year later; coalition calls on all parties in

delay was due in part to the need to draft the accompanying regulations under the *Patent Act*<sup>66</sup> and the *Food and Drugs Act*<sup>67</sup> and publish them for a period of public comment,<sup>68</sup> and in part because of further amendment to correct a minor error in the original legislation; the latter, however, could have been avoided had the federal government acted more diligently in following through on its stated commitment. Finally, on 14 May 2005, the government proclaimed the JCPA into force.<sup>69</sup> The accompanying regulations became effective upon publication in the *Canada Gazette* on 1 June 2005.<sup>70</sup> The legislative and regulatory mechanism for compulsory licensing created by the JCPA and accompanying regulations is now generally referred to by the government as “Canada’s Access to Medicines Regime” (CAMR).

In some respects, the legislation sets a number of positive precedents. But the government’s unprincipled willingness to compromise its initiative in order to placate the multinational brand-name pharmaceutical industry means that the legislation falls short of being a “model” that is worth simply replicating elsewhere. Rather, activists (and international organizations assisting efforts to scale up access to medicines) need to appreciate both its merits and its flaws. The remainder of this section provides an overview of key features of the legislation that warrant comment. The concluding section that follows then examines efforts to date to use the legislation. It identifies that in fact the fundamental problem is the basic mechanism of the WTO August 30<sup>th</sup> Decision itself. It outlines reforms that Canada should enact that would not only remedy the unnecessary limitations in Canada’s current implementation of the WTO Decision but would bypass the inherent defects of that decision so as to set a truly positive global precedent in facilitating effective use of compulsory licensing to improve access to medicines.

#### 4.1 The “Right of First Refusal”: An Unnecessary and Unjustified Hurdle Is Eliminated

When it first introduced the legislation in November 2003,<sup>71</sup> the Liberal government included, to the surprise and dismay of civil society that had previously engaged in detailed

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the House of Commons to cooperate on final procedural hurdle” (4 May 2005), online via [www.aidslaw.ca/gtag](http://www.aidslaw.ca/gtag); Canadian HIV/AIDS Legal Network, “Media release: Human rights advocacy group welcomes Canadian law coming into force, urges generic drug companies and government to follow through with lower-cost medicines” (13 May 2005) at 30, online via: [www.aidslaw.ca/media](http://www.aidslaw.ca/media).

<sup>66</sup> *Patent Act*, R.S.C. 1985, c. P-4.

<sup>67</sup> *Food and Drugs Act*, R.S.C. 1985, c. F-27.

<sup>68</sup> Submissions by the Canadian HIV/AIDS Legal Network and other Canadian civil society organizations to Industry Canada and Health Canada regarding the draft regulations accompanying Bill C-9 (16 December 2004), on file with author.

<sup>69</sup> Industry Canada, “News release and Background: Coming into force of the *Jean Chrétien Pledge to Africa Act*” (13 May 2005), online: Industry Canada <[www.ic.gc.ca](http://www.ic.gc.ca)>.

<sup>70</sup> See the following three sets of regulations: *Use of Patented Products for International Humanitarian Purposes Regulations*, S.O.R./2005-143; *Food and Drug Regulations* (1402 – Drugs for Developing Countries), S.O.R./2005-141; *Medical Devices Regulations* (Developing Countries), S.O.R./2005-142.

<sup>71</sup> The legislation was first introduced in the House of Commons on 6 November 2003 as Bill C-56, *An Act to amend the Patent Act and the Food and Drugs Act*, 2nd Sess., 37th Parl., 2003, online: <[http://www2.parl.gc.ca/content/hoc/Bills/372/Government/C-56/c-56\\_1/c-56\\_1.pdf](http://www2.parl.gc.ca/content/hoc/Bills/372/Government/C-56/c-56_1/c-56_1.pdf)>. When that House session prorogued a week later, the bill died on the order paper. When the House began a new session in early 2004, after

dialogue with government officials during the legislative drafting process, a provision that NGOs quickly condemned as a “right of first refusal” — that is, a provision that would have allowed the company with the patent on a medicine to block any compulsory licence issuing to a generic producer by scooping the contract it had negotiated with a developing country purchaser, as long as the patent-holding company was willing to match the terms negotiated in that contract. NGOs pointed out that such a provision would quickly kill any incentive for generic manufacturers to even attempt to negotiate contracts with developing countries to supply lower-cost medicines, and the entire mechanism contemplated by the legislation (and the WTO August 30<sup>th</sup> Decision on which it is based) relies upon the participation of generic pharmaceutical producers, commercial enterprises motivated principally by the imperative to maximize profits. Such a provision is not required by either the WTO August 30<sup>th</sup> Decision or TRIPS itself.<sup>72</sup> Furthermore, it flies in the face of the spirit of the 2001 Doha Declaration’s direction that TRIPS should be interpreted and implemented in a manner that promotes access to medicines, as well as the assertion in the Doha Declaration and the August 30<sup>th</sup> Decision that countries lacking manufacturing capacity need to be able to make “effective use of compulsory licensing”. Enacting a scheme that unnecessarily removes any possible incentive for generic manufacturers to be involved hardly ensures that countries will be in a position to use compulsory licensing effectively to address public health needs.<sup>73</sup>

It was evident that such a provision had been inserted at the behest, or at least to the great satisfaction, of patentee pharmaceutical companies. In response to criticism of this provision, Rx&D, the association representing the brand-name industry, suggested a supposed “alternative” at hearings of the House of Commons Standing Committee on Industry, Science and Technology that heard from witnesses in early 2004.<sup>74</sup> However, NGOs pointed out that the industry’s proposed alternative was, in essence, the same scheme dressed up in different language that would simply have the same effect while operating at an even earlier stage in the

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a change in the leadership of the governing Liberal Party from former Prime Minister Jean Chrétien to new Prime Minister Paul Martin, the legislation was eventually reintroduced, in identical form, as Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act (Jean Chrétien Pledge to Africa)*, 3rd Sess., 37th Parl., 2004, online: <[http://www2.parl.gc.ca/content/hoc/Bills/373/Government/C-9/c-9\\_4/C-9\\_4.pdf](http://www2.parl.gc.ca/content/hoc/Bills/373/Government/C-9/c-9_4/C-9_4.pdf)>.

<sup>72</sup> At various points in (non-confidential) discussion with NGOs, government representatives claimed that such a provision was required by TRIPS art. 31(b). However, such a claim is clearly a misinterpretation of that subsection. Article 31(b) merely requires, in most circumstances, that before a compulsory license may be issued there must first have been efforts to negotiate with the patentee for a voluntary license on “reasonable commercial terms and conditions”, which efforts have been unsuccessful “within a reasonable period of time”: *TRIPS Agreement*, *supra* note 1. It is patently incorrect to interpret this provision as requiring that a patentee be given the legal right to block the issuing of a compulsory license by assuming the contract negotiated by a generic manufacturer with a potential customer.

<sup>73</sup> For a more detailed critique of Bill C-56, including the “right of first refusal” provision, see: Canadian HIV/AIDS Legal Network. “Global Access to Medicines: Will Canada Meet the Challenge?”, Submission to the House of Commons Standing Committee on Industry, Science and Technology (26 February 2004) online via: <[www.aidslaw.ca/gtag](http://www.aidslaw.ca/gtag)> Publications [Submission of 26 February 2004]. See also Frederick Abbott, “Prepared Remarks before the Standing Committee on Industry, Science and Technology” (10 March 2004), online Parliament of Canada <<http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?SourceId=75333>>.

<sup>74</sup> Rx&D: Canada’s Research-based Pharmaceutical Companies, “Providing Affordable Medicines to Patients in the Developing World”, Submission to the House of Commons Standing Committee on Industry, Science and Technology, February 2004 (on file with author).

process of a developing country procuring medicines. Rather than giving the patent-holding company the right to scoop a generic producer's already-negotiated contract, it would have required a generic company to notify the patent-holder at the outset of any negotiations underway with a potential purchaser. In other words, what the industry characterized as an "equal opportunity to supply" the country in need was, according to NGOs, an "early opportunity to block competition" — and was equally an unnecessary "TRIPS-plus" provision that would render the legislation effectively meaningless.<sup>75</sup>

Ultimately, in the face of sustained lobbying and criticism by activists (including over many weeks in mass media), the government removed the "right of first refusal" and refrained from substituting any alternative along the lines suggested by the brand-name industry, thereby avoiding setting a poor "TRIPS-plus" precedent for the implementation of the August 30<sup>th</sup> Decision. NGOs issued a press release welcoming this decision and calling on the government and Committee to address the other outstanding concerns before returning an amended bill to the House of Commons.<sup>76</sup> This was a significant victory for the civil society campaign.

#### 4.2 A Positive Precedent: Circumscribing Licensing Negotiations and Defining Royalties Payable

On the positive side, and as a result of civil society advocacy, the government introduced changes to the law before it was enacted that bring some welcome clarity to vague phrases in the TRIPS agreement regarding pre-conditions to compulsory licensing. Under TRIPS Article 31(b), in most circumstances, the party that wishes to obtain a compulsory licence to use the patented invention must first attempt to secure authorization voluntarily from the patentee "on reasonable commercial terms and conditions", and only after such efforts have not succeeded "within a reasonable period of time" may a compulsory licence be granted.<sup>77</sup> However, TRIPS does not in any way define what constitutes a "reasonable period of time" for negotiating a voluntary licence, or what constitute "reasonable commercial terms and conditions". There is a very real threat in the heavily litigious pharmaceutical sector that patentees will resort to litigation (or other kinds of direct pressure on authorities responsible for compulsory licens-

<sup>75</sup> Canadian HIV/AIDS Legal Network, "Global Access to Medicines: Will Canada Meet the Challenge?", Supplementary submission to the House of Commons Standing Committee on Industry, Science and Technology (8 March 2004) online: <[www.aidslaw.ca/gtag](http://www.aidslaw.ca/gtag)> Publications [Supplementary Submission of 8 March 2004].

<sup>76</sup> Canadian HIV/AIDS Legal Network, MSF Canada, Canadian Council for International Cooperation, and Oxfam Canada, "Media release: Latest amendments to Canada Patent Act a good start, but still need work" (20 April 2004) online: <[www.aidslaw.ca/gtag](http://www.aidslaw.ca/gtag)> Publications; Canadian HIV/AIDS Legal Network, "Update - Canada's Patent Act Amendment: Allowing Compulsory Licensing for the Export of Generic Pharmaceutical Products", 20 April 2004, online: <[www.aidslaw.ca/gtag](http://www.aidslaw.ca/gtag)>.

<sup>77</sup> A WTO Member may waive this requirement to first attempt to negotiate a voluntary license "in the case of a national emergency or other circumstance of extreme urgency", "in cases of public non-commercial use" of the patented invention, or when a compulsory license "is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive": *TRIPS Agreement*, *supra* note 1 at Art. 31(b), 31(k). Unfortunately, the Canadian legislation failed to incorporate these particular TRIPS features, meaning that even in the case where the importing developing country is confronting an emergency, or procuring medicines for public non-commercial use, or remedying anti-competitive practices by a patentee, a generic manufacturer seeking authorization to produce a product for export from Canada must still go through a month-long process of trying to negotiate a voluntary license with the patentee.

ing) to dispute whether such vague preconditions have been met, thereby delaying and rendering more expensive the prospect of pursuing a compulsory licence. The possibility of having to litigate in court over whether a reasonable period of time for negotiations has passed, or as to what constitutes a reasonable royalty, is a major disincentive to any generic producer that might consider seeking a licence to manufacture products for export under a system such as that permitted under the WTO August 30<sup>th</sup> Decision. Consequently, a legislative regime that fails to rectify this vagueness is unlikely to provide the “rapid response” that WTO Members recognized, in the preamble to the decision, is needed by countries lacking pharmaceutical manufacturing capacity and trying to use compulsory licensing effectively to address public health needs.

Following submissions by NGOs, including at Standing Committee hearings, the government agreed to add a provision to the bill effectively defining the vague TRIPS reference requiring a “reasonable period of time” for attempting to negotiate a voluntary licence. As finally enacted, the legislation states that the Commissioner of Patents “shall” issue a compulsory licence as long as, in addition to fulfilling some other statutory conditions, the applicant for that licence has, at least 30 days before applying, (a) provided to the patentee(s) the detailed information that is required by the statute, and (b) sought unsuccessfully from the patentee(s) a voluntary licence “on reasonable terms and conditions”. As illustrated so far by the experience of MSF in attempting to use the legislation (discussed below), concerns remain about how this provision will play out in practice. However, it should be acknowledged that providing a clear statutory definition of the vague phrase “reasonable period of time” in TRIPS Article 31(b) sets a positive precedent.<sup>78</sup>

Similarly, the legislation as finally enacted brings clarity to the question of what constitutes “adequate remuneration” payable to the patent-holder when a compulsory licence is issued, as required by TRIPS Article 31(h) — and in doing so, implicitly creates a certain degree of automaticity in the process of determining what constitute “reasonable terms and conditions” for a voluntary licence in the requisite pre-compulsory licensing negotiations. In the original draft of the bill, the government had proposed to legislate a flat 2 percent royalty rate for the patent holder. As might be expected, the industry association for pharmaceutical patent owners objected. NGOs were generally content with this feature of the draft legislation. As the Canadian HIV/AIDS Legal Network pointed out in its initial submission to the Standing Committee, Canada is the developed country with the most extensive experience with using compulsory licensing to balance the public policy objectives of patent protection and patient access to medicines.<sup>79</sup> “The Canadian government has issued more compulsory licences on medicines than any other government... from 1969 to 1992, Canada issued more than 600 compulsory licences on medicines. In nearly every case, the compensation to the

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<sup>78</sup> The Canadian HIV/AIDS Legal Network had suggested a period of 15 days. See Submission of 26 February 2004, *supra* note 73; and Supplementary Submission of 8 March 2004, *supra* note 75. Regrettably, the government did not adopt the recommendations to waive the negotiation/waiting period in the case of compulsory licensing to respond to emergencies or other circumstances of extreme urgency, to manufacture the product for public non-commercial use of the product, or to remedy anti-competitive practice by the patent-holder, all of which are additional “flexibilities” expressly permitted under TRIPS.

<sup>79</sup> Submission of 26 February 2004, *ibid.*

patent owner was a standard 4 percent royalty applied to the generic competitor's sale price."<sup>80</sup> The Legal Network urged that however the royalty might be determined, there should be certainty for a would-be generic exporter regarding the applicable royalty in any given case, and that, given the objective of supplying medicines as inexpensively as possible to importing developing countries, in no case should the royalty rate exceed the 4 percent figure that had become the *de facto* standard for compulsory licensing for the wealthy Canadian market.<sup>81</sup> In that same submission, in making the case that the list of eligible importing countries needed to be further expanded from the original, unjustifiably narrow list, the Legal Network presented the Standing Committee with data on all developmental indicators regarding all countries, including their ranking on the UN Development Programme's Human Development Index (HDI).

Ultimately, the government's approach to the question of determining royalties was informed by those submissions. The government removed from the draft bill the flat 2 percent royalty rate for the patent owner that was originally specified. Instead, the JCPA as finally enacted simply stated that the calculation of the royalty in any given case would be determined by a formula to be set out in accompanying regulations. Government representatives stated on the record before the Standing Committee that the formula would consist of a sliding scale, based on the ranking of the importing country on the HDI. The effective cap under the regulations was to be 4 percent of the value of the contract in the case of the country with the highest HDI ranking. Obviously, the majority of developing and least developed countries that are eligible importers from Canadian generic manufacturers rank well below this on the HDI, meaning significantly lower royalties in those instances. The regulations that were eventually brought into force accorded with this representation.<sup>82</sup>

With respect to these two elements, the Canadian legislation implementing the WTO August 30th Decision sets a welcome precedent. If, after 30 days, the generic manufacturer and patentee have been unable to agree on the terms of a voluntary licence, then the Commissioner of Patents "shall" issue a compulsory licence (assuming the other preconditions in the legislation have been satisfied). There is no discretion vested in the Commissioner and no basis on which a patentee can delay the process by alleging, either before the Commissioner or a court, that insufficient negotiating time had passed or that the terms last offered by the generic manufacturer are unreasonable. Similarly, the Canadian legislation also implicitly defines what con-

<sup>80</sup> James Love, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*, Health Economics and Drugs TCM Series No. 18 (Geneva: WHO & UNDP, 2005) at 31, online: <[http://www.who.int/medicines/areas/technical\\_cooperation/WHOTCM2005.1\\_OMS.pdf](http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf)>. For additional discussion of the history of the use in Canada of compulsory licensing of pharmaceuticals, and the determination of royalties payable, see also: Jerome Reichman & Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: The Canadian Experience*, UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development (Geneva: UNCTAD & ICTSD, 2002), online: <[http://www.iprsonline.org/unctadictsd/docs/reichman\\_hasenzahl\\_Canada.pdf](http://www.iprsonline.org/unctadictsd/docs/reichman_hasenzahl_Canada.pdf)>; Joel Lexchin, "Pharmaceuticals, Patents and Politics: Canada and Bill C-22" (1993) 23 Int. J. Health Services 147-60; Joel Lexchin, "After Compulsory Licensing: Coming Issues in Canadian Pharmaceutical Policy and Politics" (1997) 40 Health Pol'y 69-80, online: Health Policy <<http://www.sciencedirect.com/science/journal/01688510>>.

<sup>81</sup> Submission of 26 February 2004, *supra* note 73.

<sup>82</sup> *Use of Patented Products for International Humanitarian Purposes Regulations*, S.O.R. 2005/143, *supra* note 70.



stitutes a reasonable royalty by way of compensation to the patentee whose patented product (or process) is used by the generic manufacturer. There is no discretion on the part of the Commissioner of Patents to vary the royalty. Clearly, then, if the law itself specifies what the royalty shall be in any given case of compulsory licensing, this effectively determines for both the generic manufacturer and the patentee what would, by default, be considered a “reasonable” royalty in exchange for a voluntary licence. In theory, then, the Canadian legislation sets a reasonably positive example of a mechanism for compulsory licensing for exports that works reasonably rapidly, as urged by WTO Members in the preamble of the August 30<sup>th</sup> Decision: in the event that a patentee is unwilling to accept the royalty proposed by a generic manufacturer, that manufacturer simply need wait 30 days and then its application for a compulsory licence “shall” be granted, with the legislatively mandated royalty rate.

#### 4.3 Limited List of Pharmaceutical Products

As noted above, in the lengthy and divisive negotiations at the WTO that ultimately led to the August 30<sup>th</sup> Decision, the U.S., EC, and other high-income Members had pushed for various restrictions on the scope of any mechanism facilitating compulsory licensing for export — including to limit its scope to addressing only specific diseases or only specific pharmaceutical products.<sup>83</sup> These efforts were roundly condemned by civil society activists as unethical and unsound health policy, and firmly rejected by developing countries. Ultimately, all WTO Members agreed that there would be no such limitations. The WTO decision states simply that the mechanism in the decision applies in the case of a “pharmaceutical product”, which is defined as follows:

“pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the [Doha] Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.<sup>84</sup>

Notwithstanding the international consensus finally achieved on this point, and sustained criticism from NGOs, the Canadian government took a step backward when it came to implementing the WTO decision in domestic law. As finally enacted, the JCPA is unnecessarily marred by a more limited and cumbersome approach: the JCPA amendments to the *Patent Act* included the creation of a Schedule 1 that sets out a limited initial list of pharmaceutical products, in specific dosage forms, that are subject to compulsory licensing for export. In its original form, the list was exceedingly limited; as a result of NGO advocacy, the final law as enacted included an initial list of 56 products that could be compulsorily licensed for export, based principally on the WHO Model List of Essential Medicines, with the addition of all

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<sup>83</sup> Abbott, “The WTO Medicines Decision”, *supra* note 52.

<sup>84</sup> *August 30th Decision*, *supra* note 2 at para. 1(a). The reference to “public health problems as recognized in paragraph 1 of the [Doha] Declaration” does not limit the scope of the *August 30th Decision* to only specific diseases. Paragraph 1 of that *Doha Declaration* states: “We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics”: *Doha Declaration*, *supra* note 38. The three diseases mentioned explicitly, and the reference to “other epidemics”, are clearly given as illustrative examples, not an exhaustive categorization of the public health problems faced by developing countries.

antiretroviral drugs used to treat HIV/AIDS that were approved at the time for sale in Canada (with one exception).<sup>85</sup>

NGOs remain(ed) critical of the list, however, not only because it misuses the WHO Model List but because it represents a step back from the international consensus achieved with the WTO Decision. By introducing a limited list of products in its implementing legislation, Canada, which had repeatedly indicated it would wait for a multilateral solution to be agreed at the WTO, has unilaterally undermined that consensus. Furthermore, the legislation creates a bureaucratic process for expanding the list — a Cabinet decision following a recommendation from each of the Ministers of Health and Industry.<sup>86</sup> As the Canadian HIV/AIDS Legal Network asked before the Standing Committee during hearings into the bill: why is Canada's Cabinet the gatekeeper for developing countries' access to less costly medicines through the use of policy tools such as compulsory licensing?<sup>87</sup> In addition, the concern was, and remains, that such a process would create further delay, as well as multiple opportunities for patent-holding pharmaceutical companies to lobby successfully to block any addition.

In the days leading up to the final vote on the bill in the House of Commons, these concerns proved well founded. Members of the Standing Committee discussed adding several medicines to the list annexed to the bill. The opposition New Democratic Party (NDP) proposed that the added drugs include moxifloxacin and clarithromycin, both of which are used to treat pneumonia, a condition of particular significance to people with compromised immune systems. Clarithromycin is also used prophylactically to prevent mycobacterium avium complex (MAC), a life-threatening infection in people living with HIV/AIDS. A version of clarithromycin produced by an Indian generic manufacturer is among the HIV/AIDS medicines pre-qualified by the World Health Organization as meeting the WHO's quality standards. At the Standing Committee, all political parties agreed that, absent any technical objections by Health Canada to a particular drug, the additional medicines under discussion would be added to the bill by motion when it came before the House of Commons for final reading and adoption. Health Canada indicated that it had no objection to the addition of either moxifloxacin or clarithromycin to the schedule in Bill C-9. But the NDP subsequently received calls from Bayer, the pharmaceutical company that holds the Canadian patent on the drug moxifloxacin,

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<sup>85</sup> The ARV enfurvitide (also known as Fuzeon or T-20), an expensive drug in the new class of fusion inhibitors, was not included on the list. Fuzeon, a medication administered through injection, was approved for sale in Canada by Health Canada's Therapeutic Products Directorate in July 2003, but government officials took the view that the drug had only recently been approved in Canada, meaning there was not the same degree of post-marketing experience with its use, and it was principally prescribed (at the time) as a component of "salvage therapy" for patients who had developed resistance to other classes of antiretrovirals. Furthermore they expressed concern about the suitability of exporting a drug administered by injection for use in settings where the infrastructure for delivering such a medicine safely and effectively (e.g., access to sterile syringes) may be limited.

<sup>86</sup> The *JCPA* also states that, within three years of the section coming into force, the Ministers of Industry and Health "shall establish" an advisory committee to advise them on their recommendations to Cabinet regarding adding products to Schedule 1, and that both a Senate and House of Commons committee "shall assess all candidates for appointment to the advisory committee": *Patent Act*, R.S. C. 1985, c. P-4, s21.18. As of October 2006, that advisory committee had not yet been established; fortunately, however, the existence of such a committee is not required for a ministerial recommendation to Cabinet to expand Schedule 1.

<sup>87</sup> Submission of 26 February 2004, *supra* note 73.

objecting to its inclusion in Bill C-9. At least one pharmaceutical company also contacted Ministers' offices objecting to the addition of any medicines to the list.<sup>88</sup> Following pressure from the pharmaceutical industry, a Minister's office subsequently contacted the NDP to request that they withdraw some of its motions to add specific drugs – products that all parties had already agreed would be added.

Subsequently, during the consideration of these motions on the floor of the House of Commons, the Liberal Party argued against the addition of these medicines to the list of products covered by its bill. Government representatives stated during the Parliamentary debate that moxifloxacin and clarithromycin were not on the WHO model list of essential medicines, and claimed (incorrectly) that these medicines were not needed to treat HIV/AIDS, TB, or malaria.<sup>89</sup> This was in direct contradiction to assurances that government officials had made repeatedly to health advocates, namely that including a list of specific products in the bill would not be used to limit the scope of the legislation to just products on the WHO list or to just medicines for treating people living with HIV/AIDS, TB, or malaria, given that the WTO Decision of 30 August 2003 does not, by international consensus, contain such restrictions.

This experience illustrates the pitfalls of having such a list of products, and calls into question the good faith of the government in promising that the list would not limit the scope of Canada's initiative. Since the passage of the legislation, the list in Schedule 1 has been amended twice in response to requests from generic manufacturers and NGOs: in September 2005 to add a fixed-dose combination AIDS drug containing the antiretroviral drugs zidovudine (AZT), lamivudine (3TC) and nevirapine (NVP) (a fixed-dose combination of which was subsequently manufactured by generic producer Apotex),<sup>90</sup> and again in September 2006 to add the anti-influenza antiviral oseltamivir (marketed by the patentee under the brand-name Tamiflu).<sup>91</sup> In each case, what had been repeatedly represented as being a simple process in fact took months before the government acted and only following repeated urging by NGOs and would-be manufacturers. Judging from the experience with the Canadian legislation, any mechanism for limiting the scope of compulsory licensing legislation to specific pharmaceutical products — which is not only unnecessary under the WTO August 30th decision, but also contrary to its very spirit — should be rejected by activists and law-makers elsewhere.

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<sup>88</sup> Glen McGregor, "Drug bill lets 'Big Pharma' call the shots: Government yields to pressure from Bayer to keep new drug off list of HIV/AIDS program", *Ottawa Citizen* (4 May 2004) A1.

<sup>89</sup> For the transcripts of House of Commons debates over Bill C-9, see the listings indexed online under the entry "Patent Act and Food and Drugs Act (amdt.)(The Jean Chrétien Pledge to Africa)(Bill C-9)" in *Hansard* (Debates of the Parliament of Canada), for the 37th Parliament, 3rd session (February 2, 2004 to May 23, 2004), online: Parliament of Canada <<http://www2.parl.gc.ca/housechamberbusiness/ChamberHome.aspx>>.

<sup>90</sup> *Order Amending Schedule 1 of the Patent Act*, SOR/2005-276 August 31, 2005, C. Gaz. 2005. II. 2145, online: <<http://canadagazette.gc.ca/partII/2005/20050921/html/sor276-e.html>>.

<sup>91</sup> *Order Amending Schedule 1 to the Patent Act (Oseltamivir Phosphate)*, SOR/2006-204, September 21, 2006, C. Gaz. 2006. II. 1308, online: <<http://canadagazette.gc.ca/partII/2006/20061004/html/sor204-e.html>>.

#### 4.4 Regulatory Review of Drugs Destined for Export Only Required for Those Produced Under Compulsory Licence

The JCPA amended not only the *Patent Act* but also the *Food and Drugs Act*. Canadian law generally does not require that a drug manufactured solely for export undergo the regulatory approval process that applies to drugs marketed in Canada. However, as a result of the JCPA, this regulatory approval now applies solely to products that are produced under compulsory license for export, in accordance with the scheme enacted by the statute.<sup>92</sup> Under the JCPA amendments to the *Patent Act*, the Commissioner of Patents may only issue a compulsory license to the manufacturer of a generic pharmaceutical product if, among other things, the Minister of Health has notified the Commissioner that the generic product in question meets the requirements of the *Food and Drugs Act*.<sup>93</sup>

While NGOs supported the principle that products exported to developing countries must be safe, effective, and of good quality, it is odd that such a concern with exported medicines has only been legislatively mandated in the case of compulsory licensing. NGOs were, and remain, concerned that such a requirement could end up blocking use of the system to produce and export needed medicines. This concern is particularly applicable in the case of “fixed-dose combination” (FDC) medicines, which combine more than one drug into a single dose. FDCs of antiretroviral drugs simplify HIV/AIDS treatment regimens, and are recognized by the WHO as being of critical importance in its efforts to dramatically scale up access to ARVs in the developing world. In the case of generic medicines being reviewed for Canadian marketing approval — the review that is now required for any drugs produced under the JCPA mechanism — standard practice is to base approval on data showing “bio-equivalence” of the generic product to an already approved brand-name product. But in the case of FDCs for treating HIV/AIDS, there were only three such products on the Canadian market. Two of these (Combivir® and Trizivir®) combine drugs patented by GlaxoSmithKline; the third (Kaletra™) combines two drugs patented by Abbott. These combination products are important, but with the exception of the constituent products in Combivir® (zidovudine and lamivudine) are not among those initially recommended in 2003 as “first-line” therapy by the WHO for use in developing country settings. At the time of writing the recommended first-line products are currently only available from generic producers.

Now that Canada has insisted that any generic pharmaceutical produced for export under compulsory license meets Canadian marketing approval standards, the onus is on the government to ensure that the process is rapid, transparent, and not overly cumbersome — particularly when it comes to enabling the production and export of products such as FDCs, which are a priority in the global effort to scale up treatment access. The issues described above will have to be dealt with via regulations, and via the policies and practices adopted by Canada’s drug regulatory authority. Health Canada’s Therapeutic Product Directorate has taken the position that, in the case of FDCs for which no already-approved reference product exists, it must apply the rules governing review in the case of “new drug submissions” under the *Food and Drugs Act*, rather than allowing for an “abbreviated new drug submission” process as is usually the case with generics that can be compared against an already-approved product. However, it has also stated that it will be sufficiently flexible in conducting its risk/benefit assessment, such as

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<sup>92</sup> *Food and Drugs Act*, *supra* note 67 at s. 37(2).

<sup>93</sup> *Patent Act*, *supra* note 66 at s. 21.04(3)(a).

basing decisions about marketing approval on bio-availability studies and other evidence in support of the use of the combination (e.g., clinical data from patients who have received each of the combination's component drugs separately).<sup>94</sup> Health Canada has also declared that it has established a separate "fast-track" process for reviewing drugs for which the generic manufacturer plans to seek a compulsory licence permitting export to eligible developing countries, which is to be welcomed; unfortunately, in the one review to date of a generic FDC product the process took seven months.<sup>95</sup>

#### 4.5 Countries Eligible To Import Generics Produced Under Compulsory Licence in Canada

The WTO August 30<sup>th</sup> Decision enables the use of compulsory licensing to produce pharmaceuticals for export to countries with "insufficient or no manufacturing capacity". An annex to the decision states that least-developed country WTO Members "are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector"; other eligible importing Members may establish their lack of capacity. As noted above, the August 30<sup>th</sup> Decision was adopted in conjunction with a statement by the Chairperson of the WTO General Council, placed on the record at the behest of the U.S. That statement outlined that certain high-income countries had "agreed to opt out of using the system as importers", while a number of other countries indicated they would use it to import only in emergency situations.<sup>96</sup>

These divisions were reflected in the JCPA. In addition to Schedule 1 that lists the pharmaceutical products eligible for compulsory licensing for export, the JCPA amendments also added a series of schedules to the *Patent Act* setting out various categories of countries and their eligibility to import generic pharmaceuticals produced under compulsory licence in Canada. On a positive note, the JCPA included (in Schedule 2 to the *Patent Act*) as eligible countries all those countries (then) recognized as "least-developed countries" by the UN — regardless of whether or not they belong to the WTO. The inclusion of non-WTO countries in the Canadian legislation sets a positive precedent, and was welcomed as such by NGOs. This approach has been adopted by some other jurisdictions that have drafted or implemented legislation or regulations pursuant to the WTO Decision.

However, NGOs criticized the bill as originally drafted in its treatment of other developing countries. They pointed out that developing countries, other than LDCs, were excluded from the relevant schedule (Schedule 3) as countries eligible to contract with a generic manu-

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<sup>94</sup> The first product to receive Health Canada's regulatory approval for possible export under compulsory licence was the fixed-dose combination AIDS drug developed by Apotex, Inc., consisting of zidovudine (AZT), lamivudine (3TC) and nevirapine (NVP). At the time of its approval, it was the only generic formulation of this combination available; subsequently, by the time of "prequalification" of the Apotex product by the WHO's Prequalification Programme, a number of Indian generic pharmaceutical companies had also developed formulations of the same product. For information regarding all WHO prequalified products and manufacturers, see WHO, "Prequalification Programme: Priority Essential Medicines", A United Nations Programme managed by WHO, online: <<http://mednet3.who.int/prequal/>>.

<sup>95</sup> MSF, "Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable – An Illustration Through Canada's Jean Chrétien Pledge to Africa" (Paper prepared for the XVI International AIDS Conference, August 2006). online: <[www.accessmed-msf.org/documents/WTOaugustreport.pdf](http://www.accessmed-msf.org/documents/WTOaugustreport.pdf)> [MSF, "Neither Expeditious, Nor a Solution"]

<sup>96</sup> *Chairperson's Statement*, *supra* note 54.

facturer to obtain lower-cost medicines manufactured in Canada, but that this was neither necessary under WTO rules (witness the government's willingness already to include non-WTO countries that are "least-developed") nor justifiable: "people in all developing countries should have access to affordable medicines regardless of whether their country belongs to the WTO".<sup>97</sup> NGOs called on the government to amend the bill to remedy this exclusion. In response, the government amended the bill during Standing Committee hearings to add new, albeit imperfect, provisions to the bill that would permit a non-WTO developing country to become eligible to purchase generics produced in Canada under compulsory licence.<sup>98</sup>

However, the approach ultimately adopted by the government on this point leaves something to be desired. As a result of the government's amendments, a developing country that is neither a WTO Member nor an LDC can procure cheaper medicines from Canadian generic producers only if:

- it is eligible for "official development assistance" according to the Organization for Economic Cooperation and Development (OECD);<sup>99</sup>
- it declares a "national emergency or other circumstances of extreme urgency"; and
- it specifies the name and quantity of a specific product needed for dealing with that emergency.<sup>100</sup>

This approach creates an indefensible double standard between developing countries that belong to the WTO and those that do not. Recall that, during the negotiations at the WTO that ultimately led to the August 30<sup>th</sup> Decision, efforts to limit sovereign developing countries to using compulsory licensing to import medicines only in "emergency" situations were rejected, and in the end the decision contains no such restriction (except in the case of some countries that agreed to such a limitation). It should also be remembered that the 2001 Doha Declaration explicitly reaffirmed that WTO Members are free to determine for themselves the grounds upon which to use compulsory licensing.

In addition to the three criteria noted above, if any non-WTO developing country (including an LDC) wishes in the future to be added to the relevant schedule of countries under the Patent Act, it must state that it undertakes to adopt the measures set out in the WTO Decision (paragraph 4) aimed at preventing diversion of the product — even though it is not bound by WTO rules.<sup>101</sup> Furthermore, a pre-condition to being eligible is that the importing country agrees that the imported product "will not be used for commercial purposes".<sup>102</sup> The government (incorrectly) asserted this condition was required by the language of the WTO General

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<sup>97</sup> Submission of 26 February 2004, *supra* note 73.

<sup>98</sup> In its original draft tabled in Parliament, the government had already decided to include non-WTO Members that were recognized by the UN as "least-developed countries", in part because they were expressly deemed in the *August 30th Decision* to lack sufficient pharmaceutical manufacturing capacity.

<sup>99</sup> In the result, five countries have no option to procure medicines from a Canadian generic supplier while those products remain under patent in Canada: Russian Federation, Ukraine, Belarus, Bahamas, and Libya.

<sup>100</sup> *Patent Act*, *supra* note 66 at s. 21.03(1)(d)(ii).

<sup>101</sup> *Ibid.*

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

Council Chairperson's Statement made in conjunction with the adoption of the August 30<sup>th</sup> Decision — namely, the “shared understanding” of WTO Members that the system set out in the Decision “should be used in good faith to protect public health and... not be an instrument to pursue industrial or commercial policy objectives”.<sup>103</sup> Under the JCPA, an importing country may be struck off the list of those eligible to import from a Canadian generic supplier if it permits such use.<sup>104</sup> Yet the term “commercial purposes” is undefined in the legislation. As has been argued elsewhere:

This provision is clearly aimed at limiting the possibility of commercial competition in the importing country's marketplace, hindering the longer-term benefit that competition could have in reducing medicine prices. It also raises questions about the distribution of imported generics via the private sector (e.g., pharmacists) in the importing country. Will this be considered a “commercial purpose”? If so, such a provision fails to recognize the reality that many people in developing countries, as elsewhere, need to turn to private pharmacies when purchasing medicines, which are also frequently paid for out of their own pocket rather than covered by a public scheme. This provision is unnecessary under TRIPS and the WTO Decision; it should not have been included in the Canadian legislation, nor should this approach be replicated by other jurisdictions.<sup>105</sup>

#### 4.6 NGO Procurement from Canadian Generic Manufacturers

As originally drafted, the JCPA did not contemplate that NGOs, such as humanitarian relief organizations, might be purchasers of generics from Canadian suppliers. The legislation only allowed that a contract between a generic manufacturer and a government or “agent of government” in an eligible importing country could be the basis for an application for a compulsory licence. However, NGOs called on the government to recognize that they could not and should not be considered to fall under the category of “agent[s] of government”, and the legislation should be amended to ensure they could obtain lower-cost generics for their field operations in eligible developing countries.

Responding to these concerns, the Liberal government amended the bill at the Standing Committee stage to authorize generic producers to sell directly to NGO purchasers for use in eligible countries. However, during the Committee proceedings, a Liberal MP from Montréal highly sympathetic to the brand-name pharmaceutical industry (which is heavily concentrated in Québec), succeeded with an individual member's motion that reinserted the qualification that the NGO had to demonstrate it had obtained some undefined “permission” from the government of the country. Although this was drawn to the attention of the government, it chose not to exercise party discipline and re-establish the amended version of this provision that would have avoided any such limitation. In the end, the JCPA was enacted with this restriction, creating yet another unnecessary and time-wasting hurdle to efforts to respond to serious health needs.<sup>106</sup>

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<sup>103</sup> *Chairperson's Statement*, *supra* note 54.

<sup>104</sup> *Patent Act*, *supra* note 66 at s. 21.03(3)(d).

<sup>105</sup> Richard Elliott, “Pledges and Pitfalls: Canada's Legislation on Compulsory Licensing of Pharmaceuticals for Export” (2006) 1 Int'l. J.I.P. Mgmt 94-112 at 105-106, online via: <[www.aidslaw.ca/gtag](http://www.aidslaw.ca/gtag)> Publications [Elliott, “Pledges and Pitfalls”].

<sup>106</sup> *Patent Act*, *supra* note 66 at s. 21.04(2)(f).

#### 4.7 Arbitrary Limit on Length of Compulsory Licences

One of the most unfortunate features of the JCPA is the arbitrary time limit it poses on any compulsory licence issued for the purposes of exporting generic pharmaceuticals. Under the legislation, not only is a compulsory licence limited to authorizing the production of solely the quantity set out in the specific contract between the generic manufacturer and a particular purchaser in a particular eligible importing country, the licence may also only be issued for a maximum period of two years.<sup>107</sup> After two years, should the generic company wish to continue supplying the product to its customer, it must apply for a new compulsory licence, based on a new (single) contract. Without such authorization in place, any further production or export of the product amounts to patent infringement, with the potential for liability. As has been pointed out previously, the government's stated rationale that such a limit is needed to preserve flexibility for developing countries is untenable:

Such a paternalistic approach, trying to legislate by proxy a limit on the term of a contract, seems strange given the government's general unwillingness to interfere with parties' freedom to bargain in the marketplace. There is little reason to believe that developing countries (or other bulk purchasers of pharmaceuticals) are unable to adequately assess and project their own medicine needs and contract accordingly. Furthermore, such a proposition is irrelevant to the issue of compulsory licensing; should this argument not also be applicable in every situation where a developing country is purchasing medicines from a pharmaceutical supplier, be it a brand-name company or a generic one? The fact that a generic producer may, in respect of a specific drug that is still patented in Canada, need a compulsory licence to manufacture and supply that medicine is a secondary consideration. It seems, rather, that this cap represents a misguided and unnecessary attempt to constrain generic producers' ability to compete effectively in the marketplace, by limiting the term of a compulsory licence available under the legislation.<sup>108</sup>

Negotiating longer-term contracts would provide more of an incentive for generic manufacturers to scale up production of a particular product and would permit greater economies of scale. This arbitrary cap on the term of a compulsory licence is a negative feature of Canada's law, and should be changed. While other, more fundamental changes to the compulsory licensing process enacted by the JCPA are required (as discussed below), even if the existing mechanism were kept basically intact, it should be amended such that a compulsory licence either runs for the remaining term of the patent on the product in question or the very least, has a term equivalent to the term of the contract that the generic manufacturer has negotiated with a purchaser and which is the basis for the compulsory licence application.

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<sup>107</sup> *Ibid.* at s. 21.09. The compulsory licence may not authorize production of the pharmaceutical product in any quantity greater than that set out in the underlying contract between the generic manufacturer and its customer, which formed the basis of the compulsory licence application. If the full quantity has not been shipped during the two-year period of the licence, the generic manufacturer may apply for the licence to be "renewed" (i.e., extended) once for up to another two years; however, only one renewal of a licence is permitted: *ibid.* at s. 21.12.

<sup>108</sup> Elliott, "Pledges and Pitfalls", *supra* note 105 at 107.



#### 4.8 Capping Generics' Prices and Profits: Policing Humanitarianism Through Self-interested Litigation

Finally, as a result of lobbying by the originator industry, the government unexpectedly amended the JCPA during Standing Committee hearings to add a series of new provisions that invite patent-holders to resort to litigation as a means of hindering or dissuading use of the legislative scheme by generic manufacturers. Despite criticisms from some NGOs of these new provisions inserted at the last minute, the government was steadfast that these changes would be made. Consequently, under the JCPA amendments, the owner of the Canadian patent(s) on the product may apply to the Federal Court of Canada for an order terminating a compulsory license, or ordering a royalty higher than what is specified by the sliding scale in the regulations under the *Patent Act*, on the basis that a generic company's contract with a purchaser is "commercial" in nature.

In such an application, the patent owner must allege that the generic producer is charging an average price for the product that exceeds 25 percent of the average price being charged for the patented product in Canada.<sup>109</sup> In determining whether the agreement is "commercial" in nature, the Federal Court must consider: (i) the need for the generic manufacturer holding the compulsory licence to make "a reasonable return sufficient to sustain a continued participation in humanitarian initiatives"; (ii) the ordinary levels of profitability in Canada of commercial agreements involving pharmaceutical products; and (iii) international trends in prices as reported by the UN for the supply of pharmaceutical products for humanitarian purposes.<sup>110</sup> If the generic producer can demonstrate, through an audit supervised by the Court, that its average price is less than 15 percent above its direct manufacturing costs, the court may not issue such an order terminating the compulsory license or varying the royalty payable.<sup>111</sup>

Government representatives have stated that these provisions in the JCPA seek to control the prices charged by generic producers to developing country purchasers. Indeed, that may well be the objective, as well as the effect. However, the measures adopted in pursuit of this objective are ill-considered, assuming for the sake of argument that they are even necessary given the likely competition in the global marketplace, from either brand-name companies pressured into lowering their prices or from other generic manufacturers, including those in other countries, some of whom likely have lower costs of production on some fronts. The objective of containing prices charged by generic manufacturers exporting medicines under compulsory licence from Canada could have been achieved through other means, such as through conditions imposed in the compulsory licence itself when issued. Instead, the Government chose a far less direct method of achieving its objective, one that coincidentally (?) places enforcement of this crude price-control provision in the hands of the patent-holding companies, who have not only a long history of vexatious litigation against generics aimed at delaying and undermining marketplace competition, but also an obvious incentive and now a legal basis for such tactics embedded right in the JCPA regime itself.

Government representatives also suggested that these provisions to control generic manufacturers' prices reflect the humanitarian, and not commercial, spirit of the WTO's August 30<sup>th</sup>

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<sup>109</sup> *Patent Act*, *supra* note 66 at s. 21.17(1).

<sup>110</sup> *Ibid.* at s. 21.17(2).

<sup>111</sup> *Ibid.* at s. 21.17(5).

Decision and give effect to Canada's obligation to act in "good faith" to prevent the use of the system agreed to in that decision from being used to pursue industrial or commercial policy objectives. However, such a detailed and obvious disincentive to generic producers using the system is in no way required by the August 30<sup>th</sup> Decision or the accompanying Chairperson's statement of the same date, nor by TRIPS itself. The stated commitment in the 2001 Doha Declaration, referred to again in the August 30<sup>th</sup> Decision, and reaffirmed yet again in the JCPA is to facilitate access to medicines to address public health problems faced by developing countries. Yet the JCPA created further privileges and legal mechanisms for patent owners to interfere with the simple, straightforward use of compulsory licensing to supply generic pharmaceuticals to developing countries.

## 5. HAVE THE JCPA AND THE WTO AUGUST 30TH DECISION DELIVERED?

In August 2006, Canada hosted the XVI International AIDS Conference in Toronto, the theme of which was "Time to Deliver", highlighting that the world now knows a great deal about what works in responding effectively to the global pandemic, and what needs to be done, but lacks the commitment, including at the highest political levels in many developing and high-income countries. It was also an occasion to take stock of whether the JCPA, enacted with such fanfare in 2004 as a major element in Canada's response to global public health inequities, has in fact delivered — and if not, to consider the reasons why and what could be done about the failure. NGO advocacy and extensive media coverage placed the issue back on the political agenda, notwithstanding the much-criticized unwillingness of the Conservative government to make any firm commitments at the Conference on behalf of Canada in the struggle, domestic or at home, against the pandemic. What, then, has happened with the JCPA since its passage in May 2004?

A few weeks after Parliament enacted the legislation, MSF publicly stated that it would seek to use it to purchase generic medicines needed for patients in its field operations in a developing country eligible to import from Canada under the JCPA.<sup>112</sup> In August 2004, MSF identified to Health Canada and representatives of the Canadian generic pharmaceutical industry five drugs that were urgently needed to treat its patients. After several more months, in December 2004 Apotex Inc., a privately-held Canadian generic pharmaceutical company, agreed to develop one of the drugs sought by MSF, a three-in-one antiretroviral combination of zidovudine, lamivudine and nevirapine (AZT+3TC+NVP).<sup>113</sup> The use of these drugs in combination represents one of the first-line treatment regimens for HIV recommended by the WHO in its efforts to scale up access to ART in resource-limited settings. At the time that MSF formulated this request, those drugs were not available from any manufacturer in the form of a fixed-dose combination (FDC), a product that would simplify treatment significantly and help with the global effort to scale up treatment.

By April 2005, Apotex had developed an active prototype of the FDC product. However, this combination drug was not on the list of products eligible for compulsory licensing for export in Schedule 1 of the *Patent Act*. In September 2005, after further pressure, the Cabinet

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<sup>112</sup> For a detailed analysis of MSF's effort to use the legislation to obtain this product, which is also one source of the information summarized here, see MSF, "Neither Expeditious, Nor a Solution" *supra* note 95.

<sup>113</sup> Ann Silversides, "Not a Single Pill" *Ottawa Citizen* (13 August 2006) C1.

made the requisite order amending Schedule 1.<sup>114</sup> As the JCPA requires Health Canada approval for any generic drug that is to be manufactured under compulsory licence for export, Apotex submitted its dossier for “fast-track” review to Health Canada in late 2005. At this time, with the assurance from Apotex that the scientific dossier was sound, but still pending Health Canada approval, MSF began discussions with authorities in a potential importing country — which country would need both to notify the WTO TRIPS Council of its intent to use the system (according to both the WTO August 30<sup>th</sup> Decision and the JCPA) and to grant permission to MSF, as a non-governmental entity, permission to import the drug from the Canadian manufacturer (pursuant to the JCPA).

During this process, it became apparent that the country in question would not consider these next steps for any drug that had not been approved by the WHO Prequalification Project, a precondition upon which many developing countries insist when making procurement decisions in the case of AIDS drugs and other medicines covered by the WHO project. As a result, additional delays were incurred while Health Canada undertook a review that was ultimately not required and then negotiated an arrangement with the WHO to minimise further duplication in the WHO’s review. The Health Canada review process took seven months; the product received approval in July 2006.<sup>115</sup> In August 2006, shortly before the XVI International AIDS Conference, the WHO Prequalification Project, having reviewed the dossier submitted to Health Canada, also gave its stamp of approval.

A flaw in the JCPA and in the WTO August 30<sup>th</sup> Decision was also highlighted in the process of getting a compulsory licence. As MSF explains:

Under the terms of the [WTO] Decision, a potential importing country must send a notification in writing to the WTO TRIPS Council, declaring its intention to import pharmaceutical products according to the provisions set out in the Decision. The notification must include the specific names and expected quantities of the

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<sup>114</sup> *Order Amending Schedule 1 of the Patent Act*, *supra* note 90.

<sup>115</sup> MSF, “Neither Expeditious, Nor a Solution”, *supra* note 95 at 6. A second effort to expand Schedule 1 has also shown the cumbersome, unresponsive nature of this feature of the JCPA. In December 2005, Canadian pharmaceutical company Biolyse Pharma announced it had developed an alternate process for producing oseltamivir phosphate, an oral antiviral medicine used for both treatment and prophylaxis of influenza, including the H5N1 variant of avian flu that has increased concern about a possible global flu pandemic. Very few developing countries have stockpiled oseltamivir in anything remotely close to the quantities recommended (including by the WHO), which means they lack one of the tools for treatment or prevention of avian flu, should such a pandemic occur. Biolyse announced that it wished to obtain a non-exclusive compulsory license to produce and export the medicine to developing countries at a reduced cost. In February 2006, Biolyse submitted a formal request to the Ministers of Health and Industry to add oseltamivir phosphate (in both capsule and powder form) to the list of products eligible for compulsory licensing for export in Schedule 1 of the Patent Act: Letter from Biolyse Pharmaceutical Corporation to the Minister of Health and the Minister of Industry (14 February 2006), online: Biolyse Pharma Corporation <[www.biolyse.ca/news.asp?story=111](http://www.biolyse.ca/news.asp?story=111)>. The multinational pharmaceutical company Hoffmann-La Roche, Inc. (Roche), which holds the relevant Canadian patents on oseltamivir, has opposed the compulsory licensing of the product. On 21 September 2006, more than 6 months later, the federal cabinet made the requisite order adding these two formulations of the drug to Schedule 1. See *Order Amending Schedule 1 to the Patent Act (Oseltamivir Phosphate)*, *supra* note 91. Biolyse has stated it plans to ramp up its production capacity, but assuming it negotiates tentative agreements with developing country purchasers, it remains to be seen what its experience will be with the protracted process for obtaining either a voluntary or compulsory licence allowing it to export.

product needed . . . The requirement that importing countries notify in advance their intention to use the August 30th Decision also opens them up to pressure from countries whose policy and practice it is to discourage the granting of compulsory licenses. Although the notification is supposed to be solely for the purpose of providing transparent information, the conditions may deter importing countries from doing so.<sup>116</sup>

A similar concern arises in the use of the Canadian legislation implementing the WTO Decision. As discussed above, under the JCPA, in implementing the TRIPS Article 31(b) requirement that a compulsory licence may not be issued unless there has first been an attempt to negotiate a voluntary licence, the law states that the Commissioner of Patents shall issue the compulsory licence only if, among other things, the generic manufacturer applicant has, at least thirty days before filing its application, sought from the patentee(s) a voluntary licence and “provided the patentee . . . in the written request for a licence, with the information that is in all material respects identical to the information” set out in the compulsory licence application — including not only the name and quantity of the product to be exported, but also “the name of the country or WTO Member to which the pharmaceutical product is to be exported”.<sup>117</sup> This process of having to disclose the name of the would-be importing country, even before the generic manufacturer is in possession of the legal authorization (i.e., the compulsory licence) to follow through on its tentative arrangement with that country, exposes a developing country to the risk of considerable pressure from countries such as the U.S. that have, for many years, actively dissuaded countries from implementing policies that would limit private intellectual property rights in pursuit of public health objectives — even to the point of threatening trade sanctions.

Seemingly in part because of this concern, as of the time of writing, the country in which MSF had hoped to use the FDC produced by Apotex had not yet filed the requisite notification to the WTO TRIPS Council, and the name of the country remained undisclosed, including to the patentees who own the relevant Canadian patents on the three drugs in the FDC developed by Apotex. Given the wording of the JCPA (s. 21.04) these patentees have a basis to claim that the preconditions for compulsory licensing have not been satisfied until they have been apprised of the name of the country to which the product is to be exported for at least 30 days. (MSF eventually advised in early 2007 that its discussions with the potential importing country had not succeeded, and the country was not, at that time, expected to file the requisite notification to the WTO of its intent to use the August 30<sup>th</sup> Decision.)

During the XVI International AIDS Conference in Toronto in August 2006, at a panel organized to discuss Canada’s Access to Medicines Regime and the underlying WTO August 30th Decision, a representative of the Clinton Foundation HIV/AIDS Initiative indicated the Foundation would be willing to place an order for the Apotex FDC product as the basis for a compulsory licence application.<sup>118</sup> Brokering a large-scale order, particularly if it involved mul-

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<sup>116</sup> MSF, “Neither Expeditious, Nor a Solution”, *ibid.*

<sup>117</sup> *Patent Act*, *supra* note 66 at s. 21.04(2)(e) and (3)(c).

<sup>118</sup> Dr. Anil Soni, “Will it Deliver? WTO Rules and Canada’s Law on Compulsory Licensing: the Continuing Challenge of Scaling-up Treatment Access” (Presentation delivered at the XVI International AIDS Conference, Satellite Session, 15 August 2006), online: XVI International AIDS Conference <<http://www.aids2006.org/PAG/PSession.aspx?s=918>>.

multiple developing countries that might thereby achieve some safety in numbers, could provide significant pressure that could break the seeming logjam in this first effort to use Canada's legislation. Almost a year later, in July 2007, reportedly at the suggestion of the Clinton Foundation HIV/AIDS Initiative, Rwanda became the first country to file with the WTO the requisite notification that it intended to use the August 30<sup>th</sup> mechanism, possibly to import the Apotex FDC product under Canada's Access to Medicines Regime.<sup>119</sup> With a would-be importing country finally identified as a potential purchaser, Apotex renewed its request for voluntary licences from the Canadian patentees of the relevant products. Having not reached the necessary agreements with all the patentees on the terms of a voluntary licence, in early September 2007, Apotex filed its application for a compulsory licence, which application was granted later that month.<sup>120</sup>

The experience of MSF and Apotex in this first effort to use the JCPA has illustrated a number of problems with both the unnecessary hurdles added by Canada in its implementation of the WTO August 30<sup>th</sup> Decision and the WTO Decision itself. Based on the analysis of the JCPA above and the experience to date, the next, final section concludes by presenting some recommendations for reform to Canada's legislation that seeks to avoid these defects and put in place a much more user-friendly and likely effective system for using compulsory licensing to supply Canadian-made generic pharmaceuticals to countries facing public health problems.

## 6. REFORMING CANADA'S LAW ON COMPULSORY LICENSING FOR EXPORT

In theory, the JCPA has made it possible for a Canadian generic pharmaceutical producer to obtain a licence to manufacture a patented medicine for export to eligible countries. The fact that a G7 country has taken the step of passing such a law is significant, because it generated needed political momentum, from a developed country, behind efforts to use TRIPS flexibilities to improve access to medicines in developing countries with limited domestic pharmaceutical manufacturing capacity and limited resources. In addition to Canada, as of October 2006, Norway, India, the European Union, the Netherlands, South Korea, and China had adopted legislation, regulations, or other instruments that in some way, with varying degrees of specificity and restrictiveness, implement the WTO August 30<sup>th</sup> Decision to permit compulsory licensing of patented pharmaceuticals for export to certain eligible countries.<sup>121</sup>

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<sup>119</sup> Government of Rwanda, *Notification under paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 19 July 2007, WTO Doc. IP/N/9/RWA/1, online: <[http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_notif\\_import\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm)>.

<sup>120</sup> Commissioner of Patents, "Authorization Under Section 21.04 of the Patent Act", 19 September 2007, online: <[http://www.ic.gc.ca/sc\\_mrksv/cipo/new/CAMR\\_Authorization.pdf](http://www.ic.gc.ca/sc_mrksv/cipo/new/CAMR_Authorization.pdf)>. For the full application by Apotex for a compulsory licence, see: <[http://www.ic.gc.ca/sc\\_mrksv/cipo/jcpa/GoodmansCAMR.pdf](http://www.ic.gc.ca/sc_mrksv/cipo/jcpa/GoodmansCAMR.pdf)>. At the time of writing, actual export of the product was still contingent upon a final decision by Rwanda to purchase the Apotex product, following the Rwandan government's accepted procurement procedures, including a public tender for bids from suppliers.

<sup>121</sup> For additional information and materials, see the collection established by Consumer Protection on Technology, "Legislation to Allow for the Export of Pharmaceuticals Under Compulsory License", online: <<http://www.cptech.org/ip/wto/p6/index.html#Legislation>>.

Yet, as of mid-2007, despite the best efforts of an NGO such as MSF, not a single tablet had been exported under the Canadian legislation. In August 2006, again under pressure from NGOs in the Global Treatment Access Group and from Stephen Lewis, UN Secretary-General's Special Envoy on HIV/AIDS in Africa, the Minister of Health publicly committed to speeding up the statutorily-mandated review of what the government now generally refers to as "Canada's Access to Medicines Regime" (CAMR), and to making necessary changes to make it work.<sup>122</sup> In any event, when the JCPA was passed in May 2004, it included a provision mandating that the Minister of Industry review the legislation and report on the results of that review to both the Senate and the House of Commons within two years of the legislation coming into force. As the amendments were proclaimed into force on 14 May 2005, the Minister was to have completed the review by 14 May 2007 at the latest, with the report to be tabled in Parliament in early June according to the parliamentary calendar.<sup>123</sup>

So what should be done to fix the regime? As should be apparent from the foregoing discussion, there are numerous reforms needed to the current Canadian legislative regime on compulsory licensing for export as set out in the JCPA's amendments to the *Patent Act* and the *Food and Drugs Act*.<sup>124</sup> Even if the basic mechanism, modelled on and implementing the WTO August 30<sup>th</sup> Decision, were to remain intact, a whole series of changes are advisable to increase the usefulness, and likely use, of the regime and to avoid burdening the already flawed, cumbersome mechanism of the August 30<sup>th</sup> Decision with additional, unnecessary and problematic features. These include the following:

- There should be no limits to the pharmaceutical products subject to compulsory licensing for export, or barriers to possible licensing. Schedule 1, the limited list of products covered by the regime, which can only be amended by a Cabinet order, should be abolished, with corresponding amendments to references to such a schedule in the body of the Act itself. As is already stated in the WTO's August 30<sup>th</sup> Decision, the law should facilitate the compulsory licensing of any patented product, or product manufactured through a patented process, of the pharmaceutical sector. With reference to the Decision,<sup>125</sup> Canada's legislation should be amended to make it clear that this includes active pharmaceutical ingredients (not just the finished product), as well as any diagnostic kits needed for the use

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<sup>122</sup> Isabel Teotonio, "Clement vows to get cheap drugs flowing", *Toronto Star* (16 August 2006) A1. In January 2007, in response to a consultation paper, the government received numerous submissions regarding directions for reform from various interested parties; it also had the benefit in April 2007 of testimony heard by the House of Commons Standing Committee on Industry, Science and Technology and of experts, including developing country representatives, at an international expert consultation co-hosted in Ottawa by the Canadian HIV/AIDS Legal Network and the North-South Institute (a report of which is available via [www.aidslaw.ca/gtag](http://www.aidslaw.ca/gtag)).

<sup>123</sup> *Patent Act*, *supra* note 66 at s. 21.2. However, Parliament rose for an extended break at the end of June 2007, and as of this writing in mid-October 2007, the government had not yet publicly released any report of its review.

<sup>124</sup> For a more detailed analysis and extensive submissions with proposed reforms, see: Canadian HIV/AIDS Legal Network, *Getting the Regime Right – Brief to the House of Commons Standing Committee of Industry, Science and Technology regarding Canada's Access to Medicines Regime*, 18 April 2007, online via: <[www.aidslaw.ca/gtag](http://www.aidslaw.ca/gtag)>.

<sup>125</sup> *August 30th Decision*, *supra* note 2 at para. 1(a).

of the product. The legislation also needs to make it clear that the compulsory licence issued on a product extends to cover any relevant product or process patents related to the production of that product. The current language of the legislation requires the generic manufacturer's application to identify "each patented invention to which the application relates". However, this language creates a potential for abuse: there are often tens, or even hundreds, of different patents related to any particular medicine (based on different formulations, manufacturing processes, intermediates, etc.), and the number and extent of patent claims often proliferates over time. It would be entirely counterproductive if this were interpreted as requiring the applicant to list every single "patented invention to which the application relates"; the application should only identify the product in question, and it should be a standard clause in the licence issued that it authorizes the manufacture or use of any patented invention reasonably necessary to permit the manufacture, export, and effective use of the product that is being produced for the developing country purchaser.<sup>126</sup>

- Parliament should abolish the provisions that impose additional requirements for non-LDC, non-WTO developing countries to become eligible to import generic pharmaceuticals manufactured in Canada under compulsory license. In particular, the requirement to declare an emergency or other circumstances of extreme urgency should be removed. Similarly, the requirement to agree that the imported product will not be used for commercial purposes should be abolished. The corresponding provisions that enable a country to be struck off the list of eligible importing countries for not satisfying these conditions should also be deleted.
- As long as the medicine satisfies the conditions established by the drug regulatory authority in the importing country, there is no reason why a non-governmental purchaser of Canadian-made generics importing those products into an eligible country should require, in addition, the "permission" of the importing country's government in order to purchase its supplies from this source. This additional hurdle is easily eliminated and should be.
- There should be no requirement that the generic manufacturer secure approval from Health Canada for its product and certainly not as a precondition to obtaining a compulsory licence. One option would be to accept either a successful Health Canada review *or* approval from the WHO's Prequalification Project as satisfactory. Alternatively, there could be no requirement for any involvement of Health Canada at all, leaving the importing country apply the standards it determines are appropriate — which could include accepting a Health Canada approval, or might be the common practice of purchasing only WHO pre-qualified products. After all, it is the importing country that the WTO's August 30<sup>th</sup>

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<sup>126</sup> This point has been highlighted in Canadian Generic Pharmaceutical Association, "Canada's Access to Medicines Regime Consultation Paper – Comments by the Canadian Generic Pharmaceutical Association" (24 January 2007) at 3, online: Canadian Generic Pharmaceutical Association <<http://www.canadiangenerics.ca>>, <<http://www.camr.gc.ca>> [CGPA].

Decision is supposed to enable “to make effective use” of compulsory licensing to address its health needs.

- Under the current regime, the Commissioner of Patents may not issue a compulsory licence unless the applicant has provided to the patentee(s), for a period of at least 30 days, not only the name and quantity of the pharmaceutical product to be exported but also “the name of the country or WTO Member to which the pharmaceutical product is to be exported”.<sup>127</sup> As a result, for at least a month, before there is even any assurance for the would-be purchasing country that the Canadian generic supplier is able legally to supply the product for which a tentative agreement has been reached, the importing country is exposed to almost certain pressure from the patented pharmaceutical industry and powerful countries such as the United States or other like-minded WTO Members to refrain from proceeding with the use of compulsory licensing to secure needed medicines. Recent history provides numerous examples of such pressure, extending even to threats of serious trade sanctions and other retaliation, notwithstanding that such conduct runs counter to the letter and spirit not only of agreements reached at the WTO (such as the WTO’s August 30<sup>th</sup> Decision underlying Canada’s regime), but also those states’ obligations under international human rights law to not impede access to medicines. This is one factor that has almost certainly contributed to the fact that no country has yet notified the WTO of its intention to use the August 30<sup>th</sup> Decision, whether to import Canadian-made generics under Canada’s legislative regime or from other jurisdictions that have implemented similar regimes. At the very least, this section of the *Patent Act* can be revised such that, even if the existing cumbersome process of applying for a compulsory licence for every specific drug order is maintained, there would be no requirement to disclose the name of the country in question as a precondition of obtaining the compulsory licence. Instead, it could be simply required that the generic manufacturer request a voluntary licence from the patentee(s) on the reasonable condition that the generic manufacturer will disclose the name of the country following receipt of the licence and will pay the applicable royalty rate pursuant to the existing formula. This is one particular example of how Canada’s legislation could be amended to reflect the political and economic reality faced by developing countries that might seek to use such a regime to import lower-cost medicines to address public health problems.
- Even if a system were retained whereby voluntary licence negotiations remain a precondition to compulsory licensing — which proposition is revisited in more detail below — there should be no need to negotiate for a voluntary licence from the owner of the Canadian patent in the event that the eligible importing country has identified that the generic product in question is needed for an emergency or other circumstances of extreme urgency, or for public non-commercial use. Nor should any such negotiation be required where the importing country is resorting to compulsory licensing to remedy a practice by the patent owner that has been found by a judicial or administrative process to be anti-competitive. The current

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<sup>127</sup> *Patent Act*, *supra* note 66 at s. 21.04.



30-day requirement for such negotiations should be automatically waived in these circumstances. This is consistent with the flexibility already provided by various subsections of TRIPS Article 31.

- There should be no arbitrary limit on the term of a compulsory licence, limiting the economies of scale needed to make compulsory licensing viable for generic manufacturers and throwing into question for potential developing-country purchasers the long-term sustainability of supplies. The current two-year limit should be abolished, and a compulsory licence should run for the remainder of the patent term on the originator product or at least for the term of the contract between the generic manufacturer and its customer. If there is a specified term of a licence, extending or renewing the licence should be a simple, largely automatic process. There should be no need to undertake anew the entire process (including attempting to negotiate a voluntary licence with the patentee) simply to continue a relationship with a developing country purchaser beyond the term of the original contract, or to expand production of the same product to supply new customers, whether in the same or another eligible importing country.
- Under the WTO's August 30<sup>th</sup> Decision, in the case that a developing or least-developed country WTO Member is party to a regional trade agreement with other countries, at least half of whom are least-developed countries, it is permitted for that country, having imported pharmaceutical products under a compulsory licence, to re-export those products to the other developing or least-developed country members of that regional trade group. At the moment, there is uncertainty under Canada's current legislative regime as to whether it would permit export from Canada, under compulsory licence, of generic pharmaceutical products to an eligible country from which re-exportation to other countries in an eligible regional trade group would or might occur, in accordance with the WTO's August 30<sup>th</sup> Decision. In particular, one sub-section of the *Patent Act* could be interpreted as permitting the termination of the generic manufacturer's authorization in such a circumstance, on the basis that "the product was exported, other than in the normal course of transit, to a country or WTO Member other than the country or WTO Member named in the authorization."<sup>128</sup> In addition, there may be uncertainty under the current legislation as to the applicable royalty rate in such a circumstance. In cases where it is known in advance that such re-exportation is planned, as part of a regional pooling between different purchasing countries in that regional trade group, such uncertainties could be resolved satisfactorily through the good faith of the patentee(s) and the licence-holder, or by specifying a particular condition in the compulsory licence itself. However, this may not be a realistic expectation. Rather, the legislation should be amended to enable, without confusion, the use of compulsory licensing to supply, under a simple process and with a single licence, a number of developing countries within a regional trade group as contemplated by the August 30<sup>th</sup> Decision.
- The provisions in the current legislative regime that grant extra rights to patentees to litigate in an effort to vary or have revoked the licence granted to a generic

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<sup>128</sup> *Ibid.* at s. 21.14(g).

manufacturer should be repealed.<sup>129</sup> These provisions are not required by the WTO's August 30th Decision, or by any WTO instrument, and create an additional disincentive to participation in the scheme by generic manufacturers. In addition to being legally unnecessary, they are not likely needed from a practical point of view: generic manufacturers will already face competitive market pressure to keep prices low in order to attract developing country purchasers, and will already have an incentive to respect conditions attached to their licences so as not to lose them. These provisions serve primarily to create additional legislative opportunities for interference by patentees, which should not be discounted given the heavily litigious relationship between the brand-name and generics industries, including in Canada.

The reforms identified above would go some way toward removing some of the disincentives and hurdles currently found in Canada's legislation. However, as the experience to date has demonstrated, a more fundamental reform to Canada's regime of compulsory licensing for export is required. The Government's review initiated in late 2006, and Parliamentary consideration of the legislation in April 2007, represent an ideal opportunity to replace the current unwieldy process with a more effective legal regime. As has been noted in the detailed review above, the Government of Canada added a number of unnecessary and burdensome features to its legislation, beyond anything required by WTO rules. Yet, the experience has highlighted a more fundamental problem – the WTO August 30<sup>th</sup> Decision itself. Recall that, more than three years after the WTO decision, not a single country had yet made the requisite notification to the WTO of its intent to use the mechanism to import generic medicines from another, exporting country.<sup>130</sup> MSF's experience, as illustrated through its hands-on effort to use the JCPA to obtain an inexpensive FDC antiretroviral drug to treat its patients living with HIV/AIDS in a particular country, has led it to conclude that the WTO's August 30th Decision is “neither expeditious, nor a solution.”<sup>131</sup>

In order to put in place a legislative regime that stands a greater chance of delivering on the “pledge” originally made in 2004, Canada's law-makers will need to be willing not only to enact the changes recommended above, but to go further — they must step away from the flawed mechanism of the WTO August 30<sup>th</sup> Decision and enact a series of changes that will simplify the process of compulsory licensing for export. The WTO Decision embodied in Canada's law ignores the realities of both generic drug manufacturers and developing countries. Developing countries need simple contract processes that will ensure sustainable supplies of essential medicines or other pharmaceutical products; these contracts must be flexible enough to adjust to changing needs. The WTO Decision as enacted by Canada, however, forces generic companies through unnecessary red tape to get a licence to manufacture and export each patented drug, and even then allows for export only in a pre-negotiated quantity and to a single country.

What is needed is for Canada to streamline the legal process so that developing countries and generic drug companies can use it more easily and will be more likely to. Generic manufac-

<sup>129</sup> *Ibid.* at ss. 21.08(4)-(7), 21.14, and 21.17.

<sup>130</sup> WTO, “TRIPS and Public Health: Dedicated Webpage for Notifications”, online: WTO <[http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm)>. Rwanda is the only importing country to have given notification, having done so on 19 July 2007.

<sup>131</sup> MSF, “Neither Expeditious, Nor a Solution” *supra* note 95.

urers should be able to begin the process by applying for a compulsory licence to manufacture and export any patented medicine, not just those on the limited list attached to the original legislation, and should be able to make such an application without any particular country or specific quantity of the product determined. Such legal authorization could be done via a standing statutory “compulsory licence” – that is, a specific section of the *Patent Act* could be enacted that statutorily authorizes the generic production of any patented pharmaceutical product solely for purposes of export to any eligible country specified in the legislation. Alternatively, if the legislation were to require a specific application for a compulsory licence on a particular product, instead of requiring a generic manufacturer to apply for a separate licence to satisfy every separate order of a drug, the law could grant that manufacturer an initial compulsory licence on a drug as of right. The licence would authorize the company to export that drug to any eligible country specified in the legislation. In either case, whether granted by statutory provision or in the form of a specific licence, certain standard conditions of the authorization, such as the obligation to pay royalties to the patent owner(s) according to the formula found in the current legislation, could be imposed as conditions of the licence (which could even be statutorily mandated). With such a licence in hand, a generic company would be able to negotiate multiple purchasing contracts with multiple developing countries — not just one-off agreements on a country-by-country, order-by-order basis for which a separate licence must then be obtained each time, as is currently the case. The economies of scale that could be achieved could be considerable, contributing to the goal of encouraging generics to participate and to lowering further the ultimate price developing countries could negotiate with the generic manufacturer.

Since the licence would already have been obtained at the outset of the process, there would be no need for a period of negotiation over the terms of a voluntary licence between generic manufacturers and brand-name patentees. Generic producers would still be required to pay royalties to the patent holders based on the contracts they do end up signing with customers; each compulsory licence could include the condition that the generic must disclose basic details about the value of those contracts and pay the applicable royalties on a regular basis to the patent owners. As described above, the existing law already contains a sensible formula that calculates the royalty payable on any given contract based on the UN Human Development Index ranking of the importing developing country; this should be preserved in a new legislative regime. By granting a compulsory licence at the outset that is not specific to any one country, and instead including a standard licence condition that legally obliges the generic manufacturer to pay royalties in accordance with this clearly defined formula, based on whatever contracts may end up being negotiated, there is no obligation for a developing country to first step forward and risk retaliation all for the uncertain reward of delivery of one medicine in a predetermined quantity for a limited period of time. In addition, countries would not be faced with the unrealistic task of predicting exactly the quantity of the drug that will be needed in a given time period; adjustments in the quantity produced and purchased could fluctuate over time depending on the health needs of the country in question. Such a process would give generic manufacturers and developing countries much more incentive to make use of the law and realize the goal of getting medicines to people who need them in developing countries.

Would such an alternative mechanism be permissible under WTO rules? It has been argued that the requirement for voluntary licence negotiations on a case-by-case basis, which is incorporated into both the August 30<sup>th</sup> Decision and Canada’s legislation, is not, in fact, required

under TRIPS Article 31(b), the provision commonly cited as the basis for this provision. If it is understood that the entire purpose of the mechanism is to “protect public health”, and not to pursue “commercial policy objectives” – as is stated in the Decision and the accompanying Chairperson’s Statement, and in Canada’s law – then the compulsory licence is being issued for “public non-commercial use” and, therefore, under TRIPS Article 31(b), the requirement of first attempting to negotiate a voluntary licence does not apply. Furthermore, at least in the case of certain products for certain health problems (e.g., the HIV pandemic), it could be said that the problem itself already amounts to a “circumstance of extreme urgency”— a characterization supported by UN agencies and even the UN General Assembly itself, which declared unanimously in 2001 that the pandemic represented a “global crisis” — in which case the requirement to first attempt voluntary licence negotiations could also be waived on this basis.<sup>132</sup>

Aside from this line of argument, clearly the streamlined process described above departs in very significant ways from the August 30th Decision that was predicted at the time to be flawed — and that has unfortunately proved so. But the August 30<sup>th</sup> Decision is not the only option open to WTO Members. The Decision states expressly:

This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the [Doha] Declaration, and to their interpretation.<sup>133</sup>

It is, therefore, time to return to the question of TRIPS Article 30 as the basis for solving the problem that was recognized in paragraph 6 of the Doha Declaration, as was originally proposed by a number of developing countries and a range of NGOs active in efforts to secure access to medicines in the developing world, with the support of the WHO.<sup>134</sup> Article 30 states:

*Exceptions to Rights Conferred*

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

As pointed out by the industry association representing generic manufacturers, “the intent of the [WTO’s August 30th] Decision is that if an eligible importing member seeks drugs under the system, a rapid response is important and consistent with the Decision (see preamble). Any conflict with normal exploitation of a patent, if consistent with that objective, cannot be unreasonable. The eligible importing member or its citizens are third parties with legitimate interests.”<sup>135</sup> It is important to note that TRIPS Article 30 is worded in a very open-ended fashion, and affords important leeway to WTO Members in implementing their other TRIPS obligations regarding granting exclusive patent rights. Furthermore, TRIPS expressly states that WTO “[m]embers shall be free to determine the appropriate method of implementing

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<sup>132</sup> See e.g. CGPA, *supra* note 126 at 7.

<sup>133</sup> *August 30th Decision*, *supra* note 2 at para. 9.

<sup>134</sup> See WHO Statement, *supra* note 49.

<sup>135</sup> CGPA, *supra* note 126 at 7.

the provisions of this Agreement within their own legal system and practice.”<sup>136</sup> In the 2001 Doha Declaration, WTO Members unanimously agreed that TRIPS should be interpreted and implemented so as to promote access to medicines and reaffirmed “the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”<sup>137</sup>

## 8. CONCLUSION

Canada has implemented the mechanism negotiated at the WTO in August 2003; so far, Canada’s model has not worked, but neither has the August 30<sup>th</sup> Decision yet worked at all for any country. As the first country to implement the WTO Decision with any sort of detailed legislative framework, and the jurisdiction in which the most concerted efforts have been made to date to use the mechanism as implemented domestically, Canada is in a position to set a positive global precedent by acknowledging that the system has not worked and by putting in place a more effective mechanism. Canada has the clear legal right to use the flexibility that it retains under TRIPS Article 30 to legislate, as a set of “limited exceptions” to exclusive patent rights, the simpler, streamlined mechanism for compulsory licensing for export that has been described above — a regime that avoids the cumbersome requirements of seeking first a voluntary licence, and failing that a compulsory licence, for every single contract that is limited to a pre-determined quantity of a particular drug for one specific country, over a period of two years at most. Canada also has an ethical duty to take action to improve access to medicines in developing countries, learning from what has not worked to date, and similarly has a legal obligation under international human rights treaties it has ratified that oblige it to take steps, individually and through international assistance and cooperation, to prevent, treat, and control epidemic and other diseases as part of achieving fully the right of everyone to the highest attainable standard of health.<sup>138</sup>

When the JCPA was enacted in 2004, it passed with the support of every single Senator and Member of Parliament, and every single party represented in Parliament declared their support for legislation that was supposed to help get more affordable medicines to patients in need in developing countries. The question is, will the federal government — or perhaps Parliament as a whole, in the case of a minority government potentially outvoted by concerted and coordinated action by the opposition parties — have the political courage of the conviction all parties stated unanimously and solemnly at that time? Or will this become another broken pledge to the developing world?

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<sup>136</sup> *TRIPS Agreement*, *supra* note 1 at art. 1(1).

<sup>137</sup> *Doha Declaration*, *supra* note 38 at para. 4.

<sup>138</sup> *International Covenant on Economic, Social and Cultural Rights*, (1966) 993 U.N.T.S. 3, Can. T.S. 1976 No. 46, in force, including Canada, 1976, at Articles 2 & 12.