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**RACE AGAINST TIME:
THE EXPORT OF ESSENTIAL
MEDICINES TO RWANDA**

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ABSTRACT

This article considers the significance of the first export of essential medicines under the *WTO General Council Decision 2003*. In July 2007, Rwanda became the first country to provide a notification under the *WTO General Council Decision 2003* of its intent to import a fixed-dose, triple combination HIV/AIDS drug manufactured by the Canadian generic pharmaceutical manufacturer, Apotex Inc. In September 2007, Apotex was granted the first compulsory licence application under Canada's Access to Medicines Regime. This article considers the convoluted and protracted negotiations between the Government of Rwanda, Apotex, and three patent holders, GlaxoSmithKline, Boehringer Ingelheim Canada and Shire BioChemical Inc. It questions the efficiency of this process. This article considers the review of the *Jean Chrétien Pledge to Africa Act 2004* (Canada). It is critical of the refusal of the Conservative Government of Canada to make any amendments to the legislation to improve the cost-effective delivery of essential medicines. This article queries the proposed Hong Kong Amendment to the *TRIPS Agreement 1994*, given the concerns of the Africa Group. It is submitted that it is undesirable to codify the *WTO General Council Decision 2003*, given its failure to provide a speedy, efficient, and cost-effective delivery of essential medicines.

KEYWORDS

Patent Law, Pharmaceutical Drugs, Compulsory Licensing, Access to Essential Medicines, HIV/AIDS, Rwanda, Canada, World Trade Organization, *TRIPS Agreement 1994*, *Doha Declaration on the TRIPS Agreement and Public Health 2001*, *WTO General Council Decision 2003*, *Jean Chrétien Pledge to Africa Act 2004* (Canada), and the Hong Kong Amendment to the *TRIPS Agreement 1994*.

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INTRODUCTION

The pandemic of HIV/AIDS feels as though it will go on forever. The adult medical wards of the urban hospitals are filled with AIDS-related illnesses, men, women, wasted and dying; aluminium coffins wheeling in and out in Kafkaesque rotation; in the pediatric wards, nurses tenderly removing the bodies of infants; funerals occupying the weekends, cemeteries running out of grave sites; in the villages, hut after hut yields a picture of a mother, usually a young woman, in the final throes of life. No one is untouched. Everyone has a heartbreaking story to tell. Virtually every country in East and Southern Africa is a nation of mourners.

Stephen Lewis, *Race against Time* (2005: 1-2).

The debate over patent law and access to medicines takes place within parameters set by the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (the *TRIPS Agreement* 1994) of the World Trade Organization (WTO) (Gervais, 2003). There has been much debate over the best means to enable poor countries without sufficient manufacturing capacity to make effective use of compulsory licensing provisions in order to gain access to essential medicines (Mayne, 2002: 255). A group of countries, led by the Africa Group, Brazil and India has promoted the development of a legally binding treaty on access to essential medicines. At a meeting in Qatar in November 2001, the members of the World Trade Organization adopted the *Doha Declaration on the TRIPS Agreement and Public Health* 2001. This declaration emphasized ‘that the *TRIPS Agreement* does not and should not prevent Members from taking measures to protect public health.’ The *Doha Declaration on the TRIPS Agreement and Public Health* 2001 deferred and postponed the resolution of the outstanding issue of the export of pharmaceutical drugs. Article 6 provides: ‘We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the *TRIPS Agreement* 1994’.

On 30 August 2003, the member governments of the World Trade Organization reached an agreement on implementing the paragraph of the *Doha Declaration on the TRIPS Agreement and Public Health* 2001 that calls for a solution to compulsory licensing for member states without manufacturing capabilities. The decision is known as the *WTO General Council Decision* 2003. Article 2 emphasizes that a member

country can export pharmaceutical products made under compulsory licences within the terms set out in the decision. Article 3 emphasizes the need for ‘adequate remuneration’ with respect to such compulsory licences. Article 4 stresses that eligible importing members should take reasonable measures to address the risk of trade diversion, and prevent re-exportation of the products. Article 5 observes that members should ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision. Article 6 enables a pharmaceutical product produced under a compulsory licence in one country to be exported to the markets of developing countries who share the health problem in question. Article 7 stresses the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem of insufficient manufacturing capacity identified in paragraph 6 of the Declaration.

A small number of developed countries and regional groups have established domestic regimes to implement the *WTO General Council Decision 2003*. In North America, Canada has established the *Jean Chrétien Pledge to Africa Act 2004* (Canada). The European Union has issued a directive regulating the export of generic pharmaceutical drugs. The Netherlands, Switzerland, and Norway have established national regimes. In Asia, India, China, and South Korea have all developed legislative regimes to allow for the export of pharmaceutical drugs to address public health concerns. However, a significant number of key developed countries have egregiously not implemented domestic regimes under the *WTO General Council Decision 2003*. Most notably, the United States, Japan, and Australia have shown little enthusiasm in establishing regimes to facilitate the export of pharmaceutical drugs to developing countries. Indeed, the United States Administration of George W. Bush has instead pursued a course of bilateral and regional free trade agreements to raise the levels of patent protection of pharmaceutical drugs in a range of jurisdictions. Such TRIPs-Plus agreements have arguably limited the availability of compulsory licences to deal with anti-competitive conduct, cases of public non-commercial use, national emergencies, and other circumstances of extreme urgency. The new Democrat leadership in the United States Congress have introduced safeguards into new bilateral free trade agreements – such as the *United States-Peru Free Trade Agreement 2007* – to recognise that the obligations do not undermine the

Doha Declaration on the TRIPS Agreement and Public Health 2001 or the *WTO General Council Decision* 2003. The partial, uneven implementation of the *WTO General Council Decision* 2003 by developed countries has raised questions about both its efficacy and its legitimacy.

In July 2007, Rwanda became the first country to notify the World Trade Organization of its intention to import essential medicines under the *WTO General Council Decision* 2003. The Delegation of Rwanda informed the TRIPS Council thus:

Based on Rwanda's present evaluation of its public health needs, we expect to import during the next two years 260,000 packs of TriAvir, a fixed-dose combination product of Zidovudine, Lamivudine and Nevirapine (hereinafter referred to as the 'Product') manufactured in Canada by Apotex, Inc. However, because it is not possible to predict with certainty the extent of the country's public health needs, we reserve the right to modify the foregoing estimate as necessary or appropriate. Pursuant to Paragraph 7 of the Doha Declaration and implementation thereof by the TRIPS Council (Decision of the Council for TRIPS of 27 June 2002), we have decided that we will not enforce rights provided under Part II Section 5 of the TRIPS Agreement that may have been granted within Rwanda's territory with respect to the Product (Rwanda, 2007).

As a least-developed country, Rwanda did not have to notify that it wanted to be an 'eligible importing member' under paragraph 1(b) of the *WTO General Council Decision* 2003.

There has been much passionate and emotional debate over patent law and access to essential medicines. The various stakeholders have developed a number of well-established positions in this ongoing debate. Major industrialised nations, brand-name pharmaceutical companies and industry groups have adopted a 'maximalist' position in respect of patent law and essential medicines. Such entities have argued that strong patent protection is necessary for the development for new pharmaceutical drugs to address infectious diseases. These patent loyalists maintain that infectious diseases would be better alleviated by the provision of better funding, medical infrastructure, and education (Mercurio, 2007). Middle tier countries - most notably India, Brazil, South Africa, Thailand and China - have been keen to push a development agenda. They have sought to take advantage of the flexibilities allowed for under the international trade regime established by the *TRIPS Agreement* 1994. Developing

countries and least-developed countries have sought to import essential medicines to combat infectious diseases because of a lack of local pharmaceutical manufacturing capacity. Non-government organisations – such as the Canadian HIV/AIDS Legal Network, Médecins Sans Frontières, and the Consumer Project on Technology - have played a key role as ginger groups in the debate over access to essential medicines. They have argued that the reform of the patent rules within the *TRIPS Agreement* 1994 will lower the prices of essential medicines and help address health crises in poor countries. There have also been a number of alternative proposals – such as prizes, gifts, and rewards - put forward to provide incentives for research and developments to address global health epidemics (Pogge, 2005; Love, 2007).

This article provides an evaluation the operation of Canada's Access to Medicines Regime, which regulates the export of pharmaceutical drugs to developing countries. It considers the first example of a compulsory licensing application for the export of patented pharmaceutical products to address public health concerns. It is a sequel to an earlier paper which considered the establishment of the export mechanism in Canada (Rimmer, 2005). The methodology of this piece is one of legal realism. This article seeks to analyse the gap between the political symbolism and the practical efficacy of the *Jean Chrétien Pledge to Africa Act* 2004 (Canada). As John Ralston Saul has once remarked, 'Canada, like other nation-states, suffers from a contradiction between its public mythologies and its reality' (Saul, 1997: 3). Part 1 provides an evaluation of the operation of the *Jean Chrétien Pledge to Africa Act* 2004 (Canada). It explores the history of the application by Rwanda for a compulsory licence for essential medicines under the Canadian scheme. It is argued that this one successful application does not necessarily validate or legitimise the *Jean Chrétien Pledge to Africa Act* 2004 (Canada), or the *WTO General Council Decision* 2003. Part 2 evaluates the review of Canada's Access to Medicines Regime. It laments the failure of the Government of Canada to recommend any legislative amendments to modernise and streamline the compulsory licensing scheme. Part 3 considers the proposed Hong Kong Amendment to the *TRIPS Agreement* 1994, in light of concerns of the African group. It is submitted that it is undesirable to codify the *WTO General Council* 2003 decision in the *TRIPS Agreement* 1994, given its failure to produce an efficient and cost-effective supply of essential medicines to developing countries and least-developed countries.

I. THE APPLICATION OF THE *JEAN CHRÉTIEN PLEDGE TO AFRICA ACT 2004 (CANADA)*

In September 2003, Stephen Lewis, the United Nations Secretary General's special envoy on HIV/AIDS, challenged the Government of Canada to amend its patent law to give poor countries devastated by AIDS a cheap source for drugs. He made a passionate plea for the Government to implement the *WTO General Council Decision 2003*: 'It's time for one of the major industrial countries, in particular, one of the G7 countries, to announce the manufacture and export of generic drugs to Africa' (Lewis, 2003). Lewis argued the support of a major industrialised nation was essential: 'If a G7 country issues a compulsory license so that its generic industry can provide the drugs, then the G7 country can join the African importing country when it goes before the WTO Council or responds to some challenge' (Lewis, 2003). He contended: 'It would at least be a small act of redemption if the same wealthy countries now provided low cost generic anti-retrovirals to help to diminish the scourge of AIDS' (Lewis, 2003). Lewis concluded: 'If a major Western government would undertake the simple legislative amendment allowing for the production and export of generic anti-retrovirals, it would make a tremendous difference for Africa' (Nolen, 2003).

Taking up the challenge, Richard Elliott of the Canadian HIV/AIDS Legal Network and the Global Treatment Action Group wrote an editorial for the *Globe and Mail*, calling upon the Government of Canada to reform its patent law to allow for access to essential medicines: 'Canada could do much, much more to respond to the desperate need for affordable medicines in many developing countries' (Elliott, 2003). Elliott emphasized that the Government of Canada could easily remove the barrier to the export of pharmaceutical drugs: 'A simple amendment to our patent legislation could authorize the manufacture of generic drugs by Canadian companies for export to those developing countries that cannot make their own' (Elliott, 2003).

In November 2003, the Canadian Prime Minister, Paul Martin, announced the introduction of a new Bill to provide low cost drugs to fight AIDS in developing countries. He dubbed the proposed legislation - *An Act to Amend the Patent Act and the Food and Drugs Act, SC 2004, c 23 - the Jean Chrétien Pledge to Africa Act 2004*

(Canada) to honour his predecessor's initiatives in that area. Martin observed: 'We will be the first country in the world with legislation to open the door to increased export and production of patented medicines to help people suffering from HIV/AIDS, malaria and TB, among other diseases, in the developing world' (Martin, 2003). This statute amends the *Patent Act*, RSC 1985, c F-27 and the *Food and Drugs Act*, RSC 1985, c P-4. to facilitate access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. The legislation was passed by the Canadian Parliament and received Royal Assent in May 2004.

The Jean Chrétien Pledge to Africa 2004 (Canada)

It is worthwhile examining the operation of the Canadian Access to Medicines Regime because not only was it the first scheme to be announced, but it has been the only regime to be thus far used for the purpose of the export of pharmaceutical drugs.

The *Jean Chrétien Pledge to Africa 2004* (Canada) provides for compulsory licences to authorise the manufacture and export of an eligible drug or medical device to an eligible country. Under the framework, the Commissioner of Patents is required to authorise the use of a patented invention by the applicant for the purpose of supplying the pharmaceutical product. The applicant must have paid the prescribed fee, and met the following conditions:

- The applicant must have met any requirement prescribed in the regulations;
- The Minister of Health must have informed the Commissioner [of Patents] that the product meets all relevant *Food and Drugs Act* requirements;
- The applicant must have provided notice to patentees; and
- The patentee must not have indicated its intention to supply the product or provide a voluntary licence.

Once the statutory and regulatory conditions have been met, the Commissioner must grant the compulsory licence to the applicant. The licensee can gain access to the patented product, without fear of an infringement suit by the patent holder. However, the licensee must pay a royalty to the patentee for the exported pharmaceutical

product. The Government has established a sliding scale for the royalty payment, linking the rate on any given contract to the importing country's ranking on the United Nation Development Program's Human Development Index. For the majority of eligible importing countries, this formula will result in a royalty that is lower than the original proposal of 2 per cent of the patented price.

Several observations about the nature of Canada's regime are in order. First, the legislation originally proposed that the patent holder should have a 'right of first refusal', so that they would be given the first opportunity to be the supplier of a requested pharmaceutical product. This clause was removed after complaints that such a measure was anti-competitive. The legislation provides for compulsory licences of two years duration (with the option for renewal for another two years if the full amount of the product specified in the licence has not been shipped). The Canadian Government has provided that a patent-holder may apply for a court order terminating a compulsory licence or ordering a higher royalty, on the basis that a generic company's contract with a purchaser is essentially 'commercial' in nature.

Second, a compulsory licence can only be issued in respect of a list of 56 essential medicines defined under Schedule One of the legislation. The Federal Cabinet may, upon the recommendation of the Ministers of Health and Industry, add other products. However, civil society has criticised this list of essential medicines as not being required under international law, and requiring ministerial recommendations and a cabinet decision to add any other product would permit lobbying by brand-name companies and create delay.

Third, the Canadian Government has restricted access to the export scheme to certain eligible countries, according to their level of development. For the least developed countries, the manufacturer would have to provide notice that it would like to acquire a licence to produce the medicine for export. For developing countries exports require not only notice, but also an attestation that the drugs cannot be manufactured in the importing countries. For certain developed countries, exports will additionally be subject to an attestation that there is an emergency. A Canadian generic producer may get a licence to export to a non-World Trade Organization Member only if that country is eligible for 'official development assistance'; declares a 'national

emergency or other circumstances of extreme urgency’; and specifies the name and quantity of a specific product needed. Such technical conditions could hinder the export of pharmaceutical drugs to non-World Trade Organization countries.

Finally, the Canadian Government allows governments and their agents to procure pharmaceutical drugs. It only enables non-government organisations to procure pharmaceutical drugs if they first obtain permission from importing countries.

In summary, Canada’s regime has a number of sui generis features, which are not required by the *WTO General Council Decision 2003*. A review of the scheme noted:

[Canada’s Access to Medicines Regime] contains a number of measures that have not been emulated elsewhere. These include its reliance on pre-approved lists of products eligible for export and countries eligible to import them and making the grant of an export licence contingent upon the health and safety review of the product by the exporting country’s regulatory authority. In addition, whereas many other regimes waive the requirement that a pharmaceutical manufacturer request a voluntary licence from the patent holder(s) prior to applying for a compulsory licence, in cases of a national emergency or circumstances of extreme urgency, [Canada’s Access to Medicines Regime] does not (Government of Canada, 2007: 29).

As such, Canada’s Access to Medicines Regime is less permissive than some of the other national regimes.

Apotex Negotiations

For all the fanfare and idealistic rhetoric which accompanied the legislative passage of the *Jean Chrétien Pledge to Africa Act 2004* (Canada), Canada’s Access to Medicines Regime has been slow to realise its goals and objectives.

Apotex is the largest Canadian-owned manufacturer of pharmaceutical drugs. Jack Kay, the President and Chief Executive Officer of the company, observes that the firm has been committed to exporting pharmaceutical drugs to countries in need:

In Africa, hundreds of thousands of people die needlessly from HIV/AIDS every year because they do not have access to such medicines. The reason is simple: the multinational

pharmaceutical industry does not like to reduce its prices, and it's better to sell to industrialized countries, where it can charge higher prices. After listening to a speech by Stephen Lewis, we made a corporate commitment to do something about the problem (Kay 2007).

Apotex has been interested in the supply of generic pharmaceutical drugs for a mixture of philanthropic and commercial motivations. The generic company is genuinely concerned about alleviating the suffering caused by infectious diseases; and at the same time is also understandably interested in the commercial opportunities offered by new markets. The company is a veteran of patent litigation with brand name pharmaceutical companies. Apotex has been involved in a numerous law suits in the Canadian courts – most notably, the Supreme Court of Canada decision in *Apotex Inc. v. Wellcome Foundation Ltd.* 2002 SCC 77 (CanLII).

In July 2007, the Government of Rwanda notified the World Trade Organization of its plan to import a fixed dose, triple combination HIV/AIDS drug manufactured by Apotex Inc. Dr Innocent Nyaruhirira, the Minister of State in Charge of HIV AIDS and Other Epidemics in Rwanda, had expressed concern about the high cost of anti-retrovirals (All Africa.com, 2007). Rwanda had in the past imported low-cost medicines from India and Brazil, but these countries had to scale back their generic manufacturing in order to comply with the *TRIPS Agreement* 1994. Nyaruhirira observed: 'If there happens to be any other country that produces such drugs with same quality at a cheap price, we will import them from there' (All Africa.com, 2007). It is difficult to determine from the public record alone what instigated this request. It would be fair to deduce that there was a convergence of various independent interests: the Government of Rwanda has been actively seeking the supply of pharmaceutical drugs to combat infectious diseases; Apotex has been looking for national governments to supply ApoTriAvir; Médecins Sans Frontières has been promoting the need for generic drugs; and the Government of Canada has been actively looking for countries to use its compulsory licensing system.

In December 2004, Apotex Inc agreed to produce a three-in-one anti-retroviral combination of Zidovudine, Lamivudine and Nevirapine (AZT+3TC+NVP), drugs which represent one of the first-line treatment regimens for HIV recommended by the World Health Organization (WHO). At the time, those drugs were not available in the

form of fixed-dose combination (FDC), a product that would simplify treatment significantly and help with the global effort to scale up treatment.

Apotex developed an active prototype of the Fixed Dose Combination by April 2005. However, this Fixed Dose Combination was not on the list of products eligible for compulsory licensing for export in Schedule 1 of the *Patent Act* RSC 1985. The addition of a new product to the schedule requires a decision of the Federal Cabinet, following the recommendation of both the Minister of Industry and the Minister of Health.

In September 2005, after further pressure, the Cabinet made the requisite order amending Schedule 1 to add ApoTriAvir to the list of 56 essential medicines. In late 2005, Apotex submitted to Health Canada an application for approval, as required under the legislation (a step not required under the *WTO General Council Decision* 2003). The Health Canada review process took seven months; the product received approval in July 2006.

After gaining regulatory approval from Health Canada, the Canadian private generic pharmaceutical company, Apotex, engaged in protracted negotiations with a number of patent holders, as it was required to do so under the *Jean Chrétien Pledge to Africa Act* 2004 (Canada). Having exhausted such discussions for voluntary licences, the generic company obtained a compulsory license in 2007 to export the triple combination HIV/AIDS drug, ApoTriAvir, to the least developed country, Rwanda.

The patent landscape was complex. It was a case of what Michael Heller and Rebecca Eisenberg would call the 'tragedy of the anti-commons', with a proliferation of fragmented and overlapping rights (Heller and Eisenberg, 1998). GlaxoSmithKline held several relevant patents (including Canada Patent Nos 2,068,790, 2,070,230, 2,286,126 and 2,311,988). The Wellcome Foundation Limited held a couple of pertinent patents (such as Canada Patent Nos 2,216,634 and 2,105,487). Shire Biochemical Inc. held some relevant patents - Canada Patent Nos 2,009,637 and 2,059,263. Boehringer Ingelheim Pharmaceuticals Inc. held the Canada Patent No. 2,030,056.

The *Jean Chrétien Pledge to Africa* 2004 (Canada) requires there to be negotiations for a voluntary licence – prior to the application for a compulsory licence. In this case, GlaxoSmithKline, Shire and Boehringer Ingelheim each put forward numerous conditions for issuing a voluntary license. In the end, GlaxoSmithKline and Shire did not oppose the application, but chose not to grant a voluntary licence, requiring Apotex to make an application under Canada’s Access to Medicines Regime. Boehringer Ingelheim was also not prepared to freely grant a licence.

In August 2007, GlaxoSmithKline announced it had given consent through Canada’s Access to Medicines Regime to enable Apotex to manufacture a generic fixed dose combination antiretroviral, containing two molecules over which GlaxoSmithKline has patent rights (Zidovudine and Lamivudine) for the treatment of HIV/AIDS in Rwanda (GlaxoSmithKline, 2007a). The pharmaceutical company agreed to waive royalties on the basis that Apotex’s triple combination generic anti-retroviral would be supplied on a not for profit basis. Paul Lucas, President and Chief Executive Officer of GlaxoSmithKline Canada observed: ‘Our decision... shows that Canada’s Access to Medicines Regime operates effectively to enable supply of medicines from Canada as envisaged under the [proposed] 31f Agreement’ (GlaxoSmithKline, 2007a).

Similarly, in August 2007, Shire BioChemical Inc. announced that it would enable Apotex to use its patented drug 3TC(R) in the generic fixed dose triple combination antiretroviral medicine (Shire BioChemical Inc. 2007). Claude Perron, Vice President and General Manager for Shire in Canada stated: ‘Today’s agreement demonstrates that Canada’s Access to Medicines Regime is an effective tool to help people living with HIV/AIDS in resource-limited settings access the treatment they need’ (Shire BioChemical Inc. 2007).

In August 2007, Boehringer Ingelheim offered Apotex Inc. a royalty free, voluntary licence to manufacture and export products containing Nevirapine to Rwanda as requested by Apotex (Boehringer Ingelheim, 2007). The President and Chief Executive Officer of the Canadian Division of the company, Ian Mills, observed that ‘if Apotex finds the terms unacceptable then we would be concerned as to whether Apotex is serious in its plans to manufacture and export such a product so that patients in developing countries can benefit’ (Boehringer Ingelheim, 2007).

In September 2007, Federal Commissioner of Patents issued a compulsory licence for ApoTriAvir under Canada's Access to Medicines Regime Program allowing Apotex to proceed with manufacturing of the product. This drug was the first product to be approved by Health Canada under the provisions of Canada's Access to Medicines Regime. ApoTriAvir was approved by Health Canada in August 2006 and was pre-qualified by the World Health Organization. Jack Kay, the President and Chief Executive Officer of Apotex, commented:

We are doing this on a not-for-profit basis and hope that this life-saving drug gets to the thousands of patients in Africa dying every month; the Canadian Federal Government must change the process to get quality affordable medicines to those who have no access (Apotex, 2007a).

Apotex noted: 'The delay between approval by Health Canada and issuance of the compulsory license highlights the problems with the process as it exists' (Apotex, 2007a). It observed: 'It is unnecessarily complex and does not adequately represent the interests of those who require treatment' (Apotex, 2007a).

Stephen Lewis was excited about the request of the Rwandan Government being processed:

The logjam has been broken . . . by the government of Rwanda request for the Canadian generic drug. It is very dramatic and very important because the dream of this legislation . . . was that it would save lives. That's what it was all about, that Canada would produce the generic drugs that would allow countries to keep their citizens alive (Ubelacker, 2007).

Céline Charveriat of Oxfam commented: 'Rwanda is making a bold move: this provision was set up to ensure poor countries get access to affordable medicines' (Associated Press, 2007). The Canadian HIV/AIDS Legal Network was cautiously optimistic about the announcement. Richard Elliott observed: 'Even if Rwanda and Apotex are successful in getting this order through, Parliament still needs to streamline the Regime to ensure that this isn't the only time we'll see the Regime used' (Canadian HIV/AIDS Legal Network, 2007). He lamented: 'The market does

not respond to the needs of poor people ... they are not a big draw for pharmaceutical producers because they don't have money' (Silversides, 2006b).

II. REVIEW OF CANADA'S ACCESS TO MEDICINES SCHEME

In the 2006 Canadian election, there were great recriminations about the failure of the *Jean Chretien Pledge to Africa Act 2004* (Canada) to achieve its stated aims. The National Democratic Party of Canada complained that 'not a single drug approved for export is in production and 'not a single pill has reached Africa' (Canadian HIV/AIDS Legal Network, 2006). The Liberal Government stressed: 'Canada has undertaken to provide a number of countries (eg South Africa, Ghana) with information on Canada's legislation and will continue to do so over the coming months' (Canadian HIV/AIDS Legal Network, 2006). The Bloc Quebecois affirmed the need for the next federal government to implement a realistic plan for Canada to increase its foreign aid to the UN target of 0.7 percent of gross national income by 2015 (Canadian HIV/AIDS Legal Network, 2006). The eventual winners of the election, the Conservatives, did not have a platform on the topic.

At the 16th International AIDS Conference, the Minister of Health, Tony Clement, confessed that Canada's access to medicines scheme had not been a success (Westhead and Talaga, 2006). He vowed that the Canadian Parliament would investigate the operation of the legislation, and seek to fix the problem: 'If we can put a man on the moon, we can solve this issue' (Teotonio, 2006).

Consultations

In November 2006, the Government of Canada released a consultation paper to review Canada's Access to Medicines Regime. Maxime Bernier, Minister of Industry, commented: 'By undertaking an early review of the relevant *Patent Act* provisions of [Canada's Access to Medicines Regime], the government is demonstrating its continued commitment to being a global leader in improving access to medicines in developing and least-developed countries' (Industry Canada, 2006). The Consultation Paper was designed to 'focus dialogue between stakeholders and government on how [Canada's Access to Medicines Regime] might better meet its humanitarian

objectives, without derogating from international trade obligations or undermining the intellectual property rights necessary for continued innovation in Canada' (Government of Canada, 2006).

A rollcall of industry groups and brand-name pharmaceutical companies made submissions to the inquiry, arguing that strong patent protection was necessary to promote research and development. GlaxoSmithKline was representative of this group in voicing its concerns: 'GSK does not believe changes to the current Access to Medicines Regime are warranted at this time' (GlaxoSmithKline, 2007b). By contrast, the Canadian Generic Pharmaceutical Association expressed a range of reservations about Canada's Access to Medicines Regime, submitting:

[Canada's Access to Medicines Regime] imposes onerous requirements on a generic manufacturer seeking to obtain and use a compulsory license, beyond what is required by the Decision. Such steps are not only unnecessary, but render [Canada's Access to Medicines Regime] unworkable. [Canada's Access to Medicines Regime] should be substantially amended to remove all unnecessary and counterproductive steps not required by the decision. However, even streamlining [Canada's Access to Medicines Regime] to track the requirements of the Decision may not be sufficient to ensure that low-cost medicines are distributed (Canadian Generic Pharmaceutical Association, 2007).

A bevy of non-government organizations also participated in the process – including Canadian Crossroads International, Canadian HIV/AIDS Legal Network, Global Treatment Access Group, Health Partners International of Canada, Médecins Sans Frontières Canada, and Oxfam Canada. There were also a number of submissions from academic groups interested in the impact of the *Jean Chretien Pledge to Africa Act 2004* (Canada).

The House of Commons Standing Committee on Industry, Science and Technology (2007) undertook a parallel study of the operational provisions of the *Jean Chrétien Pledge to Africa Act 2004* (Canada). The tenor of the report produced by the committee suggests that there needs to be wide-ranging reforms to the *Jean Chrétien Pledge to Africa Act 2004* (Canada) (House of Commons Standing Committee on Industry, Science and Technology, 2007).

Report of the Government of Canada

At the end of 2007, the Government of Canada released its report on the operation of Canada's Access to Medicines Regime (Government of Canada, 2007). In the preface to the report, the Minister for Industry, Jim Prentice, observed: 'It is hoped that other developing countries will follow Rwanda's lead and notify the WTO of the drugs they wish to import under the waiver, and that other pharmaceutical companies, both innovative and generic, will continue to pursue opportunities to supply them' (Government of Canada, 2007: 2-3). The report took comfort from the application by Rwanda under the Scheme: 'Furthermore, for the moment at least, the granting of the first and only export licence under the waiver to Apotex, and the circumstances surrounding it, suggest that [Canada's Access to Medicines Regime] works reasonably well and quickly, provided an importing country has made the requisite notification to the WTO' (Government of Canada, 2007: 36).

The Conservative administration declined to recommend any legislative changes to the regime: 'The report concludes with the finding that insufficient time has passed and insufficient evidence has accumulated since the coming into force of [Canada's Access to Medicines Regime] to warrant legislative changes to the regime, and that the Government should focus on non-legislative measures to improve access to medicines in the developing world, until a more definitive assessment can be made' (Government of Canada, 2007: 9). The Government of Canada denied that the design of the legislative regime was at fault for the failure of countries to utilise the regime: 'The view that certain unique features of [Canada's Access to Medicines Regime] make it less permissive or operationally sound than the legislation subsequently adopted in other countries to have implemented the waiver does not appear to be substantiated by the available evidence at this juncture' (Government of Canada, 2007: 35-36). The Government of Canada instead blamed economic factors for the lack of applications under the scheme: 'To date, the dearth of developing country notifications to the WTO or Canada of an intention to import drugs under the waiver appears to have more to do with above mentioned economic factors, the obligations imposed on importing countries by the August 2003 Decision, as well as a general lack of awareness among developing countries about [Canada's Access to Medicines

Regime] and the regimes in place in other countries that have implemented the waiver' (Government of Canada, 2007: 36).

The report questioned whether the Canadian generic manufacturing industry could compete with its counterparts in India and China: 'In addition, although Canada boasts a world-class generic pharmaceutical industry with the highest possible manufacturing standards and an acknowledged commitment to supporting access to medicines initiatives in the developing world, there is evidence to suggest it may have difficulty competing on price with its Indian, South African and Chinese counterparts, particularly for the supply of low-cost HIV/AIDS products to sub-Saharan Africa' (Government of Canada, 2007: 33). The Government of Canada asserted that such a position was borne out by the instance of Rwanda: 'Despite the fact that Apotex is said to be offering its product at cost, five major Indian generic pharmaceutical companies are listed on the Clinton Foundation Website as having lower-priced versions of the same product available for sale to African countries, the lowest of which is roughly half the price specified by Apotex in its application to the Commissioner' (Government of Canada, 2007: 34). The report observed that it was difficult for Canadian manufacturers to compete with its rivals in India and China: 'Generic manufacturers in these latter countries are able to sell their products for less because they have the advantage of lower overhead and labour costs, as well as cheaper access to the raw materials needed for pharmaceutical production' (Government of Canada, 2007: 33).

Arguably, the report underestimates the competitiveness of the Canadian generic manufacturing industry. First, there is scope for the production and export of Canadian medicines, because the demand for pharmaceutical drugs and medicines to address HIV/AIDS, tuberculosis, and malaria is huge. Second, there remains uncertainty about whether India and China will be able to continue to supply such a large quantity of pharmaceutical drugs, given that they have to comply with the minimum obligations for the patent protection of pharmaceutical drugs under the *TRIPS Agreement* 1994. Third, the price differential between generic medicines produced in Canada, and countries such as India and China is relatively small. The gap has been overstated by some academic commentators, such as Amir Attaran (Attaran 2007a; 2007b). The cost for the antiretroviral produced by the Indian generic

manufacturer, Ranbaxy, would be 0.306 Canadian Dollars a day; whereas ApoTriAvir would be 0.39 Canadian Dollars a day. Thus, the Canadian Access to Medicines Regime is relatively competitive, and could play a productive role (Sutoris, 2007).

As a result of its report, the Government of Canada was of the view that there was no need for immediate legislative action: 'While the Government is of the view the case for making legislative or regulatory changes to [Canada's Access to Medicines Regime] has not yet been made out, it recognizes that the regime could do more to address the underlying economic barriers and will undertake further analysis of this issue as greater experience in using the WTO waiver and other international mechanisms to improve access to medicines is gained' (Government of Canada, 2007: 36-37). At most, the Government of Canada contemplated 'the re-exportation of products imported under the waiver between similarly afflicted countries that are part of the same regional trade group' (Government of Canada, 2007: 37). In the meantime, the Government of Canada intended to 'expand and intensify its outreach activities' especially in Africa (Government of Canada, 2007: 37). The Government of Canada also boasted that it was a generous contributor to aid and humanitarian campaigns: '[Canada's Access to Medicines Regime]-related activities aside, Canada will continue to support a multitude of international and domestic initiatives designed to improve access to medicines in the developing world' (Government of Canada, 2007: 38).

Some commentators have suggested that countries have been reluctant to apply for compulsory licences because of concerns about political sanctions from the United States, and retribution from brand-name pharmaceutical companies (Lewis, 2007). The case of Thailand is a salutary example. In 2006 and 2007, the Thailand Government issued compulsory licences in respect of several pharmaceutical drugs, including the anti-retrovirals, Efavirenz, Lopinavir, and Ritonavir, and Clopidogrel, which is used to treat heart disease. In response, Thailand received a critical notice from the United States Trade Representative in its Special 301 Report, and the threat of a boycott of products from Abbott Laboratories, as well as widespread outrage from members of the brand-name pharmaceutical industry. There had also been similar disputes in South Africa and Kenya. No doubt, other countries have been intimidated by such heavy-handed tactics. The report of the Government of Canada,

though, rather naively downplayed such concerns, protesting that there was no ‘direct evidence’ of political intimidation (Government of Canada, 2007: 32-33).

The report by the Government of Canada is a complacent, unimaginative piece of work. The document offers nothing in the way of ingenious or creative policy solutions to the problems bedevilling Canada’s Access to Medicines Regime. The paper fails to substantiate that Canada’s Access to Medicines Regime has been an effective mechanism to facilitate the export of pharmaceutical drugs. The report blames the lack of utilisation of the scheme on a range of external factors – such as time lags in the research and development cycle; the operation of the market for pharmaceutical drugs; and a general lack of awareness of the regime. The Government of Canada also seems paralysed by the spectre of trade sanctions under the *TRIPS Agreement* 1994: ‘Canada has very direct experience in this regard, having attempted to defend certain measures in its *Patent Act* in a WTO dispute settlement proceeding on the basis of a large and liberal interpretation of Article 30 of TRIPS’ (Government of Canada, 2007: 35).

It could be objected – Is this criticism fair? The Government of Canada certainly deserves plaudits and acclaim for its initiative in establishing a regime, which enables the export of pharmaceutical drugs. The country has been a pioneer and path-finder, especially compared to other G7 countries. However, equally, the Conservative leadership deserves criticism for its failure to reform the legislative regime, especially given that it promised to review and improve the scheme. The Government of Canada has aligned itself to the position of brand-name pharmaceutical companies, accepting at face value their arguments that Canada’s Access to Medicines regime does not need to be reformed. It has shown little interest in the obstacles faced by generic pharmaceutical companies, such as Apotex. The Government of Canada has promoted its credentials as a charitable nation. However, a commitment to support aid and humanitarian campaigns is no substitute for substantive patent law reform.

The report of the Government of Canada raises serious doubts about the commitment of the Conservative leadership to dealing with the patent issues raised by access to essential medicines. The Liberal Opposition is an ambivalent proposition at best – as it was responsible for both the strengths and flaws of the *Jean Chrétien Pledge to*

Africa 2004 (Canada). The other significant Canadian political parties – such as the New Democratic Party of Canada and the Bloc Québécois – would appear to have a much deeper commitment to improving the operation of Canada’s Access to Medicines Regime. An overhauling of the *Jean Chrétien Pledge to Africa 2004* (Canada) will depend upon the ability of the various Opposition parties to influence and pressure the minority Conservative Government of Canada to change its stance.

A Reform Agenda

The question arises: What should be done to fix Canada’s Access to Medicines regime? For his part, Stephen Lewis was disappointed by the failure of the legislation:

It's clear to everyone that the legislation is deeply flawed. It's surely clear that we must find a way to make the issuance of a compulsory licence easier to achieve; that we must resist the curious inclination to impose conditions that go beyond the requirements of the TRIPS provisions of the WTO; that we must find a way of protecting the recipient country from any retaliatory measures; and that the brand-name pharmaceuticals and the generic industry must have a legislative regimen that results in a licence rather than an impasse. Public health is at stake, and the primacy of public health is specifically acknowledged under the TRIPS provisions (Lewis, 2007).

He maintained that it was possible for Canada to play a role as a ‘Middle Power’ in the export of pharmaceutical drugs, with the reform of the legislative regime: ‘No one should see this legislation, even with the passage of time, as redundant or beyond repair’ (Lewis, 2007).

In its 2007 submission to the Government of Canada, the Global Treatment Access Group and Canadian HIV/AIDS Legal Network provided a number of helpful recommendations to improve Canada’s Access to Medicines Regime (Elliott, 2007a). The groups called on the Government of Canada to provide authorisations to export pharmaceutical drugs, which were not limited to a single drug order to a single country. This measure could be done in a variety of ways. The Government of Canada could create a standing statutory authorization permitting export of generic medicines to eligible countries. On any given drug, they could grant a single, open-ended license to a given manufacturer. Licences additional to a first licence could be fast-tracked.

The Global Treatment Access Group and Canadian HIV/AIDS Legal Network requested that the Government of Canada remove unnecessarily restrictive and time-consuming steps in the licensing process, especially those steps not required by the *WTO General Council Decision 2003* or Canadian law. In particular, the organisations asked for the removal of the time limit on licences granted; the limitation of the requirement of negotiating with a patent-holder before seeking a compulsory license; the elimination of the list of eligible drugs, the absolute requirement of Health Canada approval, and patent-holders' extra litigation rights; and the enablement of non-government organisations to seek exports of pharmaceutical drugs in their own right. The organisations also called upon the Government of Canada to remove the double-standards that apply to some importing countries – namely, the tougher requirements for those countries who were not members of the World Trade Organization.

III. THE HONG KONG AMENDMENT TO THE *TRIPS AGREEMENT* 1994

The experience of Canada's Access to Medicines Regime casts doubt upon the efficacy of the *WTO General Council Decision 2003*. In the Canadian Parliament, the Global Treatment Access Group and the Canadian HIV/AIDS Legal Network lamented:

Canada has implemented the mechanism embodied in the [*WTO General Council Decision 2003*]. So far, Canada's model has not worked — and the [*WTO General Council Decision 2003*] has not yet worked in any other country where it has been implemented. Canada was one of the first countries to implement the [*WTO General Council Decision 2003*] with a complete legislative framework, and it is the jurisdiction in which the most concerted efforts have been made to date to use the mechanism. As such, Canada is in a position to set a positive global precedent by acknowledging that the [*WTO General Council Decision 2003*] does not address the needs of developing countries, and to implement a better model, within the bounds of WTO rules, that stands a greater likelihood of actually engaging generic producers and developing-country purchasers in increasing access to more affordable treatment for millions of people (Elliott, 2007b).

The problems experienced in the operation of Canada's Access to Medicines Regime raises questions as to whether the *WTO General Council Decision 2003* should be codified into the *TRIPS Agreement 1994*. The civil society groups contended that Canada should use its diplomatic influence and sway as a 'Middle Power' to build a consensus for a new, flexible model to facilitate the export of pharmaceutical drugs.

A Permanent Waiver?

In the lead-up to the World Trade Organization Ministerial in Hong Kong in December 2005, the Member States endorsed the proposal to transform the *WTO General Council Decision 2003* – described as a 'waiver' - into a permanent amendment of the *TRIPS Agreement 1994* (World Trade Organization General Council, 2005). In an accompanying statement to the decision, the WTO General Chairman, Pascal Lamy made a number of comments (Lamy, 2005). He promoted the amendment in these terms:

The agreement to amend the TRIPS provisions confirms once again that members are determined to ensure the WTO's trading system contributes to humanitarian and development goals as they prepare for the Hong Kong Ministerial Conference. This is of particular personal satisfaction to me, since I have been involved for years in working to ensure that the TRIPS Agreement is part of the solution to the question of ensuring the poor have access to medicines (World Trade Organization, 2005a).

Two thirds of the members will need to ratify the change by 1 December 2007. At present, there would appear to be little enthusiasm for codifying the WTO General Council Decision, given its failure to facilitate the export of pharmaceutical drugs. As at March 2008, only thirteen countries have supported the Hong Kong Amendment to the *TRIPS Agreement 1994* – including the United States; Switzerland; El Salvador; South Korea; Norway; India; the Philippines; Israel; Japan; Australia; Singapore; China; and the European Union.

On behalf of the Africa group, Rwanda has been critical of the Hong Kong Amendment to the *TRIPS Agreement 1994*. Ambassador Valentine Rugwabiza of Rwanda – who has since become a Deputy Director of the World Trade Organization - observed: 'The African Group which makes up a large portion of the WTO's

membership cannot and will not accept an interpretation of paragraph 11 that says the August decision and the Chairman's statement in its entirety should form the amendment' (Shashikant, 2005). She noted the statement adopted by participants in an African regional workshop 'stressed that the issue of the effects of patents on access to medicines is very crucial for the African region which among all continents in the world is the poorest and its people are most affected by serious diseases, and therefore the need for access to affordable effective medicines is a must' (Rwanda, 2005a). The Ambassador concluded: 'It is urgent that all countries act individually and collectively to remove all obstacles to securing sustainable supplies of essential medicines for the people of the region' (Rwanda, 2005a).

The African Group has proposed alternative amendments to the *TRIPS Agreement* 1994 to deal with the export of pharmaceutical drugs to developing countries. In essence, it has proposed to eliminate a number of provisions in the *WTO General Council Decision* 2003 as they would be redundant in the context of an amendment or where their purpose would otherwise be served by other provisions of the TRIPS Agreement, such as the Agreement's existing provisions on compulsory licences read together with the provisions on enforcement (Rwanda, 2005b).

However, the United States representative expressed serious concerns about the suggested amendment of the Africa Group to the *TRIPS Agreement* 1994 to implement the Decision (World Trade Organization, 2005b). The United States Government complained that the proposal did not make any reference to the Chairman's Statement, and omitted key safeguards from the Decision to ensure the proper functioning of the solution, such as notification and diversion. The United States delegation believed that any proposal would have to meet the basic objective of formulating an amendment that preserved the consensus and delicate balance struck by Members in August 2003.

The Reaction of Civil Society

James Love of the Consumer Project on Technology and Knowledge Ecology International was scathing about Lamy's proposed amendment to the *TRIPS Agreement* 1994

Today the WTO created some space in its patent rules for exports of generic medicines, but at a high price. The new WTO rule is complicated and designed to increase political pressure on countries that export or import generic medicines. It is protectionist by design... The developing country negotiators were bullied and pressured by the big pharmaceutical companies and the EU to accept this deal, but they should have put up more resistance. Everyone will have to make the best of this, and try to make it work, but it is an awful decision. It is anti-consumer, anti-competition, and anti-free trade (Love, 2005).

He lamented that national implementation of the *Doha Declaration on the TRIPS Agreement and Public Health* 2001 had been very patchy and poor, five years later (Love, 2006). Love has promoted an alternative regime, which promotes research and development through the provision of prizes (Love, 2007).

Médecins Sans Frontières expressed alarm at the decision of the WTO to amend the *TRIPS Agreement* 1994, contending: 'The so-called 'August 30th decision,' which was designed in 2003 to allow production and export of generic medicines, has long been viewed by MSF and public health groups as overly cumbersome and inefficient' (Médecins Sans Frontières, 2005). Ellen t' Hoen observed: 'The amendment has made permanent a burdensome drug-by-drug, country-by-country decision-making process, which does not take into account the fact that economies of scale are needed to attract interest from manufacturers of medicines' (Médecins Sans Frontières, 2005). She noted: 'Without the pull of a viable market for generic pharmaceutical products, manufacturers are not likely to want to take part in the production-for-export system on a large scale' (Médecins Sans Frontières, 2005). Hoen commented: 'Delaying the amendment would have been a far better option, as it would have ensured the possibility of testing and improving the mechanism in practice' (Médecins Sans Frontières, 2005).

Eminent international scholar Professor Frederick Abbott has commented upon the critical reaction to the *WTO General Council Decision* 2003 from both developing countries and civil society organizations:

The Decision may not be the first-best instrument from anybody's perspective, but it does give countries lacking adequate manufacturing capacity some flexibility to make use of compulsory

licensing—one of the core balancing mechanisms. The adoption of the Decision shows that the WTO can address important issues of social concern. But adoption standing alone does not show that the WTO can do so effectively. Effective implementation of the Decision is threatened by newly negotiated bilateral and regional agreements. The WTO's effectiveness can be better assessed if, and when, developing countries actually use the Decision to address their public health needs (Abbott, 2005: 356).

Abbott and his collaborator, Jerome Reichman, reflect ruefully: 'What matters most is that governments implement the Waiver Decision and/or Amendment in national law employing all options for maximum flexibility in its use' (Abbott and Reichman, 2007). Moreover, they advise: 'Developing country governments likewise should pursue programs of cooperation that will permit them to take advantage of economies of scale in purchasing, as well as in the production and distribution of pharmaceutical products' (Abbott and Reichman, 2007).

CONCLUSION

The export of essential medicines to Rwanda has been hailed as a breakthrough achievement. However, a closer inspection of this exceptional case reveals that there is scope for further reform in respect of patent law and access to essential medicines. Questioning the commitment of the United States Administration of George W. Bush to reforming the *TRIPS Agreement* 1994, Ambassador Valentine Sendanyoye Rugwabiza of Rwanda has commented that there is a need to reform the international patent system to address public health concerns:

The President of the United States... said that 'where there are serious questions and substantial doubts, our society, our laws, and our courts should have a presumption in favour of life. It should be our goal as a nation to build a culture of life'. The dedication 'to build a culture of life' should be stronger, more urgent and immediate in the TRIPS Council which has been mandated to find a permanent solution on how to ensure a sustainable supply of essential generic medicines to the millions of people dying everyday, particularly in Africa for not having access to life-saving affordable medicine because they lack the manufacturing capacity. Unfortunately this dedication and determination seems to be lacking (Rwanda, 2005a).

The national export regimes have been under-utilised thus far by developing countries and least developed countries for a myriad of reasons - including the technocratic nature of the international regime; the lack of economic incentives for generic pharmaceutical companies to participate in such a process; and fears of political intimidation from brand-name pharmaceutical companies, and hegemonic powers, such as the United States.

The *Jean Chrétien Pledge to Africa Act 2004* (Canada) provides a useful case study of the operation of a national export regime. The legislation is certainly testament to the good citizenship of Canada as a middle-power, which is genuinely interested in alleviating the hardships caused by infectious diseases. However, in practice, the compulsory licensing provisions in Canada's Access to Medicines Regime have proved to be complex and cumbersome. The Conservative Government of Canada has been unwilling to modernise or streamline this regime, arguably because it has been too sympathetic to the position of brand-name pharmaceutical companies. In its present form, it is unlikely that Canada's Access to Medicines regime will be a reliable source of generic pharmaceutical drugs to developing countries. The *WTO General Council Decision 2003* provides an imperfect model for the export of pharmaceutical drugs to developing countries. As such, the proposed Hong Kong Amendment to the *TRIPS Agreement 1994* seems inappropriate and undesirable. The codification of such a flawed model would only exacerbate the public health crisis in developing countries caused by infectious diseases, such as HIV/AIDS, tuberculosis, and malaria. There should be an effective international mechanism for the export of patented pharmaceutical drugs. As Ambassador Valentine Sendanyoye Rugwabiza reflects, the *TRIPS Agreement 1994* should seek to address public health concerns in a timely and meaningful fashion (Rwanda, 2005a).

REFERENCES

Abbott, F. (2005). 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health', *American Journal of International Law*, 99, 317-358.

Abbott, F. and J. Reichman (2007). 'Strategies for the Protection and Promotion of Public Health Arising Out of the WTO TRIPS Agreement Amendment Process', World Health Organization's

Second Public Hearing on Intellectual Property and Health,
http://www.who.int/phi/public_hearings/second/contributions_section1/Section1_Abbott&Reichman.pdf

AllAfrica.com (2007). 'No Deal Yet On AIDS Drugs', 18 August.

Apotex (2003). 'Canadian-Owned Generic Company Prepared To Provide HIV/AIDS Drug to Developing Nations', <http://www.apotex.com/PressReleases/20031107-01.asp>, 7 November.

Apotex (2007a). 'Life Saving AIDS Drug for Africa Gets Final Clearance', Toronto, ON, 20 September.

Associated Press (2007). 'Rwanda to Override Patents and Import Cheaper Generic AIDS Drugs', 23 July.

Attaran, A. (2007a). 'A Tragically Naïve Canadian Law for Tragically Neglected Global Health', *Canadian Medical Association Journal*, 176 (12), 1726-1727.

Attaran, A (2007b). 'No Time for 'Buy Canadian'', *The Toronto Star*, 10 August, AA07.

Boehringer Ingelheim (2007). 'Boehringer Ingelheim Offers a Licence to Apotex to Export BI's patented product nevirapine to Developing Countries with terms better than that required by Canadian Legislation', 23 August.

Canadian Generic Pharmaceutical Association (2007). 'Submission to Review of Canada's Access to Medicines Regime', 15 February, http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_cgpa_01_e.pdf

Canadian HIV/AIDS Legal Network (2006). 'Party Leaders Must Define Their Approaches to HIV/AIDS: Deafening Silence During Election Campaign is Unacceptable', Toronto: Ontario, 12 January.

Canadian HIV/AIDS Legal Network (2007). 'Rwanda First to Try Buying Affordable AIDS Drug From Canada Using Access to Medicines Regime', Toronto: Ontario, 20 July.

Elliott, R. (2003), 'Canada can carry much more; Canadian firms stand ready to manufacture affordable AIDS drugs. The WTO has even relaxed its patent rules. So why won't the PM give the green light?', *The Globe and Mail*, 23 September, A23.

Elliott, R. (2007a). 'Review of Canada's Access to Medicines Regime — Legal Network Submission to the Government of Canada', <http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=674>, 24 January.

Elliott, R. (2007b). 'Getting the Regime Right: Compulsory Licensing of Pharmaceuticals for Export', Brief to the House of Commons Standing Committee on Industry, Science and Technology regarding Canada's Access to Medicines Regime, 18 April.

Gervais, Daniel (2003). *The TRIPS Agreement: Drafting History and Analysis. Second Edition*. London: Sweet and Maxwell.

GlaxoSmithKline (2007a). 'GSK gives consent under Canada's Access to Medicines Regime for generic version of HIV/AIDS medicine for use in Rwanda', London, UK, Mississauga, ON, 8 August.

GlaxoSmithKline (2007b). 'Submission to Review of Canada's Access to Medicines Regime', 15 February, http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_gsk_21_e.pdf

Government of Canada (2006). 'Canada's Access to Medicines Regime – Consultation Paper', http://camr-rcam.hc-sc.gc.ca/camr_rcam_consult_e.html, (24 November)

Government of Canada (2007), 'Report on the Statutory Review of Sections 21.01 to 21.19 of the *Patent Act*', Ottawa: Industry Canada, http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_report_rapport_e.pdf

Heller, M. and R. Eisenberg (1998), 'Can Patents Deter Innovation? The Anticommons in Biomedical Research', *Science*, **280** (5364), 698 – 701.

House of Commons Standing Committee on Industry, Science and Technology (2007). 'Summary of Major Issues Raised During Hearing on Canada's Access to Medicines Regime', http://cmte.parl.gc.ca/Content/HOC/committee/391/indu/webdoc/wd2967322/391_INDU_Letter/391_INDU_Summary-e.html

Industry Canada (2006). 'Government of Canada Launches Review of Canada's Access to Medicines Regime', 24 November.

Kay, J. (2007). 'Hearing on Review of Canada's Access to Medicines Regime', Standing Committee on Industry, Science and Technology, 39th Parliament, 1st Session, 23 April.

Kiladze, T. (2006), 'Canada isn't living up to its promise', *McGill Daily*, 96 (24), 30 November.

Lamy, P. (2005). 'Chairperson's Statement on TRIPS and Public Health', World Trade Organization, http://www.wto.org/english/news_e/news05_e/trips_319_e.htm, 6 December.

Lewis, S. (2003). 'The Politics of Resource Allocation', Statement by United Nation Secretary General's Special Envoy on HIV/ AIDS, Nairobi, Kenya, 25 September, <http://www.awcfs.org/Icasa/DayFive/StephenLewis4.html>

Lewis, Stephen (2005). *Race Against Time*. Toronto: Canadian Broadcasting Corporation, p. 1-2.

Lewis, S. (2007). 'Hearing on Canada's Access to Medicines Regime', House of Commons Standing Committee on Industry, Science and Technology, 1st Session, 39th Parliament, 18 April.

Love, J. (2005). 'Statement of CPTech on TRIPS Amendment', <http://www.cptech.org/ip/wto/p6/cptech12062005.html>, 6 December.

Love, J. (2006). 'Doha + Five: The Doha Declaration on the TRIPS Agreement and Public Health, after five years', CPTech, <http://www.cptech.org/ip/health/wto/dohaplus5.html>, 5 November.

Love, J. (2007). 'Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R & D', *The University of California Davis Law Review*, 40 (3), 681-715.

Martin, P. (2003). 'Confederation Dinner' <http://www.paulmartin.ca/home/stories_e.asp?id=886> at 9 December 2003. This page is no longer available, copy on file with author.

Martin, R. (2006). 'Canada's Empty Pledge to Africa', *Politics Watch*, 16 August.

Médecins Sans Frontières (2005). 'Amendment to TRIPS Agreement Makes Access to Affordable Medicines Even More Bleak', <http://www.accessmed-msf.org/prod/publications.asp?scentid=71220051425522&contenttype=PARA&> 7 December.

Mayne, Ruth (2003). 'The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective', in Drahos, Peter and Ruth Mayne (ed). *Global Intellectual Property Rights: Knowledge, Access, and Development*. London: Palgrave Macmillan, p. 244-258.

Médecins Sans Frontières (2006). 'Neither Expeditious or Workable, the WTO General Council Decision is Unworkable', <http://www.accessmed-msf.org/documents/WTOaugustreport.pdf> (August).

Mercurio, B. (2007). 'Resolving the Public Health Problem in the Developing World: Problems and Barriers of Access to Essential Medicines', *Northwestern University Journal of International Human Rights*, 5, 1

Nolen, S. (2003). 'Spearhead AIDS fight, UN envoy tells Canada', *The Globe and Mail*, 25 September, A1.

Pogge, T. (2005). 'Human Rights and Global Health: A Research Program', *Metaphilosophy*, 36/1-2, 182-209,

Rimmer, M. (2005). 'The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid', *Expert Opinion on Therapeutic Patents*, 15 (7), 889-909.

Rwanda (2005a). 'Communication from Rwanda on Behalf of the African Group: The TRIPS Agreement and Public Health', TRIPS Council, IP/C/W/445, 6 April.

Rwanda (2005b). 'Legal Arguments to Support the African Group Proposal on the Implementation of Paragraph 11 of the 30 August 2003 Decision', IP/C/W/440, 1 March, <http://www.cptech.org/ip/wto/africagroup03012005.doc>

Rwanda (2007). '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', World Trade Organization, IP/N/9/RWA/1, 19 July.

Saul, John Ralston (1997). *Reflections of a Siamese Twin: Canada at the End of the Twentieth Century*. Toronto: Penguin Books.

Shashikant, S. (2005). 'Heated discussions as TRIPS and Health deadline is missed', South-North Development Monitor SUNS #5772, Geneva, 4 April.

Shire Biochem Inc. (2007). 'Shire Biochem Inc - Supports Canada's Access to Medicines Regime', Market News Publishing, 16 August.

Silversides, A. (2006a). 'Canada Falters on Promise of AIDS Drugs for Africa', *Ottawa Citizen*.

Silversides, A. (2006b). 'Not a Single Pill', *Ottawa Citizen*, 13 August.

Smith, G. and G. Galloway (2006). 'Chrétien's Drug Program Ineffective, Clement Says; Poor Countries Haven't Taken Advantage of Cheap Medicine, Health Minister Notes', *The Globe and Mail*, 28 April, A12.

Straight, G. (2006). 'Lewis Battles to Elevate the Politics of AIDS', The Stephen Lewis Foundation, http://www.stephenlewisfoundation.org/news_item.cfm?news=1346, 24 August.

- Sutoris, N. (2007). 'Anti-Viral Pricing Guide Can Be Confusing', *The Toronto Star*, 18 August, p. 9.
- Teotonio, I. (2006). 'Clement Vows to Get Cheap Drugs Flowing; Health Minister Decries Lack of Aid but Current Law Prevents Action', *Toronto Star*, 14 August, A01.
- Ubelacker, S. (2007). 'Low-cost HIV Drug Gets OK', CNews, 8 August.
- UNAIDS (2006). 'UNAIDS 2006 Report on the Global AIDS Epidemic', Switzerland: Geneva, <http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/Default.asp>
- Westhead, R. and T. Talaga (2006). 'Health Minister Tony Clement says he's Launching an Immediate Review of Why Canada has Failed to Deliver on a Pledge to get Low-cost AIDS Drugs to Countries in Need', *Toronto Star*, 16 August, A01.
- World Trade Organization (2001). *Doha Declaration on the TRIPS Agreement and Public Health*, 14 November, http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
- World Trade Organization (2003). *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, 30 August, http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm
- World Trade Organization (2005a). 'Members OK Amendment to Make Health Flexibility Permanent', Press/426, http://www.wto.org/english/news_e/pres05_e/pr426_e.htm, 6 December.
- World Trade Organization (2005b). 'Minutes of Meeting of the TRIPS Council', IP/C/M/47, 3 June.
- World Trade Organization General Council (2005). *Amendment of the TRIPS Agreement*, WT/L/641, http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm, 8 December.
- World Trade Organization Panel Report (2000). *Canada-Patent Protection of Pharmaceuticals, Complaint by the United States*, WT/DS170/R, 5 May; and *Canada-Patent Protection of Pharmaceutical Products Complaint by the European Communities and their Member States*, WT/DS114/R, 17 March.