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Delivery past due: global precedent set under Canada's Access to Medicines Regime

Four years to the month after Parliament passed a law to enable the supply of lower-cost generic medicines to developing countries in need, the first exports are finally about to happen. In this article, Richard Elliott provides an overview of recent developments under Canada's Access to Medicines Regime (CAMR), and identifies key reforms needed to streamline the regime so that it can more easily be used to address public health problems in developing countries.

WTO rules and Canada's law on exporting generics

Under the World Trade Organization's (WTO's) treaty on intellectual property, the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS),¹ member countries must grant exclusive patent rights on medicines. But they retain the right to grant compulsory licences, which legally authorize the production of lower-cost, generic versions of patented drugs in exchange for royalties paid to the patent-holder. Breaking the patent-holder's monopoly and introducing competition brings down prices.

TRIPS also states, however, that products made under compulsory licences must be "predominantly for the supply of the domestic market," thereby limiting the use of compulsory licensing in one WTO member country to produce generic medicines predominantly or exclusively for export to any other country. This undermines the ability of importing developing countries to use compulsory licensing effectively

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as a tool to get lower-cost treatment for patients.

In August 2003, WTO members, under pressure from developing countries and treatment activists, adopted a General Council Decision waiving this restriction under certain conditions.² In May 2004, following an eight-month advocacy campaign by civil society groups,³ both houses of the Parliament of Canada unanimously passed legislation amending the *Patent Act*⁴ and the *Food and Drugs Act* to implement this 2003 WTO Decision.⁵

Canadian civil society organizations succeeded in obtaining significant improvements to the bill originally introduced by the government, but they warned that the remaining flaws could hinder the usefulness of the legislation. Nonetheless, they said that they would support efforts to use it to benefit patients in developing countries.⁶

After further pressure from NGOs, the law and accompanying regulations were brought into force one year later, in May 2005.⁷ At the request of international humanitarian organization Médecins Sans Frontières (MSF), Canada's largest generic pharmaceutical manufacturer, Apotex, Inc., produced "Apo-Triavir," a new fixed-dose combination of existing anti-retroviral AIDS medicines zidovudine, lamivudine and nevirapine (AZT/3TC/NVP).

The combination of these three medicines into one tablet, taken twice

daily, simplifies one of the first-line combination regimens recommended by the World Health Organization (WHO) for treating people living with HIV/AIDS.⁸ This combination did not previously exist.

MSF indicated that it would seek to use the CAMR to place an order for the Apotex product for use in one or more of its AIDS treatment projects in the field. Under the CAMR and the terms of the underlying 2003 WTO Decision, this would require at least some degree of cooperation by the government of the developing country into which MSF would import the product.

Three years after the law was passed and two years after it came into force, not a single pill had yet been exported under the CAMR.

The Apotex product was approved by Health Canada as meeting the same regulatory standards as a medicine intended for sale in the domestic market, a condition imposed by Canada's legislation implementing

the 2003 WTO Decision but not required by the WTO Decision. The Health Canada review process took seven months; the product received approval in July 2006.⁹ On 10 August 2006, shortly before the XVI International AIDS Conference in Toronto, the WHO Prequalification Programme, having reviewed the dossier submitted by Apotex to Health Canada, also gave its stamp of approval.¹⁰

However, by May 2007 — three years after the law was passed and two years after it came into force — not a single pill had yet been exported under the CAMR, in part because of the apparent unwillingness of any developing country eligible to import under the CAMR to make the requisite notifications to the WTO or the Government of Canada.¹¹ As a result, MSF ultimately informed Apotex that it could not follow through on its original plan to place an order for the product.

Breakthroughs: Rwanda takes historic step, first licence issued, order placed

Finally, in July 2007, almost four years since the original WTO Decision was adopted, and following interventions by the Clinton Foundation HIV/AIDS Initiative, Rwanda became the first — and to date, only — country to notify the WTO of its intention to import the Apotex product.¹² Rwanda's noti-

fication stated that it anticipated importing up to 260 000 packs of Apo-TriAvir. Rwanda's notification was a necessary precondition for Apotex to pursue the process under Canadian law for obtaining a licence to manufacture the product legally for export.

In response, Canadian health activists expressed cautious optimism about moving this important step closer to possible use of the CAMR, but noted that even if this one case turned out to be successful, Canada still needed to reform its legislation if there was to be any real likelihood of it being used again.¹³

The following month, media reports indicated — incorrectly, as it turned out — that Apotex had succeeded in negotiating voluntary licences with all the brand-name pharmaceutical companies holding the relevant Canadian patents on the constituent products in the new generic fixed-dose combination, which licences would allow Apotex to export its generic product to Rwanda.¹⁴

In fact, in the end no voluntary licences were issued, and in early September, Apotex proceeded to file its application for a compulsory licence with the Commissioner of Patents, in accordance with the legislation.¹⁵

On 19 September 2007, the Commissioner issued the requested licence, authorizing Apotex to produce and export the quantity notified by Rwanda, amounting to 15 600 000 tablets over a period of up to two years.¹⁶ (As treatment consists of two tablets daily, this would amount to a year's course of treatment for more than 21 000 patients, or two years' worth of treatment for half that number of people.)

In October 2007, Canada notified the WTO of this compulsory licence having been issued.¹⁷

The Government of Rwanda subsequently initiated an international tendering process. Equipped with a compulsory licence authorizing the legal production of Apo-TriAvir for export to Rwanda, Apotex submitted a bid to the Rwandan government quoting a price of US\$0.195 per tablet — meaning treatment with this regimen would cost US\$146 per patient per year, lower than the then-lowest price from a generic source (US\$176 per patient per year) reported publicly.¹⁸

Canadian health advocates renewed their long-standing call to the government and to Parliament to reform the regime.

On 7 May 2008, Apotex announced that it had succeeded in the competition: The Rwandan government had decided to purchase the Apotex product.¹⁹

Canadian health advocates welcomed the announcement, but highlighted that this breakthrough came after four years and only as a result of the commitment of one company and various civil society interveners — hardly a sustainable process, and one unlikely to be repeated unless the CAMR process were drastically simplified.²⁰ They renewed their long-

standing call to the government and to Parliament to reform the regime.

Fixing the flaws: the push to reform the CAMR

The 2004 law that created the CAMR required the federal Minister of Industry to review the law within two years of it coming into force (i.e., May 2005), and to report back to Parliament shortly thereafter.

In August 2006, during the International AIDS Conference in Toronto, the Minister of Health, responding to pressure, publicly committed to speeding up the review and to making necessary changes to make it work.²¹

As part of that review, in January 2007 interested parties, including a range of civil society groups, made submissions to the Government of Canada.²² Further submissions with recommendations for reform were made three months later to a Parliamentary committee at hearings into the failure of the legislation to date to deliver on the pledge of greater access to affordable medicines.²³ An international expert consultation also identified numerous aspects of the CAMR that were of concern.²⁴

However, in a report finally tabled in Parliament on Friday, 14 December 2007 — six months late and on the last day Parliament was in session before rising for an extended break — the Minister of Industry indicated the government's view that it would be premature to bring forward any amendments to CAMR. Instead, it planned to continue publicizing the regime to developing countries.²⁵

Health advocates criticized the government for its failure to act, stepped up their lobbying of individual Members of Parliament and

began to approach members of the opposition parties about the possibility of bringing amendments forward through a private member's bill.

Remedying the regime: proposals for reform

The ostensible purpose of the CAMR is to facilitate the export of lower-cost, generic versions of medicines manufactured in Canada to eligible developing countries. The one successful use of the CAMR, which was the result of determined and persistent effort over several years, was achieved despite the disincentives built into the current regime — hard proof that the regime is workable.

Consequently, Canadian civil society advocates have identified numerous reforms aimed at making the regime more user-friendly for developing countries (i.e., the potential purchasers) and for generic manufacturers (i.e., the potential suppliers) — the two parties that must use the CAMR if patients in developing countries are to benefit.

The most concrete proposals have been prepared by a broad-based civil society coalition, the Global Treatment Access Group (GTAG),²⁶ and by the Canadian HIV/AIDS Legal Network, which fleshed out the GTAG proposals in much more technical detail — including sample statutory amendments.²⁷

A core recommendation of the civil society groups was to go beyond merely tinkering with the CAMR in the form of minor adjustments. Rather, the groups have urged the government to replace the existing CAMR process for licensing the production and exportation of generic medicines, which is based on the underlying 2003 WTO Decision, with a simpler procedure that would be

much more likely to be used repeatedly to address developing countries' public health needs. The proposals for reform advanced by civil society groups are summarized here.

Eliminate limits on products subject to compulsory licensing

Currently, the legislative provisions constituting the CAMR include a limited list of pharmaceutical products covered by the regime, consisting primarily of drugs on the WHO's Model List of Essential Medicines (as it stood in early 2004 when the law was enacted by Parliament) plus most of the other anti-retroviral AIDS drugs then under patent in Canada.²⁸

An order by Canada's federal Cabinet is required to add any product not already on the list (which step has been taken twice since the legislation was originally enacted, including to add the AZT/3TC/NVP combination product developed by Apotex).

The underlying 2003 WTO Decision imposes no requirement to limit the list of medications.

However, the underlying 2003 WTO Decision imposes no requirement to limit the list of medications. The Canadian law should be amended to remove the "gatekeeping" function of this list and of the Cabinet, and should instead clarify that a compulsory licence may be issued on

any patented product, so as to be as flexible as possible in responding to needs identified by developing countries themselves.

Given the scope of the original WTO Decision, an amended Canadian law should also clearly state that it applies to active pharmaceutical ingredients of medicines (rather than simply the finished product), and any diagnostic kits needed for the use of a pharmaceutical product.

Avoid a discriminatory double-standard against non-WTO countries

Currently, the CAMR treats all "least developed countries" (recognized as such by the United Nations) and all developing countries belonging to the WTO as potentially eligible importers of Canadian-made generics. However, the CAMR creates unjustified hurdles for developing countries that are not WTO members (and that are not "least developed countries").

Specifically, in order to be added to the list of eligible importers of Canadian-made generics, a non-WTO developing country must declare "an emergency or other circumstances of extreme urgency," and must also agree that the imported product will not be used for "commercial purposes" — a vague term which is undefined and could conceivably be interpreted to mean interference with distribution of the product in the importing country through private, for-profit pharmacies.

Contrary to oft-repeated and inaccurate claims, there is no requirement on WTO member countries to use compulsory licensing only in the event of public health crises or other emergencies (despite the best efforts by the United States and some other high income countries to include such

a provision). To impose this requirement on non-WTO countries represents a double standard and an act of bad faith.

Eliminate additional barriers to NGO procurement

Currently, the CAMR requires that a non-governmental organization (e.g., MSF) purchasing Canadian-made generics for importation into an eligible country must have the “permission” of the country — although nowhere is this term defined.

This is an unnecessary hurdle and should be eliminated. If the medicine in question meets the requirements for approval that are established by the country’s drug regulatory authority — be it a review conducted by the country’s own technical experts or, as is often the case with many developing countries, relying on approval by the WHO Prequalification Project or the drug regulatory agency in a more highly-resourced country — that should suffice.

Eliminate requirement of Health Canada approval as only one acceptable

The CAMR currently prohibits the Commissioner of Patents from granting a compulsory licence permitting exports to a generic manufacturer unless Health Canada has confirmed the product meets all the same regulatory standards as products approved for sale in Canada. The principle of ensuring the quality of medicines is a good one.

However, the current approach is unnecessarily inflexible. Instead, the CAMR could specify that *either* Health Canada approval *or* approval from the WHO’s Prequalification Project (a standard widely referenced

and understood by developing countries) is sufficient.

An alternative would be to simply leave it to the importing country to determine the standards to be met (which could very well include accepting the approval of a well-developed and stringent drug regulatory authority). This creates greater flexibility and respects better the autonomy of developing countries, while providing quality assurance.

Eliminate requirement of advance disclosure of importing country

Under the CAMR’s current provisions, before a compulsory licence can be issued to a generic manufacturer, it must first attempt to negotiate a voluntary licence with the patent-holder — and in so doing, it must have disclosed to the patent-holder(s), for a period of at least 30 days, the name and specific quantity of the product it wishes to produce for export, and also the name of the destination country that seeks to import the generic product.

This means that, even before the generic manufacturer can give the importing country any guarantee that it can legally supply the product, the country will likely face pressure from the patent-holder(s) and any governments opposed to the use of compulsory licensing (e.g., the United States) to refrain from going this route.

This concern cannot be dismissed lightly, given the history of such pressure — including, in some instances, threats of trade sanctions or refusal by patent-holding companies to register existing or new medicines in a country. This is likely one factor explaining why, to date,

Rwanda is the only country to have notified the WTO that it intends to use the mechanism of the 2003 WTO Decision.

The CAMR legislation should be amended to remove this requirement of advance disclosure as a prerequisite to getting a compulsory licence. The law could instead require simply that a generic manufacturer, when first requesting a voluntary licence from the patent-holder(s), state that it will disclose the name of the country following receipt of the licence and will pay the applicable royalty rate pursuant to the existing formula — and that, if this were not acceptable to the patent-holder(s), the generic manufacturer would then be able to proceed to apply for a compulsory licence.

To date, Rwanda is the only country to have notified the WTO that it intends to use the mechanism of the 2003 WTO Decision.

Of course, such an approach would not remove the possibility of retaliation against countries that make use of compulsory licensing. It would, however, at least eliminate an early window period during which a country risks retaliation in advance of

any certainty of obtaining the generic medicine it seeks.

Eliminate negotiations for voluntary licences in urgent situations

At the moment, the CAMR requires a generic manufacturer to first attempt to negotiate with the patent-holder(s) for a voluntary licence to produce the medicine for export. This reflects a requirement under Article 31 of the WTO's TRIPS Agreement. Yet, that article also provides that a country's law can dispense with this requirement in cases of "emergency or other circumstances of extreme urgency," in cases of public non-commercial use of the product in question, or when a compulsory licence is being issued to remedy a practice by the patent owner that has been found by a judicial or administrative process to be anti-competitive. So, it is odd that Canada's legislation does not take full advantage of this undisputed flexibility already found in TRIPS. The CAMR should be amended to eliminate the negotiating requirement.

Abolish arbitrary two-year time limit on compulsory licences

Without any foundation in any WTO legal instrument, the CAMR arbitrarily imposes a two-year limit on the length of any compulsory licence issued under its provisions, thus tying the hands of purchasing countries and generic manufacturers unnecessarily. This limitation should be removed.

Clarify option for re-exportation from importing country within regional trading bloc

Where a developing or least-developed WTO member country is party to a regional trade agreement with

other countries, at least half of whom are least-developed countries, the 2003 WTO Decision allows that country to re-export, to the other developing or least-developed country members of that regional bloc, generic pharmaceutical products that have been imported under a compulsory licensing process.

However, the current wording of the CAMR's provisions creates uncertainty as to whether this would be allowed under the terms of a compulsory licence issued to a Canadian generic manufacturer — it could arguably be grounds for terminating the compulsory licence.²⁹ Further, it is unclear what the applicable royalty rate would be in such a case.

The 2003 WTO Decision is "neither expeditious, nor a solution."

The CAMR needs to be reformed to clearly permit the issuing of a compulsory license to supply, under a simple process and with a single licence, a number of developing countries within a regional trade group, as allowed under the 2003 WTO Decision.

Eliminate extra opportunities for litigation by patent-holders

Inserted at the last minute, some provisions in the CAMR create additional opportunities for patent-holders to initiate litigation with a view to

having the courts revoke, or vary the terms of, a compulsory licence issued to a generic manufacturer.³⁰ These provisions create additional disincentives for generic manufacturers to use CAMR, and are not based on the 2003 WTO Decision.

The potential for vexatious litigation by patent-holders to block or rescind compulsory licences issued to generic manufacturers cannot be dismissed, in light of the long and litigious history between the patented and generic pharmaceutical industries. These provisions should be removed.

Streamline CAMR: the "one-licence solution"

While the reforms outlined above would eliminate certain hurdles currently marring the CAMR, what is required is more fundamental reform. The experience to date with the CAMR has highlighted that the central problem has to do with the basic process for licensing the production and exportation of generics — and that the problem is rooted in the original 2003 WTO Decision itself.

It is instructive that, more than four years after the WTO General Council adopted that Decision, Rwanda remains the sole country to have indicated its intent to use the mechanism.³¹ MSF's experience, as illustrated through its hands-on effort to use the Canadian legislation to obtain an inexpensive medicine to treat patients living with HIV/AIDS, has led it to conclude that the 2003 WTO Decision is "neither expeditious, nor a solution."³²

In May 2008, having finally succeeded in making the first — and to date, only — use of CAMR, generic manufacturer Apotex repeated that

it was not interested in attempting to use the regime again absent significant changes.³³

If Canada's Parliament wishes the CAMR to be a useable tool to assist developing countries, it will need to rethink the basics of the 2003 WTO Decision and be willing to streamline the CAMR dramatically.

The WTO Decision, as embodied in the CAMR, creates unnecessary hurdles for generic companies and developing countries to use compulsory licensing — and even if a compulsory licence is obtained to produce a given medicine, the CAMR authorizes exportation only of a pre-determined quantity and only to a single country, forcing a repeat of the process for any other drug orders from the same or other countries. The legal process must be more user-friendly for developing countries and generic manufacturers.

This basic premise is the root of the “one-licence solution” advocated by Canadian civil society organizations. Put simply, a generic manufacturer would require but one compulsory licence. That single licence should authorize the manufacturer and export any pharmaceutical product patented in Canada, not just those on CAMR's current limited list. The licence should be obtainable *before* any particular country or specific quantity of the pharmaceutical product in question has been determined.

Such legal authorization could be achieved most directly, and with the least transaction cost, by simply enacting a specific section of the *Patent Act* that statutorily authorizes the generic production of any patented pharmaceutical product solely for purposes of export to any eligible country specified in the legislation.

As an alternative, if the law maintained a requirement that a given generic manufacturer had to make a specific application for a licence on a particular product, that licence could be granted as of right, rather than requiring the manufacturer to apply for a separate licence to cover every separate order of a drug. The licence would authorize the company to export the medicine in question to any eligible country specified in the legislation.

Whichever approach to granting a licence were used, one of its conditions would be to require the generic manufacturer to pay royalties to the patent-holder(s). This could be done with the formula for calculating royalties that is already in the CAMR.

Having obtained such a licence at the outset, the generic manufacturer would be equipped to negotiate multiple contracts with multiple countries, rather than separate agreements with each country and for specific pre-determined quantities. The royalties payable would be based on whatever contracts the generic manufacturer succeeds in negotiating; it would be a condition of the licence that these details be reported periodically when remitting the royalty payments.

This simplified process, allowing for multi-country, larger-volume supply contracts, could achieve considerable economies of scale, creating further incentives for generic manufacturers to participate, and also further reducing the final price of products to developing countries. Such a process would also eliminate the need for any period of attempting to negotiate voluntary licences with patent-holders — and the accompanying exposure of a country to pressure before the generic manufac-

turer can guarantee delivery of the medicine.

Furthermore, it would allow for greater flexibility for developing countries, which would be able to adjust over time the quantities of a product that it requires, rather than, as is the case now with the CAMR and the 2003 WTO Decision, having to fix a quantity in advance and then having the generic manufacturer apply for a specific compulsory licence authorizing production of just that amount.

The mechanism set forth in the 2003 WTO Decision is not the only option open to WTO member countries.

The one-licence solution is distinct from the mechanism set forth in the 2003 WTO Decision. However, that mechanism, as embodied in the CAMR and in the law of several other jurisdictions, is not the only option open to WTO member countries. The 2003 WTO Decision explicitly states that it is “without prejudice to the rights, obligations and flexibilities that [WTO] Members have under the provisions of the TRIPS Agreement ... and to their interpretation.”³⁴

In 2002, a number of developing countries and various NGOs, with the support of the WHO, had proposed that another part of the TRIPS Agreement (Article 30) could provide

a basis for addressing the problem that the 2003 WTO Decision, as it was ultimately adopted, was supposed to solve — namely, the restrictions (under TRIPS Article 31) on the use of compulsory licensing for export.³⁵ TRIPS 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 [2003 WTO] 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.³⁶

It should be recalled as well that TRIPS Article 30 is open-ended, and that TRIPS also states explicitly that WTO “[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”³⁷

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.”³⁸

Conclusion

Canada was one of the first countries in the world to implement the 2003 WTO Decision, has witnessed sustained efforts to use its domestic regime to implement the Decision, and has seen the only use of any such mechanism to date anywhere in the world, four years after it was created.

Canada is, therefore, well positioned to show leadership in acknowledging that the current approach does not offer the rapid, flexible, sustainable solution that is needed and was promised, and to legislate instead a different approach that stands a greater chance of being workable for developing countries and generic manufacturers.

Legally, Canada could replace the current CAMR with a streamlined process along the lines of what has been proposed here, and could defend it against challenge at the WTO under the rubric of TRIPS Article 30.

The question, therefore, is not one of legal incapacity. The question is: Will Canada’s parliamentarians have the political will to take the action that is needed to help increase access to affordable AIDS or other treatment for tens or hundreds of thousands of people in the developing world?

— Richard Elliott

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¹ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 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).

² 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) [“2003 WTO Decision”], available via <http://docs.online.wto.org>. For more detailed discussion, see: R. Elliott, “Delivering on the pledge: global access to medicines, WTO rules and reforming Canada’s law on compulsory licensing for export,” *McGill International Journal of Sustainable Development Law & Policy* 3(1) (2007): 23, available via www.aidslaw.ca/gtag.

³ For a more detailed discussion of the campaigning efforts, see R. Elliott, “TRIPS from Doha to Cancún ... to Ottawa: global developments in access to treatment and Canada’s Bill C-56,” *Canadian HIV/AIDS Policy & Law Review* 8(3) (2003): 1; R. Elliott, “Steps forward, backward, and sideways: Canada’s bill on exporting generic pharmaceuticals,” *Canadian HIV/AIDS Policy & Law Review* 9(3) (2004): 15; both available via www.aidslaw.ca/review; R. Elliott, “Delivering on the pledge.”

⁴ *Patent Act*, RSC 1985, c. P-4. Available via <http://laws.justice.gc.ca>.

⁵ *An Act to Amend the Patent Act and the Food and Drugs Act (Jean Chrétien Pledge to Africa)*, S.C. 2004, c. 23, at www.canlii.org/ca/as/2004/c23/. For a quick summary, see www.parl.gc.ca/3773/parlbus/chambus/house/bills/summaries/c9-e.pdf. In addition to Canada, as of May 2008, a few other jurisdictions — Norway, India, the European Union, Netherlands, South Korea and China — had adopted legislation, regulations, policy directives or other instruments that in some way, with varying degrees of specificity and restrictiveness, implement the 2003 WTO Decision to permit compulsory licensing of patented pharmaceuticals for export to certain eligible countries. For additional information and materials, see the compilation by Knowledge Ecology International (formerly Consumer Project on Technology), “Legislation to Allow for the Export of Pharmaceuticals Under Compulsory License”, at www.cptech.org/ip/health/cl/cl-export-legislation.html.

⁶ For more detailed discussion, see: R. Elliott, “Pledges and pitfalls: Canada’s legislation on compulsory licensing of pharmaceuticals for export,” *International Journal of Intellectual Property Management* 1(1/2) (2006): 94–112, available via www.aidslaw.ca/gtag; Canadian HIV/AIDS Legal Network and Interagency Coalition on AIDS and Development, *The Jean Chrétien Pledge to Africa Act and Its Impact on Improving Access to HIV/AIDS Treatment in Developing Countries*, August 2006, available via www.aidslaw.ca/gtag.

⁷ Industry Canada, “Coming into force of the Jean Chrétien Pledge to Africa Act,” news release and backgrounder, Ottawa, 13 May 2005. Available via <http://www.ic.gc.ca>. See also, *Use of Patented Products for International Humanitarian Purposes Regulations*, S.O.R. 2005/243; *Food and Drugs Regulations* (1402 — Drugs for Developing Countries), S.O.R. 2005/141; *Medical Devices Regulations* (Developing Countries), S.O.R. 2005/142, all in the *Canada Gazette (Part II)*, Vol. 139 (No. 11), June 1, 2005, all available via <http://canadagazette.gc.ca/partII/2005/20050601/html/index-e.html>. For more information about what the government has since labelled “Canada’s Access to Medicines Regime,” see www.camr.gc.ca.

⁸ For information about the product “Apo-TriAvir,” see: www.apotex.com/apotriavir.

- ⁹ Médecins Sans Frontières, *Neither Expeditious, Nor a Solution: The WTO August 30th Decision Is Unworkable — An Illustration Through Canada's Jean Chrétien Pledge to Africa*, August 2006, at p. 6. At www.accessmed-msf.org/fileadmin/user_upload/medinnov_accesspatents/WTOaugustreport.pdf.
- ¹⁰ B. Clark, Vice-President, Apotex, Inc., presentation at satellite session, "Commitment compromised: WTO rules and Canada's law on compulsory licensing — the continuing challenge of scaling up treatment access," XVI International AIDS Conference, Toronto, 15 August 2006, on file. For information regarding the WHO Prequalification Programme, and current lists of prequalified products and producers, see: <http://healthtech.who.int/pq/>.
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- ¹² 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," WTO Doc. IP/N/9/RWA/1, 19 July 2007. Available via <http://docs-online.wto.org>.
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- ¹⁶ Commissioner of Patents (Canadian Intellectual Property Office), "Authorization Under Section 21.04 of the Patent Act," 19 September 2007. Available via http://strategis.ic.gc.ca/sc_mrksv/cipo/jcpa/p4-e.html.
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- ²¹ I. Teotonio, "Clement vows to get cheap drugs flowing," *Toronto Star*, 16 August 2006, p. A1.
- ²² For the complete text of written submissions, see http://camr-rcam.hc-sc.gc.ca/review-reviser/index_e.html.
- ²³ For the committee's summary of issues raised before it, see House of Commons Standing Committee on Industry, Science and Technology, *Letter to the Hon. Maxime Bernier, Minister of Industry*, 14 May 2007, and accompanying summary. At http://cmte.parl.gc.ca/Content/HOC/committee/391/indu/webdoc/wd2967322/391_INDU_Letter/391_INDU_RelDoc_PDF-e.pdf.
- ²⁴ Canadian HIV/AIDS Legal Network and North-South Institute, *Access to Medicines and Intellectual Property: An International Expert Meeting on Canada's Access to Medicines Regime, Global Developments, and New Strategies for Improving Access — Meeting Report*, Ottawa, 19–21 April 2007. Available via: www.aidslaw.ca/gtag, www.nsi-ins.ca.
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- ²⁶ Global Treatment Access Group, *Delivering on the Pledge: Reforming Canada's Access to Medicines Regime, Submission to the Government of Canada*, January 2007. Available via www.aidslaw.ca/gtag.
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- ²⁸ See Patent Act, Schedule 1, at <http://laws.justice.gc.ca/en/showdoc/cs/P-4/sc:1/en#anchors:c:1>.
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- ³⁰ *Ibid.*, at ss. 21.08(4)–(7), 21.14, and 21.17.
- ³¹ WTO, "TRIPS and Public Health: Dedicated Webpage for Notifications." At www.wto.org/english/tratop_e/trips_e/public_health_e.htm.
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- ³³ U. Gandhi, "Supplying generic AIDS drug called pricey process," *The Globe and Mail*, 8 May 2008.
- ³⁴ 2003 WTO Decision at para. 9.
- ³⁵ See WHO, "Statement by the Representative of the World Health Organization," WTO Council for TRIPS, 17 September 2002. At www.who.int/mediacentre/trips/en.
- ³⁶ Canadian Generic Pharmaceutical Association, *Canada's Access to Medicines Regime Consultation Paper — Comments by the Canadian Generic Pharmaceutical Association*, 24 January 2007 at p. 7. Available via www.canadiangenerics.ca, www.camrgc.ca.
- ³⁷ TRIPS, Article 1(1).
- ³⁸ 4th WTO Ministerial Conference, *Declaration on the TRIPS Agreement and Public Health*, 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2, at para. 4. At www.wto.org/english/thewto_e/minist_e/min01_e/mindcl_trips_e.htm.