Steps forward, backward, and sideways: Canada's bill on exporting generic pharmaceuticals

In May 2004 Canada's Parliament passed Bill C-9, amending the Patent Act to provide for the compulsory licensing of patented pharmaceutical products. The bill allows generic manufacturers to make cheaper, generic versions of patented products and export them to countries that do not have sufficient capacity to produce their own. Canada thus became the first country to pass legislation implementing a World Trade Organization (WTO) Decision that relaxed WTO rules on pharmaceutical patents. Civil society organizations campaigned to enhance the bill before it passed, and succeeded in obtaining significant improvements. However, the final bill is marred by flaws that mean it falls short of being a "model" that should simply be replicated elsewhere.

This article is the second in a series tracing the evolution of Canada's legislation.[1] It reviews the developments leading up to the adoption of Bill C-9 in its final form, and analyzes its positive and negative aspects. Hopefully, other advocates can learn from this experience and other countries can avoid replicating the negative aspects as they implement the WTO Decision.[2]

Background

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets out rules on patents, including for pharmaceuticals, which WTO members must follow. TRIPS allows countries to issue compulsory licences, which override exclusive patent rights and authorize someone other than the patent holder to also make a pharmaceutical product before the patent on it expires. In exchange, the recipient of the compulsory licence must pay "adequate remuneration" to the patent holder. Compulsory licensing introduces competition by generic pharmaceutical manufacturers and makes needed medicines more affordable.

But TRIPS Article 31(f) says that, ordinarily, compulsory licensing may only be used "predominantly" for the purpose of supplying the domestic market of the country where the licence is issued.[3] This limits the use of compulsory licensing to produce generic pharmaceuticals for export. For countries lacking sufficient capacity to make their own generic medicines, and therefore needing to import such medicines, Article 31(f) makes it difficult for them to use compulsory licensing to address their population's health needs.

On 30 August 2003 the WTO General Council unanimously adopted a Decision to address these difficulties, in response to demands for access to cheaper, generic medicines, particularly in the developing world.[4] The Decision waives, on an interim basis, the provision in Article 31(f).

Canadian civil society advocacy: Bill C-56, then Bill C-9

In September 2003, Canadian civil society organizations and Stephen Lewis, the UN Special Envoy on HIV/AIDS in Africa, called on the government to change Canadian patent law to implement the WTO Decision. On 6 November 2003, after two months of intense lobbying, a draft bill (Bill C-56) was introduced in Parliament .The bill was heavily criticized by civil society advocates for failing to implement the full flexibility in patent rules that had been agreed at the WTO. The bill was also criticized for giving unwarranted, unnecessary privileges to patent-holding pharmaceutical companies that would undermine the entire initiative.[5]

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In response, the government decided to refer the bill to committee for further public discussion. On 12

February 2004, after a change in government leadership, the bill was reintroduced (now re-numbered as Bill C-9) and hearings were held by the House of Commons Standing Committee on Industry, Science and Technology.

The Global Treatment Action Group (GTAG) coordinated advocacy efforts among numerous civil society organizations to improve Bill C-9 as it worked its way through the parliamentary process. GTAG engaged a wide range of organizations from across the country – from human rights advocates to development NGOs, from humanitarian organizations to faith-based groups, and from labour unions to student groups – as well as thousands of individual Canadians.

As a GTAG member, the Canadian HIV/AIDS Legal Network prepared an information package on the bill that was distributed to every Member of Parliament shortly before Committee hearings began, made a detailed oral presentation before the Committee, and made an extensive series of written submissions to the Committee. Numerous other civil society organizations, and some individual experts, also appeared before the Committee or made submissions. GTAG member groups met with many of the Committee members individually to identify needed amendments to the bill, issued numerous media releases, and hosted several press conferences.[6]

In addition, the Legal Network participated in a World Health Organization/Ford Foundation consultation on the implementation of the WTO Decision and conveyed the results of that consultation to the Standing Committee; presented an oral statement about Bill C-9 before the 60th Session of the UN Commission on Human Rights; and met with the office of the Prime Minister and the offices of most of the ministers of the five federal departments involved in the drafting of the bill. (The office of the Minister of Industry, the department with lead responsibility, did not respond to requests for a meeting.)

The intensive, sustained efforts of civil society had a major impact in improving the bill from its original form.

On 20 April 2004, having heard from witnesses over several days, the Standing Committee began its clause-by-clause analysis of the draft bill.[7] In response to pressure from civil society advocates (see below), the government said at Committee that it was prepared to remove the controversial, anticompetitive "right of first refusal" clause that would have allowed patent-holding companies to scoop contracts negotiated by a generic supplier with an importing country purchaser. Civil society advocates also spoke out against the introduction of several problematic "alternatives" to the right of first refusal proposed by the brand-name industry and the government. In the end, the Committee made several positive amendments to the bill, including the removal of the right of first refusal clause. But it also added some amendments that created new defects in the bill, which the governing Liberal Party allowed to stand in the final text.[8]

On 28 April 2004 the bill, as amended by the Standing Committee, was reported back to the House of Commons. After further motions to introduce additional amendments (see below), on 4 May 2004 Bill C-9 was put to its third and final reading and adopted unanimously by the entire House and sent to the Senate. On 13 May 2004 it received third reading and unanimous approval in the Senate. On 14 May 2004 it received Royal Assent and thereby passed into law,[9] making Canada the first country to enact such legislation.[10]

On 16 July 2004 the US and Canada adopted a Memorandum of Understanding, agreeing that the intellectual property provisions of the North American Free Trade Agreement (NAFTA) would not be applied so as to block the implementation of Canada's Bill C-9.[11]

Commentary on Bill C-9: positive and negative features of Canada's legislation

In theory, this law makes it possible for a Canadian generic pharmaceutical producer to obtain a licence to manufacture a patented medicine for export to eligible countries. How it will play out in practice remains to be seen. The fact that a G-7 country has taken the step of passing such a law is significant, because it generates needed political momentum, from a developed country, behind the implementation of the WTO Decision.

Bill C-9 also represents a victory of sorts for civil society advocates, whose intensive, sustained efforts had a major impact in improving the bill from its original form. But in light of its several defects, the bill in its entirety falls short of providing a "model" that should simply be copied elsewhere. Rather, other countries should learn from the Canadian experience and avoid replicating these flaws in their own implementation of

the WTO Decision. The rest of this article identifies the positive and negative features of Canada's approach to implementing the WTO Decision.

Limited list of products

One of the most fundamental concerns with Bill C-9 is the government's insistence on maintaining a list of pharmaceutical products subject to compulsory licensing for export. The Canadian experience to date illustrates that such an approach should be avoided.

The bill includes an initial list of 56 products to which it applies, derived principally from the World Health Organization (WHO) Model List of Essential Medicines. (In response to criticism, the government agreed to add to the original list in the bill all antiretrovirals [ARVs] for treating HIV/AIDS that are currently approved for sale in Canada.)

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The bill also states that the federal Cabinet may, upon recommendation by the ministers of both Health and Industry, add other products to the list. A committee will be established to advise the ministers regarding which products should be added. Government officials have stated that civil society will be represented on this committee, along with people who have expertise in delivering health care in resource-poor settings.

From the outset, civil society organizations were critical of the inclusion of any list , because it represented a step back from the international consensus achieved with the WTO Decision. In the negotiations leading up to the Decision, several developed countries proposed to limit its scope to just addressing specific diseases or just applying to specific pharmaceutical products. These efforts were roundly condemned by civil society activists as unethical and unsound health policy, and were firmly rejected by developing countries. Ultimately, all WTO members agreed that there would be no such limitations. By introducing a limited list of products in its implementing legislation, Canada has unilaterally undermined that consensus.

Canadian civil society groups repeatedly called on the government to abolish the list of products. They also warned that requiring a Cabinet decision to add new products would open the door to political lobbying by brand-name pharmaceutical companies to prevent the list from being expanded, thus creating further delays in the process. In the days leading up to the final vote on the bill in the House of Commons, the concerns of the civil society groups proved to be well founded.

At the Standing Committee stage, members discussed adding several medicines to the list in Bill C-9. The opposition New Democratic Party (NDP) had proposed that the added drugs include moxifloxacin and clarithromycin. Both are used to treat pneumonia. Clarithromycin is also used prophylactically to prevent mycobacterium avium complex (MAC), a life-threatening infection in people living with HIV/AIDS; a version of the drug produced by an Indian generic manufacturer is among the HIV/AIDS medicines prequalified by the WHO. At the Committee, all political parties agreed that, absent any technical objections by Health Canada to a particular drug, the additional medicines would be added to the bill by motion when it came before the House of Commons for final reading and adoption.

Health Canada indicated that it had no objection to either of these two drugs being included in Bill C-9. But the NDP subsequently received calls from Bayer, the pharmaceutical company that holds the patent on the drug moxifloxacin in Canada, objecting to its inclusion in Bill C-9. At least one pharmaceutical company also contacted ministers' offices objecting to the addition of any medicines to the list,[12] and a minister's office subsequently contacted the opposition party to request that it withdraw some of its motions to add specific drugs that had already been agreed would be added.

Subsequently, during the consideration of these motions on the floor of the House of Commons, the governing Liberal Party argued against the addition of these medicines to the list of products covered by the bill, notwithstanding the government's previous assurances that including a list of products in Bill C-9 would not be used to limit the scope of the legislation in this fashion. Government representatives stated that moxifloxacin and clarithromycin were not on the WHO Model List of Essential Medicines, and claimed (incorrectly) that these medicines were not needed to treat HIV/AIDS, tuberculosis, or malaria.[13]

This experience illustrates the pitfalls of having a list of products, and calls into question the good faith of the government in promising that the list would not limit the scope of

Canada's initiative. This does not bode well for future efforts to add products to the list of products eligible for compulsory licensing and export.

Fixed-dose combination medicines

Of particular concern is how Canada's system will treat the case where a Canadian generic manufacturer seeks a compulsory licence to produce and export a "fixed-dose combination" (FDC) medicine, which combines more than one drug into a single dose. FDCs of ARVs simplify treatment regimens and are recognized by the WHO as being of critical importance in its efforts to dramatically scale up access to ARVs in the developing world.

> The onus is on the government to ensure that the process is rapid, transparent, and not overly cumbersome.

Previously, Canadian law did not require that a drug manufactured solely for export undergo the regulatory approval process that applies to drugs marketed in Canada. Bill C-9 now imposes such a review on any pharmaceutical product manufactured under compulsory licence for export.

In the case of generic medicines being reviewed for Canadian marketing approval, standard practice is to base approval on data showing "bioequivalence" of the generic product to an already approved brand-name product. But in the case of FDCs for treating HIV/AIDS, there are only three such products on the Canadian market. Two of these (Combivir® and Trizivir®) combine drugs patented by GlaxoSmithKline; the third (Kaletra™) combines two drugs patented by Abbott . These combination products are important, but are not among those recommended as "first-line" therapy by the WHO for use in developing-country settings. The first-line products are currently only available from generic producers in countries such as India, where the drugs have not been patent protected and where it has therefore been possible to engineer their combination without infringing patents.

Now that Canada has insisted that any generic pharmaceutical produced for export under compulsory licence meet Canadian marketing approval standards, the onus is on the government to ensure that the process is rapid, transparent, and not overly cumbersome – particularly when it comes to enabling the production and export of products such as FDCs, which are a priority in the global effort to scale up treatment access. The issues described above will have to be dealt with via regulations, and via the policies and practices adopted by Canada's drug regulatory authority.

NGO procurement from generic suppliers

Originally, there was no provision in Bill C-9 that would allow an NGO to buy medicines from a Canadian generic producer. Under pressure, the government brought forward an amendment that would have solved this problem. Yet it allowed its own amendment to be largely gutted by one of its own party members at the Committee stage, and then it rejected requests that the amendment be reinstated.

As a result, under the final text of Bill C-9, any NGO in a developing country that wants to purchase medicines from a Canadian generic producer and import them must obtain the "permission" of the government of that country. "Permission" is not defined.

This requirement applies even if the product is already approved for sale in the developing country by the health regulator, and even if there is no patent barrier to importing the product (either because it is not patented in the country or because the NGO has obtained a compulsory licence from the appropriate authority under the country's legislation that authorizes it to import the product). The requirement creates an additional hurdle that is not required by any WTO obligations, thus further delaying what is supposed to be a rapid response. It also exposes NGOs to political manipulation by governments.

Royalty payable to patent holder

On the positive side, Bill C-9 will likely set a reasonably good precedent in its approach to the royalties payable to a patent holder. The original bill had proposed a standard royalty rate of two percent of the value of the contract to be paid to the Canadian patent holder. The brand-name pharmaceutical companies objected, concerned that this would set a precedent they considered undesirable. Generic producers and civil society organizations found the rate acceptable, but were also agreeable to a sliding scale, as long as the rate in any given case was predictable, and as long as there was an overall cap on the royalty to keep the costs of using this system minimal.

While the details remain to be set out in regulations, the government has committed to establishing a sliding-scale formula linking the royalty rate in any given case to the ranking of the importing country on the UN Development Programme's Human Development Index. The effective cap

will be four percent of the value of the contract for the highest-ranking country. The majority of eligible importing countries rank well below this, meaning royalties in those instances will be significantly lower.

If enacted as promised, this will be a positive feature of Canada's law. Early drafts of the regulations conform, on this point, to what was promised by government representatives before the Parliamentary committee.

Exports to non-WTO developing countries

At the time of the WTO Decision, WTO member countries had been divided into various categories for the purposes of using the Decision to import generic pharmaceuticals.[14]

Twenty-three high-income countries agreed to opt out of using the Decision to import generic medicines produced under compulsory licences.[15] Eleven middle-income countries stated that they would only use the Decision to import generic medicines produced under compulsory licence in situations of national emergency or other circumstances of extreme urgency.[16] Ten Eastern European and Baltic countries made a similar statement, further indicating that they would opt out of importing entirely upon acceding to the European Union.[17] This division of WTO members into different categories is reflected in the different country schedules attached to Canada's Bill C-9.

Civil society advocates argued that nothing in WTO law prohibited Canada from implementing the WTO Decision to authorize compulsory licensing of pharmaceuticals for export to *non*-WTO developing countries as well. As a result of that advocacy, the bill sets a positive precedent by affirming that countries implementing the WTO Decision can authorize production of generics for export to non-WTO countries. However, the bill sets out certain conditions.

All the "least-developed countries" (LDCs) currently recognized as such by the UN were included under the bill from the outset, whether or not they belong to the WTO. However, under Bill C-9, a developing country that is neither a WTO member nor an LDC can procure cheaper medicines from Canadian generic producers *only* if:

- it is eligible for "official development assistance" according to the Organization for Economic Cooperation and Development (OECD);[18]
- it declares a "national emergency or other circumstances of extreme urgency;" *and*
- it specifies the name and quantity of a specific product needed for dealing with that emergency.

This approach creates an indefensible double standard between developing countries that belong to the WTO and those that do not.

> Some provisions of Bill C-9 create an indefensible double standard between developing countries that belong to the WTO and those that do not.

In the negotiations leading to the WTO Decision, developing-country members firmly rejected efforts to limit their use of compulsory licensing to import generic medicines only in "emergency" situations. Health activists also rejected such proposals as unsound and unethical. The final WTO Decision does not impose such a limitation. It respects members' sovereignty as set out in the TRIPS Agreement and reaffirms the statement in the November 2001 Doha Declaration to the effect that countries are free to determine for themselves the grounds upon which to use compulsory licensing.

For the most part, Bill C-9 does not limit the use of compulsory licensing of pharmaceuticals to only allow exports to countries facing "emergencies."[19] Yet it does impose such a limit on the over 20 developing countries that are neither WTO members nor LDCs. This is at odds with the spirit of the consensus achieved in the WTO Decision and is an embarrassing demonstration of bad faith in the Canadian legislation.

In addition, if a non-WTO developing country or LDC is added in future to the relevant schedule of countries set out in Bill C-9, it must state that it undertakes to adopt the measures set out in the WTO Decision (paragraph 4) aimed at preventing diversion of the product. It must also agree that the product "will not be used for commercial purposes." If the country allows such use, then it may be struck off the list of countries eligible to import medicines from a Canadian generic supplier.

The term "commercial purposes" is undefined in the legislation, but is clearly aimed at limiting the possibility of commercial competition in the importing country's marketplace. This provision would hinder the longer-term benefit that competition could have in reducing medicine prices. It also raises questions about the distribution of imported generics via the private sector (eg, pharmacists) in the importing country. Will this be considered a "commercial purpose"? If so,

this provision fails to recognize the reality that many people in developing countries, as elsewhere, need to turn to private pharmacies when purchasing medicines, which are frequently paid for out of their own pocket rather than covered by a public scheme. This provision is unnecessary under TRIPS and the WTO Decision and should not have been included in the bill.

Price and profit caps

Under Bill C-9, the Canadian patent holder may apply for a court order terminating a compulsory licence or ordering a higher royalty (than what is specified by the sliding scale in the regulations) on the basis that a generic company's contract with a purchaser is "commercial" in nature. In its application to the court, the patent holder must allege that the generic producer is charging an average price for the product that exceeds 25 percent of the patent holder's average price in Canada. If the generic producer can demonstrate, through an audit, that its average price is less than 15 percent above its direct manufacturing costs, the court may not issue such an order.

Although this provision in Bill C-9 is ostensibly aimed at controlling prices charged by generic producers to developing-country purchasers, that objective could have been achieved through other means (such as through conditions imposed in the grant of the compulsory licence itself). This aspect of the law invites vexatious litigation by patent holders, is potentially a disincentive to generic producers using the system, and is not required under TRIPS or the WTO Decision. It should be avoided by other countries enacting similar legislation. Giving further privileges to patent holders to harass generic producers that are issued compulsory licences, and to interfere with production and export of generic pharmaceuticals to developing countries, is a poor way to follow through on stated commitments to increasing access to medicines for all.

Two-year limit on compulsory licences

Finally, the new law states that a compulsory licence may only be issued for a maximum period of two years.[20] After two years, the generic company must apply for a new compulsory licence, based on a new contract, if it wants to be able to manufacture a patented product for export.

To impose this cap restricts the ability of a generic producer to enter into secure supply contracts with developing-country purchasers to a two-year period, even though negotiating longer-term contracts would provide more of an incentive for generic manufacturers to scale up production of a particular product, and would permit greater economies of scale.

This arbitrary cap on the term of a compulsory licence is a negative feature of Canada's law, and should be changed. At the very least, the term of a compulsory licence should be equivalent to the term of the contract that the generic manufacturer has negotiated with a purchaser and that is the basis for its application for a compulsory licence.

Conclusion

Overall, the chief defect of Canada's Bill C-9 is that it falls short of fully reflecting the "flexibilities" allowed under TRIPS and the WTO Decision. The Canadian initiative is an important one in the context of the overall global effort to improve access to medicines, but it can and should be improved. A parliamentary review of the law will occur in two years' time, at which point it may be further amended. In the interim, other countries moving to implement the WTO Decision should learn from the Canadian experience. Similarly, as the WTO Council for TRIPS discusses some sort of permanent solution to replace the interim waiver in the Decision, the positive and negative features of Canada's law need to be understood.[21]

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The text of Bill C-9 and most of the additional materials referred to in the article above can be found at www.aidslaw.ca/Maincontent/issues/cts/patent-amend.htm.

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[1] The first article in this series was 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* 2003; 8(3): 1, 7-18.

[2] Portions of this article previously appeared, in abridged form, as: R Elliott. Canada's new patent bill provides a basis for improvement. *BRIDGES Between Trade and Sustainable Development* 2004; 8(5): 19-20, available via www.ictsd.org/monthly/archive.htm.

[3] There are some exceptions to this, such as in the case of anticompetitive practices by the patent holder: TRIPS Article 31(k).

[4] Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Document IP/C/W/405.

[5] For a detailed discussion, see Elliott, supra, note 1. See also: R Elliott. Flirting with flawed patent law amendment, Canada may undermine welcome "Access to Medicines' initiative. BRIDGES, No 8, November 2003.

[6] Most of these materials can be accessed online at www.aidslaw.ca/Maincontent/issues/cts/patent-amend.htm.

[7] For the transcript of hearings and deliberations of the Committee, see the entry "Patent Act and Food and Drugs Act (amdt.) (Bill C-9)" in the index of the Committee's proceedings at www.parl.gc.ca/InfoComDoc/37/3/INST/Meetings/Evidence/INSTin-E.htm.

[8] For the reaction of several civil society groups to the amended text, see: Canada proceeds with Bill C-9 on cheaper medicine exports: NGOs say initiative is important, and urge other countries avoid the flaws in the Canadian model. News realease, 28 April 2004. Available at www.aidslaw.ca/Media/press-releases/

e-press-apr2804.pdf.; see also Médecins Sans Frontières. Bill C-9: How Canada failed the international community. News release, 28 April 2004.

[9] An Act to amend the Patent Act and the Food and Drugs Act. SC 2004, c 23. For a quick summary, see www.parl.gc.ca/37/3/parlbus/chambus/house/bills/summaries/c9-e.pdf.

[10] On the same day, Norway promulgated changes to regulations under its Patent Act to implement the WTO Decision, although with far less detail. The regulations were scheduled to come into force on 1 June 2004. The text is available online at http://lists.essential.org/pipermail/ip-health/2004-July/006812.html.

[11] Letter from R Zoellick, US Trade Representative to Hon. J Peterson, Canadian Minister for International Trade, 16 July 2004. Available via www.aidslaw.ca/Maincontent/issues/cts/patent-amend.htm.

[12] G McGregor. Drug bill lets "Big Pharma" call the shots: government yields to pressure from Bayer to keep new drug off list of HIV/AIDS program. *Ottawa Citizen*, 4 May 2004.

[13] For the transcript of House of Commons debates over Bill C-9, see the entry "Patent Act and Food and Drugs Act (amdt.)" in the index to Hansard, the record of chamber business, at www.parl.gc.ca/37/3/parlbus/chambus/house/debates/indexE/p-37-3_-e.htm.

[14] This was reflected in a Chairperson's Statement placed on the record, at the request of the United States, in conjunction with the adoption by the WTO General Council of the Decision itself. The legal status of that Statement remains a matter of debate.

[15] The countries are Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom, and United States of America.

[16] The countries are Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates.

[17] The countries are Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic, and Slovenia. Accession occurred on 1 May 2004.

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

[19] This had been the original intent of the government, but criticism from activists led to a change in the government position that was ultimately reflected in the legislation tabled in Parliament.

[20] If the full amount of the product specified in the licence has not been shipped during that period, the licence may be renewed once for up to another two years. However, only one renewal of a licence is permitted.

[21] On 17 June 2004, WTO Council for TRIPS decided to push back its deadline for adopting a permanent solution to the TRIPS Article 31(f) problem until March 2005. See: Quiet TRIPS Council focuses on health, biodiversity-related issues. *BRIDGES Weekly Trade News Digest* Vol 8(22): 23 June 2004.