Global Access to Treatment:
Canada's Bill C-9 and the Compulsory Licensing of Pharmaceuticals for Export to Countries in Need

CANADIAN HIV•AIDS LEGAL NETWORK | RÉSEAU JURIDIQUE CANADIEN VIH•SIDA

Background: Access to medicines and the World Trade Organization

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires all World Trade Organization (WTO) member countries to adopt certain minimum standards regarding private intellectual property rights, including rules on patents for pharmaceutical products. Those rules create temporary monopolies, meaning the company holding the patent can charge high(er) prices. Developing countries and civil society organizations have pointed to these rules as one factor limiting access to more affordable medicines, particularly in the developing world. Evidence shows that competition, including from generic pharmaceutical producers, has led to significant, sustained reductions in the prices of medicines.

In response, at the Fourth Ministerial Conference of the World Trade Organization (WTO) in November 2001 (in Doha, Qatar), WTO Members unanimously adopted the *Declaration on the TRIPS Agreement and Public Health*. In the "Doha Declaration", WTO Members:

- agreed that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all";
- reaffirmed that countries belonging to the WTO have the "right to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose";
- reaffirmed that this flexibility includes the right of each country "to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." A compulsory license grants someone other than the patent owner the legal right to make, sell or import the patented product, which otherwise would infringe the patent.

Limits on exports of generic pharmaceuticals

In the Doha Declaration, WTO Members also recognized that countries face difficulties in "making effective use" of compulsory licensing to obtain cheaper generic pharmaceuticals if they lack sufficient capacity within their own borders to manufacture pharmaceuticals and therefore need to import those products.

This is because, under TRIPS, a WTO country that does have manufacturing capacity – and could be a potential supplier – may only issue compulsory licences "predominantly" for supplying its own domestic market. This limits the production of cheaper generic medicines in such a country for export to other countries in need of imports.

WTO Members agreed to find an "expeditious solution" to this problem by the end of 2002. In August 2003, WTO Members finally agreed to a solution. The WTO's General Council adopted a decision in which it waives, on an interim basis, the restriction in TRIPS that says compulsory licensing may only be used "predominantly" for supplying the domestic market. This allows countries to issue compulsory licences on pharmaceuticals that are still under patent in their territory, in order to allow generic producers to make these products for export for eligible importing countries.

Bill C-9: Canada's implementation of the WTO decision of 30 August 2003

In September 2003, Canadian civil society organizations and Stephen Lewis, UN Special Envoy on HIV/AIDS in Africa, called on Canada to implement the WTO decision. On 14 May 2004, Canada passed such legislation. The bill is expected to come into force in late 2004 once the companion regulations are finalized.

In theory, Bill C-9 (*An Act to amend the Patent Act and the Food and Drugs Act*) makes it possible for Canadian generic pharmaceutical producers to obtain licences to manufacture patented medicines for export to eligible countries. As a result of sustained civil society advocacy, the final text of Bill C-9 is improved from early drafts. However, it still falls short of providing a "model". Other countries should learn from it and avoid replicating its defects. This article reviews some key aspects, positive and negative, of Canada's legislation.

"Right of first refusal" does <u>not</u> exist in Canadian legislation

The Canadian government originally proposed to include in the legislation a "right of first refusal" clause that would have allowed patent-holders to scoop contracts negotiated between generic pharmaceutical manufacturers and developing country purchasers. Civil society organizations condemned this clause as anti-competitive, and as a "TRIPS-plus" provision demonstrating bad faith by undermining the international consensus reached in the WTO decision and setting a dangerous precedent.

Eventually, the government agreed to remove this provision, and was also persuaded to avoid substituting equally problematic "alternatives" put forward by the brand-name pharmaceutical industry. Canada's final bill does <u>not</u> include a "right of first refusal" for patent-holders.

Limited list of medicines is a serious flaw

Among the most serious remaining flaws is the bill's list of pharmaceutical products for which a compulsory licence may be issued. The federal Cabinet may, upon the recommendation of the ministers of health and industry, add other products. A ministerial advisory committee will be established.

As enacted, the bill includes an initial list of 56 products that may be subject to compulsory licensing for export. The list is derived principally from the WHO's Model List of Essential Medicines. In response to criticism, the government agreed to also include all those anti-retrovirals (ARVs) for treating HIV/AIDS that are currently approved for sale in Canada.

In the global debate leading up to the adoption of the WTO decision of 30 August 2003, one of the most contentious points was whether the decision should allow compulsory licensing of pharmaceuticals for export only in the case of specific products or only to address specific diseases. This very point delayed an international consensus by at least 8 months. But in the end, WTO Members all agreed their decision would not include these kinds of restrictions.

Canadian advocates therefore (successfully) resisted proposals to limit the Canadian bill to just medicines for HIV/AIDS, TB, malaria or other "emergencies". They also criticized the government for reneging on the international consensus by including any list of specific products, and called for the list to be abolished from the bill. They warned that requiring ministerial recommendations and a cabinet decision to add any other product would permit lobbying by brand-name companies and create delay. The government dismissed these concerns, stating the legislation would not be limited to dealing only with HIV/AIDS, tuberculosis and malaria, nor just to medicines on the WHO model list.

But experience so far indicates NGOs' concerns have proved well founded. Before the bill was passed, the opposition New Democratic Party introduced a motion in Parliament to add a number of medicines to the schedule, including two medicines to treat community-acquired pneumonia. One of those drugs (clarithromycin) is also used to prevent mycobacterium avium complex (MAC), a life-threatening infection in people living with HIV/AIDS. Clarithromycin produced by an Indian generic manufacturer is among the HIV/AIDS medicines pre-qualified by the World Health Organization as meeting quality standards.

Pharmaceutical companies lobbied against the addition of these two medicines. And, notwithstanding the government's previous assurances, its representatives also argued in Parliament against adding them, stating both that they were not on the WHO's list of essential medicines, and (incorrectly) that the medicines were not needed to treat HIV/AIDS, TB or malaria. The government and other parties voted down the motions to add the two medicines. The process illustrates the pitfalls of having such a list of products. This is a very serious flaw in the Canadian legislation.

Possibility of supplying generic fixed-dose combination (FDC) products is unclear

The government also rejected NGO proposals that the bill be amended to automatically include any generic product that has been approved by the WHO's "pre-qualification" project for HIV/AIDS, TB and malaria drugs. This would have included fixed-dose combinations (FDCs) of anti-retroviral drugs that the WHO has recommended as a critical component of efforts to scale up global access to treatment.

Bill C-9 says that any generic product manufactured under a compulsory license for export must meet the same regulatory standards as products sold in Canada. But few FDCs are produced by brand-name manufacturers, and none of the "first-line" FDCs recommended by the WHO. And without an FDC product already approved in Canada to use as a point of comparison, a generic manufacturer faces additional hurdles in getting approval by Canadian regulatory authorities to export some of the medicines that are the most needed for improving treatment access in developing countries.

Adopting a WHO pre-qualification determination as satisfactory for allowing export of a Canadian generic product would help address this problem, at least for HIV/AIDS, TB and malaria drugs. It remains to be seen whether the companion regulations to Bill C-9 will be flexible enough to address this.

NGO procurement of generic pharmaceuticals

The government had accepted arguments that NGOs should be able to purchase directly from Canadian generic manufacturers, and changed the draft bill accordingly. But it then allowed a last minute change undermining this positive change. As a result, Bill C-9 states that any NGO wanting to contract with a Canadian generic producer to obtain a product for use in another country must get the "permission" of the government of that importing country.

NGOs delivering health care services in developing countries should ideally coordinate efforts with governments, who bear the primary responsibility for ensuring access to care. But imposing a legal requirement of government approval for any given contract between an NGO and a Canadian supplier of generic medicines is unwarranted, unnecessary and counterproductive.

What would constitute satisfactory "permission" is not defined anywhere. This requirement applies even if the product is not patented in the importing country or the NGO has obtained a compulsory licence allowing importation, meaning there is no patent barrier to importing it. It also applies even if the product is approved for sale by the importing country's regulator. This requirement is not based on any WTO text. It creates unnecessary hurdles to NGOs getting cheaper medicines to patients, causes further delay in a system that is supposed to be rapid and responsive, and invites government manipulation.

Royalty payable to patent-holder: a sliding scale and an effective 4% cap

Bill C-9 will likely set a reasonably good precedent in its approach to royalties payable to a patent-holder in exchange for the licence to manufacture a patented product. The details remain to be set out in regulations, but the government has committed to establishing a formula linking the royalty rate on any given contract to the importing country's ranking on the UN Development Program's Human Development Index (HDI). The effective cap will be 4% of the value of the contract for the highest-ranking country. Most eligible importing countries rank well below this, meaning royalties in those instances will be lower. If enacted as promised, this would be a positive feature.

Non-WTO developing countries: eligible as importers, but with unjustified restrictions

The government originally intended to permit exports only to WTO Members – and to non-WTO Members recognized by the UN as "least-developed countries" (LDCs). But activists argued that Canada could and should extend this benefit to other non-WTO Members.

In the end, Bill C-9 does allow for compulsory licensing of pharmaceuticals for export to non-WTO countries, but with unjustifiable conditions. A Canadian generic producer may get a licence to export to a non-WTO Member only if that country:

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

This imposes on non-WTO developing countries an unethical "emergency" threshold that is unsound health policy and was rejected by developing countries that *do* belong to the WTO in the negotiations that produced the WTO's August 2003 decision. Imposing an emergency-by-emergency, product-by-product approach is not a sensible way to protect public health and promote access to medicines for all. There is no justification for this double standard between WTO Members and non-Members.

In addition, the country must agree the imported product "will not be used for commercial purposes". Allowing such use may lead to the country being struck off the list of countries eligible to import. This limits the possibility of commercial competition in the importing country's marketplace, undermining the potential benefits of competition in lowering prices. In addition, "commercial purposes" is undefined, raising questions about the distribution of imported generics via commercial actors in the private sector (e.g., retail pharmacies) in the importing country. This provision is unnecessary under TRIPS and the WTO decision and should be abolished.

Unnecessary price and profit caps may invite vexatious litigation

Under Bill C-9, the Canadian patent-holder may apply for a court order terminating a compulsory license or ordering a higher royalty, on the basis that a generic company's contract with a purchaser is essentially "commercial" in nature because it is charging an average price that exceeds 25% of the patent-holder's average price in Canada. The court may not issue the order if an audit demonstrates the generic producer's average price is less than 15% beyond its direct manufacturing costs. This section invites vexatious litigation by patent-holders as a disincentive to generic producers' use of this system. It is an unnecessary "TRIPS-plus" provision that could undermine the effectiveness of the bill. It should be abolished.

Future of Bill C-9 and regulations

The bill is expected to come into force in late 2004 once the companion regulations are finalized. A parliamentary review is scheduled to occur 2 years from the date it comes into force, at which time proposals for amendments may be brought forward. Canada's legislation, and the experience of addressing issues raised along the way, may offer useful lessons for other countries and other activists seeking to implement the WTO decision of 30 August 2003. But Canada's legislation suffers from some important flaws that should not be replicated by other countries. It remains to be seen whether Canada's legislation will contribute to an increased supply of cheaper generic pharmaceuticals or whether the flaws above will undermine the initiative.

The full text of Bill C-9 and numerous related documents, can be found at:
www.aidslaw.ca/Maincontent/issues/cts/patent-amend.htm [English];
www.aidslaw.ca/francais/Contenu/themes/soinstraitements/brevet-amend.htm [français].

For more information: Richard Elliott (relliott@aidslaw.ca), Director, Legal Research & Policy, Canadian HIV/AIDS Legal Network, Tel: +1 (416) 595-1666, Fax: +1 (416) 595-0094