Canada's New Patent Bill Provides a Basis for Improvement

Richard Elliot

On 14 May, Canada became the first country to adopt a law that permits the export of generic medicines manufactured under compulsory licence to developing countries. This article reviews the positive and negative features of the legislation.

On 30 August 2003, the WTO General Council unanimously adopted a Decision on 'Implementation of paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health' (IP/C/W/405). The Decision is supposed to address the difficulties faced by WTO Members lacking sufficient pharmaceutical manufacturing capacity "in making effective use of compulsory licensing" to obtain cheaper medicines. It allows countries with generic manufacturing capacity to permit exports to countries without domestic manufacturing capacity, through an (interim) waiver of the TRIPs Article 31(f) restriction that compulsory licensing may only be used 'predominantly' for supplying the domestic market of a country.

In September 2003, Canadian civil society organisations called on Canada to implement the Decision. On 14 May 2004, Canada became the first country to pass such legislation.[1] 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.

It is significant that a G-7 country has taken such a step, and civil society organisations managed to significantly improve the bill from its original form. In particular, they succeeded in eliminating the anti-competitive 'right of first refusal' clause that would have allowed patent-holders to scoop contracts negotiated by generic suppliers, and rebuffed several problematic 'alternatives' put forward by industry and government. But as the bill still falls short of providing a 'model', other countries should learn from it and avoid replicating its defects.

Limited List of Medicines

Among the most serious flaws is the bill's schedule of pharmaceutical products subject to compulsory licensing. The federal Cabinet may, upon ministerial recommendation, add other products, and an advisory committee will be established.

As enacted, the bill includes a list of 56 products, derived principally from the WHO's Model List of Essential Medicines. In response to criticism, the government agreed to include all those anti-retrovirals for treating HIV/AIDS currently approved in Canada.

WTO Members agreed they would not limit the 30 August 2003 decision to just specific diseases or products. Canadian advocates criticised the government for reneging on that international consensus and urged the list be abolished. They warned that requiring ministerial recommendations and a Cabinet decision to add any 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 these concerns proved well founded. The opposition New Democratic Party proposed the addition of a number of medicines to the schedule, including two medicines to treat community-acquired pneumonia, one of which (clarithromycin) is also used prophylactically 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 Organisation.

Pharmaceutical companies lobbied against the additions. And, notwithstanding the government's previous assurances, its representatives argued in Parliament against the motions, stating the medicines were not needed to treat HIV/AIDS, TB or malaria and were not on the WHO's list of essential medicines. The motions were defeated. The process illustrates the pitfalls of having such a list of products. This is a serious flaw in the Canadian legislation.

NGO Procurement

Bill C-9 states that any NGO wanting to contract with a Canadian generic producer must get the (undefined) 'permission' of the government of the importing country. This requirement applies even if the product is not patented in that country or the NGO has obtained a compulsory licence authorising importation, and even if the product is approved for sale. This requirement is not based on TRIPs or the Decision. It creates unnecessary hurdles to NGOs supplying cheaper medicines and invites political manipulation.

Royalty Payable to Patent-holder

Bill C-9 will likely set a reasonably good precedent in its approach to royalties payable to a patent-holder. 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. The effective cap will be four percent 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 will be a positive feature of Canada's law.

Non-WTO Developing Countries

The Government originally intended to permit exports only to WTO Members – and to non-WTO Members recognised by the UN as 'least-developed countries' (LDCs). But activists argued that nothing prohibited Canada from extending this benefit to other non-WTO Members.

In the end, the bill does allow for compulsory licensing for export to non-WTO countries, but with unjustifiable conditions attached. A Canadian generic producer may get a licence to export to a non-WTO

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Member only if that country:
- is eligible for 'official development assistance' according to the Organisation 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 WTO Members in negotiating the 30 August 2003 Decision.

In addition, the country must agree the imported product "will not be used for commercial purposes." Allowing such use may lead to it being struck off the list. This limits the possibility of commercial competition in the importing country's marketplace. The term is also 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 rejected.

Price and Profit Caps 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 'commercial' in nature. The patent-holder must allege that the generic producer is charging an average price that exceeds 25 percent of the patent-holder's average price in Canada. No such court order may be made if an audit demonstrates the generic producer's average price is less than 15 percent above its direct manufacturing costs. This section invites vexatious litigation by patent-holders as a disincentive to generic producers' use of this system, and is not required under TRIPs or the WTO Decision.

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ENDNOTES

[1] The full text of Bill C-9 and other materials can be found on-line at: http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend.htm.

Textiles Liberalisation Sparks Reactions

With the removal of quotas on textile imports scheduled for 2005, developing countries seek to ensure that other restrictions do not take their place, while textile lobbies argue for delaying action.

The US, the EU, Norway and Brazil have already officially announced that they will terminate remaining quotas on textiles and apparel by 1 January 2005 as required by the Agreement on Textiles and Clothing (ATC). Until now, the US has removed 20 percent of the 937 import quotas in place when the phase-out began, and the EU 32 percent of its original 303 quotas. As the remaining restrictions affect items of the greatest commercial value, the final quota removals will result in profound changes in the international textiles trade, with China and India in line to reap the lion's share of quota-free access to rich country markets. Smaller producers, whose market share has been protected by quotas, stand to lose from across-the-board liberalisation. Least-developed countries and others benefiting from special arrangements, such as the US African Growth and Opportunity Act (AGOA) and the EU's Everything But Arms (EBA) initiative, will see their preferential margins narrow, although continued duty-free access will cushion the effect to a certain extent.

Once textiles are integrated into the WTO in 2005, import tariff reductions will be subject to negotiations in the WTO Negotiating Group on Non-agricultural Market Access. The current average tariff is about 12 percent (compared to 3.8 percent for all industrial goods), but 'sensitive' of fully processed textiles items commonly face tariffs between 30-40 percent. The Doha Ministerial Declaration calls on Members "to reduce or as appropriate eliminate tariffs, including the reduction or elimination of tariff peaks, high tariffs, and tariff escalation, as well as non-tariff barriers, in particular on products of export interest to developing countries."

Preventive WTO Measures and Rearguard US Action Sought

On 13 May, twenty-one member countries of the International Textiles and Clothing Bureau (ITCB), which represents the interests of developing country textile exporters, circulated a communication at the WTO warning against the risk of restraining countries resorting to "alternative methods of protection" when the quotas are removed. The WTO's Textiles Monitoring Body is currently preparing a final review of the implementation of the textiles agreement, and the ITCB urged it to "underscore the desirability of restraining Members from taking steps to avoid any rush to alternate methods of protection by their domestic industries following the abolition of the large bulk of quota restrictions only at the end of the phase-out process." Such methods could include a raft of new anti-dumping and countervailing investigations or safeguard actions, as well as the use of non-tariff barriers such as hiked-up technical standards.

In contrast, the US National Council of Textile Organisations is planning to send a petition to President Bush in late May requesting him to delay the quota removal by a further three years. The letter evokes the possibility of more than 600,000 job losses in the US and as many as 30 million around the world after the quota phase-out. While the motive of the letter is to shield the US textiles industry from vastly increased competition, the Council argues that quota removal would have dire consequences for the US national security: "Many of our key allies in the war on terror, as well as our strategic trading partners, will quickly see millions of their workers put out on the street." The disappearance of jobs and economic hardship would make those nations "less able to lay out massive funds to fight terror and more likely to become hotbeds of terrorist activity," the Council warned. Among US allies likely to be most severely affected by China's dominance, the Council listed Turkey, Egypt, Indonesia, Bangladesh, the Philippines and Pakistan. In addition, the Council said that the destruction of "more than half a million textile and apparel manufacturing jobs in Latin America [would] likely trigger a new wave of illegal immigration that will further burden state and local governments at a time of economic difficulty."

So far, the US Administration has indicated that the phase-out will happen as scheduled.