

Global Access to Medicines: Canada's law on compulsory licensing for export

RICHARD ELLIOTT



Canadian
HIV/AIDS
Legal
Network | Réseau
juridique
canadien
VIH/sida

1 Compulsory licensing and WTO rules

Under the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS), WTO member countries may allow compulsory licensing of patented pharmaceutical products. Compulsory licensing authorizes the production and sale of generic drugs that are therapeutically equivalent to their patented, brand-name counterparts, without the consent of patent-holders. Patent-holders must receive “adequate remuneration” (i.e. a royalty).

By breaking the patent monopoly and introducing competition, compulsory licensing lowers the prices of medicines. Under a 2003 WTO decision, any WTO member country may allow compulsory licensing to produce generic pharmaceutical products solely or primarily for export to countries with insufficient capacity to produce their own.

2 Canada's law

In 2004, following intensive campaigning by civil society groups, the Parliament of Canada unanimously passed the *Jean Chrétien Pledge to Africa Act* to implement the WTO decision. The Act and related regulations came into force in May 2005.

3 Positive features

- The law defines a formula for calculating the royalty payable to the patent-holder when issuing a compulsory license for export. It uses a sliding scale based on the importing country's UN Human Development Index ranking. The maximum royalty is 4% of the total value of the contract between the generic manufacturer and the purchaser.
- Before a compulsory license may be issued, the generic manufacturer must attempt to negotiate a voluntary licence with the patent-holder. The law limits this negotiation period to 30 days.

By defining what constitutes a reasonable royalty rate and negotiation period, these provisions provide clarity to both generic and patent-holding manufacturers negotiating a voluntary licence.

4 Flaws to be fixed

The Act includes conditions that are not required by WTO rules and that make it less likely to be used. Upon reviewing the legislation in 2007, Parliament should repeal:

- the list of pharmaceutical products eligible for compulsory licensing for export — any pharmaceutical product should automatically be eligible;
- the two-year limit on a compulsory license for export, which unjustifiably restricts longer-term planning by governments of developing countries and generic manufacturers;
- the additional requirements that non-WTO developing countries must meet before importing Canadian-made generic drugs, such as declaring a national emergency and agreeing that the imported generics will not be used for “commercial purposes” (an undefined term that may limit distribution channels in the importing country to public facilities);
- the requirement to disclose the importing country to the patent-holder when requesting a voluntary licence — instead, this should be disclosed only after a licence is granted or issued, with the royalty rate determined by the formula contained in the Act;
- the requirement that NGOs obtain permission from a destination country's government before purchasing and importing generic products into that country; and
- the sections allowing patent-holders to start legal proceedings challenging contracts between generic manufacturers and importing countries for being “commercial” in nature.

Contact

Richard Elliott
Deputy Director
relliott@aidslaw.ca

Canadian HIV/AIDS Legal Network
1240 Bay Street, Suite 600
Toronto, Ontario M5R 2A7
Telephone: +1 416 595-1666
www.aidslaw.ca