Flirting with Flawed Patent Law Amendment, Canada May Undermine Welcome 'Access to Medicines' Initiative

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In November 2003, Canada moved to introduce compulsory licenses to authorise the production of generic pharmaceuticals for export to countries lacking sufficient manufacturing capacity. While the government's draft legislation is positive in some respects, it also contains several serious flaws. These can be easily fixed if the Canadian government has the political will to do so.

On 30 August 2003, the WTO General Council unanimously adopted its 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 solve the difficulties faced by WTO Members lacking sufficient pharmaceutical manufacturing capacity "in making effective use of compulsory licensing under the TRIPs Agreement".

At the end of September 2003, in response to calls from Canadian civil society organisations and from Stephen Lewis, the UN Special Envoy on HIV/AIDS in Africa, the Government of Canada announced it would change Canadian patent law to implement the WTO decision. Following the announcement, Canadian civil society organisations engaged in extensive discussions with government officials, with a view to ensuring that the government fully implements the WTO decision, in all its flexibility, so as to assist developing countries in making effective use of compulsory licensing in responding to their public health problems.

The government introduced a bill in Parliament on 6 November 2003. Bill C-56 would amend the Patent Act to provide for the issuance of compulsory licenses allowing generic pharmaceutical manufacturers to make and export generic versions of patented pharmaceutical products to countries lacking their own manufacturing capacity. Although the bill was not passed before Parliament ended its session on 12 November 2003, it is anticipated that it will be re-introduced in the next session, in early 2004.

Canadian civil society organisations welcomed the introduction of the legislation. The bill does not contain any restricted list of diseases or health conditions for which compulsory licensing may be used to obtain pharmaceuticals. Nor does it limit the use of compulsory licenses to only supplying countries facing an "emergency" or other circumstances of extreme urgency. These sorts of restrictions had already been rejected in multilateral negotiations leading to the WTO decision of 30 August 2003. Civil society had called on the government not to unilaterally re-introduce such restrictions in Canada's approach to implementing the WTO decision.

However, several serious concerns remain about the legislation. Canadian civil society organisations strongly support the initiative to allow compulsory licensing for exporting lower-cost generic pharmaceutical products to countries in need. But the flaws in Bill C-56, as it is currently drafted, will undermine this objective. Therefore, the legislation needs to be changed in several key respects before it is enacted.

Provisions permitting anti-competitive action by patent-holders to block licences for generic manufacturers

As introduced in Parliament, Bill C-56 creates a "TRIPs-plus" entitlement for Canadian patent-holders, permitting anti-competitive action that would block generic manufacturers from obtaining licences to produce and export pharmaceuticals.

Bill C-56 sets out a process whereby a generic manufacturer wishing to produce a patent-protected product for export must notify the Commissioner of Patents of its intent to apply for a compulsory licence. The notice must set out the name of the product, the quantity to be produced, the country to which it is to be exported, and the terms and conditions of the contract between the generic manufacturer and the government of the country in question.

The notice must also include either a declaration that the product is not patented in the destination country or, if it is patented there, a written statement from the country that it has granted or intends to grant a compulsory licence in accordance with Article 31 of TRIPs. In the case an importing country that belongs to the WTO, the document submitted must be the notice in writing that the country has provided to the TRIPs Council, in accordance with the General Council's decision of 30 August 2003.

That notice must then be sent to the holder of the Canadian patent for the product, and the patent-holder then has 30 days to decide how to respond. The patent-holder is given the right to take over contracts negotiated by generic pharmaceutical manufacturers with developing country governments. In order to do so, the patent-holding company must meet the terms of the contract negotiated by the generic manufacturer with the developing country purchaser.

Not only does the patent-holder get to assume the would-be competitor's contract, if it does so, this (a) relieves the patent-holder from any obligation to negotiate the terms of a voluntary licence for the generic manufacturer, and (b) also prevents the Commissioner of Patents from issuing a compulsory license to the generic company (with "adequate remuneration" payable to the patent-holder to be fixed by the Commissioner). The result is that no licence, either voluntary or compulsory, is obtained by the generic manufacturer.

In a few initial cases, this process could secure a lower price on a particular medicine for a developing country that has negotiated a contract with a generic manufacturer, by requiring the patent-holder to meet the contractual terms. However, under such a

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legislative scheme, generic manufacturers would quickly lose any incentive to even negotiate such contracts in the first place. The company holding the patent would be able to repeatedly block the generic manufacturer from obtaining the licence needed to make the product and fulfil the contract. In short order, there would be no potential competition from generic manufacturers and there would be no reason for the brand-name company holding the patent to lower its prices.

Such provisions will frustrate the stated objective of implementing the WTO decision of 30 August 2003. That decision is aimed at enabling countries lacking pharmaceutical manufacturing capacity to make effective use of compulsory licensing to obtain less expensive pharmaceutical products. Giving Canadian patent-holders another means of blocking generic companies from getting licences runs directly counter to this objective.

Civil society organisations have identified these provisions as 'TRIPs-plus' since they go beyond the requirements of TRIPs. They give a further entitlement to patent-holders that will be used to preclude generic manufacturers from obtaining the necessary licences to manufacture and export pharmaceutical products to developing countries with which they have negotiated supply contracts.

Under Article 31(b) of the TRIPs Agreement, the patent-holder is entitled to benefit from the requirement that, before a compulsory licence can be issued, the patent-holder must be engaged in negotiating a possible voluntary licence for the generic producer "on reasonable commercial terms." If those negotiations do not succeed "within a reasonable period of time", a compulsory licence may be issued by the appropriate authority, which then fixes the "adequate remuneration" to be paid to the patent-holder. Either way, however, the generic producer may obtain a licence and the patent-holder receives some compensation.

Under the proposed 'TRIPs-plus' provisions, generic manufacturers would quickly lose any incentive to negotiate contracts with developing countries. Giving Canadian patent-holders another means of blocking generic companies from getting licenses runs directly counter to the objective of the WTO's General Council decision on 30 August 2003.

Currently, Canada's Bill C-56 would create an added benefit for patent-holders: by taking over a contract negotiated by a generic manufacturer, the patent-holder can block the generic manufacturer from obtaining any licence at all, whether voluntary or compulsory. In this fashion, the bill goes beyond Canada's obligations under TRIPs to protect intellectual property rights, to the detriment of efforts to respond to public health problems in developing countries.

Limited list of pharmaceutical products

The bill includes a limited list of pharmaceutical products for which a compulsory license may be obtained. The bill consists of those products on the WHO Model List of Essential Medicines that are patented in Canada. The bill also states that the Cabinet of the Government of Canada may authorise the addition (or removal) of any other "patented product that may be used to address public health problems", and that the Cabinet may establish an "advisory committee" to advise it on products to be added (or removed) to the approved list.

Civil society organisations have objected to the inclusion of a limited list of products and have expressed concerns about the potential failings of the process for adding products to the list. A limited list of products would represent a step backward from the multilateral agreement reflected in the WTO decision of 30 August 2003, in which all WTO member countries endorsed an approach that is not restricted to just specific medicines or other products.

Civil society organisations have, therefore, put forward proposals to improve this aspect of the bill. The objective is to ensure that the Canadian legislation is responsive to the needs of developing countries addressing public health problems, and also respects the right of sovereign developing countries to determine, for themselves, which problems warrant the use of compulsory licensing to obtain less expensive pharmaceutical products.

Denial of benefit to some non-WTO developing countries

Under the current scheme proposed in Bill C-56, all countries recognised by the United Nations as "least-developed countries" (LDCs) may benefit from the export of generic pharmaceutical products from Canada, regardless of whether they belong to the WTO or not. However, in the case of other developing countries, which are not "least-developed" countries, Bill C-56 only recognises those countries that are WTO members. Developing countries that do not belong to the WTO are unable to benefit from the possibility of importing generic pharmaceuticals from Canada.

There is no sound basis for excluding such countries from potentially benefiting from the legislation. Civil society organisations have called on the government to correct this exclusion and to ensure that all developing countries may benefit. WTO membership should not be the price paid for being able to import lower-cost medicines from Canadian suppliers.

No provision for NGOs to procure generic medicines

Currently, Bill C-56 only contemplates that a government, or an "agent of that government", could enter into a contract with a Canadian generic manufacturer to purchase a pharmaceutical product. Non-governmental organisations and other private-sector entities providing treatment in a developing country are not "agents" of government, and may not be covered by the bill. It would be a stretch to interpret the phrase "agent of that government" as encompassing non-governmental organisations. There is nothing in the WTO decision of 30 August 2003 on compulsory licenses for export that limits the use of the system to governments and their agents, nor is this required under TRIPs. This limitation should be removed.

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