

Access to medicines and global health: Will Canada lead or flounder?

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With its Bill C-56 to amend the Patent Act and the Food and Drugs Act in order to ease patent restrictions¹ to allow the export of generic versions of patented drugs to the developing world, Canada may lead the way internationally in taking a concrete step to address the suffering of people in the developing world who lack access to essential medicines. Bill C-56 was a speedy response to challenges posed in September 2003 by Stephen Lewis, United Nations Special Envoy for HIV/AIDS in Africa,² and Canadian nongovernmental organizations. Amid much political wrangling and in the face of a leadership transition in the governing Liberal Party, the bill passed second reading in the House of Commons on Nov. 7, 2003, and will go to open committee hearings before proceeding to its third and final reading. If the bill passes, Canada will be the first country with generic pharmaceutical manufacturing capacity to respond to 2 recent World Trade Organization (WTO) agreements on access to essential medicines with domestic legislative changes that give teeth to the agreements. The question is: Will Canada lead with changes that meet both the letter and the spirit of the WTO agreements, or will it flounder with changes that address some of the elements of the agreements but fail to harmonize with their overall intent? The answer will not be determined by whether or not the bill is passed, for it surely will be, but rather by whether or not it is amended before it is passed.

When people think about access to essential medicines, many of them think about HIV/AIDS. There are 42 million people living with HIV infection worldwide, and AIDS kills more than 3 million people each year, the vast majority of whom are in the developing world. In 2002 alone, 2.1 million people died of AIDS in sub-Saharan Africa. The fastest growing rate of new infections is in India, Russia and the former Soviet republics.³ Thirty million people in sub-Saharan Africa are infected with HIV, but fewer than 30 000 of them have access to treatment with anti-retroviral drugs, which has cut mortality rates by upward of 80% in most settings. Diseases such as leishmaniasis and tuberculosis often interact synergistically with HIV/AIDS and cause untold suffering in the developing world, all but hobbling social and economic development. AIDS is a transcendent global health emergency that is threatening the very viability of many nations. Action must be taken.

Contrary to common perceptions, however, Canada's Bill C-56 is not just about exceptions to patent protection

and international trade agreements as they pertain to access to medicines for the treatment of HIV/AIDS. This is certainly an important issue, but in terms of access to essential medicines in the developing world, it is the thin edge of the wedge. Fourteen million people die of treatable infectious diseases worldwide each year (including 6 million deaths from AIDS, tuberculosis or malaria), and over 95% of these deaths occur in the developing world. African sleeping sickness, diarrheal diseases and acute respiratory tract infections are just some of the treatable infectious diseases costing the lives of millions. This burden is in addition to that caused by other treatable diseases such as diabetes, asthma and cancer. One in 3 people in the world do not have access to essential medicines, and in the most impoverished parts of Africa and Asia the figure rises to half of all people.⁴

The governments of developing countries recognized this broad reality and the corollary that exceptions to trade agreements cannot only be about emergencies such as AIDS, tuberculosis and malaria, but must also be about the sovereign responsibility of governments both to define public health needs and to act to ensure that these needs are addressed meaningfully.

As it currently stands, Canada's Bill C-56 uses much of the right language; it adopts key phrases from the *Declaration on the TRIPS Agreement and Public Health*,⁵ a companion agreement to the WTO's *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS Agreement), and one to which the WTO member nations unanimously agreed at Doha in 2001 after 3 years of intense negotiations. The negotiations pitted trade interests and the protection of patent monopolies against the duty of governments to respond to the human needs created by untreated — but treatable — disease. Humanitarian nongovernmental organizations and the governments of developing nations were on one side of the debate, the patent-protected pharmaceutical industry and the governments of mostly Western nations on the other. Every carefully crafted word of the Doha *Declaration on the TRIPS Agreement and Public Health* represented months of battle. The parties finally came to agreement and adopted the declaration on Nov. 14, 2001, only days after Canada and the United States threatened to issue a compulsory licence for the generic production of ciprofloxacin in response to the anthrax bioterrorism scare that followed the Sept. 11, 2001, terrorist attacks. Canada and the United States could not deny

that what was good for the goose (themselves) was good for the gander (developing nations).

Before the agreement in the 2001 Doha Declaration was reached, the TRIPS Agreement made no viable provisions for access to patented life-saving essential medicines for people with little or no purchasing power. The declaration did more than provide a political means to address this market failure: it reaffirmed the responsibility of nations to act to protect the public health of their citizens. The most important statement in the Doha Declaration is that “the TRIPS Agreement does not and should not prevent members from taking measures to protect public health ... and, in particular, to promote access to medicines for all.”⁵

Following further negotiations, WTO member governments reached a second unanimous agreement on access to essential medicines on Aug. 30, 2003.⁶ It provides a legal mechanism that makes it easier for countries with little or no domestic pharmaceutical manufacturing capacity to import generic versions of patented medicines, settling the one point that remained unresolved in the 2001 agreement.

A number of elements in the 2001 and 2003 agreements are noteworthy. First, in spite of enormous and unprecedented pressure from the pharmaceutical industry, the agreements were adopted without the proviso that they apply only to medicines for a particular list of diseases. It was of crucial importance to the developing nations that the other WTO member states respect their sovereign responsibility and right to protect the public good and, in so doing, to define and meet the needs of their people. Second, the agreements were adopted without the inclusion of statements that they apply only in defined types of emergencies. No one can reasonably predict all potential emergency needs, and governments must retain the right to act immediately to contain and control such threats. Third, the agreements include a provision whereby nations that decide to import generic medicines through the use of compulsory licences must notify the WTO of their intent but do not need to seek its approval, thereby avoiding an onerous bureaucratic approval process. Health needs are often pressing (as with anthrax and SARS, for example), and a government’s response cannot be left vulnerable to political interference and delaying tactics by powerful private actors, as has been the case with HIV/AIDS. For developing nations, these 3 elements are hard-won victories that embody the spirit of the 2 agreements.

Bill C-56 demonstrates that Canada has not ceded to pressure from the patent-protected pharmaceutical companies on any of these 3 points. But it may yet fail to meet the spirit of the WTO agreements. The bill currently includes a provision whereby patent holders must be given the opportunity to meet the terms of an agreement that companies manufacturing generic medicines have negotiated with a developing nation.⁷ This effectively gives patent holders the right of first refusal. Only if the patent holder declines the opportunity to take up the terms of the negotiated agreement can the Commissioner of Patents then set a reasonable

royalty payable to the patent holder and issue a compulsory licence for export to the manufacturer of the generic product. With this right of first refusal, patent holders have no incentive to negotiate lower prices with governments of developing nations on their own. For companies manufacturing generic drugs, it creates a disincentive to negotiate with the governments of developing countries, because the deal will inevitably be taken over by the patent holder⁸: it is extremely unlikely that any company would undertake the transaction costs of negotiating a deal for another company. The net effect may well be a stifling of market competition that will ultimately keep essential medicines out of the reach of people or nations with little purchasing power.

This provision in Bill C-56 protects private interests to a far greater extent than the TRIPS Agreement. If this “TRIPS-plus” provision holds, it will render the WTO negotiations of the last 5 years all but irrelevant. Several other issues, such as whether or not all non-WTO-member developing countries qualify for inclusion under the bill (currently some do not), the need to remove a defined schedule of eligible pharmaceutical products,⁹ the need to ensure that drugs or drug combinations currently not in use in Canada can be manufactured for export, and the need to ensure that nongovernmental agents or organizations can enter into a contract with a Canadian manufacturer of generic drugs that would seek a licence to export pharmaceutical products, will also have to be appropriately re-dressed before the bill reaches third and final reading.

Although Canada’s Bill C-56 has been praised by the World Health Organization¹⁰ and the UN Special Rapporteur on the Right to Health,¹¹ the question remains: Will Canada lead or will it flounder? For better or for worse, Canada’s approach will set a precedent for other nations that have a strong capacity to manufacture generic drugs. If Canada fails to make the necessary amendments to Bill C-56, it will flounder. This would be a colossal lost opportunity and may set a disastrous international precedent that would take years to overcome. In the interim, millions of people with treatable diseases would lose their lives because of lack of access to medicines. If Canada leads, by ensuring that its legislative changes meet both the letter and the intent of the 2001 and 2003 WTO agreements, it will demonstrate a visionary approach to global health for the 21st century, with positive effects for millions of people around the world. This will require that Canada be prepared to ensure, globally as well as domestically, that public interests trump private interests. Let’s see what happens.

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References

1. Bill C-56, *An Act to amend the Patent Act and the Food and Drugs Act*, 2d sess, 37th Parl, 2002–2003 (1st reading 6 Nov 2003). Available: www.parl.gc.ca/37/2/parlbus/chambus/house/bills/government/C-56/C-56_1/C-56_cover-E.html (accessed 11 Dec 2003).

2. *Statement by Stephen Lewis, the UN Secretary-General's Special Envoy for HIV/AIDS*; 25 Sept 2003. Available: www.cptech.org/ip/health/c/canada/Lewis09252003.html (accessed 11 Dec 2003).
3. Hanks C. Overview of the AIDS pandemic. In: *Presentations from the 6th International Conference on Healthcare Resource Allocation for HIV/AIDS*; 2003 Oct 13; Washington (DC). Available: www.iapac.org/text/pdf/6thICHRAPresentations/hanksFinalIapacAllocation.pdf (accessed 13 Nov 2003).
4. World Health Organization. *WHO medicines strategy: framework for action in essential drugs and medicines policy 2002-2003*. Geneva: The Organization; 2000. p. 36. Available: www.who.int/medicines/strategy/strategy.pdf (accessed 16 Dec 2003).
5. World Trade Organization. *Declaration on the TRIPS agreement and public health* [Doha WTO Ministerial 2001: TRIPS]. Geneva: The Organization; 2001 Nov 14. Available: www.wto.org/english/thewto_e/minist_e/minist01_e/mindecl_trips_e.htm (accessed 7 Nov 2003).
6. World Trade Organization. *Decision removes final patent obstacle to cheap drug imports*. Geneva: The Organization; 2003 Aug 30. Available: www.wto.org/english/news_e/pres03_e/pr350_e.htm (accessed 7 Nov 2003).
7. Bill C-56, *An Act to amend the Patent Act and the Food and Drugs Act*, 2d sess, 37th Parl, 2002-2003, cl 21.04 (6) and (7) (1st reading 6 Nov 2003). Available: www.parl.gc.ca/37/2/parlbus/chambus/house/bills/government/C-56/C-56_1/90247bE.html#2 (accessed 11 Dec 2003).
8. Canadian Press. *PM proposes law to allow drugs for poor nations*. 6 Nov 2003. Available: www.ctv.ca/servlet/ArticleNews/story/CTVNews/1068147930736_63557130//?hub=Canada (accessed 11 Dec 2003).
9. Bill C-56, *An Act to amend the Patent Act and the Food and Drugs Act*, 2d sess, 37th Parl, 2002-2003, cl 21.03 (1st reading 6 Nov 2003). Available: www.parl.gc.ca/37/2/parlbus/chambus/house/bills/government/C-56/C-56_1/90247bE.html#2 (accessed 11 Dec 2003).
10. World Health Organization. *Statement of the World Health Organization on Canada's proposed legislative changes for medicines*. 7 Nov 2003. Available: www.who.int/mediacentre/statements/2003/statement14/en/print.html (accessed 11 Dec 2003).
11. *UN rights expert welcomes Canadian initiative on access to low-cost drugs in developing countries* [press release]. 7 Nov 2003. Available: www.unog.ch/news2/documents/newsen/hr0387e.htm (accessed 11 Dec 2003).

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