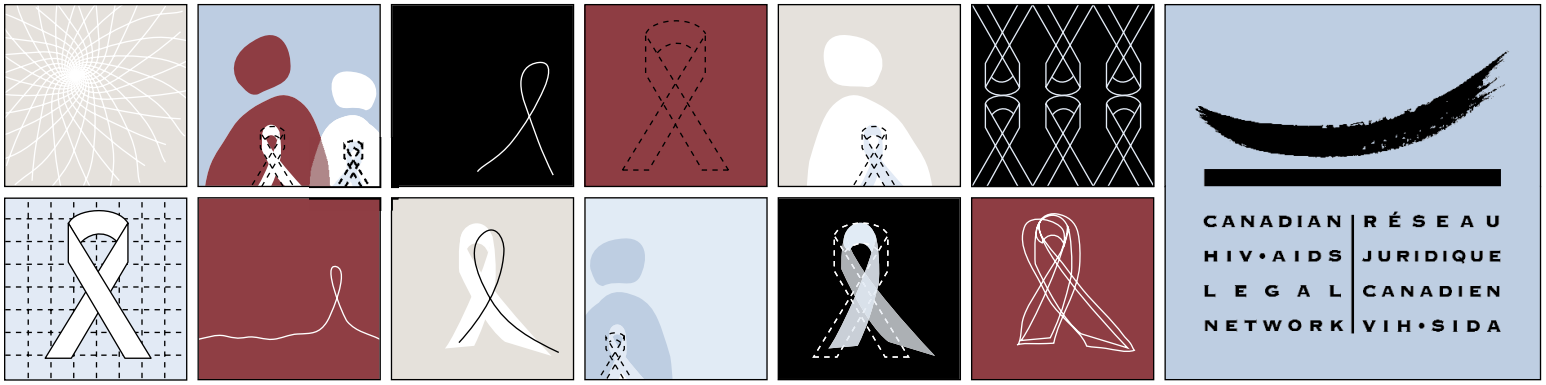


GLOBAL ACCESS TO MEDICINES:

WILL CANADA MEET THE CHALLENGE?

BRIEF TO MEMBERS OF PARLIAMENT ON BILL C-9

An Act to amend the Patent Act and the Food and Drugs Act

Many civil society organizations welcomed Bill C-9 when it was first introduced as Bill C-56 in November 2003. The bill has the potential to alleviate great suffering and save many lives in countries that cannot make their own generic medicines. Yet that objective will be undermined unless flaws currently found in Bill C-9 are fixed. This document:

- *provides background on Bill C-9;*
- *explains flaws currently found in the bill;*
- *identifies changes to the bill that will correct these flaws; and*
- *answers questions about the bill and access to medicines.*

BACKGROUND: WTO RULES ON PATENTS

Bill C-9 is supposed to implement an August 30 2003 decision of the World Trade Organization that relaxes rules on patents in the WTO's "TRIPS Agreement" (Agreement on Trade-Related Aspects of Intellectual Property Rights). Many developing countries cannot afford the prices charged by brand-name companies for patented medicines, but also lack the capacity to make lower-cost, generic medicines themselves. The TRIPS Agreement limited their ability to import drugs from countries such as Canada where generic producers exist but the medicines are under patent. The TRIPS rules restricted a country like Canada from issuing "compulsory licences" that would authorize generic companies to make cheaper, generic versions of patented medicines for export to countries in need. The August 2003 WTO decision is supposed to solve this problem.

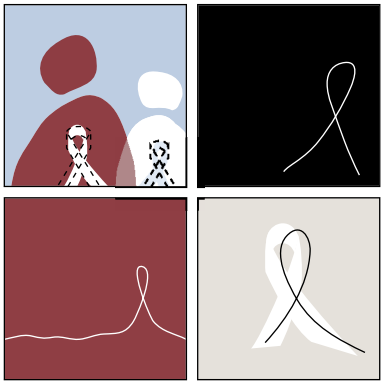
Adopted by consensus, the August 2003 decision was a concrete follow-up to the "Declaration on the TRIPS Agreement and Public Health" (the "Doha Public Health Declaration"), adopted unanimously by WTO member countries in November 2001. The Declaration affirmed the right of countries to decide when to limit patents through compulsory licensing to deal with health needs (para. 5), and agreed that patent rules in TRIPS should be interpreted and implemented so as to support countries' "right to protect public health and, in particular, to promote access to medicines for all" (para. 4).

Based on the principles set out in the Declaration, the August 2003 WTO decision allows Canada to issue licenses for generic pharmaceutical manufacturers to produce copies of medicines patented in Canada and export them to countries unable to make their own. But the decision must be implemented in Canadian law first. If done properly, Bill C-9 will make this possible.

The UN Secretary-General, the World Health Organization, the UN Special Envoy on HIV/AIDS in Africa (Stephen Lewis), and UNICEF have all welcomed Canada's initiative, as have respected human rights organizations and civil society groups from around the world. But Canada risks sabotaging this initiative unless fundamental flaws in Bill C-9 are fixed before it is enacted.

HOW BILL C-9 CAN MEET ITS OBJECTIVE

To achieve the stated objective of improving access to pharmaceutical products, Bill C-9 must be amended before it is enacted. This table outlines flaws in the bill and changes that can easily resolve these concerns.



SECTION OF BILL	WHAT MUST BE FIXED? AND HOW?
The "right of refusal" provisions (every 2 years) Sections 21.04(6)(a) 21.04(7)(a) and corresponding references in section 21.05(5) and section 21.09	Problem: In order to supply a purchaser in a developing country with a less expensive, generic version of a medicine that is under patent in Canada, the generic producer must get a licence to avoid being sued for infringing the patent. If the company holding the patent refuses to give a voluntary licence in exchange for a royalty, the generic company applies to the Commissioner of Patents for a "compulsory licence" that will allow it to fulfill its contract with the purchaser. The application must set out the terms of the contract. But **Sections 21.04(6)(a)** and **21.04(7)(a)** would give the company holding the patent on medicines the "right" to scoop contracts that generic producers have negotiated to supply products at lower prices to purchasers in developing countries. **Section 21.05(5)** says that if the company with the patent exercises this "right," the generic producer is blocked from getting any license at all, meaning it cannot fulfill its contract. Furthermore, **Section 21.09** says that generic manufacturers can only get a license for 2 years. At that time, a new application for a license must be filed, and the patent-holder again gets the "right" to take over any contract negotiated by the generic producer. This flaw goes to the very heart of the legislation. If these sections stay in Bill C-9, generic producers will have no incentive to even negotiate contracts with countries in need of cheaper medicines. In the absence of any competitive pressure, companies holding patents will also have little reason to lower their prices. Patients in developing countries will be unlikely to gain access to more affordable medicines. Bill C-9 will be meaningless. Solution: *Delete sections 21.04 (6)(a) and 7(a) and the corresponding reference to them in section 21.05(5). Amend section 21.09 to allow licenses for the duration of the generic producer's contract to supply the product for use in the importing country. These changes would mean Bill C-9 could actually achieve its objective. The bill would properly implement the WTO August 30, 2003 decision and still comply with Canada's obligations under TRIPS.*
Exclusion of some developing countries that are not WTO members Schedule 3	Problem: Under Bill C-9, all "least-developed countries" (LCDs) are eligible to import generic medicines from Canadian producers, whether or not they belong to the WTO. But **Schedule 3**, which lists developing countries – other than "least-developed" ones – that are also eligible to import generic medicines from Canada, only includes WTO members. Developing countries that do not belong to the WTO are excluded. People in all developing countries should have access to affordable medicines regardless of whether their country belongs to the WTO. Countries such as Viet Nam, East Timor, Lebanon, Uzbekistan and many others struggle with poverty, low per capita income, and many public health needs, but do not belong to the WTO. Patients in those countries should also benefit from this important legislation. Solution: *Include non-WTO developing countries in Schedule 3.*

Limited list of pharmaceutical products

SCHEDULE 1

AND

SECTION 21.03(1)(A)

PROBLEM: **Schedule 1** sets out a list of patented products for which generic manufacturers may get licenses to produce and export. **Section 21.03(1)** says that an order of the federal Cabinet is required to add products to the list.

This list should not be closed, nor should a Cabinet decision be required to add new pharmaceutical products needed by patients in developing countries. Such provisions create opportunities for political interference aimed at delaying licences for generic producers. Developing countries, as sovereign decision-makers, can determine for themselves the pharmaceutical products they need to protect public health in their context. The law of an importing country determines whether it is permitted to import a generic medicine into that country. There is no reason why Canada's federal cabinet should second-guess these decisions. This kind of red tape in Bill C-9 hinders Canadian generic pharmaceutical producers from responding to the needs of developing countries. Neither TRIPS nor the WTO's August 2003 decision requires any limited list of products. The August 2003 decision simply refers to "pharmaceutical products". The Doha Public Health Declaration expressly reaffirms countries' right to decide when to limit patents on medicines in order to deal with public health problems.

SOLUTION: *Delete Schedule 1 entirely.*

No provision for NGOs or international organizations to obtain generic medicines for patients in developing countries

SECTION 21.04(2)(F)

PROBLEM: In order to get a license to supply medicines for use in a developing country, the Canadian generic manufacturer must file certain information with the Commissioner of Patents. **Section 21.04(2)(f)** says that the manufacturer must file the terms of its contract with "the government" of that country or "agent of that government".

While it is critical that governments strengthen access to health care in the public sector, the crucial role that UN agencies and non-governmental humanitarian relief organizations play in the delivery of health care services in developing countries – operating clinics, hospitals and other treatment sites – should not be overlooked. While not "government agents," these organizations also purchase medicines from pharmaceutical companies (both brand-name and generic) and need lower-cost supplies for their patients.

Bill C-9 should acknowledge this reality. A non-governmental organization (NGO) may be entitled, under the laws of the country where it works, to import and use generic versions of a medicine for their patients – either because the medicine is not patented in that country or because the NGO has obtained the necessary licence from a court or appropriate government authority. If this is the case, then it should be able to contract directly with a Canadian generic producer to obtain the medicine.

SOLUTION: *Amend section 21.04(2)(f) to read as follows:*

"...the contractual terms and conditions of the agreement between the person and the government of the country or WTO Member, the agent of that government, or other purchaser legally entitled to import and distribute the product in the country or WTO Member, under which the pharmaceutical product referred to in paragraph (b) is to be manufactured and sold for export."

COMMON QUESTIONS

As long as cheaper medicines arrive for those who need them, does it matter whether they come from the patent holder or a generic company?

Unless it is amended, Bill C-9 will not lead to cheaper medicines. Bill C-9 gives patent holders the "right" to take over any contracts negotiated by generic manufacturers. This means that patent holders can block generic manufacturers from obtaining licences they need to fulfil their contracts, removing any real incentive for generic manufacturers to negotiate contracts to supply cheaper medicines for use in developing countries, and eliminating any pressure on brand-name companies to lower their prices. Effectively, there will be no Canadian supplier of cheaper medicines – brand-name or generic – for patients in developing countries.

Aren't the "right of refusal" provisions in Bill C-9 required under the WTO's TRIPS Agreement?

No. Under TRIPS, before a compulsory license can be issued, the patent-holder must first be asked to agree to a voluntary license "on reasonable commercial terms." If it does not agree "within a reasonable period of time," then a compulsory license may be issued by the appropriate authority under the law of the country, such as a government official or an independent court or other quasi-judicial decision-maker. This benefit – or a first 'right' of refusal – is already found in sections 21.04(6)(b) and 21.04(7)(b) of Bill C-9. These sections give the patent holder the chance to agree to issue a voluntary license to the generic manufacturer in exchange for a reasonable royalty (of 2% as set out in the bill). That is all that is required under TRIPS.

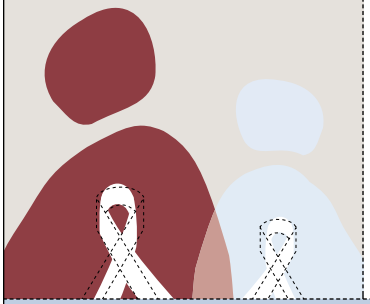
However, Bill C-9 introduces an extra, second "right" of refusal for the patent-holding company in sections 21.04(6)(a) and 21.04(7)(a). Even if it has already refused to issue a voluntary license, the company with the patent gets another opportunity – this time, to decide whether it will supply the product to the developing country purchaser itself. These sections allow patent holders to completely block any license for a generic manufacturer, by instead scooping the contract for themselves. *This is not required under TRIPS.*

In fact, these provisions are at odds with the Doha Declaration on the TRIPS Agreement and Public Health, endorsed by Canada in November 2001, which states that TRIPS should be interpreted and implemented in a manner that helps promote access to medicines for all. Canada's Bill C-9 should not introduce unnecessary "rights" for patent-holding companies that undermine the goal of getting affordable medicines to people who need them in developing countries. This would be an act of bad faith.

Why do developing countries need access to generic medicines if companies holding patents lower their prices or donate medicines?

These brand-name offers are made on drug-by-drug basis, can be withdrawn in the future, and often come with conditions and restrictions limiting the benefit to relatively few people. Countries cannot rely on charity by multinational pharmaceutical companies to ensure comprehensive, sustainable access to affordable medicines, nor should they have to. Sovereign nations are free to set their own policies for dealing with health care needs. This includes fostering market competition as a way to lower prices. The availability of generic competitor drugs has prompted significant offers by brand-name companies to reduce prices.

The ability of countries to resort to compulsory licensing to get cheaper generic medicines is crucial to creating such competitive pressure. The Doha Public Health Declaration explicitly reaffirms that every country can decide for itself when, and on what grounds, it will issue compulsory licenses. The WTO's August 2003 decision is supposed to put countries lacking the ability to make their own pharmaceuticals in a position "to make effective use of compulsory licensing." Bill C-9 should follow through properly by implementing the WTO decision in a way that makes it possible for countries to use compulsory licensing to get access to generic pharmaceuticals made in Canada.



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BY FIXING BILL C-9, CANADA CAN BECOME A LEADER IN EXPANDING ACCESS TO AFFORDABLE MEDICINES IN DEVELOPING COUNTRIES.