

Bill C-9

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

Comments from Canada's Generic Pharmaceutical Industry

February 2004



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Table of Contents

	Page
Introduction: The CGPA supports Canada's initiative to make generic medicines available to developing countries	1
What is wrong with the current legislation?	2
• Bill C-9 is unnecessarily complex and imposes an onerous burden on a generic company seeking a license	2
• Bill C-9 does not provide the generic industry with the assurance of the ability to sell the products they develop	2
• Bill C-9 creates unnecessary barriers to the delivery of affordable medicines	3
CGPA Proposed Amendments	3
1) Right of First Refusal (s. 21.04)	3
2) The buyer should not be restricted to a foreign government or its agent (s. 21.04(2)(f))	4
3) Drugs should not be limited to those listed on a schedule to Bill C-9 (Schedule 1)	5
4) Export provision	6
5) No need for scrutiny of whether the product is "distinguished" (21.05(3)(ii))	7
6) Generic should not have to file patent information about the importing country (s. 21.04(3))	8
7) Breadth of compulsory license	8
8) Canada should buy the drugs and distribute them itself	9
Conclusion	9

Appendix A:

Overview of Canada's Generic Pharmaceutical Industry

Appendix B:

Quick Facts on Prescription Drug Spending in Canada

Appendix C:

Member Companies of the Canadian Generic Pharmaceutical Association

Introduction: The CGPA supports Canada's initiative to make generic medicines available to developing countries

The Canadian Generic Pharmaceutical Association (CGPA) and its member companies support the Government of Canada's initiative to make Canadian-made generic pharmaceuticals available for export to developing countries under the landmark World Trade Organization (WTO) agreement of August 30, 2003.

Member companies of the CGPA donate millions of dollars worth of generic medicines annually to the developing world. In most cases, these drugs are donated to Non-Governmental Organizations who administer the drugs directly to people in the developing world who need them.

For example, through Mercy International, Apotex donated \$733,000 worth of generic medicines for use in Afghanistan in December 2003 and \$340,000 in medicines to Sudan in October 2003. In February 2004, Apotex donated \$250,000 in medicines to earthquake victims in Bam, Iran.

Novopharm donates millions of dollars of generic medicines annually through its Canadian Medicine Aid Program (CANMAP).

Canada's generic pharmaceutical industry has been encouraging the Government of Canada to take action to help developing nations gain access to affordable medicines since the Doha Declaration of November 2001.

While the intent of Bill C-9 is commendable, this initiative will not deliver getting Canadian-made generic pharmaceuticals to people in the developing world who desperately need them unless dramatic changes are made to the legislation.

Bill C-9 is a Government of Canada initiative that requires action by the private sector in order for it to succeed. The legislation places such onerous burdens on generic companies that they would be unlikely to consider participating in this initiative.

Our member companies make business decisions based on market prospects. At best, this initiative is a break-even proposition for generic companies as there are no assurances of a long-term ability to sell products. No company in any sector could justify making significant investments without the ability to recoup their investments.

Generic versions of the pharmaceutical products required by developing countries have not been developed by Canadian companies as they are currently protected by domestic patents. Companies will generally need to develop generic products for export before they begin to enter into contract negotiations.

The development and production of generic pharmaceuticals is a long and expensive process. It takes generic drug companies years of work and millions of dollars to bring a product to market.

This money is spent to develop processes to synthesize chemicals, to develop formulations, to develop test methods and stability data to ensure quality, to test for therapeutic equivalence in volunteers and to obtain regulatory approval from Health Canada.

The overall requirements must be greatly simplified and market certainty must be afforded before generic companies will consider participating in this initiative.

The generic pharmaceutical industry has communicated its position to the Government of Canada in consultations and in writing since the introduction of Bill C-56 in November 2003. Even though CGPA and other groups have identified major problems, the government made the decision to reinstate the legislation as Bill C-9 in the House of Commons without amendment.

What is wrong with the current legislation?

Bill C-9 is unnecessarily complex and imposes an onerous burden on a generic company seeking a license

Bill C-9 goes far beyond what is required under the World Trade Organization (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the August 30, 2003 WTO agreement on access to medicines. The reasons for these additional, stricter requirements have not been adequately explained to the CGPA by the Government of Canada.

The complexity of the legislative and regulatory requirements will dissuade generic companies from participating in this initiative. The legislation must be simplified in order to achieve its objective of making low-costs drugs accessible where they are needed.

Bill C-9 does not provide the generic industry with the assurance of the ability to sell the products they develop

The right of first refusal provision and provisions in current domestic patent law create an uncertain business environment for generic companies considering their participation in the initiative.

Generic companies are businesses like any other Canadian businesses. To make the required substantial investments, they need market certainty. Generic companies will be unlikely to participate in the initiative if they cannot recoup their investments.

Bill C-9 creates unnecessary barriers to the delivery of affordable medicines

Bill C-9 creates barriers that will limit the overall effectiveness of this initiative. The legislation unnecessarily prevents the participation of NGOs under the initiative.

CGPA Proposed Amendments

CGPA has identified several amendments that address generic industry concerns. These amendments would not adversely impact domestic pharmaceutical patent protection and would ensure that Canada continues to meet its international trade requirements.

These changes would also assist the Government of Canada in achieving its goal of delivering access to Canadian-made generic drugs to people in developing countries who desperately need them.

The following amendments are required if the legislation is to work as intended.

1) Right of first refusal to the brand (s. 21.04)

The right of first refusal provision under Bill C-9 will allow the brand-name drug makers to take over contracts negotiated by generic companies within a 30-day period.

Canadian generic pharmaceutical companies will not seek out international contracts if they are required to pass any business they find to the brand-name company that holds the Canadian patent (and that company's generic subsidiaries or licensees). Our member companies will be unlikely to participate if they do not have the ability to recoup their investments.

The right of first refusal is unnecessary and is not required by international trade agreements. It furthers the interests of multinational brand-name drug makers to the detriment of people in developing countries who lack access to affordable medicines.

Brand-name drug companies already have the de facto right of first refusal, as they are the current patent holders of the products covered under this legislation.

If these companies were prepared to provide their products at reduced prices and in adequate supply, there would have been no need for the November 2001 Doha Declaration, no need for the August 2003 WTO Decision and no need for Bill C-9.

Brand-name drug companies do not need Bill C-9 in order to provide their patented medicines at reduced prices to the developing world. These companies should not be allowed to wait to see if a generic producer intends to do so first.

Ultimately, giving legislated preference to the brand-name drug companies will limit the competition that could have been created under this initiative, and will prevent generic participation.

Alternatives to Right of First Refusal

The right of first refusal provision is not required under Canada's international trade obligations.

TRIPS, Article 31(b) requires that an effort be made to obtain authorization from the right-holder before a compulsory license is issued.

This requirement can be easily met in the following ways:

- The generic company could inform the patent holder of any tendering process it intends to enter into (so the brand company can bid, if it chooses), or
- The generic company could request the patentee to issue a 2% license on any contract in which the buyer warrants that it is satisfied the importing member will comply with the August 30 Decision.

The legislation should provide that if the brand does not issue a license within 7 days of such a request, the Commissioner of Patents will issue a compulsory license.

CGPA Recommendation:

Eliminate the right of first refusal provision (s. 21.04). Include a provision to meet TRIPS requirements as outlined above.

2) The buyer should not be restricted to a foreign government or its agent (s. 21.04(2)(f))

Bill C-9 allows a government of a developing country, or an agent of that government, to enter into a contract with a Canadian generic pharmaceutical manufacturer.

Non-governmental organizations (NGOs) are not agents of a government and are therefore not permitted to enter into contracts with generic companies under this legislation.

NGOs are delivering frontline health care services in developing countries experiencing serious health crises. These groups must have access to affordable medicines in order to ensure they reach the people who desperately need them.

Limiting the initiative to foreign governments creates an unnecessary barrier to access and reduces the effectiveness of this initiative.

This restriction is not required under Canada's international trade obligations. The WTO Decision imposes obligations on the "eligible importing Member" (defined in 1(b)) but there is no requirement that the importing Member or its agent must be the buyer. The Decision also discusses the role of the "exporting Member" (defined in 1(c)) where there is no requirement that the seller must be the Government of Canada or its agent.

CGPA Recommendation:

Eliminate/modify (s. 21.04(2)(f)) in order to allow NGOs to participate in this initiative.

3) Drugs should not be limited to those listed on a schedule to Bill C-9 (Schedule 1)

Bill C-9 includes a list of drugs that can be produced for export under Schedule 1.

If Bill C-9 is passed into law, any future changes to Schedule 1 would require Order in Council approval. This will limit Canada's ability to adapt quickly as conditions and pharmaceutical requirements change in the developing world.

International trade agreements do not require Canada to legislate or impose a list of drugs that can be produced for export.

The August 30 WTO Decision defines "pharmaceutical product" to include "any" patented product "needed to address the public health problems as recognized in paragraph 1 of the [Doha] Declaration."

The Declaration specifically allows the importing member to determine what drugs are needed and to notify Council for TRIPS under paragraph 2(a)(i).

Footnote 5 of the Declaration makes clear that the notification of what products are "needed" will be made available by the WTO Secretariat through a page on the WTO website.

International mechanisms are already in place to determine what pharmaceutical products are required by developing countries. The Government of Canada is not required to determine what drugs are required by developing countries. Listing eligible drugs in legislation will only serve to limit the ability of Canadian generic companies to adapt quickly as conditions change in the developing world

CGPA Recommendation:

In the spirit of the Doha Declaration, eliminate Schedule 1.

4) Export Provision

Current Canadian patent law extends domestic patent protection to markets in developing countries that do not have patents.

The purpose of a Canadian patent is to provide an inventor with a period of market exclusivity in the Canadian market. Inventors must seek and obtain patents in each of the countries in which they desire to obtain a period of market exclusivity.

Canadian generic drug makers should not be prevented from competing in potential foreign markets without patents by applying Canadian patents to foreign countries.

This unfairly denies persons in countries in which there is no patent access to Canadian goods. It also unfairly prevents Canadian manufacturers from competing on an equal basis with manufacturers in countries in which there is no patent.

The inappropriateness of extraterritorial application of Canadian law is explicitly recognized in Section 37(1) of the *Food and Drugs Act*, which reads:

This Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word "Export" and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect thereof in prescribed form and manner.

Adding a similar section to the Patent Act would assist the Government of Canada in achieving its goal of delivering access to affordable medicines to developing countries.

It would also allow Canadian generic firms to participate fully in providing low-cost medicines to developing countries and to compete in markets in which there is no patent.

The availability of additional export markets opened through such a provision would present long-term export opportunities for Canadian-made generic pharmaceuticals. With increased market certainty, more Canadian generic drug companies would consider exporting generic versions of patented medicines to the developing world.

Adding such a provision to the Patent Act would not violate Canada's international trade obligations.

The TRIPS agreement requires each country to permit an inventor to obtain a period of market monopoly in that country by obtaining a patent in that same country. There is no necessity under this agreement to extend patents to goods exported to countries in which there are no patents.

In addition, there would be a greater likelihood that generic versions of medicines covered by Canadian patents would already be developed in times of health crises. Canadian generic companies would then be in a position to quickly meet short-term international demands.

CGPA Recommendation:

Add an amendment to the Patent Act that is similar to Section 37(1) of the Food and Drug Act.

**5) No need for scrutiny of whether the product is “distinguished”
(21.05(3)(ii))**

Under Bill C-9, the Commissioner of Patents cannot issue the license to a generic firm until the Minister of Health has notified the Commissioner that the product is “distinguished” from the brand.

The Therapeutic Products Directorate (TPD) of Health Canada has indicated that it intends to issue regulations on this point, and also plans to perform mandatory inspections. Health Canada and Industry Canada officials have suggested to CGPA that regulatory review by Health Canada will prevent litigation.

CGPA is doubtful such a review will prevent litigation and believes this is unnecessary at a time when the Government of Canada is looking at ways to streamline regulations in all sectors through its Smart Regulation initiative.

These regulations are not required by the August 30, 2003 WTO Decision. Paragraph 2(b)(ii) of the Decision requires that the compulsory license must contain three conditions. One of these conditions is that the product must “be clearly identified” to “distinguish” it from the brand. The CGPA believes the compulsory license should meet the terms of paragraph 2(b)(ii) of the WTO Decision, but should not add additional regulatory scrutiny.

Such unnecessary regulations will increase the length of time it will take for a generic company to bring a product to market and will divert time and money from other domestic projects. This provision will further dissuade generic firms from participating in the initiative.

Generic companies have every incentive to comply with the terms of the compulsory license. Violating the terms could mean a company is liable for patent infringement and costly legal action could be pursued by the patent holder.

CGPA Recommendation:
Eliminate (21.05(3)(ii))

6) Generic should not have to file patent information about the importing country (s. 21.04(3))

Bill C-9 requires the generic manufacturer to submit complex information to the Government of Canada about the patent situation in the importing country, and whether the importing country has notified TRIPS Council that it needs the drug. This provision is overly complex and unnecessary.

Canada is not responsible for ensuring that the importing country is in compliance with TRIPS or the August 30, 2003 WTO Decision. Paragraph 2(a) of the Decision places this obligation on the importing Member. The importing Member must make a “notification” to the WTO Council confirming its intention to grant a compulsory license. Footnote 2 of the Decision does not require this information to be verified by a WTO body.

A generic manufacturer in Canada should therefore not be required to verify foreign compliance to the Canadian Commissioner of Patents. Before being granted a compulsory license by the Commissioner, the generic should simply be required to establish that the tender or contract specifies that the buyer is satisfied the importing country will comply with its obligations under paragraph 2(a) of the August 30 WTO Decision.

CGPA Recommendation:
Eliminate (s. 21.04(3))

7) Breadth of compulsory license

The legislation should be clear that a single compulsory license applies not only to the generic manufacturer, but also to its suppliers, affiliates and agents, and may also refer to several patents.

Typically, there are several companies involved in various aspects of the supply chain in the production of generic pharmaceutical products. It makes sense to have them all covered under the same compulsory license for practical purposes and to reflect the commercial reality of the pharmaceutical business.

CGPA Recommendation:
The legislation should spell out that the compulsory license applies to suppliers, affiliates and agents, and that it may cover several patents

8) Canada should buy the drugs and distribute them itself

Once workable legislation is in place, the Government of Canada should consider purchasing and distributing Canadian-made generic pharmaceutical products to the developing world as part of its foreign aid spending.

This would allow Canada to ensure its initiative is a success and deliver much-needed pharmaceutical products to those in the developing world who desperately need them.

There are no provisions under TRIPS or August 30, 2003 WTO Decision that prevents the Government of Canada and its agents from purchasing Canadian-made generic drugs and distributing them to the developing world.

If the Government of Canada purchased the drugs, there should be an automatic compulsory license.

CGPA Recommendation:

The Government of Canada should consider purchasing generic drugs for distribution through aid agencies such as CIDA in developing countries.

Conclusion

Canada is the first country to introduce legislation to allow generic pharmaceutical companies to participate in the WTO decision on access to medicines – something we should all be proud of as Canadians.

Modifications should be made to Bill C-9 so that the legislation will deliver the intended results. As a pioneer in this area, Canada must avoid providing a flawed model for other countries that might be considering similar action.

There is no doubt that this legislation will fail to deliver Canadian-made generic drugs to developing countries. Substantial amendments must be made to the Bill before Canadian generic pharmaceutical companies will be able to use it.

The Canadian Generic Pharmaceutical Association and its member companies believe strongly that Canada is doing the right thing in taking steps to provide low-cost generic medicines to developing countries. The CGPA simply wishes to ensure that the steps taken will actually provide access to affordable generic medicines by the people in developing countries who desperately need them.

Implementation of CGPA's recommendations, as outlined in this submission, will help the Government of Canada achieve this important goal.

Appendix A

Overview of Canada's Generic Pharmaceutical Industry

The Canadian Generic Pharmaceutical Association (CGPA) represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. The CGPA's 22 members represent more than 90% of Canada's generic pharmaceutical industry. A list of CGPA member companies is included in Appendix C.

Employment

- Approximately 10,000
- CGPA member companies pay out more than \$350 million annually in salaries and benefits

Innovation

- CGPA member companies spend more than \$250 million annually on R&D in Canada
- CGPA member companies invest 15% of sales in research and development R&D expenditures have increased more than seven-fold since 1990
- CGPA member companies have targeted more than \$1.25 billion for R&D over the next 4 years

Exports

- Canada's generic drug industry generates 20% of its sales volume from exporting made-in-Canada pharmaceuticals to 120 countries
- The international community also looks to Canada's generic drug makers to assist in times of health crises, such as the HIV/AIDS pandemic in sub-Saharan Africa

The price of pharmaceuticals: Brand vs. Generic

A price comparison based on data from IMS HEALTH Canada comparing brand name and generic prices of virtually every multiple source product on the Canadian market shows that the average price differential between generic and brand products is 45%.

The price of generic pharmaceuticals: Canada vs. United States

Sales data from IMS HEALTH Global Services for the 12 months ending September 2002 shows that the 28 top-selling generic drugs common to both countries are priced, on average, 28% less in Canada.

Savings to Canada's health-care system

No other industry has made, or continues to make, a greater contribution to affordable health care in Canada than the generic pharmaceutical industry. Last year alone, the use of generic pharmaceuticals saved Canada's health-care system more than \$1.5 billion.

Appendix B

Quick Facts on Prescription¹ Drug Spending in Canada

Source: IMS HEALTH Canada (12 months ending December 2003)

Generic drugs fill 40.6% of all prescriptions in Canada, yet account for only 14.8% of Canada's \$14.6 billion annual prescription drug expenditure.

Dollars

Estimated \$ value of hospital & drug store purchases: \$14.6 billion
Brand name: \$12.5 billion (85.2%)
Generic: \$2.2 billion (14.8%)

Prescriptions

Estimated total number of prescriptions filled: 356 million
Brand name: 212 million (59.4%)
Generic: 144 million (40.6%)

Price Per Prescription

Average price per prescription:	1992	2002	Increase
Brand name:	\$31.52	\$55.59	76%
Generic:	\$16.35	\$21.53	32%

¹ Includes both prescription and OTC products that must be dispensed by a hospital or retail pharmacy.

Appendix C

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