Legislative Summary **LS-474E**

BILL C-9: AN ACT TO AMEND THE PATENT ACT AND THE FOOD AND DRUGS ACT

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LEGISLATIVE HISTORY OF BILL C-9

HOUSE OF COMMONS		SENATE	
Bill Stage	**Date**	**Bill Stage**	**Date**
First Reading:	12 February 2004	First Reading:	
Second Reading:	12 February 2004	Second Reading:	
Committee Report:		Committee Report:	
Report Stage:		Report Stage:	
Third Reading:		Third Reading:	

Royal Assent:

Statutes of Canada

N.B. Any substantive changes in this Legislative Summary which have been made since the preceding issue are indicated in **bold print.**

Legislative history by Peter Niemczak

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BILL C-9: AN ACT TO AMEND THE PATENT ACT AND THE FOOD AND DRUGS ACT*

INTRODUCTION

Bill C-9, An Act to amend the *Patent Act* and the *Food and Drugs Act*,(1) was introduced in the House of Commons on 12 February 2004. It received first and second reading in the House on that same date and was referred to the Standing Committee on Industry, Science and Technology.(2) The bill seeks to amend the *Patent Act* and the *Food and Drugs Act* to facilitate access to pharmaceutical products in the developing world, in order to address public health problems, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

PROPOSED AMENDMENTS TO THE *PATENT ACT*

In August 2003, the General Council of the World Trade Organization (WTO) released a decision(3) that waives certain obligations in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).(4) The waiver allows countries to produce

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* Notice: For clarity of exposition, the legislative proposals set out in the bill described in this Legislative Summary are stated as if they had already been adopted or were in force. It is important to note, however, that bills may be amended during their consideration by the House of Commons and Senate, and have no force or effect unless and until they are passed by both Houses of Parliament, receive royal assent, and come into force.

(1) The bill is available on-line at: http://www.parl.gc.ca/37/3/parlbus/chambus/house/bills/government/C-9/C-9_1/C-9_cover-e.html.

(2) By a motion adopted on 10 February 2004, the House of Commons provided for the reintroduction in the 3rd session of government bills that had not received royal assent during the previous session and that died on the *Order Paper* when Parliament was prorogued on 12 November 2003. The bills could be reinstated at the same legislative stage that they had reached when the 2nd session was prorogued. Bill C-9 is the reinstated version of Bill C-56, which died on the *Order Paper*.

(3) "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003" (referred to in this document as "the 30 August Decision"); see http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm#fnt3.

(4) The obligations are those set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products; see http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

generic copies of patented pharmaceutical products under compulsory licences for export to developing and least-developed countries that do not have the capacity to manufacture such products domestically. The proposed amendments to the *Patent Act* (Clause 1, which adds new sections 21.01 to 21.17 after section 21) would allow for the issuance of compulsory licences to Canadian firms authorizing them to manufacture in Canada specific, patented pharmaceutical products for export to certain developing and least-developed countries.

Once amended, the *Patent Act* would include Schedules identifying the pharmaceutical products and importing countries that are eligible under the new system. The list of eligible pharmaceutical products (Schedule 1) consists of 46 products that are currently subject to a patent in Canada and appear on the World Health Organization's "model list of essential medicines."(5) Countries eligible to import pharmaceutical products under the terms of the bill(6) include all countries that have been identified by the United Nations as "least-developed"(7) (Schedule 2), and those WTO members – mainly developing countries – that have not notified the TRIPS Council that they do not intend to use the system as importers(8) (Schedule 3). A number of WTO members that are developing countries have indicated an intention to participate in the scheme as importing countries only if faced with a national emergency and insufficient manufacturing capacity to manufacture the pharmaceutical product in question (Schedule 4).(9) The Schedules do not include the WTO members that have informed the WTO that they will not use the system as importers.(10) The amendments proposed in Bill C-9 provide a mechanism for Cabinet to add to or delete from these Schedules as the need arises or as international consensus emerges.

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(5) The WHO model list of essential medicines is available on-line at: http://mednet3.who.int/eml/eml_intro.asp.

(6) To be an "eligible importing Member" under the system established by the General Council's 30 August Decision, the WTO member is required to notify the TRIPS Council of its intention to use the system as an importer (unless it is a least-developed country, in which case no such notification is required).

(7) The United Nations' list of least-developed countries as of December 2003 is available at: http://www.un.org/special-rep/ohrlls/ldc/list.htm.

(8) There are no WTO definitions of "developed" and "developing" countries. Members identify themselves as being "developed" or "developing" countries. However, other members can challenge the decision of a member to make use of provisions available to developing countries. See http://www.wto.org/english/tratop_e/devel_e/d1who_e.htm.

(9) Schedule 4 lists countries that have informed the WTO that they would use the system as importers only in situations of national emergency or other circumstances of extreme urgency. See http://www.wto.org/english/tratop_e/trips_e/gc_stat_30aug03_e.htm.

(10) Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States of America.

Under the proposed amendments, a "right of first refusal" is offered to patent-holding brand name companies such that they will be given the first opportunity to be the supplier of a requested pharmaceutical product (clause 1, proposed new paragraphs 21.04(6)(*a*) and 21.04(7)(*a*)). The Commissioner of Patents will notify the patent holder(s) when a company files a notice of intent to seek a compulsory licence to manufacture a pharmaceutical product under the scheme. The patent holder(s) will have 30 days in which to decide whether to fulfil the request. If the patent holder decides not to do so, the other company may proceed with its application for a compulsory licence.

Compulsory licences will be subject to the following terms and conditions:

- Use of the patented pharmaceutical product must be limited to a specific quantity and for use in a specific country;
- A website must be established by the licence holder that discloses information relating to the licence;
- If there is only one patentee, the licensee must pay a royalty to the patentee equal to two percent of the value of the exported pharmaceutical product. If there is more than one patentee, the licensee must pay a royalty to the patentees equal to two percent of the value of the product divided by the number of patentees;
- The licence shall be effective for a period of two years from the date it is granted; and
- Health Canada must notify the Commissioner of Patents that the pharmaceutical product meets the requirements of the *Food and Drugs Act* and its regulations, including that it be distinguishable from the domestic brand name product (e.g., by labelling, packaging, marking, embossing, etc.) in order to discourage re-importation and diversion.

A provision in the proposed amendments (clause 1, new section 21.17) requires a review by the Minister of Industry of new sections 21.01 to 21.16 and their application, three years after they come into force.

PROPOSED AMENDMENTS TO THE *FOOD AND DRUGS ACT*

Proposed amendments to the *Food and Drugs Act* (clause 2, the addition of new subsections 5 and 6 after subsection 4 of section 30) allow for changes to be made to the *Food and Drug Regulations* for the purpose of implementing the WTO General Council decision of 30 August 2003 on access to pharmaceutical products. These changes would address the

proposed amendment to the *Patent Act* that requires Health Canada to notify the Commissioner that pharmaceutical products intended for export in accordance with that WTO General Council decision comply with the regulations and that the products are distinguishable from those sold on the domestic market, in order to prevent diversion of the product from its intended destination. Additional amendments to the *Food and Drugs Act* (clause 3, the addition of new subsection 2 after subsection 1 of section 37) would ensure that pharmaceutical products intended for export to developing and least-developed countries are subject to the same regulatory approval process as those products intended for the Canadian market.

DESCRIPTION

A. Clause 1 – Amendments to the *Patent Act*

The first clause of the bill adds a new part, under the heading "Use of Patents for International Humanitarian Purposes to Address Public Health Problems," to the *Patent Act*. This new part includes sections 21.01 to 21.17.

1. Section 21.01 – Purpose

Section 21.01 sets out the purpose of these new sections, being "to facilitate access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."

2. Section 21.02 – Definitions

Section 21.02 sets out a series of definitions to apply in this part of the Act, including one for "patented product," which is defined as a product that one could not make, construct, use or sell in Canada without the consent of the patentee (patent holder), because to do so would infringe a patent. This broad definition is intended to be consistent with the 30 August Decision and to include not just pharmaceuticals *per se*, but also diagnostic or prophylactic products. The term "pharmaceutical product" includes those patented products listed in Schedule 1 to the bill. Other definitions refer to or are based on the international agreements underlying this legislative initiative.

3. Section 21.03 – Schedules

Section 21.03 establishes four schedules to the bill, and provides for their amendment by Cabinet. Schedule 1 is the list of patented products that could be used to address public health problems under the legislation. The list currently set out in the bill includes all products on the World Health Organization's (WHO) list of essential medicines that are currently under patent in Canada. Schedules 2 to 4 list all countries that would be eligible importers under the bill: Schedule 2 being the least-developed countries, whether WTO members or not; Schedule 3 being those WTO members – mainly developing countries – that have not notified the TRIPS Council that they do not intend to participate in the scheme as importers; and Schedule 4 being WTO member countries that have agreed to import patented products only in situations of emergency or extreme urgency. New section 21.03(2) precludes the addition to Schedule 3 of any WTO member country if that country has notified the TRIPS Council that it will import only in situations of emergency.

New section 21.03(3) allows Cabinet to amend Schedules 2 to 4, in specified circumstances, by removing country names if their WTO designation or notified intention regarding importing of pharmaceutical products changes.

4. Section 21.04 – Notice of Intent to Apply/Compulsory Licence

Under section 21.04, persons applying to the Commissioner of Patents for authorization to manufacture a patented product must file a notice of intent to apply, along with a series of additional documents. Section 21.04(2) requires that the notice of intent identify the product and prescribing information; quantity to be manufactured; information about the patentee; the importing country; and the terms of the contract under which the product is to be sold. The accompanying documents required under section 21.04(3) must include, in the case of a WTO member, the country's notification to the WTO of its intention to import the product, and in the case of a non-WTO member, the country's notification to the Government of Canada of its intention to import the product. The notice must also set out the patent status of the product in the importing country.

The prescribed fee must be paid at the time of filing the notice of intent, under section 21.04(4). Under section 21.04(5), if the importing country is listed in any of Schedules 2 to 4, then the Commissioner of Patents must send a copy of the notice of intent to apply to every

patentee named in the notice. If there is a single patentee, then section 21.04(6) requires that the Commissioner send a statement informing the patentee that an authorization to manufacture and sell the product (a compulsory licence) will be granted unless, within 30 days, the patentee indicates its intention either to supply the product to the importer or to grant a voluntary licence. If there is more than one patentee, then section 21.04(7) requires that a statement be sent to each patentee informing them that a compulsory licence will be granted unless one or more of them agrees to supply the product, or each of them has agreed to grant a voluntary licence.

5. Section 21.05 – Authorization

The Commissioner of Patents is required under section 21.05(1) to authorize the use of a patented invention by the applicant for the purpose of supplying the pharmaceutical product, subject to subsections (3) to (5). The applicant must have paid the prescribed fee, and met the following conditions:

- The applicant must have met any requirement prescribed in the regulations;
- The Minister of Health must have informed the Commissioner that the product meets all relevant *Food and Drugs Act* requirements;
- The applicant must have provided notice to patentees as required under section 21.04; and
- The patentee must not have indicated its intention to supply the product or provide a voluntary licence.

Once the statutory and regulatory conditions have been met, the Commissioner must grant the compulsory licence to the applicant.

6. Section 21.06 – Form of the Compulsory Licence

The authorization, or compulsory licence, must be in the prescribed form, under section 21.06, and the quantity manufactured cannot exceed the lesser of the amount specified in the applicant's notice of intent to apply or the amount requested by the importing country.

7. Section 21.07 – Disclosure of Information on Website

Before the product can be exported, the licensee (the holder of the compulsory licence) must publish on a website the name and quantity of the product to be sold, the importing country, and information about the product as required by the *Food and Drug Regulations* (section 21.07).

8. Section 21.08 – Royalty

The licensee is required under section 21.08 to pay a royalty to the patentee in the amount of two percent of the value of the products exported under the compulsory licence. If there is more than one patentee, the royalty will be divided equally among them.

9. Section 21.09 – Duration

Section 21.09 provides that a compulsory licence will be valid for two years, unless another period is prescribed in the regulations.

10. Section 21.1 and 21.11 – Use is Non-exclusive and Non-transferable

Section 21.1 provides that the licensee's use of the patented invention is non-exclusive, meaning that the patentee can continue to use the patent for commercial purposes during the term of the compulsory licence. Section 21.11 provides that the licensee's authorization is non-transferable, except as permitted by paragraph 31(e) of the TRIPS Agreement. Paragraph 31(e) provides that use of patents under compulsory licences must be non-assignable, "except with that part of the enterprise or goodwill which enjoys such use."

11. Section 21.12 – Renewal

A compulsory licence will be renewed by the Commissioner of Patents under section 21.12, if the licensee applies, pays the prescribed fee, and certifies that the quantity intended to have been exported was not exported before the licence expired.

12. Section 21.13 and 21.14 – Termination

Section 21.13 provides that compulsory licences expire on the earliest of the following dates:

- The expiry of the two-year term of the licence set under section 21.09;
- The day on which the Commissioner notifies the licensee that the Minister of Health no longer believes that the product meets the requirements of the *Food and Drugs Act* and its regulations;
- The day on which the last of the product provided for in the licence is exported;
- 60 days after the product or the importing country is removed from a Schedule under the bill; and
- Any other date prescribed in the regulations.

Licences may also be terminated under section 21.14, by order of the Federal Court of Canada, on application of the patentee, if the patentee establishes that inaccurate information had been given by the licensee, or that the licensee failed to meet its obligations under the bill, or that the product is being re-exported from the importing country.

13. Section 21.15 – Notice to Patentee

The Commissioner must, under section 21.15, notify each patentee in writing of any compulsory licence granted.

14. Section 21.16 – Advisory Committee

Under section 21.16, Cabinet, on the recommendation of the Minister of Industry and the Minister of Health, can establish an advisory committee to advise on products to be listed in Schedule 1. Although Schedule 1 of the bill currently includes the drugs on the WHO's list of essential medicines that are patented in Canada, it is intended that additional products will be added in keeping with international consensus about the scope of the 30 August Decision.

15. Section 21.17 – Ministerial Review

The bill requires that the Minister of Industry conduct a review of sections 21.01 to 21.16 and their application three years after the coming into force of section 21.17, and report to Parliament.

B. Clauses 2-3 – Amendments to the *Food and Drugs Act*

The second clause of the bill adds new provisions to the *Food and Drugs Act* to enable the making of regulations respecting the manufacture and export of drug products necessary for the implementation of the 30 August Decision.

1. Sections 30(5), 30(6) and 37(2) – Regulations and Definitions

Clause 2 adds subsection (5) to section 30 of the *Food and Drugs Act*, to permit Cabinet to make any regulations necessary for the implementation of the 30 August Decision. Subsection (6) adds the definitions that section 21.01 adds to the *Patent Act*, including definitions of the "General Council" (of the WTO), "General Council Decision" (the 30 August Decision), the TRIPS Agreement, and the WTO.

Clause 3 adds a new subsection (2) to section 37 of the *Food and Drugs Act*, to provide that the Act applies to a drug or device exported in accordance with the 30 August Decision as though the drug or device were to be sold for consumption in Canada, unless the regulations provide otherwise. Currently, exports, being excluded from the application of the Act, do not have to meet Canadian standards of safety, efficacy and quality. This amendment would have the effect of requiring that products exported under this bill meet those standards.

C. Clause 4 – Coming Into Force

Clause 4 provides that the amendments will come into force on a day to be fixed by order of the Governor in Council.

COMMENTARY

Although the goals of Bill C-9 have received widespread support from the public, non-governmental organizations and the pharmaceutical industry, a number of civil society groups have suggested that there are flaws in the bill that could undermine those goals.(11) Criticism of Bill C-9 centres on four main issues:

- The bill has a provision that offers the "right of first refusal" to patent holders (section 21.04). Critics of this provision believe that it would act as a disincentive to Canadian generic manufacturers to invest time and money in negotiating supply contracts with developing countries if the deals can be taken over by Canadian patent holders;
- Schedule 1 of the bill specifies which pharmaceutical products would be eligible for exportation under the drug access scheme. Critics suggest that developing countries should be allowed to decide themselves which drugs are needed to deal with their public health problems;

(11) See, for example, the letter sent on 12 January 2004 to the Right Honourable Paul Martin on behalf of the Canadian HIV/AIDS Legal Network, Médecins Sans Frontières, Oxfam Canada, Canadian Labour Congress, Interagency Coalition on AIDS & Development, Canadian Council for International Co-operation, Rights & Democracy, North-South Institute, CARE Canada, World Vision Canada, Canada Africa Partnership on AIDS, McGill International Health Initiative, and Students Against Global AIDS (SAGA), available on-line at: http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend/Letter_Gov_%20BillC-56_13Jan.PDF.

- Under the bill, all least-developed countries are permitted to participate in the scheme as importing countries, but only developing countries that are also WTO members are allowed to participate as importing countries. Critics say this restriction does not reflect the letter and spirit of the Doha Declaration on the TRIPS Agreement and Public Health, which refers to "access to medicines for all;"[12] and

- The bill indicates that a manufacturer intending to export a pharmaceutical product under the terms of the bill must negotiate a supply contract with the government, or the agent of that government, of the importing country (paragraph 21.04(2)(*f*)). Critics of this provision note that it does not permit contracts to be negotiated with non-governmental organizations or private-sector entities, which are important providers of health care in many developing countries.

(12) Paragraph 4, Doha Declaration on the TRIPS Agreement and Public Health, November 2001, http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.