

**BILL C-9 AN ACT TO AMEND THE PATENT ACT AND THE FOOD AND DRUGS ACT -  
A HUMANITARIAN INITIATIVE**

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On May 14<sup>th</sup>, 2004, Bill C-9 entitled *An Act to amend the Patent Act and the Food and Drugs Act* (Jean Chrétien's pledge to Africa) ("Bill C-9") received assent.

This Act was created in order to allow the manufacture and use of a patented drug for the purpose of exportation to developing and least developed countries afflicted by diseases such as HIV / AIDS, tuberculosis, malaria and other epidemics.

The Canadian *Patent Act*, as presently in force, does not include any provisions which allow a third party to import, manufacture, use or sell a patented invention for medicine without a licence while exempting that party from infringing the patent covering the invention.

Exemptions under Bill C-9 are granted only for humanitarian and non-commercial reasons. Sections 21.01 to 21.2 of Bill C-9 establish criteria that an applicant must meet and the procedures to be followed when filing an application under this statute.

Subject to certain conditions, Bill C-9 grants power to the Commissioner of Patents to authorize a person or entity to manufacture or use a patented invention solely for purposes directly related to the manufacture of the pharmaceutical product to be sold for export to a country or WTO member that is listed in any of schedules II to IV of Bill C-9.

To date, sections 21.01 to 21.2 apply to specific pharmaceutical products which are defined in schedule I by their dosage form, their strength and type of administration. About 56 pharmaceutical products are listed. The countries

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to which the products can be exported are listed in schedules II to IV of Bill C-9. About 50 countries are listed. It should be noted that these sections include provisions allowing the Governor in Council to amend schedules I to IV.

Each application should include:

- the name of the pharmaceutical product to be manufactured and sold for export under the authorization;
- information with respect to the version of the pharmaceutical product to be manufactured and sold for export under the authorization;
- the maximum quantity of the pharmaceutical product to be manufactured and sold for export under the authorization;
- for each patented invention to which the application relates, the name of the patentee of the invention and the number, as recorded at the patent office, of the issued patent in respect to that invention;
- the name of the country or WTO member to which the pharmaceutical product is to be exported; and
- the name of the governmental person or entity, or the person or entity permitted by the government of the importing country, to which the product is to be sold.

It should also be noted that an authorization granted under Bill C-9 is valid for a period of two years beginning on the day on which the authorization is granted. Furthermore, the use of a patented invention under such an authorization is not exclusive and non-transferable unless the holder of the authorization is sold, assigned or otherwise transferred.

