PATENT PROTECTION FOR PHARMACEUTICAL PRODUCTS IN CANADA - CHRONOLOGY OF SIGNIFICANT EVENTS

Prepared by:
Margaret Smith
Law and Government Division
30 March 2000

PATENT PROTECTION FOR PHARMACEUTICAL PRODUCTS IN CANADA - CHRONOLOGY OF SIGNIFICANT EVENTS

1923 -- The *Patent Act* was amended to provide for compulsory licensing for manufacturing purposes for food and drug patents. In relation to patented medicines, the amendment allowed a compulsory licence to be granted if a medicine's active ingredients were manufactured in Canada. (A compulsory licence is a statutory licence that gives the licensee the right to manufacture, use, or sell a patented invention before the patent expires. Licences could be granted without the consent of the patent holder and the licensee was required to pay a royalty.)

1969 -- The *Patent Act* was amended to permit compulsory licences to import medicines into Canada. This allowed generic drug producers to import a medicine's active ingredients and process them into final form for sale. The Commissioner of Patents was authorized to issue compulsory licences to import and to fix a royalty for them. Royalty rates were set at 4% of the net selling price of a drug in its final dosage form.

1983 -- The federal Minister of Consumer and Corporate Affairs called for a rebalancing of the 1969 policy on compulsory licensing in order to generate growth in the pharmaceutical industry.

1984 -- The federal government established the Commission of Inquiry on the Pharmaceutical Industry (Eastman Commission), part of whose mandate was to make recommendations on patent protection for the pharmaceutical industry.

1985 -- The Commission of Inquiry on the Pharmaceutical Industry recommended that an owner of a patent for a medicine be granted a short period of exclusivity (four years) from the date when a new drug received a Notice of Compliance (NOC)(1) authorizing marketing. The Commission also recommended that royalties paid under compulsory licences should be put into a special royalty fund. The royalty rate would be determined in accordance with a formula that took into account the value of a licensee's sales of compulsorily licensed products in Canada, the pharmaceutical industry's world-wide ratio of research and development to sales, plus 4%. Distributions from the fund to firms whose patents were under compulsory licence were to be based on the relative research intensity of the patent-holding firms.

1987 -- Bill C-22, which amended the *Patent Act,* made significant changes to the compulsory licensing system for patented medicines. The amendments guaranteed patent owners a period of protection from compulsory licences. A brand-name drug manufacturer receiving an NOC for a drug after 27 June 1986 was guaranteed 10 years of protection against compulsory licences to import and seven years' protection against compulsory licences to manufacture. Patented medicines for which NOCs had been issued on or before 27 June 1986, and for which generic drug producers had obtained either an NOC or a compulsory licence to import, but not both, were entitled to seven years' protection against compulsory licences to import. Similarly, medicines for which an NOC had been issued on or before 27 June 1986, but for which neither a compulsory licence nor a generic NOC had been issued, had eight years of protection against compulsory licences to import.

Additional protection was granted to drugs invented and developed in Canada; compulsory licenses to import were not available, but compulsory licences to manufacture could be issued if, within the seven years after the NOC for the drug had been issued, the inventor failed to make the drug in Canada for the purpose of completely or substantially supplying the Canadian market.

Bill C-22 also changed the general patent law to provide that the term of a patent would be 20 years from the date on which a patent application was filed, rather than 17 years from the date the patent was issued. This change became effective in 1989.

1991 -- The then Director-General of the General Agreement on Tariffs and Trade, Arthur Dunkel, compiled a Draft Final Act for the conclusion of the Uruguay Round of the GATT multilateral trade negotiations, which also contained a text of the draft Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 31 of the TRIPS agreement contained provisions on "Use Without the Authorization of the Right Holder." It was generally accepted that the Canadian compulsory licensing regime for

pharmaceutical products in existence at this time was incompatible with Article 31. (The text of the TRIPS Agreement as contained in the so-called Dunkel text was informally agreed to by all parties to the GATT negotiations and became part of the Agreement finally adopted in 1994.)

1992 -- The federal government endorsed the Dunkel text. The text of the North American Free Trade Agreement (NAFTA) was finalized, with Chapter 17 largely based on, and in many instances identical to, the provisions of the then draft TRIPS Agreement. Article 31 of the TRIPS Agreement was reproduced almost identically in Article 1709(10) of NAFTA.

1992 -- The federal government moved to further modify the *Patent Act* and to implement the TRIPS and NAFTA provisions on intellectual property by introducing Bill C-91, the Patent Act Amendment Act, 1992, in the House of Commons. The bill eliminated compulsory licences for pharmaceutical products though compulsory licences in existence before 20 December 1991 continued in effect, subject to the seven and ten-year limitations established in Bill C-22. Compulsory licences granted after 20 December 1991 but before the day the Act came into force were terminated when the Act became effective.

Bill C-91 also created two exceptions to an action for patent infringement (the rule that anyone who, without the consent of the patent owner, makes, uses or sells a product where a patent is in force is liable for patent infringement). Both exceptions permit persons to use a patented product for certain purposes before the patent expires. The first exception, known as the "early working" exception, allows a person to use a patented invention while the relevant patents are in force only for obtaining regulatory approval to sell an equivalent product after the patents have expired (section 55.2(1)). Under this provision, a generic drug manufacturer could develop a generic version of a medicine and take whatever steps were necessary to meet the regulatory requirements pertaining to its sale before the expiry of the relevant patents. The second exception ("stockpiling" exception) allows a person to use a patented invention for a period of time before the patent expires in order to manufacture and store a product intended for sale after the expiry of the patent (section 55.2(2)).

Bill C-91 also provided for product patents for pharmaceutical inventions. Prior to the bill such inventions were only patentable as process patents (or so-called "product-by-process patents").

February 1993 -- *The Patent Act Amendment Act, 1992* became law.

March 1993 -- The *Patented Medicines (Notice of Compliance) Regulations* (Linkage Regulations) detail how the granting of an NOC for a generic drug will be linked to the expiry of patents for the brand-name

equivalent drug. Essentially, these regulations provide that, unless a patentee consents to the making of the generic drug, the relevant patents are invalid, or there is no infringement of any patent rights, the Minister of Health cannot issue an NOC to a generic manufacturer until the relevant patents expire.

The *Manufacturing and Storage of Patented Medicines Regulations* provide that a generic manufacturer can stockpile a generic version of a drug six months before the relevant patents are due to expire.

April 1997 -- The House of Commons Standing Committee on Industry issued a report on the *Patent Act Amendment Act, 1992* recommending that the government re-visit the regulatory regime associated with Bill C-91.

December 1997 -- The European Union (EU) requested that Canada hold consultations under the WTO dispute settlement procedures in relation to the protection of pharmaceutical inventions under the Canadian *Patent Act* and Canada's obligations under the TRIPS Agreement.

March 1998 -- Amendments to the *Patented Medicines (Notice of Compliance) Regulations* came into effect. Although the amendments made a number of changes to the operation of the Linkage Regulations, they did not change the overall regime governing patent infringement, early working or stockpiling.

February 1999 -- The Dispute Settlement Body under the WTO established a Panel to hear the European Union's challenge under the TRIPS Agreement in respect of the early working exception (section 55.2(1)) and the stockpiling exception (section 55.2(2)) of the *Patent Act*.

The EU argued that *Patent Act* and the regulations that provide for the manufacturing and stockpiling of pharmaceutical products without the consent of the patent holder for a period of six months prior to the expiration of the 20-year patent term (section 55.2(2)) violate Canada's obligations under the TRIPS Agreement (Article 28.1 and Article 33).

Moreover, the EU maintained that by treating patent holders in the field of pharmaceutical inventions less favourably than patent holders of inventions in all other fields of technology, Canada had violated its obligations under Article 27.1 of the TRIPS agreement. This requires patents to be available and patent rights to be enjoyable without discrimination as to the field of technology.

The EU further contended that the provisions of Article 28.1 of the TRIPS Agreement are violated by the provisions of the *Patent Act* (section 55.2(1)), whereby a third party may, without the consent of the patent holder, use a patented invention while the patent remains in force in order to obtain regulatory approval for the sale of an equivalent product after the

patent has expired.

Canada, on the other hand, argued that that section 55.2(1) and 55.2(2) of the *Patent Act* did conform with Canada's obligations under the TRIPS Agreement, because:

> each of these provisions is a "limited exception" to the exclusive rights conferred by a patent within the meaning of Article 30 of the TRIPS Agreement; and
>
> these provisions neither discriminate as to the field of technology in which any relevant invention occurs nor reduce the minimum term of patent protection.

March 2000 -- The WTO Panel agreed with Canada on the early working exception in section 55.2(1) of the *Patent Act*, holding that it was not inconsistent with Canada's obligations under the TRIPS agreement; however, the Panel sided with the EU with respect to the stockpiling exception in section 55.2(2) and concluded that this was inconsistent with Canada's TRIPS obligations.

April 2000 -- Canada announced that it would implement the WTO Panel's finding that Canada's stockpiling exception is not consistent with Canada's TRIPS obligations.

May 2000 -- Ruling in favour of the United States, a WTO Panel concluded that Canada's term of patent protection for patent applications filed before 1 October 1989 (17 years from the granting of the patent) did not meet the minimum term of patent protection established under TRIPS. The Panel found that TRIPS requires a minimum term of 20 years from the date a patent application is filed.

Bill C-22 created two patent term provisions: 17 years from the granting of the patent for applications filed before 1 October 1989 ("old regime") and 20 years from the filing of the application for applications filed on or after 1 October 1989 ("new regime").

The United States claimed that TRIPS required a minimum 20-year term from the date of filing for all patents. The dispute concerned patents granted under the old regime within three years from the date that the applications for them had been filed.

Canada announced that it would appeal the WTO Panel decision.

---

(1) A Notice of Compliance is the name given to the document issued by the federal Department of Health that formally authorizes the sale of drug after it

has met the requisite safety and efficacy standards.