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PATENT PROTECTION FOR PHARMACEUTICAL PRODUCTS UNDER THE WORLD TRADE ORGANIZATION AGREEMENTS AND THE NORTH AMERICAN FREE TRADE AGREEMENT

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INTRODUCTION

Prior to the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) multinational trade negotiations, the GATT did not cover intellectual property rights. The Uruguay Round, which resulted in the creation of the World Trade Organization (WTO), also produced the Agreement on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods (TRIPS). Among other things, TRIPS contains provisions dealing with patents, trademarks, copyright and industrial design.

Similarly, the Canada-United States Free Trade Agreement did not at first cover intellectual property rights; however, these rights were subsequently protected in Chapter 17 of the North American Free Trade Agreement (NAFTA).

These notes will outline the provisions of TRIPS and NAFTA that have implications for the protection of patent rights for pharmaceutical products in Canada. Since the texts of the relevant provisions of both agreements are similar, references will be made to the relevant NAFTA provisions with the corresponding TRIPS reference following in parentheses.

PROVISIONS OF NAFTA AND TRIPS

Among other things, Article 1709(7) of NAFTA provides that patents shall be available and enjoyable without discrimination as to the place of invention, the fields of technology or whether the products are imported or produced locally (TRIPS Article 27 (1)).

Under Article 1709(2) of NAFTA, a country can exclude from patentability those inventions: (i) whose commercial exploitation must be prevented so as to protect public order or morality (including the protection of human, animal or plant life or health) or to avoid serious prejudice to nature or the environment; (ii) that involve diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and (iii) that are of plants and animals or that are essentially biological processes for the production of plants and animals (TRIPS Article 27(2)).

Article 1709(5) of NAFTA provides that the owner of a patent has the right to its exclusive use and the right to prevent other persons from making, using or selling a patented product without the owner's consent (TRIPS Article 28). The term of protection of a patent is to be at least 20 years from the date a patent application is filed or 17 years from the date a patent is granted (NAFTA Article 1709(12)). Article 33 of TRIPS provides for a term of protection of at least 20 years from the date of a patent application. Article 1709(12) of NAFTA also provides that the term of a patent may be extended to compensate for delays caused by regulatory approval processes.

Under both NAFTA and TRIPS, a country may provide limited exceptions to the exclusive rights conferred by a patent, provided the exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner (NAFTA Article 1709(6), TRIPS Article 30). In addition, NAFTA Article 1709(10) (TRIPS Article 31) states that a country can allow for the use of a patent, other than the use allowed under Article 1709(6) (TRIPS Article 30), without the consent of the patent owner, provided the conditions set out in the Agreement apply. Some of these conditions are:

- authorization of such use is to be considered on its individual merits;
- the proposed user must have tried to obtain the consent of the patent owner to use the patent on reasonable commercial terms and have been refused;
- the scope and duration of the use must be limited to the purpose for which it was authorized;
- the use must be non-exclusive;
- the patent owner must be paid adequate remuneration;
- the use is to be authorized predominantly for the supply of the domestic market; and
- the legal validity of any decision relating to the authorization of such use must be subject to judicial or independent review.

TRIPS, NAFTA AND COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS IN CANADA

Compulsory licensing is a mechanism to curb the monopoly power of a patent. A compulsory licence forces the patent owner to license the invention to which the patent applies to others, in return for a royalty fixed by the government.

In 1969, the *Patent Act* was amended to permit compulsory licences to import medicines into Canada. Among other things, the amendment provided that the Commissioner of Patents was to issue compulsory licences to import medicines and to fix the royalty for such licences unless there was good reason to deny the application. The Commissioner had little discretion in granting licences. In arm's length purchases, royalty rates were set at 4% of the selling price of a drug in its final dosage form.

Compulsory licensing has been used extensively in Canada for pharmaceuticals. The ability to obtain licences to import and to sell copies of patented medicines fostered the establishment of a number of generic drug manufacturers who produced and sold lower-priced alternatives to the drugs produced by brand-name companies. The generic sector also advanced after provincial programs were set up to cover senior citizens and recipients of social assistance for drug costs and after certain legislation began to permit pharmacists to fill prescriptions with the generic equivalents of higher-priced patented medicines.

Pressure from pharmaceutical manufacturers and a desire to make disparate intellectual property laws more uniform have fostered a world-wide trend to restrict the use of compulsory licensing. While they do not completely prohibit compulsory licensing, NAFTA and TRIPS restrict its use. As noted above, WTO and NAFTA member countries are permitted to provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal

exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner. In addition, where the laws of a member country allow the subject matter of a patent to be used without the authorization of the patent owner, there must have been efforts to obtain the authorization of the owner on reasonable commercial terms and the patent must be used predominantly to supply the domestic market of the member country authorizing the use. The requirement for authorization, however, can be waived in the event of a national emergency and both the authorization and the domestic market requirements can be waived where the use of a patent is permitted to remedy an anti-competitive practice.

In January 1992, the federal government endorsed proposals emanating from the Uruguay Round of the GATT multinational trade negotiations that eventually resulted in TRIPS. Because these proposals envisaged a compulsory licensing system that was much more restrictive than the regime operating in this country at the time, Canada was obliged to end that regime.

In June 1992, the federal government moved to implement the TRIPS provisions on intellectual property by introducing Bill C-91, which became the *Patent Act Amendment Act, 1992*.(1) Passed by Parliament in 1993, the Act eliminated the general compulsory licensing of pharmaceutical products and thus ensured that the owners of pharmaceutical patents would be protected from generic competition until their patents had expired.

Under Article 1720(6) of NAFTA and Article 70(6) of TRIPS, a country was not required to apply the conditions for the issuance of compulsory licences contained in Article 1709(10) and Article 31 (restrictions on the issuance of compulsory licences) or the requirement that there be no discrimination in the enjoyment of patent rights to compulsory licences issued before 20 December 1991 -- the date on which the draft version of TRIPS became public. This ensured that all compulsory licences issued prior to 20 December 1991 would continue after TRIPS and NAFTA became effective.

Canada’s ability to treat pharmaceutical patents differently from patents for other inventions and its freedom to reinstate the pre-Bill C-91 compulsory licensing regime for pharmaceuticals are restricted by the provisions of TRIPS and Chapter 17 of NAFTA. Compulsory licensing is permitted, however, provided the licences are issued in accordance with the conditions outlined in NAFTA and TRIPS.

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(1) Statutes of Canada 1993, c.2.