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NAFTA AND THE BIOTECHNOLOGY INDUSTRY

EILEEN MCMAHON*

This Article is intended to address some of issues in Canadian patent and drug regulatory law that have arisen as a result of or in anticipation of the ratification of the North American Free Trade Agreement (NAFTA).¹ Particular attention has been paid to the areas of drug and device approvals and biotechnological products, and remaining procedural hurdles, some of which could be considered indirect barriers to trade.

NAFTA OBJECTIVES

Protection

NAFTA was implemented on January 1, 1994 by the United States, Canada, and Mexico. Each of the signatories to the NAFTA had different aims in mind when entering into the negotiations leading up to the signing of the Agreement. The United States, as a long time net exporter of technology, has for many years sought greater protection for its innovators abroad. This is not surprising, as the U.S. is probably the greatest victim of trademark counterfeiting, copyright piracy, and patent infringement.

National Treatment

Canada sought primarily to gain better "national treatment" in the United States, having been subject to U.S. laws favoring domestic innovators. Under 35 U.S.C. § 104, as it read prior to January 1st, 1994, inventors could not rely on dates of reduction to practice of inventions from outside the United States. Prior to January 1st, 1994, Canadian inventors who failed to introduce promptly their inventions into the U.S. suffered the effects of such failures in interference proceedings.

Because 35 U.S.C. § 104, as it read prior to January 1st, 1994, did not discriminate on the basis of nationality but on *where* the invention took place, it was theoretically in accord with the Paris Convention for the Protection of Industrial Property² of 1967, to which the U.S. was a signatory. However, it worked against foreign inventors whose innovative activities normally took

* Of the law firm, Deeth Williams Wall, Toronto, Canada. I would like to thank Gordon S. Jepson, an associate lawyer with Deeth Williams Wall for his invaluable help in the preparation of this Article. Statute and Case law cited in this Article is current to the end of April, 1996.

1. North American Free Trade Agreement, Dec. 17, 1992, 32 I.L.M. 289 (1993) [hereinafter NAFTA].

2. Paris Convention, June 21, 1966, 6 I.L.M. 806 (1967).

place outside the U.S. Article 1709(7) of the NAFTA³ which requires true indifference as to nationality:

7. Subject to paragraphs 2 and 3, patents shall be available and patent rights enjoyable without discrimination as to the field of technology, the territory of the Party where the invention was made and whether products are imported or locally produced.

Article 1703(1)⁴ supports national treatment by providing that:

1. Each party shall accord to nationals of another Party treatment no less favorable than that it accords to its own nationals with regard to the protection and enforcement of all intellectual property rights. . . .

This means that Canadian and Mexican inventors could now rely, in establishing the dates of reduction to practice of their inventions, on activities that took place in their own countries.

There was a move afoot in the A.I.P.L.A.,⁵ and perhaps elsewhere, to defeat the intent of this provision through a procedural restriction based on a requirement for easy availability of evidence to examiners in both *ex parte* and interference actions.⁶ However, it now seems that these fears were unfounded, as only in the most unusual circumstances will Canadian applicants be unable to rely on inventive activities in Canada as a result of provincial "blocking statutes" or other procedural hurdles.

Adherence to International Conventions on Intellectual Property

Another important objective of the NAFTA was to ensure that all signatories adhered to all the major international intellectual property conventions. Although primarily directed at Mexico, Canada had to make one minor change to be in full compliance with the Paris Convention on the Protection of Intellectual Property of 1967. This had to do with the ability to use an invention between the time of filing or priority date of a patent application for the invention and the time of publication of the patent application. This change is canvassed below.

3. NAFTA, *supra* note 1, art. 1709, § 7, 32 I.L.M. at 673.

4. NAFTA, *supra* note 1, art. 1703, § 1, 32 I.L.M. at 671.

5. American Intellectual Property Law Association.

6. For a discussion of fears that the intent of the NAFTA provision would be circumvented, see C.L. Ghoiz, *What Article 1709(7) of NAFTA will Mean to Canadian Practitioners*, 1993 Firm paper of Oblon, Spivak, McClelland, Maier & Neustadt, P.T.I.C. J. (Spring 1993).

SUBSTANTIVE CHANGES TO PATENT AND ASSOCIATED LAW

Canada needed to implement relatively few changes to its own patent law in order to be in accordance with the requirements of the NAFTA, as most of Canada's intellectual property statutes had undergone a modernizing revision in anticipation of Canada's obligations. Nonetheless, certain changes were implemented by the NAFTA Implementation Act⁷ which came into force on January 1st, 1994. Other significant changes were made in February 1993 by the Patent Act Amendment Act,⁸ (often still referred to as Bill C-91) particularly in relation to the virtual abolition of the compulsory licensing scheme.

Scope

Chapter 17 of the NAFTA deals with intellectual property, and Article 1709 sets out the scope of patent protection required in the signatory nations. Inventions in "all fields of technology" must be patentable.⁹ Specific exclusions are permitted where

necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that the exclusion is not based solely on the ground that the Party prohibits commercial exploitation in its territory of the subject matter of the patent.¹⁰

The NAFTA also allows parties to exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than microorganisms; and
- (c) essentially biological processes for the production of plants or animals other than non-biological and microbiological processes for such production.¹¹

This allows parties to, among other things, continue to exclude the patentability of higher life forms and methods of medical treatment. Although Canada currently allows the patenting of microorganisms; plants, seeds, and animals may not be patented.¹² Methods of medical treatment

7. NAFTA Implementation Act, ch. 44, S.C. 1993 (Can.).

8. Patent Act Amendment Act, 1992, ch. 2, S.C. 1993 (Can.).

9. NAFTA, *supra* note 1, art. art. 1709, § 1, 32 I.L.M. at 673.

10. NAFTA, *supra* note 1, art. 1709, § 2, 32 I.L.M. at 673.

11. *Id.*

12. *See Pioneer Hi-Bred Ltd. v. Comm'r of Patents*, 25 C.P.R.3d 257 (1989) (Can.), where the court refused to grant a patent on a new variety of soybean prepared by cross-breeding. *See also The Plant Breeders' Rights Act*, 1 S.C., ch. 20 (1990) (Can.) (protecting new varieties of plants). For further information about the patentability of biotechnological products in Canada,

may not be patented.¹³ This is an administrative and judicial, rather than an overt political, decision.

The attempt to patent the Harvard Mouse¹⁴ in Canada recently failed at the Patent Office level, and again at the Patent Appeal Board (on August 4, 1995). The grounds for this decision were that the transgenic mouse does not constitute patentable subject matter under the Patent Act. The words "manufacture" or "composition of matter" within the definition of "invention" could not include a nonhuman mammal, the Board stated. The Board also weighed the inventors lack of control over all the characteristics of the mouse in finding that the inventors were unable to consistently reproduce the invention. Although the definitions of "invention" in the U.S. legislation and in Canada's Patent Act are similar, the Board refused to give weight to U.S. practice in interpreting Canada's Patent Act.

This decision is being appealed further to the Federal Court of Appeal, in the form of a judicial review of the decision of the Patent Appeal Board. It is not at all clear which way this matter might go, and the prospects for a political decision in this matter are not particularly rosy. The last time the Federal Court of Appeal considered the patentability of a higher life form, a new variety of soybean plant and seed produced by cross-breeding, it stated that the ordinary meaning of the words "composition of matter" and "manufacture" would be distorted if a soybean variety were included within their scope.¹⁵

There is also concern that the permitted exclusions in the NAFTA might allow large areas of technology to be declared unpatentable. The fact that a party to the NAFTA may exclude patentability on the basis of *ordre public* or morality leaves commercial interests subject to the present or future whim of the electorate. Some would argue that this is how it should be, but one does not have to look far for an example of public condemnation of business practices without any real basis in fact—the recent "Mad Cow Disease" affair in Europe¹⁶ shows how easily reality and impression can part company.

see E.M. McMahon, *Update on Canadian Law Affecting Biotechnology Products* (Feb. 29, 1993) Canadian Institute Seminar on the Business of Biotechnology; Nucleic Acid Sequences and Naturally Occurring Products: Are They Patentable in Canada? (1995), Genetics and the Law Conference [hereinafter *The Business of Biotechnology*].

13. The Patent Office will accept a claim to a "use of a drug to treat an indication," but will reject a claim to "a method of medical treatment of an indication using a drug." For a review of law on methods of medical treatment, see McMahon, *The Business of Biotechnology*, *supra* note 12.

14. The Harvard Mouse is a mouse that was genetically altered so as to be more susceptible to cancer. It was developed to serve as a model for breast cancer research. The Harvard Mouse has had patents issued from both the United States Patent and Trademark Office and the European Patent Office.

15. *Pioneer Hi-Bred Ltd v. Comm'r of Patents*, 14 C.P.R.3d 491 (1987) (Can.).

16. Bovine spongiform encephalopathy, more commonly known as "mad-cow" disease, is a brain disease which affects beef and dairy cattle. Mad-cow disease was first identified in 1986. The foremost theory for the origin of mad-cow is that it came from scrapie, a fatal viral disease found in sheep. (Scrapie is characterized by twitching, excitability, excessive thirst, weakness, and, in its latter stages, paralysis.)

Certainly, the traditional argument of developing nations and newly industrialized countries that all intellectual property should be public property could well be considered an assertion on moral grounds. Although such a divergence of public opinion and standards of belief is unlikely to arise between the U.S. and Canada, it is worth remembering that a private property right in intellectual property is a relatively new concept in Mexico and accession to western-style intellectual property rules represents one of Mexico's significant concessions in signing the NAFTA.

Of particular interest to biotechnology companies is Article 1709(4) of the NAFTA.¹⁷ It requires signatories to make available product patent protection for pharmaceutical or agricultural chemicals as of January 1, 1992 for subject matter that relates to "naturally occurring substances prepared or produced by, or significantly derived from, microbiological processes and intended for food or medicine."¹⁸ This provision was intended to ensure that signatories provide product, rather than "product-by-process" protection for biotechnological inventions by January 1, 1992. The wording in this

Britain, which has a \$7.5 billion-per-year beef industry, is the only European country in which mad-cow disease exists. This is typically explained by citing the presence of a number of factors, including a high infection rate of sheep with scrapie and the practice of grinding and then feeding to cows sheep brains as a protein supplement.

In November 1995, some scientists theorized that there is a close link between mad-cow disease and Creutzfeldt-Jakob Disease (CJD), a rare but fatal human brain disease that had recently claimed the lives of ten Britons. The theory was expanded to hypothesize that the human disease could be traced to an abnormal protein in the cell membrane which, if consumed, could be transferred and damage proteins in the host. Although the Ministry of Agriculture, Fisheries and Food produced a number of scientists who showed that it was unlikely for the disease to be transmitted across species, other scientists disagreed. Debates regarding this link were common in British medical journals.

Although no conclusive link could be proved or disproved, public opinion regarding the matter was clear. In January 1996, Nielsen statistics showed that 1.4 million households had ceased to buy British beef. From November to mid-December, beef sales declined by 25% from the similar period in 1994. The most notable decline occurred in hamburger sales, which fell by 40%. John Darnton, *Fear of Mad-Cow Disease Spoils Britain's Appetite*, N.Y. TIMES, Jan. 12, 1996, at A1.

Then, in March 1996, Health Secretary Stephen Dorrell reported to the House of Commons that the most likely explanation for the recent outbreak of CJD was exposure to mad-cow disease. Nearly every country in the European Union, as well as other countries around the world, imposed bans on the importing of British beef. But the worst blow came on March 27, 1996, when the European Commission imposed a world-wide ban on the exporting of British beef and a variety of products containing beef byproducts. John Darnton, *Europe Orders Ban on Exports of British Beef*, N.Y. TIMES, Mar. 28, 1996, at A1.

Almost three months later, on June 22, 1996, the European Commission agreed to a plan that would gradually repeal the ban on British beef. The plan, however, contains no specific dates for an end to the ban, and requires Britain to destroy approximately 120,000 cattle. John Darnton, *For the British Beef War: A Truce but No Victory*, N.Y. TIMES, June 24, 1996, at A9.

The impact of the mad-cow scare on the British economy was severe. The Office for National Statistics reported that the decline in beef sales resulting from the mad-cow scare reduced Britain's quarterly GDP growth by a tenth of a percentage point for the second quarter of 1996. Although forecasted to do so to a lesser extent, the mad-cow scare is also likely to impact Britain's third quarter GDP figures as well. *Farm Woes Curb British Growth*, N.Y. TIMES, July 27, 1996, § 1, at 40.

17. NAFTA, *supra* note 1, art. 1709, § 4, 32 I.L.M. at 673.

18. *Id.*

provision tracks the wording in the former subsection 39(1) of Canada's Patent Act, which restricted protection for foods and medicines that related to naturally occurring substances prepared or produced by, or significantly derived from microbiological processes to product by process claims.¹⁹ The Canadian Patent Office continues to apply subsection 39(1) to patent applications filed before October 1, 1989. This practice may be contrary to the NAFTA.²⁰

Other Changes

The NAFTA Implementation Act²¹ also made several less momentous changes to Canada's Patent Act.²² The previous version of the Act provided for federal government use of patents. Modifications introduced now extend the right to use patents to the provincial governments as well, but at the same time, require that the government concerned make efforts first to obtain authority for use from the patentee on "reasonable commercial terms and conditions."²³ If this fails, the Commissioner of Patent may authorize governmental use of a patent and set out terms for such use. The rules for determining compensation to the patentee in this case are less rigid than those previously set out.

The provincial governments are under increasing pressure to decrease health care costs, including the costs of patented medicines. The provincial governments' ability to use patents raises the prospect that governments will seek compulsory licenses of patented medicines and then import those medicines (or sub-license rights to import those medicines to other persons) at a lesser cost to the provincial governments than the innovators' medicines. Although NAFTA Article 1709(10)²⁴ says that the compulsory license is not assignable, it does not say that it is not sublicensable.

Formerly, subsection 27(3) of the Patent Act allowed for the prohibition of the issue of a patent for an invention having an illicit object in view. This section was removed in order to comply with the restricted list of acceptable reasons for excluding an invention from patentability set out in Article 1709(2) of the NAFTA.

The former section 55.1 provided for a presumption of infringement where a substance of the same chemical composition as that claimed in a previously issued patent was made, used, or sold. The presumption provided that the process was assumed to be the same if the result was the same. The

19. See *Eli Lilly v. Comm'r of Patents*, 42 C.P.R.3d 34 (F.C.T.D. 1992) (Can.).

20. P.C. Mendes da Costa, *NAFTA-The Canadian Response or Why Does the Canadian Patent Act Keep Changing?*, 22 AIPLA Q.J. 65, 71 (1994).

21. NAFTA Implementation Act, ch. 44, S.C. 1993 (Can.).

22. For a full discussion of these changes, see W.N. Springings, *The Impact of the NAFTA Amendment Act on Canadian IP Statutes*, 10 C.I.P.R. 475 (1994).

23. Patent Act Amendment Act, 1992, ch. 2, S.C. 1993 (Can.).

24. NAFTA, *supra* note 1, art. 1709, § 10, 32 I.L.M. at 674.

NAFTA Amendment Act²⁵ has extended this presumption to all products, not just chemical compositions.

The NAFTA Implementation Act also made some changes to the infringement exception available to previous purchasers. In the past, if a distributor imported a product into Canada before a patent application was published, the distributor could sell the product at any time without fear of infringing (although the distributor could not of course import any more product). The new provisions allow only for the sale of products imported before the filing or priority date at any time. Products imported after the filing or priority date, but before the publication date, may only be sold before the publication date.

Trade Secrets

NAFTA Article 1711 provides for the protection of trade secrets. In Canada, trade secrets are encompassed in provincial common law, which is well developed and provides all the safeguards contemplated by the NAFTA. In Canada's case, the NAFTA requires that if a party requires the "submission of undisclosed test or other data" as a condition of approval for pharmaceutical or agricultural chemical products, the government must protect that information except where disclosure is necessary to protect the public interest or unless "steps are taken to ensure that the data is protected against unfair commercial use."²⁶ In addition, where submissions are made on an equivalency basis for product approvals, the innovator is entitled to a minimum five year moratorium on the issue of approval to the competitor who relies on the innovator's data.²⁷ This requirement is reflected in changes to the regulations under Canada's Food and Drugs Act.²⁸

Bill C-91, the Intellectual Property Amendment Act

The Intellectual Property Amendment Act, still often referred to as Bill C-91, introduced many changes to Canada's patent law in advance of and in anticipation of the implementation of the NAFTA. The most important of these was the abandonment of the long-standing compulsory licensing regime for patented medicines.

Compulsory Licenses

Historically, a special situation has existed in Canada with regard to patented medicines, which has caused much alarm and despondency among

25. NAFTA Implementation Act, ch. 44, S.C. 1993 (Can.).

26. NAFTA, *supra* note 1, art. 1711, § 5, 32 I.L.M. at 675.

27. *Id.*

28. Food and Drugs Act, R.S.C., ch. F-27 (1985) (Can.).

U.S. pharmaceutical companies. Until very recently, Canada has employed an extensive compulsory licensing system, particularly in the area of patented medicines. The purpose of the compulsory licenses, which also extended to methods of production for food, was to make the product "available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention."²⁹ Between 1969 and 1989, persons seeking compulsory licenses to import patented medicines were invariably granted the licenses for 4% of the net sales price of the patented medicine in final dosage form. By Bill C-22, promulgated in 1989, the granting of compulsory licenses was somewhat restricted. In specified circumstances, the Commissioner of Patents was still *required* to issue such a license unless the drug was developed in Canada, in which case it was still open to competitors to gain a compulsory license if they could meet the more general criteria canvassed below. Then, in 1993 (in Bill C-91), compulsory licensing of patented medicines and patented foods was abolished. As a transitional provision, compulsory licenses granted before December 20, 1991, continue in force in accordance with their terms.

There was also provision for compulsory licensing of other patents in Canada, on several grounds, perhaps the most important of which was that the patent was not being worked in Canada on a commercial scale. It was held that importation did not suffice—if an invention was not being worked in Canada, this was grounds for the issue of a compulsory license. Other grounds for issue of a compulsory license included the following: where the working in Canada was being hindered by importation by the patentee or his agent; where demand for the product was not being sufficiently met; if the patentee, by refusing to issue licenses, or licenses on reasonable terms, was hindering the development of new industries or the public interest otherwise required the license; where any trade, industry or person was unfairly prejudiced; or if the patent was for a process to use or make materials and the sale or use of those materials was prohibited by the patentee. The virtual elimination of the requirement for the patent to be worked in Canada is a result of the NAFTA Implementation Act. One of the remaining requirements to "work" the patent is set out in section 65(2)(c) of the new Patent Act,³⁰ and refers to failure to supply the Canadian market being grounds for action by the Commissioner of Patents.

The more general elimination of the compulsory licensing regime for patented drugs effective February 15, 1993, was in accordance with (although in anticipation of) the requirements of the NAFTA. It was part of Bill C-91, the Patent Act Amendment Act.³¹ NAFTA Article 1709(10) requires that compulsory licensing be limited to specific situations in which

29. *Hoffmann-La Roche Ltd. v. Bell-Craig Pharmaceuticals*, [1966] S.C.R. 313, 319 (1966) (Can.).

30. Patent Act Amendment Act, 1992, ch. 2, S.C. 1993, § 65(2)(c) (Can.).

31. Patent Act Amendment Act, 1992, ch. 2, S.C. 1993 (Can.).

the patentee was abusing the rights granted by the patent, such as lack of exploitation or anti-competitive activities.³²

Some hold the opinion that compulsory licensing for patented medicines could be reintroduced in Canada and be justified under the NAFTA. In Canada, the existence of the compulsory licensing provisions created a large vested interest in the shape of the "generic" drug companies, who of course lobbied against the repeal of compulsory licensing and would strongly support its reintroduction. Persuasive arguments can be made that the "limited exceptions" to the exclusive rights conferred by a patent (permitted by NAFTA Article 1709(6)) could include a national regime of compulsory licensing for patented medicines. To assert such a position would invite much criticism from Canada's trading partners, however.³³

The government will consider the reintroduction of compulsory licensing as part of its review under the "sunset clause" of Bill C-91.³⁴ This review will take into account Canada's obligations under the NAFTA.

The Patented Medicines Prices Review Board

The Patented Medicines Prices Review Board (PMPRB), established under Bill C-22 in 1989, continues despite the pre-NAFTA and NAFTA changes to the Patent Act. The PMPRB continues to have the power to investigate and regulate excessive pricing, investigate sales and expense activities of patented medicines in Canada and review the investment by innovators in research and development of patented medicines in Canada.³⁵ To date, the PMPRB has not considered it within its jurisdiction to review the pricing of patented medical devices.

To attempt to avoid the jurisdiction of the PMPRB, companies have dedicated hundreds of patents on medicines to the public. The PMPRB has indicated recently that dedications do not remove its jurisdiction to review the pricing of patented medicines. The PMPRB's jurisdiction over patents dedicated to the public will likely be the subject of further judicial review.³⁶

32. J.R. JOHNSON, *THE NORTH AMERICAN FREE TRADE AGREEMENT, A COMPREHENSIVE GUIDE* 442 (1994).

33. For a detailed examination of the legality of compulsory licensing under the NAFTA (and the TRIPS Agreement), see J.G. Castel, *Legal Opinion with respect to Canada's Intellectual Property Obligations regarding Pharmaceutical Patent Compulsory Licensing Under the GATT and the NAFTA* (1993), prepared for the Canadian Drug Manufacturer's Association.

34. For a discussion of the economic impact of intellectual property, including compulsory licensing, on the biotechnological industry in Canada, see J.G. Heller, *Background Economic Study of the Canadian Biotechnology Industry*, Industry Canada (1995).

35. For further information on the PMPRB, see also E.M. McMahon, *Overview of the Law Relating to Pricing Biopharmaceuticals in Canada*, presented at BIO'94 (1994) (on file with author).

36. It has already been the subject of judicial review. See *Genentech Canada, Inc. v. PMPRB*, 44 C.P.R.3d 316 (1992) (Can.) (The pricing by Genentech of tissue plasminogen activator was in question.).

Other Pre- NAFTA Changes

A significant change made by Bill C-22 was the extension of the term of patents to 20 years from issue (in accordance with NAFTA Article 1709(12)) and the change from a first-to-invent system to a first-to-file system.

Bill C-91, contained a "sunset clause" which required the bill be reviewed five years after its legislation. The time for this review is quickly approaching. Despite unhappiness in some circles with the elimination of the compulsory licensing scheme, and the teething problems with its successor (see below "Indirect Barriers to Trade—Drug Approvals"), significant changes seem unlikely.

UPOV & Canada's Plant Breeders' Rights Act (PBRA)

The NAFTA mandates that plant varieties be protected under patent law, "an effective scheme of *sui generis* protection" or both.³⁷ This is a specific exception to the allowable exclusions of plants and animals from patentability. The NAFTA text requires that signatories give effect to the substantive provisions of the International Convention for the Protection of New Varieties of Plants (the "UPOV Convention"), which Canada signed in 1978 and ratified in 1991. Plant varieties are protected in Canada by the Plant Breeders' Rights Act,³⁸ which came into force August 1, 1990. Only certain specific varieties of plants set out in the accompanying regulations are eligible for protection, mostly cereal grains, beans, fruit trees, and flowers. The type of protection provided under the Act is emphatically only for varieties, not for parts of plants, such as nucleic acid sequences, vectors, plant cells, or tissue cultures. Plants are still not patentable in Canada, as are other life forms larger than microorganisms, as discussed above. The protection is attractive in that the breeder need not demonstrate non-obviousness in seeking protection of the new variety. The breeder need only demonstrate that the variety is distinct, uniform and stable.³⁹

There are provisions for compulsory licenses in the Plant Breeders' Rights Act. To date, no person has requested a compulsory license under a plant breeder's rights certificate, but companies protecting their varieties under this legislation have expressed concern about the ability of the Plant Breeders' Rights Office to grant compulsory licenses. An applicant has the onus of demonstrating that the circumstances for the grant of a compulsory license are met; this is in contrast to the former compulsory license provisions in Canada's Patent Act where the Commissioner had the onus of demonstrating that circumstances did not support the grant of a compulsory

37. NAFTA, *supra* note 1, art. 1709, § 3, 32 I.L.M. at 673.

38. The Plant Breeders' Rights Act, ch. 20, S.C. 1990 (Can.).

39. *Id.*

license. The Office does not have a published policy on how it will handle requests for compulsory licenses.

PROCEDURAL CHANGES

Provision for Delayed Approval Processes

The NAFTA provides for the extension of protection periods for intellectual property, including patents where the commercial exploitation of an invention is delayed by a prolonged process of regulatory approval.⁴⁰ However, the provision is permissive. Canada's Patent Act does not provide for patent term extension due to regulatory delays. The current belief among Canadian regulators is that no initiatives of this sort can be expected. This is particularly disappointing in view of the burdensome approval processes in Canada for many drugs, including biologics, novel foods produced by biotechnology, and medical devices.

Bioequivalency

NAFTA Article 1711(6) addresses the question of the use of innovators' data in seeking approvals for products, principally medicines. The new regulatory regime in place permits bioequivalence and bioavailability studies in seeking approval of medicines, and some of the problems attendant on the new system's implementation.⁴¹ In addition, the information disclosed by the innovator in the initial application must, under the NAFTA, be protected as a trade secret.

The NAFTA does not require the use of competitors' test data of the type contemplated in a drug approval process. NAFTA Articles 905 and 906 deal with standards related technical barriers to trade, and make recommendations only regarding the acceptance of other countries' test data, although not necessarily competitors'. NAFTA Article 906(6) reads as follows:

6. Each party shall, wherever possible, accept the results of a conformity assessment procedure conducted in the territory of another party, provided that it is satisfied that the procedure offers an assurance, equivalent to that provided by a procedure it conducts or a procedure conducted in its territory the results of which it accepts, that the relevant good or service complies with the applicable technical regulation or standard adopted or maintained in the Party's territory.⁴²

This "shall, wherever possible" language is of course permissive. As well, there is great scope for claims of higher standards.

40. NAFTA, *supra* note 1, art. 1709, § 12, 32 I.L.M. at 674.

41. For a description of the drug approval process in Canada, see E.M. McMahon, *New Drug Approval in Canada*, PAREXEL INT'L (1995).

42. NAFTA, *supra* note 1, art. 906, § 6, 32 I.L.M. at 387.

The Canadian Standards Association (CSA), assesses conformity with electrical standards of medical devices having electrical components. The CSA recognizes conformity assessments of other countries.

The Medical Devices Bureau in Canada is moving towards mutual recognition agreements with the European and U.S. regulatory authorities. These agreements would recognize regulatory reviews conducted by these authorities. The agreements may help to expedite approvals of medical devices in Canada that have been previously approved for sale in the United States or Europe. Furthermore, in the near future, a Canadian approval may offer a window to the European market as the federal government expects to sign a mutual recognition agreement with Europe sometime this year.

The Drugs Directorate in Canada is giving weight to reviews conducted by the European Medicines Evaluation Agency (EMEA) and the United States Food and Drug Administration (U.S. FDA). It has published performance targets for reviewing drug submissions at internationally competitive time frames and for internationally competitive prices. These targets may require the Drugs Directorate to give more weight to regulatory reviews of other regulatory authorities than it has previously done. Joint reviews by the Canadian Drugs Directorate and the U.S. FDA are also available.

ENFORCEMENT

The NAFTA requires that adequate enforcement provisions be in place for intellectual property right infringements. NAFTA Article 1714 states that enforcement procedures must be available, and that the procedures themselves must not be so costly or unnecessarily complicated as to themselves be indirect barriers to trade.⁴³ In addition, the procedures must not entail unreasonable time limits or unwarranted delays.⁴⁴ Certain natural justice requirements are set out at NAFTA Articles 1714(3) and 1715(1), and a right of judicial appeal at Article 1714(4). Although these and other measures, set out at Articles 1714-1718, require change mostly in Mexico, it is worth surveying the Canadian situation.

Private Enforcement

Canada of course has civil remedies for infringement of all types of intellectual property rights. In Canada, the courts are the first resort in infringement actions, there being no administrative body which deals with such actions. There is perhaps a limited exception, in that infringement of drug patents by an applicant for a Notice of Compliance relying on bioequivalence will end up in a judicial review of administrative action, although in a roundabout way. This process is addressed in detail below.

43. NAFTA, *supra* note 1, art. 1714, 32 I.L.M. at 676.

44. *Id.*

Border Seizure

NAFTA Article 1718 provides for "Enforcement of Intellectual Property Rights at the Border."⁴⁵ Although these measures are primarily directed at Mexico, Canadian law has often been remiss in these areas as well. The seizure of counterfeit and pirated goods is a great concern to corporations holding the intellectual property rights. Canada Customs can only act under the Copyright Act and the TradeMarks Act, and even those powers have been limited by narrow judicial interpretations. For companies whose

- colour, shape or size of medicine or medical device,
- packaging, labeling or product monograph, or
- trade-mark or logo, has been copied by a competitor, border seizures may be of interest.

In order for Customs to act in a trademark infringement matter, a final judgment must first be rendered by the courts, interlocutory or preliminary orders will not be sufficient.⁴⁶ For copyright piracy, an order must be obtained under the provisions of the Copyright Act, but there is no positive obligation on the Minister of National Revenue, who directs Canada Customs, to act. As a result, the courts will not issue a writ of *mandamus* to force the Minister to order the seizure.⁴⁷ Some writers have suggested that counterfeit goods are essentially allowed to enter Canada with little difficulty.⁴⁸ Clearly, there is room for improvement in this area to be in accord with the intent of the NAFTA, although no corresponding modifications in Canadian legislation have been forthcoming.

Requirement for Criminal Sanctions

NAFTA requires criminal sanctions be in place in all countries for the worst types of intellectual property infringements and offenses.⁴⁹ At a minimum, trademark counterfeiting or copyright piracy on a commercial scale would require such sanctions. Canada has criminal code provisions that cover forgery of trade-marks and trade descriptions, including passing-off. Copyright piracy is covered by Canada's criminal fraud provisions. Patent infringement remains a ground only for a civil action, and the NAFTA does not specifically contemplate any requirement for criminal sanctions in this area.

45. NAFTA, *supra* note 1, art. 1718, 32 I.L.M. at 678-79.

46. *Montres Rolex, S.A. v. Minister of Nat'l Revenue*, 17 C.P.R.3d 507 (1987) (Can.).

47. *See Dennison Mfg. Co. v. Minister of Nat'l Revenue*, 15 C.P.R.3d 67 (1987) (Can.).

48. S. Burshtein, *Impact of the North American Free Trade Agreement on Intellectual Property in Canada* (1993) (unpublished paper, on file with Blake, Cassels & Graydon).

49. NAFTA, *supra* note 1, art. 1717, 32 I.L.M. at 678.

Grey Marketing

The NAFTA drafters considered the inclusion of provisions dealing with so-called "grey marketing," but in the end the subject was not included. Nonetheless, it is a topic highly relevant to those working in innovative industries.⁵⁰ The drug industry may serve as an example. In Canada, pricing of drugs is regulated not only by the PMPRB, but also by public and private formularies and market forces. This can result in a price differential across the Canada and U.S. border. The price of one unit of drug in Canada could be \$10 U.S. while in the U.S. it could be \$15 U.S. This price differential could act as an incentive for grey marketers to buy the drug in Canada and to "dump" it into the U.S.

All the effort in the world to protect intellectual property rights on a national basis, even with international minimum standards such as are set out by NAFTA, are of lessened value where there is no effective remedy for the rights holder against "dumping" by holders of the same right in another jurisdiction. Usually it is not the local licensee itself that moves product to another jurisdiction, but another party that has bought from the licensee. Therefore, such grey marketing is often beyond the control of the local licensee, and as a result of this there is no privity of contract between the original innovator, through his licensee to the grey marketer. This lack of an effective remedy against the grey marketer is referred to as exhaustion of rights. Effective enforcement of these rights will require some statutorily created cause of action. So far, there have been no initiatives to do so.

PRACTICE CONSIDERATIONS

Indirect Barriers to Trade—Drug Approvals

With the repeal of the compulsory licensing provisions for food and medicine, an interim policy was created by the promulgation of the Patented Medicines (Notice of Compliance) Regulations,⁵¹ proclaimed in force March 24, 1993. These regulations, which were made without public consultation, have resulted in an amazing amount of litigation.⁵² They are a regulatory scheme under the authority of the Food and Drugs Act,⁵³ but have important intellectual property implications.

In order to sell a medicine in Canada, a Notice of Compliance (NOC) must be issued by Health Canada. The obtaining of such an NOC is a

50. See generally Charles S. Levy & Stuart M. Weiser, *The NAFTA: A Watershed for the Protection of Intellectual Property*, 27 INT'L L. 671 (1993).

51. SOR/93-133.

52. See *Hoffmann-La Roche Ltd. v. The Minister of Health and Welfare*, No. T-1964-93, No. T-1898-93 (March 20, 1996) (holding that "the quantity of litigation . . . and the attendant cost . . . is most disconcerting").

53. Food and Drugs Act, R.S.C., ch. F-27 (1985) (Can.).

complex, time consuming and expensive prospect, especially in view of cost recovery initiatives, discussed below. Canadian authorities wanted to allow some reliance on approvals already granted in the processing of new requests for NOCS. The procedure required by the Patented Medicines (Notice of Compliance) Regulations is that where a company files an application for an NOC and wishes to compare that drug with, or make a reference to, another drug that has been marketed in Canada (and therefore has an NOC), the company must either

- accept that the newly requested NOC will not issue until the patent on the earlier drug expires,
- allege that there is an error in one or more of the patents supporting the first drug's NOC, or
- allege that "no claim for the medicine itself and no claim for the use of the medicine would be infringed" by the new drug for which application is made.

Applicants commonly rely on the latter ground (that no claim would be infringed). This process is commonly, although unofficially, known as the issue of an "allegation" and the service of this allegation on the innovator as a "notice of allegation."

The regulations were intended to emulate the similar U.S. system, but diverge from their prototype in several areas. Firstly, the use of comparisons does not trigger the right to a conventional patent infringement action, but to an administrative remedy. Secondly, the innovator files the patent list and, with the exception of a review by the Patent Office to remove process patents, the list is not reviewed to determine whether the patents claim the medicine or the use of the medicine which is the subject of the NOC. This has resulted in controversies about the relevance of certain patents on the list.

The regulations require that the owner of the first NOC (and its supporting patents) prove that the new drug would infringe its patents. In effect, the onus is shifted onto the holder of the extant NOC. Because of the large generic industry in Canada, many of these burden-shifting applications are made.

The remedy available to the first NOC holder is to apply for an order prohibiting the issuance of an NOC by the Minister. If the original NOC holder contests the second applicant's allegation that its product does not infringe the patents on which the original NOC holding drug is based, the result is essentially a 30-month injunction against the second applicant. The holder of the original NOC will invariably contest the assertions of the second applicant (the second applicant's "notice of allegation"), because of the value of delaying a competitor's market entry.

The decisions in these matters are, in theory, made at first instance by the Minister of Health. However, because the application for prohibition is made before the Minister has considered the question, there is no consideration by the Minister of whether an NOC should issue. The court proceed-

ing is in the nature of an application for an order of prohibition before the Federal Court of Canada. As the proceedings are for prohibition with no record, evidentiary problems arise. There is no record of the deliberations of the Minister, because there have not been any deliberations, and so the court is faced with a decision to review with essentially no evidence. Affidavit evidence is admitted, but the result is what amounts to an infringement action under the guise of an application for prohibition.⁵⁴ It has been held that part of the problem is that the procedure "whose clear intention is to facilitate the protection of private commercial patent rights, have been grafted onto a regulatory scheme . . . whose sole purpose is the protection of public health and safety [and] . . . the union is not a happy one."⁵⁵

Over the past three years, numerous applications for prohibition have been undertaken as a result of these regulations. There is no doubt that these actions are cumbersome and generate unnecessary litigation. There is a move afoot in some circles to either improve or remove the regulations. It may well be that, following an intense period of judicial clarification, the process is beginning to work. In any case they are considered, at least by innovator companies, as an improvement on the compulsory licensing system.

Comparative Approvals and the "Five-Year Hold"

Another important intellectual property related effect of the Food and Drugs Act and its Regulations is the "five year hold" provision.⁵⁶ Enacted in concert with regulations allowing reliance on test data from previously marketed drugs for competitors (bioequivalency and bioavailability), it provides that no applicant who relies on comparisons with a predecessor (innovator) drug may be issued a Notice of Compliance permitting the marketing of their drug for five years from the date the innovator received its Notice of Compliance. This preserves a measure of exclusivity outside the ambit of patents for the innovator company. The requirement for a delay in the ability to rely on equivalency submissions is, required by Article 1711(6) of the NAFTA. It calls for a reasonable period before a competitor can gain product approval based on an innovator's test data. Article 1711(6) goes on to state that a "reasonable period" shall "normally" mean not less than five years.

54. See R.E. Dimock, et al., *Intellectual Property Litigation in Canada Before and After NAFTA*, 1 C.I.P.R. 341, 343 (1994).

55. *Merck Frosst Canada, Inc. v. Canada*, 55 C.P.R.3d 202, 217 (1994) (Can.).

56. Section C.08.004.1.

Other Indirect Barriers to Trade Applicable to Drugs

The NAFTA contemplates the use of international standards for compatibility and equivalence in the gaining of regulatory approval for any product, although it does not require such a system be in place.⁵⁷ The only positive obligation of this sort created by the NAFTA is not to place unnecessary obstacles in the way of trade by means of regulatory approval processes (“standards-related obstacles”); however, as long as there are legitimate concerns, regulation can be as onerous as the party desires.⁵⁸ Although efforts are underway to make use of international standards for product approvals, the process can still be cumbersome.

Further Regulatory Initiatives in Canada

In an effort to meet become more internationally competitive in their review times, most departments of the Canadian Federal Government have now adopted cost recovery programs, by which the majority of the costs involved in providing services, principally to corporations, will be borne by those corporations. At the Intellectual Property Office, this initiative is still in the future. However, costs for Drug Approvals (NOCS) from the Drugs Directorate and from the Medical Devices Bureau of Health Canada have risen considerably. The cost recovery programme at the Drugs Directorate was initiated in October 1994, and all the increases that relate to drug approvals are now in place. Although these cost increases could be considered a disincentive, they do not really constitute an indirect barrier to trade, as U.S. approvals are costly as well. In addition, costs should be reduced by new provisions allowing for reliance on extant test data.

The new Patent Rules are due out any time.⁵⁹ They are intended to reflect recent changes in the Patent Act, many of which were associated with the requirements of the NAFTA. Hopefully, they will streamline the process somewhat. They are not expected to provide for any material change in the patent application and approval process.

In addition, Health Canada intends to introduce several new initiatives over the next several years, among which will be regulations dealing with novel foods and novel food processes, regulation of the transfer and use of human organs and tissues (including eggs and zygotes), and post-approval drug regulation to ensure continuing safety. These and other regulations are of course subject to comment and modification.⁶⁰

57. NAFTA, *supra* note 1, arts. 905 & 906, 32 I.L.M. at 387.

58. NAFTA, *supra* note 1, art. 904, § 4, 32 I.L.M. at 386.

59. The draft Patent Rules have been published for comment.

60. For details, see the *Federal Regulatory Plan, 1996*, (1995) Minister of Supply and Services Canada.

CONCLUSION

The NAFTA was in large part anticipated by evolutionary changes to Canadian patent and associated law. However, those anticipatory changes were very significant, especially the virtual end of compulsory licensing for patented medicines, and the instigation of a U.S.-style equivalence approval process for non-innovator drugs. In addition, the passage of Canada's Plant Breeders' Rights Act was eventually called for by the NAFTA.

The NAFTA itself did bring changes to Canadian patent and drug regulatory and associated laws. All in all, the aims of the NAFTA have been achieved through these changes. As a general rule, access to the Canadian market will now be better for U.S. corporations, and vice-versa. In the area of patented medicines, not only have formal trade barriers disappeared but many of the indirect barriers to trade created by the drug approval and compulsory licensing systems have been removed or at least simplified.