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Non-voluntary Licensing of Patented Inventions: The Canadian Experience

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Table of Contents

Explanatory Note.....	4
1. Introduction	6
2. Abuse of the Patentee's Exclusive Rights, Including the Duty to Work.....	8
2.1 Economic Evaluation of the Local Working Requirement	10
2.2 Abusive Non-working or Importation in Selected Cases (1935-1993)	11
2.2.1 Local Working Defined	12
2.2.2 The Relevant Period of Time	14
2.2.3 Justifying a Failure to Work.....	15
2.2.4. Abusive Importation as a Separate Ground	19
2.3 Demand Not Adequately Met.....	20
2.4 Refusal to License or to License on Reasonable Terms	22
2.5 Unduly Restrictive Licensing Conditions	24
2.6 Use of Process Patent to Restrict Unpatented Products	24
2.7 Nonstatutory Abuse on Equitable Grounds.....	25
3. Competition Law	26
4. Safeguarding the Public Interest.....	33
4.1 Compulsory Licensing of Food and Pharmaceutical Patents (1923-1992)	33
4.1.1 The 1969 Reform	33
4.1.2 Implementing the Reform	35
4.2 The Compulsory Licensing Scheme Abandoned	38
4.2.1 Bill C-22: An Interim Compromise Solution.....	39
4.2.2 C-91: The Retreat from Compulsory Licensing.....	43
5. Government Use of Patented Inventions.....	45
5.1 Government Use Prior to 1994.....	45
5.2 Government Use After NAFTA and TRIPS	48

Explanatory Note

This second case study on non-voluntary licensing of patented inventions by Prof. *J. H. Reichman* has been prepared in the context of the Project on TRIPS and Development Capacity Building sponsored by the Department of International Development (DFID UK). The Project is being implemented by the secretariat of the United Nations Conference on Trade and Development (UNCTAD) (Project Number INT/OT/1BH) and the International Centre for Trade and Sustainable Development (ICTSD). The broad aim is to improve the understanding of TRIPS-related issues among developing countries and to assist them in building their capacity for ongoing as well as future negotiations on intellectual property rights (IPRs).

The Project produces a series of documents through a participatory process involving trade negotiators, national policy makers, as well as eminent experts in the field, NGOs, international organizations, and institutions in the North and the South dealing with IPRs and development. The published outputs are not intended to be academic exercises, but instruments that, in their final forms, will be the result of a thorough process of consultation. This will be achieved by rapid development of working drafts and circulation of these to experts and to the intended audiences for their comments. These documents include:

- **A Policy Discussion Paper** intended to be a clear, jargon-free synthesis of the main issues to help policy makers, stakeholders and the public in developing and developed countries to understand the varying perspectives surrounding different IPRs, their known or possible impact on sustainable livelihoods and development, and different policy positions over TRIPS. (A preliminary draft of the Paper was issued on 20 Nov. 2001)
- **The Resource Book on TRIPS and Development** conceived as a guide that will provide background and technical information on the main issues under discussion in TRIPS.
- **Case studies** on various IPRs issues to supplement the Resource Book and the Discussion Paper. This will allow concrete evidence to emerge and shed light on the impact and relevance of IPRs in developing countries. Including non-voluntary licensing, these studies cover other issues such as geographical indications (available as of June 2002) and the forthcoming studies on transfer of technology, traditional knowledge and nutrition.

In addition, the Project produces background material on Indicators of the Relative Importance of IPRs in Developing Countries (see draft of November 2001) and a Review of Activities being carried out by other organizations and institutions on TRIPS related questions and a Review of Literature (both available in the website). For details on the activities of the Project and available material, see <<http://www.ictsd.org/unctad-ictsd>>.

Comments and suggestions may be sent either to Pedro Roffe, Project Director, UNCTAD, Palais des Nations, CH-1211, Geneva 10. Fax: +4122 917 0043; e-mail: pedro.roffe@unctad.org, or to Graham Dutfield, Academic Director, Queen Mary Intellectual Property Research Institute, University of London, John Vane Science Building, Charterhouse Square, London, U.K.; email: gdutfield@ictsd.ch.

The Case Study on Non-voluntary Licensing

The case study on compulsory licensing consists of three parts. They are being published separately in order to facilitate their dissemination and to receive feedback from interested people and institutions. In their revised version, they will be part of an integrated and consolidated publication.

Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under the TRIPS Agreement, and an Overview of the Practice in Canada and the United States (available as of September 2002)

After introducing non-voluntary licensing in its historical context, the paper explains in general terms the approach taken under the TRIPS Agreement (Art. 31) and highlights the main issues. It then provides a brief, comparative overview of non-voluntary licensing in the legal systems of Canada and the United States. The purpose of this paper is to give a first insight, in an historical perspective, into the wide range of possible uses of compulsory licenses as authorized by the TRIPS Agreement.

The Canadian Experience

This survey contains a detailed analysis of the Canadian practice with respect to non-voluntary licensing. It presents both the past and the current legal approaches and illustrates them through case law. The purpose is to provide concrete examples of the approach taken by Canada, including possible problems in the implementation of non-voluntary licensing in the context of the TRIPS Agreement.

Non-Voluntary Licensing of Patented Inventions in the United States

Like the survey on the Canadian experience, this part analyses in detail the US case law. Again, the purpose is to draw lessons from the experience made by a developed country in the use of policy instruments such as non-voluntary licensing over time and at various stages of its own economic progress.

1. Introduction

From the time of the Confederation until it adhered to the North American Free Trade Agreement ("NAFTA") in 1992,¹ "Canada's explicit policy was to encourage local manufacture of patented products."² Until the 1930s, the law required either local manufacture to commence or local licensing on reasonable terms to occur within a two-year period after the patent issued. The penalty for non-compliance was forfeiture.³

This policy was refined in the patent revision of 1935, which treated failure to work or to license a patent as "abuses" of the patentee's exclusive rights.⁴ If the Commissioner found a demonstrated abuse, the standard remedy became that of compulsory licensing at a reasonable royalty, and revocation of the patent thereafter became a last resort.⁵ The provisions that codified Canada's vigorous local working requirements persisted through the revisions of 1970 and 1985,⁶ and they embodied a "made-in-Canada for Canada policy."⁷ However, these provisions have been deemed "only moderately successful."⁸ According to Professor Vaver,

The threat of intervention has not scared many patentees off. Proceedings have been prolonged and expensive; appeals are *de rigueur*; patentees, when alerted, often correct the abuse and retaliate against offending applicants.⁹

Of the 53 applicants who persisted between 1935 and 1970, 11 obtained compulsory licenses, 9 were refused, 32 applications were withdrawn or deemed abandoned, and the outcome of one is unknown.¹⁰ Some 43 additional applications for compulsory licenses were filed under section 65 of the Patent Act between 1970 and June 1989. Of these, 6 resulted in compulsory licenses, 6 were refused, 25 were withdrawn or deemed abandoned, and the outcome of 6 is not known.¹¹ All granted licenses were reportedly nonexclusive in form, and there were four reported settlements among the 25 withdrawn or abandoned applications after 1970.¹²

¹ North American Free Trade Agreement (NAFTA), 17 Dec. 1992, Can. T.S. 1994 No. 2, 32 I.L.M. 612 (entered into force, 1 Jan. 1994) [hereinafter NAFTA].

² David Vaver, *Intellectual Property - Copyright, Patents, Trade-Marks* 169 (1997) [hereinafter D. Vaver].

³ See *Re Bell Telephone Co.* (1885), 9 O. R. 339 (S.P.).

⁴ Patent Act, R.S.C. 1935, §§65-70.

⁵ See D. Vaver, *supra* note 2, at 169. For application procedures, see Roger Hughes & John Woodley, *Hughes and Woodley on Patents* §58 (2001) [hereinafter Hughes & Woodley].

⁶ Patent Act, R.S.C. 1970, c. P-4, §§67-73; Patent Act, R.S.C. 1985, c. P-4, §§65-71.

⁷ D. Vaver, *supra* note 2, at 170.

⁸ *Id.*

⁹ *Id.*

¹⁰ See *id.* See also Donald G. McFetridge, *Intellectual Property, Technology, Diffusion, and Growth in the Canadian Economy*, in *Competition Policy and Intellectual Property Rights in the Knowledge Economy* 65, 79 (Robert D. Anderson & Nancy T. Gallini, eds. 1998) [hereinafter McFetridge].

¹¹ See McFetridge, *supra* note 10, at 79.

¹² *Id.*

When Canada adhered to NAFTA in 1992, which allowed patentees to manufacture abroad and meet local demand through imports,¹³ it repealed the "local working" component of the provisions governing abuse.¹⁴ Whether NAFTA (or TRIPS) compels this retreat from the doctrine of abuse as such remains unclear, however, and should not be presumed in the absence of an authoritative judicial decision.¹⁵

In addition, Canada also made use of compulsory licenses to promote the public interest, particularly by means of special provisions bearing on patents for food and medicines. With respect to medicines, a compulsory licensing scheme was used aggressively to promote the production of generic pharmaceuticals, and this scheme reportedly produced some of the lowest consumer drug prices in the industrialized world.¹⁶ Between 1969 and 1992, there were 1,030 applications to import or manufacture medicines under such licenses, of which 613 licenses were granted. However, Canada largely abandoned this scheme in 1987 when a new political strategy was given legislative effect.¹⁷

On the whole Canada has made relatively little use of compulsory licensing to address a patentee's anticompetitive practices. It is unclear whether this practice will change in the near future.

Historically, the Canadian government (known as the Crown) could freely make use of patented inventions, although a duty to pay reasonable compensation was eventually codified. The courts have read this governmental use provision broadly to include government agents. However, independent contractors who lack agency status are not covered by the government use provision. Moreover, amendments in 1993-1994 distinguished between "government use" and "public non-commercial use", and they imposed certain limiting conditions on non-voluntary licenses issued for "government use". How these provisions will be implemented was unclear at the time of writing.

¹³ See NAFTA, *supra* note 1, Chapter 17, art. 1709.7; D. Vaver, *supra* note 2, at 170.

¹⁴ See Patent Act Amendment Act (effective 1993), R.S.C. 1992, c. P-4, §33 (3rd Supp.), R.S.C. 1992, c.1, §5 (repealing §§65(2)(a)(b) of 1985 Act).

¹⁵ The United States withdrew a WTO action against Brazil that would have resolved this question for purposes of the TRIPS Agreement. For a discussion of that case see the UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development, *The Resource Book on TRIPS and Development*, chapter 2.5.8 "Non-voluntary Uses (Compulsory Licenses, Article 31/4. WTO Jurisprudence/b. United States complaint against Brazil". See also Michael Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law*, 35 *Osgoode Hall L. J.* 243 (1997).

¹⁶ See Christopher Scott Harrison, *Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 versus the North American Free Trade Agreement and Bill C-91*, 26 *North Carolina J. Int'l. L. & Comm. Reg.* 457 (2001) [hereinafter Harrison].

¹⁷ See *id.*; *infra* text accompanying notes 270-330.

2. Abuse of the Patentee's Exclusive Rights, Including the Duty to Work

As previously noted, it was Canada's policy until 1993 not only to grant patents to encourage inventive efforts and investment, but also to ensure that new inventions should, so far as possible, be worked on a commercial scale in Canada without undue delay.¹⁸ This requirement was incorporated into the abuse sections of the relevant patent statutes enacted between 1935 and 1985.

The Patent Act of 1985, for example, allowed any interested party (or the Attorney General) to apply to the Commissioner of Patents for relief from "an abuse of the [patentee's] exclusive rights" at any time after the expiration of three years from the date the patent issued.¹⁹ The following grounds for ascertaining abuse were expressly recognized:

- "...if the patented invention (being one capable of being worked within Canada) is not being worked within Canada on a commercial scale, and no satisfactory reason can be given," and the non-working is not excusable and for good cause,²⁰
- "if the working of the invention within Canada on a commercial scale is being prevented or hindered by the importation from abroad of the patented article" by the patentee or other related parties including unprosecuted infringers.²¹

These two grounds of abuse, as carried into the Patent Act of 1985,²² were finally repealed in 1993.²³

Besides failure to work and importation to the detriment of home manufacture, the Patent Act of 1985, which essentially carried forward prior law, recognized the following acts of abuse:

- "if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms;"²⁴
- "if, by reason of the refusal of the patentee to grant a license ... upon reasonable terms," a new Canadian trade or industry has been "prejudiced, and it is in the public interest that a licence or licences should be granted;"²⁵
- "if any trade or industry in Canada ... is unfairly prejudiced by the conditions attached by the patentee ... to the purchase, hire, licence, or use of the patented article, or to the using or working of the patented process;"²⁶

¹⁸ See Patent Act, R.S.C. 1985, c.P-4, §65(2).

¹⁹ Patent Act, R.S.C. 1985, c.P-4, §§68(1)(2); Patent Act, R.S.C. 1970, c.P-4, §67(1).

²⁰ Patent Act, R.S.C. 1985, c.P-4, §65(2)(a); Patent Act, R.S.C. 1970, c.P-4, §§67(1)(d), 67(2)(a).

²¹ Patent Act, R.S.C. 1985, c.P-4, §65(2)(b); Patent Act, R.S.C. 1970, c.P-4, §67(2)(b).

²² Patent Act, R.S.C. 1985, c.P-4, §65(a)(b).

²³ Patent Act Amendment Act, S.C. 1993, c.2, §5 (repealing §§65(2)(a),(b) of 1985 Act).

²⁴ Patent Act, R.S.C. 1985, c.P-4, §65(2)(c); Patent Act, R.S.C. 1970, c.P-4, §67(2)(c).

²⁵ Patent Act, R.S.C. 1985, c.P-4, §65(2)(d); Patent Act, R.S.C. 1970, c.P-4, §67(2)(d).

²⁶ Patent Act, R.S.C. 1985, c.P-4, §67(2)(e); Patent Act, R.S.C. 1970, c.P-4, §67(2)(e).

- if the owner of a process patent for a process covering unpatented materials "or for an invention relating to a substance produced by such a process" has exercised such rights "so as unfairly to prejudice in Canada the manufacture, use or sale of any such materials."²⁷

The statute further directed that in evaluating claims for abuse, the Commission should be guided by the policy that "patents for new inventions are granted not only to encourage invention but to secure that new inventions shall so far as possible *be worked on a commercial scale in Canada without undue delay*."²⁸

The provisions thus defining abuse are overlapping and not mutually exclusive. However, there was virtually no basis for relief except on the specific grounds of abuse set out in the statutes.²⁹

Both the 1970 and 1985 statutes gave the Commissioner broad powers to grant compulsory licenses to rectify such abuses, including the power to preclude importation of the product in question.³⁰ The Commissioner was instructed, "on the one hand, [to] endeavor to secure the widest possible uses of the invention in Canada consistent with the patentee deriving a reasonable advantage from his ... rights" and, "on the other hand, [to] endeavor to secure to the patentee the maximum advantage consistent with the invention being worked by the licensee at a reasonable profit in Canada."³¹

Once an applicant for a compulsory license proved insufficient local working, the Commissioner - until the 1993 reform - was even empowered to confer the license on an exclusive basis if the patent could not be worked "without the expenditure of capital" that could not otherwise be raised in the absence of exclusive rights.³² The Commissioner could also revoke the patent if this was deemed necessary and not inconsistent with international treaty obligations.³³ In practice, an exclusive license was rarely if ever granted,³⁴ and this power was repealed in 1993.³⁵

Sometimes the Commissioner would simply render a decision to issue a compulsory license and then grant the parties 30 to 60 days leave to mutually arrive at the terms of the license. If the parties were unable to agree, the Commissioner would designate a date for a hearing to set the standards.³⁶ In 1988, the Commissioner was further empowered to adjourn the proceedings if he found that, given the nature of the invention, the patentee lacked sufficient time in which to have worked the patent on a commercial scale in Canada.³⁷

The royalty rates in these cases typically varied according to the facts. Examples include a per piece royalty of 10 cents on watch bracelets; 5 % of cost on a machine and its component parts; between 6 %

²⁷ Patent Act, R.S.C. 1985, c.P-4, §65(2)(f); Patent Act, R.S.C. 1970, §67(2)(f).

²⁸ Patent Act, R.S.C. 1985, c.P-4, §65(4); Patent Act, R.S.C. 1970, §67(3). See also Immanuel Goldsmith, *Patents of Invention 253* (1981) [hereinafter I. Goldsmith].

²⁹ See *Celotex Corp. v. Donnacona Paper Co.*, [1939] Ex. C.R. 128, 130 (Ex. Ct.).

³⁰ See Patent Act, R.S.C. 1970, c.P-4, §68(a); Patent Act, R.S.C. 1985, c.P-4, §66. See generally, Hughes & Woodley, *supra* note 5, §65.

³¹ Patent Act, R.S.C. 1970, c.P-4, §§68(a)(i),(ii). The Commissioner has also to seek "equality of advantage among the several licensees," where applicable. *Id.* §68(a)(iii). See also Patent Act, R.S.C. 1985, c.P-4, §66(4)(a)-(c) (with some changes).

³² Patent Act, R.S.C. 1985, c.P-4, §§66(1)(b), 67(1) (repealed 1993).

³³ Patent Act, R.S.C. 1970, c.P-4, §68(d); Patent Act, R.S.C. 1985, c.P-4, §66(1)(b),(d).

³⁴ See *Harvey's Skindiving Suits of Canada v. Poseidon Industries AB*, [1984] 1 C.I.P.R. 288, 295 (Comm'r of Patents); see also McFetridge, *supra* note 10, at 79.

³⁵ See *supra* note 23 and accompanying text.

³⁶ See Hughes & Woodley, *supra* note 5, §66.

³⁷ See Patent Act, R.S.C. 1985, c.P-4, §65.

and 10 % on parts for a machine with a two cent per piece minimum; and 3 ½ % of the net selling price of an article.³⁸ However, these practices should not be confused with the Commissioner's duties pursuant to applications for compulsory licensing of pharmaceutical and agricultural inventions, where he was governed by guidelines, including a 4% "rule of thumb royalty," that were not contingent on a failure to work. Those cases are discussed below,³⁹ but here one should note that royalties tended to be higher in cases dealing with the working requirement than in cases of pharmaceutical and agricultural inventions.

With such a tough and detailed statutory mandate to guide both administrators and the courts, it should come as no surprise that numerous cases deal with the specific abuse of non-working of patented inventions in Canada on a commercial scale between 1935 and 1993. If, moreover, it was true that these cases did not unduly discourage foreign patentees, as Professor Vaver reports,⁴⁰ it was not because the Commissioners took these issues lightly. On the contrary, the cases show that both administrators and the courts - including the Supreme Court - took the local non-working provisions very seriously indeed, and did their best to give them teeth. It does nonetheless seem surprising that few cases have been found in which other grounds of abuse were successfully raised in the period 1940-1993.

2.1 Economic Evaluation of the Local Working Requirement

A recent study by Professor Donald McFetridge⁴¹ sheds considerable light on the results obtained from Canada's local working requirement in the period 1935-1984. His principle finding is that, while this requirement had little impact "on the use of patented technologies in Canada," it did provide greater access to foreign technology (rather than additional knowledge) for those who already possessed the know-how and experience to exploit the opportunities the statute created.⁴²

Two drawbacks that impeded would-be applicants for compulsory licenses were their own technical shortcomings and their inability under nonexclusive licenses to force patentees to reveal more know-how than was disclosed in the relevant patent applications. A foreign patentee's failure to work the patent locally might also have signified that there was too little interest in the invention to attract local investors.⁴³

However, Professor McFetridge's skepticism is tempered by an alternative, more positive interpretation of the data. On this view, the right to apply for a compulsory license greatly improved the legal status of local defendants in infringement actions by encouraging more settlements on better terms than would otherwise have been possible.⁴⁴ From this angle, there was a certain functional equivalence between the threat of a compulsory license for abusive non-working in Canada and the threat of "misuse of the patentee's exclusive rights" in United States law, as will be seen in the separate case study on the United States. In any event, the local working requirement in Canadian law could have improved the terms on

³⁸ See Hughes & Woodley, *supra* note 5, §66 (citing authorities). "The scale of royalties is usually set on several principles in the commercial field and bears relation to the scale of damages awarded in infringement actions." I. Goldsmith, *supra* note 28, at 261-62.

³⁹ See *infra* text accompanying notes 243-269.

⁴⁰ See *supra* note 9 and accompanying text.

⁴¹ See McFetridge [Department of Economics, Carleton University], *supra* note 10.

⁴² *Id.* at 79.

⁴³ See *id.* at 80.

⁴⁴ See *id.*

which some technology was transferred, and it resulted "in more extensive licensing" than would otherwise have occurred.⁴⁵

In evaluating the overall economic benefits from these compulsory licenses, McFetridge observes that Canadians seldom claimed abuse of patented inventions on the alternative ground that the foreign technology was not available in Canada on reasonable terms.⁴⁶ However, it is unclear whether this means that Canadians were well served by normal market forces, as he thinks, or that they simply preferred to invoke a failure to work, which was easier and less costly to prove.

In the end, McFetridge finds that any real benefits likely took "the form of additional domestic spillover[s]...from the local commercial exploitation of the patent or from local follow-on innovation...."⁴⁷ Transferable learning by employees or suppliers of the license in the course of producing the goods locally would thus represent a positive gain, and one not necessarily tainted by free-riding behavior in view of the investment of money and skill it entails.⁴⁸

The professed objective of the Economic Council of Canada from 1971 on was, indeed, not to encourage free-riders, but rather to enable Canadian producers to compete more effectively in the marketplace.⁴⁹ In practice, according to Professor McFetridge, the policy was most successful when the potential local licensees already possessed enough technical skill and know-how to undertake production or follow-on applications. In other words, compulsory licensing did little to expand the pre-existing stock of technical know-how, but it may well have "facilitated *subsequent* spillover learning both from local commercial exploitation and from follow-on innovation."⁵⁰ If so, this would corroborate anecdotal evidence from Brazil, where the director of that country's pharmaceutical supply bureau has stressed the importance of acquiring local technical production capabilities before resorting to threats of compulsory licensing to extract price reductions from foreign suppliers.⁵¹

2.2 Abusive Non-working or Importation in Selected Cases (1935-1993)

Turning to the cases, it was settled that the need to work the invention "on a commercial scale" meant manufacturing the article or implementing the process described in the patent claims by means of a definite and substantial establishment or organization, and on a scale that was adequate and reasonable under the circumstances.⁵² This commercial working was to be secured "so far as possible," and was not intended to force a patentee to manufacture in the absence of any demand if that would result in unnecessary or unwarranted capital expenditure.⁵³

⁴⁵ See McFetridge, *supra* note 10, at 80. For the positive impact of even small increments in licensing of technology, see Keith Maskus, *Intellectual Property Rights in the Global Economy* (2000) [hereinafter K. Maskus].

⁴⁶ See McFetridge, *supra* note 10, at 80.

⁴⁷ *Id.*

⁴⁸ See *id.*

⁴⁹ See McFetridge, *supra* note 10, at 80 (quoting Economic Council of Canada and citing other sources).

⁵⁰ McFetridge, *supra* note 10, at 81.

⁵¹ See Papers from the Conference on Access to Essential Medicines, University of Wisconsin School of Law, 8-10 Mar. 2002 (publication forthcoming).

⁵² See, e.g., *Gordon Johnson Co. v. Callwood*, [1962] Ex. C.R. 466, 472-73 (Ex. Ct.). See also I. Goldsmith, *supra* note 28, at 254-57.

⁵³ Patent Act, R.S.C. 1985, c.P.-4, §65(3); *In re Walker & Sons Ltd.*, [1953] 13 Fox Pat. C. 190, 193 (Comm'r of Patents).

2.2.1 Local Working Defined

Whether a patented invention had been worked in Canada on a commercial scale and in reasonably close relationship to the demand had to be determined on the facts of each case, and in this context, *Rodi & Wienenberger A.G. v. Metalliflex Ltd.*⁵⁴ seems especially important. This 1962 case concerned an application for a "non-exclusive compulsory licence to manufacture and sell in Canada extensible watch bracelets embodying the features of the invention claimed in Canadian Patent No. 505676."⁵⁵ Metalliflex applied for the compulsory license after it was already engaged in making the product and as a defense to Rodi & Wienenberger's suit for patent infringement. An interlocutory injunction had prevented Metalliflex's continued manufacture of the patented product in violation of the patent holder's exclusive rights. When the Commissioner granted the defendant's application for a compulsory license, Rodi & Wienenberger appealed both the decision to authorize that license and the fixing of compensation.

Metalliflex contended that Rodi & Wienenberger's importation of the product was abusive in that it did not constitute sufficient "working on a commercial scale" in Canada within the terms of the applicable statute.⁵⁶ For the first two years after the initial grant of the patent, Rodi & Wienenberger did not work the patent in Canada at all, having chosen instead to supply the market through importation. Once Metalliflex began to infringe the patent and to manufacture the product in Canada, Rodi & Wienenberger began to assemble a portion of the goods in Canada while still importing most of the parts for the bracelets. The Court of Exchequer found that, at the time the application for a compulsory license was filed, the patent holder had not worked the invention in Canada in a manner proportionate to the demand for the patented article.⁵⁷

The court considered the following factors in determining that the patent holder had failed adequately to work the patent on a commercial scale:

- the nature of the invention;
- the amount of time required to establish a plant in Canada to work the patent;
- the amount of time that had elapsed since the grant of the patent;
- the size of the market for the patented good in Canada.⁵⁸

During the period in which the patent holder was supplying the market by importation, it had prevented at least one Canadian company from entering the market. The court did not find persuasive the patent holder's argument that the presence of infringing products in the Canadian market had deterred it from sufficiently working the patent locally. The patent holder could not otherwise justify its failure to work the patent in Canada on a commercial scale.⁵⁹

⁵⁴ *Rodi & Wienenberger A.G. v. Metalliflex Ltd.*, [1962] 40 C.P.R. 52 (Ex. Ct.).

⁵⁵ *Rodi & Wienenberger A.G. v. Metalliflex Ltd.*, [1962] 40 C.P.R. 52 (Ex. Ct.), aff'd S.C.R. 593, 50 C.P.R. 73 (Can.).

⁵⁶ Patent Act, R.S.C. 1952, c.P-4, 203 §67(2)(a).

⁵⁷ See *Rodi & Wienenberger*, [1962] 40 C.P.R. 52 (Ex. Ct.) at par.11.

⁵⁸ Id. at par.13.

⁵⁹ Id. at par.20; see also *Harvey's Skindiving Suits of Canada v. Poseidon Industries AB*, [1984] 1 C.I.P.R. 288, 293 (Comm'r of Patents).

In terms of a compensatory royalty, the Court of Exchequer found that the Commissioner's decision to pay the patent holder 10 cents per bracelet was justified in light of the compulsory licensee's need to compete with the patent holder. The court held that it was reasonable for the Commissioner to set a per piece royalty rate, rather than base it on a percentage of the selling price of the patented good. The patent holder had sought at least 10 % of the selling price, which would have yielded more than the 10 cents per piece royalty actually granted.

In 1966, the Supreme Court of Canada affirmed the lower court's decision in *Rodi & Wienenberger A.G. v. Metalliflex Ltd.*⁶⁰ It stressed that at the time the application for a compulsory license was filed, local manufacture of the bracelets in question was "virtually nonexistent." Although some of the bracelets were later assembled from imported parts, that did not satisfy the local working requirement.⁶¹ On the whole, the Supreme Court found that "there had never been anything in the way of working the invention in Canada that could be characterized as proportionate to or bearing any reasonably close relationship to the demand."⁶² The Supreme Court went on to state that sporadic attempts to catch up with the demand did not suffice and that "capacity to manufacture on an adequate scale is one thing ...[,] [a]ctual manufacture is quite a different thing."⁶³ Given the short period of time needed to establish a plant and the size of the Canadian market, insufficient local working was clearly established. The fact that the patentee had to deal with a number of infringement actions in this same period was not a valid excuse. On the contrary, the Court deemed the patentee's failure to work "to have been entirely a matter of choice," as there was never any real difficulty in obtaining a substantial market or in organizing manufacture in Canada.⁶⁴

A number of earlier cases supported the general principles upheld by the Supreme Court in *Rodi & Wienenberger*,⁶⁵ but there was always a factual question as to when and how much local working would suffice, and the Supreme Court did not resolve this question. Indeed, the Commissioner asserted an inherent power to evaluate the intensity of the working in any given case, and to draw inferences from the fact that it had occurred after an application for a compulsory license.⁶⁶

⁶⁰ *Rodi & Wienenberger A.G. v. Metalliflex Ltd.*, [1966] 50 C.P.R. 73 (Can.).

⁶¹ See *Rodi & Wienenberger*, 50 C.P.R. at par.13. See also *CIE Machinerie Rennel v. Putzmeister Interholding GMBH*, [1983] 1 C.I.P.R. 155 (Comm'r of Patents) (assembly in Canada of imported pumps was abusive; compulsory license granted); *Canadian Marconi et al. v. Nordmende Phoenix Ltd.*, [1962] 22 Fox Pat. C. 176 (Comm'r of Patents); *Dominion Auto Accessories Ltd. v. DeFrees' and Betts Machine Co.*, [1965] 33 Fox Pat. C. 137 (Comm'r of Patents).

⁶² *Rodi & Wienenberger*, 50 C.P.R. at par. 13. See also *Defrees & Betts Machine Co. v. Dominion Auto Accessories Ltd.*, [1966] 51 C.P.R. 42 (Ex. Ct.) (upholding compulsory license on patented marker lights on grounds of insufficient local working and because local working was hindered by imports; mere assembly of foreign parts in Canada held not to constitute "manufacturing on a commercial scale in Canada" on authority of the Supreme Court's decision in *Rodi & Wienenberger v. Metalliflex*).

⁶³ *Rodi & Wienenberger*, 50 C.P.R. at par.13.

⁶⁴ *Id.* at par.15.

⁶⁵ See, e.g., Harold G. Fox, *The Canadian Law and Practice Relating to Letters of Patent for Inventions* 341-47 (1969) [hereinafter H. G. Fox].

⁶⁶ Compare, e.g., *McArthur, Irwin, Ltd. v. National Lead Co.*, [1963] 24 Fox Pat. C. 184 (Comm'r of Patents) (application for compulsory license denied), with *DeFrees et al v. Dominion Auto Accessories Ltd.*, [1965] 33 Fox Pat. C. 137 (Comm'r of Patents).

Working in Canada clearly meant that the essence of the invention should be carried out in Canada,⁶⁷ and minor assembly of parts or mere finishing steps did not suffice.⁶⁸ Other cases, however, support the view that if the patent covered a useful combination of non-novel parts, then their assembly in Canada might suffice, especially if some significant operation was performed on them locally.⁶⁹

2.2.2 The Relevant Period of Time

The relevant period of time in which non-working could be considered was unclear under the statute, and all activity before and after the application might be evaluated, although activity after an application for a compulsory license was viewed more skeptically.⁷⁰ In the case of *McArthur, Irwin, Ltd. v. National Lead Co.*,⁷¹ for example, the Commissioner denied the application for a compulsory license and refused to hold a past failure to work a patent against the patent holder if it was later corrected.

The patent in that case concerned lead phthalates and the process for making them. The compulsory license applicant had demonstrated its own capacity to work the patent on a commercial scale by engaging in the manufacture of the patented product using the patented process in its own establishment. The applicant alleged that the patent was not otherwise being worked within Canada on a commercial scale, that such working had been frustrated by the importation of the product, and that it had sought to obtain a voluntary license from National Lead, but had been informed that the latter was in the final stages of preparations to begin production of the patented article using the patented process in Canada. The Commissioner found, despite its failure to work the patent locally for a period of eight years, that National Lead's preparation and efforts to do so one year before the application for a compulsory license were sufficient to excuse its prior inaction.

The message, according to one commentator, was that the "abuse sections ... are not punitive in effect."⁷² "If a patentee chooses not to work his invention on a commercial scale, he does not lose his patent, he merely becomes subject to compulsory licensing. If he fails to work for a number of years and nobody pays any attention to it and then he organizes production[,] no one could rightly claim a compulsory licence on account of the past conduct of the patentee."⁷³

⁶⁷ See, e.g., *MacKay Specialities Inc. v. Proctor & Gamble Co.*, [1981] 60 C.P.R. (2d) 96, 101 (Comm'r of Patents).

⁶⁸ See *id.* at 101; see also Hughes & Woodley, *supra* note 5, §59 (citing authorities).

⁶⁹ See *MacKay Specialities*, 60 C.P.R. (2d) at 101; see also *LPA Plastics (1976) Ltd. et al v. Windsurfing Int'l Inc.*, [1981] 59 C.P.R. (2) 188, 197-98 (Comm'r of Patents).

⁷⁰ See, e.g., Hughes & Woodley, *supra* note 5, §59 (citing authorities).

⁷¹ *McArthur, Irwin, Ltd. v. National Lead Co.*, [1963] 24 Fox Pat. C. 184 (Comm'r of Patents).

⁷² H. G. Fox, *supra* note 65, at 543.

⁷³ *Id.* at 543-544.

2.2.3 Justifying a Failure to Work

The onus was on the patentee to justify a failure to manufacture in Canada.⁷⁴ In principle, the statute did not force a patentee to manufacture if there was no demand for the product in Canada.⁷⁵ In practice, however, many decisions took a dim view of inaction on economic grounds even before the Supreme Court's 1966 decision on local working in *Rodi & Wienerberger*. The fact that industrial production of a given article or process was not as profitable in Canada as it was elsewhere, owing to differences in the costs of labor or materials, or to other local conditions, or that profits would be smaller if production occurred in Canada, were not deemed valid excuses in this period, especially if a local applicant stood ready to make the necessary investments under a compulsory license.⁷⁶ On the contrary, the policy underlying the statute was that the patentee "must ... make an effort to create a demand ... and the establishment of an industry will in itself frequently help to create a demand for the article or process in question. And regard must be had to the possible export trade ... as well."⁷⁷

After the Supreme Court's decision in 1966, lower courts and administrators seemed especially skeptical of alleged excuses to justify local non-working once an applicant for a compulsory license had surfaced. In *Atwater Bay Corp. v. Bahamas Paper Co.*,⁷⁸ for example, the carrier bags at issue had initially been manufactured in Canada and even, to a minor extent, exported to the United States. Eventually, the whole operation was discontinued in Canada and manufacture of the bags was instituted in Baltimore (Ohio, USA), with exports back to Canada. The exclusive Canadian distributor, Atwater Bay Corp., then applied for a compulsory license both on the grounds of insufficient local working and on the grounds that importation had occurred at the expense of the development of Canadian industry.⁷⁹

The Commissioner rejected the second claim, partly because importation was minimal and largely on an unclean hands notion that the local distributor should not be heard to complain about imports.⁸⁰ With regard to abuse for non-working in Canada, the patentee had argued that the Canadian market was "untested, too small and too unprofitable" to make the invention "capable" of being worked "within Canada on a commercial scale" without going into bankruptcy. The Commissioner agreed that the argument had held for a certain period of time, but only until new machines were developed - in Germany, as it happened - which subsequently made production "adequate and reasonable under the circumstances."⁸¹

⁷⁴ See *id.* at 546 (citing authorities). See also I. Goldsmith, *supra* note 28, at 256.

⁷⁵ See, e.g., *E. C. Walker & Sons Ltd. v. Lever Bias Machine Corp.*, [1953] 13 Fox Pat C. 190, 192 (Comm'r of Patents); H. G. Fox, *supra* note 65, at 546-47 (discussing U.K. precedents relied upon in Canada at an earlier period).

⁷⁶ See, e.g., H. G. Fox, *supra* note 65, at 547-48 (citing authorities); Hughes & Woodley, *supra* note 5, §59.

⁷⁷ *Celotex Corp. et al v. Donnacona Paper Co. Ltd.*, [1939] Ex. C.R. 128, 139 (Ex. Ct).

⁷⁸ [1969] 43 Fox Pat. C. 98 (Comm'r of Patents).

⁷⁹ See Patent Act, R.S.C. 152, c.203, §§67(2)(a),(b).

⁸⁰ See *Atwater Bag Corp. v. Bahamas Paper Co. Ltd.*, [1969] 61 C.P.R. 239 (Comm'r. of Patents), at pars. 30, 32.

⁸¹ *Atwater Bag*, at 61 C.P.R. par. 37.

The Commissioner found that the question, correctly stated, was similar to that raised in an old United Kingdom case: Could the patentee have worked the patent locally "if he had used his monopoly fairly as between home and foreign trade, or if he had devoted the time and money which he has expended in developing a foreign industry to developing a home industry?"⁸² The Commissioner noted that this, indeed, was "the principle which underlies the reason for compulsory licensing provisions in Canada also."⁸³

The Commissioner endorsed the view that "even though the demand may be small" at one point, "we should have manufacture in Canada to supply such demand."⁸⁴ With this in mind, "good intentions to work the patent in Canada later" were insufficient,⁸⁵ and a compulsory license was granted. An exclusive license was denied, however, as that "would tend to monopolize the market unnecessarily."⁸⁶

Similarly, two cases in the 1980s found no justifiable excuse for non-working in Canada. In the first, which involved a compulsory license application for a patented concrete pump assembly, the Commissioner found that even though the patent holder had conducted some assembly in Canada, it was too insignificant to constitute working.⁸⁷ The patent holder failed to provide a satisfactory excuse for this failure to work when he argued that each sale of the patented product in Canada was of a "custom nature, and that the size of the market did not warrant commercial sale manufacture."⁸⁸ It followed that "the appropriate relief would be the grant of a non-exclusive license upon terms which will secure the working of the invention in Canada."⁸⁹ The parties were ordered to reach agreement on the terms of the compulsory license within 30 days, failing which, a hearing would be called by the Commissioner to determine the terms.

In the second case, *Harvey's Skindiving Suits of Canada v. Poseidon Industries AB*,⁹⁰ the plaintiff applied for a compulsory license to begin manufacture of dry suits subject to a patent owned by Poseidon Industries and exclusively licensed to Parkway Fabricators. Neither the patent holder or its exclusive licensee manufactured the patented product in Canada, although the patent holder did begin negotiations for a voluntary license with a Canadian firm that was infringing the patent once Harvey's Skindiving Suits filed its application for a compulsory license.

The patent holder contested the applicant's claim that it had failed to work the patent by arguing that the manufacturers who infringed the patent were, in effect, working it in Canada. The Commissioner held that working by an alleged infringer was not sufficient to satisfy the working requirement because the patent holder could stop the infringing manufacture at any time by obtaining an injunction, thereby preventing further working of the patent.⁹¹

⁸² *Atwater Bag*, 61 C.P.R. at par. 41 (quoting *In re Hatschek's Patents*, [1909] 26 R.P.C. 228, 243).

⁸³ *Id.*

⁸⁴ *Id.* at par. 42.

⁸⁵ *Id.* at par. 43.

⁸⁶ *Id.* at par. 46.

⁸⁷ See *CIE Machinerie Rennel v. Putzmeister Interholding GMBH*, [1983] 1 C.I.P.R. 155 (Comm'r of Patents) at par. 7.

⁸⁸ *Id.* at par. 16.

⁸⁹ *Id.* at par. 19.

⁹⁰ [1984] 1 C.I.P.R. 288 (Comm'r. of Patents).

⁹¹ See *Harvey's Skindiving Suits*, 1 C.I.P.R. at par. 12.

The patent holder also attempted to excuse its failure to work the patent locally based on its ongoing negotiations with one of the infringing manufacturers for a voluntary license. The Commissioner found that the failure to work constituted undue delay and was not a valid excuse, especially given that the voluntary license negotiations had dragged on for four years, and the patent holder had apparently declared that it had no intention to work the patent in Canada.⁹²

In the *Harvey's* case, the applicant for the compulsory license demonstrated to the Commissioner's satisfaction that it had a factory capable of manufacturing the dry suits and that it possessed the requisite know-how, in fulfillment of the statutory requirements. The Commissioner then granted a nonexclusive license to Harvey's Skindiving Suits on the grounds of patent abuse owing to the patent holder's failure to work the patent on a commercial scale in Canada.

It is worth noting that the Canadian statute applicable at the time of this case allowed the Commissioner to award a compulsory license on an exclusive basis.⁹³ This type of provision was favored by developing countries in the late 1980s, but the TRIPS Agreement ultimately required compulsory licenses to be granted on a nonexclusive basis.⁹⁴ In the *Harvey's Skindiving* case, the Commissioner declined to grant the compulsory license on an exclusive basis, despite the statutory power to do so, because the capital outlay required to utilize the license did not justify the monopoly benefits of exclusivity.⁹⁵

Given the finding of abuse and the need for a compulsory license to correct it, the Commissioner also barred importation of the patented product by the patent holder or any of its licensees. As for compensation, the Commissioner ordered Harvey's Skindiving Suits to pay a royalty of five per cent of the net wholesale price to the exclusive licensee of the patent holder, Parkway. The Commissioner based the royalty determination on the royalty that had been proposed in ongoing voluntary negotiations between Parkway and a Canadian company that had infringed the patent. It thus represented a royalty rate negotiated at arm's length with a party not directly interested in the compulsory licensing proceeding.⁹⁶ The Commissioner concluded that a five per cent royalty rate would strike the balance of advantage to the patent holder and profitability to the licensee.

Notwithstanding this generally strict attitude toward non-working, there were at least two important cases in the period 1967-1993 in which a potentially abusive failure to work was "satisfactorily" excused. In *Sarco Co. v. Sarco Canada Ltd.*,⁹⁷ the Canadian market for patented steam traps was entirely supplied by imports. However, it turned out that from 1957 on, the patent holder had been making efforts to commence manufacture in Canada, but the applicant for a compulsory license had dissuaded him from pursuing this endeavor in order to encourage further importation from the applicant, who manufactured the products in the United States. In a 1962 meeting, the applicant had exerted pressure on the patent holder not to enter the Canadian market by manufacturing in Canada, exercising its "position and influence to prevent such manufacture as far as it could."⁹⁸ The patent holder then proceeded with its plans in secret, which eventually led to successful working of the patent in Canada by 1967.

⁹² See *id.* at par. 15.

⁹³ Patent Act, R.S.C. 1970, c. P-4, §68(b).

⁹⁴ See Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994 [hereinafter TRIPS Agreement], 33 I.L.M. 81 (1994), art. 31(d)..

⁹⁵ *Harvey's Skindiving Suits*, 1 C.I.P.R. at par. 23.

⁹⁶ See *Harvey's Skindiving Suits*, 1 C.I.P.R. at par. 28.

⁹⁷ [1969] 57 C.P.R. 193 (Ex. Ct.).

⁹⁸ *Id.* at par. 15.

In May 1966, the applicant learned of the patent holder's manufacture in Canada and filed for a compulsory license, which was ultimately denied on the grounds that the applicant had been primarily responsible for the abuse that it denounced. To grant relief in such a case would have acted to "encourage those who seek to avoid or prevent manufacture of patented articles in Canada," and therefore the purposes underlying the statutory provisions were best served by denying the application for a compulsory license.⁹⁹

A patentee's abusive importation and failure to work the patent locally was again excused in a 1982 case, *MacKay Specialities Inc. v. Procter & Gamble Co.*¹⁰⁰ This was an appeal from the Commissioner's decision denying MacKay's application for a compulsory license on the grounds that Procter & Gamble had abused the exclusive rights under its patent for Bounce fabric softener dryer sheets by failing to work the patent in Canada. The federal appellate court upheld the Commissioner's findings that neither the consumer's use of the products at home, nor the producer's cutting and packaging of the product in Canada constituted sufficient working, because "[i]t is essential to the working of a patent in Canada that the essence of the invention should be carried out in Canada."¹⁰¹

After finding abuse, the Commissioner had proceeded to consider whether there was a satisfactory reason for the failure to work. He declared that "[i]f the patentee rested solely on delays stemming from infringement, I would not have found for him. However, he has also placed before me extensive evidence of the steps he took to manufacture in Canada both before and after [the date that the application was filed]."¹⁰² Through various undertakings, including engineering studies and procurement of a contractor to build a manufacturing plant, the Commissioner had become convinced that the patentee made "an honest effort ... to bring the invention into Canada ... with the ultimate aim of full manufacture."¹⁰³ Given this satisfactory reason for non-working, the application for compulsory license was denied.

The Federal Court of Appeals upheld the Commissioner, finding that the *Sarco* decision entitled the latter to look at the "entire course of conduct up to the time of the hearing in determining the issues under [the working requirement]."¹⁰⁴ The Court also agreed that it would be difficult for the patentee to make plans for manufacture before the conclusion of pending infringement proceedings and that, notwithstanding the infringement proceedings, the patentee had taken "numerous significant steps toward manufacture in Canada."¹⁰⁵

⁹⁹ Id. at par. 49.

¹⁰⁰ [1982] 69 C.P.R. (2d) 90 (F.C.A.).

¹⁰¹ MacKay, 69 C.P.R.(2d) at par. 2.

¹⁰² Id. at par. 2.

¹⁰³ Id. at par. 2.

¹⁰⁴ Id. at par. 6.

¹⁰⁵ Id. at par. 9.

2.2.4. Abusive Importation as a Separate Ground

Closely related to the cases on insufficient working was the second statutory ground of abuse, which applied when the working of a patent on a commercial scale was hindered by importation of the patented products or when there were infringing activities that the patent holder ignored.¹⁰⁶ This provision was repealed along with the working requirement pursuant to the Patent Act Amendment Act of 1992,¹⁰⁷ but in what follows there is some discussion of the limited practice under this ground of abuse prior to its removal from the law.

This ground of abuse overlapped with and supplemented claims of local non-working, to which it was usually subordinated in importance. Hence, there are relatively few cases in which a claim of abusive importation was the gravamen of an application for a compulsory license, and fewer still in which such a license was granted solely on this ground.¹⁰⁸

The 1981 case of *L.P.A. Plastics (1976) Ltd. v. Windsurfing International*¹⁰⁹ demonstrates the principle that supplying the market through importation was tolerated, if not encouraged, especially when it was necessary to stimulate the demand in the Canadian market.¹¹⁰ In this case, the Commissioner found that in the long run, the importation in question would help to establish local working of the patents covering inventions of sailboards and wind-propulsion equipment by stimulating demand for the product in the Canadian market.¹¹¹ He also noted that there were several circumstances present that excused the delay in working the patent on a more significant scale, including recurring infringements of the patents that had made market identification and position uncertain; the existence of a major competitor who had suffered a million dollar loss attempting to manufacture and sell the products in Canada; and the unwillingness of a number of Canadian companies to license the patents for manufacture in Canada.¹¹² Consequently, the applicant had failed to demonstrate all of the statutory grounds for abuse, and the application for a compulsory license was denied.

In contrast, if a patent holder continues importation without making any attempt to manufacture in Canada, abuse of the patent monopoly presumably exists because the importation does not constitute working. If a compulsory license was issued, the patentee could still work the invention in Canada, but further importation could be blocked.¹¹³ For example, in *Callwood v. Gordon Johnson Co.*,¹¹⁴ the Commissioner found that the working of patents for a chicken de-featherer had been hindered by

¹⁰⁶ See Patent Act, R.S.C. 1985, c. P-4, §65(2)(b).

¹⁰⁷ See Patent Act Amendment Act, R.S.C. 1992, c.P-4, §33 (3d. Supp.), R.S.C. 1992, c.1, §5 (repealing §§65(2)(a)(b) of 1985 Act).

¹⁰⁸ About eight cases have been found in which this ground appeared relatively important and no more than four cases in the period 1935-1993 in which it played a role in triggering a compulsory license. The calculus is complicated by the fact that in most cases there is also a finding of local non-working.

¹⁰⁹ [1981] 59 C.P.R. 188 (Comm'r of Patents).

¹¹⁰ See *LPA Plastics*, 59 C.P.R. at 198-199.

¹¹¹ See *id.* at 199.

¹¹² See *LPA Plastics*, 59 C.P.R. at 199; see also *Debro Products Ltd. v. Burke Co.*, [1980] 65 C.P.R. (2d) 162, 168 (Comm'r of Patents) (excusing earlier failure to work given that the patent holder had taken reasonable steps to manufacture in Canada as soon as a "reasonable demand had been identified, such demand having been developed by the patentee through importation.").

¹¹³ See, e.g., *In re E. H. Tate Co.*, [1941] 2 Fox Pat. C. 156 (Comm'r of Patents) (fourteen years of imports was too much); *Morris Light v. Setter Bros.*, [1952] 13 Fox Pat. C. 58, 62 (Comm'r of Patents); Hughes & Woodley, *supra* note 5, §60 (citing authorities).

¹¹⁴ [1957] 17 Fox Pat. C. 136 (Comm'r of Patents).

importation into Canada of the patented machine and the replacement fingers. The Commissioner granted the application for a nonexclusive license with a royalty of ten per cent of the net sales price for each patented machine, and two cents per patented replacement finger, for which the Commissioner noted particularly strong Canadian demand.¹¹⁵

As noted earlier, both statutory grounds of abuse so far reviewed - failure to work locally and importation that hinders local working - were repealed in 1993, in the context of Canada's adherence to NAFTA.¹¹⁶ While this clearly ended the "made-in-Canada-for-Canada policy" that had been in effect for most of the twentieth century,¹¹⁷ it may also render the other grounds of statutory abuse capable of triggering a compulsory license correspondingly more important in the twenty-first century. Canadian practice under these grounds is briefly reviewed below.

2.3 Demand Not Adequately Met

Four types of statutory abuse have survived the reforms of 1992 and are retained by section 65(2) of the Canadian Patent Act.¹¹⁸ Because these grounds were rarely invoked in the past, their interpretation remains necessarily speculative.¹¹⁹

The first remaining ground of abuse for which compulsory licensing may be ordered concerns a failure to meet demand for the patented article in Canada to an adequate extent and on reasonable terms.¹²⁰ Very few reported cases appear to have raised this issue, and fewer still resulted in an order granting a compulsory license primarily on this ground.

In one 1953 case concerning actual failure to meet demand for a patented product in Canada, the meaning of "to an adequate extent" was understood to require at least a "reasonable proportion" of that demand. Even then, however, a patent holder's failure to meet a sudden demand for a unique device would not constitute abuse under this provision, according to *In re Application of E.C. Walker & Sons*.¹²¹

¹¹⁵ See *Callwood*, at pars. 14-15. It should be noted that importation of food or medicine pursuant to a compulsory license issued by the Commissioner of Patents on other grounds was allowed. While the special regime for food and medicine is discussed below, it seems worth noting that here is evidence that at least one country issuing compulsory licenses had no compunction about filling the need for patented products by resort to imports, a question that has arisen in the post-TRIPS context of access to essential medicines. See Hughes & Woodley, supra note 5, at §60.

¹¹⁶ See Patent Act Amendment Act, S.C. 1993, c.2, par. 5 (repealing Patent Act of 1985, §65(2)(a)(b)); D. Vaver, supra note 2, at 170 (stating that "NAFTA patentees can manufacture abroad as they like and can meet local demand entirely through imports").

¹¹⁷ D. Vaver, supra note 2, at 170.

¹¹⁸ See Patent Act, R.S.C. 1985, c.P-4, §65(2).

¹¹⁹ See Paul L.C. Torremans, Compulsory Licensing of Pharmaceutical Products in Canada, 27 Int'l Rev. Indus. Prop. & Copyright Law (I.I.C.) 316, 326 (1996) [Hereinafter Torremans].

¹²⁰ See Patent Act, R.S.C. 1985, c.P-4, §65(2)(c).

¹²¹ [1953] 13 Fox Pat. C. 190 (Comm'r of Patents). See also *Morris Light v. Setter Bros.*, [1954] Ex. C.R. 169 (Ex. Ct.); *In re E. H. Tate Co. v. Riley*, [1941] 2 Fox Pat. C. 156 (Comm'r of Patents); see also Hughes & Woodley, supra note 5, at §59, n.6.

The patent in this case covered a machine that produced bias tape. The applicant sought a compulsory license solely for the purpose of producing a single machine to enter into competition with the patent holder in manufacturing bias tape. The Commissioner measured relevant demand in terms of the product made with the patented machine, not in terms of the machine itself. Demand for the machine in Canada was limited to manufacturers of bias tape, and "[a] sudden demand for one machine is not in itself sufficient to condemn a patentee."¹²² Hence, the compulsory license application was denied.¹²³

A certain judicial reserve toward this ground of abuse in the pre-1993 cases would seem consistent with the hypothesis that a failure to work the invention locally was the primary expression of Canadian policy on abuse in this period. Consistent with this same hypothesis, moreover, is the appearance of two very recent cases that do invoke the "demand not adequately met" ground of abuse in the post-1993 period, i.e., once local non-working no longer qualified as an abuse in Canada.

In one of these cases, *Puckhandler Inc. v. BADS Industries, Inc.*,¹²⁴ the patent holder acknowledged that it had been unable to meet the demand for its patented hockey stick training device.¹²⁵ Finding abuse on this ground, the Commissioner authorized a compulsory license at the rate offered by the applicant who wanted to manufacture and sell the item in Canada. The license stipulated that the applicant was to provide quarterly statements and payments to the patent holder concerning the former's use under the license.¹²⁶

Another recent request for a compulsory license under this provision to facilitate exportation of a patented pharmaceutical product manufactured in Canada was denied because the relevant consideration was demand in Canada, not the demand for exports. In this case, *Torpharm Inc. v. Merck & Co.*,¹²⁷ Torpharm applied for a compulsory license to acquire bulk enalapril maleate to manufacture tablets to be sold in the United States and other countries. Torpharm thus hoped to profit from the expiration of Merck's patent in the United States, even though Merck's patent on the same product in Canada *still* remained in force for another seven years.¹²⁸ In effect, Merck sought to block cheaper exports to the United States by denying the would-be Canadian producer access to bulk supplies of the drug.

Torpharm alleged that Merck had abused its patent rights by failing to meet the demand for the patented article to an adequate extent, and it also argued that the refusal to license on reasonable terms prejudiced the trade and industry in general and particularly that of the applicant. However, the Commissioner found that the only demand not being met was that of the applicant's own desire for bulk enalapril maleate. Finding no other basis to support a conclusion that the demand was not being adequately met by the patent holder on reasonable terms, and given the applicant's failure to establish abuse on alternative grounds, the Commissioner refused to grant a compulsory license.¹²⁹

The TRIPS Agreement does not necessarily mandate the decision reached in this case. Although article 31(f) of that Agreement does attempt to limit production under a compulsory license predominantly to the supply of the local market, article 31(k) overrides this limitation "where such use is permitted to remedy a

¹²² *In re Application of E.C. Walker & Sons*, [1953] 13 Fox Pat. C. 190 (Comm'r of Patents).

¹²³ *Id.* at par. 20.

¹²⁴ [1998] 81 C.P.R. (3d) 261 (Bd. Pat. App.).

¹²⁵ See *Puckhandler Inc. v. BADS Industries*, [1998] 81 C.P.R. (3d) 261, 264 (Bd. Pat. App.).

¹²⁶ See *Puckhandler*, at 265-266.

¹²⁷ [2000] 9 C.P.R. (4th) 520 (Bd. Pat. App.).

¹²⁸ *Torpharm Inc. v. Merck & Co.*, [2000] 9 C.P.R. (4th) 520 (Bd. Pat. Appeals).

¹²⁹ *Torpharm Inc. v. Merck & Co.*, [2000] 9 C.P.R. (4th) 520 (Bd. Pat. Appeals).

practice determined after judicial or administrative process to be anticompetitive."¹³⁰ A failure to meet legitimate demand for exports could harm a country's economic development prospects, and this could arguably constitute abuse within article 31(k) of the TRIPS Agreement.¹³¹

It seems logical, moreover, that this ground of abuse could apply to future cases in which a foreign pharmaceutical producer did fail to supply the Canadian market with needed medicines at affordable prices. In that connection, it might plausibly have been invoked in the recent Cipro case, discussed below, had it ended up in court.¹³²

Generally speaking, one school of thought insists that the "grant of an exclusive license can only be justified if the patentee exploits the patent to the full extent," as this enables him to recoup his investment and to undertake further research and development projects.¹³³ On this view, pricing the product too far beyond the reach of consumers willing to buy it - i.e., creating unacceptable dead weight loss - can be treated as an abusive failure to satisfy demand within the ambit of this provision.¹³⁴ It can also be argued that, in addition to disclosure of technical know-how, the public "has...the right to see [that] its demand for the patented product or for the product made while using the patented process [is] being met on reasonable terms."¹³⁵ In any event, this provision of Canada's statute governing abuse of the patentee's exclusive rights is one that policymakers in developing countries could profitably study.

2.4 Refusal to License or to License on Reasonable Terms

The second statutory ground of abuse upon which a compulsory license may still be authorized arises when the patent holder refuses either to license at all, or to license on reasonable terms, provided that such conduct prejudices "the trade and industry of Canada, or the trade of any person or class of persons trading in Canada, or the establishment of any new trade or industry in Canada." In such cases, the applicant must also demonstrate that issuance of the compulsory license will serve the public interest,¹³⁶ which curiously blends two typically independent grounds for seeking compulsory licenses.

This ground of abuse overlaps with the previous one, but it reportedly covers cases in which a licensor unreasonably discriminates between potential licensees. For example, a continuing and unjustified refusal to grant an otherwise qualified Canadian applicant a license might trigger this provision, as might an arbitrary exclusion of certain potential licensees from the market.¹³⁷ In such cases, however, some palpable harm to the public interest must be found over and beyond harm to the interest of a particular applicant.¹³⁸

Although allegations of abuse under this section were made in some of the cases surveyed previously, it was a strategy that met with little success, usually because the applicant failed to show that the patent holder had in fact refused to license on reasonable terms. Even when some refusal to license is

¹³⁰ See TRIPS Agreement, *supra* note 94, arts. 31(f), (k).

¹³¹ See *id.* arts. 31(k), 40.2; but see *id.* art. 28.1(a) (patentee's exclusive right to sell).

¹³² See *infra* text accompanying notes 380-381.

¹³³ Torremans, *supra* note 119, at 326. In the United States, the contrary view prevails, according to which the patentee is allowed a broader range of options in this regard.

¹³⁴ See Torremans, *supra* note 119, at 326-27.

¹³⁵ *Id.* at 327.

¹³⁶ See Patent Act, R.S.C. 1985, c.P-4, §65(2)(d); I. Goldsmith, *supra* note 28, at 259.

¹³⁷ See, e.g., Torremans, *supra* note 119, at 327.

¹³⁸ See *id.*

demonstrable, the applicant may fail to show that authorization of the compulsory license promotes the public interest. In *Puckhandler Inc. v. BADS Industries, Inc.*,¹³⁹ for example, the patent holder acknowledged that it chose not to enter into a voluntary licensing arrangement with the applicant for valid business reasons, but the applicant could not demonstrate that it was in the public interest that he be granted a compulsory license. This applicant nonetheless ultimately succeeded in obtaining a compulsory license for abuse, on the alternative ground that the demand for the patented "hockey stick training device" in Canada was not being met to an adequate extent and on reasonable terms.¹⁴⁰

Case law supports the proposition that a mere neglect to answer a request for a voluntary license does not constitute an actionable refusal to deal without more.¹⁴¹ In the recent case concerning pharmaceutical products, *Torpharm Inc. v. Merck & Co.*,¹⁴² that was discussed above, the Patent Appeals Board stressed that the patentee had been given insufficient time to consider the license request (about one month) and could not therefore be deemed to have abusively refused to deal.¹⁴³ The Board also declined to equate harm to the applicant with prejudice to the relevant trade or industry as a whole.¹⁴⁴ Finally, on the question of promoting the public interest (and not just the interests of the parties), the granting of a compulsory license in this case would have exposed the patentee to "a forceful competitor in markets other than Canada."¹⁴⁵ Hence, the Board flatly denied a compulsory license, while emphasizing that the public interest in stimulating research and innovation under "a strong and predictable" patent system outweighed any benefits from a compulsory license that was likely to be used to service export markets.

In other cases, the Commissioner showed considerable reluctance to conclude that a refusal to deal was unreasonable, especially when that entailed second guessing a patentee's business decisions.¹⁴⁶ As to what "reasonable terms" implied, older case law holds that the gist of it is a "reasonable price in money" and that the patentee should not hold a patent for the sole purpose of blocking trade.¹⁴⁷

A related issue arises when a second inventor, who improves on a prior patented invention, cannot practice the improvement patent because the prior patentee refuses to deal. Ironically, Canada's patent statute, which so liberally enumerates various grounds of abuse, does not directly recognize these so-called "blocking" or "dependent" patent cases as a separate ground, and one that could justify a compulsory license.¹⁴⁸ Older case law suggests, however, that the Courts have authority to impose a compulsory license in a blocking patent situation under the statutory provision governing refusal to license in general.¹⁴⁹

¹³⁹ *Puckhandler Inc. v. BADS Industries*, [1998] 81 C.P.R. (3d) 261, 264 (Bd. Pat. App.).

¹⁴⁰ See supra text accompanying notes 125-126.

¹⁴¹ See, e.g., *Sarco Co. v. Sarco Canada Ltd.*, [1969] 2 Ex. C.R. 190, 207-08 (Ex. Ct.); *L.P.A. Plastics (1976) Ltd. v. Windsurfing Int'l Inc.*, [1981] 59 C.P.R. (2d) 188, 199 (Comm'r of Patents).

¹⁴² [2000] 9 C.P.R. (4th) 520 (Bd. Pat. App.).

¹⁴³ See *Torpharm Inc. v. Merck & Co.*, [2000] 9 C.P.R. (4th) 520 (Bd. Pat. App.).

¹⁴⁴ See *id.*; see also *In re Application of E.C. Walker & Sons Ltd.*, [1953] 13 Fox Pat. C. 190 (Comm'r of Patents).

¹⁴⁵ *Id.*

¹⁴⁶ See, e.g., *LPA Plastics (1976) Ltd. v. Windsurfing Int'l Inc.*, [1981] 59 C.P.R. (2d) 188 (Comm'r. of Patents); *Sarco Co. v. Sarco Canada Ltd.*, [1969] 57 C.P.R. 193 (Ex. Ct.).

¹⁴⁷ Hughes & Woodley, supra note 5, §62 (citing authorities).

¹⁴⁸ But see TRIPS Agreement, supra note 94, art. 31(l) (recognizing and regulating this ground for a compulsory license).

¹⁴⁹ See *International Lowe Co. v. Consolidated Water Co.*, [1926] Ex. C.R. 143, aff'd [1927] S.C.R. 300 (Can.).

As noted, a refusal to deal was seldom invoked when compulsory licenses were available for failure to work patents locally. Whether newer case law will expand this category of abuse now that "local non-working" is no longer actionable in Canada¹⁵⁰ remains to be seen.

2.5 Unduly Restrictive Licensing Conditions

The third ground of abuse for which a compulsory license may be granted arises when the patentee "attaches conditions to the acquisition, use or working of any patented article or process so as to unfairly prejudice any trade or industry in Canada or any person or class of persons engaged in the industry."¹⁵¹ The meaning of this obscurely worded provision is understood to forbid abusive tying clauses that require one who wishes to buy a patented product to also buy an undesired unpatented product.¹⁵² In the only reported case found on this issue, the Commissioner denied the application for a compulsory license.¹⁵³

However, this provision is drafted in very broad and permissive language, which could reach other restrictive clauses in licensing agreements, including unreasonable restrictions on the use which the purchaser can make of a patented product. Such restrictions must be deemed "unfair," and there are no guidelines to curb judicial discretion.¹⁵⁴

2.6 Use of Process Patent to Restrict Unpatented Products

The fourth ground of abuse capable of triggering a compulsory license arises when the holder of a process patent prejudices the supply of unpatented materials used in the process.¹⁵⁵ This is an extension of the anti-tying provision just reviewed, but the additional idea is that the patentee should not unacceptably broaden the scope of a process patent. Since only the process is patented in such a case, the patentee should arguably be restrained from disrupting the manufacture, use or sale of material required for the process.¹⁵⁶ No case law imposing a compulsory license was found at the time of writing.¹⁵⁷

¹⁵⁰ See supra text accompanying notes 14-15.

¹⁵¹ Patent Act, R.S.C. 1985, c.P-4, §65(2)(e).

¹⁵² See H. G. Fox, supra note 65, at 556.

¹⁵³ See *E.C. Walker & Sons Ltd. v. Lever Bias Machine Corp.*, [1953] 13 Fox Pat. C. 190, 194 (Comm'r of Patents). This ground of abuse figures prominently in United States law.

¹⁵⁴ See, e.g., Torremans, supra note 119, at 327.

¹⁵⁵ Patent Act, R.S.C. 1985, c.P-4, §65(2)(f).

¹⁵⁶ See, e.g., Torremans, supra note 119, at 327.

¹⁵⁷ See, e.g., Hughes & Woodley, supra note 5, §65.

2.7 Nonstatutory Abuse on Equitable Grounds

All the statutory grounds of abuse listed above can be invoked either by the Attorney General of Canada or by means of a private right of action.¹⁵⁸ After 1993, however, there is no virtually automatic grant of a compulsory license on any of these grounds - as there was, for example, with respect to pharmaceuticals under the special Canadian regime to be discussed below¹⁵⁹ - and such a license can only be granted after judicial determination that the alleged abuse actually occurred. Proving such grounds will not be easy, and it was predictable that the number of compulsory licenses issued after 1993 would correspondingly shrink.¹⁶⁰

In Canada, as in the United States, certain forms of abusive behavior can independently violate the domestic competition laws regardless of their status as technical violations of the patent laws as such. The interface between these two types of laws is briefly discussed in the next section and in the chapter on United States law.¹⁶¹

However, Canadian law in this area differs from that of the United States in the sense that it does not expressly entitle an infringer to raise competition law as a defense to a patent infringement action. In other words, while Canada's statutory abuse provisions create an affirmative cause of action not found in United States law for which a compulsory license may issue, they create no private defense to an infringement action sounding in anticompetitive behavior, of any kind.¹⁶² In contrast, a defendant in a patent infringement action in the United States, as will be seen in the separate study on that country, can raise both "misuse of exclusive rights" and "antitrust violations" as defenses.

The question arises as to whether Canadian courts, like their United States counterparts, possess an inherent equitable power to recognize "abuse of the patentee's exclusive rights" as a defense to an infringement action, even though the Canadian rules on abuse make no statutory provision for it. Those who advocate such a rule base it "on the principle that equity will require the protection of the public interest," in which case the public's right to acquire, say, patented pharmaceutical products "at a reasonable cost and on reasonable terms must clearly fall within the scope of the public interest."¹⁶³

Leaving aside both the desirability of such an approach and the extent to which Canadian courts might apply it in practice, it is worth noting that the end result would differ from that attainable under the statute that otherwise governs abuse in Canada. Specifically, a court finding abuse on equitable grounds could lack any inherent power to impose a compulsory license, and would instead logically deny the patent holder any right to enforce the patent against the alleged infringer until and unless the cause of the abuse was removed.¹⁶⁴ This result, which is tantamount to a judicially imposed royalty-free license, is the standard remedy for "misuse" of the patentee's exclusive rights in the United States, although the courts in that country have become more reluctant to impose it than in the past.¹⁶⁵

¹⁵⁸ See, e.g., Torremans, *supra* note 119, at 328.

¹⁵⁹ See *infra* text accompanying notes 226-269.

¹⁶⁰ See Torremans, *supra* note 119, at 328.

¹⁶¹ See *infra* text accompanying notes 166-224.

¹⁶² See Torremans, *supra* note 119, at 328.

¹⁶³ Torremans, *supra* note 119, at 329. Prof. Torremans cites United States law in ancillary support of this proposition, but authority for a non-statutory, common-law "public interest" defense in that country is sparse.

¹⁶⁴ Cf. Torremans, *supra* note 119, at 329.

¹⁶⁵ For details, see the separate case study on the United States.

3. Competition Law

One must now distinguish between acts deemed to constitute abuses under the patent act, for which compulsory licenses are the *primary remedy*, and acts that violate Canada's competition laws (including abuses), for which compulsory licenses are an available ancillary remedy that is, however, in no sense obligatory. Although non-voluntary licenses may theoretically be authorized to address circumstances in which an abuse of the patentee's exclusive rights also restrains trade and disrupts competition pursuant to the Competition Act, compulsory licenses have reportedly been authorized only under the Patent Act provisions in practice.¹⁶⁶

From a policy perspective, the relationship between competition law and intellectual property law is inherently complex owing to the use of legal monopolies - exclusive property rights - to stimulate the creation of new products and new markets in the first place. "Issues arise concerning the limits of the rights provided by intellectual property legislation and drawing the line between a legitimate exercise of such rights and an anti-competitive misuse of them."¹⁶⁷ Canadian authorities, like their counterparts in the United States,¹⁶⁸ are aware that heavy-handed antitrust enforcement may dampen the economic incentives that intellectual property rights confer, and the Competition Bureau is reportedly "concerned to avoid any unnecessary chilling effect on innovation."¹⁶⁹

The interaction of competition and intellectual property laws has been the subject of numerous official studies, most of which - until recently at least - took a dim view of certain uses of the patentee's exclusive rights. For example, a 1946 Report on international cartels criticized the use of patents to control comprehensive marketing schemes within national territories.¹⁷⁰ A 1948 Report on the optical goods industry found an abusive use of patent rights to control trade.¹⁷¹

Of interest for purposes of this study is a 1963 report by the Restrictive Trade Practices Commission ("RTPC"), which found that "the control over drugs exercised through patents in Canada was disadvantageous to Canadian consumers because it enabled the drug suppliers to charge high prices in relation to their cost, production and distribution."¹⁷² As a direct result of this report, the Patent Act was amended to strengthen provisions that provided for compulsory licensing of drug patents in Canada, a topic discussed at length below.¹⁷³ Still another report on pesticides in 1965 "recognized that the tying of the sale of patented and unpatented products by a firm with market power could constitute an abuse of intellectual property rights."¹⁷⁴

¹⁶⁶ See Kent Daniels, Patents, in *Intellectual Property Law of Canada*, §4.09[2] (E. Stikeman ed. 1999) [hereinafter E. Stikeman, *Intellectual Property Law of Canada*]; see also I. Goldsmith, *supra* note 28, at 266.

¹⁶⁷ Competition Law of Canada, Ch. 12 ("Intellectual Property and Competition Law") §12.01 (Davies, Ward & Beck, eds. 1999) [hereinafter *Competition Law of Canada*].

¹⁶⁸ See the separate case study on the United States.

¹⁶⁹ Competition Law of Canada, *supra* note 167, §12.01 (citing authorities).

¹⁷⁰ See Competition Law of Canada, *supra* note 167, §12.02 (citing Canada and International Cartels, Commissioner, Combines Investigation Act, Ottawa, 1946 (patent pools operating in Canada said to restrict prices, sourcing, and terms of sale)).

¹⁷¹ See Competition Law of Canada, *supra* note 167, §12.02 (citing authorities).

¹⁷² Competition Law of Canada, *supra* note 167, §12.02 (citing Restrictive Trade Practices Commission, *Distribution and Pricing of Pesticides: A Report Concerning the Manufacture, Distribution and Sale of Drugs* (1963) RTPC No.24, at 523).

¹⁷³ See *infra* text accompanying notes 226-330.

¹⁷⁴ Competition Law of Canada, *supra* note 167, §12.01 (citing authorities).

As early as 1910, the Canadian Parliament enacted provisions to ensure that patent owners did not unduly restrict competition beyond the scope of their exclusive rights, and these provisions later gave rise to section 32 of the Competition Act of 1985, as amended, which remains in force.¹⁷⁵ Section 32 of the Competition Act seeks to restrain the exercise of intellectual property rights in a manner that unduly prevents or lessens competition. If it is determined that a party has exercised exclusive patent rights so as to produce such a restraint on trade,¹⁷⁶ the Attorney General of Canada may apply to the Federal Court for an order to prevent that use, but no private cause of action becomes available. However, private parties who suffered loss or damage because of conduct that violates the competition laws may bring an action for damages, and this right may form the basis of a counterclaim to an action for patent infringement.¹⁷⁷

Remedies available to the Federal Court include declaring void any license, arrangement or agreement pertaining to the use;¹⁷⁸ restraining a party from carrying out the terms of an offending license, arrangement or agreement;¹⁷⁹ *directing the grant of licenses under any such patent on such terms as it deems appropriate, or directing revocation of the patent*;¹⁸⁰ or directing any other measures that it deems are necessary to prevent such use.¹⁸¹ Before taking remedial action under this provision, the Attorney General must show that the alleged behavior has produced "undue" anticompetitive effects, a test that has been considered fairly difficult to meet.¹⁸²

No order issued under section 32 may be "at variance with any treaty, convention, arrangement or engagement with any other country respecting patents, trademarks, copyrights or integrated circuit topographies to which Canada is a party."¹⁸³ This proviso acquired added importance in November 2001, when the WTO Ministerial Conference at Doha put competition law on the working agenda for the new Doha Round of Multilateral Trade Negotiations.¹⁸⁴

¹⁷⁵ Competition Act, R.S.1985, c.-34, §§1, 32; Competition Tribunal Act, R.S. 1985, C.19 (2d Supp.), § 19; see also Competition Law of Canada, supra note 167, §12.02[1]. The Competition Act contains a number of provisions that are relevant to patent law, including (1) powers of the Federal Court in cases where a patent is used in restraint of trade; (2) powers of the Competition Tribunal to review certain trade practices; (3) offenses relating to competition; and (4) actions for damages by a party suffering a loss as a result of the commission of an offence under Part VI of the Act, for the failure of any party to comply with an order of the Tribunal or of the court. See Competition Tribunal Act, R.S.C. 1985, c.19 (2d Supp.); Competition Act, R.S.C. 1985, c. C-34 (amended R.S.C. 1985, c.27 (1st Supp.), c. 19 (2d Supp.), c.34 (3d Supp.), c. 1 (4th Supp.), c.10 (4th Supp.)), S.C. 1990, c.37.

¹⁷⁶ As defined in the Competition Act, supra note 175, §§32(1)(a)-(d).

¹⁷⁷ Because the statute provides that only the Attorney General may bring the action, the availability of the provision is limited. A private cause of action lies only when a party adjudicated to be in violation of these provisions fails to comply with a court order, §36(1)(b), or for damages suffered, id. § 31.1. See also I. Goldsmith, supra note 28, at 267.

¹⁷⁸ See Competition Act of 1985, supra note 175, §32(2)(a).

¹⁷⁹ Id. §32(2)(b).

¹⁸⁰ Id. §32(2)(c) (italics added).

¹⁸¹ Id. §32(2)(e).

¹⁸² See Howard I. Wetston, The Treatment of Intellectual Property Rights Under Canadian Competition Law, in Patent Laws and Legislation 309, 313 (Gordon F. Henderson, ed. 1994) [hereinafter Wetston].

¹⁸³ Competition Act, supra note 175, §32(3).

¹⁸⁴ See Ministerial Declaration, Ministerial Conference (4th Session), Doha, 9-14 Nov. 2001, WT/MIN(01)/DEC/W/1, 14 Nov. 2001 [hereinafter Doha Ministerial Declaration].

In practice, the Attorney General has seldom invoked section 32 since the late 1960s, when it was twice applied against Union Carbide.¹⁸⁵ In the first case, the Attorney General alleged that Union Carbide's patent licenses implemented an illegal tying scheme by preventing the use in Canada of comparatively inexpensive imported polyethylene resin in conjunction with the company's patented machines and processes. The licensee was required to purchase the resin either from Union Carbide or its designee, or face a royalty for the use of the patented process. The Attorney General applied for an order to void all the licenses containing the restrictive provisions because they limited competition. Before the order was granted, Union Carbide agreed to grant a royalty-free license for the resin to any Canadian manufacturer and to dedicate the interest in one of its non-critical patents to the government of Canada.¹⁸⁶

The other case concerned allegedly restrictive terms in Union Carbide's licenses for a patented process for treating polyethylene film processing.¹⁸⁷ The Attorney General also alleged that the licenses contained discriminatory provisions designed to exclude small purchasers from a substantial portion of the market for film sheets. Union Carbide agreed to revise the licenses to remove the offending terms.

Although Canadian courts have reportedly not yet identified an abuse of the patentee's exclusive rights that rose to the level of anticompetitive behavior, there are instances where the proceedings stopped just short of such a conclusion.¹⁸⁸ In 1965, for example, the Restrictive Trade Practices Commission, in the case of a chemical supplier, issued a report that exclusive patent and trademark rights had been abused when the proprietor refused to sell a plant growth chemical to one of its former distributors.¹⁸⁹ The report stated in part that "where a manufacturer enjoys a sole position in a market, that power must not be used to limit distribution for the purpose of controlling competition in the marketplace."¹⁹⁰ Ultimately, no action was taken in this case due to a subsequent collapse in the market for the product in question. However, the report remains significant because it suggests that tying the sale of patented and unpatented products by a firm with market power potentially constitutes an abuse that violates the competition law.¹⁹¹

Under the Combines Investigation Act ("CIA"), the predecessor to the current Competition Act, one court addressed anticompetitive licensing practices involving General Electric and Union Carbide, which concerned a patent for a plastic compound used in electrical wires.¹⁹² Allegedly, the license to Union Carbide from General Electric constituted a shared monopoly in violation of the CIA because the license terms prevented Union Carbide from selling the patented compound to customers who did not have a certain kind of machinery. Because only four firms in Canada actually possessed that machinery, the

¹⁸⁵ See Competition Law of Canada, supra note 167, §12.02[1].

¹⁸⁶ See Competition Law of Canada, supra note 167, §12.02[1], nn. 7-8 (citing authorities). See also Report of the Director of Investigation and Research, Combines Investigation Act, for the year ended 31 Mar. 1970 at 54-56.

¹⁸⁷ Among the challenged provisions were those 1)prohibiting use of the patented process on specific products; (2)giving the patentee a grant-back license on improvements; (3)prohibiting the licensee from disputing the validity of the patent; (4) requiring the licensee to recognize the patents beyond expiration of the patent term. See Competition Law of Canada, supra note 167, §12.02[1]. A technical analysis of the competition law statutes is beyond the scope of this study.

¹⁸⁸ See Richard F. D. Corley, paper presented to the Second Annual Symposium on Information Technology and Cyberspace Law, Osgoode Hall Law School of York University, 10-13 May 2000 [hereinafter Corley] (copy on file with author).

¹⁸⁹ See Restrictive Trade Practices Commission, Distribution and Pricing of Pesticides: A Report in the Matter of an Inquiry Relating to the Manufacture, Formulation, Distribution and Sale of Weed Killer, Insecticides and Related Products (1965), RTPC No. 37.

¹⁹⁰ See id. at 40.

¹⁹¹ See Corley, supra note 188, at 29.

¹⁹² See *R. v. Canadian General Electric and Union Carbide Canada Limited*, unreported decision of Judge Charles (Provincial Court, Judicial District of York, 9 March 1979).

terms of the license blocked market entry. Despite these facts, the Crown failed to meet the CIA's high standard of demonstrable harm to the public interest, and the case was dismissed. Yet, the court did consider that the CIA would have applied to abusive licensing practices if the standards were met.¹⁹³

While section 32 of the Competition Act applies specifically to intellectual property rights, a patent owner's conduct when exercising his exclusive rights is - like conduct affecting any other property - "potentially subject to the general criminal prohibitions and reviewable practices provisions" of that same Act.¹⁹⁴ The most important provisions that indirectly relate to patents concern conspiracies to restrain or injure competition unduly,¹⁹⁵ price discrimination,¹⁹⁶ or price maintenance.¹⁹⁷

Conspiracies to lessen or restrain trade unduly can occur in the form of patent pools if there is sufficient market power and an anticompetitive effect.¹⁹⁸ The Competition Act does permit parties to register certain types of "specialization agreements" with the Commission Tribunal if the Tribunal finds that permitting the agreement is likely to produce efficiencies that outweigh the anticompetitive effects. Once an agreement is registered, it becomes exempt from charges of conspiracy, exclusive dealing, tied selling and market restrictions under the relevant provisions of the Act, but the Tribunal may order the patent holder to engage in wider licensing as a condition of registration.¹⁹⁹ The purpose of this provision is to help Canadian firms compete more effectively in international markets and to facilitate industrial rationalization.²⁰⁰ As of November 1999, no such registrations had been undertaken.²⁰¹

As noted, price maintenance is prohibited under section 61 of the Competition Act, and it makes specific reference to intellectual property rights by providing that

"[n]o person ... who has the exclusive rights conferred by a patent ... shall, directly or indirectly,

1. by agreement, threat, promise or any like means, attempt to influence upward or to discourage the reduction of, the price at which any other person engaged in business in Canada supplies ... a product within Canada; or

2. refuse to supply a product to or otherwise discriminate against any other person engaged in business in Canada because of the low pricing policy of other persons."²⁰²

¹⁹³ See Corley, *supra* note 188, at 26-27.

¹⁹⁴ See Competition Act of 1985, *supra* note 175, §§45-62; Competition Law of Canada, *supra* note 167, §12.03.

¹⁹⁵ See Competition Act of 1985, *supra* note 175, §§45(1)(a)-(d).

¹⁹⁶ See Competition Act of 1985, *supra* note 175, §§50, 51.

¹⁹⁷ See Competition Act of 1985, *supra* note 175, §61. For example, a provision in an intellectual property license that imposes a minimum resale price or advertised price on the licensee may violate section 61. Competition Law of Canada, *supra* note 167, §12.03[2].

¹⁹⁸ See Competition Law of Canada, *supra* note 167, §12.03[2]. To decrease the risks for joint ventures and other collaborative efforts, the Competition Bureau has issued guidelines concerning strategic alliances. For details, see *id.*

¹⁹⁹ See Competition Act of 1985, *supra* note 175, §§85-90.

²⁰⁰ See Wetston, *supra* note 182, at 313.

²⁰¹ See Competition Law of Canada, *supra* note 167, §12.03[2].

²⁰² See Competition Act of 1985, *supra* note 175, §61(1).

This provision would reportedly prohibit a patent license that imposes a minimum resale price or an advertised price on the licensee,²⁰³ and criminal penalties could apply.

Besides unlawful price maintenance and conspiracies to lessen competition unduly, other provisions of the Competition Act that deal with abuse of a dominant position, with undue product and territorial restrictions, with refusals to supply, and with impermissible mergers all have potential implications for intellectual property rights in general and patent rights in particular.²⁰⁴ The abuse of dominance provisions have the greatest potential applicability to a wide range of practices related to the exercise of intellectual property rights.²⁰⁵

Section 78 of the Competition Act includes a non-exhaustive list of practices that potentially constitute anticompetitive acts that are subject to the abuse of dominance provisions of section 79, including tie-ins, field-of-use restrictions, and exclusive purchasing restrictions.²⁰⁶ However, section 79(5) provides that acts pursuant only to the exercise of any right or enjoyment of any interest derived under any of the federal intellectual property statutes are not anticompetitive acts as such for the purposes of the abuse of dominance provisions. It remains to be seen "where the Tribunal will draw the line between the mere exercise of statutory rights and the misuse of an intellectual property right."²⁰⁷ The provision applies only in the context of abuse of dominance proceedings, and there is no comparable provision with respect to the other practices that are reviewable by the Tribunal.²⁰⁸

The first case brought under the abuse of dominance provisions dealt partly with abusive use of trademark rights in the brand name, NutraSweet, and partly with the same company's attempt to leverage its United States patent against its Canadian supplier even though its Canadian patent had expired.²⁰⁹ The Tribunal held this to be an anticompetitive act and beyond the mere exercise of intellectual property rights, and at least one authority believes that the Tribunal will take "a fairly strict approach" to any attempts artificially to extend the duration or scope of patent rights by contractual or other means.²¹⁰ The same authority suggests that the Tribunal's reading of section 79(5) "does not limit the application of the section to IPR-related contractual and other practices when they are deemed to constitute anticompetitive acts."²¹¹

Actions under the "refusal to supply" provision have yielded mixed results. In cases where spare parts were denied to former customers, the Tribunal ordered that the supply be resumed to what it regarded as "captive" entities.²¹² In a 1997 copyright case, however, the Tribunal concluded that the "right granted by Parliament to exclude others is fundamental to intellectual property rights and cannot be considered to be anticompetitive, and there is nothing in the legislative history ... [to] reveal an intention to have section 75

²⁰³ See Competition Law of Canada, supra note 167, §12.03[2].

²⁰⁴ See generally Competition Law of Canada, supra note 167, §§12.03[1]-[2], [5]. A technical analysis of these topics is beyond the scope of this study.

²⁰⁵ See Wetston, supra note 182, at 311.

²⁰⁶ See Competition Act of 1985, supra note 175, §§78-79; Competition Law of Canada, supra note 167, §12.03[2].

²⁰⁷ See Competition Law of Canada, supra note 167, §12.03[2].

²⁰⁸ See id.

²⁰⁹ See *Canada (Director of Investigation and Research) v. NutraSweet Co.*, [1990] 32 C.P.R. (3d) 1 (Competition Trib.), 41-42 (trademarks), 45-52 (patents).

²¹⁰ Competition Law of Canada, supra note 167, §12.03[3], quoting Wetston [former Director of Bureau], supra note 182, §12.01 n. 10.

²¹¹ Wetston, supra note 182, at 315.

²¹² See Competition Act of 1985, supra note 175, §75; Competition Law of Canada, supra note 167, §12.03[5] (noting that it was unclear whether the parts at issue in the Xerox and Chrysler cases were patented or not, but there appeared to be no third-party suppliers).

operate as a compulsory licensing provision for intellectual property."²¹³ In this case, the Tribunal also stressed the need to defer to international treaty rights, as the Competition Act expressly requires.²¹⁴ The extent to which the holding in this case is fact specific rather than a portent of things to come remains uncertain.²¹⁵

With regard to mergers, the acquisition of a significant interest in another entity as a result of the purchase or licensing of patent rights could enable the Commissioner to petition the Tribunal for an order to block the transaction if there is a finding that it would negatively impact competition in the market.²¹⁶ More importantly, the intellectual property rights of the respective corporations that are party to a merger or acquisition may affect the Competition Bureau's assessment of a proposed merger. For example, in one recent case concerning markets for patented gene therapies, both the Canadian and United States authorities were concerned about potential barriers to entry if likely entrants had to invent around an array of patents, or otherwise be subject to fewer licensing opportunities.²¹⁷ As a result, the merging parties agreed to respect the terms of a United States consent decree in Canada, which required them to license certain patents *and to provide access to the contents of certain drug regulatory files on a nonexclusive basis to third parties*. The goal was to enable third parties to continue research on the specific types of gene therapy affected by the relevant patents.²¹⁸

In evaluating the potential impact of competition law on patent practices in Canada, account must be taken of speeches by Bureau executives and of official guidelines. In 1974, for example, a Deputy Director of the Competition Bureau published a list of licensing provisions and practices that could be deemed to unreasonably extend intellectual property rights.²¹⁹ More recently, the Deputy Director of the Civil Branch of the Competition Bureau acknowledged that the misuse of intellectual property rights could constitute anticompetitive behavior actionable under the Competition Act. He predicted that

[a]s we move towards a knowledge-based economy ... the [Competition] Bureau will become more and more involved in reviewing and resolving allegations of abusive conduct arising from the misuse of intellectual property rights. These cases may be addressed under sections 32 or 79 of the Competition Act. Section 32 provides for a special remedy involving the use of intellectual property rights where their use has injured the competitive market process. In addition, a situation could arise where the alleged abusive conduct has had or will continue to lessen competition substantially in a market and be addressed under the abuse of dominance provisions.

²¹³ *Director of Investigation and Research v. Warner Music Canada Ltd.*, [1997] 78 C.P.R. (3d) 321, 333 (Comp. Trib.).

²¹⁴ *Id.* at 332; see supra note 183 and accompanying text.

²¹⁵ See, e.g., Competition Law of Canada, supra note 167, §12.03[5], at 12-24.

²¹⁶ See *id.* §12.03[6].

²¹⁷ In the matter of Ciba-Geigy Limited, a Corporation [et al, including Chiron, Sandoz, and Novartis], File No. 961-0055, Federal Trade Commission, 1996, FTC 701 (LEXIS); see also Competition Law of Canada, supra note 167, §12.03[6].

²¹⁸ Competition Law of Canada, supra note 167, §12.03[6], at 12-25 (citing Canadian authorities). See also *In re Sensormatic Electronics Corp.*, FTC File No. 941-0126, 4 Jan. 1995 (FTC concerned that proposed acquisition would decrease competition in U.S. and Canadian markets for systems to prevent retail shoplifting; consent decree barred acquisition of certain patents or other exclusive property rights while permitting Sensormatic to acquire nonexclusive licenses and to sell relevant product in either country). In the latter case, there was no public record evincing the Canadian Competition Bureau's concerns about this merger. See Competition Law of Canada, supra note 167, §12.03[6], at 12-25.

²¹⁹ See Address of Roy M. Davidson, "Combines Considerations and the Licensing of Patents," 14 June 1974, summarized in Competition Law of Canada, supra note 167, §12.04.

Were there to be a challenge under section 79, the interesting issue would be to determine whether the act complained of was only the exercise of an intellectual property right or the enjoyment of any interest derived thereunder, and therefore exempt from the abuse of dominance provisions, or whether it could be characterized as an anti-competitive act. The wording of section 79(5) indicates clearly that the provisions remain applicable to practices that are shown to constitute abuses of intellectual property rights, as opposed to the mere exercise of such rights.²²⁰

At the same time, several Directors have repeatedly stressed the pro-competitive effects of intellectual property rights and the fact that they are key factors in stimulating innovation and growth.²²¹ In 1998, the Bureau announced it was developing a set of guidelines that 1) would equate the treatment of intellectual property with that of other forms of property; 2) would not equate the exercise of exclusive rights with market power in the absence of evidence about the extent to which effective substitutes constrain the intellectual property owner's pricing and other elements of competition; and 3) would presume that the licensing of intellectual property rights was generally pro-competitive.²²²

The latest pronouncements clearly reflect the influence of developments in the United States, where antitrust law has been greatly influenced by the Chicago School of economics and other conservative authorities.²²³ However, nothing obliges the developing countries to follow the latest trend or fashion rather than earlier principles concerned with domestic development and fairness,²²⁴ although care must be taken to preserve this autonomy during the coming Doha Round of Multilateral Trade Negotiations.

²²⁰ Gilles Menard, Deputy Director of Investigation and Research (Civil Matters), "Abuse of Dominance: Some Reflections on Recent Cases and Emerging Issues," address to the Conference of the Canadian Institute on Competition Law and Competitive Business Practices, 10 May 1996, at 22.

²²¹ See Competition Law of Canada, *supra* note 167, §12.04 (citing and quoting authorities).

²²² See Competition Law of Canada, *supra* note 167, §12.05 (citing and quoting authorities).

²²³ For the situation in the United States, see the separate case study on that country.

²²⁴ See, e.g., Eleanor Fox, Trade, Competition and Intellectual Property - TRIPS and Its Antitrust Counterparts, 29 *Vand. J. Transnat'l L.* 481 (1996).

4. Safeguarding the Public Interest

Canada's need for provisions to derogate from a patentee's exclusive rights in order to safeguard the public interest seem largely to have been satisfied by the provisions previously reviewed, which dealt with abuses, including local working, and anticompetitive acts. Canada's recourse to governmental uses of patented inventions is discussed later in this chapter.²²⁵ Nevertheless, a special regime that subjected patents on foods and medicines to compulsory licensing was instituted in 1923, and it was not repealed until 1993, in connection with political changes and industry lobbying pressures. In what follows, the pre-1993 law and practice is briefly reviewed, and there is also a summary of the new legislation that displaced it.

4.1 Compulsory Licensing of Food and Pharmaceutical Patents (1923-1992)

In 1923, Canada first introduced the possibility of compulsory licensing for patented pharmaceutical and food products into its legislation, but these provisions were used aggressively only after they were amended in 1969.²²⁶ Between 1935 and 1969, there were 49 applications for compulsory licenses to manufacture either patented foods or medicines, of which 22 were granted, 23 were withdrawn, and four were denied.²²⁷ The bulk of these applications dealt with patented medicines, and the fact that so many were granted reflects Canada's early concern with the public interest in access to medicines.

In 1961, the Restrictive Trade Practices Commission issued its Report Concerning the Manufacture, Distribution and Sale of Drugs, which found that the prices of patented medicines in Canada "were excessive; that there was little price competition; and that patents inhibited competition."²²⁸ Two other government reports in the early sixties reached similar conclusions,²²⁹ and the Royal Commission on Health Services (or "Hall Commission") declared that "either the industry will make ... drugs available at the lowest possible cost, or it will be necessary for ... government to do so."²³⁰

4.1.1 The 1969 Reform

Rather than abolish pharmaceutical patents outright, the Canadian Parliament amended the patent act in 1969, with a view to significantly increasing public access to low cost drugs.²³¹ Under the scheme that emerged in 1969, only process and product-by-process patents remained available for pharmaceutical inventions, but not product patents as such. Compulsory licenses to prepare or manufacture medicines

²²⁵ See *infra* text accompanying notes 331-387.

²²⁶ See S.C. 1923, c.23, §17; Act to Amend the Patent Act, the Trade Marks Act and the Food and Drug Act, S.C. 1968-69, c.49; I. Goldsmith, *supra* note 28, at 155-61.

²²⁷ See McFetridge, *supra* note 10, at 81-82.

²²⁸ See Robert M. Campbell & Leslie A. Pal, *The Real Worlds of Canadian Politics* 32 (1994) [hereinafter Campbell & Pal] (citing and quoting Restrictive Trade Practices Commission, Report Concerning the Manufacture, Distribution and Sale of Drugs (1963)); Harrison, *supra* note 16, at 501.

²²⁹ See Campbell & Pal, *supra* note 228 (citing Royal Commission on Patents, Copyrights and Industrial Designs Report (1960) and Royal Commission on Health Services, Report 40 (1964)); Harrison, *supra* note 16, at 501.

²³⁰ See Campbell & Pal, *supra* note 228, at 32 (quoting Royal Commission on Health Services, Report 40 (1964)); Harrison, *supra* note 16, at 501.

²³¹ See, e.g., Torremans, *supra* note 119, at 316-17.

covered by patented processes also remained available as before.²³² In addition, the crux of the reform was to allow any person to apply for a compulsory license to import any medicines produced with patented processes, an activity that the 1923 Act had forbidden. The policy rationale was that allowing imports would effectively "eliminate the largest barrier to entry: the manufacturing restriction."²³³

In a 1997 case, *Lilly v. S & U Chemicals*,²³⁴ the Supreme Court quotes with approval a passage from a decision by the Commissioner of Patents reflecting on the overall impact of the legislative changes in 1969:

The basic change to s.41 was to enable the Commissioner of Patents to issue *compulsory licences for the importation of medicines* produced by patented processes or substances produced by patented processes used in the preparation or production of medicines, whereas prior to the new enactment, the Commissioner had authority only to issue to applicants *compulsory licences to manufacture* under the patent affected ... In my view, and in spite of the amendments, the direction to the Commissioner of Patents relating to the fixing of the royalty or other considerations in settling the terms of the licence has not ... fundamentally been changed; and hence the principles determined by the Courts in the interpretation of the former s.41(3) still remain applicable.²³⁵

Section 41(4) of the 1969 Act further directed that the "Commissioner shall grant to the applicant a licence to do the things specified in the application" unless he had good reason not to do so.²³⁶ It instructed him to "have regard to the desirability of making the medicine available to the public at the lowest possible price, consistent with giving to the patentee due reward for...research..."²³⁷

²³² See, e.g., McFetridge, supra note 10, at 81 (citing section 41(1) of the 1969 Patent Act).

²³³ See Harrison, supra note 16, at 507; see also I. Goldsmith, supra note 28, at 157. Compulsory licenses for imports were not previously granted. See *Gilbert Surgical Co. v. Parke-Davis & Co.*, [1958] 18 Fox Pat. C. 62 (Ex. Ct.). To prevent a subsequent allegation of abuse through importation, section 39(3) specifically provided that granting a compulsory license for importation of medicines would not be considered an abuse of the Patent Act.

²³⁴ [1997] 1 S.C.R. 536 (Can.).

²³⁵ *Lilly v. S & U Chemicals Ltd.*, [1997] 1 S.C.R. 536 (Can.), at par.9 (quoting *Frank W. Horner Ltd. v. Hoffman-La Roche Ltd.*, [1976] 61 C.P.R. 243, 248 (Comm'r of Patents), aff'd [1972] S.C.R. vi (Can.)) (emphasis added).

²³⁶ Section 41(4) of the 1969 Act provided as follows:

Where, in the case of any patent for an invention intended or capable of being used for medicine or for the preparation or production of medicine, an application is made by any person for a license to do one or more of the following things as specified in the application, namely:

(a) where the invention is a process, to use the invention for the preparation or production of medicine, import any medicine in the preparation or production of which the invention has been used or sell any medicine in the preparation or production of which the invention has been used or sell any medicine in the preparation or production of which the invention has been used, or

(b) where the invention is other than a process, to import, make, use or sell the invention for medicine or for the preparation or production of medicine, the Commissioner shall grant to the applicant a licence to do the things specified in the application except such, if any, of those things in respect of which he sees good reason not to grant such a licence; and, in settling the terms of the licence and fixing the amount of royalty or other consideration payable, the Commissioner shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention and for such other factors as may be prescribed.

²³⁷ Torremans, supra note 119, at 317 (quoting section 41(4) of 1919 Patent Act).

The statutory mandate was thus drawn very broadly. It resulted in "licences to import the medicine or the bulk active ingredient, licences to manufacture the active ingredient in Canada, licences to compound the bulk medicine into final dosage form, licences to sell these dosage forms in Canada for local consumption and licences to export the medicine as bulk or in dosage form."²³⁸

Anyone could apply for a compulsory license under this provision, and there were no qualifications to be met.²³⁹ Applicants did not even have to prove that they were capable or competent to exploit the license or handle pharmaceutical products.²⁴⁰ The result was "a flourishing 'generic' drug industry in which firms could copy the patented products of large international drug firms, but sell them at 50-80% less due to their lack of research, development and marketing costs."²⁴¹ According to Professor McFetridge, the availability of generic substitutes, "together with formularies and substitution rules, reduced drug costs for consumers," although pricing remained oligopolistic and above the range of equivalent off-patent drugs in the United States.²⁴²

4.1.2 Implementing the Reform

The legislation separated the subject matter classes of food and medicine. The new importation provision applied specifically to inventions "intended or capable of being used for medicine or for the preparation or production of medicine,"²⁴³ without extending the importation right to the subject matter of food patents. Section 39(3) had generally permitted the compulsory licensing of inventions for use in the preparation or production of food or medicine unless the Commissioner determined that there was "good reason to the contrary." In both cases, the Commissioner was directed to regard the desirability of making the food or medicine available to the public at the lowest possible price consistent with giving the inventor due reward for the research leading up to the invention when settling the terms of the license, including the amount of the royalty.²⁴⁴

In order to obtain a compulsory license, an interested party was required to make an application to the Commissioner of Patents. The Patent Act also provided that six months after submitting the application for a compulsory license to the Commissioner, if there had been no final disposition, the applicant could petition the Commissioner to secure a six month interim license.²⁴⁵ Although the Commissioner, in his discretion, could deny an application for cause, he rarely did so. Short of a showing that the applicant was bankrupt or had submitted false statements, the Commissioner tended to reject all other objections. It was reportedly his view that "the grant of a compulsory license would lead to enhanced competition and...this would lead to lower prices for pharmaceutical products," which was the underlying statutory objective.²⁴⁶ In other words, the statute meant that "normally the grant of a compulsory license was in the public interest."²⁴⁷

²³⁸ Torremans, supra note 119, at 317.

²³⁹ See H.G. Fox, supra note 65, at 306.

²⁴⁰ See, e.g., Torremans, supra note 119, at 317.

²⁴¹ See, e.g., George Francis Takach, *Patents - A Canadian Compendium of Law and Practice* 114 (1993) [hereinafter G. F. Takach].

²⁴² See McFetridge, supra note 10, at 83.

²⁴³ Cf. Patent Act, R.S.C. 1985, c.P-4, §39(3).

²⁴⁴ Id.; I. Goldsmith, supra note 28, at 155-57.

²⁴⁵ See Torremans, supra note 119, at 317-18; see also Patent Act, R.S.C. 1985, c.P-4, §39(10).

²⁴⁶ Torremans, supra note 119, at 318.

²⁴⁷ Id.

A body of case law developed pertaining to issues considered to fall outside the scope of proper consideration by the Commissioner. In *Smith, Kline & French Laboratories Ltd. v. Frank W. Horner Ltd.*,²⁴⁸ for example, the patent holder argued that if the Commissioner were to authorize the applicant's request for a compulsory license for the production of Cimetidine under two of its patents, it would have considerable difficulty monitoring the reliability of post-market efforts to evaluate the drug's effects. The Commissioner questioned the relevance of this inquiry to his determination and noted that if the Minister of National Health did not perceive the problem as a threat to public safety, then it was not a good reason to deny the license. The Federal Court of Appeals upheld the Commissioner's assessment.²⁴⁹

In one pre-1969 case, *Hoffman-La Roche Ltd. v. Delmar Chem. Ltd.*,²⁵⁰ the patent holder argued that the applicant should be denied a compulsory license given that the process required a great deal of care due to the volatile and unstable nature of the substance used. The court held that since patent holders are under a statutory duty to disclose an invention sufficiently to allow others to make use of it upon expiration of the patent, it could not be argued in opposition to an application that an applicant, skilled in the art, could not produce the product safely in accordance with the specifications.²⁵¹

As the Commissioner was required to grant a compulsory license unless there was good reason not to do so,²⁵² commentators have characterized the system as one where compulsory licenses were available "almost for the asking,"²⁵³ or "as of right."²⁵⁴ Formally, however, the Supreme Court of Canada, in the 1965 decision, *Hoffman-La Roche Ltd. v. Delmar Chemicals Ltd.*,²⁵⁵ declined to characterize the provision as a "licence of right,"²⁵⁶ given the Commissioner's ability to refuse an application for a compulsory license for cause. Even so, the Patent Act - in the Court's view - did not require the Commissioner to provide an oral hearing on the decision as to whether a compulsory license should be authorized for medicine or food patents if one of the parties requests it, as is required under the provisions authorizing the grant of a compulsory license on the grounds of patent abuse.²⁵⁷

²⁴⁸ [1983] 1 C.I.P.R. 183 (F.C.A.).

²⁴⁹ See *id.* at 190.

²⁵⁰ [1964] 27 Pat. Fox C. 178 (Ex. Ct.); *aff'd* [1965] 45 C.P.R. 235 (Can.).

²⁵¹ *Hoffman-La Roche*, at 184. See also *Lilly v. S & U Chemicals*, [1977] S.C.R. 356 (Can.) (in which the Supreme Court of Canada found that it is "completely outside the scope of the duty of the Commissioner to inquire into the adequacy of the Food and Drugs Directorate requirements in licensing a patented drug-making process, as it would be for him to inquire into the same agency's requirements concerning the safety of the drug itself before issuing the patent" (at par.21)); *Syntex Corporation v. Apotex Inc.*, [1984] 2 C.I.P.R. 73 (F.C.A.) (holding that the potential danger to health associated with the inherent thallium present in the production of naproxin was not a matter within the scope of the Commissioner's duty of inquiry pursuant to §41 of the Patent Act of 1970).

²⁵² Patent Act, R.S.C. 1985, c.P-4, §39(4).

²⁵³ William A. Hayhurst, *Remedies*, in *Patent Law of Canada* 265, 276 (Gordon F. Henderson, ed. 1994).

²⁵⁴ Torremans, *supra* note 119, at 318.

²⁵⁵ See *Hoffman-La Roche Ltd. v. Delmar Chemicals Ltd.*, [1965] 45 C.P.R. 235 (Can.).

²⁵⁶ *Id.*

²⁵⁷ Patent Act, R.S.C. 1985, c.P-4, §69(2). This provision allows an oral hearing on the matter if either of the parties requests it, or if the Commissioner deems that a hearing is necessary. In *Hoffman-La Roche Ltd. v. Delmar Chemicals Ltd.*, the patent holder appealed the Commissioner's decision to order a compulsory license of its patents based in part on the failure of the Commissioner to provide an oral hearing at its request. The Court held that under the medicines provision, the Commissioner is empowered to set the procedure and to make the determination of whether an oral hearing is necessary, as opposed to the abuse provisions, where the statute delineates the parties' ability to compel a hearing. The Commissioner had the power to render a decision on the license before the parties made evidentiary submissions in the proceedings. See *Hoffman-La Roche Ltd. v. Delmar Chemicals Ltd.*, [1965] 45 C.P.R. 235, 245 (Can.).

The right to judicial review of the final grant did not appreciably constrain the Commissioner's discretionary powers to implement the statutory goals. In effect, the Commissioner's decision could not successfully be appealed unless the appellant was capable of demonstrating that the determination was manifestly wrong, or that the Commissioner had acted on a wrong principle.²⁵⁸ Reportedly, the Federal Court of Appeals never set aside any decision of the Commissioner to grant a compulsory license under this provision, despite its power to do so.²⁵⁹

Despite this high standard of review, most of the Commissioner's decisions were appealed to the Courts in the early years of aggressive compulsory licensing. By 1971, 43 such decisions granting compulsory licenses had been appealed, which prompted the federal courts to criticize the Pharmaceutical Association of Canada for this "reactionary trend."²⁶⁰

Although the declared goal of the 1969 reform was to make compulsory licenses available on terms that encouraged lower prices, the statute expressly stated that the patentee should receive "due reward for the research leading to the invention and for such other factors as may be prescribed."²⁶¹ In practice, however, the Commissioner's very first decision under these provisions established a royalty amounting to four percent of the net selling price of the drug in final dosage form,²⁶² and this formula was routinely applied in most pharmaceutical cases.²⁶³

The research-based pharmaceutical manufacturers objected to the four percent royalty rate and claimed that it yielded an insufficient return on investments in research and development.²⁶⁴ The Federal Court of Appeal later echoed this criticism and suggested that an automatic royalty rate was legally insufficient.²⁶⁵ Higher royalty rates were subsequently applied in two 1992 cases, when the compulsory licensing scheme had come under pressure.²⁶⁶

²⁵⁸ Patent Act, R.S.C. 1985, c.P-4, §39(12); *Novopharm v. Upjohn*, [1984] 2 C.P.R. (3d) 43 (F.C.A.), reversing 74 C.P.R. (2d) 228 (holding that the decision of the Commissioner to grant a compulsory license could not be interfered absent a showing that there was an error in the law as applied by the Commissioner).

²⁵⁹ See Torremans, *supra* note 119, at 318. If the Commissioner determined in light of the circumstances that the authorization of the license would result in an increase rather than a decrease in the price of the medicine, or that it would have a negative effect on research expenditure, he was empowered to conclude that there was "good reason" to refuse the license. See H.G. Fox, *supra* note 65, at 307. In addition to the public interest, the Commissioner was to consider the patent holder's interest in such matters as the assurance that the royalty would be paid by the licensee, and in the event that such assurance could not be provided, the Commissioner could possibly find good reason not to grant the license. See *Delmar Chemicals Ltd. v. American Cyanamid Co.*, [1959] 20 Fox Pat. C. 51.

²⁶⁰ See Harrison, *supra* note 16, at 507.

²⁶¹ See *supra* note 236; see also *American Home Products Corp. v. ICN Canada Ltd.*, [1985] 5 C.P.R. (3d) 1 (F.C.A.).

²⁶² *Hoffman-LaRoche v. Frank W. Horner*, [1970] 61 C.P.R. 243 (Comm'r of Patents).

²⁶³ See Torremans, *supra* note 119, at 318-19.

²⁶⁴ See Intellectual Property Law of Canada 4-59 (Stewart McCormack ed. 1999).

²⁶⁵ See *Imperial Chemical Industries PLC Ltd. v. Novopharm Ltd.*, [1991] 35 C.P.R. 3^d 137, 139-40 (F.C.A.); G. F. Takach, *supra* note 241, at 114.

²⁶⁶ *Novopharm Ltd. v. Eli Lilly & Co.*, [1992] 42 C.P.R. (3d) 27 (Comm'r of Patents); *Delmar Chemicals Inc. v. Merck & Co.*, [1992] 42 C.P.R. (3d) 135 (Comm'r of Patents).

The 1969 reform induced a steep rise in applications for compulsory licenses covering medicines produced by patented processes. Between 1969 and 1992, there were 1,030 applications to import or manufacture such medicines, of which 613 licenses were granted.²⁶⁷ On the whole, some 20 to 30 new applications were made each year, except for 1984 and 1985, when 77 and 132 applications were made, respectively. Between 1985 and 1987, some 184 compulsory licenses were reportedly granted.²⁶⁸

Over the years, Canada thus made considerable use of the statutory program to bolster the development of its domestic generic pharmaceutical industry and to increase the availability of lower-priced drugs in the Canadian market. During this period, indeed, the strength of the public interest trumped the private interests of pharmaceutical and agricultural patent holders, and no absolute monopoly could be obtained in a process for the production of either food or medicine.²⁶⁹

4.2 The Compulsory Licensing Scheme Abandoned

Critics of the compulsory licensing scheme considered it to adversely affect the research-based pharmaceutical industry, and this allegation was further affected by interprovincial rivalries that began to destabilize Canada in the 1980s. Although support for compulsory licensing had been strong while the Canadian economy remained strong, the program was subjected to increased scrutiny when research and development and other pharmaceutical investment decreased during an economic downturn.²⁷⁰

As the issue became more and more controversial, the Minister of Science and Technology appointed a Royal Commission of Inquiry on the Pharmaceutical Industry, or the Eastman Commission, which delivered its report in 1985. The Eastman Commission concluded that the practice of compulsory licensing *had not adversely affected* the research-based Canadian pharmaceutical industry and that the program had saved Canadian consumers some \$200 million in 1983.²⁷¹ The report also found that the practice failed to have a significant effect on the research and development decisions of the multinational pharmaceutical industry. Since these firms all remained active in Canada, there was some inference that they still made profits, in addition to maintaining market share. Meanwhile, a number of generic firms did quite well.²⁷² The report concluded by suggesting a four year term of exclusive patent protection for pharmaceutical products in Canada, with a higher royalty rate to reward companies that engaged in research and development of pharmaceutical products in that country.²⁷³

²⁶⁷ See McFetridge, *supra* note 10, at 82. It seems a fair assumption that applications not granted were almost always withdrawn, but no source to back this assumption has been found.

²⁶⁸ See *id.*

²⁶⁹ See *Hoffman-La Roche Ltd. v. Bell-Craig Pharmaceuticals Div. of L.D. Craig Ltd.*, [1966] 48 C.P.R. 137, 144 (Can.) (holding that "Parliament intended that, in the public interest, there should be competition in the production and marketing of such products produced by a patented process, in order that as the section states, they may be 'available to the public' at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention").

²⁷⁰ See, e.g., Harrison, *supra* note 16, at 509; see also G. F. Takach, *supra* note 241, at 114.

²⁷¹ See Harry C. Eastman, Report of the Commission of Inquiry on the Pharmaceutical Industry (Ottawa Supply Services Canada 1985) [hereinafter Eastman Report].

²⁷² See Torremans, *supra* note 119, at 319.

²⁷³ See Eastman Report, *supra* note 271; Torremans, *supra* note 119, at 319.

Meanwhile, pressures from abroad grew intense, owing to lobbying by the big pharmaceutical companies against inadequate protection in foreign countries generally and in Canada specifically due to its compulsory licensing scheme.²⁷⁴ Canada was placed on the first Special 301 Watch List issued by the United States Trade Representative ("U.S.T.R.") pursuant to section 301 of the Trade Act of 1974, which has been described as the "thermonuclear bomb" of foreign economic policy.²⁷⁵

Canada needed investment and a growth strategy, and it was willing to make concessions concerning pharmaceutical patents to other countries such as the United States, especially after the elections in September 1984.²⁷⁶ These factors ultimately led to the 1987 legislation known as C-22.²⁷⁷

4.2.1 Bill C-22: An Interim Compromise Solution

In 1987, Canada adopted new legislation governing the compulsory licensing of medicinal patents, which sought to increase the research industry's incentives to invest while preserving many of the public interest benefits that derived from the prior regime. This reform, known as Bill C-22,²⁷⁸ repealed the former section 41(1) and thus recognized product patents, not just process patents, in these subject matter areas for the first time.²⁷⁹ The Bill also endowed holders of pharmaceutical patents with a period of exclusivity that was projected to last at least seven years and possibly longer.²⁸⁰

The policy ensuring access to medicines at affordable prices continued to be implemented by the prior system of compulsory licenses, which kicked in after the new periods of exclusivity. In other words, the regime governing pharmaceutical patents, including the system of compulsory licenses, remained largely unchanged except for the "deferral periods" of exclusivity introduced in 1987 and for certain "made-in-Canada" inventions discussed below.²⁸¹ In addition, a Patent Medicine Prices Review Board ("PMPRB") was set up for the first time, with a view to exerting more direct public control over prices in Canada.²⁸²

The 1987 compromise primarily sought to tailor the regulatory regime to the needs of Canada by discriminating between domestic and foreign suppliers, and it particularly sought to encourage both local research and local production. If a firm invented or developed a pharmaceutical product in Canada, for example, other firms could not obtain compulsory licenses either for the purpose of importing generic

²⁷⁴ See, e.g., Giles Gherson, Free Trade Flash Points: Lumber, Drugs, Publishing are Prickly Issues, *Fin. Post*, 21 Dec. 1985, at 1; Harrison, *supra* note 16, at 501.

²⁷⁵ See Harrison, *supra* note 16, at 501 (citing authorities).

²⁷⁶ See Torremans, *supra* note 119, at 320. Bill C-22, the 1987 bill that virtually halted the practice of compulsory licensing for pharmaceuticals and food, was introduced shortly after United States President Reagan visited Canadian Prime Minister Brian Mulroney to express his displeasure with the compulsory licensing system that compromised the interests of the United States' research based pharmaceutical industry. See David J. French, Patent Law Reform in Canada, 4 *Can. Intell. Prop. Rev.* 337, 341-342 (1997) [hereinafter French].

²⁷⁷ R.S.C. 1985, c.33 (3rd Supp.), §15 (1987).

²⁷⁸ Bill C-22, 33rd Parliament, 2d Sess., 35-36 Eliz. II (1986-1987), *Can. Rev. Stat* §41 et seq. (1987).

²⁷⁹ See, e.g., Torremans, *supra* note 119, at 320.

²⁸⁰ See, e.g., Torremans, *supra* note 119, at 321. However, the Governor-in-Council was given extraordinary power to reduce the statutory periods of exclusivity to discretionary levels if the multinational pharmaceutical companies failed to implement commitments to invest in Canada. See, e.g., John W. Rogers, III, *The Revised Canadian Patent Act, the Free Trade Agreement, and Pharmaceutical Patents: An Overview of Pharmaceutical Compulsory Licensing in Canada*, 12 *E.I.P.R.* 351, 355 (1990) [hereinafter Rogers].

²⁸¹ See, e.g., Torremans, *supra* note 119, at 320-21.

²⁸² See *id.* at 321-22.

substitutes or apparently for local production if the patentee was producing the product locally.²⁸³ Made-in-Canada pharmaceutical discoveries might thus have become altogether immune from the special regime of compulsory licenses.²⁸⁴

As to pharmaceutical products invented or produced abroad, the "deferral period" of exclusivity varied with whether the generic substitutes would be imported or locally manufactured. If imported, then the would-be importer could not generally obtain a compulsory license until ten years from the date on which the first Notice of Compliance had been issued. If, instead, production of generic substitutes occurred in Canada, without importation, then the compulsory license became available after seven years from the Notice of Compliance.²⁸⁵ In either event, a 1989 judicial decision, *Imperial Chemical Industries PLC v. Apotex Inc.*,²⁸⁶ settled that holders of compulsory licenses could import the patented products and could even stockpile them until the deferral period of exclusivity had elapsed in order to expedite market entry.

A third option arose if the pharmaceutical product was manufactured in Canada for export. In that case, compulsory licensing under the 1987 reform could reportedly become available as soon as the Notice of Compliance was granted. However, the royalty rate imposed for such exports could amount to fifteen per cent of the net bulk sales price of the product instead of the standard four per cent rate that the Commissioner continued to apply for compulsory licenses in the domestic market.²⁸⁷

After the 1987 amendments were enacted, case law upheld the Commissioner's power to continue authorizing compulsory licenses during the period of exclusivity, which would take effect in the future.²⁸⁸ The case law also stressed the importance of promoting exports. In *Otsuka Pharmaceutical Co. v. Torcan Chemical Ltd.*,²⁸⁹ for example, there was an application for a compulsory license to produce the patented medication, Carteolol, which implicated two process patents held by Otsuka Pharmaceutical. Torcan Chemical, the applicant, primarily intended to offer the drug in bulk sales for the export market, although the applicant did articulate in the application a further intention to make the drug available in bulk in Canada "as and when the situation warranted."²⁹⁰ The patent holder appealed the Commissioner's decision to authorize the compulsory license, but the Federal Court of Appeal defended the decision, given that the applicant did express a "firm intention to market the medicine in Canada at some future date," which is not inconsistent with the legislative intent of the section still permitting compulsory licensing.²⁹¹

²⁸³ See, e.g., Torremans, *supra* note 119, at 321.

²⁸⁴ See *id.*; see also Rogers, *supra* note 280, at 356.

²⁸⁵ See Torremans, *supra* note 119, at 321. In certain cases, the ten-year period could be reduced to seven or eight years under transitional provisions contained in Bill C-22. See *id.*; see also G.F. Takach, *supra* note 241, at 114-15.

²⁸⁶ [1989] C.I.P.R. 201 (F.C.T.D.).

²⁸⁷ See Gunars A. Gaikis, *Pharmaceutical Patents in Canada - An Update on Compulsory Licensing*, Patent World, May 1992, at 19, 21 [hereinafter Gaikis].

²⁸⁸ See *Novopharm Ltd. v. Yamanouchi Pharmaceutical Co.*, [1989] 27 C.P.R. (3d) (Comm'r of Patents).

²⁸⁹ [1988] 20 C.P.R. (3d) 35 (F.C.A.).

²⁹⁰ *Otsuka Pharmaceutical Co.*, 20 C.P.R. (3d) at par. 5.

²⁹¹ *Id.*

The Patented Medicines Price Review Board was instituted to deal with the upward pressure on pharmaceutical prices that necessarily resulted from the prolonged periods of exclusivity that Bill C-22 introduced in 1987.²⁹² The Board was supposed to monitor the producers' costs of research and development, in part to ascertain if they had kept their promises to increase investment in Canada by some 1.4 billion dollars in exchange for the new periods of exclusivity.²⁹³ The Board also had authority to lower the prices of certain drugs and even to revoke the deferral of compulsory licenses.²⁹⁴

The statute granted the Board a wide range of ancillary powers. Patentees and licensees were obliged to report drug prices, as well as production and marketing costs, to the Board, along with such other information as it might require. If a patentee subsequently raised prices above allowable percentage increases based on the Canadian Consumer Price Index, the Board could demand further information justifying the increase if it was within the "knowledge and control of the patentee." Moreover, the Board could invoke punitive powers if the patentee wrongfully withheld information, or if it sold a pharmaceutical product in Canada at a price deemed excessive in relation to international transfer prices generally.²⁹⁵

Some statutory guidelines helped the Board determine whether prices were excessive, and these included the following benchmarks:

- (1) The price of the drug as sold by the patentee over the previous five years;
- (2) The price of parallel medicines of the same class as sold in Canada for the previous five years;
- (3) The price of parallel medicines of the same class as sold abroad for the previous five years; and
- (4) The Consumer Price Index.²⁹⁶

The Board could also take other factors into account, especially the costs of R&D and revenues from sales, which companies were obligated to declare.²⁹⁷ The Board's punitive powers enabled it to order a price reduction in lieu of cancelling the period of exclusivity, or it could cancel the deferral periods for both an overpriced drug and one other patented medicine as a punishment.²⁹⁸ Of great practical importance, the Board also possessed all the powers and rights of a superior court of record, including the power to subpoena information from third parties, but its decisions were not appealable.²⁹⁹

From a policy perspective, the 1987 compromise remains extremely controversial, with diametrically opposite opinions being expressed about its relative merits or demerits.³⁰⁰ While the objective was clear - namely, to "strike a more acceptable balance between domestic and international intellectual property rights, industrial benefits, Canada's health care system and consumer interests,"³⁰¹ the little empirical evidence available is hotly disputed and cuts both ways. There is no consensus, for example, that Canada

²⁹² See, e.g., Torremans, *supra* note 119, at 321.

²⁹³ See, e.g., Rogers, *supra* note 280, at 357; Harrison, *supra* note 16, at 515. See also Randy Marusyk, *The Beginning of the End of Compulsory Licensing in Canada*, 11 *Biotech L. Report* 671 (1992) (stressing importance of these promises in securing the reform).

²⁹⁴ See, e.g., Torremans, *supra* note 119, at 321-22.

²⁹⁵ See Rogers, *supra* note 280, at 357. See also Patricia I. Carter, *Federal Regulation of Pharmaceuticals in the United States and Canada*, 21 *Loy. L.A. Int'l & Comp. L.J.* 215, 245 (1999).

²⁹⁶ Patent Act, R.S.C. 1987, §41.15(5) (as amended).

²⁹⁷ See Rogers, *supra* note 280, at 357.

²⁹⁸ See *id.*

²⁹⁹ See *id.*

³⁰⁰ For a summary of conflicting assessments, see Torremans, *supra* note 119, at 322.

³⁰¹ Marusyk & Swain, *Price Control of Patented Medicines in Canada*, 10 *C.I.P.R.* 159, 162 (1993), quoted in Torremans, *supra* note 119, at 322.

benefitted from increased foreign investment in the pharmaceutical sector during this period or even that the PMPRB succeeded in controlling the rise of drug prices. At bottom, the 1987 reform simply did not last long enough to yield credible empirical evidence about its potential benefits, while on the costs side of the ledger, generic manufacturers were reportedly more willing to challenge the validity of pharmaceutical patents after the reform.³⁰²

From a political standpoint, the Canadian reform of 1987 became emblematic of the type of regime the United States Trade Representative would challenge in the course of regional and international trade negotiations. In particular, the United States objected to the more favorable treatment given pharmaceutical products invented or developed in Canada, and it also objected to the very idea of a separate regime of compulsory licensing for pharmaceutical products. To underscore its displeasure, the U.S.T.R. put Canada on the section 301 "watch list" from 1989 to 1991.³⁰³

Meanwhile, the regional trade negotiations that led to NAFTA took direct aim at the Canadian reform. Besides requiring participants to patent both pharmaceutical products and processes,³⁰⁴ which the reform had already introduced, the NAFTA intellectual property regime barred the wholesale exclusion of any product category from subject-matter eligibility.³⁰⁵ It also forbids discrimination on the basis of where the product or process was invented or whether it is locally manufactured or used,³⁰⁶ which was a core tenet of the "made-in-Canada" thrust of the 1987 regime. Moreover, while the NAFTA provisions permit compulsory licensing of patented inventions on specified conditions, they also prevent participating countries from singling out a particular subject-matter category - such as "pharmaceutical products" - as a whole. Rather, they require that compulsory licenses should be granted case-by-case according to circumstances,³⁰⁷ or, perhaps, to address particular social needs requiring compulsory licensing of reasonably differentiated subcategories of eligible matter.³⁰⁸

These NAFTA provisions then became a blueprint for the TRIPS Agreement.³⁰⁹ Not only was there a risk that other countries without a major domestic innovative pharmaceutical sector might use the 1987 Canadian regime as a model,³¹⁰ the United States companies feared that their own government might adopt the Canadian system of compulsory licenses to control drug prices.³¹¹

³⁰² See, e.g., Torremans, *supra* note 119, at 322; Gaikis, *supra* note 287, at 24-25. For the view that the PMPRB did succeed in keeping drug prices down, see Gaikis, *supra* note 287, at 23. For the view that there was a dramatic growth in R&D investment in the domestic pharmaceutical industry after 1987, see Henry Grabowski, "Patents, Innovation and Access to New Pharmaceuticals", at 7 (forthcoming 2002).

³⁰³ See, e.g., Torremans, *supra* note 119.

³⁰⁴ See NAFTA, *supra* note 1, art. 1709(1).

³⁰⁵ *Id.*

³⁰⁶ See NAFTA, *supra* note 1, art. 1709(7).

³⁰⁷ See NAFTA, *supra* note 1, arts. 1709 (10)(a), (g).

³⁰⁸ Cf. *Canada -- Patent Protection of Pharmaceutical Products, Report of the Panel, WT/DS114/R (17 Mar. 2000)* [hereinafter *Canadian Pharmaceutical Products Decision*].

³⁰⁹ See TRIPS Agreement, *supra* note 94, arts. 27, 28, 31. "With two international negotiations occurring concomitantly, the research industry was aware that an agreement on intellectual property within NAFTA that allowed Canada to continue to provide compulsory licenses for pharmaceuticals would end any chance of achieving an acceptable comprehensive international minimum standard with the GATT." See Harrison, *supra* note 16, at 522 (citing and quoting Ross Duncan & Dave Blaker, *Trends in the Pharmaceutical Industry in Canada in the Past 1987 Environment* (Ottawa: Interdepartmental Working Group, Intellectual Property Research Branch, Dep't of Consumer and Corporate Affairs, unpublished and undated) (stressing potential role of C-22 as a model law for other countries)).

³¹⁰ See Harrison, *supra* note 16, at 522-23.

³¹¹ *Id.*

After the repeal of Bill C-22 by Bill C-91 in 1992,³¹² the Uruguay Round of Multilateral Trade Negotiations ensured that the Canadian model adopted in 1987 could not subsequently be duplicated by any other WTO Member State, unless they took account of the flexibility otherwise built into the TRIPS Agreement.³¹³ This means that, henceforth, WTO Members seeking to strike a balance comparable to that of the 1987 reform in Canada must fall back upon parallel imports, the residual local working requirement of the Paris Convention, local regulation of abuses, the general regime of compulsory licensing allowed under TRIPS, and the special facilitations afforded essential medicines under the Doha Ministerial Declaration on TRIPS and Public Health.³¹⁴

4.2.2 C-91: The Retreat from Compulsory Licensing

After further lobbying and the signing of NAFTA, the Canadian Parliament passed Bill C-91, the Patent Act Amendment Act of 1992, which took effect on March 12, 1993.³¹⁵ These amendments abolished the special regime of compulsory licensing for patented medicines altogether and terminated the power to grant licenses under the former section 39 after December 20, 1991. As a result, pharmaceutical patents are generally treated like other patents, except for certain measures to enable generic manufacturers to enter the market promptly once these patents expire. In a recent WTO dispute-settlement decision, a panel held that Canada could continue to facilitate the reverse-engineering of patented medicines for this purpose, but that it could no longer permit the stockpiling of finished generic products prior to expiration of the relevant patents.³¹⁶

At the same time, Bill C-91 strengthened the investigatory and regulatory powers of the Patented Medicine Prices Review Board.³¹⁷ While the Board no longer retains the power to revoke patents, its capacity to impose fines and even imprisonment for failure to comply with its price guidelines was enhanced.³¹⁸

The PMPRB thus continues to exist under the current Canadian law, and it operates in generally the same way as it did when it was created in 1987. If the Board determines that a drug price is excessive, it initially approaches the manufacturer seeking a voluntary price reduction,³¹⁹ which has typically succeeded.³²⁰ If negotiations with the patent holder fail, the PMPRB may proceed with public hearings that can result in either the Board's ordering a price reduction for the subject medicine, or for another patented medicine owned by the patent holder, or it may assess damages payable to the Crown.³²¹

³¹² See infra note 315 and accompanying text.

³¹³ See generally J.H. Reichman, *From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement*, 29 *NYU J. Int'l L. & Pol.* 11, 52-58 (1997).

³¹⁴ See the separate case study on "Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under the TRIPS Agreement, and an Overview of the Practice in Canada and the United States", text accompanying notes 103-138; see also Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, study prepared for the World Health Organization (June 2002).

³¹⁵ S.C. 1993, c.2, §§10, 11, 12; G. F. Takach, *supra* note 241, at 115.

³¹⁶ See *Canadian Pharmaceutical Products Decision*, *supra* note 308.

³¹⁷ See G. F. Takach, *supra* note 241, at 115 (citing authorities).

³¹⁸ See Ron J. T. Corbett, *Impact of NAFTA and TRIPS on Intellectual Property Rights Protections in Canada and the United States*, 6 *NAFTA: L. & Bus. Rev. Am.* 591 (Fall 2000).

³¹⁹ See Patent Act Amendment Act, S.C. 1993, c.2, §81(2).

³²⁰ See U.S. General Accounting Office, *Prescription Drug Prices: Analysis of Canada's Patent Medicine Prices Review Board* 7, GAO/HRD-93-51 (Feb. 1993).

³²¹ Patent Act Amendment Act, S.C. 1993, c.2, §§83(2)(a)-(c).

However, one of the most significant effects of the new scheme was the removal of the remedy of compulsory licensing to address the problem of maintaining low prices for medicines.³²²

The PMPRB also monitors compliance of the research-based pharmaceutical sector with its obligations to invest a significant share of profits in local research and development. According to a PMPRB press release of June 20, 2002, the R&D-to-sales ratio for members of Canada's Research-Based Pharmaceutical Companies was 10.6% in 2001, unchanged from 2000. This amounted to a total R&D expenditure by pharmaceutical patentees of one billion dollars in 2001. In the same period, Canadian prices remained relatively stable at levels ranging between 5% to 12% below median international prices.

The 1993 changes to the law thus functionally ended the special system of compulsory licensing for medicines.³²³ The amendments provided that licenses issued before December 20, 1991 would remain in force.³²⁴ It further exempted pharmaceutical and agricultural products from both the failure to work and importation grounds of abuse that had previously made compulsory licensing available as a remedy.³²⁵

In *Apotex Inc. v. Canada*,³²⁶ the Federal Court of Appeal cast these latest changes to the compulsory licensing law as an effort "to protect innovator pharmaceutical companies' distribution and sale rights to patented drugs ... [This was] a reversal of government policy adopted by Parliament in 1923."³²⁷ Hence, at the time of writing, the only mechanisms remaining in the Canadian patent law that permit the compulsory licensing of patented medicines are the truncated abuse provisions of section 65(2),³²⁸ the government use provisions of section 19,³²⁹ and the laws regulating anticompetitive conduct.³³⁰

³²² See Sheldon Burshtein, *Sublicense or Supply Agreement? Supreme Court of Canada Interpretation Benefits Generic Pharmaceutical Industry*, 54 *Food Drug L. J.* 73, 75 (1999).

³²³ Patent Act Amendment Act, S.C. 1993, c.2, §3.

³²⁴ The date of December 20, 1991, incidentally is the date that the Dunkel Draft of the TRIPS Agreement was released. See French, *supra* note 276, at 383.

³²⁵ Bill S-17, S.C. 1993, c.2.

³²⁶ [1994] 1 F.C. 742 (F.C.A.).

³²⁷ *Apotex v. Canada*, 1 F.C. at 754.

³²⁸ See *supra* text accompanying notes 118-157.

³²⁹ See *infra* text accompanying notes 331-387.

³³⁰ See *supra* text accompanying notes 175-222.

5. Government Use of Patented Inventions

Historically, the Government of Canada (also known as Crown) could freely make use of patented inventions at its desire without compensation to the patent holder based on the ground that "the grant of a patent was simply an exercise of the prerogative."³³¹ Canadian patent holders finally obtained the right to reasonable compensation for government use in the case of *Bradley v. The King* in 1941,³³² after this right had been memorialized in the Patent Act of 1935.³³³ Reasonable compensation is determined initially by the Commissioner of Patents whose ruling can be appealed to the Federal Court.³³⁴

5.1 Government Use Prior to 1994

Until Canada joined NAFTA in 1993, the codified governmental use provision, which derived from English law, was very broadly worded:

"The Government of Canada may, at any time, use any patented invention, paying to the patentee such a sum as the Commissioner reports to be a reasonable compensation for the use thereof, and any decision of the Commissioner under this section is subject to appeal to the Exchequer Court."³³⁵

The injured patent holder was required to petition the Commissioner of Patents for redress, who would in turn notify the relevant government department and request that it either acknowledge or deny the use of the patented invention and the validity of the patent.³³⁶ The notion of governmental use was given a broad reading by the courts, and it included the right to sell patented articles, including patented articles covered by a process patent.³³⁷

When either the government or its agents invoked the governmental use privilege before 1993, they had an unrestricted right to use the patent, and they were immune from suit for infringement.³³⁸ This principle was settled in a 1968 Supreme Court decision, *Formea Chemicals Ltd. v. Polymer Corporation Ltd.*³³⁹

In *Formea Chemicals*, Formea held a patent for synthetic rubber that Polymer was engaged in using to supply the Crown. But Polymer was no ordinary private company in the sense that the Crown had "caused...[it] to be incorporated to manufacture, sell and deal in synthetic rubber and made ...[it], for all its purposes, its agent."³⁴⁰ The patent had been initially assigned to Polymer, and then was subsequently assigned to Formea, who brought an action for infringement against Polymer for its continued use of the patent.

³³¹ See H.G. Fox, supra note 65, at 571.

³³² See *Bradley v. The King*, [1941] S.C.R. 270 (Can.). An 1872 statute gave the patentee the privilege to claim compensation from the government for use, but the patentee did not actually have the right to compensation until the case noted above. See H.G. Fox, supra note 65, at 571.

³³³ See Patent Act of 1935, §19 (as amended).

³³⁴ See supra note 333; Federal Court Act, R.S.C. 1985, c.F-7, §24 (1), in S.C. 1990, c.8, §6. See also G.F. Takach, supra note 241, at 111-112.

³³⁵ H. G. Fox, supra note 65, at 571 (quoting §19 of Patent Act of Canada as it stood in 1969).

³³⁶ H. G. Fox, supra note 65, at 572-3.

³³⁷ See id. at 572 (citing authorities); see also G. F. Takach, supra note 241, at 111-12.

³³⁸ H. G. Fox, supra note 65, at 274.

³³⁹ [1968] 38 Fox Pat. C. 116 (Can.).

³⁴⁰ See *Formea Chemicals Ltd. v. Polymer Corporation Ltd.*, [1968] 38 Fox Pat. C. 116, 125 (Can.).

The Supreme Court held that it was "unnecessary to determine, in the circumstances of the present case, what may be the liability of an agent of the Crown, which, without authority, infringes upon the rights of others."³⁴¹ Here, the infringement claim failed because Polymer had statutory authority to make use of the patent under the government use provision of section 19 of the Patent Act.³⁴²

The Supreme Court decision clarified that the exception to patent protection for government use "must be not only in favour of the Crown, but in favour also of those who act on behalf of, and as agents of, the Crown."³⁴³ Therefore, as an agent of the Crown, because "[t]he use by [Polymer] of the patent was, in the circumstances, a use by the Crown within [section] 19," there was no infringement of the patent.³⁴⁴

While this decision clarified the status of government agents, the status of independent contractors engaged by the Government to work the invention remained doubtful for a long time.³⁴⁵ It ultimately became clear that under Canadian law, independent contractors who supply governmental needs without agency status are not covered by the statutory exception for governmental use.³⁴⁶ This practice differs from that under United States law.³⁴⁷

Special provisions deal with inventions of war and inventions pertaining to defense and national security. Inventions covering munitions of war must be assigned to the Minister of National Defense if required, and they will be compensated.³⁴⁸ Both the inventions and the Minister's application may be kept secret. Good faith users during the period of secrecy may later obtain a license of right to manufacture, use and sell the inventions after publication on terms to be settled by agreement with the Commissioner, subject to judicial review.³⁴⁹

The Minister responsible for the Defence Production Act "may contract with any person and thereby relieve him from any claim for use or infringement of a patent."³⁵⁰ Assuming patent validity, the federal government must compensate the patentee.³⁵¹ The Commissioner fixes the amount of compensation, and the decision can be appealed to the Federal Court. The process of claiming compensation is governed by the government use provision of section 19 of the Patent Act.³⁵²

³⁴¹ *Formea Chemicals*, 38 Fox Pat. C. at 119.

³⁴² See *id.*

³⁴³ *Formea Chemicals*, 38 Fox Pat. C. at 122 (quoting *Dixon v. The London Small Arms Company Limited*, (1875-6) 1 A.C. 632 at 641).

³⁴⁴ See *Formea Chemicals*, at 124-25.

³⁴⁵ See H. G. Fox, *supra* note 65, at 574-75.

³⁴⁶ See *In re Minister of Highways and Fitzpatrick*, [1980] 53 C.P.R. (2d) 165, 167-68 (F.C.A.) (holding that Ministry of Transportation and Communications was not entitled to use independent contractors to construct a patented dome for use with salt and sand on a royalty-free basis). See also G.F. Takach *supra* note 241, at 111-12.

³⁴⁷ H. G. Fox, *supra* note 65, at 574-75; see the separate case study on the United States.

³⁴⁸ Patent Act, §§20(2)-(4), (16-17); see also E. Stikeman, *Intellectual Property Law of Canada*, *supra* note 168, §4.09[2].

³⁴⁹ *Id.* §§20(7)-(11), 20(15), 91-93(2); see also G. F. Takach, *supra* note 241, at 113.

³⁵⁰ G.F. Takach, *supra* note 241, at 113 (citing R.S.C. 1985, c.D-1, §22).

³⁵¹ R.S.C. 1985, c.D-1, §22; see *Curtiss-Wright Corp. v. The Queen*, [1968] 1 Ex.C.R. 519 (Ex. Ct.), *aff'd* [1969] S.C.R. 529 (Can.) (holding that "[a]s there are no rights under an invalid patent, there can be no 'infringement' of an invalid patent").

³⁵² See *R. v. Irving Air Chute Inc.*, [1949] 10 C.P.R. 1 (Can.) (noting that it was the first case to come before the Supreme Court of Canada concerning the "quantum of compensation to be paid under section 19 of the Patent Act ... respecting Government use of patented inventions").

In this context, the uncertainty that surrounded the status of independent contractors in Canada caused problems during the Second World War because of the need to ensure uninterrupted supplies of munitions. The temporary solution was a series of Orders in Council that enabled the Government to indemnify war contractors against claims for patent infringement and to ensure that patentees received some reasonable royalties.³⁵³ This system was later codified by the Defence Production Act of 1952, which relieves defense contractors from liability for claims of patent infringement while awarding reasonable compensation to patentees or their assignees.³⁵⁴

A conceptual distinction between uses under authority of the Defence Production Act,³⁵⁵ as it is now known, and true governmental use is worth noting. "When the Crown makes use of the invention under section 19, it, in a sense, exercises a right reserved out of the patent granted by it, and the statutory right to be paid reasonable compensation ... is not related to any infringement."³⁵⁶ In contrast, under the Defence Production Act, the patentee obtains a valid cause of action, which the statute overrides subject to an indemnity that takes the place of damages.³⁵⁷

Closely related to the special treatment afforded to the Government under the Defense Production Act is a similar statutory provision governing rights to patents concerning atomic energy. If the Commissioner of Patents determines that any patent application "relates to the production, application or use of atomic energy," he must notify the Atomic Energy Control Board before making it available for public inspection.³⁵⁸ The Atomic Energy Control Act empowers the Board to expropriate or license "patent rights related to atomic energy and any works of property for production of, or research or investigations with respect to, atomic energy, subject to compensation."³⁵⁹

As noted, when true governmental use has been asserted, the measure of compensation is not fixed on the basis of damages, but rather on the basis of a reasonable royalty such as a willing licensee and licensor might determine under normal market conditions.³⁶⁰ This in turn entails some assessment of the qualitative technical advance the patentee has made over the prior art.³⁶¹

However, fairness to the patentee must be balanced against fairness to the government and its public purpose, so that the claimant may not exploit emergencies to unduly improve his position.³⁶²

Questions of patent validity and infringement may always arise in Government use cases, and the Commissioner may not decide them if the Government refuses to concede either point. In that event, such issues must be litigated in the Federal Court.³⁶³

³⁵³ See H.G. Fox, *supra* note 65, at 574-75.

³⁵⁴ See *id.*

³⁵⁵ Defence Production Act, R.S.C. 1985, c.D-1, §22.

³⁵⁶ H. G. Fox, *supra* note 65, at 575.

³⁵⁷ See *id.*

³⁵⁸ Patent Act, R.S.C. 1985, c.P-4, §22.

³⁵⁹ See Atomic Energy Control Act, R.S.C. 1985, c.A-16, §§10(c), (d), 14; G. F. Takach, *supra* note 241, at 113.

³⁶⁰ See, e.g., *In re Pathfinder Camping Products Ltd.*, [1982] 65 C.P.R. (2d) 119; see also D. Vaver, *supra* note 2, at 168.

³⁶¹ See, e.g., G.F. Takach, *supra* note 241, at 112.

³⁶² See, e.g., H. G. Fox, *supra* note 65, at 575-77.

³⁶³ See, e.g., G.F. Takach, *supra* note 241, at 112 (citing *Honeywell Inc. v. Litton*).

While the Commissioner has broad discretion to determine both the amount and modality of compensation for any governmental use under the statutes, his exercise of that discretion is subject to judicial review. For example, in *R. v. Irving Air Chute Inc.*,³⁶⁴ the method of setting a proper royalty for government use of five patents held by Irving regarding a parachute apparatus and pack was successfully challenged before the Supreme Court. Irving filed a petition of right against the Crown to recover compensation for the use pursuant to section 19 of the Patent Act of 1935. The government admitted its use of the patents and their validity for the purposes of this proceeding, and the Commissioner of Patents fixed the royalty at CDN\$2 per parachute pack.

The Supreme Court found that the Commissioner's royalty rate under-compensated the patentee. Irving was entitled to compensation based on the complete parachute unit, rather than just the harness and the container.³⁶⁵ The Exchequer Court, while holding that Irving was entitled to compensation beyond the parts of the chute that represented changes to the prior art, felt that it did not have the power to determine the appropriate royalty, a power that was statutorily lodged in the Commissioner.³⁶⁶ The Supreme Court nonetheless remanded the case to the Commissioner of Patents for his determination of an appropriate remedy based on the value of the item as a whole.³⁶⁷

5.2 Government Use After NAFTA and TRIPS

After Canada joined NAFTA in 1992, the relevant statutory provisions governing governmental use were amended to conform to that agreement and subsequently to the TRIPS Agreement. Under the 1993 and 1994 amendments to the Patent Act of 1985,³⁶⁸ the authorizing language remains extremely broad, viz, "[s]ubject to section 19.1, the Commissioner may, on application by the Government of Canada or the government of a province, authorize the use of a patented invention by that government."³⁶⁹ What has changed is that technically both the federal and provincial governments are now bound by the Patent Act,³⁷⁰ and their ability to invoke government use may become subject to certain conditions.

The new statutes are understood to distinguish between general government use and "public non-commercial uses,"³⁷¹ for example, "building a bridge where any tolls only amortize building and financing costs."³⁷² This distinction seems puzzling because the logical construction of art. 31(b) of the TRIPS Agreement is that it employs the term "public non-commercial use" as a synonym for "government use" under section 1498 of the United States Code, which is discussed in the separate case study on that country.³⁷³

³⁶⁴ [1949] S.C.R. 613 (Can.).

³⁶⁵ See *R. v. Irving Air Chute Inc.*, [1949] S.C.R. 613 (Can.) at pars. 27-28.

³⁶⁶ See *id.* at par. 37.

³⁶⁷ See *id.* at par. 41.

³⁶⁸ See R.S.C. 1993, c.44, §191 and R.S.C. 1994, c.47, §142, amending Patent Act of 1985, R.S.C. 1985, c.P-4, §19.

³⁶⁹ See Patent Act of 1985, *supra* note 368, §19(1) (as amended).

³⁷⁰ See D. Vaver, *supra* note 2, at 168. The provincial governments may apply to the Commissioner for authorization to use patented inventions subject to reasonable compensation. See G.F. Takach, *supra* note 241, at 112-13.

³⁷¹ See D. Vaver, *supra* note 2, at 168.

³⁷² *Id.*

³⁷³ See TRIPS Agreement, *supra* note 94, art. 31(b); Jayashree Watal, Intellectual Property Rights in the WTO and Developing Countries 319-21 (2002); see also the separate case study on the United States. The relevant NAFTA provision seems identical to the relevant TRIPS provision in its material aspects. See NAFTA, *supra* note 1, art. 1709(10)(b).

Nevertheless, with this tenuous distinction in mind, the Government is reportedly obliged to seek a voluntary license on reasonable terms from the patent holder in prior negotiations before taking formal action to invoke government use.³⁷⁴ Only if such negotiations fail can the Government apply to the Commissioner for a nonexclusive right to use the invention domestically.³⁷⁵ While prior principles of remuneration continue to apply, the non-voluntary license must be "tailored in scope and duration to the government's necessities, but can, on the patentee's request, be terminated when the government no longer needs it."³⁷⁶

However, if the Government invokes the ground of "public non-commercial use," it may avoid the obligation to negotiate with the patentee, and may proceed more or less as before, subject to a duty to notify the patentee of its action.³⁷⁷ This exception is fully consistent with TRIPS and NAFTA, and it remains unclear why Canada seems to have undertaken any obligation to negotiate for any government use.

Both NAFTA and the TRIPS Agreement allow governments to waive the duty of prior negotiations in the case of a national emergency or other circumstances of extreme urgency,³⁷⁸ as well as in cases of public non-commercial use. While the 1993 and 1994 amendments to the Patent Act attempt to codify this exception, it seems that they nonetheless technically require the federal or provincial governments to apply to the Commissioner for authorization to invoke governmental use of patents.³⁷⁹ If so, this approach once again seems more restrictive with respect to the federal government than the international treaties require, although it makes some sense with respect to the provincial governments.

How these revised governmental use provisions will be implemented in the post-TRIPS environment remains to be seen, but the possibilities are at least hinted at in a recent case concerning the anthrax scare in 2001. In October of 2001, Health Canada's Emergency Services branch became concerned about the threat of anthrax and the availability of affordable antibiotics to treat it. Ciproflaxin, although not specifically approved in Canada as a treatment for anthrax, became the focus of the government's stockpiling efforts. Despite Bayer's offer to triple production of its drug, Cipro, to facilitate stockpiling, Health Canada entered into a contract with Apotex, one of Canada's largest generic manufacturers, to produce Apo-Cipro in disregard of Bayer's Canadian patent, which does not expire until 2004. Under the contract, Apotex was to provide Health Canada with one million tablets at a cost of CDN\$1.50 per pill, compared to the CDN\$2.50 per pill cost of Bayer's patented medication.³⁸⁰

³⁷⁴ See D. Vaver, *supra* note 2, at 168 (citing Patent Act, §§19(1), 19(2)(b), (c) and *id.* §§19.1(1), (6)).

³⁷⁵ See D. Vaver, *supra* note 2, at 168.

³⁷⁶ *Id.*

³⁷⁷ See D. Vaver, *supra* note 2, at 168. The Commissioner may not issue a compulsory license for patented semiconductor technology other than for public non-commercial use. See Patent Act of 1985, §19.1(4).

³⁷⁸ See TRIPS Agreement, *supra* note 94, art. 31(b); NAFTA, *supra* note 1, art. 1709(10)(b).

³⁷⁹ See D. Vaver, *supra* note 2, at 168.

³⁸⁰ See Rob Ferguson, Health Canada Orders 1 Million Anti-Anthrax Pills, *Toronto Star*, 18 Oct. 2001. The article reports that Apotex began production of Apo-Cipro on 16 October 2001. See *id.*

No official source has been found to explain the legal basis for this contract with the generic producer, and no compulsory license was reportedly authorized. It seems likely that the government would have ultimately claimed that its use was made pursuant to section 19 of the Patent Act and that the formalities of that provision were excused given the circumstances of national emergency or other circumstances of extreme urgency, or, perhaps, that only public noncommercial use was envisioned. Making such a claim would presumably permit the government to forego the formalities of first negotiating with Bayer on reasonable commercial terms for a reasonable period of time.³⁸¹

It turns out that Apotex had challenged Bayer's Cipro patent several times in the past, arguing that its version was produced using a different process and that the product Apo-Cipro was not an infringement of the Bayer patent.³⁸² Some Canadian legal experts are said to believe that the government would have lost if Bayer had challenged the government's contract with Apotex in the courts,³⁸³ but it is hard to see why, if the government acted under its public health emergency powers, as suggested above.

As matters turned out, a mere four days after beginning production under the contract with Apotex, the Canadian government altered its position and announced successful negotiations with Bayer to reduce the price of Cipro. Bayer agreed to supply one million tablets of Cipro within 48 hours upon request for Health Canada's National Emergency Stockpile System. Reportedly, "the effective price for Cipro supplied to the National Emergency Stockpile System will be CDN\$1.50, significantly below the regulated price," which has been quoted at CDN\$2.00-2.50.³⁸⁴ In return, Health Canada assured Bayer that it would exclusively purchase all its Ciproflaxin from Bayer for the remainder of the Bayer patent.³⁸⁵

Health Canada also affirmed the validity of the Bayer patent and the fact that Bayer is "the only Canadian manufacturer holding a notice of compliance that establishes the safety and efficacy of Cipro."³⁸⁶ The government made only a vague reference to the contract with Apotex, stating that "Health Canada has agreed to deal appropriately with the order placed with Apotex for ciproflaxin hydrochloride tablets in a manner acceptable to both Bayer Inc. and Health Canada."³⁸⁷

³⁸¹ See Patent Act, R.S.C. 1985, c.P-4, §19.1(2) (as amended). The President of Apotex stated that the company did not have a certificate exempting the company from patent protection laws. He was quoted as saying, "[t]hey [the government] don't care, they need the drug." See Rob Ferguson, *supra* note 380.

³⁸² The latest challenge of the Bayer patent by Apotex was dismissed in September by the Federal Court of Appeal. See *Bayer AG v. Apotex Inc.*, [2001] FCA 263.

³⁸³ See Geoff Dyer & Adrian Michaels, A Bitter Pill for the Drug Makers, *Financial Times*, 22 Oct. 2001.

³⁸⁴ Canada NewsWire, *Financial News*, Toronto, 25 Oct. 2001.

³⁸⁵ See Health Canada Press Release, Health Canada and Bayer Inc. Confirm Supply Agreement for Ciproflaxin Hydrochloride, 22 Oct. 2001.

³⁸⁶ *Id.*

³⁸⁷ *Id.*