SMART & BIGGAR

Watch Out! Compulsory Licensing Lurks Around Global Corners (The View from Canada)

By Matthew Zischka, Y. Lynn Ing and Keith Chung[1]

I. Introduction

International humanitarian efforts, culminating with the 2001 Doha Declaration on the TRIPS Agreement and Public Health, have brought the arcane topic of compulsory patent licensing to the public consciousness. Compulsory patent licensing as permitted by national patent laws and contained by international treaties, has had a long and chequered history. Its public prominence today may merely signify a swing of the pendulum away from strong patentee rights.

This paper examines the availability of such compulsory licenses primarily under Canadian law, in an effort to shed light on why and to what extent such licenses have been and remain available globally, in countries that are signatories to major intellectual property conventions.

A. Background to the patent system

Patents are state-granted monopolies, granting a patent holder exclusive, time limited rights in an invention. Although such rights are national in scope, patents are subject to similar, but distinct patentability requirements in different countries. Ongoing efforts to harmonize patent laws and practice worldwide[2] have yet to result in anything that resembles a true international patent.

Historically, the introduction of national patent laws was often justified as promoting domestic industry.[3] While some continue to argue a role in promoting domestic industry, modern legal and political theories of patent law suggest a general reluctance towards justifying the grant of patents on this basis.[4] Instead, two familiar public policies are now most often used to justify modern patent monopolies.

---

1 Matthew Zischka (mzischka@smart-biggar.ca) is a partner with Smart & Biggar, Toronto, Ontario. Lynn Ing (yling@smart-biggar.ca) is an associate with Smart & Biggar, Toronto, Ontario. Keith Chung is a student-at-law, Smart & Biggar.

2 See generally *Paris Convention for the Protection of Industrial Property* ("*Paris Convention*"), March 20, 1883, as revised at Brussels on Dec. 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, and as last amended on September 28, 1979, 21 U.S.T. 1583, 828 U.N.T.S. 303; *Patent Cooperation Treaty* ("PCT"), June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231, 9 I.L.M. 978 (1970); and *Patent Law Treaty* ("PLT"), June 1, 2000, 39 I.L.M. 1047.

3 Halewood, M., "Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law" (1997), 35(2) Osgoode Hall L.J. 243 at 252.

4 *Agreement on Trade-Related Aspects of Intellectual Property Rights* ("TRIPS"), Apr. 15, 1994, *Marrakesh Agreement Establishing the World Trade Organization*, Annex 1C, (1994), 1869 U.N.T.S. 299, 33 I.L.M. 1197. Article 27.1 of TRIPS reads "*in part … patents shall be available and patent rights enjoyable without discrimination as to … whether products are imported or locally produced*". See also Halewood, *supra*, note 3 at 252.

The first is that patents provide an incentive for earlier and better public disclosure of the results of private research and development: patents provide an incentive to disclose what would otherwise not be disclosed. Currently, judicial thinking at the Supreme Court of Canada echoes this justification of the monopoly:

> A patent is a statutory monopoly which is given in exchange for a full and complete disclosure by the patentee of his or her invention. The disclosure is the essence of the bargain between the patentee, who obtained at the time a 17-year monopoly on exploiting the invention, and the public, which obtains open access to all of the information necessary to practise the invention. Accordingly, at least one of the policy objectives underlying the statutory remedies available to a patent owner is to make disclosure more attractive, and thus hasten the availability of useful knowledge in the public sphere in the public interest.[5]

The second is that patents enhance the underlying economic incentives to innovate, and correct market failures: the monopoly provides an incentive for research, invention and innovation by preventing free-riders. As stated by the Supreme Court of Canada:

> There is no doubt that two of the central objects of the [Patent] Act are "to advance research and development and to encourage broader economic activity" (see *Free World Trust v. Électro Santé Inc.*, [2000] 2 S.C.R. 1024, 2000 SCC 66, 9 C.P.R. (4th) 168, 194 D.L.R. (4th) 232, at para. 42).[6]

Primarily on the basis of these two justifications, nearly all national governments grant (or justify the grant of) patents. On balance, the articulated benefits outweigh the monopoly rents extracted by the pricing of patented inventions.

B. Background to patent licensing

Generally, patent licenses are voluntarily granted by patentees to make, use, or sell the claimed subject matter, subject to negotiated terms and conditions. In contrast, a compulsory license results from a third party (generally a governmental or judicial body) compelling a patentee to grant a license to a specific licensee. While the legal authority for such compulsion usually prescribes specific terms and conditions (including compensation to the patentee), the patentee's consent is not required.

A number of justifications are routinely cited for the grant of compulsory licenses. Although, the specifics vary, the themes can be generalized: compulsory licenses may be appropriate if the public benefits of increased use of the patented invention outweigh the long term public costs of reduced disclosure and innovation; and the public interest in expanded working of the patented invention outweigh the patentee's private interests.[7]

---

5 *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142 at para. 46 (S.C.C.).

6 *Harvard College v. Canada (Commissioner of Patents)* (2002), 21 C.P.R. 417 at 490 (S.C.C.).

7 Reichman, J. and Hasenzhal, C. "Non-voluntary licensing of patented inventions. Historical perspective, legal framework under TRIPS, and an overview of the practice in Canada and the USA" (2003), ICTSD Programme on IPRs and Sustainable Development Issue paper no. 5 at 10.

For example, compulsory licenses have been granted:[8]

1. in times of public emergency;[9]
2. for inventions produced in whole or in part through public funding;[10]
3. as a remedy to counteract anti-competitive practices or effects;[11]
4. where the statutory monopoly causes undue or unexpected harm to the public or is abused by the patentee;[12] and
5. where an invention concerns a field of technology deemed particularly crucial.[13]

Today, many jurisdictions, including the U.S., Japan, all of the EU, and other major markets including the U.K., China, India, Brazil, Russia, and Canada, recognize at least some form of compulsory patent licensing.[14] While the basic principles are similar in that the patentee is compelled to grant the license, the specific requirements and mechanisms for obtaining compulsory licenses differ widely between jurisdictions.

For example, though the U.S. Supreme Court may consider that "compulsory patent licensing is a well recognized remedy where patent abuses are proved in antitrust actions,"[15] it also considers that outside of competition law, "compulsory licensing is a rarity in our patent system."[16]

Canada, by contrast, has proceeded otherwise. While there has been relatively little use of compulsory licensing as a remedy to anticompetitive activity, compulsory licenses have long been authorized by statute, and available in defined circumstances. As a result, licenses were commonly applied for and granted for both the import and domestic working of both pharmaceutical and other patented inventions. For example, prior to the 1990s, over a thousand applications for compulsory licenses were made, and the majority granted.[17]

---

8 Anér, *infra,* note 20 at 18. See also Reichman, *supra,* note 7 at 12.

9 *North American Free Trade Agreement* ("NAFTA"), December 17, 1992, (1993), 32 I.L.M. 289, Chapter 17, Article 1709.10(b).

10 35 U.S.C. §203.

11 TRIPS, *supra,* note 4, Part II, Article 40. See also Competition Bureau, "Intellectual Property Enforcement Guidelines" (Ottawa: Industry Canada, 2000).

12 *Patent Act (1985), infra,* note 18, s. 65.

13 See 42 U.S.C. §7608 – Mandatory Licensing (of air pollution prevention inventions); See also 42 U.S.C. §2183 – Nonmilitary utilization (of patents related to special nuclear material or atomic energy).

14 Reichman, *supra,* note 7 at 12. See also Dratler, J., *Licensing of Intellectual Property* (Law Journal Press 1994) at §3.03[1][a].

15 *Besser Mfg. Co. v. United States* (1952), 72 S.Ct. 838, 343 U.S. 444 at 447.

16 *Dawson Chem. Co. v. Rohm & Haas Co.* (1980), 100 S. Ct. 2601, 448 U.S. 176 at 215. See also Reichman, *supra,* note 7 at 21; Dratler, *supra,* note 14 at §3.03[2][a].

17 Reichman, *supra,* note 7 at 20.

In Canada, compulsory licensing continues to be condoned by section 66(1)(a) of the Canadian *Patent Act*:[18]

> 66. (1) On being satisfied that a case of abuse of the exclusive rights under a patent has been established, the Commissioner may exercise any of the following powers as he may deem expedient in the circumstances:
>
> (a) he may order the grant to the applicant of a licence on such terms as the Commissioner may think expedient, including a term precluding the licensee from importing into Canada any goods the importation of which, if made by persons other than the patentee or persons claiming under him, would be an infringement of the patent, and in that case the patentee and all licensees for the time being shall be deemed to have mutually covenanted against that importation;

There is little doubt that these provisions reduce the incentives provided by a patent system.[19] However, there remains much debate about the extent to which licenses weaken the system.[20]

II. Compulsory Licensing as Relief for Patentees

A. Canada (1869 to 1923)

As noted, early patent laws were justified as beneficial for domestic industry. Not surprising, the earliest known patent system, the Venetian *Patent Act of 1474*, required a patentee to "work" his invention locally as part of the bargain for a patent.[21] "Local working" refers generally to the requirement that a patentee exploit the patented invention, for example by manufacturing the patented article or using the patented process, within the physical territory of the patent granting state.[22]

Likewise in Canada, working an invention in Canada had "always has been the spirit of the several Patent Acts in force in this country, at least for a long time".[23] For example, under Canada's first federal patent legislation (*An Act respecting Patents of Invention*, 1869), patent rights were conditional. If after three years, the patentee did not commence and carry on construction or manufacture of the invention in Canada, all rights and privileges granted under the patent would cease, and the patent became null and void.[24] In addition, if the patentee imported, or caused to be imported, the invention into Canada after a certain period after grant,

---

[18] *Patent Act*, R.S., 1985, c. P-4, s. 66(1)(a). Except where indicated otherwise, references in this paper to the Canadian *Patent Act* refer to the current (1985, as amended) version.

[19] Delrahim, M. "Forcing Firms to Share the Sandbox: Compulsory Licensing of Intellectual Property Rights and Antitrust", presented at the British Institute of International and Comparative Law (2004) at 2.

[20] Anér, E., "The WTO Decision on Compulsory Licensing", Stockholm: Kommerskollegium, 2008 at 35. See also Chien, C. "Cheap Drugs at What Price to Innovation: Does the compulsory licensing of pharmaceuticals hurt innovation?" (2003), 18 Berkeley Tech. L. J. 853.

[21] Halewood, *supra,* note 3 at 251. See also Mandich, G, "Venetian Patents (1450-1550)" (1948), 30 Journal of the Patent and Trademark Office Society 166 at 176-177.

[22] Halewood, *supra*, note 3 at 236.

[23] *Celotex Corp. et al. v. Donnacona Paper Co. Ltd.* (1939), 2 C.P.R., 26 at 50-51 (Ex. Ct.) ("*Celotex*").

[24] *An Act respecting Patents of Invention*, Cap. 11, 1869, s. 28.

the patent became void. Although recognized to be at times impractical or oppressive,[25] these provision were enacted with a view to establishing new industries in the country.

Only beginning in 1903, were the harsh consequences of forfeiture softened, as the Canadian *Patent Act* now provided that the conditions requiring manufacturing could be "substituted" with a compulsory license (although that term was not used). Any person could petition the Commissioner of Patents for a license to make, construct, use and sell the patented invention. The Commissioner was obligated to hear the person and the patentee and, if satisfied that "the reasonable requirements of the public in reference to the invention have not been satisfied by reason of the neglect or refusal of the patentee", order the patentee to grant the applicant a license on reasonable terms.[26]

B. Paris Convention (1883 to 1925)

During the second half of the 19th century, patent forfeiture was also becoming an international concern. As a consequence, the first multi-state, fruitful discussions of compulsory licensing are believed to have occurred at the Congress of Vienna for Patent Reform in 1873, which eventually led to the first major international intellectual property convention, the *Paris Convention for the Protection of Industrial Property* (the "*Paris Convention*") in 1883.[27] One of the outcomes of the Vienna Congress was a resolution that compulsory licenses be made available where the public interest required it. This resolution resulted in a compulsory licensing provision being adopted in Germany in 1877.[28]

Surprisingly, the *Paris Convention* as originally adopted contained no explicit provision for compulsory licensing. A patentee, however, could no longer lose his patent merely by importing the patented product. Nevertheless, the treaty allowed national laws to require working the invention, locally. Thus, forfeiture for non-working remained a possibility.[29]

In 1911, the *Paris Convention* was revised to allow patentees greater flexibility in commercializing and bringing patented inventions to the local market. The revision mandated a minimum three year grace period after filing the patent application in that country before any

---

[25] *Celotex*, *supra,* note 23 at 41.

[26] *An Act to amend the Patent Act*, Chap. 46, 1903, s. 7.

[27] World Intellectual Property Organization ("WIPO"), "WIPO Intellectual Property Handbook: Policy, Law and Use" (2004), WIPO Publication No. 489 (E) at 241. See also *Paris Convention*, *supra*, note 2, generally and Article 25(1), 1979 text.

[28] Halewood, *supra*, note 3 at 266.

[29] *Paris Convention*, *supra*, note 2, Article 5A, 1883 text:

> (1) The introduction by the patentee into the country where the patent has been granted of objects manufactured in any of the States of the Union shall not entail forfeiture.
>
> (2) Nevertheless, the patentee shall remain bound to work his patent in conformity with the laws of the country into which he introduces the patented objects.

potential forfeiture for non-working,[30] and the opportunity for the patentee to justify his inaction.[31]

It was not until 1925 that further revisions introduced the first mention of compulsory licenses in the *Paris Convention*, as a preliminary condition prior to forfeiture for failure to work the invention. While a contracting country could take legislative measures to prevent *inter alia* failure to work:

> These measures shall not provide for forfeiture of the patent unless the grant of compulsory licenses is insufficient to prevent such abuses.[32]

Thus, in effect, early efforts to allow the grant of compulsory licenses acted to attenuate the severity of the "all or nothing" effect of forfeiture.[33]

III. Compulsory Licensing in the (Domestic) Public Interest

A. Paris Convention (1925 to present)

While compulsory licenses were perhaps contemplated in the 1925 revision of the *Paris Convention* as a control against forfeiture, through the introduction of the notion of abuse, it was also contemplated that the circumstances in which patentees could lose patent rights went beyond non-working. As indicated above, it became expressly permissible for contracting countries to take *"the necessary legislative measures to prevent abuses, which might result from the exclusive rights conferred by the patent"*.[34]

In the 1958 revisions, the *Paris Convention* explicitly provided the right to grant compulsory licenses to prevent patent abuse:

> Each country of the union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses, which might result from the exclusive rights conferred by the patent, for example, failure to work.[35]

The language of the provision against forfeiture unless the grant of compulsory licenses *"is insufficient"* to prevent abuses was amended to *"would not have been sufficient"*.[36] There were also substantive limitations placed on compulsory licenses, including the requirement that they be non-exclusive and non-transferable.[37]

---

[30] In 1925, the grace period was effectively increased, to three years from the date of grant. In 1934, the grace period was increased further by stipulation that no proceedings for the forfeiture or revocation of a patent may be instituted before the expiry of two years from the grant of the first compulsory license.

[31] *Paris Convention*, *supra*, note 2, Article 5A, 1911 text.

[32] *Paris Convention*, *supra*, note 2, Article 5A, 1925 text.

[33] Reichman, *supra,* note 7 at 10.

[34] *Paris Convention*, *supra*, note 2, Article 5A, 1925 text.

[35] *Paris Convention*, *supra*, note 2, Article 5A, 1958 text.

[36] *Paris Convention*, *supra*, note 2, Article 5A(2), 1958 text.

[37] *Paris Convention*, *supra*, note 2, Article 5A(4), 1958 text.

Article 5A of the current (1967) version of the *Paris Convention*,[38] which is substantially similar to the 1958 revision, states:

> (1) Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.
>
> (2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.
>
> (3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.
>
> (4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non–exclusive and shall not be transferable, even in the form of the grant of a sub–license, except with that part of the enterprise or goodwill which exploits such license.
>
> (5) The foregoing provisions shall be applicable, mutatis mutandis, to utility models.[39]

B. Policy to "secure", not just encourage inventions: abuse provisions in Canada (1923 to present)

Canada acceded to the *Paris Convention* on June 12, 1925.[40] Amendments to Canada's Patent Act were already made two years earlier, in 1923, to implement the minimum standards of the *Paris Convention*.[41]

Conditions as to manufacture were continued in the 1923 *Act*; however, they were now explicitly tied to the public interest:

> Every patentee shall satisfy the reasonable requirements of the public with reference to his patent and to that end shall adequately manufacture the patented article or carry on the patented process within Canada;[42]

---

[38] The vast majority of contracting parties are parties to the 1967 revision: WIPO Intellectual Property Handbook, *supra*, note 27.

[39] *Paris Convention*, *supra*, note 2, Article 5A, 1967 text.

[40] "Treaties Database – Contracting Parties", *WIPO*, December 13, 2008 available at <http://www.wipo.int/treaties/en/Remarks.jsp?cnty_id=205C>.

[41] Biggar, M., "Canadian Patent Law and Practice" (Toronto, 1927) at 77.

[42] *Patent Act*, R.S.C. 1923, c. 23 ("*Patent Act (1923)*"), s. 40(a).

These "reasonable requirements" were defined as manufacture of the patented article "to an adequate extent and supply on reasonable terms" or carrying on the process in Canada "to an adequate extent or to grant licenses on reasonable terms", and "not unfairly prejudice" any trade or industry in Canada.[43] The failure to meet these "reasonable requirements" allowed the Commissioner of Patents to compel supply or grant licenses for the use of the patented invention.[44]

The language of "abuse" of patent rights did not actually appear in the *Patent Act* until 1935. The new abuse provisions in s. 65 of the Act listed the circumstances in which patent rights were deemed to have been abused:

1. the patented invention was not being worked in Canada on a commercial scale, and no satisfactory reason can be given for such non-working;[45]
2. the patented invention was imported into Canada thereby preventing or hindering the working of the invention on a commercial scale in Canada;[46]
3. demand for the patented article in Canada was not being met to an adequate extent and on reasonable terms;[47]
4. trade or industry in Canada was being prejudiced by the refusal to license the patent upon reasonable terms;[48]
5. trade or industry in Canada was unfairly prejudiced by conditions attached to the purchase of the patented article or the working of the patented process;[49] or
6. the patented process was being used so as to unfairly prejudice in Canada the manufacture, use or sale of unpatented materials used in the process.[50]

---

[43] *Patent Act (1923), supra,* note 42, s. 40(d).

[44] *Patent Act (1923), supra,* note 42, s. 40(c).

[45] *Patent Act* 1935, R.S.C. 1935, c. 32 ("*Patent Act (1935)*"), s. 65(2)(a):

> 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 for such non-working…

[46] *Patent Act (1935)*, *supra,* note 45, s. 65(2)(b):

> 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 persons claiming under him, or by persons directly or indirectly purchasing from him, or by other persons against whom the patentee is not taking or has not taken any proceedings for infringement;

[47] *Patent Act (1935)*, *supra,* note 45, s. 65(2)(c):

> If the demand for the patented article in Canada, is not being met to an adequate extent and on reasonable terms;

[48] *Patent Act (1935)*, *supra,* note 45, s. 65(2)(d):

> If, by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or 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, is prejudiced, and it is in the public interest that a licence or licences should be granted;

[49] *Patent Act (1935)*, *supra,* note 45, s. 65(2)(e):

> If any trade or industry in Canada, or any person or class of persons engaged therein, is unfairly prejudiced by the conditions attached by the patentee, whether before or after the passing of this Act, to the purchase, hire, licence or use of the patented article, or to the using or working of the patented process;

[50] *Patent Act (1935)*, *supra,* note 45, s. 65(2)(f):

> If it is shown that the existence of the patent, being a patent for an invention relating to a process involving the use of materials not protected by the patent or for an invention relating to a substance produced by such a process, has been utilized by the patentee so as unfairly to prejudice in Canada the manufacture, use or sale of any materials.

Applicants could petition the Commissioner of Patents to investigate and grant a compulsory license on the basis of such abuse.[51]

Importantly, the section stated that the policy underlying the grant of patents was not merely to "encourage" inventions but to "secure" their working in Canada:

> … for the purpose of determining whether there has been any abuse of the exclusive rights under a patent, it shall be taken that patents for new inventions are granted not only to encourage invention but to secure that new inventions shall as far as possible be worked on a commercial scale in Canada without undue delay.[52]

The Courts thus sometimes took an unsympathetic approach in finding that a patentee had not met the statutory requirements:

> It is the responsibility of one holding rights under the patent law of this country to see that commercial working of the patent in Canada within the limits indicated is secured, and if he fails to secure it and finds as a result that the powers of s. 68 are exercised with respect to his patent he has none but himself to blame for he holds the patent not alone for his own enrichment but for the purposes as well of the policy declared by the statute.[53]

While the terms "working" and "non-working" were not defined in the *Patent Act*, "work on a commercial scale" was defined in s. 2 as:

> [T]he manufacture of the article or the carrying on of the process described and claimed in a specification for a patent, in or by means of a definite and substantial establishment or organization and on a scale which is adequate and reasonable under the circumstances.[54]

Under the jurisprudence, importation of a patented article was not considered to be working on a commercial scale, nor mere assembly of the patented invention (unless the nature of the patent was the assembly of parts).[55]

Interestingly, the abuse provisions resulted in only 96 applications for a compulsory license between 1935 and 1993. Of these, only 17 resulted in the grant of a compulsory license.[56]

---

[51] *Patent Act (1935), supra,* note 45, s. 66:

> On being satisfied that a case of abuse of the exclusive rights under a patent has been established, the Commissioner may exercise any of the following powers as he may deem expedient in the circumstances: (a) He may order the grant to the applicant of a licence on such terms as the Commissioner may think expedient…

[52] *Patent Act (1935), supra,* note 45, s. 65(3).

[53] *Gordon Johnson Co. and Graham Metal Products Ltd. v. Callwood* (1960), 34 C.P.R. 73 at 82 (Ex. Ct.).

[54] *Patent Act (1935), supra,* note 45, s. 2(j).

[55] *Celotex*, *supra,* note 23 at 49. See also *De Frees & Betts Machine Co. v. Dom. Auto Accessories Ltd.* (1967), 51 C.P.R. 42 (Ex. Ct.); *L.P.A. Plastics (1976) Ltd. et al. v. Windsurfing Int. Inc.* (1982), 59 C.P.R. (2d) 188 at 197 (Commissioner of Patents).

[56] McFetridge, D. G., "Intellectual Property, Technology, Diffusion, and Growth in the Canadian Economy", in Anderson, R. and Gallini, N., eds., *Competition Policy and Intellectual Property Rights in the Knowledge Economy* (Calgary: University of Calgary Press, 1998) at 79.

Whether this small number is indicative of the full effect of these compulsory licensing and abuse provisions is unclear. Possibly, the threat of compulsory licensing resulted in more voluntary licenses and agreements than would otherwise have occurred.[57]

Except for the repeal in 1993 of the provisions relating to working on a commercial scale (discussed below), the abuse provisions in Canada's *Patent Act* have remained substantially the same to date.

C. Policy favouring health cost savings: food and medicine provisions in Canada (1923 to 1993)

In many countries, at least for most of the 20th century, medicines have been treated as a special category in patent matters in view of their important role in promoting public health.[58] Canada introduced such legislation in 1923. The *Paris Convention* did not (and does not) prohibit countries from implementing special rules for certain fields of invention. As such, under section 17 of Canada's 1923 Patent Act, chemical processes for producing food or medicine and the food or medicine when made by such processes could be claimed, but not the food or medicine itself. The underlying legislative policy was that all new substances are in the public interest to be free from legalized monopoly,[59] which continued until repeal of the corresponding section in 1987.

In addition to the general provisions discussed above for compulsory licensing in circumstances when the patentee has failed to meet the "reasonable requirements of the public" or of abuse, the 1923 Act also introduced compulsory licensing specific to the manufacture of food and medicine:

> In the case of any patent for an invention intended for or capable of being used for the preparation or production of food or medicine, the Commissioner shall, unless he sees good reason to the contrary, grant to any person applying for the same, a license limited to the use of the invention for the purposes of the preparation or production of food or medicine but not otherwise; and, in settling the terms of such license and fixing the amount of royalty or other consideration payable, the Commissioner shall have regard to the desirability of making the food or medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention.[60]

These compulsory licenses were limited to inventions "for the purposes of preparation or production of food or medicine" in Canada. In contrast to the language of the limitation on claims, the subsection did not apply narrowly to process inventions only. Although an invention could be capable of other uses, the license that could be granted under the subsection was limited to use for the purposes of preparation or production of food or medicine.[61]

---

[57] McFetridge, *supra,* note 56 at 80.

[58] Chien, *supra,* note 20 at 12-13.

[59] *Parke, Davis & Co. v. Fine Chemicals of Canada Ltd.* (1959), 30 C.P.R. 59 at 62 (S.C.C.) ("*Parke Davis*").

[60] *Patent Act (1923), supra,* note 42, s. 17. See also *Patent Act (1935), supra,* note 45, ss. 40(1) and 40(3).

[61] *Parke Davis*, *supra,* note 59 at 66-67.

In 1969, the ambit of compulsory licensing was expanded to include the import of medicines themselves.

> (4) 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 …
>
> (a) where the invention is a process, …import 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 … the invention for medicine or for the preparation or production of medicine,
>
> the Commissioner shall grant to the applicant a licence… except such, if any, of those things in respect of which he sees good reason not to grant such a licence…[62]

The Commissioner of Patents "shall" grant a licence unless "he sees good reason" not to. Thus, there was a presumption created in favour of the grant of the licence.[63] The Commissioner's decision could only be overturned if manifestly wrong.[64]

On the face of the legislation, as interpreted by the courts, the object of s. 41 was clearly to avoid a monopoly in the sale of medicines, thereby permitting competition which, it was anticipated, would cause a reduction in the price of medicines.[65]

In *Hoffmann-La Roche Ltd v. L.D. Craig Ltd., Bell-Craig Pharmaceuticals Division*, the Exchequer Court[66] had considered the legislative intent of the provision (in the *Patent Act* of 1952):

> In my view, the objective of the provision is to bring about competition. On balance, in most fields, competition is regarded by Parliament as being in the public interest because competition regulates prices in the public interest and also because competition tends to bring about greater efficiency, better service, and further research. The monopoly granted to an inventor is an exception to this general principle in our law. Section 41(3) was passed because, in the field to which it applies, "the specific public interest in free competition" was deemed to be more important than the maintenance of the patentee's monopoly rights…[67]

---

62 *Patent Act,* R.S.C. 1952, c. 203 as amended by 1953-54, c.19, 1953-54, c.40, s.15, 1966-67, c. 25, s.38, 1967-68, c.16, s. 10, 1968-69, cc. 28, 49, 55, s. 41(4).

63 *Smith Kline & French Laboratories Limited et al. v. Attorney General of Canada* (1985), 7 C.P.R. (3d) 145 at 172 (F.C.T.D.); aff'd (1986) 12 C.P.R. (3d) 385 (F.C.A.) ("*Smith Kline*").

64 *Parke Davis, supra,* note 59 at 67.

65 *Smith Kline, supra,* note 63 at 173.

66 The Exchequer Court of Canada was created in 1875 and succeeded by the Federal Court of Canada in 1971.

67 *Hoffmann-La Roche Ltd. v. L.D. Craig Ltd, Bell-Craig Pharmaceuticals Division* (1965), 46 C.P.R. 32 at 50 (Ex. Ct).

On appeal, the Supreme Court of Canada affirmed this view:

> In my view, the purpose of s. 41(3) is clear. Shortly stated it is this. No absolute monopoly can be obtained in a process for the production of food or medicine. On the contrary, 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."[68]

The Supreme Court noted in a subsequent decision "the legislative policy behind compulsory licensing, namely, [is] to avoid any practical monopoly of the manufacture of drugs by patented processes and to foster competition."[69] More recently, the Supreme Court of Canada described the compulsory licensing scheme as reflecting Parliament's policy "to favour health cost savings over the protection of intellectual property".[70]

While the stated purpose of the subsection was to make food or medicine available to the public at the lowest possible price *consistent with giving the inventor due reward for the research*, innovative drug companies argued before the Royal Commission on Patents, Copyright and Industrial Designs (the first of a number of commissions and parliamentary committees reviewing the compulsory licensing system) that stimulus to research and make new discoveries was lost in the compulsory licensing system.[71]

The percentage royalty payable to the patentee was not statutorily imposed. In practice, the royalty rate was nominal and did not reflect the costs of research. The Court held that the royalty allowed should be commensurate with "the maintenance of research incentive and the importance of both process and substance". Also, the royalty should be consistent with giving due reward to the *inventor*, not the patentee. Hence, the royalty payable by a licensee for using a patented process was one of his costs of production, justifying a royalty based on the sale of the bulk material produced by the patented process (e.g. 15% of the bulk chemical selling price).[72] In the first application subsequent to the 1969 amendments, the Commissioner of Patents chose 4% of the net selling price and thereafter generally applied the same percentage.[73]

Reviewing the scheme in 2005, the Supreme Court of Canada recognized that linking license fees to the cost of the "research leading to the invention" did not cover the cost of massive research programs required by innovators to produce the few "winners" from the many false starts and failed research projects that never went to market.[74] However, promoting research was not the primary objective of the scheme.

---

[68] *Hoffmann-La Roche Ltd. v. L.D. Craig Ltd, Bell-Craig Pharmaceuticals Division* (1966), 48 C.P.R. 137 at 144 (S.C.C.) ("*Bell Craig*").

[69] *Eli Lilly & Co. v. S & U Chemicals Ltd.* (1976), 26 C.P.R. (2d) 141 at 146 (S.C.C.).

[70] *Bristol-Myers Squibb Co. v. Canada (Attorney General)* (2005), 39 C.P.R. (4th) 449 (S.C.C.) at para. 8 ("*Biolyse").*

[71] Presentation by Ayerst, McKenna & Harrison, Hoffman-La Roche and Sterling Drug Manufacturers Co. Limited (1955), 23 C.P.R. 149.

[72] *Parke Davis supra,* note 59 at 68. See also *Bell Craig*, *supra,* note 68 at 144-145 and editorial note thereto.

[73] *Hoffmann-La Roche v. Frank W. Horner* (1970), 61 C.P.R. 243.

[74] *Biolyse, supra,* note 70 at para. 8.

After licenses for imports were allowed in 1969, compulsory licensing "gathered momentum" in Canada.[75] Between 1935 and 1969, 49 applications were made under this legislation, resulting in the grant of 22 compulsory licenses for manufacture.[76] In contrast, during the 23 years subsequent to the 1969 amendments, over 600 licenses were granted in response to 1030 applications, almost all for import.[77]

The growth of the Canadian generic drug industry is commonly attributed to these compulsory licenses.[78]

A 1985 Canadian government report by the Commission of Inquiry on the Pharmaceutical Industry (known as the Eastman Commission) evaluated the effects of compulsory licensing.[79] The Eastman Commission came to number of conclusions, among them that Canada's regime of compulsory licensing contributed to the growth of the Canadian generic drug industry[80] and had minimally adversely affected the research and development occurring in Canada.[81] (However, another conclusion was that Canada was not well placed to become a major world centre for pharmaceutical research[82]). The Eastman Commission found that due to the use of compulsory licensing, Canadian consumers saved $211 million in 1983 on actual sales of medicines of $1.6 billion.[83]

The report concluded that Canada's compulsory licensing regime was "an effective component of an appropriate patent policy for the pharmaceutical industry" and that it should be continued, albeit with some changes.[84] Recommendations included an increase of the standard 4% royalty to 14%,[85] that some period of market exclusivity be granted prior to the introduction of compulsory licenses, and removal of the prohibition against product claims pertaining to foods or medicines.[86]

In a constitutional challenge to s. 41(4) (the importing of medicine provision) in 1985, on the evidence before it (including the Eastman Commission report), the Federal Court of Canada

---

75 *Biolyse, supra,* note 70 at para. 8.

76 McFetridge, *supra,* note 56 at 81.

77 Hill, E. and Steinberg, J. "Bill C-22 and Compulsory Licensing of Pharmaceutical Patents" (1987), 4 C.I.P.R. 44 at 45. See also McFetridge, *supra,* note 56 at 82.

78 McFetridge, *supra,* note 56 at 83.

79 Canada, Commission of Inquiry on the Pharmaceutical Industry, *The Report of the Commission of Inquiry on the Pharmaceutical Industry* ("Eastman Commission"), Minister of Supply and Services, Ottawa, 1985.

80 *Ibid* at xxxvi.

81 *Ibid* at xviii.

82 *Ibid* at xxxi.

83 *Ibid* at xvii and 317

84 *Ibid* at xix.

85 *Ibid* at xx-xxi.

86 *Ibid* at xx and xxiii. The report characterized the prohibition on product claims as a poor method of increasing competition as compared to compulsory licensing. This is because it incentivized the wasteful duplication of different manufacturing processes for the same beneficial product, a misdirection of research and development efforts.

concluded that the effect of compulsory licensing had not been deleterious to the Canadian pharmaceutical industry as a whole.[87]

The Canadian government's response to the Eastman Commission report was Bill C-22, "*An Act to amend the Patent Act and to provide for certain matters in relation thereto*" (1986).[88] Changes to the *Patent Act*, which came into force in November 1987, gave back some exclusivity to patentees.[89] The prohibition against food and medicine product claims was eliminated by changing "chemical" processes to "microbiological".[90] The change was intended to increase the patent protection afforded to the inventors of substances intended for food or medicine and prepared by non-microbiological processes by allowing them to claim the substances without any process limitations, i.e. in *per se* form.[91] In addition, the subsection was to cease having effect in four years.[92]

Compulsory licensing was retained; however, new sections prohibited a licensee from exercising any right under a compulsory license until seven to ten years after the date of marketing approval of the medicine in Canada.[93] This deferral ensured the patentee exclusivity for a portion of the patent term.[94] Provisions for licenses with restrictions on making the medicine were also enacted for medicines invented and developed in Canada.[95]

To balance the increased patent protection with the policy of affordable health care costs, the 1987 amendments also introduced price controls on patented medicines through the creation of the Patented Medicines Prices Review Board (PMPRB). The PMPRB is mandated to ensure the prices for new and existing patented medicines are not "excessive", as measured by a variety of comparison based tests, by limiting the maximum price at which the patentee sells the medicine (as opposed to the grant of a compulsory license to another manufacturer).[96]

---

87 *Smith Kline*, *supra,* note 63 at 168-169. Smith, Kline & French Laboratories Inc. argued that the compulsory licensing provision was unconstitutional on three grounds: it fell within provincial (and not federal) jurisdiction, it violated the right to due process and equality under the Canadian Bill of Rights, and it violated the right to security of the person and non-discrimination under the Canadian Charter of Rights and Freedoms.

88 *An Act to amend the Patent Act and to provide for certain matters in relation thereto*, S.C.1987, c.41. ("*Bill C-22*").

89 Canada and the United States signed the Canada-U.S. Free Trade Agreement on January 3, 1988. This agreement contained no pharmaceutical patent provisions and only one IP provision generally but IP was of some controversy during negotiations. According to the Canadian government, the changes to the compulsory licensing provisions and other pharmaceutical-related amendments in 1987 were not connected to the signing of the agreement in January 1988. It is known, however, that intellectual property rights were a primary concern for the US during negotiations and it has been alleged that the FTA was directly linked to the 1987 amendments to the *Patent Act.* See also Battram, S. and Webster, W. L. "The Canada/United States Free Trade Agreement" (1988), 4 C.I.P.R. 267 at 271. See also *Canada-United States Free Trade Agreement Implementation Act*, 1988, c. 65, Article 2004:

> "The Parties shall cooperate in the Uruguay Round of multilateral trade negotiations and in other international forums to improve protection of intellectual property."

90 *Bill C-22*, *supra,* note 88, s. 14. See also *Patent Act* (1987), R.S.C. 1985, c. 33 (3rd Supp.) ("*Patent Act* (1987)"), s. 39(1).

91 *Application for Patent by Eli Lilly & Co., Re*, 1995 CarswellNat 1914, Patent Appeal Board Decision dated January 13, 1995.

92 *Patent Act* (1987), *supra,* note 90, s. 39(1.1).

93 *Patent Act* (1987), *supra,* note 90, ss. 39.11 and 39.14. The deferral period depended on certain circumstances existing as of June 27, 1986.

94 *Patent Act* (1987), *supra,* note 90. See also *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 77 D.L.R. (4th) 485, aff'd 96 D.L.R. (4th) 606 at paras. 8-9 (Man. C.A.).

95 *Patent Act* (1987), *supra,* note 90, s. 39.16.

96 "Compendium of Guidelines, Policies, and Procedures", Patented Medicines Prices Review Board, (March 2008). See also *Manitoba Society of Seniors Inc. v. Canada (Attorney General), supra,* note 94 at paras. 11-13.

IV. NAFTA and TRIPS: Decline of Compulsory Licensing in Canada (1980s and 1990s)

Following Canada's partial retreat in 1987 from its longstanding compulsory licensing policy for food and medicine, two major developments eventually led to a reversal of policy in 1993, namely the *North American Free Trade Agreement* ("NAFTA") and the *Agreement on Trade-Related aspects of IP Rights* ("TRIPS").

NAFTA and TRIPS exemplify, for Canada, a shift from the *Paris Convention* as the primary framework of patent law internationally,[97] to the use of trade agreements through which parties may impose more specific requirements on patent policy (in these cases, reflecting in particular the pro-patentee view of Canada's neighbour and largest trading partner).[98] Indeed, NAFTA and TRIPS followed the collapse of the Conference to Revise the Paris Convention from 1979 to 1985, resulting from tensions arising from compulsory licensing policies. Developing countries proposed to strengthen compulsory licensing provisions and restrict patentees' rights, including whether patentees could remain in the market together with licensees. In the end, efforts to reform international intellectual property law was moved from the exclusive jurisdiction of the World Intellectual Property Organization ("WIPO") and included within the jurisdiction of the World Trade Organization ("WTO").[99]

A. NAFTA

Through NAFTA, the governments of Canada, Mexico, and the US resolved, amongst other things, to "*foster creativity and innovation, and promote trade in goods and services that are the subject of intellectual property rights*".[100] One of the six enumerated objectives of NAFTA relates to intellectual property, namely to "*provide adequate and effective protection and enforcement of intellectual property rights in each Party's territory*".[101] Chapter 17 specifically deals with intellectual property, including enforcement[102] and minimum standards for the availability of protection which are the same or higher than those of the *Paris Convention*.[103]

---

[97] Article 19 of the *Paris Convention* explicitly allows for contracting parties to make separate agreements that remain consistent with its provisions. *Paris Convention*, *supra*, note 2, Article 19, 1979 text:

> It is understood that the countries of the Union reserve the right to make separately between themselves special agreements for the protection of industrial property, in so far as these agreements do not contravene the provisions of this Convention.

[98] Earlier large regional trade agreements such as the *Convention Establishing the European Free Trade Association,* 4 January 1960, 370 U.N.T.S. 5, Annex J include intellectual property provisions but do not specifically deal with compulsory licensing.

[99] Reichman, *supra,* note 7 at 12-13.

[100] NAFTA, *supra,* note 9, preamble.

[101] NAFTA, *supra,* note 9, Chapter 1, Article 102(d).

[102] NAFTA, *supra,* note 9, Chapter 17, Articles 1714 - 1718.

[103] NAFTA, *supra,* note 9, Chapter 17, Article 1701.2 states that each party shall, at a minimum, give effect to the substantive provisions of *inter alia* the *Paris Convention*.

Article 1704 permits each country to specify in its domestic laws licensing measures to prevent or control "*abuse of intellectual property rights having an adverse effect on competition*".[104]

Article 1709 relates to patents. Paragraph 6 states that a party may provide limited exceptions to the exclusive rights conferred by a patent.[105] Notably, unlike the *Paris Convention*, paragraph 7 requires that patent rights must be "enjoyable without discrimination as to the field of technology, the territory of the Party where the invention was made and whether products are imported or locally produced".[106]

In paragraph 8, Article 1709 expressly mentions compulsory licensing: a patent may only be revoked when *inter alia* the grant of a compulsory license has not remedied the lack of exploitation of the patent.[107]

Paragraph 10 of Article 1709 encompasses compulsory licensing, permitting laws allowing "the use of the subject matter of a patent… without the authorization of the right holder", subject to certain criteria:

> 10. Where the law of a Party allows for use of the subject matter of a patent, other than that use allowed under paragraph 6, without the authorization of the right holder, including use by the government or other persons authorized by the government, the Party shall respect the following provisions: …
>
> a) authorization of such use shall be considered on its individual merits;
>
> b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and such efforts have not been successful within a reasonable period of time. The requirement to make such efforts may be waived by a Party in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

---

[104] NAFTA, *supra,* note 9, Chapter 17, Article 1704:

> Nothing in this Chapter shall prevent a Party from specifying in its domestic law licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. A Party may adopt or maintain, consistent with the other provisions of this Agreement, appropriate measures to prevent or control such practices or conditions.

[105] NAFTA, *supra,* note 9, Chapter 17, Article 1709.6:

> A Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of other persons.

[106] NAFTA, *supra,* note 9, Chapter 17, Article 1709.7:

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

[107] NAFTA, *supra,* note 9, Chapter 17, Article 1709.8.

c) the scope and duration of such use shall be limited to the purpose for which it was authorized;

d) such use shall be non-exclusive;

e) such use shall be non-assignable, except with that part of the enterprise or goodwill that enjoys such use;

f) any such use shall be authorized predominantly for the supply of the Party's domestic market;

g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances that led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, on motivated request, the continued existence of these circumstances;

h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

i) the legal validity of any decision relating to the authorization shall be subject to judicial or other independent review by a distinct higher authority;

j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial or other independent review by a distinct higher authority;

k) the Party shall not be obliged to apply the conditions set out in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anticompetitive. The need to correct anticompetitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions that led to such authorization are likely to recur;

l) the Party shall not authorize the use of the subject matter of a patent to permit the exploitation of another patent except as a remedy for an adjudicated violation of domestic laws regarding anticompetitive practices. [108]

Thus, like the *Paris Convention*, the use must be non-exclusive and non-assignable,[109] while several further limits apply. These relate to remuneration, scope and duration, and the predominant purpose being for the supply of the party's domestic market.[110]

B. TRIPS

The *General Agreement on Tariffs and Trade* ("GATT") was established in 1947 with a goal of reducing barriers to international trade.[111] More so a set of rules than an international

[108] NAFTA, *supra,* note 9, Chapter 17, Article 1709.10.

[109] NAFTA, *supra,* note 9, Chapter 17, Articles 1709.10(d) and 1709.10(e).

[110] NAFTA, *supra,* note 9, Chapter 17, Articles 1709.10(c), 1709.10(f), 1709.10(h).

[111] *General Agreement on Tariffs and Trade* ("GATT"), Oct. 30, 1947, 55 U.N.T.S. 194; 61 Stat. pt. 5; T.I.A.S. No. 1700.

organization, its final round of negotiations was the Uruguay Round between 1986 and 1993.[112] The Marrakesh Agreement that concluded the Uruguay Round established the World Trade Organization ("WTO") as a formal organization designed to provide a forum for negotiating agreements to reduce obstacles to international trade, including dispute settlement.[113]

> The WTO shall provide the common institutional framework for the conduct of trade relations among its Members in matters related to the agreements and associated legal instruments included in the Annexes to this Agreement.[114]

Annexed to the Marrakesh Agreement was TRIPS, the most comprehensive multilateral intellectual property treaty to date.[115] TRIPS requires the domestic laws of signatories to meet its minimum standards relating to patents, trade-marks, copyright, industrial designs, geographical indicators, plant variety protection, integrated circuit protection, trade secrets and test data.[116] All 153 WTO members have ratified TRIPS. Ratification of TRIPS is currently a prerequisite to WTO membership.

During the Uruguay Round, a major objective of many participants was the elimination of compulsory licensing provisions respecting patented foods and medicines in national intellectual property laws.[117]

As a result, Article 27.1[118] of TRIPS (like NAFTA Article 1709.7) prohibits discrimination on the basis of field of technology, territory of the party where the invention was made and whether products are imported or locally produced. Its structure and wording is said to reflect two separate negotiating thrusts: a desire to ensure that patents would be available for inventions in all fields of technology, subject to certain listed exceptions, and a desire to eliminate compulsory licensing provisions respecting food and drug products in national laws.[119]

Article 30[120] permits limited exceptions to the exclusive rights of a patentee (like Article 1709.6 of NAFTA).

---

[112] "What is the World Trade Organization?", World Trade Organization, December 13, 2008, available at <http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm>.

[113] *Marrakesh Agreement Establishing the World Trade Organization*, Apr. 15, 1994, 1867 U.N.T.S. 154; 33 I.L.M. 1144 (1994), Annex J, Article 2.

[114] *Ibid,* Article II, para. 1.

[115] TRIPS, *supra,* note 4.

[116] TRIPS, *supra,* note 4, Parts I, Part II.

[117] *Canada - Patent Protection of Pharmaceutical Products - Complaint by the European Communities and their Member States - Report of the Panel*, March 17, 2000, WT/DS114/R at 28 ("*WTO Panel Report - Canada*"). This Report held that some of Canada's new laws in 1993 relating to "stockpiling" as an exception to infringement substantially curtailed the exclusive rights of patentees and were not in compliance with TRIPS.

[118] TRIPS, *supra,* note 4, Article 27:

> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

[119] *WTO Panel Report – Canada, supra,* note 117 at 4.17.

[120] TRIPS, *supra,* note 4, Article 30:

Article 31, "Other Use Without Authorization of the Right Holder" addresses compulsory licensing (although the term is not used). Article 31 is almost identical[121] to Article 1709.10 of NAFTA:

> Where the law of a Member allows for other use[122] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
>
> a) authorization of such use shall be considered on its individual merits;
>
> b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
>
> c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
>
> d) such use shall be non-exclusive;
>
> e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
>
> f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
>
> g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
>
> h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

[121] Article 31 contains an additional restriction with respect to scope and duration of semi-conductor technology (Art. 31(c)) and also permits authorized exploitation of a second patent which cannot be exploited without the infringing a first patent, with conditions, whereas NAFTA, *supra,* note 9, Chapter 17, Article 1709.10(l) states

> the Party shall not authorize the use of the subject matter of a patent to permit the exploitation of another patent except as a remedy for an adjudicated violation of domestic laws regarding anticompetitive practices.

[122] "Other use" refers to use other than that allowed under Article 30.

i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

   i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

   ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

   iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.[123]

The similarity of the text of TRIPS to that of NAFTA is not merely coincidental. In fact, a draft text of TRIPS had been released in December 1991 when Canada, the US and Mexico were negotiating NAFTA and was incorporated thereto. As indicated by a member of the Canadian TRIPS and NAFTA negotiating teams, "NAFTA closely tracks the language of the 1991 Dunkel draft of the TRIPS negotiating text. Therefore NAFTA's Chapter 17 and TRIPS generally are textually close enough to ensure that interpretations of the meaning of one would be directly relevant to the elucidation of the other. IP-related findings of eventual NAFTA panels may, therefore, powerfully influence TRIPs interpretation and vice versa."[124]

C. Canada (1993 to present)

On January 1, 1994, legislation implementing NAFTA came into force in Canada.[125] On January 1, 1995, Canada became a member of TRIPS.[126] In anticipation of its obligations under these agreements, Canada abolished almost all of its compulsory licensing provisions in the *Patent Act* in 1993.

---

[123] TRIPS, *supra,* note 4, Article 31.

[124] *WTO Panel Report – Canada, supra,* note 117, footnote 29 citing Canada-United States Law Journal, Vol. 23 (1997).

[125] *North American Free Trade Agreement Implementation Act,* SC 1993, c. 44.

[126] *World Trade Organization Agreement Implementation Act*, 1994, c. 47.

In view of the prohibitions against discrimination by field of technology, Bill C-91 (*Patent Act Amendment Act*), introduced in Parliament on June 23, 1992, removed all provisions relating specifically to food and medicine.[127] Similarly, in view of the prohibitions against discrimination based on whether are products are imported or locally produced, all provisions relating to the requirement to work on a commercial scale were repealed in the *NAFTA Implementation Act*, effective January 1, 1994. Thus, subject to the recent introduction of compulsory licensing on humanitarian grounds (discussed below), only the grounds of patent abuse now found in ss. 65(2)(c) to (f) of the *Patent Act* were retained as a basis for a compulsory license in Canada. The 1993 revisions and remaining provisions are summarized in the Appendix to this paper.

V. Re-emergence of Compulsory Licensing: Public Health Policy (2001 to present)

A. The Doha Declaration

Within a few years after TRIPS came into effect, several conflicts arose which put into question the adequacy of TRIPS. In 2001, the United States launched a complaint with the WTO over Brazil's compulsory patent licensing regime in its 1996 Industrial Property Law.[128] In South Africa, the United States and the European Union, supporting the pharmaceutical industry, challenged a 1997 amendment to legislation governing compulsory licensing, parallel imports and the price regulation of medicines.[129]

Against this background, during the 2001 Doha round of negotiations, the WTO adopted a Ministerial Declaration that recognized the importance of interpreting and implementing TRIPS in a manner supportive of public health.

> We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate Declaration.[130]

In the separate declaration, which has become known as the "Doha Declaration", the Ministerial Conference expressly recognized the flexibility of the TRIPS Agreement to support members' right to protect public health and, in particular, to promote access to medicines for all. A number of non-exhaustive "flexibilities" were enumerated, including the right of members to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are

---

[127] *Patent Act Amendment Act*, S.C. 1993, c. 2, s. 3.

[128] A challenge was brought by the U.S. to the WTO Dispute Settlement Body. The U.S. disputed the compliance of Brazil's compulsory licensing laws in the event a patented invention was not worked locally. This dispute was settled by Brazil committing to not issue a compulsory license with respect to a U.S. owned patent without consultation. See also "Brazil - Measures Affecting Patent Protection - Notification of Mutually Agreed Solution", WT/DS199/4. See also Anér, *supra,* note 20 at 21.

[129] The Pharmaceutical Manufacturer's Association of South Africa challenged South Africa's legislation on the basis that it was a violation of TRIPS. International public pressure subsequently caused the Association to withdraw its challenge in 2001. See also Anér, *supra,* note 20 at 21.

[130] "Ministerial Declaration", adopted on November 14, 2001, (November 20, 2001), WT/MIN(01)/DEC/1 at para. 17.

granted, and the right to determine what constitutes a national emergency or other circumstances of extreme urgency. HIV/AIDS, tuberculosis, malaria and other epidemics were expressly mentioned.[131]

Paragraph 6 of the Doha Declaration directed the Council for TRIPS to find an "expeditious solution" to the problem faced by countries that, in effect, they cannot use compulsory licensing to obtain local manufacture of medicines and also cannot use compulsory licensing to import the medicines due to the "predominantly for the supply of the domestic market" requirement of Article 31(f).

> We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.132

Accordingly, on August 30, 2003, the General Council released "the Doha Implementation Decision"[133] waiving three requirements of TRIPS under Articles 31(f) and 31(h): (i) subject to terms and conditions, compulsory licenses can be issued for export; (ii) remuneration to the patentee need only be paid in the exporting member while the obligation is waived in the importing member; and (iii) the re-export of imported medicines within the scope of a regional trade agreement is allowed in certain circumstances.[134] Compulsory licenses under the decision must allow manufacture only of the amount necessary to meet the needs of the eligible importing member and the conditions that the entirety of the amount must be exported, anti-diversion labelling applied, and that the licensee post on a website quantity and labelling information.[135] In addition, importing members must provide a notification to the WTO, including expected product needs, confirmation regarding its insufficient or lack of pharmaceutical manufacturing capacity, and confirmation of the grant or intent to grant a compulsory license under the provisions of the decision. Exporting members must provide notification of the grant of the license and information regarding the conditions attached to it. Reflected in the decision, twenty-three developed countries, including Canada, indicated that they would not rely upon the system to import drugs.[136]

A proposed amendment to TRIPS was submitted by the Council for TRIPS in December 2005 that would permanently incorporate the waivers set out in the Implementation Decision.[137]

---

[131] "Declaration on the TRIPS Agreement and Public Health" (November 20, 2001), WT/MIN(01)/DEC/2 at paras. 4-5 ("Doha Declaration").

[132] Doha Declaration, *supra,* note 131 at para. 6.

[133] "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health", (September 1, 2003), WT/L/540 and Corr. 1 ("Doha Implementation Decision").

[134] *Ibid*, ss. 2, 3, and 6.

[135] *Ibid*, s. 2.

[136] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America: Doha Implementation Decision, *supra,* note 133, s. 1(b).

[137] "Amendment of the TRIPS Agreement", (December 8, 2005), WT/L/641.

Approval of two-thirds of WTO members, by December 31, 2009 (extended from an initial deadline of December 1, 2007) is required to formally adopt this amendment.[138]

B. Humanitarian provisions in Canada

In September 2003, Canada became the first country to announce its intention to implement the Doha Decision and, in May 2004, passed Bill C-9, *An Act to Amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa).*[139]

Canada subsequently reached an agreement with the United States to ensure that "NAFTA's provisions will not stand in the way of Canada's implementation of its new law on pharmaceuticals".[140] In a letter comprising a memorandum of understanding, Canada and the United States consented, as between themselves, to suspension of Article 1709.10(f) of NAFTA with respect to compulsory licenses issued in accordance with the terms of the Doha Implementation Decision and that adequate remuneration pursuant to Article 1709.10(h) of NAFTA would be paid in the exporting party taking into account the economic value to the importing country of the use that has been authorized in the exporting party.[141]

The legislation came into force on May 14, 2005 and is now known as Canada's Access to Medicines Regime ("CAMR"). Specifically, CAMR amended the *Patent Act* by adding sections 21.01 to 21.2 ("Use of Patents for International Humanitarian Purposes to Address Public Health Problems"), together with its accompanying *Use of Patented Products for International Humanitarian Purposes Regulations*, and amended the *Food and Drugs Act* by adding sections 30(5), 30(6) and 37(2).

Section 21.01 of the *Patent Act* states that the purpose of the new sections is:

> … to give effect to Canada's and Jean Chrétien's pledge to Africa by facilitating access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

A list of eligible pharmaceutical products[142] and a list of eligible countries[143] are provided in Schedules to the *Patent Act*. All WTO member countries that have not notified that that they will not use the system to import, and all non-WTO member countries that are identified by the

---

[138] Or such later date as may be decided by the Ministerial Conference. See also "Amendment of the Trips Agreement – Extension of the Period for the Acceptance by members of the Protocol Amending the TRIPS Agreement", (December 21, 2007), WT/L/711.

[139] "Report on the Statutory Review of Sections 21.01 to 21.19 of the *Patent Act*", December 14, 2007, available at <http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_report_rapport-eng.pdf> at 7-8 ("Statutory Report on CAMR").

[140] "U.S. and Canada Agree to Assist Poor Countries Access to Medicine", Office of the United States Trade Representative, press release, July 16, 2004.

[141] "Memorandum of Understanding", July 16, 2004. The letter states that Canada and the U.S. intend to notify the Mexican government of this understanding. No objections are known to have been raised by Mexico.

[142] *Patent Act, supra,* note 18, schedule 1.

[143] *Patent Act, supra,* note 18, schedules 2, 3, 4.

United Nations as least-developed, are eligible countries. Some WTO member countries are restricted to importing only in cases of extreme urgency or national emergency.[144] Less vulnerable non-WTO developing countries are ineligible to import, but may be added to the list on a case-by-case assessment by the Canadian government.

A person may apply to the Commissioner of Patents for authorization to make, construct and use a patented invention for export, provided it satisfies a number of conditions.[145] The conditions include notification by the Minister of Health that the version of the relevant drug product meets the requirements of the *Food and Drugs Act*, and a declaration from the applicant that it had, prior to the filing of the application, unsuccessfully sought from the patentee(s) a license to manufacture and sell the product for export on reasonable terms and conditions.[146] The applicant must also have provided the patentee, in its request for a license, with information comprising the name of the product, the maximum quantity of the product, the relevant patents, and the name of the importing country.[147] An authorization is valid for two years, beginning on the day it is granted, and is non-transferable subject to a few exceptions. Furthermore, an authorization may be renewed.[148] The Commissioner of Patents has no discretion to refuse a license so long the statutory requirements are met.[149]

The holder of an authorization must also, before export, establish a website which discloses information including: the name of the product, the name of the country or WTO member to which the drug is being exported, the quantity that it is authorized to manufacture and export, and distinguishing features of the product.[150]

If an authorization is granted, the patentee is entitled to royalties from the holder of the authorization.[151] Calculation of the royalty is prescribed in the regulations, subject to judicial review.[152] The Federal Court of Canada also has jurisdiction, on the application of the patentee, to terminate the authorization under circumstances including commercial use of the product by the importing country, failure of the holder of the authorization to pay the royalty, or inaccurate material information in the original application.[153]

The *Food and Drugs Act* was amended to provide that it and its accompanying regulations apply to any drug to be exported as though it were a drug to be manufactured and sold for consumption in Canada.[154] Thus, pharmaceutical products to be exported under *CAMR* must meet Canadian standards before the Commissioner of Patents may issue an authorization. Health Canada is the

---

144 *Patent Act, supra,* note 18, s. 21.03.

145 *Patent Act, supra,* note 18, s. 21.04.

146 *Patent Act, supra,* note 18, s. 21.04 (3)(c)(i).

147 *Patent Act, supra,* note 18, s. 21.04 (3)(c)(ii).

148 *Patent Act, supra,* note 18, s. 21.09-21.12.

149 *Patent Act*, *supra*, note 18, s. 21.04.

150 *Patent Act*, *supra,* note 18, s. 21.06.

151 *Patent Act, supra,* note 18, s. 21.08.

152 *Use of Patented Products for International Humanitarian Purposes Regulations,* SOR/2005-143, s. 8. See also *Patent Act, supra,* note 18, s. 21.08.

153 *Patent Act, supra,* note 18, s. 21.14.

154 *Patent Act, supra,* note 18, s. 37 (2).

federal department responsible for ensuring that the product meets Canadian standards of efficacy, safety and quality.[155] The *Patent Act* mandates that the Minister of Health notify the Commissioner of Patents that the product to be exported meets the requirements of the *Food and Drugs Act*.[156]

Furthermore, there are anti-diversion provisions which require an "XCL" marking on the drug or container and label, that the color of the drug be significantly different from the color of the drug sold in Canada, and labeling requirements, including that the label state "FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA."[157]

On September 19, 2007, the Commissioner of Patents granted the first and thus far only authorization under CAMR. Canadian generic drug manufacturer Apotex Inc. has been granted authorization to make, construct and use certain patented inventions solely for the purposes of manufacturing a triple combination HIV/AIDS drug, APO-TRIAVIR, for export to Rwanda. There are nine patents identified in the authorization. In the fall of 2008, Apotex began shipping tablets to Rwanda under this authorization.[158]

C. Is the pendulum swinging?

In addition to Canada, a number of jurisdictions worldwide have modified or proposed modifications to their domestic law to implement the Doha waivers, including the European Union, Switzerland, Norway, India, China, Korea, and the Netherlands.[159] However, none of these jurisdictions has yet granted a compulsory license under its regime. Thus, in terms of concrete results, the impact of the Doha Implementation Decision has been minimal so far. The shipment of HIV/AIDS medicines to Rwanda in 2008 remains not merely the only delivery thus far under Canada's humanitarian compulsory licensing regime; it is the only one under the Doha Implementation Decision thus far anywhere. In view of the absence of compulsory licenses for export other than in Canada, it may be premature to draw conclusions at this point in time about the future popularity of compulsory licensing arising from the Doha Implementation Decision, or the merits of different legal frameworks.

In a report of the Canadian government tabled in December 2007 as part of a mandatory review of the CAMR amendments,[160] the government concluded that "CAMR works reasonably well and quickly" and that no legislative or regulatory changes to CAMR were warranted.[161] The review includes a comparison of requirements under the different regimes of the above jurisdictions. Clearly, Canada has adopted a more stringent approach, including schedules

---

[155] *Food and Drug Regulations,* C.R.C., c.870, Part C, Division 7, C.07.004 (b) and C.07.005.

[156] *Patent Act*, *supra,* note 18, s. 21.04(3)(b)

[157] *Food and Drug Regulations*, *supra,* note 155, ss. C.07.008(a), (b) and (c).

[158] Statutory Report on CAMR, *supra*, note 139.

[159] "Canada's Access to Medicines Regime – Consultation Paper", November 24, 2006, available at <http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_consult_e.pdf> at 21.

[160] "A review of sections 21.01 to 21.19 and their application must be completed by the Minister two years after this section comes into force": *Patent Act*, *supra*, note 18, s. 21.1.

[161] Statutory Report on CAMR, *supra*, note 139 at 36.

explicitly listing eligible countries, eligible products, and specific terms and conditions, in contrast to the typically broader language used to define criteria and the lack of a mandatory health and safety review in other jurisdictions. By minimizing the discretionary elements of a decision of the Commissioner of Patents, it was thought that clarity and expeditiousness of the decision-making process would be fostered, which would also make the outcome less vulnerable to legal challenge.[162] The government pointed to the experience with the single license as bearing out this perspective.[163] On the other hand, the generic licensee has recently criticized CAMR as "unworkable" and "too complex", calling on the federal government to fix the regime.[164]

Despite the flexibilities affirmed in the Doha Declaration, an apparently countervailing direction has emerged in the form of bilateral or regional trade agreements incorporating intellectual property provisions that go beyond the minimum standards set by TRIPS (so-called "TRIPS-plus agreements"). Sought by the United States and other developed members, these agreements are criticized by opponents as potentially limiting implementation of the Doha waivers.[165] The use of such agreements is considered largely to be a forum-shifting strategy by developed countries in response to their inability to successfully incorporate stronger patent protection under the multilateral rubric of the WTO/TRIPS.[166] In particular, the opposition of large, medium income developing nations such as Brazil and India innovating at a relatively lower rate given their comparatively limited research and development funding has allegedly stymied the incorporation of increased IP protection into more recently negotiated multilateral agreements.[167]

Examples of TRIPS-plus agreements are free trade agreements signed between the United States and Jordan,[168] Singapore,[169] and Australia.[170] Commentators argue that such agreements are contrary to the spirit of the Doha Declaration because they restrict the grounds upon which

---

[162] Statutory Report on CAMR, *supra*, note 139 at 30.

[163] Statutory Report on CAMR, *supra*, note 139 at 30.

[164] "Canadian-Made Life Saving HIV/AIDS Drug Heading To Africa Under Canada's Access To Medicines Regime (CAMR)", Apotex Inc., press release, September 23, 2008; "Canadian Company Receives Final Tender Approval From Rwanda For Vital AIDS Drug", Apotex Inc., press release, May 7, 2008. See also <http://www.apotex.com/apotriavir/default.asp>.

[165] Morin, J., "Tripping up TRIPS debates IP and health in bilateral agreements" (2006), 1(1/2) Int. J. Intellectual Property Management 37 at 38. See also Roffe, P. "The Impact of FTAs on public health policies and TRIPS flexibilities" (2006), 1(1/2) Int. J. Intellectual Property Management 75; Anér, *supra,* note 20 at 52-56. While not a trade agreement, CAMR has similarly been criticized as including "TRIPS-plus features that undermine its functionality": Elliott, R., "Pledges and pitfalls, Canada's legislation on compulsory licensing of pharmaceuticals for export" (2006), 1(1/2) Int. J. Intellectual Property Management 94.

[166] Roffe, *supra,* note 165 at 79.

[167] Morin, *supra,* note 165 at 38.

[168] *Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area*, Oct. 24, 2000, 41 I.L.M. 63. For example, Article 20 states:

> Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances: (a) to remedy a practice determined after judicial or administrative process to be anti-competitive; (b) in cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or (c) on the ground of failure to meet working requirements, provided that importation shall constitute working. Where the law of a Party allows for such use pursuant to sub-paragraphs (a), (b) or (c), the Party shall respect the provisions of Article 31 of TRIPS and Article 5A(4) of the Paris Convention.

[169] *United States – Singapore Free Trade Agreement*, January 15, 2003, 42 I.L.M. 1026.

[170] *United States – Australia Free Trade Agreement*, May 18, 2004, 43 I.L.M. 1248.

compulsory licenses may be issued and impede the ability of parties countries to issue compulsory licenses for export without further negotiation.[171] Notably, while such trade agreements are notionally bilateral (or regional), Article 4 of TRIPS has the effect of greatly enhancing their effect. By requiring the extension of any benefits to all other WTO members, any TRIPS-plus provision agreed to by a WTO member applies to its dealings with all other WTO members:

> With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members.[172]

Finally, some of the reasons contributing to the lack of utilization of the Doha waivers may be unrelated to the legal regimes. Lack of awareness or reluctance to be identified on the part of developing countries have been identified as practical impediments.[173] To date only one country, Rwanda, has given notification of its intention to use the system.[174]

VI. Summary

It has historically been difficult, in the context of multilateral negotiations to adopt provisions that clearly enhance or detract from the protection afforded patentees. While developed nations with large research and development budgets have a vested interest in ensuring strong worldwide protection for innovative intellectual property, developing nations have a corresponding vested interest in cheap access to the global pool of knowledge and innovation. Although global agreements have substantially affected the scope of allowable compulsory licensing, it will likely remain, for the foreseeable future, an allowable limitation on patentee rights in patent jurisdictions worldwide.

Even in developed nations such as Canada, with strong incentives to ensure strong patent protection, compulsory licensing was - historically but no longer - justified on the basis of the public interest in having food and medicines and the manufacture thereof being free from monopoly and consequently available at lower prices. Moreover, even today in developed nations compulsory licensing remains present as an intermediate remedy for the abuse or potential abuse of patent rights. While industrialized countries may continue to push to strengthened intellectual property laws, and increased limits on compulsory licensing (or equivalent) through the use of regional trade agreements, a role for compulsory licensing appears to have been generally conceded. Insofar as there is an inherent tension between patent rights and the public benefit, compulsory licensing will likely continue to help in mediating the conflict.

---

[171] Roffe, *supra,* note 165 at 80. See also Morin, *supra,* note 165 at 47.

[172] TRIPS, *supra,* note 4, Part I, Article 4.

[173] Statutory Report on CAMR, *supra*, note 139 at 32-33.

[174] "Notification under paragraph 2(a) of the 30 August 2003 Decision", received July 19, 2007, IP/N/9/RWA/1.

Appendix. Compulsory licensing provisions in Canada's *Patent Act*
(sections repealed in 1993 due to NAFTA and TRIPS shown in grey)

Patent Act	NAFTA	TRIPS
CHEMICAL PRODUCTS AND SUBSTANCES		
39. (3) *Licence under patent relating to food.* – In the case of any patent for an invention intended or capable of being used for the preparation or production of food, the Commissioner shall, unless he sees good reason to the contrary, grant to any person applying therefore a licence limited to the use of the invention for the purpose of the preparation or production of food, 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 food available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention. (4) *Licence under patent relating to medicine.* – Where, in the case of any patent for an invention intended or capable of being used for medicine or for the preparation of production of medicine, an application is made by any person for a licence 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 (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 license 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 a licence. Repealed [ss. 39-39.26], *Patent Act Amendment Act*, S.C. 1993, c. 2, s. 3.	1709.7. … patents shall be available and patent rights enjoyable without discrimination as to the field of technology…	27.1. … patents shall be available and patent rights enjoyable without discrimination as to… the field of technology…
CONDITIONS		
64. (1) *Information Relating to Patents.* – The Commissioner may, at any time, by giving notice to the patentee of any patent specified by the Commissioner, or to the patentee's registered representative in Canada, and to every person who has a registered interest in the patent, require every person to whom notice has been given to transmit and deliver to the Commissioner within sixty days after the date of the notice a return stating (a) whether the patented invention is being worked on a commercial scale in Canada, and the place where and the name and address of the person by whom the patented invention is being so worked; and (b) the reasons, if any, why the patented invention is not being worked on a commercial scale in Canada. (2) *Effect of failure to comply.* – The failure of the patentee of his registered representative in Canada or that of any person having a registered interest in the patent to comply with the terms of the notice mentioned in subsection (1) shall be deemed to be an admission on the part of the patentee or the person, as the case may be, so failing, that the patented invention is not being worked on a commercial scale in Canada.	1709.7. … patents shall be available and patent rights enjoyable without discrimination as to … whether products are imported or locally produced.	27.1. … patents shall be available and patent rights enjoyable without discrimination as to … whether products are imported or locally produced.

Patent Act	NAFTA	TRIPS
Repealed, *North American Free Trade Agreement Implementation Act*, S.C. 1993, c. 44, s. 195. Repealed "work on a commercial scale" [s. 2 *Definitions*], *North American Free Trade Agreement Implementation Act*, S.C. 1993, c. 44, s. 189.		
65. (1) *Abuse of rights under patents.* – The Attorney General of Canada or any person interested may, at any time after the expiration of three years from the date of the grant of a patent, apply to the Commissioner alleging in the case of that patent that there has been an abuse of the exclusive rights thereunder and asking for relief under this Act. (2) *What amounts to abuse.* – The exclusive rights under a patent shall be deemed to have been abused in any of the following circumstances		
(a) if the patented invention, other than an invention pertaining to a medicine within the meaning of subsection 79(2) is capable of being worked within Canada but is not being worked within Canada on a commercial scale and no satisfactory reason can be given for that non-working; (b) if the working of the patented invention, other than an invention pertaining to a medicine within the meaning of subsection 79(2), within Canada on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by the patentee or persons claiming under the patentee, by persons directly or indirectly purchasing from the patentee or by other persons against whom the patentee is not taking or has not taken any proceedings for infringement. Repealed, *North American Free Trade Agreement Implementation Act,* S.C. 1993, c. 44, s. 196(1).	1709.7. … patents shall be available and patent rights enjoyable without discrimination as to … whether products are imported or locally produced.	27.1. … patents shall be available and patent rights enjoyable without discrimination as to … whether products are imported or locally produced.
(c) if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms; (d) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, the trade or 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, is prejudiced, and it is in the public interest that a licence or licences should be granted; (e) if any trade or industry in Canada, or any person or class of persons engaged therein, is unfairly prejudiced by the conditions attached by the patentee, whether before or after the passing of this Act, to the purchase, hire, licence or use of the patented article or to the using or working of the patented process; or (f) if it is shown that the existence of the patent, being a patent for an invention relating to a process involving the use of materials not protected by the patent or for an invention relating to a substance produced by such a process, has been utilized by the patentee so as unfairly to prejudice in Canada the manufacture, use or sale of any materials.		
66. (1) *Power of Commissioner in cases of abuse.* – On being satisfied that a case of abuse of the exclusive rights under a patent has been established, the Commissioner may exercise any of the following powers as he may deem expedient in the circumstances: (a) he may order the grant to the applicant of a licence on such terms as the		

Patent Act	NAFTA	TRIPS
Commissioner may think expedient, including a term precluding the licensee from importing into Canada any goods the importation of which, if made by persons other than the patentee or persons claiming under him, would be an infringement of the patent, and in that case the patentee and all licensees for the time being shall be deemed to have mutually covenanted against that importation;		
(b) if the Commissioner is satisfied that the invention is not being worked on a commercial scale within Canada, and is such that it cannot be so worked without the expenditure of capital for the raising of which it will be necessary to rely on the exclusive rights under the patent, he may, unless the patentee or those claiming under him will undertake to find that capital, order the grant to the applicant, or any other person, or to the applicant and any other person or persons jointly, if able and willing to provide that capital, of an exclusive licence on such terms as the Commissioner may think just, but subject to this Act; Repealed, *North American Free Trade Agreement Implementation Act,* S.C. 1993, c. 44, s. 197(1).	1709.10. Where the law of a Party allows for use of the subject matter of a patent, other than that use allowed under paragraph 6, without the authorization of the right holder, including use by the government or other persons authorized by the government, the Party shall respect the following provisions: … d. such use shall be non-exclusive	31. Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: … (d) such use shall be non-exclusive;
(c) if the Commissioner is satisfied that the exclusive rights have been abused in the circumstances specified in paragraph 65(2)(f), he may order the grant of licences to the applicant and to such of his customers, and containing such terms, as the Commissioner may think expedient; (d) if the Commissioner is satisfied that the objects of this section and section 65 cannot be attained by the exercise of any of the foregoing powers, the Commissioner shall order the patent to be revoked, either forthwith or after such reasonable interval as may be specified in the order, unless in the meantime such conditions as may be specified in the order with a view to attaining the objects of this section and section 65 are fulfilled, and the Commissioner may, on reasonable cause shown in any case, by subsequent order extend the interval so specified, but the Commissioner shall not make an order for revocation which is at variance with any treaty, convention, arrangement, or engagement with any other country to which Canada is a party; or (e) if the Commissioner is of opinion that the objects of this section and section 65 will be best attained by not making an order under the provisions of this section, he may make an order refusing the application and dispose of any question as to costs thereon as he thinks just.		
66. (4) *Considerations by which Commissioner to be guided.* – In settling the terms of a licence under paragraph (1)(a), the Commissioner shall be guided as far as possible by the following considerations: (a) he shall endeavour to secure the widest possible use of the invention in		

Patent Act	NAFTA	TRIPS
Canada consistent with the patentee deriving a reasonable advantage from his patent rights; (b) he shall endeavour to secure to the patentee the maximum advantage consistent with the invention being worked by the licensee at a reasonable profit in Canada; and		
(c) he shall endeavour to secure equality of advantage among the several licensees, and for this purpose may, on due cause being shown, reduce the royalties or other payments accruing to the patentee under any licence previously granted[~~, and in considering the question of equality of advantage, the Commissioner shall take into account any work done or outlay incurred by any previous licensee with a view to testing the commercial value of the invention or to securing the working thereof on a commercial scale in Canada~~]. Amended, *North American Free Trade Agreement Implementation Act,* S.C. 1993, c. 44, s. 197.	1709.7. … patents shall be available and patent rights enjoyable without discrimination as to … whether products are imported or locally produced.	27.1. … patents shall be available and patent rights enjoyable without discrimination as to … whether products are imported or locally produced.
67. (1) *Terms of order for license.* – In settling the terms of any exclusive licence as is provided in paragraph 66(1)(b), due regard shall be had to the risks undertaken by the licensee in providing the capital and working the invention, but, subject thereto, the licence shall be so framed as (a) to secure to the patentee the maximum royalty compatible with the licensee working the invention within Canada on a commercial scale and at a reasonable profit, and (b) to guarantee to the patentee a minimum yearly sum by way of royalty, if and so far as it is reasonable to do so, having regard to the capital requisite for the proper working of the invention and all the circumstances of the case, and, in addition to any other powers expressed in the licence or order, the licence and the order granting the licence shall be made revocable at the discretion of the Commissioner if the licensee fails to expend the amount specified in the licence as being the amount that he is able and willing to provide for the purpose of working the invention on a commercial scale within Canada, or if he fails to work the invention within the time specified in the order. (2) In deciding to whom an exclusive licence is to be granted, the Commissioner shall, unless good reason is shown to the contrary, prefer an existing licensee to a person having no registered interest in the patent. (3) The order granting an exclusive licence under section 66 operates to take away from the patentee any right that he may have as patentee to work or use the invention and to revoke all existing licences, unless otherwise provided in the order, but, on granting an exclusive licence, the Commissioner may, if he thinks it fair and equitable, make it a condition that the licensee shall give proper compensation to be fixed by the Commissioner for any money or labour expended by the patentee or any existing licensee in developing or exploiting the invention. Repealed, *North American Free Trade Agreement Implementation Act,* S.C. 1993, c. 44, s. 198.	1709.10. Where the law of a Party allows for use of the subject matter of a patent, other than that use allowed under paragraph 6, without the authorization of the right holder, including use by the government or other persons authorized by the government, the Party shall respect the following provisions: … d. such use shall be non-exclusive;	31. Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: … (d) such use shall be non-exclusive;